



# *NATIONAL EMERGING CONTAMINANTS RESEARCH INITIATIVE*

*A Report by the*  
JOINT SUBCOMMITTEE ON ENVIRONMENT, INNOVATION, AND  
PUBLIC HEALTH  
CONTAMINANTS OF EMERGING CONCERN STRATEGY TEAM  
*of the*  
NATIONAL SCIENCE AND TECHNOLOGY COUNCIL

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## About the Contaminants of Emerging Concern Strategy Team

The Contaminants of Emerging Concern (CECs) Interagency Working Group (IWG) was established in May 2020 in response to the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2020, in which Congress directed the IWG to coordinate federal research on CECs.<sup>1</sup> This effort extends the work of the Task Force on Emerging Contaminants that produced the 2018 document, “Plan for Addressing Critical Research Gaps Related to Emerging Contaminants in Drinking Water” in response to FY2018 Appropriations legislation.<sup>2</sup> The CEC IWG updated the 2018 Plan in response to FY2019 Appropriations legislation.<sup>3</sup> The IWG also organized technical advice for a national CEC research initiative and launched near-term interagency coordination actions. The IWG was reconfigured as a NSTC Strategy Team (ST) under the Joint Subcommittee on Environment, Innovation, and Public Health (JSC EIPH) in the Fall of 2021. The ST is co-chaired by EPA, NIH, and OSTP; and consists of the following agencies: DHS, DOC/NIST, DoD, DOE, DOT/FAA, EOP/OMB, EOP/OSTP, EPA, HHS/ATSDR, HHS/CDC, HHS/FDA, HHS/NIH/NIEHS, NASA, NSF, SBA, USDA, USGS. The ST coordinates interagency CEC activities and supports the development and implementation of the CEC research initiative.

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<sup>1</sup> National Defense Authorization Act for Fiscal Year 2020 (Pub. L. 116-92) (hereafter “FY2020 NDAA”) § 7342(b) (15 U.S.C. §8952(b)).

<sup>2</sup> S. Rept. 115-139 (Committee Report to accompany S. 1662, Departments of Commerce and Justice, Science and Related Agencies Appropriations Bill, 2018) adopted by reference in the Explanatory Statement for Division B—Commerce, Justice, Science, and Related Agencies Appropriations Act, 2018 of the House Amendment to Senate Amendment on H.R. 1625, Consolidated Appropriations Act, 2018 (Pub. L. 115-141) (hereafter “FY2018 Appropriations Report”), at 101.

<sup>3</sup> H. Rept. 116-9 (Conference Report to accompany H.J. Res. 31, Making Further Continuing Appropriations for the Department of Homeland Security for Fiscal Year 2019, and for Other Purposes (Pub. L. 116-6)) (hereafter “FY2019 Appropriations Report”), at 633.

## About this Document

The FY2020 NDAA directs OSTP, in coordination with several federal agencies that are members of the CEC IWG, to create a national research initiative to improve the identification, analysis, monitoring, and treatment methods of CECs, and develop any necessary program, policy, or budget to support the implementation of the initiative.<sup>4</sup> OSTP solicited input from five CEC IWG technical teams on critical research gaps and needs for emerging contaminants and exposure, human health effects, risk characterization, risk mitigation, and risk communication. OSTP also issued a Request for Information to receive public comment. The National Emerging Contaminants Research Initiative (NECRI) organizes CEC research into five strategic goals and provides guidance for an implementation plan that outlines steps to achieve the strategic goals and metrics to track progress. While DW is the medium of focus for the NECRI, it is recognized that CECs exist in multiple media that may be relevant for addressing public and environmental health needs. These are considered, where appropriate, in this document. Further, multi-media (and other) considerations are expected to be addressed in the implementation of the NECRI. The capabilities and approaches developed under the NECRI should lead to a holistic treatment of CECs.

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<sup>4</sup> FY2020 NDAA § 7342(c) (15 U.S.C. §8952(c)).

<sup>5</sup> See 17 U.S.C. § 105.

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Deputy Assistant to the President and Deputy  
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the National Toxicology Program, NIH/NIEHS

### Executive Secretary

**Brooke Holmes,** Program Analyst, Office of  
Research and Development, EPA

## CONTAMINANTS OF EMERGING CONCERN STRATEGY TEAM

### Co-Chairs

**Melanie Buser,** Assistant Director for  
Environmental Health, OSTP

**Annette Guiseppi-Elie,** Acting National  
Program Director, Chemical Safety for  
Sustainability, EPA

**David Balshaw**, Chief, Exposure, Response,  
and Technology Branch, NIH/NIEHS

**Executive Secretary**

**Jennifer Collins**, Health Specialist, Exposure,  
Response, and Technology Branch, NIH/NIEHS

**Strategy Team Members**

**Astrika Adams**, SBA  
**Jonathan Alter**, SBA  
**Timothy Appleman**, NASA  
**Pamela Protzel Berman**, HHS/CDC/ATSDR  
**Jay Collert**, DHS  
**Jessica Cox**, DHS  
**Elizabeth Ditto**, DOT/FAA  
**James Dobrowolski**, USDA/NIFA  
**Suzanne Fitzpatrick**, FDA  
**Michael Focazio**, USGS  
**Carlos Gonzalez**, NIST  
**Tracy Hancock**, USDA/FS  
**Mark Johnson**, DoD  
**Rudy Johnson**, HHS/CDC/ATSDR  
**April Kluever**, OMB  
**Moiz Mumtaz**, HHS/CDC/ATSDR  
**Mitchell Otey**, FAA

**Amina Pollard**, EPA  
**Lisa Quiveors**, DHS  
**Chris Reh**, HHS/CDC/ATSDR  
**Rachel Rogers**, HHS/CDC/ATSDR  
**Debbie Rosano**, DOE  
**Nora Savage**, NSF  
**Anne-Marie Schmoltner**, NSF  
**Robert Seifert**, DOE  
**Daniel Shaughnessy**, NIH/NIEHS  
**Jennifer Shieh**, SBA  
**Kelly Smalling**, USGS  
**James Smith**, DoD  
**James Tyree**, DOE  
**Patricia Underwood**, DoD  
**Natalia Vinas**, DoD  
**David Whitman**, FDA  
**Christine Whittaker**, HHS/NIOSH

**Technical Team Members**

**ATSDR**

Gaston Casillas  
Janine Cory  
Elizabeth Irvin  
Troy Ritter  
Rachel Rogers  
Terry Tincher

**CDC**

Antonia Calafat  
Andrea Winquist  
Christine Whittaker

**DoD**

Jayne-Anne Bond  
Miranda Brannon  
Lyle Burgoon

Jen Corak  
Chuck Coyle  
David Hines  
Brian Howard  
Mark Johnson  
Andrea Leeson  
Victor Medina  
Anita Meyer  
Ed Perkins  
Michael Quinn Jason  
Speicher  
Patricia Underwood  
Matthew Waterbury

**EPA**

Michelle Angrish

Steve Blaze  
David Charters  
Allison Crimmins  
Jeffrey Dean  
Colleen Flaherty  
Susan Glassmeyer  
Jackie Harwood  
Elizabeth Hedrick  
Rich Henry  
Jodi Howard  
Chris Impellitteri  
Kristin Isaacs  
Terrence Johnson  
Tom Kady  
Andrea Kirk  
Emma Lavoie Marc Mills  
Seth Newton  
Kelly O'Neal

## NATIONAL EMERGING CONTAMINANTS RESEARCH INITIATIVE

---

Amina Pollard  
Jon Sobus  
Thomas Speth  
Lingamanaidu Ravichandran  
Michele Taylor  
Kris Thayer  
John Wambaugh  
Richard Weisman

### **FDA**

Suzanne Fitzpatrick

### **NIH**

David Balshaw  
Danielle Carlin  
Yuxia Cui

Kelly Lenox  
Ravichandran Lingamanaidu  
Stephen Ferguson

### **NIST**

Ashley Boggs  
Carlos Gonzalez  
John Kuckclik  
Ben Place  
Jessica Reiner

### **NRC**

Jessica Kratchman

### **NSF**

Mamadou Diallo

Laura Lautz  
Karl Rockne  
Nora Savage

### **OMB**

April Kluever

### **USDA**

James Dobrowolski  
Clinton Williams

### **USGS**

Paul Bradley  
Michael Focazio  
Kelly Smalling

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## Abbreviations and Acronyms

<b>ATSDR</b>	Agency for Toxic Substances and Disease Registry	<b>NIFA</b>	National Institute of Food and Agriculture
<b>CDC</b>	Centers for Disease Control and Prevention	<b>NIST</b>	National Institute of Standards and Technology
<b>CECs</b>	Contaminants of Emerging Concern	<b>NSF</b>	National Science Foundation
<b>CERCLA</b>	Comprehensive Environmental Response, Compensation, and Liability Act	<b>NSTC</b>	National Science and Technology Council
<b>CWA</b>	Clean Water Act	<b>NTA</b>	Non-targeted analysis
<b>DHS</b>	Department of Homeland Security	<b>OSTP</b>	Office of Science and Technology Policy
<b>DOC</b>	Department of Commerce	<b>ORD</b>	EPA Office of Research and Development
<b>DoD</b>	Department of Defense	<b>OMB</b>	Office of Management and Budget
<b>DOE</b>	Department of Energy	<b>OW</b>	EPA Office of Water
<b>DOT</b>	Department of Transportation	<b>SBA</b>	Small Business Administration
<b>DW</b>	Drinking Water	<b>SDWA</b>	Safe Drinking Water Act
<b>EOP</b>	Executive Office of the President	<b>ST</b>	Strategy Team
<b>EPA</b>	Environmental Protection Agency	<b>TSCA</b>	Toxic Substances Control Act
<b>FAA</b>	Federal Aviation Administration	<b>USDA</b>	United States Department of Agriculture
<b>FDA</b>	Food and Drug Administration	<b>USGS</b>	United States Geological Survey
<b>FS</b>	Forest Service		
<b>HHS</b>	Department of Health & Human Services		
<b>HTS</b>	High throughput screening		
<b>IWG</b>	Interagency Working Group		
<b>MCDA</b>	Multi-criteria decision analysis		
<b>NASA</b>	National Aeronautics and Space Administration		
<b>NDAA</b>	National Defense Authorization Act		
<b>NECRI</b>	National Emerging Contaminants Research Initiative		
<b>NIH</b>	National Institutes of Health		
<b>NIEHS</b>	National Institute of Environmental Health Sciences		

## Executive Summary

The National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2020 directs the White House Office of Science and Technology Policy (OSTP), in coordination with several federal agencies that are members of the Contaminants of Emerging Concern (CEC) Interagency Working Group (IWG), to create a national research initiative to improve the identification, analysis, monitoring, and treatment methods of CECs, and develop any necessary program, policy, or budget to support the implementation of the initiative.<sup>6</sup> This effort builds on the CEC IWG's 2018 document, "Plan for Addressing Critical Research Gaps Related to Emerging Contaminants in Drinking Water," published in response to FY2018 Appropriations legislation,<sup>7</sup> and the update to the Plan published in February 2022, in response to report language in FY2019 Appropriations legislation.<sup>8</sup> To develop the national research initiative, OSTP solicited input from five CEC IWG technical teams on critical research gaps and needs for emerging contaminant identification and exposure characterization, human health effects assessment, risk characterization, risk mitigation, and risk communication. OSTP also issued a Request for Information (RFI) to receive public comments that would inform the development of the research initiative.

The National Emerging Contaminants Research Initiative (NECRI) establishes a national vision—access to clean and plentiful drinking water for every person in the nation—and outlines a Federal strategy to address critical research gaps related to detecting and assessing emerging contaminants in drinking water and identifying and mitigating adverse health effects. The NECRI emphasizes the importance of partnerships and effective communication in building a strong foundation for future research. The NECRI also integrates climate change and environmental justice tenets to ensure equitable access to clean water.

The NECRI organizes CEC research into five strategic goals that address data gaps and priority areas that, when addressed, will generate actionable information for CEC mitigation and risk communication.

### **Goal 1: Decrease the time from drinking water (DW) CEC identification to risk mitigation.**

Five areas of DW CEC research are essential to decreasing the time from CEC identification to risk mitigation: contaminant identification and exposure characterization, human health effects assessment, risk characterization, risk mitigation, and risk communication. Advancing critical research priorities in these overlapping, transdisciplinary areas and linking findings across disciplines will allow more rapid identification, understanding, and mitigation of CECs and the communication of appropriate, trustworthy information to collaborators and partners.

### **Goal 2: Promote technological innovation in tools to discover, track, and mitigate DW CECs.**

DW CEC measurement and analysis tools establish the type and magnitude of a contaminant exposure as well as potential effects. Development and deployment of cost-effective and broadly applicable and accessible next-generation tools are essential to understand DW CEC exposure through time-resolved, near real-time, and real-time monitoring, screening, and

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<sup>6</sup> FY2020 NDAA § 7342(c) (15 U.S.C. §8952(c)).

<sup>7</sup> FY2018 Appropriations Report, at 101.

<sup>8</sup> FY2019 Appropriations Report, at 633.

reporting. Tool development critical to achieve the NECRI vision are sensing and screening technologies to identify and monitor CECs, and biomarkers and models to measure effects.

**Goal 3: Develop and deploy tools and approaches for DW CEC decision making.**

Protecting populations from potential adverse effects of CECs necessitates forward planning, research, and policy decisions. Innovative research and analytical tools support these actions by providing approaches to collect and organize data within a decision framework, apply advanced computational approaches to maximize understanding of the data, and provide feedback for further research, decision making, and mitigation. Tools to accomplish these actions are grouped as (1) tools to reduce uncertainty in decision making and (2) frameworks for decision making.

**Goal 4: Coordinate transdisciplinary DW CEC research activities among Federal and non-Federal partners.**

A network of CEC research centers would advance research capabilities, reduce the potential for duplicative efforts, minimize the potential to miss major challenges or issues, and increase the communication and synergy among collaborators and partners. To fully leverage the CEC research and communication activities, centers would link to each other as well as other efforts in water research, water management, and policy. Data would be shared through a data repository and organized through a data management plan.

**Goal 5: Foster transparency and public trust when communicating about DW CECs.**

CEC exposures and effects occur within a societal context that requires effective communication of complex, transdisciplinary, and multifaceted data. Effective communication at every step from fundamental research to mitigation is critically important to establish transparency and build public trust among all collaborators and partners. CEC risk communication priorities include engagement and inclusion, communications research, and incorporation of communications research into the CEC research network.

## Vision and Strategic Approach

*Access to clean and plentiful drinking water for every person in our Nation*

This National Emerging Contaminants Research Initiative (NECRI) outlines a Federal strategy to address critical research gaps related to detecting and assessing emerging contaminants in drinking water and identifying and mitigating adverse health effects. The NECRI also emphasizes the importance of partnerships and effective communication in building a strong foundation for future research and ensuring equitable access to clean water through the integration of climate change and environmental justice tenets.

## Understanding the CEC Research Landscape

A constellation of factors—scientific, technological, societal, environmental, economic, and social—form the context in which emerging contaminants research is performed. These factors include the broad scope of the problem (definition of contaminants of emerging concern [CECs] and the drinking water [DW] cycle), data collection (transdisciplinary research and evolving data) and societal considerations (environmental justice and climate change). This section describes key elements of the CEC research landscape, and the NECRI goals reflect their incorporation into Federal CEC research. While DW is the medium of focus for the NECRI, it is recognized that CECs exist in multiple media that may be relevant for addressing public and environmental health needs. The capabilities and approaches developed under the NECRI should lead to a holistic treatment of CECs.

## Contaminants of Emerging Concern in Drinking Water

Emerging contaminants, also called CECs, are newly identified or reemerging manufactured or naturally occurring physical, chemical, biological, radiological, or nuclear materials that may cause adverse effects to human health or the environment and do not currently have a national primary DW regulation.<sup>9,10</sup> Major sources of CECs include everyday consumer products (e.g., disinfecting products, plastics, pharmaceuticals, personal care products), industrial manufacturing processes (e.g., solvents), and agricultural practices (e.g., antibiotics and pesticides).<sup>11,12</sup> These substances and the chemicals that result from their transformation (e.g., degradation) by biotic and abiotic processes can be released into the environment and into the DW cycle.

Research has shown that DW CECs may cause direct or indirect adverse effects in humans, animals, and the environment. For example, exposure to agricultural pesticides can result in both short-term effects such as eye and skin irritation and long-term effects such as liver

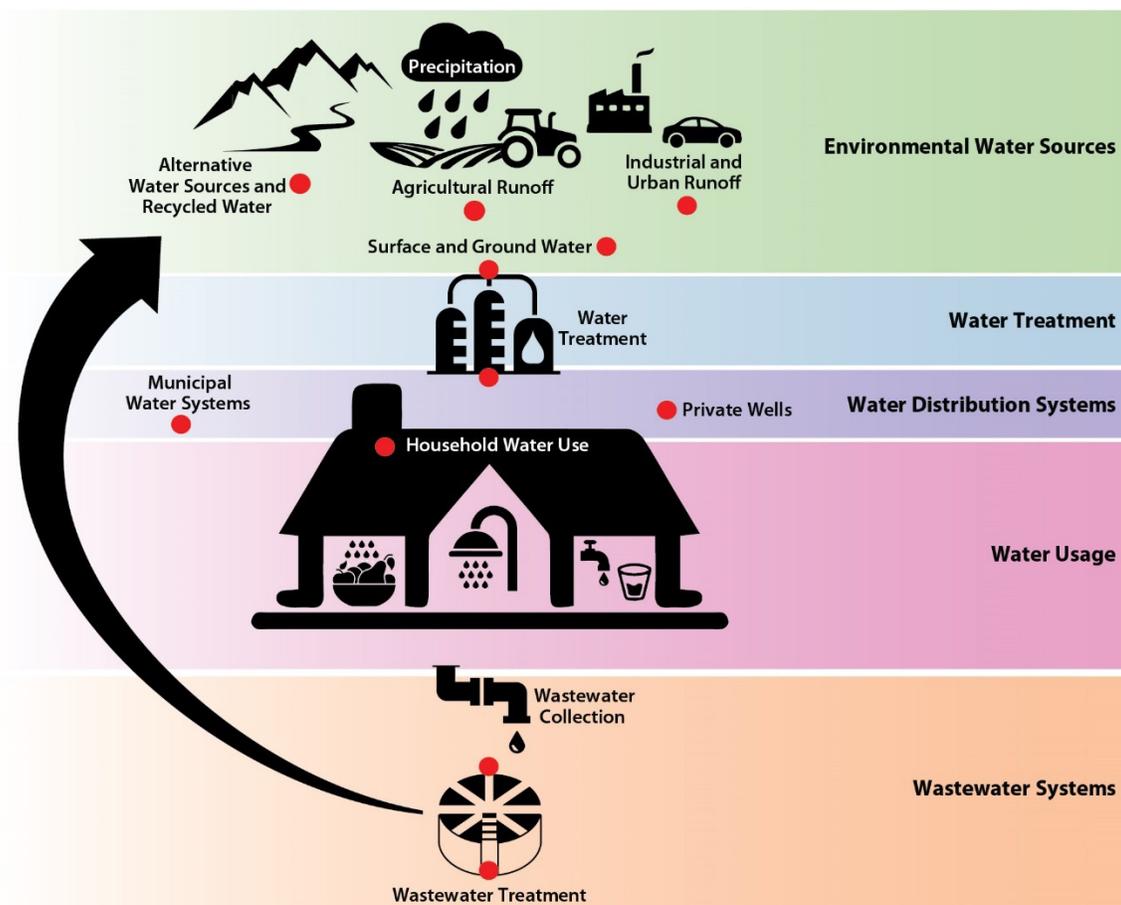
<sup>9</sup> This definition was developed by consensus of the Contaminant of Emerging Concern Interagency Working Group and is consistent with the definition in Section 7341(2) of the FY2020 NDAA (15 U.S.C. §8951(2)).

<sup>10</sup> Note that *national primary drinking water regulation* refers to the maximum contaminant level under the Safe Drinking Water Act.

<sup>11</sup> USGS. n.d. “Emerging Contaminants.” <https://www.usgs.gov/mission-areas/water-resources/science/emerging-contaminants>

<sup>12</sup> EPA. 2021. “Emerging Contaminants and Facility Contaminants of Concern.” August 31, 2021. <https://www.epa.gov/fedfac/emerging-contaminants-and-federal-facility-contaminants-concern>





**Figure 1. Drinking Water Cycle for Household Water Use**

The primary components of the water cycle are portrayed graphically on the left side of the image and in the list on the right. The red dots designate potential water sample collection points for monitoring, research, and remediation.

### Current Research Approach

CECs are most often identified and characterized contaminant-by-contaminant, an approach that does not consider their frequent occurrence in mixtures (with the potential for synergistic or additive effects) and that limits generalization of research findings. The breadth and complexity of CEC research requires transdisciplinary science and many collaborators and partners, including academic, private sector and Federal researchers; policy makers; regulators; water utility managers, and the general public. DW CEC research also involves multiple Federal agencies, each with its own mission-related responsibilities. This breadth of interest in, and responsibility for, DW CEC research, coupled with the pace of research and the challenges of identifying emerging contaminants, can lead to gaps in research, information sharing, and decision making.

### Evolving Data

Decision makers are challenged by incomplete, diverse, and evolving data that make it difficult to amass sufficient evidence to confidently identify causal or functional relationships between CECs and their effects. The data are often generated by diverse methods and lines of evidence may conflict, or available data may not be applicable to the decisions at hand. Uncertainty is

also inherent in understanding data in a societal and economic context. Uncertainty and variability in research data can lead to uncertainty in data-dependent actions, such as mitigation and communication, and these factors can be magnified when exposures occur in emergency situations that require immediate response.

### Environmental Justice

Due to historical and ongoing inequities, disadvantaged communities<sup>21</sup> have experienced greater exposure to environmental contaminants, more adverse health effects, and often limited resources to mitigate the hazards and risks of CECs.<sup>22</sup> While these conditions are due to many factors, socioeconomic status and geographical proximity are significant contributors. Toxic emissions and waste sites are more likely to be located in or near low-income neighborhoods, many of which include communities of color or Indigenous populations.<sup>23</sup> Research provides a basis for action to protect the health and environment of populations that may be especially vulnerable (e.g., children and the elderly) to environmental hazards,<sup>24</sup> and incorporating the principles of environmental justice into CEC research would promote practices that could ameliorate disproportional cumulative impacts of chronic exposure to environmental contaminants and provide better access to safe DW.

### Climate Change

Increasing temperatures, sea level rise, changing patterns of precipitation and flow of water through watersheds, changes in soil microbes, and extreme weather events are expected to damage the infrastructure or disrupt water sources on which we rely for clean water.<sup>25</sup> For example, climate change increases the likelihood that flooding, fire, and other natural disasters would threaten source waters and water treatment systems, increase the frequency of harmful algal blooms,<sup>26</sup> and change patterns of surface runoff and the type or volume of contaminants released into a watershed. Climate change increases the prevalence of extreme weather events (e.g., hurricanes) that may cause unintended industrial chemical releases, leading to acute

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<sup>21</sup> NIH designates defined disadvantaged populations to include African Americans, Hispanics, Latinos, Native Americans, Alaska natives, Asian Americans, native Hawaiians and other Pacific islanders, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities. For more information, see <https://www.nimhd.nih.gov/about/overview/>

<sup>22</sup> Johnston, Jill and Lara Cushing. 2020. "Chemical exposures, health, and environmental justice in communities living on the fence line of industry." *Current environmental health reports* 7 (1):48-57. <https://doi.org/10.1007/s40572-020-00263-8>

<sup>23</sup> Collins, Mary B., Ian Munoz, and Joseph JaJa. 2016. "Linking 'toxic outliers' to environmental justice communities." *Environmental Research Letters* 11 (1):015004. <https://doi.org/10.1088/1748-9326/11/1/015004>

<sup>24</sup> EPA Office of Environmental Justice. 2017. "Office of Environmental Justice in Action." [https://www.epa.gov/sites/default/files/2017-09/documents/epa\\_office\\_of\\_environmental\\_justice\\_factsheet.pdf](https://www.epa.gov/sites/default/files/2017-09/documents/epa_office_of_environmental_justice_factsheet.pdf)

<sup>25</sup> U.S. Global Change Research Program (USGCRP). 2018. *Impacts, Risks, and Adaptation in the United States: Fourth National Climate Assessment, Volume II*: [Reidmiller, D.R., C.W. Avery, D.R. Easterling, K.E. Kunkel, K.L.M. Lewis, T.K. Maycock, and B.C. Stewart (eds.)]. U.S. Global Change Research Program, Washington, DC, USA. <https://doi.org/10.7930/NCA4.2018201820182018201820182018>

<sup>26</sup> Jiang, Peng, Xiao Liu, Jingjie Zhang, Shu Tarn Te, Karina Yew-Hoong Gin, Yee Van Fan, Jiří Jaromír Klemesš, and Christine A. Shoemaker. 2021. "Cyanobacterial risk prevention under global warming using an extended Bayesian network." *Journal of Cleaner Production* 312:127729. <https://doi.org/10.1016/j.jclepro.2021.127729>

contaminant exposures.<sup>27</sup> The consequences of climate change also contribute to the use of more alternative water sources (e.g., seawater, saline aquifers, wastewater reuse) to obtain adequate amounts of potable water. As noted in the previous section, the health of children and the elderly, Black, indigenous, and low-income individuals in defined geographic areas are disproportionately affected by contaminant exposure; these conditions are likely to be compounded by climate change.<sup>28</sup>

## National Emerging Contaminants Research Initiative

With the complex and continually shifting CEC research landscape, an integrated strategic Federal approach is needed to address data gaps and generate timely, actionable information for CEC identification, quantification, mitigation, and communication. The interagency CEC Strategy Team (ST) acknowledges that the NECRI does not contain all possible areas of CEC research. Rather, it identifies critical priority areas that, if achieved, will significantly advance CEC research in the near- and mid-term, and lay a foundation for longer-term research.

The NECRI organizes critical research and coordination priorities through five goals:

**Goal 1.** Decrease the time from DW CEC identification to risk mitigation

**Goal 2.** Promote technological innovation in tools to discover, track, understand, and mitigate DW CECs

**Goal 3.** Develop and deploy tools and approaches for DW CEC decision making

**Goal 4.** Coordinate transdisciplinary DW CEC research activities among Federal and non-Federal partners

**Goal 5.** Foster transparency and public trust when communicating about DW CECs

Fulfilling these goals will require transdisciplinary research that spans the life sciences, engineering, the social sciences, public health, and other expertise. It will also require the inclusion of all communities affected by a CEC exposure, and the phrase *collaborators and partners* is used to reflect this breadth of involvement. The NECRI will harness existing research and fuel transformative advancements to rapidly anticipate, detect, understand, communicate, and mitigate the potential effects of DW CECs on public health. These improvements will, in turn, help to inform DW advisories, standards, and public health actions for the Nation.

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<sup>27</sup> Johnston, Jill and Lara Cushing. 2020. "Chemical exposures, health, and environmental justice in communities living on the fenceline of industry." *Current environmental health reports* 7 (1):48-57. <https://doi.org/10.1007/s40572-020-00263-8>

<sup>28</sup> U.S. Global Change Research Program (USGCRP). 2018. *Impacts, Risks, and Adaptation in the United States: Fourth National Climate Assessment, Volume II*: [Reidmiller, D.R., C.W. Avery, D.R. Easterling, K.E. Kunkel, K.L.M. Lewis, T.K. Maycock, and B.C. Stewart (eds.)]. U.S. Global Change Research Program, Washington, DC, USA. <https://doi.org/10.7930/NCA4.2018>

## **Goal 1: Decrease the time from DW CEC identification to risk mitigation**

Five areas of DW CEC research are essential to decreasing the time from CEC identification to risk mitigation: contaminant identification and exposure characterization, effects assessment, risk characterization, risk mitigation, and risk communication. These overlapping, transdisciplinary areas contribute to the collection, organization, and analysis of data needed to characterize the CEC exposure and effects. The research is needed to mitigate the exposure and communicate appropriate, trustworthy information to collaborators and partners. Advancing critical research priorities in all of these areas and linking findings across disciplines will allow more rapid identification, understanding, and mitigation of CECs.

### **Contaminant Identification and Exposure Characterization**

Contaminant detection and identification are the first steps to understand and manage CECs. These data directly inform assessments of exposure and potential effects and contribute to risk mitigation and communication efforts. Detection and identification require the collection and analysis of water samples, water treatment-associated solid materials (e.g., sludge, biosolids), and environmental receptors at critical control points in real time and across the water cycle. Control points would include source waters; treatment facilities; delivery systems, including proximity plumbing; and locations for reuse and recycling; (Figure 1).

Analysis of these samples would provide information on CEC concentrations, type(s) of contaminant, structural and chemical characteristics, and fate and transport in the environment and before and after water treatment. These data would also establish an exposure scenario, that is, the direct or indirect route through which DW CECs reach individuals (e.g., drinking contaminated water vs eating food prepared with contaminated water). Currently, targeted monitoring methods are used to analyze known contaminants; generalized, non-targeted monitoring methods identify novel CECs, especially those in mixtures for which there is little or no existing knowledge, nor standard reference materials. More systematic and timely CEC identification and exposure characterization not only improve risk characterization, but also provide better context for the assessment of biological effects.

### Developing DW CEC Profiles

A CEC sampling and characterization strategy that integrates existing and developing tools, and includes consideration of mixtures and the synergistic effects of co-contamination, has the potential to link data derived at critical control points across the drinking water cycle into contaminant profiles. The profiles would document changes in contaminant chemistry and concentrations in surface waters, watersheds, aquifers and groundwater; through plumbing systems and the various stages of water treatment to the point of consumption; and recycling (Figure 1). Using surface water<sup>1</sup> and groundwater flow models,<sup>2</sup> profiles for surface and ground water contaminants could also be extrapolated to private water wells that are often untested.<sup>3</sup> Contaminant profile development would clarify exposure scenarios and shift the direction of the current contaminant-by-contaminant research approach to one in which contaminants that have similar profiles can be more readily identified and characterized.

<sup>1</sup> EPA. 2021. "Surface Water Models to Assess Exposures." <https://www.epa.gov/ceam/surface-water-models-assess-exposures>

<sup>2</sup> EPA. 2021. "Ground Water Modeling Research." <https://www.epa.gov/land-research/ground-water-modeling-research>

<sup>3</sup> EPA. 2022. "Potential Well Water Contaminants and Their Impacts." <https://www.epa.gov/privatewells/potential-well-water-contaminants-and-their-impacts>

## Human Health Effects Assessment

Characterizing the adverse effects of CECs requires recognizing, measuring, and understanding changes in biological activity<sup>29</sup> in response to a CEC exposure in the local environment. The type and magnitude of response varies as individuals respond differently to the same dose of a contaminant due to factors such as life stage, sex, body weight, and health status. Research challenges posed by CECs derive from the potential novelty of the emerging contaminant causing the adverse effect(s) and its presence at low concentrations or in mixtures. Additionally, there are unique challenges associated with long-term or multi-generational CEC exposures. Understanding the exposure concentration causing changes in biological activity or health status is essential to establish context for understanding health outcomes. Contaminant exposures could cause responses that compromise human health or cause adaptive responses through which the body compensates for an environmental exposure and returns to pre-exposure health status. In addition, the severity of the outcomes ranges from "adverse" (e.g., respiratory distress) to "more adverse" effects (e.g., infertility or death).

Currently, human- and animal-based cell cultures, biochemical assays, model organisms, and animal models are used to determine contaminant-related biological effects at critical biological endpoints in model systems.<sup>30</sup> Systematic reviews of published toxicological information that combine data from model organisms, laboratory and epidemiological studies, and clinical studies to identify human health effects use weight-of-evidence approaches to establish potential hazards and toxicity profiles. Expanding and adopting rapid assessment methods and linking the data to critical biological endpoints and exposure scenarios would provide more timely, relevant data for risk characterization, mitigation, and communication.

<sup>29</sup> While human health is described here, research efforts can be broader to include environmental effects.

<sup>30</sup> National Center for Advancing Translational Sciences (NCATS). 2021. "Toxicology in the 21<sup>st</sup> Century (Tox21)." November 11, 201. <https://ncats.nih.gov/tox21>

## **Risk Characterization**

Risk characterization is the process through which data generated through contaminant identification and human health effects research are organized and analyzed for use in risk mitigation and risk communication. Determining, communicating, and mitigating the potential human health effects in any scenario requires risk characterization approaches that are fit-for-purpose, that is, appropriate to the risk mitigation options under consideration and responsive to collaborators and partners conveying and receiving risk information. Because research data are acquired over time, risk characterization is an iterative process, providing the best available analysis at the time in which it is conducted.

Risk characterization requires broad access to a wide array of data and increasingly advanced tools that synthesize exposure and health effects information and incorporate the uncertainty and variability associated with these data. For CECs, especially those that occur in emergency situations, early information on contaminant hazard and exposure is often sparse and fragmented. Advances in, and integration of, data from contaminant identification, exposure characterization, and biological effects assessments would allow for more focused and timely risk characterization. The inclusion of factors such as geographical areas, personal behavior, the effects of climate change on CEC release and toxicity, and the disproportionate impact of DW CEC exposure on populations at higher risk would make the process more comprehensive and relevant.

## **Risk Mitigation**

Risk mitigation is a decision-making and treatment step that uses risk characterization data to determine actions that reduce the magnitude of a contaminant release, and the likelihood of exposure and adverse health effects. Presently, mitigation efforts for CECs are based on a broad range of risk mitigation strategies developed for regulated chemicals and include removal and reduction of containment in source waters; environmental attenuation, treatment, mitigation, and remediation; and removal by distributed point-of-use treatment systems. In cases where contaminants cannot be removed from the environment, physical barriers and institutional controls (e.g., regulatory and administrative measures) may be employed. The process of risk mitigation is dependent on the generation of data on contaminant identification, exposure, and effects; and the process for risk characterization provides information essential for more timely and focused mitigation decisions.

Prevention is an important mitigation strategy that addresses the root cause of CEC exposures and effects by circumventing CEC release into the environment. Prevention may be a mitigation option when CECs are difficult to treat and remediation costs prohibitive (e.g., in groundwater and in surface water<sup>31</sup>). It also includes opportunities to employ sustainable practices that remove hazardous substances from manufacturing processes and products (e.g., substitution),

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<sup>31</sup> Surface water refers to rivers, streams, lakes, reservoirs, springs, while groundwater is the water that exists underground in soil, sand and rock. If groundwater flows naturally out of rock materials or can be removed by pumping, the rock materials are called aquifers. More information at <https://www.groundwater.org/get-informed/basics/groundwater.html>.

or as a pre-treatment option to remove CECs from effluent prior to release. While source<sup>32</sup> and receiving waters<sup>33</sup> are the primary sites for DW CEC prevention efforts, remediation of soil, sediment, and air may provide an indirect, cost-effective strategy to prevent CEC water contamination.

### **Risk Communication**

Contaminant exposures occur in an environmental and societal context that requires the communication of scientific, technical, and human health information to many types of collaborators and partners. The information communicated is dependent on the type, amount, and timeliness of data on contaminant identification, exposure, and health effects. The risk characterization process also informs what information is communicated and how.

Risk communication for CECs is a type of transdisciplinary communication for which information is limited and public anxiety may be high. Uncertainty and variability in CEC data make understanding and accepting scientific risk information more challenging. Communication approaches should engage a diverse set of scientific disciplines, management strategies, communities and audiences, and traditional and social media environments to proactively build public trust. Risk communicators should follow the most current research on effective strategies for scientific communication, such as tailoring messages to offer accurate information in the context of strongly held beliefs, values, and interests. This communication requires an understanding of the diversity of interests and needs of those involved in communication, such as the transdisciplinary research teams, DW consumers, utilities, and those who may be affected by exposure to DW CECs. Better sociological, psychological, and socio-behavioral understanding of risk communication is essential for integrating and communicating complex scientific information about a CEC exposure and mitigation strategies.

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<sup>32</sup> Source water refers to sources of water (such as rivers, streams, lakes, reservoirs, springs, and groundwater) that provide water to public drinking water supplies and private wells. More information at <https://www.epa.gov/sourcewaterprotection/basic-information-about-source-water-protection>

<sup>33</sup> Receiving waters refers to any stream, river, lake, ocean, or other surface or groundwaters into which treated or untreated wastewater is discharged. From <https://www.owp.csus.edu/glossary/receiving-water.php>

## Goal 2: Promote technological innovation in tools to discover, track, understand, and mitigate DW CECs

DW CEC measurement tools establish the type and magnitude of a contaminant exposure as well as potential effects. Development and deployment of cost-effective and broadly applicable next-generation tools are essential to understand DW CEC exposure through time-resolved, near real-time, and real-time monitoring, screening, and reporting. When possible, the development of new CEC tools should align with the goal of New Approach Methods (NAMs) to avoid the use of whole animals when obtaining information on contaminant exposure and effects.<sup>34,35,36,37</sup> Three areas of tool development critical to achieve the NECRI vision are sensing and screening technologies to identify and monitor CECs, and biomarkers and models to measure effects.

### New Approach Methods (NAMs)

Research is being conducted by Federal agencies and the research community to reduce, refine, and replace the use of vertebrate animals in the testing of chemicals and mixtures to the greatest extent possible, and to develop new methods that do not require vertebrate animal testing. New Approach Methods (NAMs) are any *in silico*, *in chemico*, or *in vitro* assay method, or approach that does not use intact animals to generate data on potential CEC hazards and risks.<sup>1</sup> Examples of NAMs include high-throughput screening, computational toxicology and bioinformatics, tiered testing methods, and systems biology.<sup>1</sup> Using NAMs instead of traditional animal testing methods has the potential to provide faster, more cost-effective and more human-relevant information for toxicological studies.<sup>1</sup>

<sup>1</sup> EPA. 2020. *New approach methods work plan: Reducing use of animals in chemical testing*. U.S. Environmental Protection Agency, Washington, DC. EPA 615B2001. [https://www.epa.gov/sites/production/files/2020-06/documents/epa\\_nam\\_work\\_plan.pdf](https://www.epa.gov/sites/production/files/2020-06/documents/epa_nam_work_plan.pdf)

## Sensing Technologies to Identify and Monitor Contaminants

Sensors detect and measure a constituent of interest or a surrogate of that constituent. Next-generation CEC sensing technologies could incorporate recent progress in microfluidics, electrochemistry, and advanced materials, dynamic, on-demand controls, and real- and near-real-time monitoring. Wearable sensors could be used to monitor individual exposures and, coupled to sensors deployed in geographic locations and public water supply monitoring networks, would provide a more comprehensive understanding of CEC exposures. In many sensing environments, the incorporation of wireless telemetry allows for off-site monitoring of

<sup>34</sup> EPA. 2021. "EPA New Approach Methods Work Plan: Reducing Use of Animals in Chemical Testing." February 3, 2021. <https://www.epa.gov/chemical-research/epa-new-approach-methods-work-plan-reducing-use-animals-chemical-testing>

<sup>35</sup> Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). 2018. *A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States*. <https://dx.doi.org/10.22427/NTP-ICCVAM-ROADMAP2018>

<sup>36</sup> Andersen, Melvin E., Patrick D. McMullen, Martin B. Phillips, Miyoung Yoon, Salil N. Pendse, Harvey J. Clewell, Jessica K. Hartman, Marjory Moreau, Richard A. Becker, Rebecca A. Clewell. 2019. "Developing Context Appropriate Toxicity Testing Approaches using New Alternative Methods (NAMs)." *ALTEX*. 36 (4):523-534. <https://doi.org/10.14573/altex.1906261>

<sup>37</sup> Wambaugh, John F., Jane C. Bare, Courtney C. Carignan, Kathie L. Dionisio, Robin E. Dodson, Olivier Jolliet, Xiaoyu Liu, David E. Meyer, Seth R. Newton, Katherine A. Phillips, et al. 2019. "New Approach Methodologies for Exposure Science." *Current Opinion in Toxicology*. 15:76-92. <https://doi.org/10.1016/j.cotox.2019.07.001>

CECs. Nature-based solutions (e.g., microbes for detection, decontamination, and detoxification) should be explored. Deployment could occur during an acute contaminant release or as continuous monitoring to track contaminant emergence or reemergence. To maximize adoption of new sensor technologies, they would be field-tested, reconfigurable for targeted and non-targeted use, recyclable, and cost effective.

In addition to ground-based sensors, remote geospatial technologies are being used to map large scale environmental conditions (e.g., drought, harmful algal blooms, changes in watershed conditions, deforestation) with social determinants (e.g., race, ethnicity, location, income). Linking this information with contaminant exposure profiles could generate geographically localized and temporal exposure profiles for mitigation and health decisions.<sup>38</sup>

### Screening Technologies to Identify and Monitor Contaminants

Targeted and non-targeted monitoring are both components of a comprehensive and integrated approach to identify contaminants. Targeted monitoring generates quantitative data for previously-identified contaminants, whereas the goal of non-targeted analysis (NTA) is to rapidly and accurately detect, identify, and estimate concentrations of novel CECs in source waters and at the point-of-use.<sup>39,40,41</sup> NTA would benefit from improved instrumentation and computational analysis of non-targeted data, more comprehensive mass spectra databases, reference databases, and model training sets, and rigorous methods for statistical bounding of concentration estimates.

The application of high-throughput screening (HTS) to CEC research offers options for targeted and non-targeted contaminant screening that quantitatively estimates exposures and identifies biological activity associated with such exposures. It also may provide for targeted and non-targeted biological screening of the distribution of CECs among tissues (e.g., toxicokinetics) and organ and cellular responses to contaminants (e.g., genomics, transcriptomics, metabolomics, and phenotypic profiling).<sup>42</sup> Applied to CEC identification and effects measurement, HTS accelerates the discovery of adverse effects, pathways that could lead to specific adverse effects, and contaminant concentrations and contaminant phase of matter producing the response—all of which contribute to more rapid development of predictive models of *in vivo* toxicity for research prioritization.

<sup>38</sup> NASEM. 2021. “Leveraging Advances in Remote Geospatial Technologies to Inform Precision Environmental Health Decisions - A Workshop.” <https://www.nationalacademies.org/event/04-14-2021/leveraging-advances-in-remote-geospatial-technologies-to-inform-precision-environmental-health-decisions-a-workshop>

<sup>39</sup> Sobus, Jon R., John F. Wambaugh, Kristin K. Isaacs, Antony J. Williams, Andrew D. McEachran, Ann M. Richard, Christopher M. Grulke, et al. 2018. “Integrating tools for non-targeted analysis research and chemical safety evaluations at the US EPA.” *Journal of exposure science & environmental epidemiology* 28 (5):411-426. <https://doi.org/10.1038/s41470-017-0012-y>

<sup>40</sup> McCord, James. 2020. “Non-Targeted Analysis Approaches in Environmental Chemistry.” International Society of Indoor Air Quality and Climate Scientific and Technical Committee. Webinar, February 13, 2020. [https://cfpub.epa.gov/si/si\\_public\\_record\\_report.cfm](https://cfpub.epa.gov/si/si_public_record_report.cfm)

<sup>41</sup> Schymanski, Emma L., Junho Jeon, Rebekka Gulde, Kathrin Fenner, Matthias Ruff, Heinz P. Singer, and Juliane Hollender. 2014. “Identifying Small Molecules via High Resolution Mass Spectrometry: Communicating Confidence.” *Environmental Science & Technology*. 48(4):2097-2098. <https://doi.org/10.1021/es5002105>

<sup>42</sup> Espín-Pérez, Almudena, Julian Krauskopf, J., Theo M. de Kok, and Jos C. Kleinjans. 2014. “‘OMICS-based’ Biomarkers for Environmental Health Studies.” *Current Environmental Health Reports*. 1:353–362. <https://doi.org/10.1007/s40572-014-0028-6>

## Biomarkers and Model Systems to Measure Effects

Biomarkers are indicators of normal biological or pathological processes. Biomarkers can be used to indicate the possibility of contaminant exposure or adverse biological activities in response to an exposure and can be used to determine the type and extent of exposure for a population or geographical area. A “biomarker of exposure” could be a chemical, its metabolite, or the product of an interaction between a chemical and some target molecule or cell. “Biomarkers of effect” or “effects biomarkers” indicate a change in biological activity that could be used to determine if contaminant exposure causes adaptive effects or acute or chronic adverse outcomes. Effects biomarkers that measure biological response, mutagenicity, and genotoxicity are well established, whereas biomarkers of behavioral changes (e.g., aggressiveness, attention deficits, depression, hyperactivity, anxiety, and poor social communication) linked to the endocrine and neurological systems are not as established. If integrated into epidemiological studies, more definitive linkages between biomarkers of CEC exposure and effects would provide a better understanding of CECs in a population.<sup>43</sup>

Methods to assess contaminant-induced changes in neurodevelopment and related behavior changes remain elusive. Aquatic animal models of neurodevelopment (zebrafish, amphibian and avian embryos) are widely used in research, and rodents are the sentinel species for neurodevelopment-related changes in behavior.<sup>44</sup> Human and rodent cortical neuron development assays and microelectrode array assays<sup>45</sup> are promising alternatives to these models, and screening technologies could be used to identify new biological endpoints.

### Effects-Based Monitoring

In the same way that non-targeted analysis (NTA) can be used to identify novel contaminants, effects-based monitoring (EBM) uses biological tools, such as bioassays and biomarkers, to identify the potential biological effects of CEC exposures. EBM can be incorporated into monitoring programs of the DW cycle (Figure 1) to link chemical monitoring data to biological effects in DW samples.<sup>1</sup> For example, some CECs have the potential to disrupt hormone function, and EBM methods that measure relevant gene expression or protein levels can detect these effects. These measurements can be made in fish living in DW source waters to identify the presence of hormone-disrupting CECs, and can be supported by NTA to identify the contaminants that are causing the effect. In this way, using NTA and EBM in tandem provides a more comprehensive understanding of CEC hazards and risks and can be used for risk characterization and risk prioritization related to water quality.

<sup>1</sup> Cavallin, J.E. et al. 2021. “Effects-Based Monitoring of Bioactive Chemicals Discharged to the Colorado River before and after a Municipal Wastewater Treatment Plant Replacement.” *Environmental Science and Technology* 55(2):974-84.

<sup>43</sup> Shoaff et al. 2019. “Endocrine disrupting chemical exposure and maladaptive behavior during adolescence.” *Environmental Research*, 172:231-241

<sup>44</sup> Lázaro et al. 2019. “Reduced Prefrontal Synaptic Connectivity and Disturbed Oscillatory Population Dynamics in the CNTNAP2 Model of Autism.” *Cell Reports*, 27(9):2567-2578

<sup>45</sup> Zhao, Xinyu, and Anita Bhattacharyya. 2018. “Human models are needed for studying human neurodevelopmental disorders.” *The American Journal of Human Genetics*, 103 (6):829-857. <https://doi.org/10.1016/j.ajhg.2018.10.009>

### **Goal 3: Develop and deploy tools and approaches for DW CEC decision making**

Protecting populations from potential adverse effects of CECs necessitates forward planning, research, and policy decisions. Innovative research and analytical tools support these actions by providing approaches to collect and organize data within a decision framework, apply advanced computational approaches to maximize understanding of the data, and provide feedback for further research, decision making, and mitigation. Tools to accomplish these actions are grouped as (1) tools to reduce uncertainty in decision making and (2) frameworks for decision making.

#### **Tools to Reduce Uncertainty in Decision Making**

Tools and approaches are needed to identify and manage the types, sources, and magnitude of data and communication uncertainty across a CEC decision-making framework. Their application would improve data analysis, structure uncertainty and variability assessments, and help to balance different perspectives on and interpretation of diverse data and risk with the potential consequences of the decision.

##### ***Computational Tools***

A suite of computational tools would provide opportunities to extract insights and knowledge more efficiently from structured and unstructured data, compare known and unknown compounds to establish chemical identity and potential risks, and generate information relevant to a broad range of questions and decisions.<sup>46</sup> The application of computational tools to datasets of historical contaminants would provide additional information on chemical structure, property, and activity relationships for known contaminants and context for novel emerging contaminants, including mixtures.

Computational pattern recognition and advanced analytical methods could be leveraged to accelerate the research process. Cloud-based artificial intelligence and machine learning computing methods would improve computational screening by training predictive models to identify key chemical and biomolecular features of novel emerging contaminants. Pattern recognition methods, similar to quantitative structure-activity relationship approaches, could be used to classify features of CECs into potential functional or chemical classes and mine data in peer-reviewed publications from laboratories performing smaller-scale studies on the same contaminants.

##### ***Predictive Models***

In-silico predictive models are a maturing technology that integrates available exposure data—such as production volume, chemical characteristics, and fate and transport—with biological effects data and results from screening chemical libraries for substances with elevated exposure potential.<sup>47</sup> Model development should employ current statistical and data analysis techniques, incorporate uncertainty and variability for the data collected, and accommodate the data needs for risk characterization and mitigation.

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<sup>46</sup> For more information see: <https://comptox.epa.gov/dashboard/about>

<sup>47</sup> Zang, Qingda, Kamel Mansouri, Antony J. Williams, Richard S. Judson, David G. Allen, Warren M. Casey, and Nicole C. Kleinstreuer. 2017. "In silico prediction of physiochemical properties of environmental chemicals using molecular fingerprints and machine learning." *Journal of chemical information and modeling* 57 (1):36-49. <https://doi.org/10.1021/acs.jcim.6b00625>

Although models continue to be refined as they are applied, they represent a comparatively quick, low-cost method to identify likely CEC exposure pathways, potential for bioaccumulation and environmental persistence, and chemical and biological structure-activity relationships. Data from animal models, high-throughput screening, biomarker assessment, *in vitro* tests, and contaminant profiles would provide experimental data to corroborate predictive models.

***Exposome: An Integrated Conceptual Framework for Human Health***

The concept of the exposome began to evolve in 2005 to recognize the totality of exposures and other factors that influence health status.<sup>48</sup> The concept addresses the concern that health effects measured from a single exposure are incomplete or potentially misleading when the multiplicity of external environmental and internal biological factors is not considered in tandem. In context of the exposome, the term *exposure* includes: general external factors that might influence an individual's health status, such as the urban-rural environment, climate factors, socioeconomic status, and education; external factors specific to the individual, such as diet, physical activity, tobacco use, infection, and occupation; and internal biological factors, such as metabolism, gut microflora, inflammation, oxidative stress, and aging.

Although tools and technologies to assess the exposome are evolving and application of the exposome concept to CECs is still in its infancy, the exposome provides an organizing construct for CEC experimental design and context to interpret data derived from CEC research. While data collection and analysis challenges remain, the exposome framework has the potential to identify temporal and spatial patterns of CEC release and link them to acute and chronic changes in health status.<sup>49</sup> It may be possible, over time, to link exposome profiles with epidemiological studies and build a database of exposures and effects at critical points across the DW cycle and at critical points across life stages.<sup>50</sup>

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<sup>48</sup> Siroux, Valérie, Lydiane Agier, and Rémy Slama. 2016. "The exposome concept: a challenge and a potential driver for environmental health research." *European Respiratory Review* 25 (140):124-129. <https://doi.org/10.1183/16000617.0034-2016>

<sup>49</sup> Jang, S., T. J. McDonald, S. Bhandari, et al. 2021. "Spatial and temporal distribution of surface water contaminants in the Houston Ship Channel after the Intercontinental Terminal Company Fire." *J Expo Sci Environ Epidemiol* 31:887-899. <https://doi.org/10.1038/s41370-021-00343-3>

<sup>50</sup> Vineis, Paolo, Marc Chadeau-Hyam, Hans Gmuender, John Gulliver, Zdenko Herceg, Jos Kleinjans, Manolis Kogevinas et al. 2017. "The exposome in practice: design of the EXPOsOMICS project." *International journal of hygiene and environmental health* 220 (2):142-151. <https://doi.org/10.1016/2Fj.ijheh.2016.08.001>

### Exposome, Biomarkers, and Disadvantaged Communities

Biomarkers, as indicators of environmental impacts on health, have been correlated with chemical and non-chemical stressors whose impact accumulates over a lifetime. This accumulation of stressors is referred to as “allostatic load.” Disadvantaged communities are often subject to larger allostatic load due, in part, to lack of access to health-promoting resources and greater exposure to contaminants (stressors known to increase susceptibility to diseases such as diabetes). In utilizing the exposome as a conceptual framework for CEC exposures, biomarkers of broad chemical and non-chemical stress can be used to better understand the relationships between allostatic load, health disparities, and contaminant exposure.

National Academies of Sciences, Engineering, and Medicine. 2020. *Predicting Human Health Effects from Environmental Exposures: Applying Translatable and Accessible Biomarkers of Effect: Proceedings of a Workshop-in Brief*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25962>.

### Decision Support Frameworks

Decision support frameworks are used to balance the scientific, technical, economic, and societal complexities inherent in environmental contaminant decisions, maximize the potential to obtain information from CEC data, and link exposure conditions to risk characterization and mitigation options.<sup>51,52</sup> Research is needed to develop frameworks that can provide a process through which to assemble, weigh, and evaluate diverse data sets and develop scientifically defensible options to manage risk.<sup>53,54</sup> Additionally, these frameworks need to be developed in a way that acknowledges and accommodates uncertainty to better support communities. To function optimally across the different types of CECs, such decision frameworks should be inclusive and participatory, flexible and adaptive, and transdisciplinary.<sup>55</sup>

<sup>51</sup> Kurth, Margaret H., Sabrina Larkin, Jeffrey M. Keisler, and Igor Linkov. 2017. "Trends and applications of multi-criteria decision analysis: use in government agencies." *Environment Systems and Decisions* 37 (2):134-143. <https://doi.org/10.1007/s10669-017-9644-7>

<sup>52</sup> Reis, Jacques, and Peter S. Spencer. 2019. "Decision-making under uncertainty in environmental health policy: new approaches." *Environmental Health and Preventive Medicine* 24 (1):1-8. <https://doi.org/10.1186/s12199-019-0813-9>

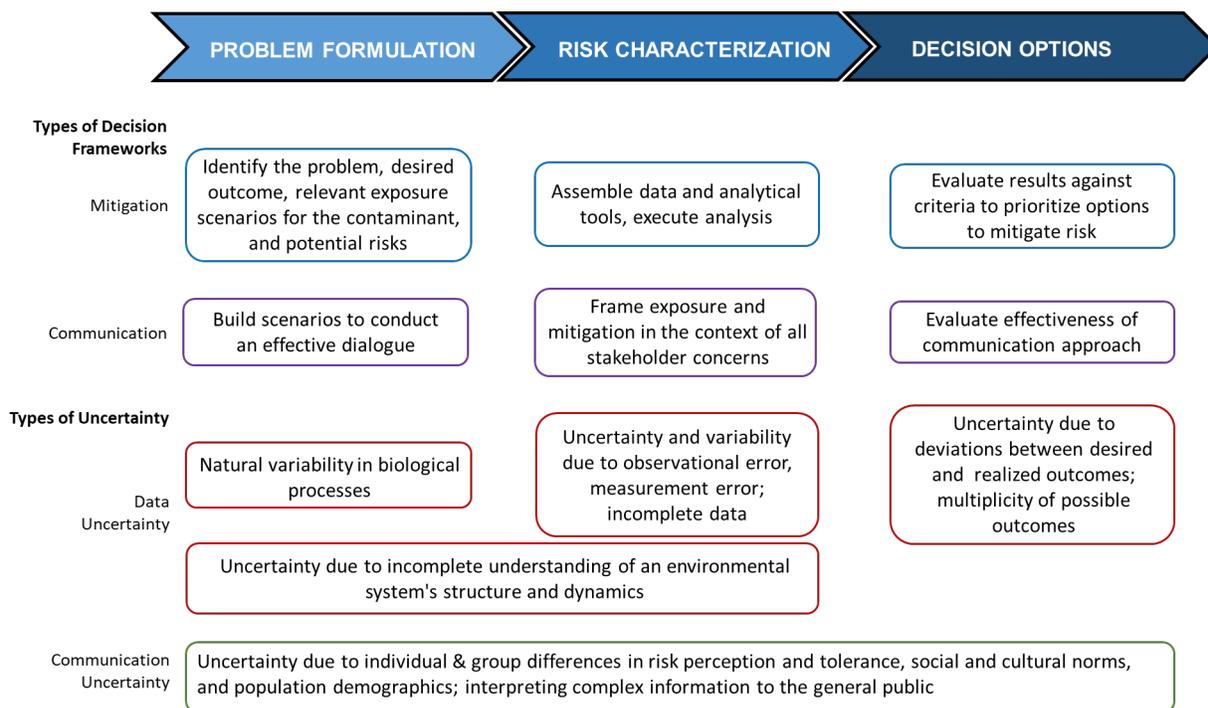
<sup>53</sup> Huang, Ivy B., Jeffrey Keisler, and Igor Linkov. 2011. "Multi-criteria decision analysis in environmental sciences: Ten years of applications and trends." *Science of the Total Environment* 409 (19):3578-3594. <https://doi.org/10.1016/j.scitotenv.2011.06.022>

<sup>54</sup> Society for Environmental Toxicology and Chemistry. 2018. *Technical Issue Paper: Weight of Evidence in Environmental Risk Assessment of Chemicals*. [https://cdn.ymaws.com/www.setac.org/resource/resmgr/publications\\_and\\_resources/setac\\_tip\\_weight\\_of\\_evidence.pdf](https://cdn.ymaws.com/www.setac.org/resource/resmgr/publications_and_resources/setac_tip_weight_of_evidence.pdf)

<sup>55</sup> Moosavi, Sareh, and Geoffrey R. Browne. 2021. "Advancing the Adaptive, Participatory and Transdisciplinary decision-making framework: The case of a coastal brownfield transformation." *Cities* 111:103106. <https://doi.org/10.1016/j.cities.2021.103106>

**Multi-step Process**

Most decision support frameworks are multi-step processes that include some form of problem formulation, risk characterization, and decision options (Figure 2).<sup>56</sup> Applied to risk mitigation, problems for an analysis are identified, structured, and analyzed. Based on risk characterization data and the context for problem formulation, a range of decision options can be identified and prioritized.



**Figure 2. Basic Elements in a Mitigation and Communication Decision Framework**

CECs pose challenges at each step of the decision framework, and analytical challenges occur because datasets are quantitative and qualitative, ranging from scientific and economic data to social, policy, and environmental considerations that are not amenable to quantification or valuation.<sup>57</sup> These multiple types of data, sometimes discordant, underscore the need for flexibility in design of the analysis and access to a wide range of analytical tools. Criteria to evaluate options to mitigate risk should align with the goals developed during problem formulation and could include the effectiveness and consequences of the mitigation, vulnerability of those exposed, and unintended consequences for implementing the mitigation, or not.

The CEC risk mitigation decision-making process would engage collaborators and partners, including disadvantaged communities, in the development and implementation of environmental decisions and policies. These communities would participate in the formulation of research questions, the research process, and communication of research findings about hazards, risks, and uncertainties. Research could identify water treatment solutions that serve resource-constrained communities.

<sup>56</sup> National Research Council. 2009. Science and Decisions: Advancing Risk Assessment. Washington, DC: The National Academies Press. <https://doi.org/10.17226/12209>

<sup>57</sup> Ibid.

### ***Uncertainty in Decision Making***

A systematic assessment of the uncertainties associated with CEC data, risk mitigation, and risk communication, as well as the application of computational tools and predictive models, are critical to informed, evidence-based decisions. However, these are infrequently incorporated into decision frameworks and less frequently agreed upon.<sup>58</sup> Types of uncertainty integral to CEC data range from biological variability in an environmental system to data errors and multiple, diverse potential outcomes (Figure 2, Data Uncertainty). Uncertainty in risk communication derives from the interpretation of complex scientific information, which can vary due to audiences with variable scientific literacy, individual and group differences in the perception of hazard and risk, social and cultural norms, and population demographics (Figure 2, Communication Uncertainty). Data and communication uncertainties are compounded by the addition of new scientific data over time and changes in the communities and partners engaged in the decision-making process. Engaging with collaborators and partners at every step in the risk mitigation decision-making process could allow for an effective understanding of audience-specific communication needs. This, in turn, allows for uncertainties in data and communication to be explored and explained at every stage of the process, allowing for greater transparency and trust.

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<sup>58</sup> Kurth, Margaret H., Sabrina Larkin, Jeffrey M. Keisler, and Igor Linkov. 2017. "Trends and applications of multi-criteria decision analysis: use in government agencies." *Environment Systems and Decisions* 37 (2):134-143. <https://doi.org/10.1007/s10669-017-9644-7>

## **Goal 4: Coordinate transdisciplinary DW CEC research activities among Federal and non-Federal partners**

The geographical regionality of many CEC releases and the transdisciplinary nature of CEC research makes coordination of research and communication among collaborators and partners challenging. Federal agencies could leverage long-standing experience to develop a network of CEC research centers that would advance research capabilities, reduce the potential for duplicative efforts, minimize the potential to miss major challenges or issues, and increase the communication and synergy among collaborators and partners. To fully leverage the CEC research and communication activities, centers would link to each other as well as other efforts in water research, water management, and policy. Data would be shared through a data repository and organized through a data management plan.

### **Networking CEC Research Programs**

Regional research centers composed of university, industry, Federal, State, local, and Tribal government partners, non-government organizations, and civil society would formalize a collaborative CEC network that could provide access to research data, methods, tools, and equipment. The network would include existing regional centers and encourage the development of new centers that fill geographical or research gaps. The network would also provide a platform for community engagement and considerations of environmental justice and climate change. It would equip communities and geographic regions, including emergency responders and citizen scientists, with the necessary tools and technologies to understand and respond to contaminant exposures, while allowing Federal entities to learn from the local experts.

### **Coordinating the Research Network and Data Repository**

Successful collaboration networks often benefit from a central component to administer, coordinate, and facilitate tasks and to streamline operations. Such a component would serve as a centralized access point to a data repository that would serve as a shared environment for data storage, access, and computing.

Using the FAIR data principles (findability, accessibility, interoperability, and reusability),<sup>59</sup> a CEC data repository has the potential to streamline data access, use, and integrity while protecting data confidentiality<sup>60</sup> and decreasing data costs. The repository could host emerging and historical CEC data that is currently distributed among many different Federal, State, local, and Tribal governments as well as academia, industries, water utilities, and non-profits. While the FAIR data principles were developed for research data, their applicability to the breadth of CEC data in the network would make CEC data available to those for whom access is currently limited, such as underrepresented and disadvantaged groups.

### **Data Management**

The utility of data to identify, understand, mitigate, and communicate CEC hazards and risks is dependent on the ability to systematically and sustainably collect and manage the data life cycle from collection through archiving and reuse (Figure 3). Systematic management would require a unified data

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<sup>59</sup> Wilkinson, Mark D., Michel Dumontier, IJsbrand Jan Aalbersberg, Gabrielle Appleton, Myles Axton, Arie Baak, Niklas Blomberg, et al. 2016. "The FAIR Guiding Principles for scientific data management and stewardship." *Scientific Data* 3 (1):1-9. <https://doi.org/10.1038/sdata.2016.18>

<sup>60</sup> NIH. 2018. "Strategic Plan for Data Science." <https://datascience.nih.gov/nih-strategic-plan-data-science>

infrastructure to allow for data sharing and interoperability and a data management plan. Such a plan would incorporate Federal data sharing policies and include guidelines for access to the data repository, review of existing data; decisions about the format, content, and provenance for generated data; and best practices to organize, secure, and store data. The plan would encompass files management to support analysis and research context. At the culmination of the research effort, data would be published and archived for use with future research questions and to inform risk characterization, mitigation, and communication.

The sum of the data in the data repository could also provide training sets to develop and refine computational tools, standardize measurements, and refine best practices for ensuring data quality.

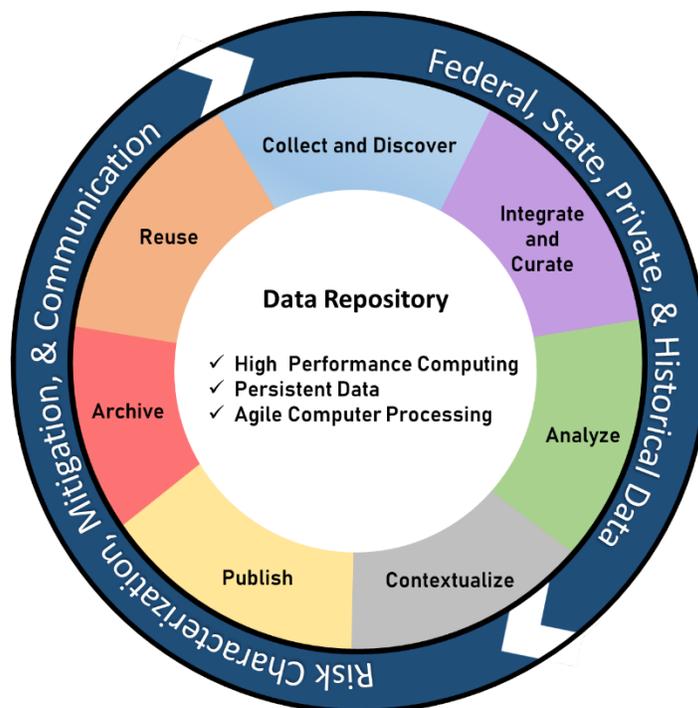


Figure 3. CEC Data Life Cycle and Analytics

## Goal 5: Foster transparency and public trust when communicating about DW CECs

CEC exposures and effects occur within a societal context that requires effective communication of multiple types of information among a diverse group of collaborators and partners. The effectiveness of this communication is dependent on the interpretation of complex, transdisciplinary, and multifaceted data in the context of those who are initiating the communication and those who are receiving the communication. Effective communication at every step from research to mitigation is critically important to establishing transparency and building public trust among all collaborators and partners. Additionally, ensuring community engagement reflected throughout the hierarchy of the decision-making process is crucial to ensure equitable outcomes and benefits. CEC risk communication priorities are organized as engagement and inclusion, communications research, and incorporation of communications research into the CEC research network.

### Engagement and Inclusion

In addition to those experiencing a CEC exposure, collaborators and partners range from researchers and citizen scientists, to public health experts, industries, governments (Federal, State, local, and Tribal), non-governmental organizations, and civil society. Creating an inclusive and participatory decision framework necessitates understanding the breadth and diversity of these communities. Engaging communities from the initiation of a decision-making process through mitigation and evaluation of results is a mechanism to build public trust. This could also increase equity in decision making and mitigation outcomes by ensuring engagement with underrepresented and disproportionately impacted groups.

Findings from the social sciences offer insights into effective coordination, collaboration, and co-development of partnerships and shared knowledge. As one example within a broader frame of processes, social scientists developed the process of scenario-building to conduct an effective dialogue that produces a mutual decision among individuals and groups with differing cultures, values, agendas, and goals.<sup>61,62</sup> This process is consistent with the problem formulation phase of a decision framework, as it would be used to identify and convene collaborators and partners, frame exposure and mitigation in the context of collaborator and partner concerns, and develop effective ways to communicate information, assumptions, and uncertainties. These outcomes would inform selection of qualitative and quantitative data for risk characterization, the development of options for risk mitigation, and final decisions. Incorporation of collaborator and partner communication into the CEC framework also provides a traceable decision path from identification of hazards and risks to final decisions.

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<sup>61</sup> Trump, Benjamin D., Danail Hristozov, Timothy Malloy, and Igor Linkov. 2018. "Risk associated with engineered nanomaterials: Different tools for different ways to govern." *Nano Today* 21:9-13. <https://doi.org/10.1016/j.nantod.2018.03.002>

<sup>62</sup> Oye, Kenneth A. 2012. "Proactive and adaptive governance of emerging risks: the case of DNA synthesis and synthetic biology." Prepared for the International Risk Governance Council (IRGC). [https://irgc.org/wp-content/uploads/2018/09/FINAL\\_Synthetic-Biology-case\\_K-Oye\\_2013.pdf](https://irgc.org/wp-content/uploads/2018/09/FINAL_Synthetic-Biology-case_K-Oye_2013.pdf)

### Scenario-Building

Scenario-building is a process to gather or generate critical information for a set of conditions, such as setting a research agenda or responding to a contaminant exposure. This process encourages creating and exploring scenarios (unknown but plausible future events or conditions in human-environmental systems) by a diversity of relevant parties, often through a workshop setting. Scenario-building can be used to help identify alternative futures and is particularly valuable in cases of high uncertainty. Scenario-building was used by the Department of Interior to provide rapid scientific assessment of system-wide impacts from the 2010 Deepwater Horizon oil spill and provide usable information to decision-makers. Scientists from diverse disciplines and from Federal, academic, and nongovernmental organizations were assembled and developed scenarios. Scenarios were constructed with cascading consequences and varying levels of uncertainty, and participants helped provide decision makers with possible intervention points for given scenarios.

Machlis, Gary E., and Marcia K. McNutt. 2010. "Scenario-building for the Deepwater Horizon oil spill." *Science* 329 (5995):1018-1019. <https://doi.org/10.1126/science.1195382>

### Communication Research

Mechanisms of communication—including how information is provided, the language used, and how messages are distributed—can influence how information is perceived among research experts and in populations potentially at risk of or experiencing a CEC exposure. Communication expertise is critical to navigate the complex, dynamic, and competitive media environment that exists, as well as to utilize media to manage science-related controversy as it emerges. Engaging with communication experts and considering how these mechanisms influence collaborator and partner relationships is essential to CEC research efforts and mitigation. In this context, a systems approach that recognizes the complexity of the communication and the need for an ongoing, diverse, flexible communication infrastructure is essential. The CEC decision frameworks would be one component of this approach.

### Science Communication, Research, and Vulnerable Communities

Engagement and inclusion build public trust in CEC research and mitigation efforts when communication practices are tailored to the population in question. For example, a National Academies workshop about biomarkers presented lessons learned in research efforts with Native American communities. Honesty in describing research processes, such as sampling, analysis, and result distribution, was key to establish trust and respect, as was the need to work directly with tribal leadership and community members in the research process. This approach promotes research that clarifies for all collaborators and partners expectations of the research process. The importance of having a diverse group of researchers that more closely resembled the population at hand, especially for vulnerable populations, played a strong role in building trust and finding research success.

National Academies of Sciences, Engineering, and Medicine. 2020. *Predicting Human Health Effects from Environmental Exposures: Applying Translatable and Accessible Biomarkers of Effect: Proceedings of a Workshop-in Brief*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25962>.

### **Communication as an Element of the CEC Research Network**

The integration of risk communication and a greater diversity of collaborators and partners into the CEC decision framework underscores the need for the transdisciplinary CEC research network to have communication and public health experts on, or closely associated with, research teams.<sup>63</sup> These experts would participate in communications research alongside exposure, effects, and risk researchers to develop and foster CEC communication best practices. The communication efforts would also facilitate critical multi-directional communication across the CEC research network and from the network to external collaborators and partners, including the general public. These relationships would provide the opportunity for researchers to understand the concerns, values, and perspectives of collaborators and partners, as well as allow for transparency, openness, and clear communication. It would also provide communities the opportunity to engage the centers as authoritative and, perhaps over time, trusted sources of information.

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<sup>63</sup> Green, Lawrence W., Judith M. Ottoson, Cesar Garcia, and Robert A. Hiatt. 2009. "Diffusion theory and knowledge dissemination, utilization, and integration in public health." *Annual Review of Public Health* 30: 151-174. <https://doi.org/10.1146/annurev.publhealth.031308.100049>

## Metrics for Measuring Progress

The passing of the Foundations for Evidence-Based Policy Making Act of 2018 (Evidence Act) emphasized the importance of creating and considering metrics across the Federal Government. This commitment to information sharing and accountability carries over into CEC research. Shared metrics across agencies and for the CEC ST are needed to assess progress to achieve the goals of this research initiative. Once metrics are established, an infrastructure is needed to support the collection and analysis of the data. Metrics and their supporting infrastructure would be established with the implementation plan and reviewed every 5 years to ensure the metrics remain current with the research and coordination activities.

### Types of Metrics

Metrics to assess progress on achieving the NECRI goals and assessing research outcomes include process, research, tools, coordination, health, and communication metrics. Development of metrics within each category should consider the data needed to conduct the assessment and the ability of the agencies to collect that data.

- **Process metrics** include the number of joint agency solicitations, joint reviews, joint funding decisions, timelines, and progress reports—as well as the effectiveness of these processes to accomplish these actions. Process metrics would also include basic program data such as number of funded projects or amount of funding. The agencies track this information through their budget processes.
- **Research metrics** assess research outputs and their alignment with programmatic goals. Traditional research metrics include number of publications or citations resulting from a CEC intervention or research award, and alternative metrics assess social media data on research findings. Other metrics could include length of time from research award to actionable data, as well as the diversity of awards. These metrics would assess whether DW CEC research was filling data and tool gaps and decreasing the time from CEC discovery to mitigation. Additionally, research metrics could assess research study design, risk characterization, mitigation and communications efforts to ensure that all populations, especially underrepresented or disproportionately impacted groups, are receiving equitable benefits.
- **Tools metrics** assess the number of new tools, methods, and approaches developed for CEC research and the research that is currently possible. As such, a variety of technology transfer metrics could be applied. These data could be in the published literature and patent databases, or in open source databases. These metrics would assess the development or refinement of advanced tools to discover, track, and mitigate DW CECs exposures and effects.
- **Coordination metrics** could include measures such as number of convening events, or an inventory of transdisciplinary, collaborator, and partner DW CEC research activities with State, local, and Tribal partners. These efforts may include counts of Federal agencies and partners developing and implementing planning and decision tools, their activities, and the growth and longevity of the collaboration. These metrics could also track coordination activities developed through the network of CEC research centers and those organized through the CEC ST.
- **Health metrics** include longer-term measures of CEC research on population health. They can utilize public health surveillance data and environmental monitoring data, and align it with the assessment of research outputs and tool development. These metrics should include measures of environmental justice that mitigate disproportionate exposure and effect.

- **Communication metrics** would assess both process and outcome measures. Within CEC research, communication metrics would assess the integration of communication and public health experts into research teams and their efforts to enhance multi-directional communication within CEC research centers, the research network, and with collaborators and partners. Measures of the effectiveness of communication efforts include measures of a population's understanding of CEC exposure, risk, health effects, and mitigation, as well as participation in decision support frameworks, research, and outreach. In addition, metrics could include measures of transparency and public trust when communicating about DW CEC research. These data will be challenging to identify and collect; however, they are critical to an assessment of communication goals.

## Implementation of NECRI Research and Collaboration Goals

Following publication, the CEC ST will establish an implementation framework to operationalize the goals of the NECRI to maximize Federal agency collaboration and coordination. The following descriptions provide content considerations for the CEC ST.

**Objectives and actions that align with NECRI goals:** Objectives and specific actions would be developed for each of the research goals to facilitate effective agency and interagency activities and program developments. For example, the CEC ST may develop an objective for Goal 1 to establish a more robust source-to-tap monitoring program and include a list of tangible intra- and interagency actions.

**Lead and facilitating agencies and government bodies for objectives and actions:** Objectives and actions laid out in the implementation plan should recognize agencies, inter-agency groups, and any additional governmental bodies that are best able to commit to and undertake the activities to meet the research goals of this NECRI. Objectives and actions may each be allocated to multiple agencies, or individual agencies may be allocated particular action items aligning to their current activities. For example, if action items are established to support an objective for more robust source-to-tap monitoring, CEC ST agencies could be listed as either lead or facilitating agencies for accomplishing these actions.

**Recognition of budget requirements:** The implementation plan should recognize the resources required to meet the objectives and actions for each of the five goals of the NECRI. This budget information may be agency-specific; may lay out monetary requirements for each of the research goals, objectives, or actions; or may acknowledge which agency or interagency bodies are going to allocate funds for research efforts. For example, for the objective to develop more effective source-to-tap monitoring, the CEC ST may estimate budget resources necessary for the Federal Government to accomplish this objective, considering the specific actions and responsible parties identified.

**Approaches for Collaborator and Partner Outreach:** To be responsive to the FY2020 NDAA, the implementation plan would include options for collaborators and partners to advise on research directions and participate in the research activities. The CEC ST should be inclusive of and responsive to non-research collaborators and partners (e.g., water utilities, State and local groups, and disadvantaged populations). For example, the implementation plan could include the development of workshops and webinars on source-to-tap monitoring that seek collaborator and partner comments, as well as opportunities to respond to an RFI.

**Timeline for accomplishing NECRI goals:** An implementation plan could include estimated timelines for agencies and inter-agency bodies to complete the objectives and actions. These timelines may indicate specific months or years expected for task completion, or may characterize action items as short-, medium-, and long-term activities. For example, the implementation plan could include how many years it will take lead and facilitating agencies to establish more effective source-to-tap monitoring that considers budget allocations and technical feasibility.

**Deliverables and measures of success:** The implementation plan could acknowledge deliverables and success metrics that will characterize the outcomes of the objectives and actions designed to meet the NECRI research goals. For example, an objective to develop more robust source-to-tap monitoring may include a description for tools, models, data sets, communication and information sharing mechanisms, including publications and reports.

## **Summary and Next Steps**

In response to the FY2020 NDAA, OSTP, in collaboration with the CEC ST, drafted the NECRI to improve the identification, analysis, monitoring, and mitigation of CECs. Five strategic goals address data gaps and critical priority areas that, when addressed, will generate actionable information for CEC mitigation and risk communication. The NECRI also provides guidance to Federal agencies and CEC collaborators and partners to create a transdisciplinary, inclusive research environment. While DW is the medium of focus for the NECRI, it is recognized that CECs exist in multiple media that may be relevant for addressing public and environmental health needs. These are considered, where appropriate, in this document. Further, multi-media (and other) considerations are expected to be addressed in the implementation of the NECRI. The capabilities and approaches developed under the NECRI should lead to a holistic treatment of CECs. Over the next year, the CEC ST will operationalize the NECRI through an implementation framework that organizes and coordinates the strategic goals, harnesses existing research, and fuels transformative advancements. The information derived from these actions will, in turn, inform DW advisories, standards, and public health actions and help our Nation to realize the vision of safe and plentiful DW for every person.