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Environmental Health Risk Assessment in the Federal Government: A Visual Overview and a Renewed Call for Coordination

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Abstract

In the United States (U.S.), chemical evaluations and assessments are conducted by seven federal agencies responding to distinct statutory requirements and focusing on different exposure scenarios. While risk assessment is a fundamental concept in public health practice and policy, there is no clear, central, and concise summary of these processes. The novel infographic presented here depicts more than 30 different evaluation and assessment processes conducted by federal agencies for chemicals found in the environment, workplace, consumer products, hazardous waste sites, food, and/or cosmetics. The majority of these assessments are statutorily required. Most serve as sources of authoritative information to provide public health guidance or recommendations. Less than half directly result in risk management actions or regulations. Understanding these roles and processes can facilitate engagement from the broader community, including by highlighting priority areas for research to inform public health policy. This infographic also illustrates the opportunity and need for further intra- and interagency collaboration and coordination – including a particular focus on aggregate risk assessment, given that the population regularly experiences exposures from multiple sources crossing agency domains.

Graphical Abstract

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Supporting Information

The Supporting Information is available free of charge at https://pubs.acs.org/doi/10.1021/acs.est.1c01955.

An overview of federal chemical evaluations and assessments in the United States (ZIP)

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Keywords

risk assessment; hazard identification; federal policy; aggregate risk; environmental health

INTRODUCTION

Risk assessment and its components, including hazard identification, exposure assessment, and risk characterization, are central concepts in environmental public health. Over the years, there have been several seminal National Academies reports on recommendations for optimal risk assessment processes[1-4] as well as numerous journal publications discussing the application of research to risk assessment.[5-9]

It can be difficult, however, to understand the myriad ways that these approaches are applied in practice across the U.S. federal government, the similarities and differences between them, and their ultimate relation to health policy, guidance, and regulation. Some but not all of these processes have been reviewed previously.[2,10-13] This brief commentary provides narrative context for an infographic (see Figure 1) that was created to illustrate the different applications and downstream purposes of risk assessment and its components across multiple agencies in the federal government. This commentary will not cover theoretical and conceptual issues related to risk, risk assessment, and standard-setting. There are two primary objectives of this commentary and infographic: first, to provide the environmental health community with a better understanding of hazard assessment, exposure assessment, and risk assessment processes at the federal level; and second, to highlight the opportunities for enhanced intra- and interagency collaboration and coordination–including through the implementation of aggregate risk assessment,[1,14] given that the population regularly experiences exposures from multiple sources crossing agency domains.

METHODS

Information for the infographic was obtained from federal agency Web sites and through personal communication with agency employees (for additional details as well as to ensure that all relevant programs were included).

The infographic is organized by federal agency, which in most cases corresponds closely with where or how a chemical is found or used. There is a secondary level of organization based on the main statute that governs the assessment or evaluation process. For some agencies (e.g., Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA)), there are additional levels of organization based on the specific agency's purview. Boxes within each agency subsection provide information on the evaluations and assessments as well as the downstream product or purpose of each. Underlined text denotes active hyperlinks available for further reference in the fully interactive HTML version that is available as Supporting Information.

DISCUSSION

Infographic Overview and Key Findings.

There are seven federal agencies responsible for conducting more than 30 different types of chemical assessments and evaluations relevant to environmental health. These assessments and evaluations cover chemical exposures in the environment, workplace, consumer products, hazardous waste sites, food, and cosmetics. Some are solely hazard assessments, while others include the additional steps of dose–response and exposure assessment.

The majority of these processes are statutorily mandated. For example, under the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which updates the Toxic Substances Control Act (TSCA), EPA is required to conduct risk evaluations on high priority existing chemicals in commerce. Similarly, the Public Health Service Act requires the National Toxicology Program (NTP) to develop the Report on Carcinogens (RoC), which identifies carcinogenic hazards (currently, on a biennial basis). By contrast, the Integrated Risk Information System (IRIS) assessment process is not specifically described in a federal statute but provides essential, centralized hazard characterization to support multiple EPA statutes as well as state and local health agencies.

Each of these assessments and evaluations serves a distinct and important purpose. Those conducted by regulatory agencies—such as EPA, FDA, the Occupational Safety and Health Administration (OSHA), and the Consumer Product Safety Commission (CPSC)—can contribute directly to risk management activities or regulations. For example, under the Clean Air Act, EPA conducts an Integrated Science Assessment (ISA)—a synthesis of policy relevant science—and, if warranted, a Risk/Exposure Assessment (REA)—a characterization of exposure and risk—for criteria air pollutants, such as ozone and particulate matter (PM). These assessments, which are followed by Policy Assessments (PA), inform the National Ambient Air Quality Standards (NAAQS). Other evaluations—including those conducted by nonregulatory agencies (National Institute for Occupational Safety and Health (NIOSH), Agency for Toxic Substances and Disease Registry (ATSDR), and NTP—serve instead as central, authoritative sources of information to federal, state, and local health and environmental agencies. For example, ATSDR develops Toxicological Profiles (ToxProfiles) for prioritized substances found at National Priority List (NPL) hazardous sites, which are then used by local agencies and first responders to identify potential risk. ATSDR also develops site-specific Public Health Assessments, which can be used to advise EPA and inform cleanup activity and community education.

While the infographic illustrates processes occurring at the federal level, it should be noted that there are additional chemical assessments conducted by state governmental agencies. Often, these state-based assessments address chemicals that have not been prioritized for federal review but present particular local concerns.[10]

Demystifying Federal Risk Assessment for the Environmental Health Community.

Risk assessment is a core concept across environmental public health. Yet, to my knowledge, there have been no previous attempts to bridge theory and practice by comprehensively illustrating how the ideas of risk assessment are operationalized across federal agencies.

The entire environmental health community can utilize and benefit from this infographic. First, it can be used as a teaching tool, to help explain the division of responsibilities and provide an overview of these processes in a digestible format. Second, it can highlight opportunities for targeted research to advance health policy. Because environmental public health research is often conducted with the goal of informing policy and decision-making, it is essential that researchers understand these various assessment processes and how their work could help fill crucial data gaps in different domains. For example, researchers with expertise in water pollutants could familiarize themselves with the milestones and deadlines under the Safe Drinking Water Act (SDWA), so that their work could inform the Contaminant Candidate List (CCL), Regulatory Determination Report, and National Primary Drinking Water Regulations. Third, with an enhanced understanding of the assessments, stakeholders can be better prepared to contribute their expertise by providing review of draft agency documents during relevant public comment periods. Fourth, this infographic can highlight regulatory gaps and/or priority areas for improvements in the domain of federal risk assessment. An example of a key gap is that EPA does not currently regulate indoor air quality; the Clean Air Act covers ambient (outdoor) air only. An additional area for improvement in federal risk assessment is discussed in the section below, Seeing the Big Picture: A Renewed Call for Agency Coordination and Aggregate Risk Assessment

Federal agency employees involved in specific assessments or evaluations may already be familiar with certain components of the infographic but may lack a larger perspective on all of the different processes. This infographic can clarify the distinct purposes of each assessment and provide context for how specific program work contributes to larger agency and interagency priorities.

Seeing the Big Picture: A Renewed Call for Agency Coordination and Aggregate Risk Assessment.

A great strength of the current federal system is that different agencies can focus their attention on the particular issues relevant to their own mandates and priorities. As highlighted in a U.S. Government Accountability Office (GAO) 2014 report, “while these federal agencies’ all provide information on this same broad area, their activities differ in type and purpose.”[10] The exposure scenarios most important to OSHA (i.e., occupational exposures for workers) are distinct from those relevant to the CPSC (i.e., consumer product exposures across the general population). The existing system allows agencies to “tailor initiatives to suit their specific missions and needs.”[10]

However, with this system, as the infographic illustrates, there is potential for "fragmentation"[10] and a tendency to "view environmental problems separately."[15] The concern is that these independent agencies produce siloed evaluations and assessments that neglect the "real-world" situation in which there are exposures from multiple pathways spanning multiple agency domains. The remedy is strengthened intra- and interagency coordination, including through consistent consideration of aggregate risk.

The need for improved coordination has been recommended previously. In the 1983 report *Risk Assessment in the Federal Government*, the National Research Council "endorse[d] coordination in assessing the risks of chemicals that are likely candidates for regulation by two or more agencies."[2] Specifically, the Council recommended the "establishment of an interagency task force," which would function on an ad-hoc basis in responding to the particular assessment needs.[2] The 2014 GAO report, *Chemical Assessments: Agencies Coordinate Activities, but Additional Action Could Enhance Efforts*, suggested that the Office of Science and Technology Policy (OSTP) National Science and Technology Council (NSTC) "could serve an interagency coordinating function to address certain cross-cutting challenges" to help federal agencies "better coordinate their assessment activities in the most effective and efficient manner."[10] The status of progress in these areas is unclear.

Nevertheless, it should be noted that there are ongoing efforts for coordination and communication related to specific issue areas. A recent example is the memorandum of understanding (MOU) between EPA and OSHA for EPA's review of new chemicals under TSCA.[16] This MOU allows EPA to seek input from OSHA on workplace exposures and consult with OSHA on potential workplace-related prohibitions or restrictions, although it is too soon to evaluate the effectiveness of this effort. Another example is the current focus on per- and polyfluoroalkyl substances (PFAS). PFAS can be found in food packaging, household/consumer products, ambient air, drinking water, hazardous waste sites, and the workplace,[17] spanning the purviews of all seven agencies highlighted in the infographic. EPA has embarked on a coordinated program, which includes a cross-agency working group, to address the growing national emergency of PFAS.[18] However, details on interagency activities are difficult to ascertain, and therefore it is challenging to comment on the scope or success of this effort. Enhanced interagency collaboration on this class of chemicals is necessary, since any evaluation that only considers pathways relevant to a single agency—as is the existing approach, for example, with consideration of drinking water exposures by EPA separate from that of food contact applications by FDA—would underestimate total risk to the population. Yet, the situation with PFAS is not unique. There are countless chemicals with exposure routes spanning distinct agencies: lead, arsenic, and phthalates are a few common examples.[12,19,20] Thus, this type of broad coordination should be the norm, rather than the exception.

The best way to ensure more concerted intra- and interagency coordination would be routine examination of aggregate risk–the analysis of exposure to a chemical by multiple routes and pathways – in any federal risk assessment. This requirement could be initiated through an executive order. There has been increasing discussion about the importance of aggregate (and cumulative) risk assessments in recent years,[1,14,21,22] but this infographic suggests an urgent need for more consistent consideration of scenarios that cross agency domains.[23] The

European Commission's 2020 *Chemicals Strategy for Sustainability Toward a Toxic-Free Environment*, which aims to implement a "one substance, one assessment" approach,[24] could serve as an exciting model for a more integrated system. Without analogous efforts in the U.S., agency and pathway-specific assessments will likely underestimate public health risk.

Summary.

The U.S. has multiple agencies tasked with undertaking a wide array of chemical evaluations and assessments. Each of these assessments serves a different purpose, and all are essential for improving our overall understanding of hazard and risk. This infographic can serve as a central resource for the environmental health community to support education, research, and policy engagement.

Importantly, this infographic also highlights the need for further intra- and interagency collaboration and coordination, including a more consistent focus on aggregate risk assessment. With a new administration voicing a renewed commitment to public health and the environment,[25] the time may be right for the country to take on this challenge.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Biography

Dr. Rachel M. Shaffer completed her MPH (Environmental and Occupational Health) and PhD (Environmental Toxicology) at the University of Washington-Seattle School of Public Health. She also has a BA (Environmental Studies) from Yale University. Dr. Shaffer has a broad background in environmental health sciences, with graduate training spanning *in vitro, in vivo*, and human epidemiological research. She has published on air pollution, glyphosate,

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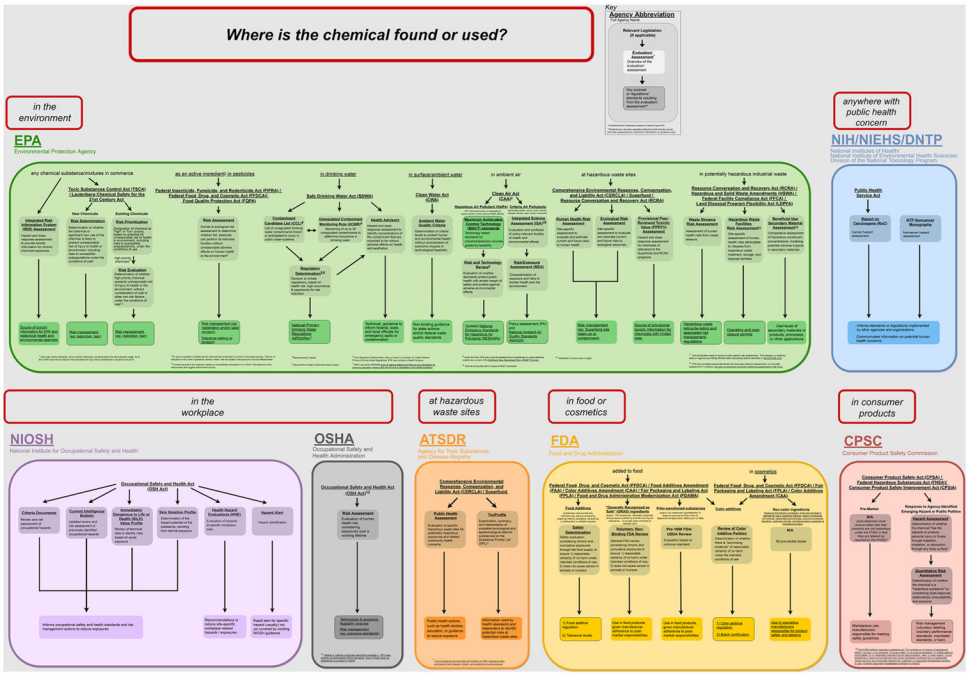

Figure 1.

An overview of federal chemical evaluations and assessments in the United States. As indicated by the figure key, the agency abbreviation and full agency name are located in the upper left corner above each subsection. Within each subsection, arrows lead from the relevant legislation (if applicable) to the evaluation or assessment (light shaded box) and then further to the downstream purpose of each (dark shaded box). For EPA and FDA, there are additional levels of organization above each statute based on where the chemical is found. Outlined boxes at the bottom of each subsection indicate a formal regulation or standard that directly results from the evaluation or assessment; non-outlined boxes indicate non-binding guidelines or recommendations alone. Underlined text denotes active hyperlinks available for further reference in the interactive HTML version. A fully interactive version of this image is available as Supporting Information.