EPA Offers Guidance for Chemical-Exposure Assessments, but Its Risk Assessments Are Still Plagued by Inadequate Scientific Support

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The US Environmental Protection Agency (EPA)'s Integrated Risk Information System (IRIS) Program undertakes assessments of exposures to various chemicals in order to determine corresponding health hazards and toxicity values. On December 22, 2022, the EPA published new procedures for these IRIS assessments, prescribing scientific methods for the analysis of case studies of individuals exposed to various chemicals. The EPA's new procedures are set forth in the Office of Research and Development Staff Handbook for Developing IRIS Assessments. The IRIS handbook provides procedures for developing IRIS assessments, including how to apply systematic review approaches. Systematic review uses pre-specified scientific methods to identify, select, assess and synthesize the findings of similar, but separate, studies. In IRIS assessments, such studies are used to identify human health hazards associated with exposure to chemicals found in the environment and derive toxicity values for health effects resulting from exposure. The procedures set forth in the IRIS handbook will apply prospectively to new IRIS assessments, but EPA claims that many elements of the handbook procedures were incorporated in recently finalized assessments and assessments that are currently in progress.

In releasing its new IRIS handbook, the EPA stated that it "is committed to developing IRIS assessments using consistent, transparent and scientifically rigorous methods." That statement seems to be a direct response to numerous criticisms of, and challenges to, EPA's scientific methodology for risk assessments that underlie its regulatory actions. Last year, the American Chemistry Council released scathing findings from its review of the EPA's IRIS assessment for formaldehyde, which it claims revealed "a troubling pattern of process irregularities, lack of independence, bias and conflicts of interest that demonstrates a need for greater scrutiny and transparency." Previously, the National Academy of Sciences, Engineering and Medicine (NAS) criticized the EPA's systematic review process for risk evaluations under the Toxic Substances Control Act, finding it suffers from "inadequate documentation, itself an indication of failing at being comprehensive, workable, objective and transparent."

Before publishing its IRIS handbook, the EPA sought guidance from the NAS, which reviewed a draft of the handbook. NAS found that the handbook reflected significant improvements in its assessment process, though it still had a number of criticisms and recommendations to improve the handbook and risk assessment processes. Such improvements across the EPA's risk assessment processes will be critical, as it is likely that the science that serves as the basis for its forthcoming regulations concerning PFAS, including its promulgation of Maximum Contaminant Levels and designation of perfluorooctanoic acid and perfluorooctane sulfonic acid as hazardous substances under CERCLA, is likely to be challenged.

On the same day that the EPA announced its IRIS handbook, it also published its IRIS assessment of perfluorobutanoic acid (PFBA) and related salts. PFBA is a breakdown product of other per- and polyfluoroalkyl substances (PFAS) that are often used in stain-resistant carpet, water-repellent clothing and paper packaging, among other products. While the stability of PFBA facilitates the stain and grease resistance of these products, the same chemical-composition may lead to bioaccumulation in human. The EPA's IRIS assessment of PFBA determined that there is "inadequate information to assess carcinogenic potential" of PFBA. It did, however, find that sufficient levels of exposure to PFBA likely causes thyroid, liver and developmental effects. The EPA, however, admits that "[t]he

ability to draw conclusions regarding these associations is limited due to the methodological conduct of the studies (studies were generally considered low confidence…); the small number of studies per health outcome; and the generally null findings coincident with notable sources of study insensitivity due to lack of detecting quantifiable levels of PFBA in blood samples or a narrow concentration range across exposure groups." Consequently, it is expected that industry groups are likely to challenge these findings, as they have with respect to EPA risk assessments for other PFAS chemicals.

While it is clear that the EPA is attempting to improve its process conducting for risk assessments, particularly when it comes to its review of PFAS, these assessments will continue to suffer as long as there is insufficient epidemiological evidence that PFAS chemicals actually cause adverse health effects. As a result, you can expect that industry will challenge the EPA's PFAS regulations based on inadequate scientific support for the regulations.