

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, DC 20503

January 8, 2020

MEMORANDUM

TO: Andrew R. Wheeler,
Administrator, Environmental Protection Agency

FROM: Paul J. Ray
Administrator, Office of Information and Regulatory Affairs

SUBJECT: E.O. 12866 Review of U. S. Environmental Protection Agency (EPA)
Integrated Risk Information System (IRIS) Assessments

Executive Order No. 12866 “Regulatory Planning and Review,” directs the Office of Management and Budget (OMB) to carry out the centralized review of significant regulatory actions under development at regulatory agencies. Within OMB, the Office of Information and Regulatory Affairs (OIRA) has the primary responsibility under the E.O. for a number of the specific regulatory review and planning functions. OIRA has a longstanding practice of designating guidance documents as significant under E.O. 12866, a position that has been affirmed across administrations.¹ Also relevant to this memorandum, E.O. 13891 reforms federal guidance practice and directs that significant guidance documents must be submitted to OIRA for E.O. 12866 review. The Environmental Protection Agency’s E.O. 13891 implementing regulations further support the long-established practice of E.O. 12866 review of significant guidance documents.²

The IRIS program supports EPA’s mission to protect human health and the environment. IRIS Assessments are influential or highly influential scientific documents that play a foundational role in agency-wide regulatory policy choices and also serve as a scientific resource to states, local government, tribal agencies, other Federal agencies, and international health organizations.

¹ See, e.g., *Guidance for Regulatory Review, M-09-31* (March 4, 2009) (“During this period, OIRA reviewed all significant proposed or final agency actions, including significant policy and guidance documents. Such agency actions and documents remain subject to OIRA’s review under Executive Order 12866.”).

² *EPA Guidance; Administrative Procedures for Issuance and Public Petitions*, 85 *Fed. Reg.* 66230, at 66238 (“*Significant guidance document* means a guidance document that is determined to be “significant” pursuant to Executive Order 12866 and Executive Order 13891.”).

I have determined that IRIS Assessments qualify as “guidance documents” within the meaning of E.O. 13891³ and that certain of these Assessments historically have qualified, and are likely to continue to qualify, as “significant” as that term is defined in E.O. 12866 and E.O. 13891. Under the terms of both of these Orders, therefore, “draft” and “final” IRIS Assessments should be submitted to OIRA for determination of significance and, for Assessments deemed significant, for interagency review.

This determination applies to EPA health-based values used in lieu of IRIS values; for example, provisional peer-reviewed toxicity values (PPRTVs) that may be reasonably anticipated to be used in the context of contaminant cleanup under CERCLA/RCRA, local or state health-based decision-making, or private sector decisions. Guidance to the public or internal to EPA but affecting the behavior of the public regarding the development, application, or use of these IRIS or PPRTV values would also qualify as guidance.⁴

IRIS Assessments and related documents can trigger any number of “significant” factors under section 3(f) of E.O. 12866.

Annual effect on the economy & budgetary impacts.

As a result of IRIS Assessments’ role in EPA policy decisions as well as state and local regulations or contaminant clean-up processes, these Assessments very often would qualify as either economically significant or likely to materially alter budgetary impacts as defined under section 3(f)(1) and (3) of E.O. 12866.

Interagency equities.

IRIS Assessments have the potential to create a serious inconsistency or otherwise interfere with an action taken or planned by another agency under section 3(f)(2) of E.O. 12866. Executive branch agencies face unique challenges related to cleaning up chemical contamination on federal sites and use the IRIS values to guide cleanup as dictated by EPA’s statutory authorities. OIRA is uniquely well-positioned to adjudicate potential interagency disagreements, as recognized in E.O. 12866.

Novel legal or policy issues.

IRIS Assessments often break new policy ground in both scientific and regulatory policy arenas, and when they do, would qualify as significant under section 3(f)(4) of E.O. 12866. Development of IRIS Assessments sometimes require the resolution of cutting-edge scientific questions or novel legal issues; the perspective of scientists from throughout the federal government, brought together in the interagency process, can be particularly valuable in grappling with these issues.

³ IRIS Assessments qualify as agency statements of general applicability, intended to have future effects on the behavior of regulated parties, that set forth a policy on a statutory, regulatory, or technical issue. *See* E.O. 13891 section 2(b).

⁴ *See, e.g.,* U.S. EPA. *ORD Staff Handbook for Developing IRIS Assessments* (Public Comment Draft, Nov 2020); U.S. EPA. *Office of Solid Waste and Emergency Response, Directive 9285.7-53: Human Health Toxicity Values in Superfund Risk Assessments*, 12/5/2003”