United States Environmental Protection Agency

UPDATE ON THE INTEGRATED RISK INFORMATION SYSTEM

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EPA SAB Meeting

May 31-June 1, 2018

- **Created in 1985 to foster consistency in the evaluation of chemical toxicity across the Agency.**
- **IRIS assessments contribute to decisions across EPA and other health agencies.**
- **Toxicity values**
  - Noncancer: Reference Doses (RfDs) and Reference Concentrations (RfCs).
  - Cancer: Oral Slope Factors (OSFs) and Inhalation Unit Risks (IURs).
- **IRIS assessments have no direct regulatory impact until they are combined with**
  - Extent of exposure to people, cost of cleanup, available technology, etc.
  - Regulatory options.
  - Both of these are the purview of EPA's program offices.

IRIS Provides Scientific Foundation for Agency Decision Making

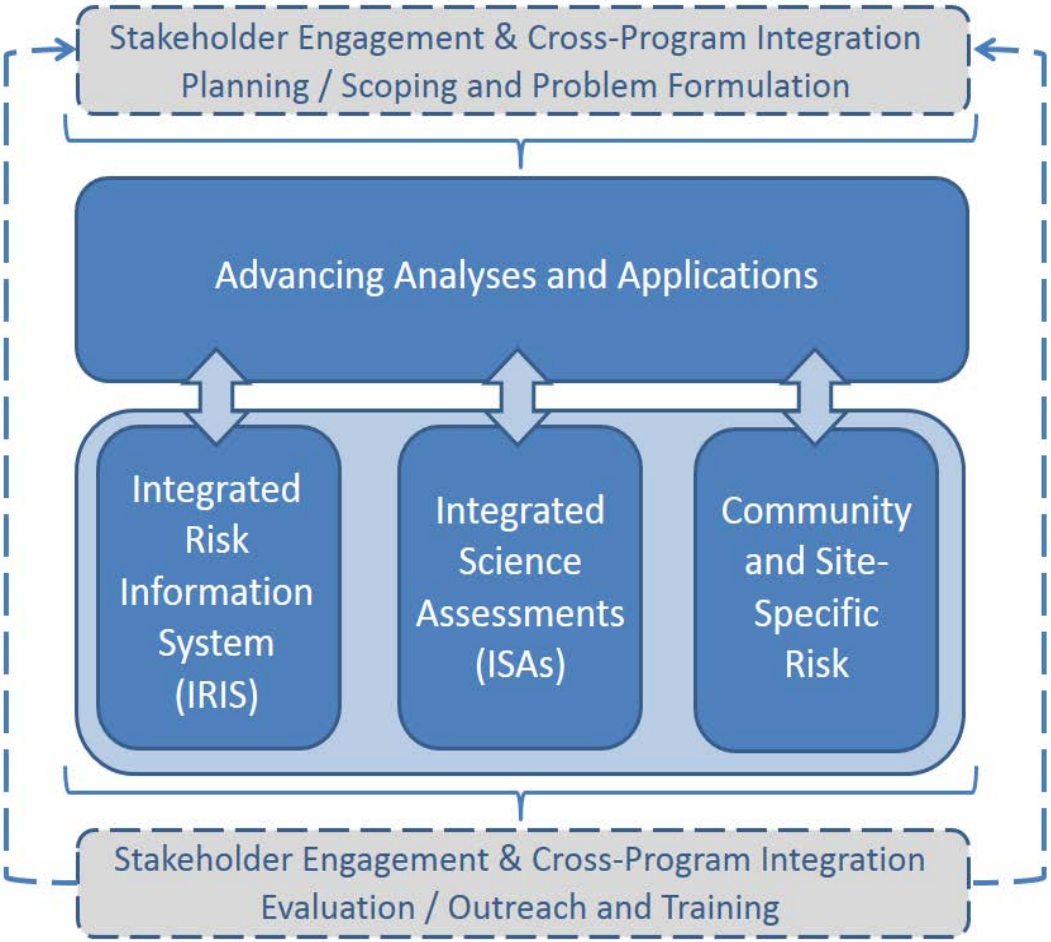
IRIS

- Clean Air Act (CAA)
- Safe Drinking Water Act (SDWA)
- Food Quality Protection Act (FQPA)
- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)
- Resource Conservation and Recovery Act (RCRA)
- Toxic Substances Control Act (TSCA)

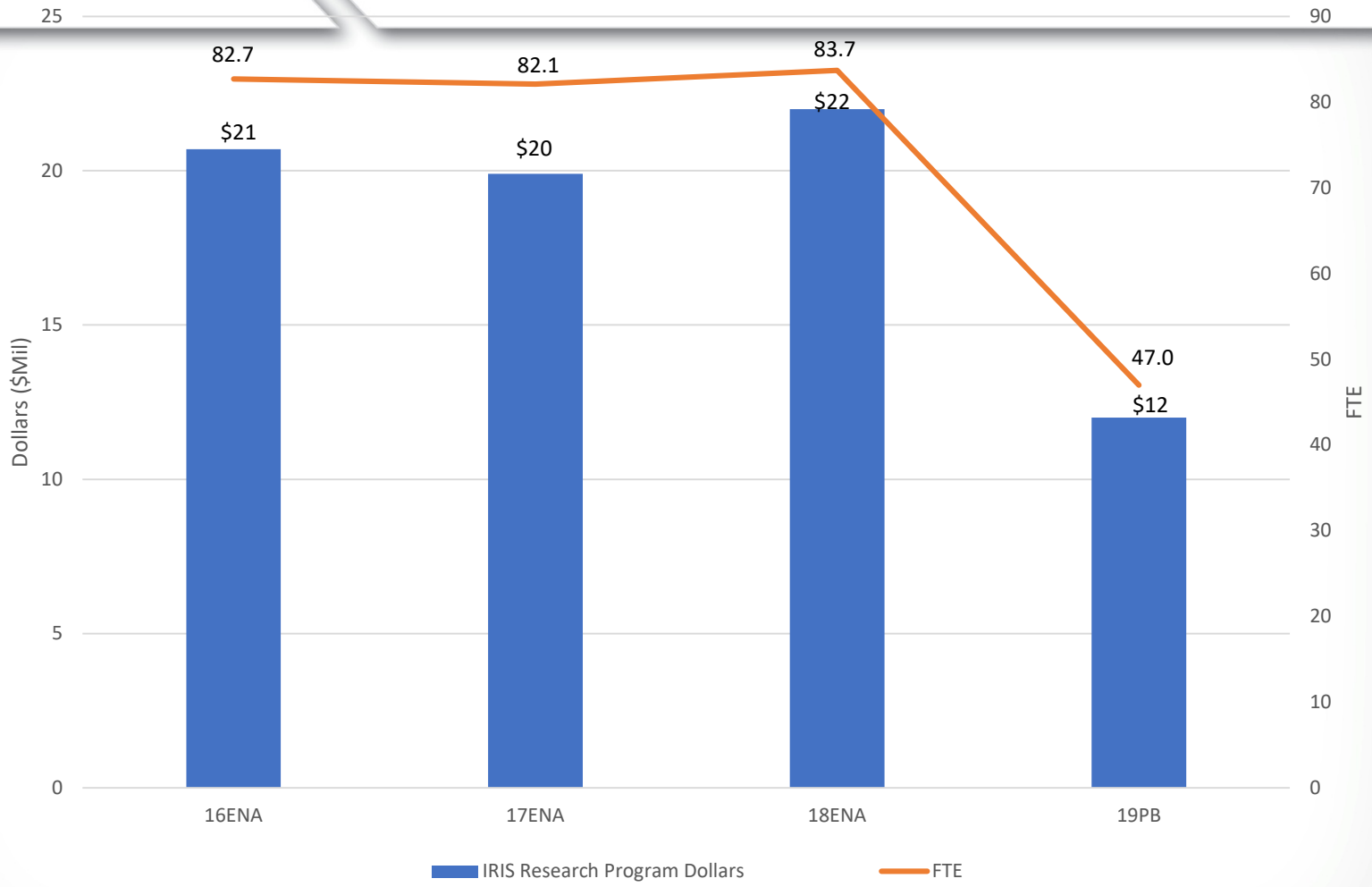
Broad Input to Support

- Agency Strategic Goals
- Children's Health
- Environmental Justice

Human Health Risk Assessment (HHRA)



IRIS Program Resources: FY 16-19 Dollars and FTE



Note 1: All IRIS resources include S&T and SF appropriations.

Note 2: FY17 information reflects resources prior to cancellations of funds.

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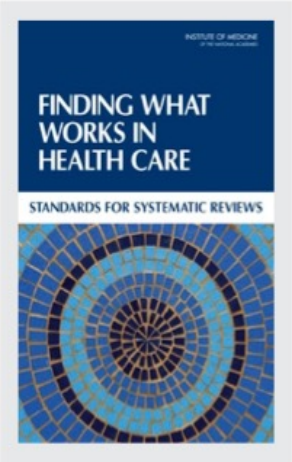
SYSTEMATIC REVIEW

Office of Research and Development
NCEA, IRIS

Systematic Review

A structured and documented process for transparent literature review[1]

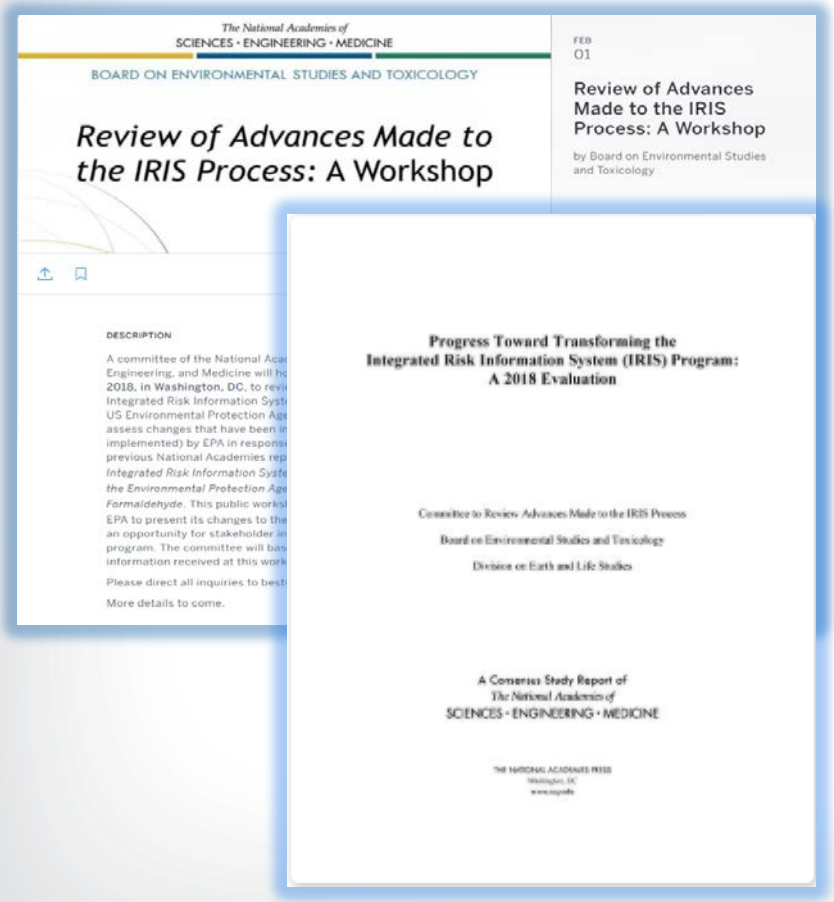


"As defined by IOM [Institute of Medicine], systematic review 'is a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies.'" [p. 4] (NRC, 2014)

[1] Institute of Medicine. Finding What works in Health Care: Standards for Systematic Reviews. p.13-34. The National Academies Press. Washington, D.C. 2011

NAS IRIS Workshop Report

- **A consensus report by the National Academy of Sciences on progress made in the IRIS Program (based on a February 1-2, 2018 workshop) is now available**

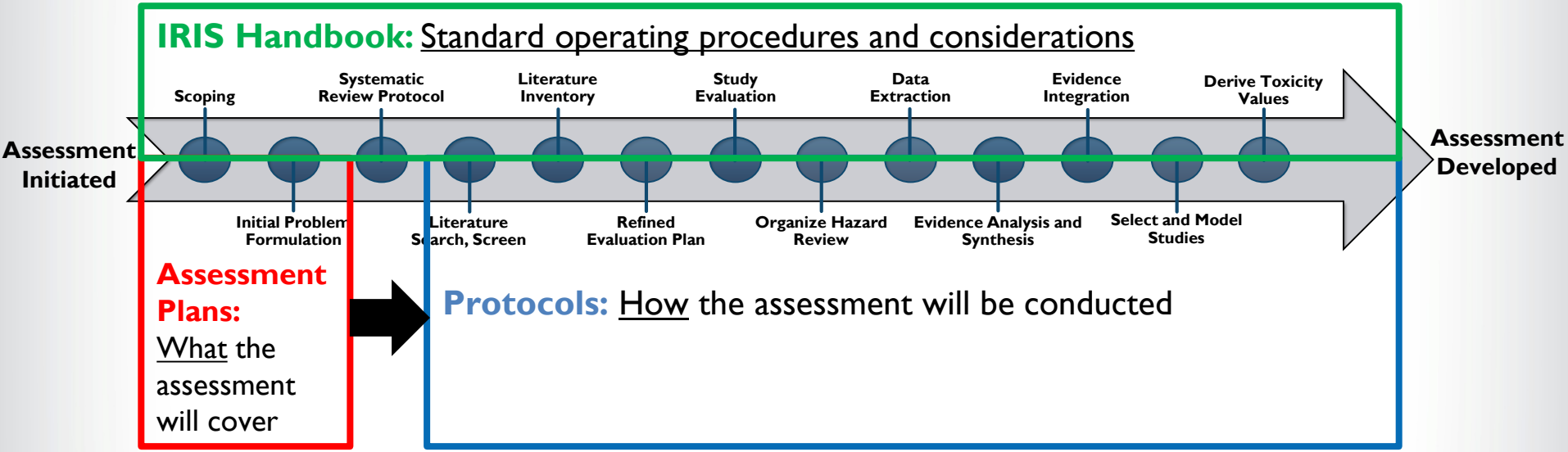


Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation (released April 11, 2018)

IRIS is currently working with NAS to organize workshops on:

- Mechanistic evidence: Strategies and tools for screening, evaluation and integration in chemical assessments conducted using systematic review (FY19/Q1)
- Evidence integration (FY19)

IRIS Systematic Review Documents



IRIS Systematic Review Documents

Chemicals	Assessment Plans	Protocols
Chloroform	Sept 2017 (SAB CAAC)	January 2018
Ethylbenzene	Sept 2017 (SAB CAAC)	
Nitrate/nitrite	Sept 2017 (SAB CAAC)	
Uranium	January 31, 2018 (webinar March 22, 2018)	
Ammonia (oral)	April 16, 2018 (webinar May 23, 2018)	
Naphthalene	FY18 (Q3)	
Hexavalent chromium		FY18 (Q4)
Arsenic		FY18 (Q4)

IRIS Handbook

- **FY2018 budget language on Handbook**

> the program to do so, while also encouraging the program to ensure that all IRIS methodologies attain the highest scientific rigor. Finally, the Committees urge the expedited completion of the IRIS handbook and direct that the public be afforded an opportunity to provide comment on the handbook before it is placed in use.

- **Plan to have the Handbook peer-reviewed by the SAB Chemical Assessment Advisory Committee (2019)**
  - **Will undergo public comment and Agency/Interagency comment prior to external peer-review**
  - **Currently being updated to reflect hands-on experience in implementing, public comments on chloroform protocol, and NAS workshop report**

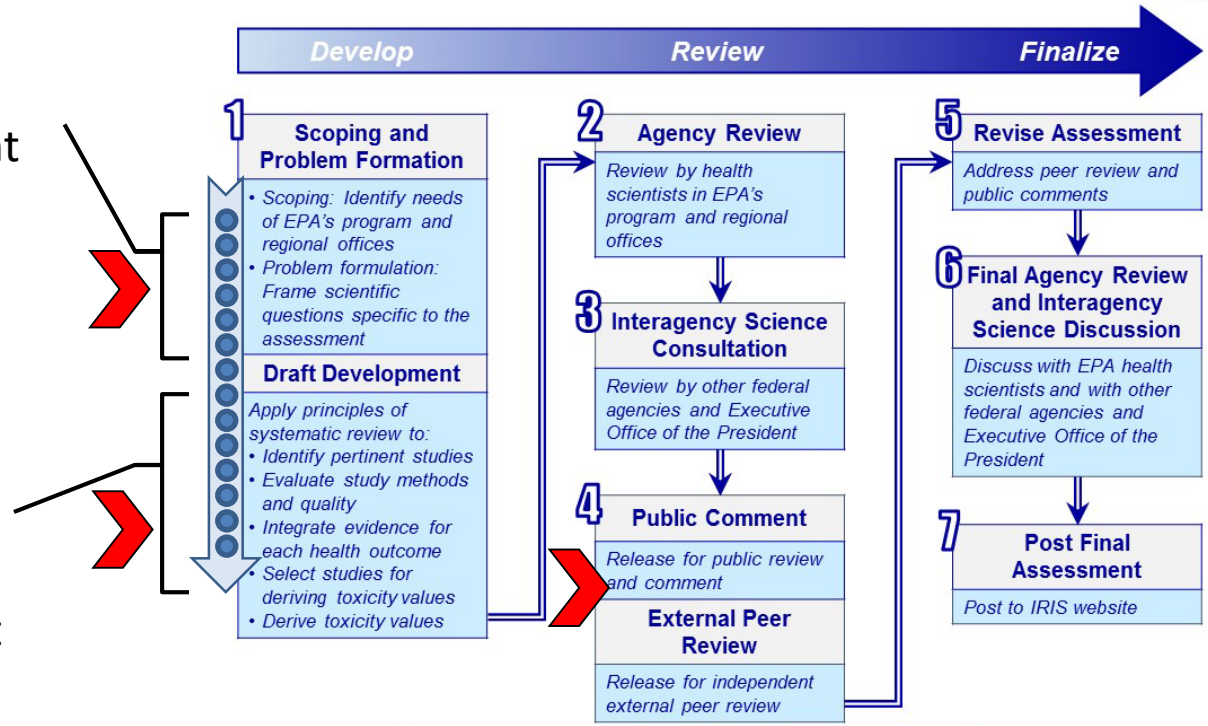
IRIS Assessment Plans, Protocols, and 7-Step IRIS Process

Early Step 1: IRIS Assessment Plans

- What the assessment covers
- 30-day public comment period + public science meeting

Mid-Step 1: Protocols

- How the assessment will be conducted
- 30-day public comment



Opportunities for Public Comment

https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process

New GAO Engagement

- Subject: "EPA's Chemical Management Strategies" (code 102673)
- GAO began this work on its own initiative pursuant to its authority under 31 U.S.C. 717
- GAO objectives:
  - To what extent has EPA demonstrated progress assessing chemicals through the Integrated Risk Information System (IRIS) program and how have recent changes to the program addressed underlying challenges?
  - To what extent has EPA demonstrated progress implementing the Toxic Substances Control Act (TSCA), as amended by the Lautenberg Act, and ensured that EPA has the resources necessary?
- Engagement initiated March 2018, report expected early 2019

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PORFOLIO APPROACH TO CHEMICAL ASSESSMENTS

Office of Research and Development
NCEA, IRIS

A Portfolio Approach

- **Moving away from a 'one-size-fits-all' approach to risk assessment towards a spectrum of assessment products to meet specific decision contexts;**
- **Facilitating the incorporation of new science into risk assessment and decision-making;**
- **Enabling assessments to be better tailored to meet needs of decision makers;**
- **Increasing the number of chemicals that can be evaluated for their effects on human health by utilizing constrained resources in the most efficient manner.**

IRIS Multi-Year Agenda

- **Released to the public December 2015**
  - Result of a survey EPA program and regional offices for their assessment needs balanced with resource availability.
  - Other chemicals were also carried over from earlier prioritizations
  - Reflects global priorities
- **In FY 2018, reaffirm priorities; identify new or more urgent needs.**
- **Engage states.**

Group	Chemicals
1	Manganese
	Mercury/methylmercury
	Nitrate/nitrite
	Perfluoroalkyl compounds
	Vanadium and compounds
2	Acetaldehyde
	Ammonia (oral)
	Cadmium and compounds
	Uranium
3	Di-(2-ethylhexyl) phthalate
	Dichlorobenzene isomers
	Methyl t-butyl ether (MTBE)
	Nickel and compounds
	Styrene

"Ground Truthing"

- Augmented and enhanced engagement strategy with program and regional offices.
- Affirmatively evaluate their continued need for and interest in existing assessment products in the IRIS pipeline,
  - their priority or urgency, and additional considerations for the development of the assessment, including the specific form or focus of the product (portfolio approach)
  - timeline.
- New priority areas of interest were also identified
- Project/program management to calibrate resource commitments
- Monthly EPA-wide calls for routine bi-directional updates;
- Frequent chemical-specific micro-updates to the offices/regions around critical milestones in assessment development.

IRIS Program Outlook

Table 1. IRIS Program Outlook – May 2018

Current Status	Assessment	Next Anticipated Step Product/	Projected/Actual Date
Assessment Revision (Post-Peer Review)	Hexahydro-1,3,5- trinitro-1,3,5- triazine (RDX) [1]	Step 7: Final	FY18 – Q4
Peer Review	Ethyl tertiary butyl ether (ETBE) [1,2]	Step 7: Final	TBD
	tert-Butanol[1,2]	Step 7: Final	TBD
Draft Development	Arsenic, Inorganic[3]	Step 1: Systematic Review Protocol	FY18 – Q4
		Step 4: Public Comment Draft	FY20 – Q2
		Step 4: E	
	Chloroform	Step 1: I	
		Step 1: S	
		Step 4: P	
		Step 4: E	
	Formaldehyde	Step 4: P	
		Step 4: E	
	Hexavalent Chromium[3]	Step 1: S	
		Step 4: P	
		Step 4: E	
	PCBs[3]	Step 1: S	
		Step 4: P	
		Step 4: E	
	PAH Mixtures	Step 4: P	
		Step 4: E	
Scoping and Problem Formulation	Ammonia (Oral)	Step 1: I	
		Step 1: S	
		Step 4: P	
		Step 4: External Peer Review	FY20 – Q3

To maintain transparency, the IRIS Program is providing an updated outlook of program activities. Table 1 describes assessments that are in development and projected milestone dates. The anticipated dates are based on several factors including expression of continuing need from EPA's Program and Regional offices, states, and tribes, complexity of the assessment products, and the availability of resources.

Following discussions with IRIS program and regional partners, the EPA has decided to discontinue assessment development for hexabromocyclododecane (HBCD), acrylonitrile, n-butyl alcohol, and phthalates (butyl benzyl phthalate, dibutyl phthalate, diethyl phthalate, di-isobutyl phthalate, and di-isononyl phthalate) based on changing needs and priorities. Moving forward, the IRIS Program will focus on the assessments in-progress listed below, chemicals from the 2015 IRIS multi-year agenda, targeted updates of existing IRIS assessments to meet program needs, as well as emerging issues of concern that have been identified as higher priorities by EPA partners (such as perfluorinated compounds).