

**From:** Orme-Zavaleta, Jennifer  
**Sent:** Tuesday, December 4, 2018 9:50 AM  
**To:** [REDACTED]  
**Subject:** FW: Updated Priorities for IRIS Assessments  
**Attachments:** Updated Priorities for IRIS Assessments.pdf

Jennifer Orme-Zavaleta, PhD  
Principal Deputy Assistant Administrator for Science  
Office of Research and Development  
US Environmental Protection Agency  
[REDACTED]

---

**From:** Gentry, Nathan On Behalf Of Orme-Zavaleta, Jennifer  
**Sent:** Tuesday, December 4, 2018 9:46 AM  
**To:** Leadership\_Assistant\_Administrators <Leadership\_Assistant\_Administrators@epa.gov>; DAA <DAA@epa.gov>  
**Cc:** Wheeler, Andrew <wheeler.andrew@epa.gov>; Darwin, Henry <darwin.henry@epa.gov>; Dunlap, David <dunlap.david@epa.gov>; Leadership\_Regional\_Administrators <Leadership\_Regional\_Administrators@epa.gov>; Leadership\_Deputy\_Regional\_Administrators <Leadership\_Deputy\_Regional\_Administrators@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>  
**Subject:** Updated Priorities for IRIS Assessments

**MEMORANDUM**

**SUBJECT:** Updated Priorities for IRIS Assessments

**FROM:** Jennifer Orme-Zavaleta, Ph.D.  
Principal Deputy Assistant Administrator for Science  
Office of Research and Development

**TO:** Assistant Administrators and Deputies

I am writing to update you on the input received by the Office of Research and Development on priorities for Integrated Risk Information System (IRIS) assessments. We recently consolidated your input on high-priority assessment needs and presented this information to the Acting Administrator. Based on the input received, ORD will be proceeding with development of the following priority assessments:

| <b>Chemical</b>     | <b>Requested Routes of Exposure and Scope</b> | <b>Sponsoring Office</b> |
|---------------------|-----------------------------------------------|--------------------------|
| Hexavalent Chromium | Oral and inhalation cancer and noncancer      | OW, OLEM                 |
| Inorganic Arsenic   | Oral and inhalation cancer and noncancer      | OW, OLEM                 |

|                                       |                                          |      |
|---------------------------------------|------------------------------------------|------|
| Mercury salts                         | Oral and inhalation cancer and noncancer | OLEM |
| Methylmercury                         | Oral and inhalation noncancer            | OLEM |
| PCBs                                  | Oral and inhalation noncancer            | OLEM |
| PFAS (PFBA, PFHxA, PFHxS, PFDA, PFNA) | Oral cancer and noncancer                | OW   |
| Vanadium                              | Oral cancer and noncancer                | OW   |

I want to thank each of you for providing your updated priorities to ORD. This information will help ensure that the assessments developed will meet program office needs, and in a timeframe to meet your regulatory or decision-making context. As ORD reengages on the assessments listed above, we will be holding kick-off meetings with the sponsoring offices, as well as any other offices that may want to be aware of our efforts. These kick-off meetings will be critically important to confirming that all interested parties agree on the scope and approach being employed in the development of specific assessments.

Thank you again for your assistance in developing the refined list of priorities. We remain committed to ensuring IRIS Program activities are focused on the most important Agency needs. If you have any questions, feel free to contact me.

**CC:** Andrew Wheeler, Acting Administrator  
Henry Darwin, Associate Deputy Administrator and Chief of Operations  
David Dunlap, Deputy Assistant Administrator for Research and Development  
Regional Administrators and Deputies  
IRIS Points of Contact



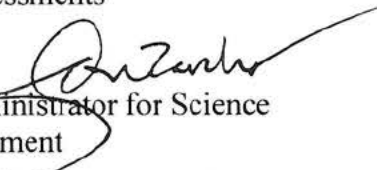
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
RESEARCH AND DEVELOPMENT

**MEMORANDUM**

DEC 04 2018

**SUBJECT:** Updated Priorities for IRIS Assessments

**FROM:** Jennifer Orme-Zavaleta, Ph.D.   
Principal Deputy Assistant Administrator for Science  
Office of Research and Development

**TO:** Assistant Administrators and Deputies

I am writing to update you on the input received by the Office of Research and Development on priorities for Integrated Risk Information System (IRIS) assessments. We recently consolidated your input on high-priority assessment needs and presented this information to the Acting Administrator. Based on the input received, ORD will be proceeding with development of the following priority assessments:

| Chemical                              | Requested Routes of Exposure and Scope   | Sponsoring Office |
|---------------------------------------|------------------------------------------|-------------------|
| Hexavalent Chromium                   | Oral and inhalation cancer and noncancer | OW, OLEM          |
| Inorganic Arsenic                     | Oral and inhalation cancer and noncancer | OW, OLEM          |
| Mercury salts                         | Oral and inhalation cancer and noncancer | OLEM              |
| Methylmercury                         | Oral and inhalation noncancer            | OLEM              |
| PCBs                                  | Oral and inhalation noncancer            | OLEM              |
| PFAS (PFBA, PFHxA, PFHxS, PFDA, PFNA) | Oral cancer and noncancer                | OW                |
| Vanadium                              | Oral cancer and noncancer                | OW                |

I want to thank each of you for providing your updated priorities to ORD. This information will help ensure that the assessments developed will meet program office needs, and in a timeframe to meet your regulatory or decision-making context. As ORD reengages on the assessments listed above, we will be holding kick-off meetings with the sponsoring offices, as well as any other offices that may want to be aware of our efforts. These kick-off meetings will be critically important to confirming that all interested parties agree on the scope and approach being employed in the development of specific assessments.

Thank you again for your assistance in developing the refined list of priorities. We remain committed to ensuring IRIS Program activities are focused on the most important Agency needs. If you have any questions, feel free to contact me.

**CC:** Andrew Wheeler, Acting Administrator  
Henry Darwin, Associate Deputy Administrator and Chief of Operations  
David Dunlap, Deputy Assistant Administrator for Research  
and Development  
Regional Administrators and Deputies  
IRIS Points of Contact

## **A Message from the IRIS Program**

December 19, 2018

The IRIS Program is committed to producing assessments in a timely and transparent manner. Since January 2017, IRIS has been working to modernize its workflow. As part of this modernization, IRIS has moved away from one-size-fits-all assessments to a portfolio of chemical evaluation products to meet specific decision contexts. This approach optimizes the application of best practices in systematic review in the IRIS Program.

As part of its commitment to transparency, the IRIS Program is providing an updated outlook of program activities. Table 1 describes assessments that are currently in development and their projected milestone dates. The IRIS Program is providing this information for stakeholders to be aware of upcoming products, and to allow the public and research community an opportunity to communicate relevant research to EPA. The anticipated dates are based on several factors, including complexity of the assessment products and the availability of resources. While projected dates reflect the IRIS Program's best estimate based on available information, they are subject to change. Accordingly, updates to the table below will be provided as needed.

For more information on public meetings and comment periods, visit the [IRIS website](#) or subscribe to [EPA's Integrated Risk Information System Bulletin](#).

**Table 1. IRIS Program Outlook – December 2018**

| <b>Current Status</b>                       | <b>Assessment</b>                                        | <b>Next Anticipated Public Step(s)</b> | <b>Projected Date</b> |
|---------------------------------------------|----------------------------------------------------------|----------------------------------------|-----------------------|
| Peer Review                                 | Ethyl tertiary butyl ether (ETBE) <sup>1</sup>           | Step 7: Final                          | TBD                   |
|                                             | tert-Butyl Alcohol <sup>1</sup>                          | Step 7: Final                          | TBD                   |
| Draft Development                           | Arsenic, Inorganic <sup>2</sup>                          | Step 1: Systematic Review Protocol     | FY19 – Q2             |
|                                             |                                                          | Step 4: Public Comment Draft           | FY20 – Q2             |
|                                             |                                                          | Step 4: External Peer Review           | FY21 – Q1             |
|                                             | Chromium VI <sup>2</sup>                                 | Step 1: Systematic Review Protocol     | FY19 – Q2             |
|                                             |                                                          | Step 4: Public Comment Draft           | FY20 – Q1             |
|                                             |                                                          | Step 4: External Peer Review           | FY20 – Q3             |
|                                             | Polychlorinated Biphenyls (PCBs; noncancer) <sup>2</sup> | Step 1: Systematic Review Protocol     | FY19 – Q4             |
|                                             |                                                          | Step 4: Public Comment Draft           | FY21 – Q1             |
|                                             |                                                          | Step 4: External Peer Review           | FY21 – Q2             |
|                                             | Perfluorononanoic Acid (PFNA) <sup>3</sup>               | Step 1: Systematic Review Protocol     | TBD                   |
|                                             |                                                          | Step 4: Public Comment Draft           | TBD                   |
|                                             |                                                          | Step 4: External Peer Review           | TBD                   |
|                                             | Perfluorobutanoic Acid (PFBA) <sup>3</sup>               | Step 1: Systematic Review Protocol     | TBD                   |
|                                             |                                                          | Step 4: Public Comment Draft           | TBD                   |
|                                             |                                                          | Step 4: External Peer Review           | TBD                   |
| Perfluorohexanoic Acid (PFHxA) <sup>3</sup> | Step 1: Systematic Review Protocol                       | TBD                                    |                       |
|                                             | Step 4: Public Comment Draft                             | TBD                                    |                       |
|                                             | Step 4: External Peer Review                             | TBD                                    |                       |

| Current Status                  | Assessment                                     | Next Anticipated Public Step(s)    | Projected Date |
|---------------------------------|------------------------------------------------|------------------------------------|----------------|
| Draft Development               | Perfluorohexane Sulfonate (PFHxS) <sup>3</sup> | Step 1: Systematic Review Protocol | TBD            |
|                                 |                                                | Step 4: Public Comment Draft       | TBD            |
|                                 |                                                | Step 4: External Peer Review       | TBD            |
|                                 | Perfluorodecanoic Acid (PFDA) <sup>3</sup>     | Step 1: Systematic Review Protocol | TBD            |
|                                 |                                                | Step 4: Public Comment Draft       | TBD            |
|                                 |                                                | Step 4: External Peer Review       | TBD            |
| Scoping and Problem Formulation | Mercury salts                                  | Step 1: IRIS Assessment Plan       | FY19 – Q3      |
|                                 |                                                | Step 1: Systematic Review Protocol | FY20 – Q1      |
|                                 |                                                | Step 4: Public Comment Draft       | FY20 – Q4      |
|                                 |                                                | Step 4: External Peer Review       | FY21 – Q2      |
|                                 | Methylmercury                                  | Step 1: IRIS Assessment Plan       | FY19 – Q2      |
|                                 |                                                | Step 1: Systematic Review Protocol | FY20 – Q1      |
|                                 |                                                | Step 4: Public Comment Draft       | FY21 – Q2      |
|                                 |                                                | Step 4: External Peer Review       | FY22 – Q1      |
|                                 | Vanadium and Compounds                         | Step 1: IRIS Assessment Plan       | TBD            |
|                                 |                                                | Step 1: Systematic Review Protocol | TBD            |
|                                 |                                                | Step 4: Public Comment Draft       | TBD            |
|                                 |                                                | Step 4: External Peer Review       | TBD            |

<sup>1</sup>The IRIS assessments of ethyl tert-butyl ether and *tert*-butanol are currently undergoing external peer review by EPA’s Science Advisory Board-Chemical Assessment Advisory Committee (SAB-CAAC). Upon receipt of the final external peer review report, the IRIS Program will update Table 1 with the projected date for the next public milestone. Assessments in peer-review incorporate elements of systematic review consistent with the practices of the IRIS Program at the time of assessment development. These mature assessments may not reflect all the current IRIS Program systematic review feature.

<sup>2</sup>In line with recent advancements in IRIS systematic review practices, assessments already in draft development will publish a systematic review

protocol for public comment to promote consistency with assessments started more recently. The publication of assessment protocols conforms to well-established systematic review practices and implementation of National Academies' systematic review recommendations within the IRIS Program.

<sup>3</sup>Per- and Polyfluoroalkyl Substances (PFAS) assessments under development are in support of [EPA's Actions to Address PFAS](#). For more information, visit [EPA's Per- and Polyfluoroalkyl Substances \(PFAS\) website](#).