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

August 31, 2018

MEMORANDUM

OFFICE OF
CHILDREN'S HEALTH PROTECTION

Subject: Response to ORD Solicitation: OCHP Nominations for IRIS Risk Assessment Chemicals

From: Helena Wooden-Aguilar, Acting Deputy Chief of Staff, Office of the Administrator

To: Jennifer Orme-Zavaleta, Principal Deputy Assistant Administrator for Science, Office of Research and Development

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On behalf of the Office of Children's Health Protection (OCHP), please accept the following input in response to the IRIS program's request for Agency priority chemical assessments. The attached request forms have been completed for chemicals currently ongoing or planned in the IRIS FY 2018–2019 Portfolio, some of which OCHP has previously nominated. Additionally, these forms describe the children's health-related information that further supports other EPA program or regional office's children's health needs. Through EPA's *Policy on Evaluating Health Risks to Children* (https://www.epa.gov/children/epas-policy-evaluating-risk-children), EPA has a commitment to "consider the risks to infants and children consistently and explicitly as part of risk assessments generated during its decision-making process."

As OCHP does not have specific regulatory needs beyond adherence to the children's health policy, we have not identified completion dates or prioritization. We appreciate that the IRIS FY18-19 ongoing and planned assessments includes chemicals of concern for children's health. Therefore, we are not putting forward any new nominations at this time. Chemicals that have been identified as potentially of concern for children's health (e.g., chemicals with reproductive or developmental effects), or chemicals used in children's products or in products to which children may be highly exposed, should be a factor in making prioritization decisions.

Please accept the signature on this letter as representing my support for all of the chemicals being put forward by OCHP. Thank you for the opportunity to provide input. Should you need additional follow-up, please contact [redacted]

Cc:

Ruth Etzel, OCHP
Michael Firestone, OCHP
Brenda Foos, OCHP
Rebecca Dzubow, OCHP
Susan Euling, OCHP
Tina Bahadori, ORD
Kris Thayer, ORD
Emma Lavoie, ORD

Attachments: IRIS Assessment Request Forms 1-14

Attachment 1
IRIS Form

IRIS Assessment Request Form

Requesting Office: OCHP

Request Date: August 31, 2018

Requested Completion Date:

Chemical Nominated for Assessment: Ammonia (oral)

Priority of Assessment:

General Background of Chemical:

As ammonia is highly soluble in water and applied to drinking water as a disinfectant (EPA 2018, *IRIS Assessment Plan for Ammonia and Ammonium Salts: Noncancer Assessment for Oral Exposure*), there will be direct exposure to the child via drinking water. In particular, drinking water exposure is highest per body weight for bottle-fed infants, as compared to other lifestages (EPA 2011, *Exposure Factors Handbook, Chapter 3*). Ammonia can cross the blood-brain barrier (Skowrońska and Albrecht, 2012), and infants and children may be particularly susceptible to the neurotoxic effects due to ongoing brain development. Ammonia also can cause metabolic acidosis leading to impaired growth in children (EPA, 2018).

Scope of Assessment Request:

IRIS developed an inhalation RfC for ammonia in 2016, but currently no oral RfD exists. Based on the oral exposure concerns outlined above for children, we believe an RfD is warranted.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

OCHP has not previously nominated ammonia to the IRIS program for review, but did provide comment on the draft IAP. We have identified children's health concerns here in support of nomination by others. In accordance with EPA's Policy on Evaluating Health Risks to Children, EPA has a commitment to "consider the risks to infants and children consistently and explicitly as part of risk assessments generated during its decision-making process."

[Signature]

Helena Wooden-Aguilar, Acting Deputy Chief of Staff, Office of the Administrator

[Signature]

ORD Principal Deputy Assistant Administrator for Science

Attachment 2
IRIS Form

IRIS Assessment Request Form

Requesting Office: OCHP

Request Date: August 31, 2018 **Requested Completion Date:**

Chemical Nominated for Assessment: Arsenic, inorganic **Priority of Assessment:**

General Background of Chemical:

Arsenic can cross the placenta (Punshon et al., 2015), and is found in breast milk (Carignan et al., 2015) and baby food (Gundert-Remy et al., 2015; Karagas et al., 2016), and water. In particular, drinking water exposure is highest per body weight for bottle-fed infants, as compared to other lifestages EPA 2011, *Exposure Factors Handbook, Chapter 3)*. Further, formula-fed infants may consume higher levels of arsenic than breast-fed babies due to higher water intake (Carignan et al., 2015). Studies have found early life arsenic exposure to be associated with DNA damage, adverse pregnancy outcomes, decreased postnatal growth, developmental neurotoxicity, developmental immunotoxicity, respiratory, and cardiovascular toxicity (EPA 2014, IRIS Bimonthly Public Meeting). Early life exposure to arsenic can also lead to adverse health outcomes in adults, including increases in tumors in various organs, heart disease, and lung, thymic as well as neurological impairment. (Note that much of this early life data is from the Dartmouth's EPA/NIEHS Children's Environmental Health and Disease Prevention Center). Arsenic is often a co-contaminant with lead, a known neurotoxicant.

Scope of Assessment Request:

IRIS has previously developed an RfD and a cancer assessment for oral and inhalation exposure in 1991. Since that time, a large amount of additional data has been published that may lead to lower reference values. Based on the concerns outlined above for children, we believe updated values are warranted.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

OCHP has not previously nominated arsenic to the IRIS program for review, but did provide comments on prior drafts. We have identified children's health concerns here in support of nomination by others. In accordance with EPA's Policy on Evaluating Health Risks to Children, EPA has a commitment to "consider the risks to infants and children consistently and explicitly as part of risk assessments generated during its decision-making process." We are aware that "arsenic and arsenic compounds" is on the 2014 TSCA Workplan. However, TSCA prioritization has not been completed for selecting the next 20 high priority chemicals to begin risk evaluation in 2019, so it is unclear when the OPPT Risk Evaluations will be performed. Further, IRIS assessments provide gold standard risk values that can be utilized across EPA programs and regions. As a result, the IRIS reference values provide great efficiency for cross-EPA use.

[Signature] 

Helena Wooden-Aguilar, Acting Deputy Chief of Staff, Office of the Administrator

[Signature]

ORD Principal Deputy Assistant Administrator for Science

Draft/Deliberative. Please do not share, cite, or quote.

Attachment 3
IRIS Form

IRIS Assessment Request Form

Requesting Office: OCHP

Request Date: August 31, 2018 **Requested Completion Date:**

Chemical Nominated for Assessment: Ethylbenzene **Priority of Assessment:**

General Background of Chemical:

IRIS has previously developed an RfD and RfC for ethylbenzene in 1987 and 1991, with the RfC being based on developmental toxicity. Since that time, additional data has been published that may lead to lower reference values (EPA 2017, *IRIS Assessment Plan for Ethylbenzene*). Some newer developmental studies include studies by Saillenfait et al. (2003; 2006; 2007) and Faber et al. (2006; 2007), mainly showing decreased fetal body weight.

Scope of Assessment Request:

Based on the concerns outlined above for children, we believe an updated RfD and RfC are warranted.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

OCHP has not previously nominated ethylbenzene to the IRIS program for review, but did provide comments on the draft IAP. We have identified children's health concerns here in support of nomination by others. In accordance with EPA's Policy on Evaluating Health Risks to Children, EPA has a commitment to "consider the risks to infants and children consistently and explicitly as part of risk assessments generated during its decision-making process." We are aware that this chemical is also on the 2014 TSCA Workplan. However, TSCA prioritization has not been completed for selecting the next 20 high priority chemicals to begin risk evaluation in 2019, so it is unclear when the OPPT Risk Evaluations will be performed. Further, IRIS assessments provide gold standard risk values that can be utilized across EPA programs and regions. As a result, the IRIS reference values provide great efficiency for cross-EPA use.

[Signature]

Helena Wooden-Aguilar, Acting Deputy Chief of Staff, Office of the Administrator

[Signature]

ORD Principal Deputy Assistant Administrator for Science

Attachment 4
IRIS Form

IRIS Assessment Request Form

Requesting Office: OCHP

Request Date: August 31, 2018 **Requested Completion Date:**

Chemical Nominated for Assessment: Formaldehyde **Priority of Assessment:**

General Background of Chemical:

The formaldehyde assessment remains a priority for OCHP as its inhalation has been associated with increased asthma incidence, including in children. Children are exposed via multiple sources, including from off-gassing of pressed wood products, including baby furniture, as addressed in the 2016 rule for Formaldehyde Emission Standards for Composite Wood Products.

Scope of Assessment Request:

IRIS has previously developed an RfD and inhalation cancer assessment in 1990 and 1989. Since that time, a large amount of additional data has been published that may lead to lower reference values. Based on the concerns outlined above for children, we believe updated values are warranted.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

OCHP has previously nominated formaldehyde to the IRIS program for review, and provided comments on prior draft assessments. In accordance with EPA's Policy on Evaluating Health Risks to Children, EPA has a commitment to "consider the risks to infants and children consistently and explicitly as part of risk assessments generated during its decision-making process." We are aware that this chemical is also on the 2014 TSCA Workplan. However, TSCA prioritization has not been completed for selecting the next 20 high priority chemicals to begin risk evaluation in 2019, so it is unclear when the OPPT Risk Evaluations will be performed. Further, IRIS assessments provide gold standard risk values that can be utilized across EPA programs and regions. As a result, the IRIS reference values provide great efficiency to EPA for cross-EPA use.

[Signature]

Helena Wooden-Aguilar, Acting Deputy Chief of Staff, Office of the Administrator

[Signature]

ORD Principal Deputy Assistant Administrator for Science

Attachment 5
IRIS Form

IRIS Assessment Request Form

Requesting Office: OCHP

Request Date: August 31, 2018 **Requested Completion Date:**

Chemical Nominated for Assessment: Hexavalent Chromium **Priority of Assessment:**

General Background of Chemical:

Hexavalent chromium is a known human carcinogen, and its mode of action is possibly mutagenic (EPA 2010, *Toxicological Review of Chromium VI External Review Draft;* EPA 2014, IRIS Bimonthly Public Meeting) which would require the application of age-dependent adjustment factors (ADAFs) due to early life sensitivity (US EPA 2005, *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*).

Scope of Assessment Request:

IRIS assessed inhalation cancer and non-cancer estimates for chromium IV in 1998. Since that time, significant additional data has been published that may lead to lower reference values, including possible application of an ADAF. Based on the concerns outlined above for children, we believe updated values are warranted.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

OCHP has previously nominated hexavalent chromium to the IRIS program for review, and provided comments on prior draft assessments. In accordance with EPA's Policy on Evaluating Health Risks to Children, EPA has a commitment to "consider the risks to infants and children consistently and explicitly as part of risk assessments generated during its decision-making process." We are aware that chromium and chromium compounds is on the 2014 TSCA Workplan. However, TSCA prioritization has not been completed for selecting the next 20 high priority chemicals to begin risk evaluation in 2019, so it is unclear when the OPPT Risk Evaluations will be performed. Further, IRIS assessments provide gold standard risk values that can be utilized across EPA programs and regions. As a result, the IRIS reference values provide great efficiency to EPA for cross-EPA use.

[Signature]

Helena Wooden-Aguilar, Acting Deputy Chief of Staff, Office of the Administrator

[Signature]

ORD Principal Deputy Assistant Administrator for Science

Attachment 6
IRIS Form

IRIS Assessment Request Form

Requesting Office: OCHP

Request Date: August 31, 2018 **Requested Completion Date:**

Chemical Nominated for Assessment: Naphthalene **Priority of Assessment:**

General Background of Chemical:

Naphthalene is a PAH commonly used in mothballs as a moth or animal repellant. Children have the most incident reports from ingestion of mothballs, and while banned in Europe since 2008, EPA has restricted its packaging to avoid children's incidental oral exposure (EPA 2008, *Registration Eligibility Decision for Naphthalene*). Naphthalene is detected in umbilical cord blood, breast milk, urine of children, food, soil and air (EPA 2018, *IRIS Assessment Plan for Naphthalene*). Neonates are the most susceptible lifestage as their livers are not yet fully developed, and early life exposure can result in hemolytic anemia which can progress to organ damage and death if untreated (EPA, 2018). IRIS previously assessed naphthalene in 1998, developing an RfC and RfD. Since that time, a large amount of additional data has been published that may lead to lower reference values.

Scope of Assessment Request:

OCHP is interested in this assessment as the critical endpoint is hemolytic anemia in infants. The children's issues of early life exposure and very severe health outcomes such as hemolytic anemia are of great concern.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

OCHP has previously nominated naphthalene to the IRIS program for review, and provided comments on the initial scoping phase and draft IAP. In accordance with EPA's Policy on Evaluating Health Risks to Children, EPA has a commitment to "consider the risks to infants and children consistently and explicitly as part of risk assessments generated during its decision-making process."

[Signature]

Helena Wooden-Aguilar, Acting Deputy Chief of Staff, Office of the Administrator

[Signature]

ORD Principal Deputy Assistant Administrator for Science

Attachment 7
IRIS Form

IRIS Assessment Request Form

Requesting Office: OCHP

Request Date: August 31, 2018 **Requested Completion Date:**

Chemical Nominated for Assessment: Nitrate/Nitrite **Priority of Assessment:**

General Background of Chemical:

Infants ingesting contaminated drinking water ingest are at risk for methemoglobinemia (EPA 2017, *IRIS Assessment Plan for Nitrate and Nitrite*), the inability of blood to carry oxygens to tissues. In particular, drinking water exposure is highest per body weight for bottle-fed infants, as compared to other lifestages (EPA 2011, *Exposure Factors Handbook, Chapter 3*). This effect is also known as "blue baby syndrome". IRIS developed RfDs for nitrite in 1987 and nitrate in 1991, both based on increased methemoglobinemia in infants. Newer studies indicate an impact on the thyroid, resulting in possible developmental neurotoxic effects.

Scope of Assessment Request:

OCHP is interested in the children's health component of the document, specifically the critical endpoint currently being methemoglobinemia in infants.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

OCHP has not previously nominated nitrate or nitrite to the IRIS program for review, but did provide comments on the initial scoping phase and draft IAP. We have identified children's health concerns here in support of nomination by others. In accordance with EPA's Policy on Evaluating Health Risks to Children, EPA has a commitment to "consider the risks to infants and children consistently and explicitly as part of risk assessments generated during its decision-making process."

[Signature]

Helena Wooden-Aguilar, Acting Deputy Chief of Staff, Office of the Administrator

[Signature]

ORD Principal Deputy Assistant Administrator for Science

Attachment 8
IRIS Form

IRIS Assessment Request Form

Requesting Office: OCHP

Request Date: August 31, 2018 **Requested Completion Date:**

Chemical Nominated for Assessment: PCBs **Priority of Assessment:**

General Background of Chemical:

Exposure to PCBs during early life is of great concern because the effects of PCBs on sensitive immature tissues, organs and systems can have serious long-lasting consequences. PCBs have been linked to various health outcomes such as decreased gestational age, lower birth weight, depressed immune responses, impaired mental development, and growth retardation. Nursing infants may have especially high exposures as PCBs are lipophilic substances, and can accumulate in breast milk. Additionally, high indoor air concentrations have been measured in school buildings across the country from failing fluorescent light ballasts and PCB-laden caulk, as well as during building renovations. ORD has set Exposure Levels for Evaluating Polychlorinated Biphenyls (PCBs) in Schools, and regions continue to deal with concerns in schools.

Scope of Assessment Request:

One of the three non-cancer RfDs for Alochlor mixtures developed by IRIS in the 1990s has a critical effect of reduced birth weight. However, these assessments do not consider inhalation route for non-cancer effects, and does not consider newer information that is important to children's health.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

OCHP has previously nominated PCBs to the IRIS program for review, and provided comments on the initial scoping phase and draft IAP. In accordance with EPA's Policy on Evaluating Health Risks to Children, EPA has a commitment to "consider the risks to infants and children consistently and explicitly as part of risk assessments generated during its decision-making process."

[Signature]

Helena Wooden-Aguilar, Acting Deputy Chief of Staff, Office of the Administrator

[Signature]

ORD Principal Deputy Assistant Administrator for Science

Attachment 9
IRIS Form

IRIS Assessment Request Form

Requesting Office: OCHP

Request Date: August 31, 2018 **Requested Completion Date:**

Chemical Nominated for Assessment: Uranium **Priority of Assessment:**

General Background of Chemical:

There is not much information on the non-radiological effects after uranium exposure in early life (EPA 2018, *IRIS Assessment Plan for Uranium (Oral Reference Dose)*. We do note that since uranium can be taken up at higher amounts during bone development, early life exposures to uranium may be stored and then released from bone leading to increased exposure later in development, during pregnancy, or old age when bone loss occurs.

Scope of Assessment Request:

IRIS conducted an RfD of uranium salts in 1989. Since that time, additional data has been published that may lead to lower reference values. OCHP supports the uranium IRIS assessment Plan (EPA, 2018) that states that the "update will include examination of potentially susceptible populations, including women of child-bearing age, pregnant women, infants and children."

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

OCHP has not previously nominated uranium to the IRIS program for review, but did provide comments on the draft IAP. We have identified children's health concerns here in support of nomination by others. In accordance with EPA's Policy on Evaluating Health Risks to Children, EPA has a commitment to "consider the risks to infants and children consistently and explicitly as part of risk assessments generated during its decision-making process."

[Signature]

Helena Wooden-Aguilar, Acting Deputy Chief of Staff, Office of the Administrator

[Signature]

ORD Principal Deputy Assistant Administrator for Science

Attachment 10
IRIS Form

IRIS Assessment Request Form

Requesting Office: OCHP

Request Date: August 31, 2018 **Requested Completion Date:**

Chemical Nominated for Assessment: Manganese **Priority of Assessment:**

General Background of Chemical:

Manganese (Mn) is an essential nutrient, but higher doses can cause neurotoxicity. Therefore, the dose-response assessment of manganese is complicated by the fact that some doses support healthy development and yet, higher doses lead to toxicities. This assessment is an opportunity to develop dose-response methods that can be broadly applicable to other chemicals with similar dose-response healthy vs. toxicity characteristics. The critical effects for the RfD and RfC from the 1990s are based on adult neurotoxicity (CNS effects and impairment of neurobehavioral function). Since that time, a large amount of additional data has been published that may lead to lower reference values. In particular, there are a number of studies demonstrating developmental neurotoxicity. Moreover, Mn is a drinking water contaminant, and drinking water exposure is highest per body weight for bottle-fed infants, as compared to other lifestages EPA 2011, *Exposure Factors Handbook, Chapter 3*).

Scope of Assessment Request:

OCHP has held numerous discussions with NCEA on the decision to use adult data only for the RfC assessment. We support an RfC that considers early life data, and back any programmatic or regional needs to develop an RfD.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

OCHP has previously nominated Mn to the IRIS program for review, and provided significant comments on the initial draft IAP. We appreciate the effort that has gone into the sensitivity analysis to address our concerns regarding the decision to use adult data only for the RfC, and we look forward to any future discussions on lifestage comparisons. In accordance with EPA's Policy on Evaluating Health Risks to Children, EPA has a commitment to "consider the risks to infants and children consistently and explicitly as part of risk assessments generated during its decision-making process."

[Signature]

Helena Wooden-Aguilar, Acting Deputy Chief of Staff, Office of the Administrator

[Signature]

ORD Principal Deputy Assistant Administrator for Science

Attachment 11
IRIS Form

IRIS Assessment Request Form

Requesting Office: OCHP

Request Date: August 31, 2018 **Requested Completion Date:**

Chemical Nominated for Assessment: Mercury Salts **Priority of Assessment:**

General Background of Chemical:

Mercury salts, or inorganic mercury compounds, consist of mercury combined with other elements such as sulfur or oxygen. They occur naturally in the environment, and are used in industrial processes. Adverse health effects from mercury salts include gastrointestinal effects and neurological impairment. Importantly, mercury salts can become methylmercury in the environment. Please refer to the following methylmercury page for children's environmental health concerns associated with methylmercury.

Scope of Assessment Request:

Mercuric chloride and elemental mercury were previously assessed by IRIS in 1995; since that time, a large amount of additional data has been published that may lead to lower reference values. Based on the concerns outlined above for children, we believe updated values are warranted.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

OCHP has previously nominated mercury to the IRIS program for review, and provided comments on the initial scoping phase. In accordance with EPA's Policy on Evaluating Health Risks to Children, EPA has a commitment to "consider the risks to infants and children consistently and explicitly as part of risk assessments generated during its decision-making process."

[Signature]

Helena Wooden-Aguilar, Acting Deputy Chief of Staff, Office of the Administrator

[Signature]

ORD Principal Deputy Assistant Administrator for Science

Attachment 12
IRIS Form

IRIS Assessment Request Form

Requesting Office: OCHP

Request Date: August 31, 2018 **Requested Completion Date:**

Chemical Nominated for Assessment: Methylmercury **Priority of Assessment:**

General Background of Chemical:

Methylmercury is a known developmental neurotoxicant. The critical effect for both the RfC and RfD in the 2001 IRIS assessment was determined to be developmental neuropsychological impairment. Since that time, a large amount of additional data has been published that may lead to lower reference values. In particular, postnatal exposures are not well assessed to determine if there is concern for that window of exposure as well. Consumption of contaminated fish by reproductive age women is a major source of exposure to the developing fetus and infant. Methylmercury can cross the placenta, has been found in higher levels in cord blood than maternal blood, and can be transferred via breastmilk.

Scope of Assessment Request:

We support a focused reassessment on developmental neurotoxicity via the oral route as presented in the current IRIS assessment plan (IAP). However, this focused assessment is also an opportunity for IRIS to develop new methodologies for application of the database uncertainty factor.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

OCHP has previously nominated methylmercury to the IRIS program for review, and provided comments on the initial scoping phase and draft IAP. In accordance with EPA's Policy on Evaluating Health Risks to Children, EPA has a commitment to "consider the risks to infants and children consistently and explicitly as part of risk assessments generated during its decision-making process."

[Signature]

Helena Wooden-Aguilar, Acting Deputy Chief of Staff, Office of the Administrator

[Signature]

ORD Principal Deputy Assistant Administrator for Science

Attachment 13
IRIS Form

IRIS Assessment Request Form

Requesting Office: OCHP

Request Date: August 31, 2018 **Requested Completion Date:**

Chemical Nominated for Assessment: perfluorinated chemicals (PFBA, PFHxA, PFHxS, PFDA, PFNA) **Priority of Assessment:**

General Background of Chemical:

With PFOS and PFOA replacement chemicals being developed at a rapid pace, studies and risk assessments are needed to assess human health impacts and avoid public health crises. We appreciate that IRIS is taking a forward-looking approach by assessing PFOS and PFOA replacement PFAS chemicals. As these chemicals are found in drinking water, bottle-fed infants will have the highest exposure per body weight (EPA 2011, *Exposure Factors Handbook, Chapter 3*). Additionally, pregnant women and children may be exposed in food or household products. Available data on PFAS chemicals indicate the potential for adverse effects on the thyroid and hormone levels, exposure to which can cause premature delivery, perinatal mortality, birth defects, decreased growth, neurodevelopment and immune effects. Additionally, there are adverse health impacts for reproductive ability, such as and delayed onset of puberty, and sperm health.

Scope of Assessment Request:

Based on the concerns outlined above for children, we believe these new values are warranted.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

OCHP has not previously nominated perfluorinated chemicals to the IRIS program for review, but did provide comments on the draft GenX and PFBS assessments. We have identified children's health concerns here in support of nomination by others. In accordance with EPA's Policy on Evaluating Health Risks to Children, EPA has a commitment to "consider the risks to infants and children consistently and explicitly as part of risk assessments generated during its decision-making process."

[Signature]

Helena Wooden-Aguilar, Acting Deputy Chief of Staff, Office of the Administrator

[Signature]

ORD Principal Deputy Assistant Administrator for Science

Attachment 14
IRIS Form

IRIS Assessment Request Form

Requesting Office: OCHP

Request Date: August 31, 2018 **Requested Completion Date:**

Chemical Nominated for Assessment: PAH Mixtures **Priority of Assessment:**

General Background of Chemical:

PAH compounds can cross the placental and blood-brain barrier. DNA adducts have been detected in cord blood and epigenetic effects have been observed. Adverse health effects may include neurodevelopmental effects, including anxiety/depression and attention problems, and endocrine disruption. An assessment on mixtures containing multiple PAHs is important to determine if exposure can result in additive or synergistic effects. IRIS recently completed the benzo(a)pyrene assessment, which is one of the PAH compounds. The RfD and RfC were both based on developmental endpoints (neurobehavior and decreased embryo/fetal survival, respectively). Additionally, benzo[a]pyrene was determined to be a mutagenic carcinogen, requiring the application of age-dependent adjustment factors (ADAFs) due to early life sensitivity.

Scope of Assessment Request:

Based on the concerns outlined above for children, we believe updated values are warranted.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

OCHP has not previously nominated PAH mixtures for to the IRIS program for review; however, we have identified children's health concerns in support of nomination by others. In accordance with EPA's Policy on Evaluating Health Risks to Children, EPA has a commitment to "consider the risks to infants and children consistently and explicitly as part of risk assessments generated during its decision-making process."

[Signature]

Helena Wooden-Aguilar, Acting Deputy Chief of Staff, Office of the Administrator

[Signature]

ORD Principal Deputy Assistant Administrator for Science

From: [redacted]
Sent: Thursday, August 30, 2018 4:33 PM
To: [redacted]
Subject: Re: Soliciting Requests for IRIS Assessments

Hi [redacted]

My reason for selecting Formaldehyde and Acrolein in association with children's health concerns reflects the inquiries that I have gotten relative to E-cigarette contributions to environmental levels of these chemicals. The mayor in Louisville KY even called for discussions with FDA and EPA to this end (https://louisvilleky.gov/news/mayor-fischer-calls-community-conversation-dangers-e-cigarettes-hookah). Also, because numerous counties in the southeast have high wood smoke levels during Winter months, my office receives questions regarding increased levels of these chemicals during burning events. Last of all, Formaldehyde in associated with asthma in children and I receive inquiries regarding ambient levels in various communities as parents try to understand their children's asthma episodes.

Mayor Fischer calls for community conversation on dangers ...

louisvilleky.gov

Cites research suggesting that both are gateway to smoking Mayor Greg Fischer announced

today that he has asked the Louisville Department of Public Health and Wellness to lead a community conversation on the possibility of expanding Louisville's current smoking ban to include e-cigarettes and hookah.

[redacted] Senior Toxicologist, Risk Assessment Forum Member, and Regional Human Research Ethics Council Member ¦ Air, Pesticides & Toxics Management Division ¦ U.S. Environmental Protection Agency ¦ 61 Forsyth Street, SW ¦ Atlanta, GA 30303 ¦ V[redacted]

From: [redacted]
Sent: Wednesday, August 29, 2018 9:22:11 AM
To: [redacted]
Subject: RE: Soliciting Requests for IRIS Assessments

Hi [redacted],

Thanks for your reply. If there is a specific children's health and/or regional issue, that would be helpful to know.

[redacted]

[redacted]
Health Scientist
U.S. EPA Office of Children's Health Protection | Regulatory Support and Science Policy Division
1200 Pennsylvania Avenue, NW (1107T) | Washington, DC 20460
[redacted]

From: [redacted]
Sent: Wednesday, August 29, 2018 6:52 AM
To: [redacted]
Subject: Re: Soliciting Requests for IRIS Assessments

Good morning [redacted],

Please add Region 4 to the following chemicals:

Formaldehyde

Acrolein

Thanks.

[redacted] Senior Toxicologist, Risk Assessment Forum Member, and

Regional Human Research Ethics Council Member ¦ Air, Pesticides & Toxics Management Division ¦ U.S. Environmental Protection Agency ¦ 61 Forsyth Street, SW ¦ Atlanta, GA 30303 ¦ [redacted]

[redacted]

From: [redacted]
Sent: Tuesday, August 28, 2018 2:38:59 PM
To: [redacted]
Subject: FW: Soliciting Requests for IRIS Assessments

Hi [redacted],

We're working on final touches on OCHP's priorities for IRIS. In addition to identifying which chemicals have children's health concerns, we would like to offer support for R4's needs as they relate to children's health. If you can articulate these needs for any of the current IRIS portfolio chemicals (attached), or any new chemicals R4 is nominating, we can include similar language.

Thanks,

[redacted]

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[redacted]

Health Scientist
U.S. EPA Office of Children's Health Protection | Regulatory Support and Science Policy Division
1200 Pennsylvania Avenue, NW (1107T) | Washington, DC 20460
[redacted]

From: Christian, Megan **On Behalf Of** Orme-Zavaleta, Jennifer
Sent: Friday, August 10, 2018 4:25 PM
To: Leadership_Assistant_Administators <Leadership_Assistant_Administators@epa.gov>; Leadership_Deputy_Assistant_Administrators <Leadership_Deputy_Assistant_Administrators@epa.gov>
Cc: Wheeler, Andrew <wheeler.andrew@epa.gov>; Leadership_Deputy_Regional_Administrators

[redacted]
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Subject: Soliciting Requests for IRIS Assessments

AAs and DAAs,

On behalf of the Acting Administrator, the Office of Research and Development (ORD) is soliciting program input on priorities for future Integrated Risk Information System (IRIS) assessments as well as the chemicals currently prioritized for the IRIS FY 2018–2019 Portfolio. This request is part of our continuing effort to ensure IRIS assessment activities are focused on the most important Agency needs.

To request an IRIS assessment or to confirm your continued interest in the assessments that are underway within IRIS, please coordinate with ORD to complete an IRIS Assessment Request Form (Attachment 1).

Central to effective implementation of IRIS is information that allows for a clear and common understanding by ORD and your program, not just of priorities, but of the decision or regulatory context for each IRIS assessment. Additionally, this information helps to determine the type of assessment required to meet your program needs. To ensure proper scope and timeliness, the form requires information on the decision context, level of priority your assessment needs, and a requested completion date.

To inform your requests, I am providing a list of assessments currently in the IRIS FY 2018–2019 Portfolio and the expected timeline for completion of an agency draft (Attachment 2). ORD will solicit programmatic input for new assessment needs on an annual basis, but requests for new IRIS priorities can be made at any time.

Please complete these forms by August 31, 2018, and return to me for concurrence. I will synthesize all the responses and report to the Acting Administrator. If you have any questions regarding this request, please feel free to contact me. Thank you.

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

[redacted]

From: [redacted]
To: Orme-Zavaleta, Jennifer
Cc: [redacted]
Subject: RE: Soliciting Requests for IRIS Assessments – OLEM response
Date: Thursday, September 13, 2018 11:46:11 AM
Attachments: iris signed packet2018-09-13-2018.OLEM.pdf

Jennifer,

OLEM would like to thank ORD for the opportunity to provide input on the ongoing IRIS assessments and to nominate needed new chemicals. Barry Breen has asked me to transmit OLEM's response to your request for IRIS assessment nominations.

Per your request, OLEM has incorporated responses from the Regions into our submission. The cover pages of the attached package provide information about organization of the package. We have also provided some summary information, in the hopes of making it a bit easier to review. Please let me know if you need any additional information, and thank you again for your support of our programs.

[redacted]

[redacted]

Senior Science Advisor
Policy Analysis and Regulatory Management Staff
Office of Land and Emergency Management (OLEM)
U.S. EPA

[redacted]

Mailcode 5103T

From: Christian, Megan **On Behalf Of** Orme-Zavaleta, Jennifer
Sent: Friday, August 10, 2018 4:25 PM
To: Leadership_Assistant_Administators <Leadership_Assistant_Administators@epa.gov>; Leadership_Deputy_Assistant_Administrators <Leadership_Deputy_Assistant_Administrators@epa.gov>
Cc: Wheeler, Andrew <wheeler.andrew@epa.gov>; Leadership_Deputy_Regional_Administrators
[redacted]

[redacted] Bob

Subject: Soliciting Requests for IRIS Assessments

AAs and DAAs,

On behalf of the Acting Administrator, the Office of Research and Development (ORD) is soliciting program input on priorities for future Integrated Risk Information System (IRIS) assessments as well as the chemicals currently prioritized for the IRIS FY 2018–2019 Portfolio. This request is part of our continuing effort to ensure IRIS assessment activities are focused on the most important Agency needs.

To request an IRIS assessment or to confirm your continued interest in the assessments that are underway within IRIS, please coordinate with ORD to complete an IRIS Assessment Request Form (Attachment 1).

Central to effective implementation of IRIS is information that allows for a clear and common understanding by ORD and your program, not just of priorities, but of the decision or regulatory context for each IRIS assessment. Additionally, this information helps to determine the type of assessment required to meet your program needs. To ensure proper scope and timeliness, the form requires information on the decision context, level of priority your assessment needs, and a requested completion date.

To inform your requests, I am providing a list of assessments currently in the IRIS FY 2018–2019 Portfolio and the expected timeline for completion of an agency draft (Attachment 2). ORD will solicit programmatic input for new assessment needs on an annual basis, but requests for new IRIS priorities can be made at any time.

Please complete these forms by August 31, 2018, and return to me for concurrence. I will synthesize all the responses and report to the Acting Administrator. If you have any questions regarding this request, please feel free to contact me. Thank you.

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

OLEM Response – Request for IRIS Assessments
September 12, 2018
Summary/Overview Information

- **Overall Summary**
  - OLEM would like to thank ORD for the opportunity to provide input on ongoing programmatic needs for assessments in the IRIS portfolio.
  - OLEM has a strong need for completion of most of the ongoing IRIS assessments; more detailed information about the specific needs for individual chemicals is provided below and in the attached nomination forms.
    - Three of the ongoing assessments are of less importance for OLEM (see below).
  - OLEM requests further engagement with ORD regarding potential use of alternative types of toxicity values for two categories of chemicals:
    - Fuel additive chemicals, for which assessments are required under the Energy Policy Act of 2005 and were to be completed by EPA within two years.
    - PFAS chemicals (beyond those currently underway)
- **Summary of process**
  - As requested, OLEM is providing input on OLEM priorities for IRIS assessments (both ongoing and proposed new assessments).
  - We have also solicited and incorporated input from Regional offices regarding their needs in support of OLEM programs.
- **Overview of Results**
  - Nominations Received
    - In response to the ORD solicitation, OLEM received input from multiple OLEM offices and from nine Regional offices. In addition to affirmations of need for ongoing assessments, OLEM offices and Regions provided additional nominations supporting the need for chemical assessments beyond those currently underway.
  - Summary information provided
    - To provide an overview of the information received, we have constructed three summary tables:
      - Table 1 (Current IRIS Nominations) provides a list of chemical assessments currently underway, and details which OLEM offices and Regions indicated the need for assessments of those chemicals. For context, we have also included information regarding the number of Superfund sites at which the chemical has been identified as a chemical of concern.
      - Table 2 (Proposed New IRIS Nominations) provides a list of submitted new chemical nominations, including the nominating organization and the specific assessment needs.
      - Table 3 (OUST Nominations Ongoing but not on NCEA list) includes four chemicals requested by our OUST program that were not on the list of

ongoing chemicals, but for which assessments are currently underway (Two in the IRIS program and two in the PPRTV program); we want to affirm our ongoing need for these assessments, which don't fit into either of the previous categories.

- In addition, many submitters included a cross-chemical justification regarding the utility of IRIS assessments as compared to other types of chemical assessments. For the sake of efficiency, we have extracted those cross-chemical justifications into a single document (Attachment 1), and have incorporated it by reference into each of the individual nomination forms.

- Nomination form packages -- we have organized the provided nomination forms into three separate sets:
  - For ongoing assessments, we have provided a package of completed chemical nominations forms for individual chemicals, with collated program and regional chemical specific needs and background information [p.].
  - For new nominations, we have provided a package of completed individual nomination forms, as they were provided to OLEM [p.]. None of the chemicals requested as a new nomination was submitted by more than one submitting organization.
  - For the four ongoing nominations not included in the list received from NCEA, we have provided a package of individual nomination forms for those chemicals, including a notation on our understanding of their current status [p.].

- **Summary**
  - General conclusions:
    - OLEM has a strong need for completion of most of the ongoing assessments
      - The chemicals are chemicals of concern at a large number of OLEM sites
      - Current values are outdated and/or nonexistent
      - IRIS assessments are very valuable for our programs, due to the strong peer review and public review process.
    - OLEM has a need for Ammonia toxicity values for short term inhalation exposure, but it is our understanding that the current Ammonia assessment focuses on long term oral ingestion. Based on that understanding, the ongoing Ammonia assessment is of lower importance to OLEM programs.
    - Three other chemicals are generally of less importance for OLEM programs: Formaldehyde, Nitrate/Nitrite, Acrolein
    - Due to our ongoing and longstanding need, as well as the large number of sites, we have designated all but four of the ongoing assessments as high priority. If a more refined prioritization is needed, we can discuss whether sub-prioritization within the 'high' category might be possible.
    - OLEM's needs for these assessments is ongoing, due to both current programmatic work and anticipated future work (e.g., 5 year reviews will necessitate review of remedy protectiveness, even after risk assessments have been completed).
  - We would like to support the IRIS programs proposal to develop a fit-for-purpose portfolio of assessments:

        - We believe it would be useful to discuss whether the OUST nominations might be considered for such an approach.
        - We would like to discuss the process for PFAS assessments, and in particular to discuss with ORD and NCEA how to address toxicity for the larger group of PFAS (e.g., the 31 PFAS identified by the PFAS Toxicity Workgroup, for which literature searches have already been completed).
    - Please contact Kathleen Raffaele if you have questions about any of the information we have submitted, or if additional information is needed.

Iris Nominations – Regional Affirming Officials

Region 1 – Memo from Bryan Olson, Director, Office of Site Remediation and Restoration, cc'd to Deb Szaro, DRA

Region 2 – John Prince, Acting Director, Emergency and Remedial Response Division

Region 3 – Karen Melvin, Region 3 Hazardous Site Cleanup Division Director

Region 4 – Submission okay'd by DRA and RA

Region 5 – Jim Payne, Acting DRA

Region 6 – David Gray, DRA

Region 7 – Ed Chu, DRA

Region 9 – Deborah Jordan, DRA

Region 10 – Michele Pirzadeh, DRA

Table 1: Current IRIS Nominations

		OLEM OFFICES			REGIONS									
	Total (# in support/total # responded)	OUST	OSRTI	ORCR	R1	R2	R3	R4	R5	R6	R7	R9	R10	Total # of Sites
Ammonia (oral)	5/12		X		X		X	X			X			82
Arsenic, inorganic	10/12		X	X	X	X	X	X	**		X	X	X	1028
Chloroform	7/12		X	X	X	X	X	X			X			450
Ethylbenzene	9/12		X	X	X	X	X	X	X	X	X			470
Formaldehyde	5/12		X		X		X	X	**		X			10
Hexavalent Chromium	11/12		X	X	X	X	X	X	X	X	X	X	X	131
Naphthalene	7/12	X	X	X	X		X	X		X	X			371
Nitrate/Nitrite	5/12		X		X		X	X	**		X			60/6
PCBs (noncancer)	11/12		X	X	X	X	X	X	X	X	X	X	X	407
Uranium	8/12		X	X	X		X	X		X	X		X	72
Manganese	9/12		X	X	X	X	X	X	**	X	X		X	555
Mercury Salts	8/12		X	X	X	X	X	X			X		X	817*
Methylmercury	10/12		X	X	X	X	X	X	X	X	X		X	10/817*
PFAS	4/12		X		X		X	X	**					
Acrolein	3/12		X		X			X						
PAH Mixtures	7/12		X	X	X		X	X	X				X	

*Many sites analyzed for total mercury, not mercury salts or methylmercury

**Region 5 submitted nominations through other offices

IRIS Assessment Request Form – Ongoing Assessments	
Requesting Office: OLEM	
Request Date: September, 2018	**Requested Completion Date:** As soon as possible, but we have long-term needs for this assessment.
Chemical Nominated for Assessment: Arsenic, inorganic	**Priority of Assessment: High**

General Background of Chemical:

"Arsenic is a naturally occurring element that is found in combination with either inorganic or organic substances to form many different compounds. Inorganic arsenic compounds are found in soils, sediments, and groundwater. These compounds occur either naturally or as a result of mining, ore smelting, and industrial use of arsenic. Organic arsenic compounds are found mainly in fish and shellfish. In the past, inorganic forms of arsenic were used in pesticides and paint pigment. They were also used as wood preservatives and as a treatment for a variety of ailments. Today, usage of arsenic-containing pesticides and wood preservatives is restricted.

People are most likely to be exposed to inorganic arsenic through drinking water and to a lesser extent through various foods. Water sources in some parts of the United States have higher naturally occurring levels of inorganic arsenic than other areas. Other sources of inorganic arsenic exposure include contact with contaminated soil or with wood preserved with arsenic. People are exposed to organic arsenic by consuming seafood. Long-term exposure to high levels of inorganic arsenic in drinking water has been associated with skin disorders and increased risks for diabetes, high blood pressure, and several types of cancer. Inorganic arsenic and arsenic compounds are considered to be cancer-causing chemicals."

Reference: CDC Fact Sheet on Arsenic. https://www.epa.gov/sites/production/files/2014-03/documents/arsenic_factsheet_cdc_2013.pdf. Accessed on 9/4/18)

The RfD for arsenic was lasted updated in 1991 and the cancer values were finalized in 1995. Since then a lot of newer studies have been conducted, including studies in the US and studies that include several noncancer outcomes that were not considered before, including diseases of the circulatory system, which appear to be a very sensitive endpoint.

Scope of Assessment Request:

OLEM programs and regions have a need for all relevant toxicity metrics that can be supported by the available data (oral and inhalation, cancer and noncancer, RfD, RfC, CSF, IUR). However, OLEM's primary need is for oral ingestion values and we would prioritize an updated CSF and RfD.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

See accompanying document summarizing OLEM program needs for IRIS assessments (Attachment 1).

Supporting OLEM programs: ORCR, OSRTI
Supporting Regions (submitted to OLEM): 2, 3, 4, [5], 9,10. [R5 submitted through another program.]
High priority for Regions 2, 5, 9, 10

Additional Chemical-specific information:

OSRTI and Regions: Arsenic is a contaminant of concern for at least 1028 Superfund Sites, and it is the risk driver at a number of these sites. We need updated toxicity values to develop protective

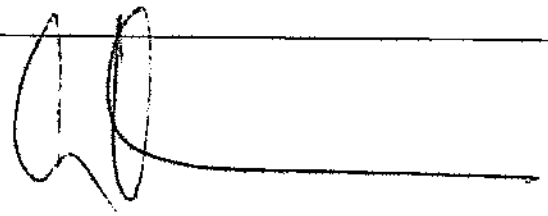
remedies that will return sites to anticipated use, and to complete our five-year reviews to ensure remedies are still protective when contamination is left in place.

ORCR: Arsenic is one of the most frequent risk drivers in recent national-level assessments. ORCR has needs related to arsenic both as a toxicity characteristic chemical and a corrective action chemical.

Region 2: COC at 156/218 Superfund sites. Arsenic was identified at landfills, former manufacturing facilities, scrap metal sites and federal facilities. It is found primarily in soil and groundwater. IRIS Chemical file for arsenic indicates that the oral Reference Dose (RfD) was last updated in 1991 and the cancer assessment was last updated 1995.

R9: Updated & revised toxicity criteria will be used to derive site-specific remedial goals for multimedia arsenic contamination in various RCRA, CERCLA & other cleanup sites within Region IX.

R10: The IRIS inorganic arsenic toxicity metrics will be used in the CERCLA program for hazard ranking, derivation of risk based goals, characterization of site risks, evaluation of remedial alternatives and derivation of cleanup goals. Updated information will also support the technical analyses of remedy effectiveness during the Five-Year Review process for ongoing cleanups actions.
Supporting



Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form – Ongoing Assessments	
Requesting Office: OLEM	
Request Date: September, 2018	**Requested Completion Date:** As soon as possible, but we have long-term needs for these assessments
Chemical Nominated for Assessment: Ammonia (oral)	**Priority of Assessment:**

General Background of Chemical:

Ammonia (NH3) is a clear caustic gas with a pungent odor, highly soluble in water and in blood. U.S. production of ammonia and ammonium salts totals tens of billions of pounds per year, most of which is used for agricultural fertilizers, but also in drinking water disinfection, wastewater treatment, and explosive production. In addition, ammonia and ammonium sulfate are EPA-registered pesticides for controlling micro-organisms (algae, bacteria, fungi), and ammonium sulfamate was an EPA-registered herbicide. Several ammonium compounds are inert ingredients in pesticide formulations. The principal route of human exposure is oral.

From IRIS Assessment Plan for Ammonia (Oral Exposure):
http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=535564

Scope of Assessment Request:

Oral noncancer RfD, Short term inhalation RfC

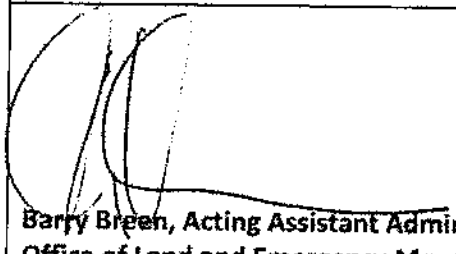
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

See accompanying document summarizing OLEM program needs for IRIS assessments (Attachment 1).

Supporting OLEM Programs: OSRTI
Supporting Regions: 3, 4

Ammonia is a contaminant of concern for at least 82 Superfund sites.

Ammonia is also of concern for emergency response situations, but the need in those situations would be for a toxicity value for short term inhalation exposures. It is our understanding that the ongoing IRIS assessment does not include evaluation of inhalation toxicity.

 **Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management**	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form – Ongoing Assessments	
Requesting Office: OLEM	
Request Date: September 7, 2018	**Requested Completion Date:** As soon as possible, but we have long-term needs for this assessment.
Chemical Nominated for Assessment: Chloroform	**Priority of Assessment: High**
General Background of Chemical:	
Chloroform (trichloromethane) is a colorless, nonflammable and volatile liquid with a distinct odor. It is slightly soluble in water and is readily miscible with most organic solvents. Because chloroform is relatively volatile, it tends to escape from contaminated environmental media (e.g., water or soil) into air and may also be released in vapor form from some types of industrial or chemical operations. Therefore, humans may be exposed to chloroform not only by ingestion of chloroform in drinking water, food, or soil, but also by dermal contact with contaminated media (especially water) and by inhalation of vapor (especially in indoor air). The inhalation assessment (posted in 1987) derived an inhalation unit risk (IUR) for chloroform of 2.3 × 10-5 per µg/m3. This assessment did not include the derivation of a reference concentration (RfC) for chloroform.	
Scope of Assessment Request:	
OLEM: Inhalation noncancer (RfC) Region 2: Clarification of the relationship of the cancer and noncancer assessments.	
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*	
See accompanying document summarizing OLEM program needs for IRIS assessments (attachment 1). Supporting OLEM programs: OSRTI, ORCR Supporting Regions: 1, 2, 3, 4, 7 High priority: Regions 2, 3,4 Chloroform is a contaminant of concern at 450 Superfund sites. Additional chemical information: OSRTI: Superfund NPL Listing, Risk Assessment, Remedy Decisions, and Five Year Reviews. ORCR: RCRA toxicity characteristic and corrective action chemical Region 2: RCRA program need	
Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form – Ongoing Assessments	
Requesting Office: OLEM	
Request Date: September, 2018	**Requested Completion Date:** As soon as possible, but we have long-term needs for this assessment.
Chemical Nominated for Assessment: Ethylbenzene	**Priority of Assessment: High**

General Background of Chemical:

Ethylbenzene, also known as phenylethane, is an aromatic hydrocarbon present in crude petroleum and gasoline. It is used in the production of styrene monomer (IPCS, 1996), primarily as a chemical intermediate. Ethylbenzene also is used as an industrial solvent and a diluent in the paint industry and in the manufacture of synthetic rubber, acetophenone, and cellulose acetate (Cal/EPA, 1997). It is present in naphtha and asphalt and as an impurity in xylene solvents (Cal/EPA, 1997). Individuals that may be exposed are those living near manufacturing and processing facilities, petroleum refineries, and hazardous waste sites where ethylbenzene has been detected or those using well water downgradient from leaking underground storage tanks (ATSDR, 2010). It is also found or used as a solvent for paint, varnish, ink, and surface coatings. It is present in all transportation fuels (gasoline, marine, aviation). Exposure occurs to the general population through direct contact or inhalation of gasoline vapors and solvents. Releases of petroleum products to land or dumping of petroleum products to uncontrolled landfills can lead to contamination of downstream groundwater and surface water. Exposure to the worker population can occur at styrene and paint production facilities. Other workers with significant exposure are those who work routinely around motor vehicles (gas stations, highway workers, parking lots). An oral RfD of 1 x 10-1 mg/kg-day was posted in 1987 based on hepatic and renal toxicity. An inhalation RfC of 1 mg/m3 was posted in 1991 based on developmental toxicity. In 1988 the cancer weight of evidence for ethylbenzene was categorized as "Group D," that is, not classified concerning its potential to cause cancer in humans, due to a lack of animal and human data. Since then, several relevant studies on ethylbenzene toxicity have been completed and new data have become available.

From IRIS Assessment Plan for Ethylbenzene:
http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=532215
OUST: Ethylbenzene is present in gasoline and is still present at many release sites of motor fuels from leaking UST sites. Gasoline is comprised of hundreds of compounds. Gasoline is stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included ethylbenzene and have the potential to contaminate drinking water supplies.

Scope of Assessment Request:

OLEM: cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation (RfD, RfC, IUR, CSF)

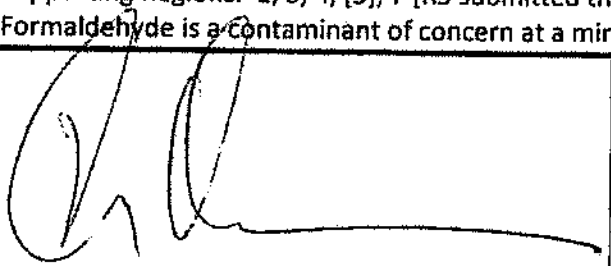
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

See accompanying document summarizing OLEM program needs for IRIS assessments (attachment 1).
Supporting OLEM offices: OSRTI, ORCR, OUST
Supporting Regions: 1, 2, 3, 4, 5, 6, 7; high priority for Regions 2, 4, 5, 7 and OUST

Additional Chemical information:
OSRTI: Ethylbenzene is a contaminant of concern at more than 470 Superfund sites.
ORCR: Ethylbenzene is found at many corrective action sites.

OUST: Ethylbenzene is one of the four most common groundwater contaminants from leaking USTs. High priority for OUST; these are Benzene, Toluene, Ethylbenzene, and Xylenes ("BTEX"). Toxicity values for all of the exposure pathways (i.e., dermal, ingestion, inhalation) and for both cancer and non-cancer effects are not presently available.
Region 2: COC at 94/219 sites. Sites contaminated include landfills, oil refineries, trucking facilities, former manufacturing facilities and federal facilities. Oral Rfd and inhalation RfC last updated in 1987 and 1991 respectively. Cancer assessment last updated 1988.
R5: Updated Ethylbenzene toxicity values (Inhalation & Oral exposure) are required to set risk-based screening levels, derive baseline risk assessments, and establish remediation goals at 30-40 Superfund and RCRA sites in Region 5. Ethylbenzene is a Hazardous Air Pollutant under the CAA. Region 5 is required to determine which air emission facilities should include ethylbenzene in air emission risk assessments and air monitoring programs. Toxicity values are needed to evaluate residual risk from air emissions. Current toxicity factors for Ethylbenzene are 30 years old. Much newer toxicological information is available which covers updated studies in lab animal models and epidemiological studies for the occupational and general population. Updated Inhalation RfC and Oral RfD toxicity values need to be derived by employing Benchmark Dose Modeling and PBPK Modeling. Revisiting the cancer assessment will require an analysis of a new body of animal bioassay data.
R7: Neither an oral cancer slope factor nor an inhalation unit risk for ethylbenzene are available from IRIS. Three decades ago, in 1988, IRIS determined that the carcinogenicity of ethylbenzene was not classifiable due to a lack of animal and human studies at that time. Later, in 1999, the National Toxicology Program found clear evidence of carcinogenicity in male rats exposed to ethylbenzene for two years via inhalation. This study was the basis for the inhalation unit risk and cancer slope factor derived by the California Environmental Protection Agency. Since no IRIS cancer toxicity values exist, the CalEPA IUR and CSF are the values used by the regions to derive screening levels and preliminary remediation goals for soil, water, and air. Notably, the cancer-based PRGs are significantly lower than values based on non-cancer health effects. The current MCL for ethylbenzene is based on non-cancer health effects and does not take into account carcinogenicity. Region 7 has numerous Superfund and RCRA sites where ethylbenzene is a chemical of concern, including former refineries, coal gasification sites, former manufactured gas plants, manufacturing facilities, and federal facilities. The CalEPA toxicity values indicate that exposures to ethylbenzene in groundwater at the MCL, which is used as the cleanup standard, may pose unacceptable health risks. New cancer toxicity values for ethylbenzene would likely trigger re-valuation of the MCL, which may result in lower cleanup goals at new and existing sites. Additionally, ethylbenzene is sufficiently volatile such that it may enter structures via subsurface vapor intrusion, and new IRIS cancer toxicity values would impact evaluation of this pathway. We note that EPA released ethylbenzene scoping and problem formulation materials for public comment in July 2014, and completion of an Agency draft is anticipated in the fourth quarter of FY 2019. Region 7 encourages the IRIS program to complete this assessment as quickly as possible to meet a critical regional need.

Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form – Ongoing Assessments	
Requesting Office: OLEM	
Request Date: September, 2018	**Requested Completion Date:** As soon as possible, but we have long-term needs for this assessment.
Chemical Nominated for Assessment: Formaldehyde	**Priority of Assessment:**
General Background of Chemical:	
Formaldehyde is a colorless, flammable gas at room temperature and has a strong odor. Exposure to formaldehyde may cause adverse health effects.	
Scope of Assessment Request:	
Inhalation risk estimates (cancer and non-cancer; RfC and IUR)	
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*	
See accompanying document summarizing OLEM program needs for IRIS assessments. Supporting OLEM offices: OSRTI Supporting Regions: 1, 3, 4, [5], 7 [R5 submitted through another program.] Formaldehyde is a contaminant of concern at a minimum of 10 Superfund sites	
 **Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management**	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form – Ongoing Assessments	
Requesting Office: OLEM	
Request Date: September, 2018	**Requested Completion Date:** As soon as possible; OLEM and Regional needs are ongoing
Chemical Nominated for Assessment: Hexavalent Chromium	**Priority of Assessment:** High

General Background of Chemical:

Chromium is a transition metal element. It is present in the Earth's crust and has oxidation states ranging from -2 to +6, with the +3 (trivalent) and +6 (hexavalent) states being the most predominant. Chromium can originate from both natural and man-made sources, but compounds containing the hexavalent oxidation state primarily arise from anthropogenic sources, with the largest releases occurring from industrial sources (ATSDR, 2012). Hexavalent chromium compounds are widely used as corrosion inhibitors, in the manufacture of pigments, in metal finishing and chrome plating, in stainless-steel production, in leather tanning, in wood preservatives, in textile dyeing processes, printing inks, drilling muds, pyrotechnics, water treatment, chemical synthesis, and plastics. Industries with the largest contribution to chromium release or disposal of chromium and chromium compounds include metal processing, tannery facilities, chromate production, stainless steel welding, electric utility companies, and ferrochrome and chrome pigment production (HSDB, 2014; U.S. EPA, 2014a). The general population may be exposed to hexavalent chromium compounds via inhalation of ambient air, ingestion of water or food, or dermal contact with chromium-containing products such as pressure-treated wood. Significant new epidemiologic and experimental animal toxicity information for Cr(VI) has become available since EPA's IRIS assessment for Cr(VI) was posted in 1998, including updates of occupational cohort studies (Proctor et al., 2016; Gibb et al., 2015) and a National Toxicology Program (NTP) bioassay that reported increased incidences of tumors in rats and mice exposed to Cr(VI) in drinking water (NTP, 2008). The NTP (2008) bioassay findings are significant because they provide evidence of carcinogenicity from ingested Cr(VI). The dose-response information from epidemiologic and experimental animal studies published since 1998 could result in changes to current toxicity values.

Source: Scoping Information, Preliminary Literature Search, Associated Strategy and Evidence Tables for Cr(VI) Part 2. (PDF)

References:

ATSDR (Agency for Toxic Substances and Disease Registry). (2012). Toxicological profile for chromium. Atlanta, GA: US Department of Health and Human Services, Public Health Service. http://www.atsdr.cdc.gov/toxprofiles/tp7.pdf

HSDB (Hazardous Substances Data Bank). (2014). Chromium compounds. Washington, D.C.: National Library of Medicine. http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB

U.S. EPA (U.S. Environmental Protection Agency). (2014b). The third Unregulated Contaminant Monitoring Rule (UCMR 3) occurrence data. Retrieved from http://water.epa.gov/lawsregs/rulesregs/sdwa/ucmr/data.cfm#ucmr2013

Scope of Assessment Request:
All toxicity metrics, oral and inhalation, cancer and noncancer (RfD, RfC, CSF, IUR)
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*
See accompanying document summarizing OLEM program needs for IRIS assessments (Attachment 1). Supporting OLEM programs: OSRTI, ORCR Supporting Regional programs: 1, 2, 3, 4, 5, 6, 7, 9, 10 High priority for regions 2, 4, 5, 7, 9, 10 Cr VI is found at a minimum of 131 Superfund sites.
Additional chemical specific information: ORCR: It is needed for RCRA Corrective Action, as well as being a toxicity characteristic chemical (total Cr). Region 2: Identified as COC at 21/218 sites which include circuit board and plating facilities, federal facilities, landfills and refining facilities. Oral Rfd, inhalation RfC and cancer assessment last updated in 1998. R5: Cr(VI) has been identified as a contaminant of concern at hazardous waste sites, including more than a thousand National Priority List sites. IRIS values are used to set remediation targets for contaminated sites. In the 2008 Appropriations Bill, Congress asked EPA to develop an updated health standard for ingested Cr(VI), and use this standard to revise the maximum contaminant level goal (MCLG) for drinking water as soon as possible. An updated IRIS assessment for Cr(VI) will be directly responsive to Congress and to the Administrator's commitment to develop a health assessment for Cr(VI). Chromium compounds are hazardous air pollutants under the CAA. Health risks from air toxics are assessed under the National-Scale Air Toxics Assessment (NATA). NATA provides estimates of cancer and noncancer health effects based on chronic inhalation exposure from outdoor sources, and is used to identify and prioritize air toxic emission source types and locations that are of greatest potential concern for contributing to population risk. Updated IRIS values for inhalation of Cr(VI) will be used in generating better assessments for population risks. R7: An oral cancer slope factor is currently not available from IRIS. However, in 2008, the National Toxicology Program found clear evidence of carcinogenicity in rats and mice exposed to hexavalent chromium in drinking water for two years. The EPA's Office of Pesticide Programs, CalEPA, and other state agencies used the NTP studies to establish cancer slope factors for hexavalent chromium. The regions currently use the CalEPA CSF for hexavalent chromium to evaluate potential health risks, but we use the MCL for total chromium as the cleanup goal for groundwater. For example, at the Ace Services site in Colby, Kansas, treated groundwater is discharged to the city public water system, with discharge limits of 17 µg/L hexavalent chromium and 100 µg/L total chromium, which is the MCL. Based on the CalEPA CSF, a discharge limit of 17 µg/L hexavalent chromium exceeds the EPA's target cancer risk range if the water is directly ingested. The Office of Water has indicated that a revised IRIS toxicological assessment is necessary before they can propose a new MCL based on the oral carcinogenicity of hexavalent chromium. Region 7 has several plating sites and federal facilities where hexavalent chromium is a chemical of concern. New IRIS toxicity values could result in a new MCL, which in turn could alter the remedies and cleanup goals used at our sites to ensure protection of human health. In the meantime, a state in Region 7 indicated, "Given the ongoing debate on this issue and lack of a consensus approach among agencies nationwide at the present time, [we] decided to seek an independent evaluation of the MOA for CrVI oral carcinogenicity and a weight-of-evidence

determination of the most scientifically defensible approach." This state ultimately approved the use of cleanup goals developed by a responsible party that were based on a non-linear mode of action. Lack of IRIS values for hexavalent chromium could lead to inconsistent decisions across our regions and our states, some of which may not adequately protect human health. We note that EPA began work on the hexavalent chromium toxicological review shortly after the NTP study was published in 2008, and completion of an Agency draft is anticipated in the third quarter of FY 2019. Region 7 encourages the IRIS program to complete this assessment as quickly as possible to meet a critical regional need.

R9: The derivation of health-based remedial goals for hazardous waste sites contaminated with Chrome +6 remains a high priority for both the Superfund & RCRA programs. The derivation of updated toxicity criteria will support cleanup actions taken by Cal-EPA at sites contaminated with hexavalent chrome.

R10: IRIS hexavalent chromium toxicity metrics are broadly used in CERCLA actions. These actions include, but are not limited to, site hazard ranking, derivation of risk-based goals, evaluation of total/background/site risks, characterization of site risks, evaluation of remedial alternatives and derivation of cleanup goals. Region 10 has recently issued a ROD for cleanup of hexavalent chromium in groundwater (Hanford 100 area), and more defensible toxicity criteria will be important to assess remedy effectiveness in the ongoing Five Year Reviews while the remedy is in progress.

Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form – Ongoing Assessments	
Requesting Office: OLEM	
Request Date: September, 2018	**Requested Completion Date:** As soon as possible, but we have long-term needs for this assessment.
Chemical Nominated for Assessment: Naphthalene	**Priority of Assessment: High**
General Background of Chemical:	
Naphthalene is a polycyclic aromatic hydrocarbon and naturally occurring substance that is most abundantly found in coal tar, coal and petroleum. Naphthalene is a component of fuel oil and gasoline and is produced as a combustion by-product in vehicle exhaust. The public can be exposed to naphthalene via inhalation, ingestion, and dermal routes. Inhalation is generally considered to be the predominant route of exposure. Exposure to naphthalene may also come from contact with contaminated land and water resulting from spills during storage, transportation and disposal of fuel oil, coal tar, etc. In 1988, the EPA produced a Naphthalene assessment conducted using guidance from EPA's 1986 Cancer Guidelines (U.S. EPA, 1986), that includes a review of inhalation studies which provide support for a reference concentration (RfC) of 3 × 10-3 mg/m3 for noncancer effects based on hyperplasia and metaplasia in respiratory and olfactory epithelium in mice, and a review of oral studies which provide support for a reference dose (RfD) of 2 × 10-2 mg/kg-day for noncancer effects based on decreased body weight in male rats. EPA's 1998 IRIS assessment classified naphthalene as a Group C, possible human carcinogen. Since the posting of IRIS toxicological review of naphthalene in 1998 and the release, in 2005, of EPA's final cancer guidelines (U.S. EPA, 2005), new information on naphthalene has become available, including bioassay data, potency estimations, and physiologically-based pharmacokinetic (PBPK) models with potential to assist in performing route-to-route and animal-to-human extrapolations. Source: IRIS Assessment Plan for Naphthalene (Scoping and Problem Formulation Materials) (PDF) OUST: Motor fuels (e.g., gasoline, diesel) are comprised of hundreds of compounds. Naphthalene is a significant component of diesel fuel and a minor component of gasoline. Motor fuels are stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included naphthalene and have the potential to contaminate drinking water supplies.	
Scope of Assessment Request:	
Complete IRIS Toxicological Review including both inhalation, dermal, and oral, cancer and non-cancer (RfD, RfC, IUR, CSF).	
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*	
See accompanying document summarizing OLEM program and Regional needs for IRIS assessments (Attachment 1). Supporting OLEM programs: OSRTI, ORCR Supporting Regional programs: 1, 3, 4, 6,7, 9, 10 High priority for OUST and regions 3 and 7	
Additional chemical specific information: OLEM: This contaminant has been found at more than 372 OLEM sites. However, it is important to be aware that EPA's environmental occurrence data likely underestimates the actual occurrence because	

compounds without toxicity values are often not analyzed at sites.
OSRTI: Superfund NPL Listing, Risk Assessment, Remedy Decisions, and Five Year Reviews.
ORCR: Naphthalene is a chemical of concern at Corrective Action Sites.
OUST: Naphthalene is a common groundwater contaminant from leaking USTs. Toxicity values for all of the exposure pathways (i.e., dermal, ingestion, inhalation) and for both cancer and non-cancer effects are not presently available.

R7: Neither an oral cancer slope factor nor an inhalation unit risk for napthalene are available from IRIS. Last updated in 1998, the IRIS program did not consider the 2000 National Toxicology Program study that found clear evidence of carcinogenicity in rats exposed to naphthalene for two years via inhalation. This study was used to derive the CalEPA cancer toxicity values that are used by the regions, in the absence of IRIS values. An MCL for naphthalene is not currently available. Thus, risk-based levels derived using CalEPA toxicity values are currently used to establish cleanup levels for naphthalene in all media. Region 7 has experienced push-back on this approach. For example, an industrial facility argued against direction from Region 7 to use the naphthalene inhalation unit risk value from CalEPA because the existing IRIS assessment states that carcinogenicity cannot be determined at this time, even though that statement was made in 1996. Region 7 has numerous Superfund and RCRA sites where naphthalene is a chemical of concern, including former refineries, coal gasification sites, former manufactured gas plants, manufacturing facilities, and federal facilities. Additionally, naphthalene is sufficiently volatile such that it may enter structures via subsurface vapor intrusion, and new IRIS cancer toxicity values would impact evaluation of this pathway.
We note that EPA started the IRIS assessment of cancer risks stemming from the inhalation of naphthalene in 2002, and completion of an Agency draft is anticipated in the fourth quarter of FY 2019. Region 7 encourages the IRIS program to complete this assessment as quickly as possible to meet a critical regional need.

Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form – Ongoing Assessments	
Requesting Office: OLEM	
Request Date: September, 2018	**Requested Completion Date:** As soon as possible, but we have long-term needs for this assessment.
Chemical Nominated for Assessment: Nitrate/Nitrite	**Priority of Assessment:**

General Background of Chemical:

Nitrate (NO3−) and nitrite (NO2−), naturally occurring anions in the environment, play an essential role in Earth's nitrogen cycle. Since 1950, human sources of reactive nitrogen into the environment—released either intentionally (e.g., through fertilizer application) or unintentionally (e.g., as a byproduct of fossil fuel combustion)—have increased substantially (Fields, 2004). Nitrate salts are mainly used as nitrogen fertilizers and in industrial explosives, fireworks, and glass making; nitrites are largely used as preservatives for meat and fish curing and as color fixatives (IARC, 2010; Pokorny L, 2006).

The general population is exposed to nitrate in both drinking water and food. Vegetables are the main source of exposure to ingested nitrate, with leafy vegetables comprising nearly 80% of nitrate exposure in an average person's diet. Other sources of dietary nitrate include cured meats/fish, cereal grains, dairy products, and beer (ATSDR, 2017; IARC, 2010). In contrast to nitrates, endogenous sources account for approximately 80% of all nitrites in the human body, as 5–8% of the total nitrate intake is converted into nitrite (WHO, 2016; Mensinga et al., 2003). Almost all exogenous exposure to nitrite comes from food, with relatively higher nitrite concentrations found in cured meats (IARC, 2010). Drinking water is generally a minor source of exposure to nitrite (IARC, 2010).

The IRIS Program previously evaluated the oral health effects of nitrate and nitrite; oral reference doses (RfDs) for nitrite and nitrate were posted to the IRIS database in 1987 and 1991, respectively. EPA based these RfDs on surveys of clinical cases of methemoglobinemia in infants associated with ingestion of nitrate-containing drinking water conducted in the early 1950s (Walton, 1951; Bosch et al., 1950). Since 1987, a growing body of literature indicates potential associations between nitrate/nitrite exposure and other noncancer health effects. Some epidemiological studies also suggest an increased risk of cancer, especially gastric cancer, associated with dietary nitrite exposure (ATSDR, 2017). Cancer risk associated with nitrate or nitrite exposure is complicated by the fact that, under conditions of concurrent exposure to amines or amides or low levels of antioxidants, endogenous nitrosation can occur, leading to the formation of carcinogenic nitroso compounds (ATSDR, 2017; IARC, 2010). IARC (2010) concluded that ingested nitrate or nitrite under conditions that result in endogenous nitrosation is probably carcinogenic to humans.

From IRIS Assessment Plan for Nitrate and Nitrite,
http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=532696

Scope of Assessment Request:

Oral RfD and cancer CSF

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

See accompanying document summarizing OLEM program needs for IRIS assessments (Attachment 1).

Supporting OLEM programs: OSRTI Supporting Regions (submitted to OLEM): 1, 3, 4, [5], 7. [R5 submitted through another program.] This contaminant has been found at more than 60 OLEM sites No chemical-specific information provided.

Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form – Ongoing Assessments	
Requesting Office: OLEM	
Request Date: September, 2018	**Requested Completion Date:** As soon as possible, but we have long-term needs for this assessment.
Chemical Nominated for Assessment: PCBs (noncancer)	**Priority of Assessment: High**

General Background of Chemical:

Polychlorinated biphenyls (PCBs) are a class of synthetic compounds characterized by a biphenyl structure with chlorine substitutions at up to ten positions. PCBs were manufactured and marketed in the United States between about 1930 and 1977 under the trade name Aroclor. PCBs were used in many industrial applications because of their electrical insulating properties, chemical stability, and relative inflammability. EPA issued final regulations banning the manufacture of PCBs and phasing out most PCB uses in 1979 under the Toxic Substances Control Act (TSCA) due to evidence that they persist and accumulate in the environment, and can cause toxic effects. Despite the ban on manufacturing, humans continue to be exposed to PCBs by inhalation of volatilized PCBs, inhalation of contaminated dust, contact with contaminated dust, contact with primary or secondary sources of PCBs, and ingestion of foods contaminated with PCBs. The non-cancer assessment for Aroclor 1016 was completed in 1993; assessments for Aroclors 1248 and 1254 were completed in 1994. The cancer assessment for environmental PCB mixtures was completed in 1996. There is no IRIS RfD for complex PCB mixtures in general. Nor is there an IRIS inhalation reference concentration (RfC) for PCBs. Since 1994, a number of studies on the non-cancer health effects of exposure to environmentally-relevant PCB mixtures (e.g., similar to those found in contaminated fish or human milk) have been conducted, and new data are available.

Source: Scoping and Problem Formulation Materials for Polychlorinated Biphenyls (PCBS): Effects Other Than Cancer (PDF)

Polychlorinated Biphenyls (PCBs) are high volume legacy pollutants found in every environmental compartment (soils, sediments, air). PCBs are highly persistent in the environment and bioaccumulate into and upward through the food train. Contamination of the food chain has resulted in fish consumption as a primary exposure pathway for the U.S. population, especially for recreational and subsistence fishers. In addition, PCBs are found as legacy contaminants in older buildings (constructed before 1978) because of PCBs residues in paint, caulking, and light ballasts. Many of the older buildings include schools where exposure to children is a significant potential.

Scope of Assessment Request:

OLEM: IRIS Toxicological Review, noncancer, inhalation and oral (RfD and RfC)
Region 2: Reference Concentration (RfC) for noncancer hazard calculations from air exposure
R5: The Non-Cancer IRIS assessment needs to be completed as an Agency-wide priority. The current EPA toxicity factors for PCB mixtures are outdated and based on toxicological data that is decades old. Current information shows that PCBs are developmental toxicants for children that affect neurological and immunological pathways. This new toxicological data needs to be included in the IRIS assessment.
R9: Region IX requests that the IRIS PCB assessment provide an updated RfD & a new RfC.

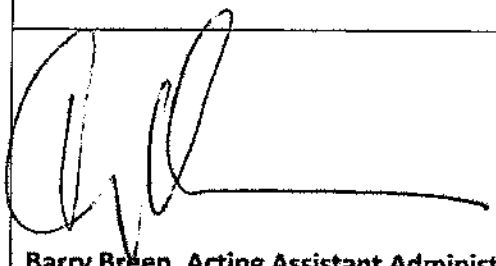
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

See accompanying document summarizing OLEM program needs for IRIS assessments (Attachment 1).

Supporting OLEM programs: ORCR, OSRTI
Supporting Regions (submitted to OLEM): 1, 2, 3, 4, 5, 7, 9, 10
High priority for Regions 2, 4, 5, 9, 10

OLEM: This contaminant has been found at more than 407 OLEM sites. However, it is important to be aware that EPA's environmental occurrence data likely underestimates the actual occurrence because compounds without toxicity values are often not analyzed at sites.
OLEM-OSRTI: Superfund NPL Listing, Risk Assessment, Remedy Decisions, and Five Year Reviews.
OLEM-ORCR: RCRA Corrective Action chemical.
Region 2: Present at 66 of 218 Superfund sites. High profile sites addressing PCBs include: Hudson River, Passaic River, Massena area sites that include Indian Lands and large number of landfills. PCBs in air are a concern for Superfund sites where remediation is being conducted. Having the toxicological data to support developing health-based air screening levels is critical.
R5: PCBs are found as contaminants at many Region 5 Superfund and RCRA sites because of historical industrial operations which included use of PCB hydraulic fluid machinery for casting metal parts.
IRIS Toxicity Values are needed to support the following regulatory and remediation decisions:
Determination of Remediation Goals for 15-20 PCB sediment sites along the Great Lakes, including Great Lakes harbors and along Great Lakes tributaries.
Determination of PCB Remediation Goals for soils/sediments at 30-40 Superfund & RCRA sites in R5.
Risk-Based Approval Decisions needed for sites that fall under TSCA Enforcement. These includes sites where: a) PCBs have been unlawfully disposed to soils/sediments; and b) Buildings (including schools) where legacy PCBs are detected above TSCA regulatory levels in buildings materials.
R9: Toxicity Criteria for Lower Molecular Weight/Lower Chlorinated PCB Congeners
EPA currently has only two toxicity estimates for the non-cancer or systemically-toxic impacts associated with PCBs when they are identified by their Aroclor content. Reference dose values are available for PCB Aroclor 1254 and PCB Aroclor 1016 only. There remains an outstanding scientific need for additional toxicity information on inadvertent PCBs and more generally for the lower molecular weight (MW) or lower chlorinated (content) PCBs. A list of inadvertent congeners most likely to be found in products, the environment, or human blood has been generated by the Inadvertent PCB Workgroup, and could be used to narrow down the congeners assessed. The new ToxCast tools available to ORD may be a viable screening tool to begin assessment.
R10: PCBs are a ubiquitous contaminant and the primary risk driver on several large Region 10 NPL and sediment sites, including Portland Harbor, the Lower Duwamish Waterway, and Commencement Bay, as well as numerous sediment sites under state oversight. PCBs in fish tissue are a public health concern throughout our Region, disproportionally impacting Native American and U populations. EPA's current PCB assessment dates to 1994 and should be updated to include updated scientific information, such as the ability of PCBs to affect thyroid hormone function.

Cleanup goals PCB cancer risk and noncancer hazard estimates are the limiting factor for the cleanup of several CERCIA sites. EPA's 2011 draft was groundbreaking in its assessment of bioaccumulative exposure pathways to PCBs, and there is substantial evidence that the noncancer effects associated with PCB exposures are as critical as cancer risks. The cleanup of these large sediment mega-sites is ongoing, and a revised IRIS assessment will greatly inform the technical analyses of remedy effectiveness and performance in the Five Year Review process at these sites. RiO strongly supports the completion is this assessment.

 **Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management**	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form – Ongoing Assessments	
Requesting Office: OLEM	
Request Date: September, 2018	**Requested Completion Date:** As soon as possible, but we have long-term needs for this assessment.
Chemical Nominated for Assessment: Uranium	**Priority of Assessment: High**

General Background of Chemical:

Uranium, in nature, is a mixture of three isotopes: 234U, 235U, and 238U. The most common isotope, 238U, makes up about 99% of natural uranium, and due to that predominance, is thought to be primarily responsible for the chemical toxicity of uranium. Uranium metal is almost as hard as steel and much denser than lead. Due to its physical properties, depleted uranium is used as counterweights in aircraft applications, for shielding against ionizing radiation, as military armor, and in armor-penetrating munitions. Environmental exposures to uranium from contaminated sites can involve multiple pathways including ingestion of soil, foods, surface water, or ground water as well as consumption of locally grown or foraged food Uranium is naturally present in many soils with an average concentration in the United States of about 3 ppm; some areas, particularly in the western United States, have higher concentrations. Uranium mining, milling, and processing operations have released uranium into the environment leading to elevated levels of uranium in affected soils and dusts (ATSDR, 2013) The general population is primarily exposed to uranium through food and drinking water. Human daily intake of uranium from typical diets has been estimated to range from 0.9 to 1.5 µg/day. In most areas of the United States, low levels of uranium are found in drinking water, with a population mean concentration of about 1 µg U/L. Higher levels of uranium are seen in water from wells in uranium-rich rock. Approximately 4% of reporting US drinking water systems (serving 8 million people in total) reported some exceedance of the EPA maximum contaminant limit (MCL) for uranium of 30 µg/L (US EPA, 2016).

Source: IRIS Assessment Plan for Uranium (Oral Reference Dose) (Scoping and Problem Formulation Materials) (PDF)

Scope of Assessment Request:

Oral noncancer (RfD)

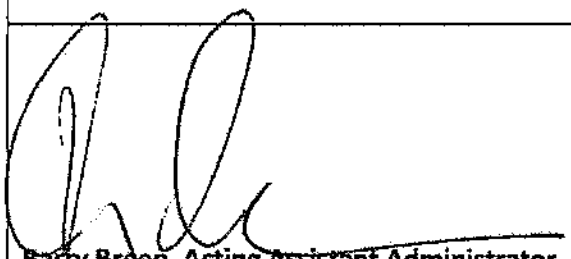
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

See accompanying document summarizing OLEM program needs for IRIS assessments (Attachment 1).

Supporting OLEM programs: ORCR, OSRTI
Supporting Regions (submitted to OLEM): 1, 3, 4, 6, 7, 10.
High priority for Region 10

Additional Supporting information:
OLEM: This contaminant has been found at more than 72 OLEM sites. However, it is important to be aware that EPA's environmental occurrence data likely underestimates the actual occurrence because compounds without toxicity values are often not analyzed at sites.
OLEM-OSRTI: Superfund NPL Listing, Risk Assessment, Remedy Decisions, and Five Year Reviews.
OLEM-ORCR: RCRA Corrective Action chemical.

R10: Uranium is contaminant of concern at many large Region 10 NPL mining sites and the Hanford Nuclear Reservation. Region 10 has been actively coordinating with OLEM and IRIS to support the Uranium assessment and looks forward to its timely completion.
The IRIS uranium RfD will be used in the CERCLA program for hazard ranking, derivation of risk based goals, characterization of site risks, evaluation of remedial alternatives and derivation of cleanup goals. Updated information will also support the technical analyses of remedy effectiveness during the Five Year Review process for ongoing cleanups actions.



Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management

ORD Principal Deputy Assistant Administrator for Science

IRIS Assessment Request Form – Ongoing Assessments	
Requesting Office: OLEM	
Request Date: September, 2018	**Requested Completion Date:** As soon as possible, but we have long-term needs for this assessment.
Chemical Nominated for Assessment: Manganese	**Priority of Assessment: High**

General Background of Chemical:

Manganese (Mn) is a naturally occurring element Manganese does not exist in nature in elemental form but is found mainly in its oxidized forms. Inorganic Mn, which includes the oxidized Mn, is the predominate form found in the air around U.S. industrial facilities. Inorganic Mn oxides are not volatile but can exist in the air as an aerosol and may be carried by the wind over kilometers. The predominant oxidation states, found in inhalable aerosols near Mn industrial facilities, are Mn(II), Mn(III) and Mn(IV) oxides (O'Neal and Zheng, 2015; ATSDR, 2012; Thomassen et al., 2001). Common sources of Mn are industrial emissions, resuspended soils and dust from Superfund sites or natural erosion of soils (ATSDR, 2015, 2012). Manganese ore is mined, smelted, and used in the production of iron and steel and other alloys, the manufacturing of potassium permanganate (used primarily as an oxidant for cleaning, bleaching, and disinfection purposes), dry cell batteries, ceramics, glass, leather and textile, matches and fireworks, oxidizing agent for electrode coating in welding rods, and cosmetics. Organic forms of Mn are used as fungicides, smoke inhibitors, an anti-knock additive in gasoline, and a medical imaging contrast agent. United States populations are exposed to Mn from both natural and anthropogenic sources, including via water, food, and air. There is a wide range of airborne Mn concentrations in the United States (ATSDR, 2012), while the average ambient air of manganese is 0.02 µg/m3, the levels are significantly increased by an order of magnitude (0.22-0.3 µg/m3) in the areas near industrial sources. In 1993, EPA published an IRIS inhalation reference concentration (RfC) for Mn of 0.05 µg/m3 (Mn in respirable PM). EPA derived the RfC using a composite uncertainty factor of 1000 based on human variability, extrapolating from a lowest-observed-adverse-effect-level (LOAEL) to a no-observed-adverse-effect-level (NOAEL), and database uncertainties.

Source:

IRIS Assessment Plan for Manganese (Inhalation) (Scoping and Problem Formulation Materials) final draft 2018

Scope of Assessment Request:

OLEM: IRIS Tox Review, inhalation and oral, cancer, noncancer, (RfD, RfC, IUR, CSF)

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

See accompanying document summarizing OLEM program needs for IRIS assessments (Attachment 1).

Supporting OLEM programs: ORCR, OSRTI
Supporting Regions (submitted to OLEM): 1, 2, 3, 4, [5], 6, 7, 10. [R5 submitted through another program.]
High priority for Regions 2 and 10

OLEM: This contaminant has been found at more than 555 OLEM sites. However, it is important to be aware that EPA's environmental occurrence data likely underestimates the actual occurrence because compounds without toxicity values are often not analyzed at sites.
OLEM-OSRTI: Superfund NPL Listing, Risk Assessment, Remedy Decisions, and Five Year Reviews.
OLEM-ORCR: Corrective Action Site chemical.
Region 2: Identified as COC at 95/218 superfund sites which include: landfills, former manufacturing facilities, village wellfields, federal facilities, and a power plant. Updates to the toxicity assessment for noncancer last updated in 1995 and the assessment for carcinogenicity last updated in 1988.
Region 10: Manganese is a contaminant of concern at 36 out of 108 Region 10 NPL sites, including Portland Harbor. Region 10 supports updating the manganese IRIS assessment that is over 20 years old. IRIS manganese toxicity metrics will be used in the CERCLA program for hazard ranking, derivation of risk based goals, characterization of site risks, evaluation of remedial alternatives and derivation of cleanup goals. Updated information will also support the technical analyses of remedy effectiveness during the Five Year Review process for ongoing cleanups actions. Of particular concern is a large groundwater plume discharging to the Willamette River in Portland Harbor, which represents a potential drinking water source under Oregon law.

Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form – Ongoing Assessments	
Requesting Office:	
Request Date: September, 2018	**Requested Completion Date:** As soon as possible, but we have long-term needs for this assessment.
Chemical Nominated for Assessment: Mercury Salts	**Priority of Assessment: High**

General Background of Chemical:

Mercury occurs naturally in the environment and can exist as elemental, organic, or inorganic mercury. Inorganic mercury is formed when mercury combines with elements such as chlorine, sulfur, or oxygen. These mercury compounds are also called inorganic mercury salts. In this assessment health effects of three inorganic mercury salts – mercuric chloride ($HgCl_2$), mercuric sulfide (HgS, cinnabar) and mercurous chloride (Hg_2Cl_2, calomel) will be assessed.

The most common natural forms of mercury found in the environment are metallic mercury, mercuric sulfide, mercuric chloride and methyl mercury (ATSDR, 1999). Inorganic mercury salts, formed from mercury interacting with other compounds in the air, can be transported to water or soil. Inorganic mercury enters the air from mining deposits of ores that contain mercury, from the emissions of coal-fired power plants, burning municipal and medical waste, uncontrolled releases in factories that use mercury. They can also enter water or soil from weather of rocks that contain mercury, from factories or water treatment facilities that release water contaminated with mercury.

Mercuric chloride is used in photography, topical antiseptic and disinfectant, wood preservatives and fungicides. Mercurous chloride has been widely used in medicinal products including laxatives, worming medications, and teething powders. Mercuric sulfide is used to color paints and one of the red coloring agents used in tattoo dyes.

Exposure to inorganic mercury salts may occur both in occupational and environmental settings (ATSDR, 1989). Exposure to mercurous chloride can occur when applying outdated medicinal products such as laxatives, worming medications and teething powders. Exposure to inorganic mercury salts can occur occupationally when workers are exposed from breather air that contains mercury vapors. Occupations that have greater exposure to mercury and its salts include mining, manufacturing electrical equipment, chemical processing plants that use mercury, metal processing etc.

Inorganic mercury compounds can enter the human body through inhalation, ingestion or through the skin. When inhaled, they are not expected to enter your body easily. However, when ingested, up to 40% can enter through the stomach and intestines. Small amounts of inorganic mercury can enter through skin. Once in the body, inorganic mercury gets into the bloodstream and moves to different tissues. Inorganic mercury salts accumulate mostly in the kidney and not as easily in the brain. However, occasionally some of methylmercury can be converted in inorganic mercury in the brain and if this happens, it can remain in the brain for a long time. It is excreted through urine or feces over a period of several weeks or months (ATSDR, 1999). The elimination half-life for inorganic salts is about 40 days (Goyer, 1991).

IRIS has derived an oral RfD for mercuric chloride based on autoimmune effects (autoimmune glomerulonephritis) of 3 x 104 mg/kg-day using Brown Norway rat subchronic feeding study in 1995. An RfD for mercuric sulfide is not available on IRIS. Derivation of a provisional RfD value was attempted in 2002, however, due to the lack of data in humans and of adequate subchronic or chronic oral data in animals, no provisional RfD was derived for mercuric sulfide.

Scope of Assessment Request:

Oral and Inhalation toxicity values, cancer and noncancer (RfC, RfD, IUR, CSF)

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

See accompanying document summarizing OLEM program needs for IRIS assessments (Attachment 1).

Supporting OLEM programs: ORCR, OSRTI
Supporting Regions (submitted to OLEM): 1, 2, 3, 4, 7, 10.
High priority for Regions 2, 3, 10

OLEM: This contaminant has been found at more than 817 OLEM sites (analyzed as total Hg). However, it is important to be aware that EPA's environmental occurrence data likely underestimates the actual occurrence because compounds without toxicity values are often not analyzed at sites.

Region 2: Mercury was identified as a COC at 108 of 218 sites including high-profile sites such as Berry's Creek Study area of the Ventron/Vesicol site, as well as landfills, federal facilities and manufacturing facilities. The RfD assessment and the cancer assessment were last updated in 1995.
Region 10: Mercury salts are a contaminant of concern associated with mercury mining and processing. Region 10 supports updating the toxicity value which is over 20 years old. EPA Region 10 is specifically interested in a comprehensive assessment of mercuric sulfide, or cinnabar, which is a naturally occurring mineralized form of mercury found in many areas of Alaska and Oregon. IRIS mercury salt toxicity metrics will be used in the CERCLA program for hazard ranking, derivation of risk based goals, characterization of site risks, evaluation of remedial alternatives and derivation of cleanup goals. Updated information will also support the technical analyses of remedy effectiveness during the Five Year Review process for ongoing cleanups actions.

Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form – Ongoing Assessments	
Requesting Office: OLEM	
Request Date: September, 2018	**Requested Completion Date:** As soon as possible, but we have long-term needs for this assessment.
Chemical Nominated for Assessment: Methylmercury	**Priority of Assessment: High**

General Background of Chemical:

Multiple health agencies (ATSDR, 1999; US EPA, 1997; US EPA, 2001; Health Canada, 2007), the National Academy of Sciences (NAS) (National Research Council (NRC), 2000), and international organizations (e.g., UNEP, 2002) have established that oral exposure to methylmercury in humans is a developmental neurotoxicity (DNT) hazard.

The existing IRIS RfD for methylmercury was published in 2001 (US EPA, 2001) and was based on analyses in an NAS assessment (NRC, 2000). The 2001 IRIS assessment identified developmental neuropsychological impairment as the critical effect, specifically, impaired cognitive function in children from a Faroe Islands cohort who were prenatally exposed to methylmercury, and derived the RfD from the associated epidemiological studies (Grandjean et al., 1997; Budtz-Jørgensen et al., 1999). Similarly, EPA's previous 1995 RfD for methylmercury was based on developmental neurotoxicity (DNT) effects using data from a 1971 Iraqi poisoning incident in which highly contaminated grains were consumed (derivation described in US EPA, 1997). In both assessments, DNT endpoints were concluded to be the most sensitive. The 2001 RfD of 0.1 µg/kg-day is based on maternal daily intakes of 0.86-1.47 µg/kg-day, estimated to result in the dose expressed in maternal blood corresponding to multiple DNT measures in 7-year-old children.

There are no current uses of methylmercury. However, elemental mercury is released into the atmosphere (e.g., the result of the burning of fossil fuels) and then falls to the ground with rain and snow. When it reaches water bodies, it is converted to methylmercury by microbes and accumulates up the food chain. Therefore, the major exposure pathway for methylmercury is through consumption of contaminated fish and shellfish (NRC, 2000). Average methylmercury blood levels in the U.S. population ranged from 0.434 to 0.498 µg/L between 2011 and 2014 (CDC, 2017). Estimated average daily intake of methylmercury for the general North American population was 6.1-69.5 ug/day, as reported by studies in the United States and Canada (Noisel et al., 2011; Stern, 2005).

When pregnant women are exposed to methylmercury, their fetuses are exposed as well because methylmercury readily crosses the placenta. Mercury also concentrates in cord blood at higher levels than in maternal blood (Stern et al., 2003). In addition, methylmercury is transferred to breastmilk in lactating women, which leads to infant exposures (ATSDR, 1999; CDC, 2009). As noted earlier, the developing nervous system is particularly sensitive to methylmercury exposure so these prenatal and postnatal exposures are of great concern.

Subsistence fishing communities and others with high dietary intake of top predatory fish species may be exposed to higher than average levels of methylmercury. People who consume fish from environments with large microbial populations that convert mercury to methylmercury may have particularly high exposures. This includes people eating fish from certain types of wetlands, dilute low-pH lakes in the Northeast and Northcentral United States, parts of the Florida Everglades, newly

flooded reservoirs, and coastal wetlands, particularly along the Gulf of Mexico, Atlantic Ocean, and San Francisco Bay (USGS, 2000). In some regions of the world, consumption of fish from waters polluted by small scale and artisanal gold mining may result in high methylmercury exposure as well.

From IRIS Assessment Plan for Methylmercury, September 2017

Scope of Assessment Request:

OLEM: IRIS Toxicological Review (inhalation and oral, RfD and RfC)
R5: Because of the large number of studies published on MeHg since 2001 and its many potential health effects, a reassessment of the DNT dose-response is needed because many recent epidemiology studies have evaluated DNT effects at lower MeHg exposure levels than were previously evaluated by the NAS (NRC, 2000) and EPA (US EPA, 2001). Many of these recent studies provide exposure-response information, which would enable re-evaluation of the current reference dose. EPA needs to explore the literature on several non-DNT health effects of methylmercury to determine if additional dose-response factors are warranted for other health effects, including behavioral, morphological, and electrophysiological. Many of Non-DNT outcomes affect the general population, and not just women of child-bearing age and their children. EPA needs to determine if there is sufficient evidence to conduct a hazard assessment and derive reference values for these other health outcomes.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

See accompanying document summarizing OLEM program needs for IRIS assessments (Attachment 1).

Supporting OLEM programs: ORCR, OSRTI
Supporting Regions (submitted to OLEM): 1, 2, 3, 4, 5, 6, 7, 10
High priority for Regions 2, 5, and 10

OLEM: This contaminant has been found at more than 817 OLEM sites (analyzed as total Hg), and at more than 10 sites (analyzed as methyl mercury). However, it is important to be aware that EPA's environmental occurrence data likely underestimates the actual occurrence because compounds without toxicity values are often not analyzed at sites.
OLEM-OSRTI: Superfund NPL Listing, Risk Assessment, Remedy Decisions, and Five Year Reviews.
OLEM-ORCR: Toxicity characteristic chemical and also found at RCRA Corrective Action Sites.
Region 2: Mercury was identified as a COC at 108 of 218 sites including high-profile sites such as Berry's Creek Study area of the Ventron/Vesicol site, as well as landfills, federal facilities and manufacturing facilities. The RfD assessment and the cancer assessment were last updated in 1995.
R5: Updated oral reference dose factors for MeHg are needed to complete accurate risk assessments for consumption of fish from waterbodies which receive Hg deposition of air emissions from facilities. These include facilities that conduct waste combustion and coal-fired utilities. The risk assessments are used to set EPA and State air regulatory and air permit emission limits for dozens of facilities in Region 5. Section 304(a) of the CWA requires EPA to develop water quality criteria for states and tribes to use to develop water quality standards. Section 303(c) requires states and tribes to adopt water quality criteria that protect designated uses such as fish consumption. Section 303(c)(1) requires that states and authorized tribes review their water quality standards every three years and modify them based on updated health effects studies derived by EPA.

Region 10: Region 10 supports updating the IRIS assessment for methylmercury, which has not been updated since 2001. Methylmercury is a concern for populations with high fish consumption rates in Region 10, including Native American and Alaskan subsistence consumers. Almost half of all federally recognized tribes reside in Region 10 where fish consumption isa foundation of Native American culture. The IRIS methylmercury RfD will be used in the CERCLA program for hazard ranking, derivation of risk based goals, characterization of site risks, evaluation of remedial alternatives and derivation of cleanup goals. Updated information will also support the technical analyses of remedy effectiveness during the Five Year Review process for ongoing cleanups actions.

Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form – Ongoing Assessments	
Requesting Office: OLEM	
Request Date: September, 2018	**Requested Completion Date:** As soon as possible, but we have long-term needs for this assessment.
Chemical Nominated for Assessment: PFAS	**Priority of Assessment: High**

General Background of Chemical:

PFAS are a class of synthetic (manmade) fluorinated compounds; these compounds are used in many industrial and consumer products, including defense-related applications (ATSDR, 2009; UNEP, 2006). As a result of their valuable properties such as fire resistance and oil, stain, grease, and water repellence, PFAS were used in a wide variety of industrial and commercial products. There are several hundred PFAS in commerce and many intermediates and end products resulting from environmental degradation. The two most studied PFCs, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), are used as surface-active agents in various applications, such as surfactants, coating on surfaces to impart non-stick properties and/or stain resistance, firefighting agents and many other others (Schultz, et al., 2003; UNEP, 2005). Both PFOA and PFOS and their precursors have been used as protectants for textiles and leather products, carpets and domestic furniture treatment, paper and packaging products (e.g., food wrappers), cleaning products, and as surfactants, emulsifiers, wetting agents, additives and coatings (ATSDR, 2009). PFOA has also been used in the manufacture of fluoropolymers used in a wide variety of mechanical and industrial components, including electrical wire casings, fire- and chemical-resistant tubing, and plumbing seal tape.

Past manufacturing processes released PFOS and PFOA into the air, surface water, groundwater and soil in and around fluorochemical manufacturing and use facilities (ATSDR, 2009). In several cities in the United States, sampling has detected PFOS and PFOA and their precursors in surface and groundwater, in sediments downstream of former fluorochemical production facilities, wastewater treatment plant effluent, sewage sludge and landfill leachate (EPA, 2002; OECD, 2002). PFCs were used to manufacture PFOS-based Aqueous Film Forming Foam (AFFF) to extinguish flammable liquid fires (e.g., hydrocarbon fueled), such as fires involving jet fuel, gas tankers and oil refineries and military fire training exercises (EPA 2013a; DOD SERDP 2012). The largest consumer of AFFF was the Department of Defense, particularly at Navy and Air Force installations (Schultz, et al., 2004; DOD SERDP, 2012, 2013).

Long chain PFAS (including PFOA and PFOS) use is being reduced in response to several regulatory and non-regulatory efforts by EPA and various industries. PFOS and PFOA, their precursors and other, related long chain PFAS are regulated under several TSCA Significant New Use Rules (SNURs). PFOA and PFOS, are being monitored in public drinking water systems as part of the Safe Drinking Water Act (SDWA) Unregulated Contaminant Monitoring Rule 3 (UCMR 3). This program provides EPA and other interested parties with scientifically valid data on the occurrence of these unregulated contaminants in drinking water, enabling the assessment of the number of people potentially exposed and the levels of that exposure. These data are one of the primary sources of occurrence and exposure information the agency uses to develop drinking water regulatory decisions.

Provisional Health Advisories (PHA) for drinking water were published for PFOA and PFOS in 2009 (EPA, 2009), and draft Health Effects Documents for PFOA and PFOS have been released for public comment (EPA, 2014b).

Source: FFRRO Interim PFC Roadmap.

Scope of Assessment Request:

OLEM: Toxicity values (inhalation and oral, cancer and noncancer [RfD, RfC, CSF, IUR) are needed for multiple PFAS chemicals, including those currently proposed for NCEA review (PFBA, PFHxA, PFHxS, PFDA, PFNA). We would like to further discuss need for assessments of additional PFAS from the 31 previously identified by the PFAS Toxicity Workgroup (or alternatives for evaluating the toxicity of those and other PFAS).

Region1:
Region 1 is also in need of toxicity information for PFOA, PFOS and other PFAS for routes of exposure beyond ingestion (e.g., dermal).

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

See accompanying document summarizing OLEM program needs for IRIS assessments (Attachment 1).

Supporting OLEM programs: ORCR, OSRTI
Supporting Regions (submitted to OLEM): 1, 3, 4, [5], 7. [R5 submitted through another program.]
High priority for OLEM FFRRO, Region 1, 3

OLEM: PFAS chemicals have been detected at a large number of federal facilities, particularly Navy and Air Force sites where fire training activities have been conducted, and are also being detected at a growing number of non-federal sites. Values are needed for Risk Assessment and Remedy Decisions.

Region 1:
Region 1 also supports any efforts to develop toxicity values for Per- and Polyfluoroalkyl Substances (PFAS). In particular, we support the development of toxicity values for PFHpA, PFHxS and PFNA. Given the anticipated release of a toxicity value for PFBS in the coming months, PFHpA, PFHxS and PFNA are the last three compounds included in the UCMR3 effort without toxicity values. Region 1 has sampled groundwater associated with dozens of National Priorities List (NPL) sites. In the majority of cases our initial sampling is focused on the six PFAS included in the UCMR3 effort. In addition to PFOA and PFOS, PFHpA, PFHxS and PFNA are frequently detected. The lack of toxicity information for these compounds increases the uncertainty in site-specific risk assessments, hinders risk communication efforts and will complicate decision-making.

Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form – Ongoing Assessments	
Requesting Office: OLEM	
Request Date: September, 2018	**Requested Completion Date:** As soon as possible, but we have long-term needs for this assessment.
Chemical Nominated for Assessment: Acrolein	**Priority of Assessment:**

General Background of Chemical:

From Acrolein Reference Concentration (Chronic) Update, August 2018

Acrolein is a colorless to yellowish flammable liquid, extremely acrid and irritating to mucous membranes {ACGIH, 1991, 632413}. Acrolein is used as an intermediate in the synthesis of acrylic acid, glycerine, methionine, glutaraldehyde and other organic chemicals (HSDB, 2003). Acrolein is also an herbicide used for control of vegetation in irrigation canals and as a biocide in water pumped into injection wells associated with petroleum production (U.S. EPA, 2012, 1502936}. In addition, acrolein is used to promote cross-linking of protein collagen in leather tanning, and as a tissue fixative for histological samples {IARC, 1995, 2298229}.

Acrolein is released to the environment through manufacturing processes, exhaust gas from combustion processes, including tobacco smoke, emissions from forest fires, and auto exhaust. It is also detected in volatile components of food and the products from heating animal fats and vegetable oils (HSDB, 2003). If released to air, acrolein exists in vapor-phase in the ambient atmosphere, if released into soil, acrolein may volatilize from dry soil surfaces. However, if released into water, acrolein is not expected to adsorb to suspended solids and sediment. Figure 1 provides a summary of acrolein emission from the 2014 National Emissions Inventory {U.S. EPA, 2018, 4440637}

Humans are exposed to acrolein primarily through tobacco smoke, gasoline and diesel exhaust, structural and forest fires, and partially combusted animal fats and vegetable oils {Beauchamp, 1985, 7387}. {Seaman, 2007, 1319786@@author-year} reported that human exposure to acrolein is dominated by indoor air (3-40 times higher than concentrations measured in outdoor). Occupational exposure to acrolein may occur through inhalation and dermal contact at workplaces where it is produced or used.

Since the posting of the 2003 IRIS assessment of acrolein, additional studies have been published that have been used as the basis for toxicity value derivation in assessments conducted by others. Most recently, in 2008, OEHHA {OEHHA, 2008, 192315} derived a chronic reference exposure level (REL) for acrolein that was based on a more recent subchronic rodent study {Dorman, 2008, 180108} which identified a NOAEL for nasal lesions and application of results from advanced dosimetric modelsBased on the results of this study, a NOAEL of 0.2 ppm for nasal respiratory epithelium (RE) lesions and a NOAEL of 0.6 ppm for olfactory epithelium (OE) lesions was established. The recent assessment by the Texas Commission on Environmental Equality also used {Dorman, 2008, 180108@@author-year} for development of their 2014 updated chronic reference value (ReV) {TCEQ, 2016, 4764709}.

A survey of the literature published since the 2008 CalEPA REL ({CalEPA, 2008, 2298217@@author-year}, described in this targeted update) indicates the {Dorman, 2008, 180108@@author-year} study as still the most appropriate study for chronic toxicity value derivation. In addition, many advances

have been made in the dosimetric modeling of gases in the respiratory tract (U.S. EPA, 2012, 1502936), two of which are specific for acrolein (Corley, 2012, 1066330;Schroeter, 2008, 632800). Thus, the IRIS Program has conducted a targeted RfC update for acrolein that can be used in risk assessments for hazardous air pollutants.
Scope of Assessment Request:
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

Barry Breen, Acting Assistant Administrator; Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form – Ongoing Assessments	
Requesting Office: OLEM	
Request Date: September, 2018	**Requested Completion Date:** As soon as possible, but we have long-term needs for this assessment.
Chemical Nominated for Assessment: PAH Mixtures	**Priority of Assessment: High**

General Background of Chemical:

PAHs are a class of organic compounds containing either two or more fused rings made up of hydrogen and carbon atoms. PAHs are not found in the environment as isolated individual compounds. They occur as complex mixtures generated from the incomplete combustion or pyrolysis of substances containing hydrocarbons. Some of the complex mixtures containing PAHs typically found in the environment include coal tar, manufactured gas plant residues, coke oven emissions, diesel and gasoline exhaust, and coal-fired utility air emissions. Air emissions result in PAH deposition to land, surface water, and sediments. PAHs are also directly released to land from petroleum spills at oil refineries and from leaking underground storage tanks (USTs).

Many PAHs are known to be carcinogenic and/or mutagenic in animal bioassays. Several PAHs (e.g., Benzo[a]pyrene; Dibenz[a,h]anthracene; Chrysene) are probable human carcinogens. Several individual PAHs and complex mixtures of PAHs have been classified as possibly carcinogenic, probably carcinogenic, or carcinogenic to humans {Boström, 2002, 1012125;Straif, 2005, 1011948;ATSDR, 1995, 625705;IARC, 2010, 1011776;U.S. EPA, 2002, 2820931;IPCS, 1998, 51286;IARC, 1983, 27000;IARC, 1985, 1290566;IARC, 1984, 1104500;IARC, 1984, 1104563}, but quantitative dose-response evaluations have largely been limited to individual PAHs. Quantitative cancer dose-response information exists for only a few whole PAH mixtures, which may be composed of hundreds or thousands of chemicals, including a substantial unidentified fraction; examples include tobacco smoke, coke oven emissions, and emissions from roofing tar pots {see Boström, 2002, 1012125;Albert, 1983, 1846}. U.S. EPA's Integrated Risk Information System (IRIS) database currently includes assessments for only three PAH-containing whole mixtures: coke oven emissions (US EPA, 1989), creosote (1988), and diesel exhaust emissions (US EPA, 2003). While the availability of oral carcinogenicity bioassays of coal tar preparations {Culp, 1998, 1012242;Gaylor, 1998, 2819780}, also known as manufactured gas plant (MGP) residue {Weyand, 1995, 1012268}, has expanded the PAH mixture cancer database, there remain significant data gaps in the carcinogenicity data for the numerous PAH mixtures that occur in the environment. In 2002, U.S. EPA conducted a peer consultation workshop to evaluate the available approaches to PAH health risk assessment. Although participants expressed a preference for whole mixtures approaches, they acknowledged the practical advantage of the RPF approach for use when the source and composition of a mixture are uncertain. EPA will continue to evaluate options for implementing whole mixture approaches for PAH cancer risk assessment. However, until mixture-based approaches for PAH mixtures have been adequately developed, the Agency will continue to rely upon a relative potency approach to assess cancer risks from PAH mixtures that have not been adequately tested.
From DEVELOPMENT OF A RELATIVE POTENCY FACTOR (RPF) APPROACH FOR POLYCYCLIC AROMATIC HYDROCARBON (PAH) MIXTURES draft, October 2017

Scope of Assessment Request:

Relative potency factors for carcinogenicity.
R5: IRIS needs to complete the "Development of a Relative Potency Factor (RPF) Approach for Polycyclic Aromatic Hydrocarbon (PAH) Mixtures." The RPF analysis provides a cancer risk estimate for PAH mixtures by summing doses of component PAHs after scaling the doses (with

RPFs) relative to the potency of an index PAH (i.e., benzo[a]pyrene). Cancer risk is then estimated using the dose-response factor for the index PAH. The EPA SAB has already endorsed the RPF approach for 24 PAH compounds. Implementation of the RPF approach will greatly improve risk assessments for PAH mixtures and reduce uncertainty for cleanup decisions at contaminated sites.

Region 10: Update and finalize 2010 revised draft assessment of relative cancer potencies

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

See accompanying document summarizing OLEM program needs for IRIS assessments (Attachment 1).

Supporting OLEM programs: ORCR, OSRTI
Supporting Regions (submitted to OLEM): 1, 3, 4, 5, 10
High priority for Regions 5 and 10

OLEM: This contaminant has been found at more than 481 OLEM sites (analyzed as benzo(a)pyrene). However, it is important to be aware that EPA's environmental occurrence data likely underestimates the actual occurrence because compounds without toxicity values are often not analyzed at sites.

OLEM-OSRTI: Superfund NPL Listing, Risk Assessment, Remedy Decisions, and Five Year Reviews.

OLEM-ORCR: Found at RCRA Corrective Action Sites.

R5: An IRIS PAH Mixtures approach and RPF values are needed for completion of risk assessments to support the following regulatory and remediation decisions: Determination of risk-based Remediation Goals for 15-20 PAH contaminated sediment sites along the Great Lakes, including Great Lakes harbors and along Great Lakes tributaries; Determination of risk-based PAH Remediation Goals for soils/sediments at 30-40 Superfund & RCRA sites in Region 5; Determination by EPA and State agencies of PAH Remediation Goals for petroleum releases at more than 100 UST sites in Region 5.

Region 10: The IRIS program recently completed an updated assessment for benzo(a)pyrene (2017). However, PARs occur as mixtures, and an updated assessment of evaluating exposure and risk to these complex mixtures is long overdue. EPA's current "state of the science" for addressing PAR mixtures dates to 1993. Benzo[a]pyrene is a chemical of concern at 32 out of 108 CERCLA sites in RiO (30 percent), an indicator of the prevalence of polycyclic aromatic hydrocarbon mixtures at RiO CERCLA sites. Relative potencies of individual PAHs will be used in the CERCLA program for hazard ranking, derivation of risk based goals, characterization of site risks, evaluation of remedial alternatives and derivation of cleanup goals. Updated information will also support the technical analyses of remedy effectiveness during the Five Year Review process for ongoing cleanups actions. Bremerton Gasworks is currently in the RI phase, and updated toxicity criteria for PAR mixtures will greatly enhance the selection of a defensible remedy at this site.

Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

Attachment 1: Supporting Rationale for IRIS Nominations
Overarching comments from individual submitters

Office of Land and Emergency Management – Office of Resource Conservation and Recovery

Key messages:

- ORCR has a long-term need for IRIS assessments previously identified as OLEM priorities
- ORCR's needs for IRIS assessments have remained largely the same over the last 5+ years
- IRIS is the only source of top tier toxicity information for OLEM

ORCR worked with OLEM to provide the IRIS Program with a list of high priority assessments most recently in 2015. The 2015 list of chemicals was largely unchanged from the previous information collection conducted in 2013 and the need for these chemicals persists as they continue to occur in or as a result of various wastes.

IRIS assessments are needed by ORCR to provide a firm basis to:

List/delist hazardous wastes

IRIS health benchmarks can be used in defining hazardous wastes using the toxicity characteristic. Industry can also petition EPA to "delist" a specific waste: to change the waste's designation from RCRA Hazardous to RCRA Nonhazardous. Agency deliberations for these petitions include reliance on IRIS assessments.

Review/revise hazardous and non-hazardous waste rules per 2002(b).

RCRA Section 2002(b) requires the Agency to review every regulation promulgated under the Act, no less frequently than every three years. This includes the Toxicity Characteristic and any rules based upon the Toxicity Characteristic, as well as regulations supported by health risk assessments of relevant chemicals.

Inform beneficial use decisions by States

EPA/ORCR encourages beneficial use of RCRA industrial non-hazardous secondary materials if such uses are protective of human health and the environment. State environmental agencies oversee and manage the beneficial use of secondary materials. EPA supports State decision-makers and other stakeholders with tools to help evaluate the potential for adverse impacts to human health and the environment associated with the beneficial use of secondary materials. Decisions are often waste- and use-specific, and are based on chemical constituent toxicity and concentrations.

Conduct and review RCRA Correction Action cleanups by EPA and States

Decisions related to contaminated site cleanups conducted under RCRA Corrective Actions are reviewed every 5 – 10 years. These reviews include updating the health benchmarks used in supporting health risk assessments to see if the decisions remain protective.

Office of Land and Emergency Management – Office of Superfund Remediation and Technology Innovation: [addressing Superfund, including emergency management and federal facilities]

The Office of Land and Emergency Management programs rely heavily for IRIS assessments for programmatic actions.

The following actions require toxicity assessments in the Superfund program:

- Hazard Ranking System evaluation for adding sites to the National Priorities List regulation
- Emergency response actions
- Assessing human health risk for current and future exposure scenarios
- Deriving cleanups levels for Superfund sites
- Evaluate the protectiveness of the remedy in five-year reviews.

IRIS toxicity values are the first tier of the hierarchy of sources of toxicity information. OLEM would be less reliant on state and other federal values that may not have the stringent level of peer review that IRIS provides. State delegated and voluntary waste programs rely on IRIS toxicity data to determine cleanup goals.

If a toxicity value doesn't exist, Potential Responsible Parties will not sample for it because the human health risk can't be quantified.

Office of Underground Storage Tanks

Groundwater contaminants released from Underground Storage Tanks; mandates from the Energy Policy Act of 2005.

Regions

Region 1

Region 1 relies on IRIS program toxicity values to complete human health risk assessments at numerous sites every year. This includes sites within our remedial, removal and RCRA Corrective Action universe. In addition, our state partners look to the IRIS program to help them complete their work. We strongly support the IRIS program.

Region 1 is not nominating any new chemicals to the IRIS priority list, but would like to reiterate our need for toxicity values for chemicals currently on the IRIS FY2018-2019 Portfolio list and support for completion of these reviews.

Region 1 also supports any efforts to develop toxicity values for Per- and Polyfluoroalkyl Substances (PFAS). In particular, we support the development of toxicity values for PFHpA, PFHxS, and PFNA. Given the anticipated release of a toxicity value for PFBS in the coming months, PFHpA, PFHxS and PFNA are the last three compounds included in the UCMR3 effort without toxicity values. Region 1 has sampled groundwater associated with dozens of National Priorities List (NPL) sites. In the majority of cases our initial sampling is focused on the six PFAS included in the UCMR3 effort. In addition to PFOA and PFOS, PFHpA, PFHxS and PFNA are frequently detected. The lack of toxicity information for these compounds

increases the uncertainty in site-specific risk assessments, hinders risk communication efforts and will complicate decision-making.

Region 1 is also in need of toxicity information for PFOA, PFOS, and other PFAS for routes of exposure beyond ingestion (e.g., dermal).

Region 2

Superfund

Within the Superfund program, toxicity information from the Integrated Risk Information System (IRIS) is used in the following steps of the Human Health Risk Assessment (HHRA) process:

- Selecting Chemicals of Potential Concern that will be evaluated in the full HHRA;
- Determining the cancer risks and noncancer health hazards posed by the chemicals to support decisions regarding the need to take remedial action at a site;
- Developing risk- based remediation levels;
- Determining the amount of soil, groundwater, sediment, or other media that may require remedial action to meet the remediation levels; and
- Evaluating the protectiveness of the remedy for those sites where contamination remains on site during the Five- Year Review.

The following chemicals were nominated to the IRIS program by Region 2 previously. The regional need for completion of these IRIS assessment remains. Based on an evaluation of the 218 sites currently on the National Priorities List (NPL), the previously-nominated chemicals were identified as chemicals of concern (COCs) for many of them. These chemicals are priorities for Region 2 based on their prevalence, the age of their IRIS assessments and their importance in overall site remedy decision making.

Resource Conservation and Recovery Act

Region 2 also wishes to support the nomination by Region 4, the Office of Land and Emergency Management (OLEM) and the Office of Air (OAR) to revisit the 2001 IRIS Chemical Assessment for Chloroform to clarify the relationship of the cancer and noncancer assessments. IRIS values are used by the Region 2 RCRA program in the same manner as those used in the Superfund program.

Region 3

In response to the ORD memorandum *Soliciting Requests for IRIS Assessments* from Dr. Jennifer Orme-Zavaleta (dated August 18, 2018), the Region 3 Hazardous Site Cleanup Division presents the following information demonstrating the need and support for specific chemical assessments. Region 3 HSCD supports the continued development of the IRIS Toxicological Assessments for the chemicals, as well as for the other relevant NCEA assessments, provided below. In addition to the IRIS assessments under development, Region 3 HSCD nominates the chemicals listed below and designates the route of toxicity needed.

Region 4

The Scientific Support Section in Region 4 supports both the Superfund and RCRA programs which both rely heavily on IRIS assessments for programmatic actions. This document is in support of IRIS continued work in providing the most up-to-date toxicological values in this country based on the best science.

The following actions require toxicity assessments in the Superfund and/or RCRA programs and having IRIS values helps the Region in risk assessment and risk management decisions.

- Hazard Ranking Scoring for adding sites to the National Priority List regulation
- Emergency response actions
- Assessing human health risk for current and future exposure scenarios at sites
- Derive cleanup levels for contaminants at Superfund and RCRA sites
- Evaluate the protectiveness of the remedy in five-year reviews
- Evaluate the risk and protectiveness related to PCBs for TSCA enforcement

IRIS toxicity values are the first tier in EPA's hierarchy of sources of toxicity information. Without IRIS toxicity values, EPA must rely on state and other federal values that usually do not have as stringent level of peer review that IRIS provides. Also, State delegated and voluntary waste programs rely on IRIS toxicity data to determine cleanup goals. If a toxicity value doesn't exist, Potential Responsible Parties and Facilities sometimes may not sample for it because the human health risk can't be quantified.

The chemicals in the fiscal year 2018 – 2019 ORD Portfolio are contaminants of concern at Superfund and RCRA sites across the country. Region 4 recommends that all the IRIS work on these contaminants be continued, but if a priority is needed **Chloroform, Ethylbenzene, Chromium IV, and Polychlorinated biphenyls (PCBs)** have a significant importance to Region 4's Superfund and RCRA programs.

Region 5

No generic text provided

Region 6

Thank you for the opportunity to provide input on priorities for the Integrated Risk Information System (IRIS) assessment FY2018-2019 Portfolio. Region 6 supports the continuation of ongoing IRIS assessments, which have been identified as a priority in our Region.

Superfund, Federal Facilities, and the RCRA cleanup programs extensively use the IRIS program, and it enables the Region to establish consistent cleanup levels that are protective of public health and the environment. Our state and federal partners also rely on the IRIS toxicity values to establish cleanup levels at their sites.

Region 7

Region 7 confirms our continued interest in all of the chemicals currently prioritized for the IRIS FY 2018-2019 portfolio that have previously been identified as critical needs by national program and regional offices across the Agency. We did notice that Region 7 was not listed in Attachment 2 as having previously indicated interest in the current IRIS portfolio, even though we have done so in the past. Please add Region 7 to the list of offices that support continuing assessments on all chemicals listed in Attachment 2.

The EPA regional offices consider IRIS as the preferred source of toxicity values to use in human health risk assessments for sites that fall under CERCLA or RCRA corrective action. IRIS toxicity values are a critical component of determining whether removal or remedial actions are warranted; scoring sites for potential inclusion on the National Priority List; establishing protective cleanup levels for soil, sediment, groundwater, surface water, and air; and evaluating whether remedies remain protective at sites where waste remains in place and statutory five-year reviews are required.

When current IRIS toxicity values are unavailable, the regions may have to base these critical decisions on outdated toxicity values that do not reflect the latest science and methodology and/or toxicity values from sources other than IRIS that may be less transparent and undergo a less rigorous degree of peer review. Although the regions do rely upon toxicity values from other sources when IRIS values are unavailable, Region 7 has experienced refusal by outside parties to use these values because they do not represent EPA consensus values. In addition, Region 7 is aware that state approval has been granted to a site that derived their own toxicity values for a chemical lacking IRIS values, which may be precedent-setting. It is also unclear whether these values are protective of human health.

Region 7 employs three human health risk assessors/toxicologists to provide technical support on all of our Superfund and RCRA corrective action sites. We lack the resources and technical expertise required to derive defensible, peer-reviewed toxicity values accepted as the Agency's official scientific position. As a final note, information regarding the toxicity of chemicals continues to evolve, particularly given advances in computational toxicology and adverse outcome pathways. Therefore, it is imperative that the IRIS program finish work already begun to provide new toxicity values and update existing values, some of which were developed more than three decades ago.

Listed below are chemicals that are of particular importance to Region 7 and information on why IRIS values are needed for these chemicals.

Region 9

No generic text provided

Region 10 – See information in specific assessments.

The IRIS RfD will be used in the CERCLA program for hazard ranking, derivation of risk based goals, characterization of site risks, evaluation of remedial alternatives and derivation of cleanup goals. Updated information will also support the technical analyses of remedy effectiveness during the Five Year Review process for ongoing cleanups actions.

Table 2: Proposed New IRIS Nominations			
Chemical Request	**Office Requesting**	**Service Requesting**	**Submitted Priority**
Alkylates	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation	High
n-butanol	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation	High
Iso-octane	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation	High
Methyl Tertiary-butyl ether (MTBE)	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation	High
iso-buytl Alcohol (IBA)	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation	High
t-Amyl ethyl ether (TAEE)	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation	High
DI isopropyl ether (DIPE)	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation	High
Benzene	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation	High
Toluene	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation	High
Xylenes (mixture)	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation	High
Ethanol	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation	High
Ethylene Di-Bromide (EDB)	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation	High
Ethylene Di-Chloride (EDC)	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation	High
Tetra-ethyl lead (TEL)	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation	High
Tetra-methyl lead (TML)	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation	High
Methylcyclopentadienyl manganese	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation	High
Dieldrin	OSRTI	Oral slope factor, inhalation unit risk and reference overdose	High
Lindane	OSRTI	Oral slope factor, inhalation unit risk and reference overdose	High
Dioxin	Region 3	Cancer	High
1,4-dichlorobenzene	Region 3	Oral and inhalation toxicity	High
Cadmium and compounds	Region 3	Inhalation toxicity	High
Chlorobenzene	Region 3	Inhalation toxicity	Medium
Copper	Region 3	Oral and inhalation toxicity	Medium
Hexachlorobutadience	Region 3	Oral toxicity	Medium
Hexamethylphosphoramide (HMPA)	Region 3	Oral and inhalation toxicity	Medium
Vanadium and compounds	Region 3	Oral and inhalation toxicity	Medium
Chloroprene	Region 6	PBPK model for Inhalation Unit Risk	High

**The Energy Policy Act (EPAct) of 2005 removed the fuel oxygen content mandate (which was met primarily by MTBE and to a lesser extent ethanol). Many states have also banned MTBE. With MTBE use being eliminated other fractions and additives are likely to be increasingly used as alternatives to MTBE both to increase octane and make up some of the volume formerly provided by MTBE. An IRIS assessment for alkylates is necessitated by EPAct requirements (specifically Section 1505) which directs the Administrator to conduct toxicological assessments of not only alkylates but other ethers and heavy alcohols. EPAct requires that these assessments be completed by August 2007. To date, these assessments have not been conducted.

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: **Alkylates** Cyclohexane Methylcyclohexane 2-Methylbutane 2-Methylpentane 3-Methylpentane n-Heptane n-Octane 2,2,5-Trimethylhexane 2,3,3-Trimethylpentane 2,3,4-Trimethylpentane	**Priority of Assessment: high**

General Background of Chemical:

Alkylates are a distillation fraction of petroleum and are present in gasoline. Gasoline is comprised of hundreds of compounds. Gasoline is stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included alkylates and have the potential to contaminate drinking water supplies.

Scope of Assessment Request:

Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

The Energy Policy Act (EPAct) of 2005 removed the fuel oxygen content mandate (which was met primarily by MTBE and to a lesser extent ethanol). Many states have also banned MTBE. With MTBE use being eliminated other fractions and additives are likely to be increasingly used as alternatives to MTBE both to increase octane and make up some of the volume formerly provided by MTBE. An IRIS assessment for alkylates is necessitated by EPAct requirements (specifically Section 1505) which directs the Administrator to conduct toxicological assessments of not only alkylates but other ethers and heavy alcohols. EPAct requires that these assessments be completed by August 2007. To date, these assessments have not been conducted.

Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: n-Butanol	**Priority of Assessment: high**

General Background of Chemical:

N-Butanol is present in some formulations of gasoline as an oxygenate. N-butanol has been considered as a potential biofuel. Gasoline is stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included n-butanol and have the potential to contaminate drinking water supplies.

Scope of Assessment Request:

Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

The Energy Policy Act (EPAct) of 2005 removed the fuel oxygen content mandate (which was met primarily by MTBE and to a lesser extent ethanol). Many states have also banned MTBE. With MTBE use being eliminated other fractions and additives are likely to be increasingly used as alternatives to MTBE both to increase octane and make up some of the volume formerly provided by MTBE. An IRIS assessment for alkylates is necessitated by EPAct requirements (specifically Section 1505) which directs the Administrator to conduct toxicological assessments of not only alkylates but other ethers and heavy alcohols. EPAct requires that these assessments be completed by August 2007. To date, these assessments have not been conducted.

Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: **Iso-octane** **(2,2,4-Trimethylpentane)**	**Priority of Assessment: high**

General Background of Chemical:

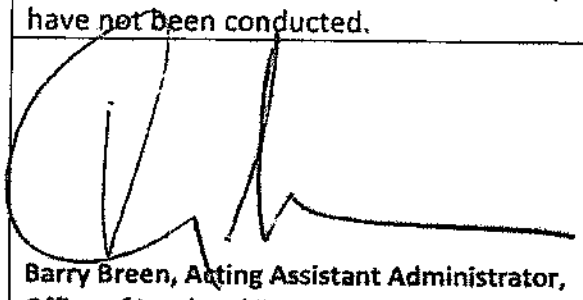
Iso-octane is a gasoline additive. Gasoline is stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have likely included iso-octane. Iso-octane has the potential to contaminate drinking water supplies.

Scope of Assessment Request:

Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

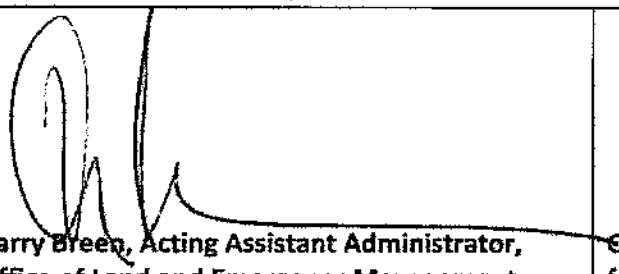
The Energy Policy Act (EPAct) of 2005 removed the fuel oxygen content mandate (which was met primarily by MTBE and to a lesser extent ethanol). Many states have also banned MTBE. With MTBE use being eliminated other fractions and additives are likely to be increasingly used as alternatives to MTBE both to increase octane and make up some of the volume formerly provided by MTBE. An IRIS assessment for alkylates is necessitated by EPAct requirements (specifically Section 1505) which directs the Administrator to conduct toxicological assessments of not only alkylates but other ethers and heavy alcohols. EPAct requires that these assessments be completed by August 2007. To date, these assessments have not been conducted.



Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: **MTBE** Methyl tertiary-butyl ether	**Priority of Assessment: high**
General Background of Chemical:	
MTBE is an ether gasoline additive used as an oxygenate. Gasoline is stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included MTBE. MTBE is highly soluble and has the potential to contaminate drinking water supplies.	
Scope of Assessment Request:	
Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.	
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*	
The Energy Policy Act (EPAct) of 2005 removed the fuel oxygen content mandate (which was met primarily by MTBE and to a lesser extent ethanol). Many states have also banned MTBE. With MTBE use being eliminated other fractions and additives are likely to be increasingly used as alternatives to MTBE both to increase octane and make up some of the volume formerly provided by MTBE. An IRIS assessment for alkylates is necessitated by EPAct requirements (specifically Section 1505) which directs the Administrator to conduct toxicological assessments of not only alkylates but other ethers and heavy alcohols. EPAct requires that these assessments be completed by August 2007. To date, these assessments have not been conducted.	
Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: **IBA** iso-butyl Alcohol	**Priority of Assessment: high**
General Background of Chemical:	
IBA is a gasoline additive used as an oxygenate. Gasoline is stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included IBA. IBA is highly soluble and has the potential to contaminate drinking water supplies.	
Scope of Assessment Request:	
Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.	
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*	
The Energy Policy Act (EPAct) of 2005 removed the fuel oxygen content mandate (which was met primarily by MTBE and to a lesser extent ethanol). Many states have also banned MTBE. With MTBE use being eliminated other fractions and additives are likely to be increasingly used as alternatives to MTBE both to increase octane and make up some of the volume formerly provided by MTBE. An IRIS assessment for alkylates is necessitated by EPAct requirements (specifically Section 1505) which directs the Administrator to conduct toxicological assessments of not only alkylates but other ethers and heavy alcohols. EPAct requires that these assessments be completed by August 2007. To date, these assessments have not been conducted.	
Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: **TAEE** *t*-Amyl ethyl ether 4,4-Dimethyl-3-oxahexane	**Priority of Assessment:** high
General Background of Chemical:	
TAEE is an ether gasoline additive used as an oxygenate. Gasoline is stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included TAEE. TAEE is highly soluble and has the potential to contaminate drinking water supplies.	
Scope of Assessment Request:	
Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.	
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*	
The Energy Policy Act (EPAct) of 2005 removed the fuel oxygen content mandate (which was met primarily by MTBE and to a lesser extent ethanol). Many states have also banned MTBE. With MTBE use being eliminated other fractions and additives are likely to be increasingly used as alternatives to MTBE both to increase octane and make up some of the volume formerly provided by MTBE. An IRIS assessment for alkylates is necessitated by EPAct requirements (specifically Section 1505) which directs the Administrator to conduct toxicological assessments of not only alkylates but other ethers and heavy alcohols. EPAct requires that these assessments be completed by August 2007. To date, these assessments have not been conducted.	
 **Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management**	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: Di isopropyl ether **DIPE**	**Priority of Assessment: high**
General Background of Chemical:	
DIPE is an ether gasoline additive used as an oxygenate. Gasoline is stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included DIPE. DIPE is highly soluble and has the potential to contaminate drinking water supplies.	
Scope of Assessment Request:	
Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.	
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*	
The Energy Policy Act (EPAct) of 2005 removed the fuel oxygen content mandate (which was met primarily by MTBE and to a lesser extent ethanol). Many states have also banned MTBE. With MTBE use being eliminated other fractions and additives are likely to be increasingly used as alternatives to MTBE both to increase octane and make up some of the volume formerly provided by MTBE. An IRIS assessment for alkylates is necessitated by EPAct requirements (specifically Section 1505) which directs the Administrator to conduct toxicological assessments of not only alkylates but other ethers and heavy alcohols. EPAct requires that these assessments be completed by August 2007. To date, these assessments have not been conducted.	
Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: Benzene	**Priority of Assessment: high**

General Background of Chemical:

Benezene is a known carcinogen that is present in gasoline. Though the benzene content has been reduced over the past 30 years, it is still present at low concentrations and at many release sites benzene is often the driver for cleanup. Gasoline is comprised of hundreds of compounds. Gasoline is stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included benzene and have the potential to contaminate drinking water supplies.

Scope of Assessment Request:

Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

Benzene is one of the 4 most common groundwater contaminants from leaking USTs; these are Benzene, Toluene, Ethylbenzene, and Xylenes ("BTEX"). Despite being a known carcinogen, toxicity values for all of the exposure pathways (i.e., dermal, ingestion, inhalation) and for both cancer and non-cancer effects are not presently available.

Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: Toluene	**Priority of Assessment: high**
General Background of Chemical:	
Toluene is present in gasoline and is still present at many release sites of motor fuels from leaking UST sites. Gasoline is comprised of hundreds of compounds. Gasoline is stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included toluene and have the potential to contaminate drinking water supplies.	
Scope of Assessment Request:	
Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.	
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*	
Toluene is one of the 4 most common groundwater contaminants from leaking USTs; these are Benzene, Toluene, Ethylbenzene, and Xylenes ("BTEX"). Toxicity values for all of the exposure pathways (i.e., dermal, ingestion, inhalation) and for both cancer and non-cancer effects are not presently available.	
Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: Xylenes (as a mixture) o-xylene m-xylene p-xylene	**Priority of Assessment: high**
General Background of Chemical:	
Xylenes, as a mixture, is comprised of 3 isomers: o-xylene, m-xylene, and p-xylene. Xylenes are present in gasoline and are still present at many release sites of motor fuels from leaking UST sites. Gasoline is comprised of hundreds of compounds. Gasoline is stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included Xylenes and have the potential to contaminate drinking water supplies.	
Scope of Assessment Request:	
Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.	
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*	
Xylenes are one of the 4 most common groundwater contaminants from leaking USTs; these are Benzene, Toluene, Ethylbenzene, and Xylenes ("BTEX"). Toxicity values for all of the exposure pathways (i.e., dermal, ingestion, inhalation) and for both cancer and non-cancer effects are not presently available.	
Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: Ethanol	**Priority of Assessment: high**

General Background of Chemical:

Ethanol is present in some formulations of gasoline as an oxygenate. Ethanol is in widespread use as a renewable biofuel. Gasoline is stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included ethanol and have the potential to contaminate drinking water supplies.

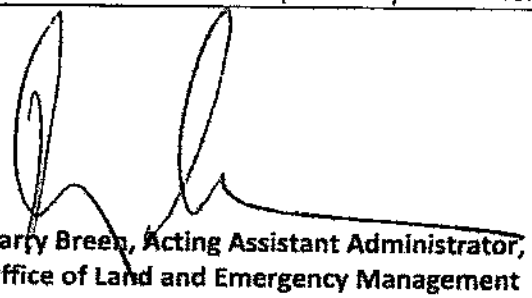
Scope of Assessment Request:

Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

The Energy Policy Act (EPAct) of 2005 removed the fuel oxygen content mandate (which was met primarily by MTBE and to a lesser extent ethanol). Many states have also banned MTBE. With MTBE use being eliminated other fractions and additives are likely to be increasingly used as alternatives to MTBE both to increase octane and make up some of the volume formerly provided by MTBE. An IRIS assessment for alkylates is necessitated by EPAct requirements (specifically Section 1505) which directs the Administrator to conduct toxicological assessments of not only alkylates but other ethers and heavy alcohols. EPAct requires that these assessments be completed by August 2007. To date, these assessments have not been conducted.

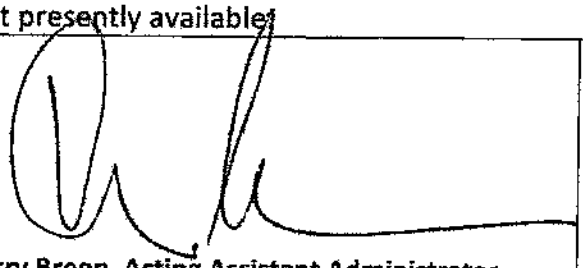
Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: **EDB** Ethylene Di-Bromide 1,2-dibromoethane	**Priority of Assessment: high**
General Background of Chemical:	
EDB is a gasoline additive used as a lead scavenger. Gasoline is stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included EDB. EDB is highly soluble and has the potential to contaminate drinking water supplies.	
Scope of Assessment Request:	
Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.	
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*	
EDB was a common groundwater contaminant from leaking USTs when leaded gasoline was in widespread use; it is still present at many legacy UST release sites. Toxicity values for all of the exposure pathways (i.e., dermal, ingestion, inhalation) and for both cancer and non-cancer effects are not presently available.	
 **Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management**	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: **EDC** Ethylene Di-Chloride 1,2-dichloroethane (1,2-DCA)	**Priority of Assessment: high**
General Background of Chemical:	
EDC is a gasoline additive used as a lead scavenger. Gasoline is stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included EDC. EDC is highly soluble and has the potential to contaminate drinking water supplies.	
Scope of Assessment Request:	
Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.	
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*	
EDC was a common groundwater contaminant from leaking USTs when leaded gasoline was in widespread use; it is still present at many legacy UST release sites. Toxicity values for all of the exposure pathways (i.e., dermal, ingestion, inhalation) and for both cancer and non-cancer effects are not presently available.	
Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: **TEL** **Tetra-ethyl lead**	**Priority of Assessment: high**
General Background of Chemical:	
TEL is a gasoline lead additive used as an antiknock compound. Leaded gasoline was stored in underground storage tanks (USTs) nationwide before its use in on-road motor fuels was banned. Lead is still used in aviation gasoline and some formulations of racing fuel. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included TEL. TEL has the potential to contaminate drinking water supplies.	
Scope of Assessment Request:	
Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.	
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*	
TEL was a common groundwater contaminant from leaking USTs when leaded gasoline was in widespread use; it is still present at many legacy UST release sites. Toxicity values for all of the exposure pathways (i.e., dermal, ingestion, inhalation) and for both cancer and non-cancer effects are not presently available.	
Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: **TML** **Tetra-methyl lead**	**Priority of Assessment: high**
General Background of Chemical:	
TML is a gasoline lead additive used as an antiknock compound. Leaded gasoline was stored in underground storage tanks (USTs) nationwide before its use in on-road motor fuels was banned. Lead is still used in aviation gasoline and some formulations of racing fuel. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included TML. TML has the potential to contaminate drinking water supplies.	
Scope of Assessment Request:	
Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.	
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*	
TML was a common groundwater contaminant from leaking USTs when leaded gasoline was in widespread use; it is still present at many legacy UST release sites. Toxicity values for all of the exposure pathways (i.e., dermal, ingestion, inhalation) and for both cancer and non-cancer effects are not presently available.	
Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: **MMT** Methylcyclopentadienyl manganese tricarbonyl	**Priority of Assessment: high**
General Background of Chemical:	
MMT was initially marketed as a supplement for use in leaded gasoline, and then was later used in unleaded gasoline to increase the octane rating. Both leaded and unleaded gasoline has been stored in underground storage tanks (USTs) nationwide. There have been nearly one-half million releases of regulated substances from USTs and some of these releases have included MMT. MMT has the potential to contaminate drinking water supplies.	
Scope of Assessment Request:	
Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.	
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*	
MMT was a common groundwater contaminant from leaking USTs when leaded gasoline was in widespread use; it is still present at many legacy UST release sites and potentially present at many unleaded gasoline release sites nationwide. Toxicity values for all of the exposure pathways (i.e., dermal, ingestion, inhalation) and for both cancer and non-cancer effects are not presently available.	
 **Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management**	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: OLEM – Office of Superfund Remediation and Technology Innovation (OSRTI)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: Dieldrin	**Priority of Assessment: high**
General Background of Chemical:	
Dieldrin is a pesticide at many Superfund sites. It is commonly found at formularies as well as land application. It is toxic, persistent and bioaccumulates.	
Scope of Assessment Request:	
Updated oral slope factor, inhalation unit risk and oral reference dose.	
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*	
Dieldrin has been found at 282 Superfund sites and is the driver of many cleanups. It is commonly found in groundwater, soil and fish tissue. The IRIS values are from 1988. It was nominated for the Peer-Reviewed Provisional Toxicity Value (PPRTV); however, it was too data rich to develop a PPRTV. Therefore, it would be an ideal candidate for an IRIS update.	
Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: OLEM – Office of Superfund Remediation and Technology Innovation (OSRTI)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: Lindane (gamma-Hexachlorocylcohexane)	**Priority of Assessment: high**
General Background of Chemical:	
Lindane (gamma-hexachlorocylcohexane) is a pesticide at many Superfund sites. It is commonly found at formularies as well as land application for fruit, vegetable, and forest crops. It is toxic, persistent and bioaccumulates. Lindane has not been produced in the United States since 1976. Agricultural use in the US ended 2007; the Stockholm Convention (2009) banned production and agricultural use, but pharmaceutical use is allowed until 2015.	
Scope of Assessment Request:	
Updated oral slop factor, inhalation unit risk and oral reference dose.	
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*	
Lindane has been found at 145 Superfund sites and is the driver of many cleanups. It is commonly found in groundwater, soil and fish tissue. The IRIS values are from 1987 and California EPA values are from 2009. It was nominated for the Peer-Reviewed Provisional Toxicity Value (PPRTV); however, it was too data rich to develop a PPRTV, it would be an ideal candidate for an IRIS update.	
Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: Region 3	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: Cobalt, Dioxin 1,4-dichlorobenzene Cadmium and compounds Chlorobenzene Copper Hexachlorobutadience Hexamethylphosphoramide (HMPA) Vanadium and compounds	**Priority of Assessment: high**
General Background of Chemical:	
Scope of Assessment Request:	
Oral and inhalation toxicity, cancer	
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*	
Specific information not provided	
Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form - New Nominations - OLEM Submission	
Requesting Office: Region 6	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: Chloroprene	**Priority of Assessment: medium**

General Background of Chemical:

EPA and Louisiana Department of Environmental Quality (LDEQ) is investigating the air levels of chloroprene in La Place, Louisiana. The chloroprene is associated with the production of neoprene at the Denka Performance Elastomer facility. The chloroprene air levels are being investigated due to the 2011 National Air Toxics Assessment (NATA) to verify the actual local conditions.

Scope of Assessment Request:

Examine the physiologically based pharmacokinetic (PBPK) model for chloroprene associated with the inhalation unit risk (IUR).

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

The risk estimates using the IUR for chloroprene is of importance to Region 6 and LDEQ. These risk estimates are being used by EPA and LDEQ to determine regulatory compliance by the Denka facility.

Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

	Table 3: OUST Nominations Ongoing but not on NCEA List		
Chemical Request	**Office Requesting**	**Service Requesting**	**Submitted Priority**
Tertiary-butyl Alcohol (TBA)	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact and inhalation	High
Ethyl tertiary-butyl ether (ETBE)	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact and inhalation	High
Total Petroleum Hydrocarbons	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact and inhalation	High
Iso-Butanol	OUST**	Cancer and non-cancer toxicity values for ingestion, dermal contact and inhalation	High

IRIS Assessment Request Form – OUST Ongoing Nominations	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: **TBA** Tertiary-butyl Alcohol	**Priority of Assessment: high**

General Background of Chemical:

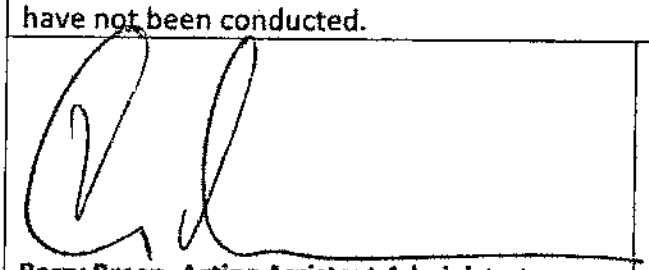
TBA is a gasoline additive used as an oxygenate and it is also a degradation byproduct of MTBE. Gasoline is stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included TBA. TBA is highly soluble and has the potential to contaminate drinking water supplies.

Scope of Assessment Request:

Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

The Energy Policy Act (EPAct) of 2005 removed the fuel oxygen content mandate (which was met primarily by MTBE and to a lesser extent ethanol). Many states have also banned MTBE. With MTBE use being eliminated other fractions and additives are likely to be increasingly used as alternatives to MTBE both to increase octane and make up some of the volume formerly provided by MTBE. An IRIS assessment for alkylates is necessitated by EPAct requirements (specifically Section 1505) which directs the Administrator to conduct toxicological assessments of not only alkylates but other ethers and heavy alcohols. EPAct requires that these assessments be completed by August 2007. To date, these assessments have not been conducted.



Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form – OUST Ongoing Nominations	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: Ethyl tertiary-butyl ether **ETBE**	**Priority of Assessment: high**
General Background of Chemical:	
ETBE is an ether gasoline additive used as an oxygenate. Gasoline is stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included ETBE. ETBE is highly soluble and has the potential to contaminate drinking water supplies.	
Scope of Assessment Request:	
Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.	
Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*	
The Energy Policy Act (EPAct) of 2005 removed the fuel oxygen content mandate (which was met primarily by MTBE and to a lesser extent ethanol). Many states have also banned MTBE. With MTBE use being eliminated other fractions and additives are likely to be increasingly used as alternatives to MTBE both to increase octane and make up some of the volume formerly provided by MTBE. An IRIS assessment for alkylates is necessitated by EPAct requirements (specifically Section 1505) which directs the Administrator to conduct toxicological assessments of not only alkylates but other ethers and heavy alcohols. EPAct requires that these assessments be completed by August 2007. To date, these assessments have not been conducted.	
Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form – OUST Ongoing Nominations	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: **Total Petroleum Hydrocarbons**-Mixture (Fractions that are consistent with other toxicity data sources, such as GRO and DRO – gasoline range organics and diesel range organics, respectively)	**Priority of Assessment: high**

General Background of Chemical:

Total Petroleum Hydrocarbons are a mixture of various petroleum hydrocarbons that are present in motor fuels (and there are some naturally-occurring compounds that frequently are mixed in with TPH because they elute at the same temperatures. Gasoline and diesel are comprised of hundreds of compounds. Gasoline and diesel are stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980s. Some of these releases have included compounds in typical TPH mixtures and have the potential to contaminate drinking water supplies.

Scope of Assessment Request:

Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

The Energy Policy Act (EPAct) of 2005 removed the fuel oxygen content mandate (which was met primarily by MTBE and to a lesser extent ethanol). Many states have also banned MTBE. With MTBE use being eliminated other fractions and additives are likely to be increasingly used as alternatives to MTBE both to increase octane and make up some of the volume formerly provided by MTBE. An IRIS assessment for alkylates is necessitated by EPAct requirements (specifically Section 1505) which directs the Administrator to conduct toxicological assessments of not only alkylates but other ethers and heavy alcohols. EPAct requires that these assessments be completed by August 2007. To date, these assessments have not been conducted.

Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

IRIS Assessment Request Form – OUST Ongoing Nominations	
Requesting Office: OLEM - Office of Underground Storage Tanks (OUST)	
Request Date: 8/27/2018	**Requested Completion Date:** asap
Chemical Nominated for Assessment: Iso-butanol	**Priority of Assessment:** high

General Background of Chemical:

Iso-butanol is a potential gasoline additive as well as a potential alternative fuel in its own right. Gasoline (and alternative fuels) is (are) stored in underground storage tanks (USTs) at more than 250,000 facilities nationwide. There have been nearly one-half million releases of regulated substances from USTs since the late 1980's. Iso-butanol has the potential to contaminate drinking water supplies.

Scope of Assessment Request:

Cancer and non-cancer toxicity values for ingestion, dermal contact, and inhalation.

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

The Energy Policy Act (EPAct) of 2005 removed the fuel oxygen content mandate (which was met primarily by MTBE and to a lesser extent ethanol). Many states have also banned MTBE. With MTBE use being eliminated other fractions and additives are likely to be increasingly used as alternatives to MTBE both to increase octane and make up some of the volume formerly provided by MTBE. An IRIS assessment for alkylates is necessitated by EPAct requirements (specifically Section 1505) which directs the Administrator to conduct toxicological assessments of not only alkylates but other ethers and heavy alcohols. EPAct requires that these assessments be completed by August 2007. To date, these assessments have not been conducted.

Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management	**ORD Principal Deputy Assistant Administrator for Science**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2
290 BROADWAY
NEW YORK, NY 10007-1866

AUG 29 2018

MEMORANDUM

SUBJECT: Region 2 Nominations to the Office of Land and Emergency Management for Continuing IRIS Assessments in FY18-19

FROM: John B. Prince, Acting Director
Emergency and Remedial Response Division

TO: Kathleen Raffaele, Science Advisor
Office of Land and Emergency Management

I am writing to provide Region 2's support for the selection of several chemicals in the FY18-19 Portfolio for continued evaluation by the Integrated Risk Information System (IRIS) Program. We understand that you are coordinating a response to the August 10, 2018 request from the Dr. Jennifer Orme-Zavaleta, Principal Deputy Assistant Administrator for Science in the Office of Research and Development, confirming the need for the chemicals listed in the Portfolio in support of decision making.

Attached is a description of Region 2's ongoing need for continuation of the IRIS assessments under the Superfund and RCRA programs. The IRIS section of this attachment provides the support for PCBs, arsenic, ethylbenzene, hexavalent chromium, manganese and mercury based on the ongoing Superfund program activities that include assessment of risks and remedy protectiveness. In addition, we received support for the chloroform nomination from our RCRA program. Region 2 also supports the continued NCEA assessment of the five perfluorinated chemicals and PAH mixtures.

We look forward to working with OLEM and NCEA to ensure these chemicals are assessed in a timely manner to support defensible decision making in the Superfund and RCRA programs. If you have any questions, please feel free to contact me at [redacted].

Attachment

cc: [redacted]

Attachment

Region 2 Justification for Integrated Risk Information Chemical Nominations Under the Superfund Program and the Resource Conservation and Recovery Act

Superfund

Within the Superfund program, toxicity information from the Integrated Risk Information System (IRIS) is used in the following steps of the Human Health Risk Assessment (HHRA) process:

- Selecting Chemicals of Potential Concern that will be evaluated in the full HHRA;
- Determining the cancer risks and noncancer health hazards posed by the chemicals to support decisions regarding the need to take remedial action at a site;
- Developing risk- based remediation levels;
- Determining the amount of soil, groundwater, sediment, or other media that may require remedial action to meet the remediation levels; and
- Evaluating the protectiveness of the remedy for those sites where contamination remains on site during the Five-Year Review.

The following chemicals were nominated to the IRIS program by Region 2 previously. The regional need for completion of these IRIS assessment remains. Based on an evaluation of the 218 sites currently on the National Priorities List (NPL), the previously-nominated chemicals were identified as chemicals of concern (COCs) for many of them. These chemicals are priorities for Region 2 based on their prevalence, the age of their IRIS assessments and their importance in overall site remedy decision making.

Polychlorinated biphenyls (PCBs). PCBs are a COC at 66 of 218 Superfund Sites. High-profile sites currently addressing PCBs include: Hudson River PCBs, Passaic River, Massena area sites that include Indian Lands and a large number of landfills. PCBs in air are a concern at Superfund sites where remediation is being conducted. Having the toxicological data to support developing health-based air screening levels is critical. To that end, Region 2 is requesting a Reference Concentration (RfC) to allow the calculation of noncancer hazards from exposure to PCBs in air.

Arsenic. Arsenic is a COC at 156 of the 218 Superfund Sites. Arsenic was identified at landfills, former manufacturing facilities, scrap metal refining sites and federal facilities. Arsenic is found primarily in soil and groundwater. The IRIS Chemical File for arsenic indicates that the oral Reference Dose (RfD) was last updated in 1991 and the cancer assessment was last updated in 1995.

Ethylbenzene. Ethylbenzene was identified as a COC at 94 of 218 sites. The sites with ethylbenzene contamination include: landfills, oil refineries, trucking facilities, former manufacturing facilities and federal facilities. The oral RfD and inhalation RfC were last updated in 1987 and 1991, respectively. The cancer assessment was last updated in 1988.

Hexavalent Chromium. Hexavalent chromium was identified as a COC at 21 of 218 sites. The sites include: circuit board and plating facilities; federal facilities; landfills and refining facilities. The oral RfD, inhalation RfC and cancer assessment were last updated in 1998.

Manganese. Manganese was identified as a COC at 95 of 218 sites. The sites include: landfills, former manufacturing facilities, village wellfields, federal facilities, and a power plant. Updates to the toxicity assessment for noncancer was last conducted in 1995 and the assessment for carcinogenicity was last updated in 1988.

Mercury Salts/Methyl Mercury. Mercury was identified as a COC at 108 of the 218 sites. The sites include such high-profile sites as the Berry's Creek Study Area of the Ventron/Vesicol site, as well as landfills, federal facilities and manufacturing facilities. The RfD assessment and the cancer assessment were last updated in 1995.

Resource Conservation and Recovery Act

Region 2 also wishes to support the nomination by Region 4, the Office of Land and Emergency Management (OLEM) and the Office of Air (OAR) to revisit the 2001 IRIS Chemical Assessment for Chloroform to clarify the relationship of the cancer and noncancer assessments. IRIS values are used by the Region 2 RCRA program in the same manner as those used in the Superfund program.

From: [redacted]
To: Orme-Zavaleta, Jennifer
Cc: [redacted]
Subject: OW's Nominations for IRIS FY 2018-2019 Portfolio
Date: Friday, September 14, 2018 1:56:26 PM
Attachments: OW IRIS Nomination Forms.pdf

Dear Jennifer,

Thank you for the opportunity to reaffirm the Office of Water's (OW's) needs for the IRIS FY 2018-2019 Portfolio. We have re-evaluated the chemicals that we submitted to ORD in 2014 as "high priority" for IRIS work products. We are pleased to see many of 2014 nominations appear in the IRIS FY 2018-2019 Portfolio. We reaffirm that we have continued interest in assessments for these chemicals. We have added Methylmercury to our list of OW priorities. This chemical is included in the IRIS FY 2018 -2019 Portfolio. We also reaffirm OW's interest in the completion of health assessments for PFAS chemicals not in the "classical" IRIS portfolio. PFAS is an Agency priority and OW would benefit from having a better understanding of human health risks associated with drinking water exposure to PFAS chemicals.

In our 2014 IRIS nominations we also included Vanadium, Acetaldehyde, and Cadmium. These chemicals appeared on the 2015 IRIS Agenda; however, they are not included on the IRIS FY 2018 – 2019 Portfolio. We continue to have a need for IRIS assessments for Vanadium, Cadmium, and Acetaldehyde. Therefore, we are requesting full IRIS assessments for these chemicals. We are also putting forward the chemicals N-methyl-2-pyrrolidone and Urethane for assessments. See attached IRIS Nomination Request Forms for more information.

We thank you again for the opportunity to provide OW's input on the IRIS FY 2018 – 2019 Portfolio and on future assessment needs. We look forward to status updates and the completion of these assessments.

Please contact Ed Ohanian for any additional details and/or questions regarding OW's IRIS nominations.

Thank you.

Regards,

Benita

Benita Best-Wong
Acting Principal Deputy Assistant Administrator
Office of Water

Attachment 1
IRIS Form

IRIS Assessment Request Form

Requesting Office: Office of Water

Request Date: August 2018

Requested Completion Date: See "Need" Section

Chemical Nominated for Assessment: See "General Background of Chemical" Section

Priority of Assessment: See "General Background of Chemical" Section

REAFFIRMATION

General Background of Chemical:

OW has continued interests in IRIS assessments nominated in 2014. The below list includes chemicals we nominated in 2014. We are adding Methylmercury to the list of OW priority chemicals. These chemicals are also included in the IRIS FY2018-2019 Portfolio.

1. **Ammonia (Oral)**
2. **Arsenic, Inorganic**
3. **Ethylbenzene**
4. **Formaldehyde**
5. **Hexavalent Chromium**
6. **Nitrate/Nitrite**
7. **PCBs**
8. **Uranium**
9. **Manganese**
10. **Methylmercury**

PFAS is an Agency priority. OW is also re-affirming our interest in PFAS health assessments.

1. **PFBA**
2. **PFHxA**
3. **PFHxS**
4. **PFDA**
5. **PFNA**

Scope of Assessment Request:

1. **Ammonia (Oral) – RfD; chronic cancer**
2. **Arsenic, Inorganic – RfD; oral cancer**
3. **Ethylbenzene – RfD; oral cancer/non-cancer**
4. **Formaldehyde – RfD; oral cancer**
5. **Hexavalent Chromium – RfD; oral cancer/non-cancer**
6. **Nitrate/Nitrite – RfDs – oral chronic cancer: life-time and short-term**
7. **PCBs – RfD; oral cancer/non-cancer**
8. **Uranium – RfD; oral cancer/non-cancer**
9. **Manganese – RfD; oral cancer/non-cancer**
10. **Methylmercury – RfD; non-cancer (neurodevelopmental)**

Scope of Assessment Request (continued):

11. **PFBA - RfD; oral cancer/non-cancer**
12. **PFHxA - RfD; oral cancer/non-cancer**
13. **PFHxS - RfD; oral cancer/non-cancer**
14. **PFDA - RfD; oral cancer/non-cancer**
15. **PFNA - RfD; oral cancer/non-cancer**

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

1. **Ammonia (Oral) – Nitrification in distribution systems; IRIS product needed by December 2024**
2. **Arsenic, Inorganic – Six Year Review 4; IRIS product needed by December 2020**
3. **Ethylbenzene – Six Year Review 4; IRIS product needed by December 2020**
4. **Formaldehyde – Preliminary Regulatory Determination 5 - December 2024**
5. **Hexavalent Chromium – Six Year Review 4; IRIS product needed by December 2020**
6. **Nitrate/Nitrite – Six Year Review 4; IRIS product needed by December 2020**
7. **PCBs – Update Human Health Criteria in Ambient Water; IRIS product needed by December 2024; Inform human health screening values for fish consumption advisories**
8. **Uranium – Six Year Review 4; IRIS product needed by December 2020**
9. **Manganese – Preliminary Regulatory Determination 5 – December 2024**
10. **Methylmercury – inform human health screening values for fish consumption advisories**
11. **PFBA — Preliminary Regulatory Determination 4 – February 2019**
12. **PFHxA — Preliminary Regulatory Determination 4 – February 2019**
13. **PFHxS — Preliminary Regulatory Determination 4 – February 2019**
14. **PFDA — Preliminary Regulatory Determination 4 – February 2019**
15. **PFNA — Preliminary Regulatory Determination 4 – February 2019**

Signature: Benita Best-Wong **Signature:**

Benita Best-Wong **ORD Principal Deputy Assistant Administrator for Science**

Acting Principal DAA

Office of Water

Requesting Office: Office of Water

Request Date: August 2018 **Requested Completion Date: FY 25**

Chemical Nominated for Assessment: Acetaldehyde **Priority of Assessment: Medium**

ACETALDEHYDE

General Background of Chemical:

Acetaldehyde is a byproduct of ozonation, a DBP.

Scope of Assessment Request:

RfD; oral cancer slope factor

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

Contaminant is being considered for inclusion on the UCMR 5 list -- an assessment of toxicity will be helpful in comparing monitored results to make potential regulatory determinations. **Preliminary Regulatory Determination 5 – December 2024**

Signature: **Signature:**

Benita Best-Wong

Acting Principal DAA

Office of Water

ORD Principal Deputy Assistant Administrator for Science

Requesting Office: Office of Water

Request Date: August 2018 **Requested Completion Date: FY 25**

Chemical Nominated for Assessment: Vanadium **Priority of Assessment: Medium**

VANADIUM

General Background of Chemical:

Vanadium has developmental/reproductive effects. UCMR 3 monitoring data show:

- 3,625 PWSs measured vanadium in at least one sample
- 163 out of 4,922 PWSs (3.3%) had results at or above the reference concentration (21 µg/L)

Naturally occurring; found in about 65 minerals.

Scope of Assessment Request:

RfD; oral cancer/non-cancer

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

EPA has monitored drinking water systems for Vanadium under UCMR3. An up-to-date assessment of oral toxicity will be needed to make a regulatory determination.
Preliminary Regulatory Determination 5 - December 2024

Signature: **Signature:**

Benita Best-Wong **ORD Principal Deputy Assistant Administrator for Science**

Acting Principal DAA

Office of Water

Requesting Office: Office of Water

Request Date: August 2018 **Requested Completion Date: FY 21**

Chemical Nominated for Assessment: Cadmium **Priority of Assessment: Medium**

CADMIUM

General Background of Chemical:

SDWA regulated chemical.
Cadmium has been shown to cause renal problems.
Sources of contaminant in drinking water: Corrosion of galvanized pipes; erosion of natural deposits; discharge from metal refineries; runoff from waste batteries and paints.

Scope of Assessment Request:

RfD; oral cancer slope factor

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels*

Cadmium needs an updated health assessment, Six-year Review 3 classified Cadmium as "Not Appropriate for Revision at this Time" due to the fact that a health effects assessment is in progress. In OW's opinion, this statement in the FR commits EPA to producing a health effects assessment for Cadmium. Updating the cadmium 304(a) Human Health Criteria is also a priority.
Six Year Review 4; IRIS product needed by December 2020

Signature: **Signature:**

Benita Best-Wong **ORD Principal Deputy Assistant Administrator for Science**

Acting Principal DAA

Office of Water

Requesting Office: Office of Water

Request Date: August 2018 **Requested Completion Date: FY 25**

Chemical Nominated for Assessment: N-Methy-2-pyrrolidone **Priority of Assessment: Medium**

N-Methyl-2-pyrrolidone

General Background of Chemical:

N-Methyl-2-pyrrolidone is a solvent in the chemical industry. It is solvent for pesticide application in food packaging materials.
Included on CCL 3/CCL 4 based on Toxic Release Inventory data.

Scope of Assessment Request:

RfD; oral cancer/non-cancer

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels*

Contaminant is being considered for inclusion on the UCMR 5 list -- an assessment of toxicity will be helpful in evaluating UCMR 5 results and making potential regulatory determinations.
Preliminary Regulatory Determination 5 – December 2024

Signature: **Signature:**

Benita Best-Wong **ORD Principal Deputy Assistant Administrator for Science**

Acting Principal DAA

Office of Water

Requesting Office: Office of Water

Request Date: August 2018 **Requested Completion Date: FY 25**

Chemical Nominated for Assessment: Urethane **Priority of Assessment: Medium**

URETHANE

General Background of Chemical:

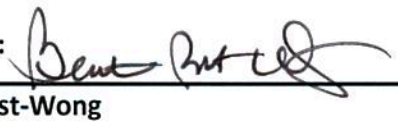
Urethane is a paint ingredient. Included on CCL 3/CCL 4 based on Toxic Release Inventory data.

Scope of Assessment Request:

RfD; oral cancer/non-cancer

Need *(Please include decision context. Ex: regulatory driver; or to identify cleanup levels)*

Contaminant is being considered for inclusion on the UCMR 5 list -- an assessment of toxicity will be helpful in evaluating UCMR 5 results and making potential regulatory determinations. **Preliminary Regulatory Determination 5 – December 2024**

Signature:  **Signature:**

Benita Best-Wong **ORD Principal Deputy Assistant Administrator for Science**

Acting Principal DAA

Office of Water