ICYMI: EPA’s IRIS Program is Ramping up its Activity for chemicals, including PFAS; EPA’s TSCA Program Releases Guidance for Exemptions to CDR Reporting.

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8.18.2021 EPA Finalizes Hazard Assessments for Two Fuel Additives (ETBE and tert-Butanol):

On August 18th, EPA finalized the long-awaited hazard assessments for both Ethyl Tertiary Butyl Ether (ETBE) and tert-Butyl Alcohol (tert-Butanol). ETBE was previously added to gasoline to increase its octane levels. It is still registered with EPA for use as a fuel additive, but it is not used currently in the United States. tert-
Butanol is one of the primary metabolites of ETBE and has also been used as a fuel oxygenate. It is also used for other purposes including as a solvent and as a dehydrating agent.

These hazard assessments, developed by EPA’s Integrated Risk Information System (IRIS), provide toxicity values for health effects that result from chronic exposure to the chemistries. IRIS values, when combined with exposure information, are used by state, federal and international authorities, as well as private sector groups to characterize potential human health risks in specific scenarios. IRIS assessments are not regulations; however, the values are often used in the scientific underpinnings of many regulations across EPA air, water, chemical, and clean-up programs. In addition, IRIS values are used in important tools such as EPA’s Environmental Justice Screening and Mapping tool (EJSCREEN) and EPA’s National Air Toxics Assessment (NATA). The hazard values for ETBE and tert-Butanol are available here. If you are interested in understanding how EPA uses scientific information and science-based default assumptions to calculate these and similar values, Hunton Andrews Kurth LLP can provide assistance.

8.19.2021 EPA Proposes Safe Levels for another PFAS Compound (PFBA):

EPA has released for public comment and peer review the draft IRIS Toxicological Review for Perfluorobutanoic Acid (PFBA) and Related Compound Ammonium Perfluorobutanoic Acid. While EPA has finalized human health toxicity values for three other PFAS compounds, this is the first PFAS draft proposed by EPA’s IRIS program. Perfluorobutane sulfonic acid (PFBS) human health toxicity values were finalized in April 2021. Human health toxicity values for Perfluorooctanesulfonic acid (PFOS) and Perfluorooctanoic acid (PFOA) were released by EPA in 2016.

The proposed PFBA toxicity value, shown in the table below, provides an estimate that is likely to be without appreciable risk of deleterious effects during a lifetime of exposure for human populations, including sensitive subgroups. The PFBA value, based on data from rat studies, is driven by potential concerns for liver and thyroid effects, as seen in the rats.

<table>
<thead>
<tr>
<th>PFAS Compound</th>
<th>Chronic RfD (mg/kg-day)</th>
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<tbody>
<tr>
<td>PFOA (2016)</td>
<td>0.00002</td>
</tr>
<tr>
<td>PFOS (2016)</td>
<td>0.00002</td>
</tr>
<tr>
<td>PFBS (2021)</td>
<td>0.0003</td>
</tr>
<tr>
<td><strong>PFBA (Proposed)</strong></td>
<td><strong>0.001</strong></td>
</tr>
</tbody>
</table>
EPA is seeking public comment on the draft PFBA assessment and will conduct a contractor-led external peer review of the document. As noted in the Federal Register, comments are due to EPA by October 22, 2021. If PFBA is a PFAS compound of concern to you, Hunton Andrews Kurth LLC can provide technical assistance to assist you with your comments to EPA.

8.23.2021 EPA Seeks Nominations of Scientific Experts to Review Five PFAS Compounds

Although EPA has only released the draft for PFBA (discussed above), EPA is planning to soon release draft toxicity assessments for four additional PFAS compounds. The assessments coming soon will be for Perfluorodecanoic Acid (PFDA), Perfluorononanoic Acid (PFNA), Perfluorohexanoic Acid (PFHxA), and Perfluorohexanesulfonic acid (PFHxS).

EPA intends to have a single peer review panel review all five PFAS toxicity assessments. EPA is now seeking nominations for nationally and internationally recognized scientific experts with PFAS expertise for this panel. The specific expertise EPA is seeking includes:

- Environmental epidemiology with experience in the application of systematic review principles to environmental exposures and/or immunotoxicity expertise;
- Experimental toxicology with experience in the application of systematic review principles to environmental exposures and/or immunotoxicity expertise, hepatic effects, thyroid effects, developmental effects, biological mechanisms of human disease/health effects, and absorption, distribution, metabolism, and excretion (ADME) knowledge; and physiologically-based pharmacokinetic (PBPK) modeling, toxicokinetics, and dose-response modeling of animal data.

All nominations must be sent to the EPA contractor by September 22, 2021. The details regarding how to submit a nomination can be found in the Federal Register notice. Hunton Andrews Kurth LLC is available to assist you with any nominations you may wish to make.

8.23.2021 EPA Releases and Seeks Comment on Guidance for Preparing and Submitting Petitions for Exemptions to TSCA Chemical Data Reporting Rule (CDR).

The Chemical Data Reporting (CDR) rule, under the Toxic Substances Control Act (TSCA), requires manufacturers (including importers) to provide EPA with information on the production and use of chemicals in commerce. Reporting under this rule provides EPA with basic exposure-related information including information on the types, quantities and uses of chemical substances produced domestically and imported into the United States. This information is collected every four years. Among other uses, CDR data helps inform TSCA risk evaluations for existing chemicals. More information on the CDR rule is available here.
The 2020 CDR rulemaking established a byproduct exemption petition process. EPA is soliciting public comment on guidance on the processes applicable to: 1) Petitions for full exemption of byproduct substances that are recycled or otherwise used within site-limited, physically enclosed systems and 2) Petitions for partial exemption of chemicals for which the CDR processing and use information has been determined to be of “low current interest” by the Agency. The guidance is designed to elucidate the process and requirements of CDR-specific petitions.

**EPA states that** the information in the guidance is similar to and expands upon information that has already been available on the CDR website for the existing partial exemption petition process (40 CFR 711.6(b)(2)). Given that the new byproduct exemption petition process was modeled in part after the existing partial exemption petition process, EPA decided to have the guidance cover both petition processes.

EPA is accepting comments on this guidance until **December 21, 2021**, but also notes that the public may consult this guidance immediately. Public comments will be taken into consideration by EPA when determining if updating the guidance is appropriate as part of EPA’s continuous improvement efforts.

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