Toxicology and Risk Assessment Challenges with Evaluating Health Effects of PFAS

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State Toxicologist
Maine Center for Disease Control and Prevention
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Risk Assessment

Risk

Toxicity

Exposure

Concentration in Media

Contact / Intake Rate for Media

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PFOS

Carbon backbone

H H H H H H H H H H H H H H H H H H
H—C—C—C—C—C—C—C—C—C—C—H
H H H H H H H H H H H

Acid Group

O

SO

Octane

Perfluorooctane sulfonic acid (PFOS)
## Available Toxicity Data

### Human Studies
- Liver damage*
- Thyroid hormone disruption*
- Decreased immune response to vaccinations*
- Low birth weight (LBW)*
- Testicular, kidney and prostate cancer (PFOA)*
- Ulcerative colitis
- Changes in cholesterol
- Hypertension during pregnancy

### Animal Studies
- Increased liver size / liver damage*
- Thyroid hormone disruption*
- Changes in immune function*
- LBW and other developmental effects*
- Liver, testicular and pancreatic cancers (PFOA)*
- Increased kidney weight

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Key Decisions in Deriving Toxicity Values

- Use human or animal data?
- If animal, which animal study?
- What endpoint from any given animal study?
- How to adjust for much longer half-life in humans versus animals?
- What to apply for additional uncertainty factors to extrapolate to sensitive humans?
Deriving a Toxicity Value for PFOS

100,000 ng/kg/day

Rodent to human conversion

Human equivalent dose

Human protections

No adverse effect observed in rodent pups

Dose that is safe in the most vulnerable people (like developing babies)

~200x

~30x

510 ng/kg/day

20 ng/kg/day

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## Differences in Toxicity Values for PFOS

<table>
<thead>
<tr>
<th>Agency</th>
<th>Endpoint</th>
<th>Species</th>
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<th>Cumulative uncertainty factor</th>
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* Proposed/Draft
Deriving EPA’s Drinking Water Health Advisory

- **Toxicity Value**: 20 ng/kg/day
- **Water Intake Rate**: 0.054 L/kg/day
- **Drinking Water Exposure Limit**: 370 ng/L
- **Background Exposure (RSC) 20% Default**: 70 ng/L

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### Other Drinking Water Guidelines for PFOS

<table>
<thead>
<tr>
<th>Agency</th>
<th>Reference dose (ng/kg/day)</th>
<th>Receptor</th>
<th>Drinking water intake (L/kg/day)</th>
<th>Relative source contribution</th>
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<td>600</td>
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</tbody>
</table>

* Proposed / Draft.
Who is most at risk from water exposure?

- Exposure During Pregnancy
- Formula Fed
- Breastfeeding

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Spike in Infant PFOS Serum Levels from Breastfeeding

Breastfed Infant Scenario PFOS Serum Concentration at Water Concentration - 70 ng/L

Helen M. Goeden ● Christopher W. Greene ● James A. Jacobus

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Background Exposure Estimated from U.S. Population PFOS Serum Levels

National Biomonitoting PFOS Serum Levels  
Children 12 years and older and adults

Estimated Daily Intake
1.5 ng/kg/day
0.4 ng/kg/day

National Report on Human Exposure to Environmental Chemicals – US CDC: 
https://www.cdc.gov/exposurereport/index.html

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Irrigation Water Screening Levels

PFOS
300 - 800 ng/L

Transfer pathways:

1. Deposition
2. Soil resuspension
3. Root uptake

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Soil Related Exposure Pathways

- Residential Soil
- Soil-to-Groundwater
- Agronomic
PFOS Soil Levels for Residential Soil Exposure Pathway

Based on Chapter 418 risk standard of 0.5 HI, USEPA RSL model with standard (EPA/ME) defaults, and USEPA RfD.

PFOS
1500 µg/kg
PFOS Soil Levels for StoneRidge Farm

Surface Soil Data - January - May 2017

<table>
<thead>
<tr>
<th>Sample Location</th>
<th>PFOS Level (µg/kg dry weight)</th>
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PFOS levels in µg/kg dry weight.
Based on Chapter 418 risk standard of 0.5 HI, USEPA RSL tap water model modified with use of SESOIL soil to groundwater model, and USEPA RfD.
PFOS Soil Levels for Agronomic Exposure Pathway

- **PFOS in Soil:**
  - **3.1 µg/kg (hay)**
  - **6.5 µg/kg (corn)**

*DRAFT – Under development.* Chapter 418 risk standard of 0.5 HI, USEPA PRG agronomic model, MECDC milk action level (210 ppt) based on USEPA RfD.
Deriving a Milk Action Level for “adulterated” Milk

Toxicity Value
20 ng/kg/day

Milk Intake Rate
0.074 L/kg/day

Milk Exposure Limit
270 ng/L

Relative Source Contribution
80%

Action Level
210 ng/L

1-2 year old

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Key Questions:

- Should we continue to rely on EPA toxicity values?
- Should we use the transgenerational breast fed receptor?
- How much to extend agronomic screening levels?
- Should we derive toxicity values for other PFAS (e.g., PFHxS, PFHxA, PFNA)?
- Should we continue with a chemical-by-chemical approach, or a grouping of “like” PFAS approach?
### Toxicity Values for Other PFAS

#### Reference dose by Agency or various States

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<tr>
<th>PFAS</th>
<th>EPA</th>
<th>ATSDR</th>
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* Proposed

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Questions?

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