Message

**From:** Orme-Zavaleta, Jennifer [Orme-Zavaleta.Jennifer@epa.gov]
**Sent:** 1/6/2021 10:29:43 PM
**To:** Jones, Samantha [Jones.Samantha@epa.gov]; D'Amico, Louis [DAmico.Louis@epa.gov]
**Subject:** RE: Need answer quickly

Thanks

helpful

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator
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DC
Cel Ex. 6 Personal Privacy (PP)

**From:** Jones, Samantha <Jones.Samantha@epa.gov>
**Sent:** Wednesday, January 6, 2021 5:27 PM
**To:** D'Amico, Louis <DAmico.Louis@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
**Subject:** RE: Need answer quickly

Agreed and that second yellow highlight should NOT be in a scientific foundational document. It would go into the risk assessment by the program.

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**From:** D'Amico, Louis <DAmico.Louis@epa.gov>
**Sent:** Wednesday, January 6, 2021 5:24 PM
**To:** Jones, Samantha <Jones.Samantha@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
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Also, note that the "revised" version from ocspp modifies text in PFBS to state:

The range of values for the chronic RfD is derived to be protective of all types of effects across studies and species following oral chronic exposure and is intended to protect the population as a whole, including potentially susceptible populations and life stages (U.S. EPA, 2002). The individual value applied will depend on the needs of the program office and in the type of risk assessment being performed (e.g., general population).

This is precedent setting, and flies completely in the face of legitimate and necessary separation between risk assessment and risk management. A decision to release a "range of values" in EPA assessments should be discussed across the agency, including program offices and regions.

-Lou

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**From:** Jones, Samantha <Jones.Samantha@epa.gov>
**Sent:** Wednesday, January 6, 2021 5:18 PM
**To:** Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>
**Subject:** RE: Need answer quickly

For PFBS, we develop a chronic RfD with a database UF of 10. The rationale is as follows:

A $UF_D$ of 10 is applied to account for database deficiencies. The oral exposure database contains multiple short-term and subchronic-duration toxicity studies of laboratory animals (NTP, 2019; Bijland et al., 2011; Lieder et al., 2009a; 3M, 2001, 2000d), a two-generation reproductive toxicity study in rats (Lieder et al., 2009b), and multiple developmental toxicity studies in mice and rats (Feng et al., 2017; York, 2002). However, as thyroid hormone is known to be critical during developmental life stages, particularly for neurodevelopment, the database is limited by the lack of developmental neurotoxicity studies. Further, due to the lack of chronic duration studies, there is additional uncertainty regarding how longer-term exposures might impact hazard identification and dose-response assessment for PFBS via the oral route (e.g., potentially more sensitive effects). Lastly, as immunotoxicity and mammary gland development are effects of increasing concern across several members of the larger PFAS family (Grandjean, 2018; Liew et al., 2018; White et al., 2007), the lack of studies evaluating these outcomes following PFBS exposure is a limitation in the database.

We also developed a subchronic RfD, the database UF is a 3 and the rationale is as follows:

A $UF_D$ of 3 is applied due to database deficiencies. The oral exposure database contains multiple short-term and subchronic-duration toxicity studies of laboratory animals (NTP, 2019; Bijland et al., 2011; 3M, 2010; Lieder et al., 2009a; 3M, 2001, 2000d), a two-generation reproductive toxicity study in rats (Lieder et al., 2009b), and multiple developmental toxicity studies in mice and rats (Feng et al., 2017; York, 2002). However, the observation of decreased thyroid hormone is known to be a crucial element during developmental life stages, particularly for neurodevelopment, and the database is limited by the lack of developmental neurotoxicity studies. In addition, as other health effect domains such as immunotoxicity and mammary gland development are effects of increasing concern across several members of the larger PFAS family (Grandjean, 2018; Liew et al., 2018; White et al., 2007) the lack of studies evaluating these outcomes following PFBS exposure is a limitation in the database.

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**From:** Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
**Sent:** Wednesday, January 6, 2021 5:13 PM
**To:** Jones, Samantha <Jones.Samantha@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>
**Subject:** Need answer quickly

Had a call from Alex. What is the pfbs data base factor. And basis for it

I was pretty frank w her.

Thanks

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Offic
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Sent from my iPhone