Message

**Sent**: 8/20/2019 11:48:38 PM
**To**: Rodan, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Rodan, Bruce]
**CC**: Fleming, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14b4c2e10bf84f1fa9a3f91f5ca1c4c0-Fleming, Megan]; Frithsen, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3743bd6f3c345baaae407c1d6f78e92-FRITHSEN, JEFF]
**Subject**: RE: ADVANCE NOTIFICATION - Lang et al. Evaluation of PFESA-BP2 Toxicity in Mice

Good evening Bruce,

Thanks for taking the time to look at this so closely – your insights are always valuable.

This particular manuscript has some extenuating circumstances behind it that I would like you to be aware of, but that should be a phone conversation. I am certainly available this evening if you are – otherwise, can you

Ron

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**From:** Rodan, Bruce <rodan.bruce@epa.gov>
**Sent:** Tuesday, August 20, 2019 7:12 PM
**To:** Hines, Ronald <Hines.Ronald@epa.gov>
**Cc:** Fleming, Megan <Fleming.Megan@epa.gov>; Gillespie, Andrew <Gillespie.Andrew@epa.gov>; Deener, Kathleen <Deener.Kathleen@epa.gov>; Frithsen, Jeff <Frithsen.Jeff@epa.gov>; VanDrunick, Suzanne <vanDrunick.Suzanne@epa.gov>
**Subject:** RE: ADVANCE NOTIFICATION - Lang et al. Evaluation of PFESA-BP2 Toxicity in Mice

Ron,

**Ex. 5 Deliberative Process (DP)**

Bruce Rodan
Associate Director for Science
EPA Office of Research and Development

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**From:** Hines, Ronald <Hines.Ronald@epa.gov>
**Sent:** Monday, August 19, 2019 8:47 AM
**To:** Rodan, Bruce <rodan.bruce@epa.gov>; Gillespie, Andrew <Gillespie.Andrew@epa.gov>
**Cc:** Fleming, Megan <Fleming.Megan@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Fisher, Bill <Fisher.William@epa.gov>; Saterson, Kathryn <Saterson.Kathryn@epa.gov>; Russell, Marc <Russell.Marc@epa.gov>;

Jones, Marjorie <Jones.Marjorie@epa.gov>
**Subject:** ADVANCE NOTIFICATION - Lang et al. Evaluation of PFESA-BP2 Toxicity in Mice

Good morning Bruce,

Consistent with the current policy on manuscripts containing information on PFAS, NHEERL is initiating advance notification of the manuscript entitled "Toxicity of Balb-C Mice Exposed to 1,1,2,2-Tetrafluoro-2-[1,1,1,2,3,3-hexafluoro-3-(1,1,2,2-tetrafluoroethoxy)propan-2-yl]oxyethane-1-sulfonic acid (PFESA-BP2)" authored by J Lang (ORISE), M Strynar (NERL), A Lindstrom (NERL), A Okickich (ORISE), H Huang (ORISE), J Schmid (NHEERL), D Hill (NHEERL) and N Chernoff (NHEERL). This study was conducted as a pilot under the Sustainable and Health Communities project, technical support for policy, guidance, and targeted research for contaminated site management (SHC 3.1.3.2). Given the nature of the findings, the manuscript should be of considerable interest to OLEM, OW, and OCSPP, as well as Region 4. Once cleared, the manuscript will be submitted to *Environmental Science and Technology Letters* for publication consideration.

In 2015, a perfluoroalkyl ether sulfonic acid (PFESA-BP2, Nafion Byproduct 2) was reported in the Cape Fear River downstream of an industrial manufacturing facility (Strynar et al, 2015). This manuscript only indicated the presence of PFESA-BP2 in the river and did not quantify the amount because of the lack of authentic standards. It was later detected in 99% of the serum samples evaluated from residents of Wilmington, North Carolina, using the Cape Fear River for their drinking water supply source. Given the complete absence of any information on PFESA-BP2 toxicity and the similarity to PFOS, a known toxicant, this study evaluated PFESA-BP2*in vivo* hepatic toxicity and bioaccumulation in mice after dosing for 7 days at 0.04, 0.4, 3, and 6 mg/kg-day by oral gavage.

Both male and female mice demonstrated significant increases in liver to body weight ratios compared to the controls at 3 and 6 mg/kg-day, but only the males demonstrated significant increases for the 0.4 mg/kg-day dose groups. Liver histopathology was observed at these same doses. Male mice demonstrated significantly elevated serum levels of ALT and GLDH at 3 and 6 mg/kg/day, females had significant increases in ALT and AST at 6 mg/kg/day. There were no effects in the 0.04 mg/kg/day group. PFESA-BP2 serum concentrations in mice at the 0.04 mg/kg-day dose were approximately 100- to 200-times higher than levels previously reported in the residents of Wilmington NC.

I have attached a copy of the manuscript, a file with supplemental information, an fact sheet/impact statement, and an OW transmittal form. Please let me know if you have any concerns or questions.

Ron Hines, PhD
Associate Director for Health
US EPA, NHEERL
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Tel: 919 541-5622
Ex. 6 Personal Privacy (PP)