



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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

September 21, 2021

**MEMORANDUM**

**SUBJECT:** Materials for Review by Human Studies Review Board for the October 21, 2021 Meeting

**TO:** Thomas O'Farrell  
Designated Federal Official Human Studies Review Board Office of Science Advisor

**FROM:** Michelle Arling  
Human Research Ethics Review Officer  
Office of the Director  
Office of Pesticide Programs

This memorandum identifies the materials that the Environmental Protection Agency's (EPA's) Office of Pesticide Programs is providing for review by the Human Studies Review Board (HSRB or Board) at the teleconference and virtual meeting scheduled for October 21, 2021. During the October discussion, EPA will ask the Board to respond to specific science and ethics questions focused on the research identified below.

*Rosenheck, L. (2021) A study for Measurement of Potential Dermal and Inhalation Exposure During Antimicrobial Applications Involving Immersion, Dip, and Soak. Sponsored by the Antimicrobial Exposure Assessment Task Force II. Study Number AEA12, 1133 pages. May 5, 2021. MRID 51588901.*

EPA has reviewed this completed study report submission that presents the results of research conducted "to measure the potential dermal and inhalation exposure to consumers and/or professional workers who conduct manual immersion/dipping/soaking (IDS) of articles, equipment, and/or utensils into solutions containing an antimicrobial to sanitize hard surfaces" (p. 13). The study had three distinct scenarios for assessing exposures: bucket and rag/sponge, 3-compartment sink, and clean-out-of-place (COP) tank. Subject monitoring for the bucket and rag/sponge scenario and the 3-compartment sink scenario occurred at three different facilities rented in Orlando, Florida between March 4, and March 31, 2019. Each of the facilities had a commercial 3-compartment sink and various surfaces that could be wiped. The facilities varied in size and layout. For the COP scenario, monitoring occurred between April 26 and May 4, 2019 at a single location in Madison, Wisconsin.

To measure exposure, subjects wore inner and outer dosimeters and an air sampling pump. For the bucket and rag/sponge and 3-compartment sink scenarios, the inner and outer dosimeter tops were short sleeved because the tasks involved immersing the hands and forearms into liquid. For the COP scenario, the dosimeter tops were long sleeved. All subjects wore long pants and their own footwear. Dermal exposure to the face and neck was measured by hand washes and face/neck wipes. Researchers also performed forearm washes to measure dermal exposure to subjects in the bucket and rag/sponge and 3-compartment sink scenarios. The study uses the term “monitoring event” (ME) to refer to a single subject’s one-day participation in the study. A total of 18 MEs per scenario, or 54 MEs total, were conducted under this study.

Scientific aspects of the research are assessed in terms of the recommendations of the EPA Guidelines Series 875. Ethical aspects of the research are assessed in terms of the standards defined by 40 CFR 26 subpart Q.

The HSRB reviewed the protocol for this research along with EPA’s reviews on October 23, 2018.

The charge questions for the HSRB’s consideration are provided below:

**Charge to the Board - Science:**

- Did the research in study AEA12 generate scientifically reliable data, useful for assessing the exposure of individuals who perform immersing, dipping, and/or soaking activities to sanitize hard surfaces?

**Charge to the Board - Ethics:**

- Does the available information support a determination that the research was conducted in substantial compliance with the requirements of 40 CFR part 26, subpart Q?

**Documents:** EPA is providing for HSRB review the following documents:

- a) EPA Science Review of AEATF II Immerse, Dip, Soak Study (AEA12) (dated September 20, 2021)
- b) Appendix A EPA Science Review Statistical Analysis
- c) Supplement to Appendix A
- d) SAS Code - EPA Science Review
- e) Excel spreadsheet – EPA Science Review
- f) EPA Ethics Review of AEATF II Immerse, Dip, Soak Study (AEA12) (dated September 16, 2021)
- g) AEATF II Submission – Immerse, Dip, Soak Study (AEA12) – **6 parts**
  - Part 1 – Pages 1-329
  - Part 2 – Pages 330-343
  - Part 3 – Pages 344-697
  - Part 4 – Pages 698-953
  - Part 5 – Pages 954-1056
  - Part 6 – Pages 1057-1133
- h) HSRB: Final report of the October 2019 HSRB meeting