



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

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

March 22, 2022

MEMORANDUM

SUBJECT: Materials for Review by Human Studies Review
Board for the April 26 Meeting

TO: Thomas Tracy
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 April 27, 2022. EPA will ask the Board to respond to specific science and ethics questions focused on the research identified below.

1) Completed Study: "A Study for Measurement of Potential Dermal and Inhalation Exposure During Pressurized Hand-Wand Spraying of Antimicrobial Products; Scenario 2b: Measurement of Potential Dermal and Inhalation Exposure During Indoor Electrostatic Spraying of Sanitizers and Disinfectants."

The Antimicrobial Exposure Assessment Task Force II (AEATF-II) submitted this study to the EPA. The EPA has reviewed this study report and associated documents for measuring dermal and inhalation exposure to workers using electrostatic sprayers to sanitize indoor spaces from both scientific and ethics perspectives. 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 subparts K and L. The protocol for this completed study was previously reviewed by the EPA and the Human Studies Review Board (HSRB) under the larger hand-wand sprayer study protocol for ethical and scientific design June 22, 2020, and July 21-22, 2020, respectively. This ESS study is only one of the scenarios from the larger hand-wand study (i.e., Scenario 2b: ESS). The other

scenarios within the hand-wand study will be completed and submitted to the EPA at a later date. The HSRB agreed with the EPA's assessment that the research proposed would result in a scientifically and ethically valid study, provided the EPA's and the HSRB's recommendations were addressed prior to the initiation of the research.

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

Charge to the Board - Science:

- Did the research summarized in "A Study for Measurement of Potential Dermal and Inhalation Exposure During Pressurized Hand-Wand Spraying of Antimicrobial Products; Scenario 2b: Measurement of Potential Dermal and Inhalation Exposure During Indoor Electrostatic Spraying of Sanitizers and Disinfectants" generate scientifically reliable data, useful for assessing the exposure of those who apply antimicrobial pesticides using electrostatic sprayers?

Charge to the Board - Ethics:

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

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

- a) Study Report "A Study for Measurement of Potential Dermal and Inhalation Exposure During Pressurized Hand-Wand Spraying of Antimicrobial Products; Scenario 2b: Measurement of Potential Dermal and Inhalation Exposure During Indoor Electrostatic Spraying of Sanitizers and Disinfectants"
Note: This will come as 5 files due to the size of the report. They will be numbered a1 – a5.
- b) AEATF Worker Reminder Checklist for Scenario 2b
- c) EPA draft science review: "Science Review of the AEATF II Scenario 2b: Electrostatic Spray (ESS) Human Exposure Monitoring Study (AEATF II Project ID AEA14; MRID 51707701)"
- d) EPA Appendix A ESS Statistical Review
- e) EPA Supplement to Appendix A Statistical Review
- f) EPA draft ethics review: "Ethics Review of Electrostatic Sprayer Scenario 2b of AEATF II Study (AEA14)"
- g) July 20-22, 2020 EPA HSRB Meeting Report