



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

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

September 27, 2018

MEMORANDUM

SUBJECT: Materials for Review by Human Studies Review Board for the October 23, 2018 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 23, 2018. EPA will ask the Board to respond to specific science and ethics questions focused on the research identified below.

- Protocol submitted by the Antimicrobial Exposure Assessment Task Force II (AEATF II) titled "A Study for Measurement of Potential Dermal and Inhalation Exposure During Antimicrobial Applications Involving Immersion, Dip, and Soak" (AEA12)

This protocol proposes to evaluate potential dermal and inhalation exposure to consumers and/or occupational workers during the sanitizing of surfaces and equipment using an antimicrobial product in the following three scenarios: (1) bucket & sponge/rag, (2) 3-compartment sink, and (3) Clean-Out-of-Place (COP). EPA has reviewed the protocol from both scientific and ethics perspectives. Scientific aspects of the proposed research are assessed in terms of the recommendations of the EPA Guidelines Series 875 and of the EPA Human Studies Review Board. Ethical aspects of the proposed research are assessed in terms of the standards defined by 40 CFR 26 subparts K and L and the recommendations of the EPA Human Studies Review Board.

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

Charge to the Board - Science:

- Is the protocol ““A Study for Measurement of Potential Dermal and Inhalation Exposure During Antimicrobial Applications Involving Immersion, Dip, and Soak” likely to generate scientifically reliable data, useful for assessing the exposure of those who use products containing antimicrobial pesticides for sanitizing surfaces and equipment?

Charge to the Board - Ethics:

- Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

Documents for Review

The documents provided to the HSRB for review are listed below. EPA appreciates the HSRB members taking the time to review these materials in advance of the October 25-26, 2017 HSRB meeting.

1. EPA Science and Ethics Review of AEATF II Immersion/Dip/Soak Scenario Design and Protocol for Exposure Monitoring (dated September 27, 2018)
2. Volume 1: AEATF-II Immersion/Dip/Soak Protocol Submission
 - Transmittal Letter
 - 40 CFR 26.1125 Checklist
 - Immersion/Dip/Soak Study Design Document (Study Number AEA12): Rationale for Study Design
3. Volume 2: AEATF-II Immersion/Dip/Soak Protocol Submission
 - Study Protocol Dated 7/13/18 - Approved 7/18/19
 - Approved Bucket and Rag/Sponge Informed Consent Form Version 7/25/17 – Approved 7/25/18
 - Approved COP Tank Informed Consent Form Version 7/25/17 – Approved 7/25/18
 - Approved 3-Compartment Sink Informed Consent Form Version 7/25/17 – Approved 7/25/18
 - Approved Recruitment/Study-Related Materials – Approved 7/18/18
 - Advarra IRB Protocol Approval Letter (Dated 7/20/18)
 - Advarra IRB ICFs Approval Letter (Dated 7/26/18)
4. Volume 3: AEATF-II Immersion/Dip/Soak Protocol Submission
 - Records of Advarra IRB Review of Study AEA12 and Correspondence
 - Advarra IRB Meeting Minutes
5. Volume 4: AEATF-II Immersion/Dip/Soak Protocol Submission
 - CVs and Ethics Training Records
 - SOPs Referenced in AEA12 Protocol