



## OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

September 9, 2025

### **MEMORANDUM**

**SUBJECT:** Materials for Review by Human Studies Review Board for the October 14-16 Meeting

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

**TO:** Tom Tracy  
Designated Federal Official  
Human Studies Review Board  
Office of Science Advisor

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 virtual meeting scheduled for October 14-16, 2025. During this meeting, EPA will ask the Board to respond to specific science and ethics questions focused on the research identified below.

Russell R. (2025) Mancozeb: Liquid Spray On-Farm Potato Seed Treatment Study to Determine Dermal and Inhalation Exposure of Workers to Mancozeb during the On-Farm Treating, Loading, and Planting of Treated Potato Seed Pieces, unpublished protocol dated May 13, 2025, prepared for UPL NA, Inc., 73 p.

EPA has reviewed the referenced protocol titled *"Mancozeb: Liquid Spray On-Farm Potato Seed Treatment Study to Determine Dermal and Inhalation Exposure of Workers to Mancozeb during the On-Farm Treating, Loading, and Planting of Treated Potato Seed Pieces"* as well as *"Overview and Justification For New Mancozeb Handler Exposure Study Scenarios"* submitted by UPL Limited to determine if the protocol meets requirements based on current guidelines. The study's protocol was submitted to EPA in June 2025. This protocol is intended to collect occupational exposure measurements (dermal and inhalation) to represent potential exposures to mancozeb for three handler scenarios related to "on-farm" liquid pesticide treatment<sup>1</sup> of potato seed pieces (PSPs) and

---

<sup>1</sup> Seed treatment can be conducted commercially or 'on-farm'. Commercial seed treatment is a much larger-scale operation of treating and storing seeds while on-farm treated seeds are generally loaded and planted directly after treatment (although short-term storage is sometimes necessary).

provide more representative exposure data for these on-farm activities, according to the protocol. The following scenarios are to be addressed in the study:

- (1) Treating PSPs on-farm with a liquid spray (T-PSP-L-OF),
- (2) Loading treated PSPs on-farm into a multi-row potato planter (L-PSP-OF), and
- (3) Planting treated PSPs (P-PSP-OF).

Scientific aspects of the proposed research are assessed in terms of the recommendations of the EPA Series 875 Guidelines and of the Human Studies Review Board (HSRB). Ethical aspects of the proposed research are assessed in terms of the standards defined by 40 CFR 26 subparts K and L.

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

**Charge to the Board - Science:**

- Is the protocol "Mancozeb: Liquid Spray On-Farm Potato Seed Treatment Study to Determine Dermal and Inhalation Exposure of Workers to Mancozeb during the On-Farm Treating, Loading, and Planting of Treated Potato Seed Pieces" likely to generate scientifically reliable data, useful for estimating and assessing the exposure of those who conduct on-farm potato seed treatment, loading, and planting?

**Charge to the Board - Ethics:**

- If amended to address the EPA's and the HSRB's recommendations, 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.

**Submission to EPA**

- 1a. Mancozeb Protocol Dated May 13 2025 Testing Facility Number LR25237
- 1b. UPL NA Inc. Overview and Justification For New Mancozeb Handler Exposure Study Scenarios June 11 2025
- 1c. Advarra IRB Correspondence submission and emails
- 1d. Advarra IRB Correspondence file documents
- 1e. Main Informed Consent Form Advarra IRB Approved Version 6 Jun 2025
- 1f. Telephone Screening Script Employer Farm Telephone Script \_ Screening Dated 13 May 2025
- 1g. Telephone Screening Script Potential Volunteer Participant Telephone Script \_ Screening Dated 13 May 2025
- 1g. Telephone Screening Script Potential Volunteer Participant Telephone Script \_ Screening Dated 13 May 2025
- 1i. Flyer\_poster\_or bulletin board\_Research Study Volunteers Needed\_Dated 13 May 2025
- 1j. Research Participants Bill of Rights Dated 13 May 2025

EPA documents

2. Draft EPA Science and Ethics Review of Mancozeb Seed Treatment Protocol\_August 2025

Additional materials

3. AHETF Governing Document Appendix C - August 2010