



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

OFFICE OF CHEMICAL  
SAFETY AND POLLUTION  
PREVENTION

September 3, 2024

**MEMORANDUM**

**SUBJECT:** Materials for Review by Human Studies Review  
Board for the October 9-11, 2024 Meeting

**TO:** Tom Tracy  
Designated Federal Official  
Human Studies Review Board  
Office of Research and Development

**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 virtual meeting scheduled for October 9-11, 2024. During this meeting, EPA will ask the Board to respond to specific science and ethics questions focused on the research identified below.

**Thouvenin, I, Bouneb, F, Mercier, T. Operator dermal exposure and individual protection provided by personal protective equipment during application using a backpack sprayer in vineyards. Journal of Consumer Protection and Food Safety. (2016) 11:325-336. DOI: 10.1007/s00003-016-1049-z**

The study was conducted monitor agricultural handlers' dermal exposure when applying fungicides using a backpack fogger in vineyards and to evaluate the effectiveness of the personal protective equipment (PPE) worn by the applicators. The study was conducted in France and funded by ANSES, the French agency for food, environmental, and occupational health and safety. A total of 10 male applicators were enrolled in the study: 4 individuals who worked for a vine growing farm and 6 individuals from a contract application company. The applicators used their own equipment and engaged in their normal application practices. Applicators wore two dosimeters – an inner dosimeter, which was a 2-piece cotton garment, and an outer dosimeter, which was a coverall. Hand exposure was measured through a standard hand wash procedure,

conducted at times the applicator would normally wash their hands and at the end of the day. Applicators also wore gloves, which were collected and analyzed. Head exposure was measured through analysis of the coverall hood and a bandana worn on the head (at the applicator's discretion).

EPA is proposing to use the data in the publication for assessing exposure and risk to individuals mixing, loading, applying any formulation using handheld fogger/mister equipment in agricultural settings. The data may be used in regulatory assessments of occupational exposure.

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

**Charge to the Board - Science:**

- Does the research described in the published study "*Operator dermal exposure and protective factors provided by personal protective equipment during foliar application using backpack sprayer in vineyards*" (I. Thouvenin, et al., 2016) provide scientifically reliable data for assessing the exposure of workers mixing, loading, and/or applying liquid solutions using motorized handheld fogger/mister equipment?

**Charge to the Board - Ethics:**

- Does available information support a determination that the conduct of the research was not fundamentally unethical?
- Does available information support a determination that the research was not deficient relative to the ethical standards prevailing at the time the research was conducted or conducted in a way that placed participants at increased risk of harm or impaired their informed consent?

**Documents for Review**

The documents provided for the HSRB are listed below.

- 1a. Thouvenin et al. France ANSES vineyard worker
- 1b. EPA Handheld Fogger Review HSRB Draft Final
- 1c. Thouvenin et al. Vineyard Worker Handheld Fogger Sprayer Ethics Review Draft Final
- 1d. OECD Guidelines for Worker Exposure Studies 1997