



## BEYOND PESTICIDES

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February 28, 2007

Office of Pesticide Programs (OPP)  
Regulatory Public Docket (7502P)  
Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460-0001

**Re: Chloropicrin Risk Assessments (EPA-HQ-OPP-2006-0661)**

Beyond Pesticides appreciates the opportunity to comment on the chloropicrin risk assessments. Beyond Pesticides' interest in this issue lies in our mission to seek to restrict pesticide use in a manner that protects public health and the environment, and advance alternatives that eliminate dependency on toxic chemicals.

***Beyond Pesticides requests EPA reject data obtained through human testing.*** EPA states the Human Studies Review Board (HSRB) "concluded that there was not clear and convincing evidence that that conduct of the research was either fundamentally unethical or significantly deficient relative to the ethical standards prevailing when the study was conducted."<sup>1</sup> This HSRB conclusion is false.

The study *does not* meet the ethical standards prevailing at the time it was conducted. The Nuremberg Code has been a fundamental international standard for over half a century. The second article the Code lists, after informed consent, is that for an experiment that uses human subjects to be ethical, "The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature."<sup>2</sup>

Consider EPA's own characterization of the human irritation study for chloropicrin: "Responses of participating subjects are consistent with symptoms reported from public health data. Specifically individuals exposed to the agricultural use of chloropicrin typically complain of lacrimation, irritation to throat, headache, coughing, and difficulty breathing."<sup>3</sup>

EPA has accepted data from a human study that caused intentional harm to its subjects by a chemical described as "the major toxic gas used in WWI." When asked if

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<sup>1</sup> EPA. Human health risk assessment. EPA-HQ-OPP-2006-0661-0003

<sup>2</sup> National Institutes of Health, Office of Human Subjects Research. Nuremberg Code. <http://ohsr.od.nih.gov/guidelines/nuremberg.html>

<sup>3</sup> EPA. Human health.

there was an alternative to human dosing, EPA stated to HSRB that, “chloropicrin does have a solid animal toxicity data base.”

The study intentionally exposed human subjects, using a “walk-in chamber” for two of three research phases, to a toxic chemical, for data that offers no societal benefit, was indeed procurable by other methods and was unnecessary.<sup>4</sup> This is fundamentally unethical.

Beyond Pesticides continues to be extremely alarmed that EPA has not evidenced a procedure or protocol for evaluating the societal benefits of pesticides that are tested on humans with results utilized in risk assessments for pesticide registration or reregistration. In this context, chloropicrin human data violates national and international standards.

***Beyond Pesticides also requests, at a minimum, EPA restore uncertainty factors to uncompromised levels for all exposure scenarios.*** Clearly, the rejection of the human testing data dictates that the interspecies uncertainty factor must be reestablished to at least 10X. We also request EPA reestablish the FQPA factor of 10X due to potential bystander exposure. EPA did not deem the FQPA factor necessary. However, spray drift and other agricultural uses of chloropicrin may result in exposure of sensitive populations, such as pregnant women and children.<sup>5</sup>

In conclusion, Beyond Pesticides requests EPA reject human testing data for chloropicrin on the grounds that the study is fundamentally unethical, and requests EPA restore uncertainty factors to protective levels.

Sincerely,

Laura Hepting  
Special Projects Coordinator

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<sup>4</sup> EPA. Minutes of the Human Studies Review Board Meeting, June 27-30, 2006. EPA-HQ-ORD-2006-0384

<sup>5</sup> Sass, J. NRDC Comments on Chloropicrin Risk Assessments (Phase 3), February 28, 2007.