November 25, 2013

Ms. Carolyn Schroeder
Chloropicrin Chemical Review Manager
Pesticide Re-Evaluation Division (7508P)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave. NW.,
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Dear Ms. Schroeder,

We are writing in regards to Docket # EPA-HQ-OPP-2013-0153, the start of the Registration Review process for chloropicrin. Thank you for the opportunity to comment.

In brief, we provide in this letter new information from the work done in California under the Toxic Air Contaminant (TAC) program on chloropicrin, as well as air monitoring work that Pesticide Action Network North America (PANNA) and Pesticide Research Institute (PRI) have done (see Attachments B and C). This new information indicates US EPA's current risk assessment of chloropicrin is not sufficiently health protective. During the TAC review of chloropicrin, concerns were raised by an external scientific peer review committee and the California Department of Pesticide Regulation (DPR) toxicologists regarding US EPA's selection of both acute and chronic endpoints, the carcinogenicity of chloropicrin, and the methodology used to assess bystander exposure. The fact remains that that multiple poisoning events have occurred in California as a result of soil fumigant uses of chloropicrin. The imposition of 25–100 foot buffer zones (such as those recently mandated by US EPA) would not have prevented these incidents and is not sufficient to prevent even acute bystander poisonings, not to mention chronic effects such as respiratory illness and cancer. These issues are even more problematic for workers who apply fumigants, conduct tarp removal, and work in fields adjacent to fumigation sites. In light of the new California risk assessment and peer review, it is time for US EPA to take a serious look at whether chloropicrin can be used at all in close proximity to areas where people spend time. The data already in hand indicate that if the risk assessment is done using a scientifically valid approach, EPA will find that chloropicrin cannot be used safely, and should be cancelled.

In February 2010, DPR released a two-part report entitled "Evaluation of Chloropicrin as a Toxic Air Contaminant," in which DPR's scientific staff evaluated the exposure potential and human health risks from bystander exposure to chloropicrin from its use as a soil fumigant, in greenhouses, and as a warning agent in structural fumigations.[1] Following review by the California Office of Environmental Health Hazard Assessment (OEHHA), and the Toxic Air Contaminant Scientific Review Panel (SRP), DPR proposed on April 15, 2010 to list chloropicrin as a toxic air contaminant.[2] DPR issued a final regulation listing chloropicrin as a toxic air contaminant on December 9, 2010, effective January 8, 2011.[3]

When chloropicrin was evaluated as a Toxic Air Contaminant, the toxicologists from DPR who wrote the Human Health Risk Assessment,[4] the OEHHA scientists,[5] and the Scientific Review Panel[6] who peer reviewed it all concluded that chloropicrin is a potent carcinogen with a low threshold for acute eye and respiratory irritation, recommending an 8–24 hr acute Reference Concentration (RfC) of 2.7 ppb and a unit inhalation lifetime cancer risk value of 0.24 parts per *trillion* (ppt). A comprehensive chloropicrin risk assessment completed by DPR toxicologists in 2012 reaffirmed DPR scientists' conclusion that chloropicrin is a carcinogen and severe irritant.[7]

The California peer review and scrutiny of US EPA's chloropicrin Reregistration Eligibility Decision (RED) by DPR and OEHHA brought to light a number of inadequacies in US EPA's initial risk assessment for chloropicrin. As a result, several of the foregone conclusions in the Registration Review scoping document need to be reconsidered. In particular:

1) **Levels of concern must be reevaluated:** US EPA needs to reevaluate the points of departure (PODs) and uncertainty factors (UFs) used for the residential and occupational exposure assessments. The acute level of concern of 73 ppb averaged over 8 hours is not sufficiently protective, a point that was clearly made in the California review and by US EPA's Human Subjects Review Panel. Since chloropicrin has short-term irritant properties, the acute level of concern is also relevant for short-term exposures, as recognized by DPR in their Risk Characterization document.

2) **The bystander exposure assessment must be re-done:** The Office of Pesticide Programs should eliminate any use of the "whole field" method of exposure assessment that averages concentrations and results in substantially underestimated exposure predictions. The "maximum direction" method used by CDPR should be utilized instead because it provides a more realistic estimate of worst-case (but very common) bystander exposures downwind from a fumigation application. In addition, the ISCST3 model on which PERFUM is based is out of date, and US EPA's Office of Air and Radiation indicates that the current preferred models for atmospheric exposure assessments are either AERMOD or CALPUFF. These models will better handle calm wind conditions.

3) **The carcinogenicity of chloropicrin must be reevaluated:** Significant concerns were raised by the DPR toxicologists, OEHHA toxicologists, and the SRP members regarding the carcinogenicity of chloropicrin. DPR management's classification of chloropicrin carcinogenicity as "equivocal" is in contradiction to the conclusions reached by DPR and OEHHA scientists and the SRP, a point we discuss at greater length below. For the chloropicrin reregistration, US EPA did not conduct an assessment of the carcinogenicity of chloropicrin stating that:

   " . . . chloropicrin is currently not considered a carcinogen by the inhalation route of exposure since there is no evidence of increased tumorigenesis after chronic inhalation exposure."

   This is incorrect. There is substantial evidence of carcinogenicity from less-than-lifetime mouse and rat inhalation studies. Less-than-lifetime studies are well known to have reduced sensitivity for determining the statistical significance of observed effects. In

consideration of the fact that mutagenicity studies and a number of oral-dose animal studies provide data indicating that chloropicrin is a potent carcinogen, US EPA must reevaluate its carcinogenicity. Because the existing studies were so poorly conducted, it may be necessary for US EPA to call in an additional lifetime inhalation cancer study.

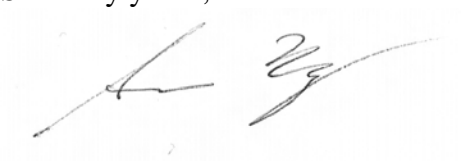
4) **Chloropicrin cannot be used safely—it should not be re-registered. However, if EPA allows its continued use, buffer zones will need to be reevaluated:** Based on changes in 1), 2) and potentially 3) above, buffer zones will need to be recalculated, and mitigations to protect handlers will need to be reassessed to be protective of human health. However, we think it is likely that mitigations that would prevent unreasonable adverse effects on human health or the environment will not prove possible, let alone practical, so chloropicrin re-registration will not be supportable.

5) **Fumigant use is costly in many ways, and promising alternatives are available:** Fumigations are expensive, with many of the costs externalized to neighbors and farm workers. California is aggressively pursuing alternatives to fumigants, with encouraging results. US EPA BEAD should evaluate these methods when they do their economic risk/benefit assessment for the use of chloropicrin.

6) **The risk assessment results need to be more clearly communicated:** The 2009 US EPA Reregistration Eligibility Decision (RED) document for chloropicrin is poorly written, with important terms and abbreviations left undefined, and substantial inaccuracies in the summaries of the toxicology studies. In particular, US EPA does not even provide a term for concentrations of concern. It is important to include such a term to provide language for discussing the risk assessment. In the past, EPA has called these regulatory endpoints Reference Concentrations (RfCs), and in 2002, EPA Office of Research and Development (ORD) suggested new language for use in labeling endpoints and regulatory target concentrations that more clearly defines exposure route and duration.[8] We urge EPA to adopt ORD's suggested language and clean up the risk assessment in order to clearly communicate the science.

We expand on these five topics in greater detail in the following pages and urge US EPA to carefully consider the points raised. In light of the new California risk assessment and peer review, it is time for US EPA to take a serious look at whether chloropicrin can be used at all in close proximity to areas where people spend time. We are confident that, if the risk assessment is conducted with careful attention to scientific integrity and public health protection, EPA will find that chloropicrin cannot be used safely, and should be cancelled.

Sincerely yours,



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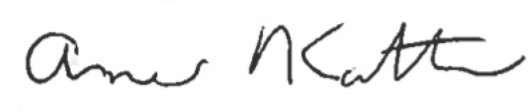

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