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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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Re: Chlorpyrifos petition dated September 12, 2007

Dear Mr. Colangelo and Dr. Reeves:

I am writing to provide you with an update on the U.S. Environmental Protection Agency's (EPA) plans for further responding to the petition dated September 12, 2007 (Petition), submitted jointly by the Natural Resources Defense Council (NRDC) and Pesticide Action Network North America (PANNA). The petition specifically requested that EPA revoke all tolerances and cancel all registrations for the insecticide chlorpyrifos.

As you are aware, in a letter dated July 16th of this year, EPA provided you with a partial response to six of the 10 claims raised in the petition and outlined its intended approach for completing work on the remaining four claims. At the same time, EPA partially granted your petition with its response to one part of your inhalation exposure risk claim, announcing that EPA was taking action to address risks from primary spray drift by limiting application rates and imposing buffer zones around sensitive sites adjacent to agricultural applications. I am pleased to announce that registrants have submitted draft amended labels for all agricultural use products to implement these additional use limitations. EPA anticipates its approval of these 41 amended labels by December 31, 2012.

In the partial response, we also informed you that EPA intended to provide its written response to the remaining issues by December 2012. We noted that it was our intention that the response be informed by the recommendations of the July 2012 FIFRA Scientific Advisory

Panel (SAP or Panel) report[1] that addressed issues relevant to three of petitioners' remaining four claims -- that EPA failed to quantitatively incorporate data exhibiting long-lasting effects from early life exposure to chlorpyrifos in children; that EPA disregarded data demonstrating that there is no evidence of a safe level of exposure during pre-birth and early life stages; and that EPA failed to cite or quantitatively incorporate studies and clinical reports suggesting potential adverse effects below 10% cholinesterase inhibition. Further, we also noted in the partial response that our work on the volatilization component of the fourth remaining claim (inhalation exposure) was also ongoing and would be impacted by the results of the SAP report. However, because EPA had just received the SAP report prior to the release of the partial response, EPA had not completed its review of the SAP's recommendations at that time. Thus, the extent and nature of the work necessary to address those recommendations was an uncertainty.

The recent SAP report contained several recommendations which require additional analyses by EPA to address the toxicology issues raised in your petition. Specifically, the SAP recommended that EPA conduct a dose reconstruction analysis of potential exposures to women and children studied in the Columbia University-sponsored epidemiology study[2] as an approach to aid in assessing the degree to which individuals in the cohort may or may not have experienced acetylcholinesterase inhibition. In addition, the Panel recommended that additional analyses of the epidemiological data be conducted, particularly in the areas of biological marker of exposure data and multi-chemical exposures.

EPA has made progress on the dose reconstruction analysis. However, the analysis of the biomarker of exposure data and evaluation of the multi-chemical exposures suggested by the Panel necessitate that EPA obtain the raw data from the epidemiology study. At this time, EPA only has access to summary information provided by the publications, but has been working to obtain the original data from the study authors to conduct the needed analyses.

Two additional considerations have necessitated further analysis of the toxicology issues raised in your petition. First, members of the Panel expressed concern during the oral deliberations that scientific experts in diagnostic and analytic tools, like those used to assess neuro- and motor development of the children in the epidemiology studies, were not included on the Panel. Second, after the SAP was held, a new epidemiology study from the Columbia University researchers describing the results of magnetic resonance imaging (MRI) on a subset of children in the cohort was published. Between August 2012 and October 2012, EPA solicited comments from scientists within the federal government who have expertise in these two scientific areas and is currently evaluating this input.

With respect to the volatility of chlorpyrifos, EPA has reviewed a new field volatility study recently submitted by Dow AgroSciences in response to the data call-in requirements for the chlorpyrifos registration review. EPA is currently working to complete its assessment of the

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[1] Available at http://www.epa.gov/scipoly/sap/meetings/2012/april/041012minutes.pdf

[2] Rauh, V., Arunajadai, S., Horton, M., Perera, F., Hoepner, L., Barr, D. B., & Whyatt, R. (2011). Seven-year neurodevelopmental scores and prenatal exposure to chlorpyrifos, a common agricultural pesticide. Environ Health Perspect, 119(8), 1196-1201. doi: 10.1289/ehp.1003160; Rauh, V. A., Garfinkel, R., Perera, F. P., Andrews, H. F., Hoepner, L., Barr, D. B., Whyatt, R. W. (2006). Impact of prenatal chlorpyrifos exposure on neurodevelopment in the first 3 years of life among inner-city children. Pediatrics, 118(6), e1845-1859. doi: 10.1542/peds.2006-0338.

potential risks associated with volatilization from chlorpyrifos applications. The scope and content of this on-going assessment is informed by recent risk assessments of field volatility of fumigant pesticides[3], Dow AgroSciences' recently submitted chlorpyrifos field volatility study coupled with existing volatility data found in the open literature, EPA modeling tools, and the report and recommendations from the 2009 SAP meeting[4] on pesticide volatilization where chlorpyrifos was one of the case studies presented.

While EPA has been working diligently, as outlined in the preceding paragraphs, and has made significant progress in addressing the recommendations of the SAP and completing our response to all four remaining claims in your petition, EPA will not be in a position to provide a complete response to the petition this month, as we previously believed. EPA currently intends to provide a further response to the petition by the end of January 2013 that will address some, but likely not all, of the four remaining claims. To the extent certain issues remain unaddressed, the January 2013 response will explain the additional work we will be doing and will set forth our anticipated timeline for completing the response.

Steven P. Bradbury, Ph.D.
Director, Office of Pesticide Programs

[3] The assessments can be found in the dockets for each fumigant. Four of which are provided here chloropicrin - EPA-HQ-OPP-2007-0350; dazomet - EPA-HQ-OPP-2005-0128; metam sodium/potassium - EPA-HQ-OPP-2005-0125; and methyl bromide - EPA-HQ-OPP-2005-0123.

[4] Available at http://www.epa.gov/scipoly/sap/meetings/2009/december/120309meetingminutes.pdf.