Dow AgroSciences LLC
9330 Zionsville Road, Bldg 308/2B
Indianapolis, Indiana 46268

July 20, 2011

EPA-HQ-OPP-2008-0850
Submitted via www.regulations.gov

Mr. Richard P. Keigwin, Jr., Director
Pesticide Re-Evaluation Division (PRD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

PRELIMINARY HUMAN HEALTH RISK ASSESSMENT FOR CHLORPYRIFOS:
REQUEST FOR EXTENSION OF REGISTRATION REVIEW PUBLIC COMMENT PERIOD

Dow AgroSciences (DAS) is requesting extension of the public comment period for the preliminary human health assessment for chlorpyrifos, which was recently released by EPA as part of its Registration Review program. A portion of the assessment was posted to the EPA website on July 1. The assessment summary and most supporting science assessment memos were posted to the Federal Docket (EPA-OPP-HQ-2008-0850) on July 6, 2011. Copies of supporting appendices were posted to the Federal Docket on July 15, 2011. In association with the July 6 posting, EPA indicated (76 Fed. Reg. 39400, 2011) that it was opening a 60-day public comment period on the preliminary human health assessment to close on September 6, 2011. **We are respectfully requesting a 60-day extension of the public comment period** so that comments may be accepted through November 6, 2011. We believe this request is justified and reasonable in view of the need to ensure a sound scientific approach and to maintain the integrity of the Agency's Registration Review process. Adequate time is needed for the EPA preliminary assessment to be thoroughly reviewed and for useful comments to be developed and submitted. A 60-day comment period would deprive DAS and other critical stakeholders of the necessary time required to construct the most thoughtful and cogent comments for the benefit of the EPA. Our rationale for this requested extension is described below.

More than 60 days is required for review and comment on detailed scientific assessments such as this. EPA announced Registration Review as a process that would emphasize sound science and be characterized by a high degree of transparency and public participation. During the first two years of the program, the Agency allotted a 90-day public comment period when dockets were opened and preliminary work plans were released (Phase I). During March of 2009, EPA indicated it was truncating the comment periods under Registration Review to a uniform 60-days, based on experience during the first two years. However, DAS would like to point out the tremendous difference between the materials being released for review and comment as part of Phase I Registration Review (i.e., a couple of 20-30 page science scoping documents and a work plan summary memo and fact sheet) and the detailed and extensive scientific assessments released as part of Phase II. For example, the "chlorpyrifos preliminary human health assessment" released by EPA includes more than 1200 pages of detailed scientific text distributed among 8 different assessment documents and their associated appendices. Thus, although 60 days may be a sufficient period for public comments on the few details included in a preliminary work plan,

significantly more time is necessary to allow the public to digest the voluminous details released as part of a comprehensive human health assessment. EPA has devoted significant resources and much time to reach this milestone. It would be very unfortunate if the Agency were to receive rushed, ill-conceived, and poorly constructed comments in view of EPA's detailed and complex analysis.

The preliminary chlorpyrifos human health assessment includes complex issues and application of precedent-setting policies requiring extensive study and evaluation. Not only is the chlorpyrifos assessment the first substantive human health assessment prepared as part of the Registration Review program but, as EPA has indicated on its website, this is a "complex and refined chemical assessment". Scientifically challenging human health assessment issues and methodologies for chlorpyrifos have been the subject of two meetings of EPA's Scientific Advisory Panel (September of 2009; February of 2011). There are pending human health assessment methodologies and science policies that EPA will be first applying to chlorpyrifos that will have important ramifications for all pesticides to follow in Registration Review. These include methodologies for estimation of bystander inhalation exposures (December 2009 SAP), consideration of epidemiology studies as a factor in the "weight of evidence" for risk assessment purposes (February 2010 SAP), and application of EPA's revised risk assessment methods for workers (EPA-HQ-OPP-2009-0889-0002). The public and the scientific community clearly need adequate time to consider the complex issues involved with EPA's chlorpyrifos human health risk assessment as well as the precedent-setting application of these new methodologies and science policies.

EPA has taken far more time to prepare the assessment than anticipated, and the public requires adequate time to review the assessment. Per the EPA Registration Review "final work plan" for chlorpyrifos of September 2009, the assessment was supposed to be prepared and released for public comment during July-September, 2010. This did not occur. Subsequently, EPA announced during December 2010 that it would produce the preliminary assessment for public comment no later than June 1, 2011. This also did not occur. The publication by EPA of draft assessment documents on July 6 and 15, 2011, one year later than originally scheduled, serves as an indicator of the complex nature of the assessment and the difficulties experienced by Agency scientists in preparing this comprehensive and complex assessment. Since EPA took significantly longer than originally scheduled to produce this draft assessment, presumably due to unforeseen difficulties and complexities, it is only logical that the public be given a reasonable amount of time to provide meaningful comments on the assessment.

EPA has allotted significant comment period extensions for other precedent-setting risk assessments associated with Registration Review. During 2009, EPA allotted 120-day comment periods (including 60-day extensions) for both the fomesafen and clomazone preliminary environmental risk assessments released as part of Registration Review. Although the Agency offered no rationale for extending these comment periods (Federal Register Vol. 74, No. 115, page 28698), presumably the fact that these were the first substantive environmental risk assessments released as part of Registration Review played an important role in the decision to grant the extensions requested by the registrants. If EPA considered it important to provide an extended comment period for consideration of the first substantive *environmental* assessments prepared for Registration Review, EPA should also be willing to provide an extended comment period for the first substantive *human health* assessments.

Chlorpyrifos is one of the most important pesticides in U.S. agriculture and many stakeholders are affected. Chlorpyrifos is recognized as one of the most important insecticides for agricultural pest management in the U.S. and there are limited alternatives for some key crops and pests. Many U.S. growers have a stake in the outcome of this assessment and need an opportunity in the middle of a busy growing season to study the EPA documents and provide meaningful inputs. EPA has publicly stated its disappointment in both the quality and quantity of public comments submitted in response to Registration Review dockets. Allowing ample time for growers and other stakeholders to examine the detailed Agency documents will increase the utility of submitted comments for aiding EPA's efforts at preparing a refined, finalized assessment.

The EPA assessment should not be rushed to completion based on litigation or threats from anti-pesticide advocacy organizations. EPA has displayed an unusual degree of deference to the needs and desires of pesticide opponents who have petitioned and sued the Agency in an attempt to influence the Registration Review program for chlorpyrifos. Based on these external pressures, the EPA final Registration Review work plan of September 2009 included an unusual and highly accelerated schedule for development of the human health assessment. During December of 2010, the Agency entered into a settlement agreement with these parties and placed the human health assessment on an accelerated schedule, thus potentially compromising what must ultimately be an unbiased, science-based, and transparent regulatory process. Limiting time for public comment on the preliminary human health assessment is inconsistent with the general principles of regulation expressed by President Obama in his Executive Order, *Improving Regulation and Regulatory Review*, which clearly states that the U.S. regulatory system must allow for public participation and an open exchange of ideas, EPA's Office of Pesticide Programs should not allow threats or lawsuits from anti-pesticide advocates to push a final risk assessment or regulatory decision without allowing ample time for public review and comment. Rather, EPA should seek a balance among the interests of anti-pesticide advocates, agricultural stakeholders, registrants, academic scientists, and the general public, by providing adequate time for review and comment by all parties.

Thank you for your consideration of this urgent request for extension of the public comment period for the preliminary human health assessment for chlorpyrifos.

Sincerely,

Kenneth D. Racke, Ph.D.
Regulatory Manager – U.S. Regulatory
(317) 337-4654
kracke@dow.com

cc: Steven Bradbury, OPP, Office Director
Jack Fowle, OPP/HED, Deputy Division Director
Mary Manibuson, OPP/PRD/RMIB II, Branch Chief
Tom Myers, OPP/PRD/RMIB II, Team Leader