

Dow AgroSciences Responds to EPA's Preliminary Chlorpyrifos Human Health Assessment:

Screening-Level Models and Lack of Reliance on Real-World Data Result in Unrealistic Projections of Risk from Drinking Water Exposures

In a detailed, 900-page response to EPA's preliminary chlorpyrifos human health assessment (submitted October 5), Dow AgroSciences notes significant areas in which the current EPA assessment represents an advance over human health assessments of chlorpyrifos completed by the Agency in the past.

It also notes important areas of the preliminary chlorpyrifos human health assessment that EPA has not yet completed and made available for stakeholder review and comment. It is essential that stakeholders be given opportunity to review and comment on EPA methods and conclusions in these areas.

Finally, Dow AgroSciences details areas where unrealistic assumptions, failure to rely on real-world data and over-reliance on screening-level models have significantly skewed the Agency's hazard and exposure estimates, greatly exaggerating projected risks.

Improvements Noted Since Last Assessment in 2000

- Based on new, state-of-the-art guideline research, EPA has established revised regulatory endpoints that fully account for all sensitive lifestages. This research has resolved an area of uncertainty from past reviews by confirming that young animals are not significantly more sensitive than adults at environmentally relevant doses.
- Consistent with this new understanding, EPA has made the appropriate science-based decision to reduce the chlorpyrifos Food Quality Protection Act (FQPA) uncertainty factor from 10x to 1x.
- Moreover, based on air monitoring data made available since the last assessment, EPA has determined that neighbors and bystanders face no substantive risk from inhalation exposures resulting from authorized chlorpyrifos uses.

Several Key Sections of the Assessment Remain Incomplete

- EPA has not yet completed its planned weight-of-the-evidence evaluation of recent epidemiology studies alleging links between organophosphate exposure and a conflicting spectrum of alleged developmental effects. This weight-of-the-evidence evaluation was recommended by the Agency's Science Advisory Panel because the EPA has so far been unable to interpret the findings of these studies in any coherent fashion consistent with existing laboratory studies on plausible mechanisms of action. Dow AgroSciences has provided EPA with an independent weight-of-the-evidence evaluation of these studies relative to chlorpyrifos demonstrating that, taken together, the findings of these studies are inconsistent and contradictory
- Further work by EPA will also be necessary to complete the toxicology chapter of the preliminary chlorpyrifos human health assessment, including the Agency's planned evaluation of the scientific literature for evidence of alleged non-cholinergic effects at environmentally relevant exposure levels.

Screening-Level Models and Lack of Reliance on Real-World Data Unrealistically Inflate Risks

- EPA has projected highly implausible exposures to chlorpyrifos in drinking water as a result of screening-level computer modeling using highly unrealistic assumptions about how the product is used (For instance, grape growers do not use 33 pounds of chlorpyrifos per acre; sod farm managers do not apply the product 26 times per year).
- This highly assumption-based projection by EPA is clearly indefensible since in ten years of real-world U.S. drinking water monitoring based on extensive national sampling, no detection of chlorpyrifos in drinking water has been found.
- Dow AgroSciences has provided EPA with a realistic, more highly refined drinking water assessment using the best available data. When real-world drinking water monitoring data are used, projected chlorpyrifos exposures fall well below EPA levels of regulatory concern.

Given EPA's commitment to transparency and stakeholder participation, and also because of the precedent-setting nature of this assessment – the first in the Agency's new Registration Review program – Dow AgroSciences recommends that the Agency prepare a second draft assessment, including those areas that were not offered for review in the first draft and also incorporating changes resulting from the current round of public comment. This revised, second draft should be published for stakeholder input during an additional 90-day period.

About Chlorpyrifos

The insecticide chlorpyrifos is one of the most widely used crop protection products in the world. It has been on the market for 40 years and is currently registered in more than 100 nations. Chlorpyrifos protects many fruit, nut, vegetable and grain crops from destructive pests; and the product has been determined by regulatory authorities to pose negligible risk with authorized use. Chlorpyrifos is registered for use in most developed nations, including Australia, Canada, France, Italy, Japan, New Zealand, Spain, the United Kingdom and the U.S. The product has been extensively researched, and its labeled uses are supported by more than 3,600 studies and reports. No crop protection product has been more thoroughly studied.