Update on US EPA Registration Review

For Aluminum Phosphide, Magnesium Phosphide & Phosphine Fumigants

Proposed Interim Decision (PID)

Registration Review Timeline

- September 25, 2013: Docket opened for Review and Comment
- November 25, 2013: 60-day Public Comment Period closed
- September 24, 2014: Generic Data Call-in Notice
- October 2014 – August 2020: Development of Protocols, Completion of Data Studies and Waiver Requests
- October 23, 2020: Proposed Interim Decision (PID) and Opening of Public Comment Period
- December 15, 2020: PID Comment Period Extended to January 21, 2021
- January 21, 2021: PID Comment Period Closed

Proposed Risk Mitigation in the PID

- Updated Description of PPE Fit: The Agency is proposing that labels specify that occupational handlers wear loose-fitting PPE and that labels prohibit occupational handler from wearing jewelry, in order to prevent phosphine from becoming trapped against the skin in the event of dermal contact, worsening potential dermal irritation.
- Buffer Zones: EPA is proposing that fumigant applicators establish treatment and aeration buffer zones around all phosphine, aluminum phosphide, and magnesium phosphide commodity application sites.
- Pesticide Resistance Management: EPA is proposing resistance-management labeling.

Updated Description of PPE Fit

- The Phosphine Producers Association does not take issue with this proposed measure, however it is recognized that this is primarily an issue for cylinderized phosphine rather than metal phosphide formulations.

Buffer Zones

- The Agency proposes to develop buffers based on single application PERFUM outputs. For sites with multiple sequential applications, the Agency proposes to require buffer zones to be sized based on the total volume fumigated, the application rate, and the type of aeration equipment.
- The Agency proposes a minimum buffer of 10 feet for all fumigations.
- Based on current PERFUM calculations, and data on phosphine and metal phosphide use and usage, the Agency is proposing buffers of 10 feet to 500 feet.

Pesticide Resistance Management

- EPA is proposing resistance-management labeling for products containing phosphine and the metal phosphides, in order to provide pesticide users with easy access to important information to help maintain the effectiveness of useful pesticides.
- The mode of action box, fumigant or other pesticide rotation (when possible), consideration of non-chemical practices (e.g., sanitation), and sampling for pests before and after use of the fumigant may be applicable for phosphine and metal phosphide products.
- The PPA's position is that due to the unique nature of these products, the generic language proposed by EPA could be confusing or even inaccurate for end-users. The PPA instead proposes that "Best Practices" language be inserted to address potential resistance concerns.

PID “Talking Points” for Industry: Buffer Zones

- Metal phosphides are essential tools to treat a wide variety of commodities safely and economically, and to protect the world’s food supply from stored product pests.
- Metal phosphides preserve the flow of commerce, as many foreign purchasers of US commodities require fumigation of bulk shipments. In many export markets, phosphine is the only acceptable treatment option.
- The Agency has indicated that treatment and aeration buffer zones will be proposed for all metal phosphide and phosphine fumigations. However, other that the proposed minimum 10-foot buffer zone, the exact size of the proposed buffers has not been provided.

PID “Talking Points” for Industry

- Generic buffer zones for a set of operating parameters are in contrast to current label requirements, in which careful evaluation of site information, fumigation history, and current conditions is conducted in the development of a Fumigation Management Plan (FMP). Look-up tables may therefore impose unnecessary restrictions on sites where fumigations may be performed, even though bystander concerns at these locations have already been addressed by the current requirements of an FMP.

PID “Talking Points” for Industry

- FMP are prepared by certified applicators who have an understanding of the fumigant, the fumigation site, and the commodity to be fumigated. Any buffer zone established by the FMP are based on the construction and location of the site, fumigation history of the site, current conditions, and monitoring data collected. The FMP requires tailored measures that address potential issues that may arise in a particular application. It is the responsibility of the certified applicator to make adjustments as needed to maintain proper buffer zones. Generic buffers do not account for this key factor. Applicator education, training and experience; coupled with on-site monitoring, are more effective than setting a buffer zone at an arbitrary distance based on generic modeling.

PID “Talking Points” for Industry

- Generic buffer zones may imperil metal phosphine use at sites with a long history of safe applications if the generic buffer zone implemented is greater than that which can be accommodated at the facility. Fumigations often take place within fixed structures, with fixed infrastructure, that cannot be easily or economically relocated. Generic buffer zones could prove to be unworkable at many facilities and are unnecessary, as bystanders are already being protected by the requirements of the FMP.

PID “Talking Points” for Industry

- Generic buffer zones would not result in improved protection for bystanders and could actually result in increased risk, as the generic buffer zone would supplant the fumigator’s expertise in tailoring an appropriate boundary based on prior experience and in response to current on-site conditions. Experienced fumigators have emphasized that all fumigations are unique and must be treated independently, reflecting site-specific considerations not accounted for in generic buffer zone tables. FMP as currently implemented have shown to be protective of potential bystander exposure.

PID “Talking Points” for Industry

- No justification has been given for the minimum 10-foot buffer zone for all fumigations. Imposing a minimum buffer zone in situations where it is not needed would effectively eliminate fumigations at many sites, as in many instances, a 10-foot buffer zone would be challenging or impossible to implement. Phosphine fumigations are conducted according to the FMP, and monitoring is conducted per label requirements to ensure no bystander exposures above the Permissible Exposure Limit (PEL). If there is no risk of bystander exposure to phosphine concentrations above the PEL at a shorter distance, it is unclear why a minimum 10-foot buffer zone is being proposed.

Next Steps …

- EPA to review, evaluate, post and respond to public comments.
- Interim Registration Review Decision
- A final decision on the phosphine and the metal phosphides registration review case will occur after: an EDSP (Endocrine Disruptor Screening Program) FFDCA determination, an endangered species determination under the ESA, and any needed consultation with the Services.
- The revised labels and requests for amendment of registrations must be submitted to the Agency for review within 60 days following issuance of the Interim Registration Review Decision in the docket.