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NEWSLETTER

Risk Management Lessons from Fumigants

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Over the past several years, the U.S. Environmental Protection Agency (EPA) has negotiated and implemented a series of new risk mitigation measures for the use of a group of fumigant pesticide products, including 1,3-Dichloropropene, Chloropicrin, Metam Sodium, Metam Potassium, and Methyl Bromide. With these products, EPA has introduced restrictions not previously seen for pesticides, such as significant buffer zones around application sites, mandatory EPA-approved training for applicators, community notification and outreach, and extensive fumigant management plans.

Registrants of all agricultural pesticides should be concerned by EPA's approach to the fumigants. While fumigants present a number of particularly unique characteristics–they are gaseous–over the past year EPA has publicly indicated that it intends to use the same approach for other pesticides during the registration review process.

EPA's use of these significant and novel approaches imposes broad restrictions on the use of pesticide products in ways that directly impact the ability of growers to rely on these products to treat their fields. Not only are the new restrictions particularly onerous, but the experience of the fumigants also shows that EPA often makes assumptions that are not based on the most recent or reliable data when performing its risk calculations. Registrants must be prepared to correct any errors in EPA's analysis to ensure that products are not overburdened with unnecessary restrictions.

In the fumigant situation, EPA proposed the use of mandatory buffer zones around each fumigation site into which bystanders or application workers could not enter without wearing appropriate personal protective equipment (PPE), such as respirators. EPA sought these buffer zones in an attempt to address its stated concerns regarding "bystander exposure," or that persons not involved in the

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fumigation may be exposed to the product.

To calculate the distances EPA believed necessary, EPA adopted the Probabilistic Exposure and Risk Model for FUMigants (PERFUM) and other models to predict the amount of product it believed would drift into nearby areas. EPA's modeling started with known rates at which fumigants escape from the treated area and attempted to calculate distances at which the agency felt concentrations of concern might be found for each application rate and application type.

When the registrants were presented with EPA's initial results, they discovered numerous incorrect assumptions or calculation errors. While the registrants were able to correct many erroneous modeling assumptions, EPA's final implementation still imposed buffer zones that, in many cases, far exceed the distances at which dangerous levels of fumigant have ever been detected. Among other corrections the registrants achieved were the establishment of buffer zone "credits" that allow the modeled buffer zones to be reduced when the applicator uses certain approved types of tarps or other good application practices.

Implementation of the buffer zones requires a series of voluminous tables, printed on each label, which the applicator references to look up the application method, the size of the application site, and the application rate to determine an initial minimum buffer zone distance. The applicators must also look up the appropriate buffer zone credit and then calculate the final, required minimum buffer zone distance. Recognizing the convoluted process this imposes, EPA eventually published an online buffer zone calculator, which generates these distances without the need for large, printed tables. But applicators still must determine the buffer zone distance for each separate fumigation because the distance may change from site to site.

EPA also mandated that the registrants of fumigant products develop extensive applicator training programs and required every certified applicator to take and pass the training prior to fumigation. Some states now also have their own EPA-approved program. A group of registrants developed a joint, comprehensive online training system that allows certified applicators to take a series of "general" training modules, so that common information does not have to be repeated. Based on EPA's requirements, training for a single fumigant will take the applicator at least five hours, with each additional fumigant requiring an additional hour. While EPA's original requirement indicated only that EPA would have to approve the program as a whole, during the development process EPA staff demanded very detailed line-by-line editorial control over the program's content, design, and functionality, causing extensive delays and cost overruns. Despite numerous delays and the extended development process, the program has been successfully training applicators for the past year at www.fumiganttraining.com.

EPA next sought to require the registrants to implement a program to provide notice to the public about pesticide applications, as well as provide the public with basic information on the risks of the products. EPA's original idea would have required the registrants to develop and broadcast public service announcements on local media and to publish announcements in local newspapers in the counties where fumigants are used. In light of the significant burden this would have presented, and the estimated low impact on public awareness, EPA agreed to allow the registrants to publish an informational website with EPA's desired information on fumigants, and to make that website available to the entire public.

Finally, EPA expanded upon the concept of fumigant management plans (FMPs) that had been in place for many products for some time. Whereas prior FMP requirements set out the general requirements of an FMP, and left implementation to the applicator, the new FMP requirements detail, line by line, every single item required in a standard template form. These FMPs impose significant paperwork and recordkeeping requirements on certified applicators and land owners to document all aspects of the application. Notably, failure to include any one of the hundreds of elements could constitute a Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) violation.

One of EPA's first indications that it will continue applying these tenets in other circumstances has been its approach to chlorpyrifos, normally sold as a liquid. In February of this year, EPA released its preliminary volatilization assessment for the registration review of chlorpyrifos. Interestingly, while PERFUM was developed specifically for fumigants, that assessment utilized PERFUM to model potential bystander exposures. It appears likely the EPA will try to extend the rest of the new mandatory elements pushed on the fumigants to other products as well.

Wiley Rein has intimate knowledge of EPA's use of PERFUM, as well as EPA's efforts to implement new bystander measures. Wiley Rein represented registrants of one of the fumigants throughout the reregistration process.