

## Despite Early Threats, 2,4-D Emerges From Reregistration Relatively Unscathed

***After successfully navigating a lengthy 17-year reregistration process, 2,4-D registrants show industry how to answer critics and resolve initial EPA threats to impose severe restrictions. The new RED nonetheless requires some additional studies and includes numerous mitigation measures, although none are major.***

EPA has issued a green light for the reregistration of 2,4-D, one of the most common – and among the most controversial – herbicides used in the United States.

The Agency's Office of Pesticide Programs announced the availability of its Reregistration Eligibility Decision for 2,4-D in the Aug. 8 *Federal Register* (70 FR 45719) (Docket Number OPP-2004-0167). The RED ends a nearly 20-year reregistration process for 2,4-D.

However, research on 2,4-D, along with the controversy surrounding some of its uses, have not ended with the RED decision. OPP will be asking the technical registrants to submit data from new and repeat studies, and environmental groups will surely keep the residential uses of 2,4-D in their crosshairs.

For now, however, 2,4-D registrants and users are relieved that the RED has been issued without the tough risk-mitigation measures proposed by OPP earlier this year.

### A DRAWN-OUT PROCESS

"This has been a very long process which started when the 1988 FIFRA reregistration standards were issued," Larry Hammond, Chairman of the Technical Committee of the Industry Task Force II on 2,4-D Research Data (a.k.a., the 2,4-D Task Force), told *Insider*. "My overall view is that it's been carried out much longer than expected.

"The reason for that," Hammond continued, "is primarily a shift in Agency priorities. When the Food Quality Protection Act was enacted, they prioritized potential carcinogens, carbamates and organophosphates for reregistration review, while the herbicides were pushed down to a lower level of concern. At that point, EPA said it would be three or four years before the 2,4-D reregistration would be finished, even though – I would say – we had completed all of our reregistration requirements by December of '95.

"So," Hammond added, "we're very pleased that we're finally out of the 10-year holding pattern. The bottom line is that we maintained all of the uses we had on the label, and added three new crops – hops, wild rice and soybeans – which is great for an old product like this. Previously, there were [FIFRA] Section 18 [emergency] uses for wild rice and soybeans, but now those time-limited uses and tolerances are permanent."

The August 8, 2005 *Federal Register* announcing the availability of EPA's Reregistration Eligibility Decision for 2,4-dichlorophenoxyacetic acid (2,4-D) is available at:  
[www.pesticide.net/x/fedreg/2005/EPA-20050808A.html](http://www.pesticide.net/x/fedreg/2005/EPA-20050808A.html)

## WORKGROUP INPUT

The ad hoc Working Group for the Registration of Pesticides for Aquatic Weeds provided a great deal of input for the 2,4-D review performed by OPP's Special Review and Reregistration Division. One of the experts on that panel, Kurt Getsinger – who also served as the U.S. Army Corps of Engineers liaison to SRRD – “played a key role in the EPA decisions to provide good flexibility in the [aquatic-use] mitigation,” Hammond said.

One of the aquatic-use mitigation proposals at issue was a 45-day waiting period for drinking water withdrawals from treated sources. The 45-day waiting period was a concern to states, like New Hampshire, with a large number of permanent and seasonal lake dwellers (see *Insider*, Vo.2, No. 6, “Aquatic Weed Infestations in New Hampshire,” March 29, 2005).

“We said that a 45-day waiting period was unreasonable,” Hammond said. “EPA had a 3X uncertainty factor on the 2,4-D dissipation half-life of 15 days, but it was an artificial number and we showed them new data developed over the last three years, and they realized that our dissipation data, which wasn't required [as a guideline study], showed that 21 days was the longest period necessary to get down to below the [maximum contaminant level for drinking water] even at a starting concentration of 4 ppm.”

## HEALTH AND SAFETY ISSUES

Asked why, in his opinion, 2,4-D has been a lightning rod for concerns about health effects, Hammond said, “There are several reasons. It had a lot of ‘old baggage’ because it's an old product and a number of old studies that were not well performed had results that were favorable to the activist point of view. For example, in an Argentine university study, they injected high 2,4-D doses directly into mouse brains to see what would happen and, of course, there were negative effects. The published report indicated brain damage. There have been other studies like that. Current GLP studies have shown that the findings of the old studies are incorrect.”

Other, more recent studies, Hammond added, have “led the PMRA, the EC, the WHO and now the EPA to conclude that 2,4-D is not an animal carcinogen. But people selectively refer to the old [cancer] studies because 2,4-D carries the stigma of its association with the dioxin issues raised by Agent Orange. But the dioxin issues were related to the 2,4,5-T [which is a confirmed carcinogen] in the [Agent Orange] mixture.

“In fact, most of the activist response to the preliminary risk assessment,” Hammond continued, “focused on the use of 2,4-D in some weed-and-feed products, with exposure to children being their main point of concern. That's the most important lightning rod, but, the data and the studies demonstrate that there isn't any justification for concerns about

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dioxin in 2,4-D. It's not possible to produce dioxin in the 2,4-D process unless you introduce a contaminant along the way. In fact, we view 2,4-D as practically a reduced-risk pesticide under the Agency criteria for those compounds. The main difference is that many of the reduced-risk compounds are applied in ounces or grams per acre, whereas 2,4-D is applied in pounds per acre."

### **EPA RESPONSE TO SAFETY CONCERNS**

In its July 12 response to concerns about dioxin in 2,4-D, SRRD says, among other things, that a worst-case assessment of potential dioxin contamination in dietary exposures "were considered to be of no toxicological concern at the time of the assessment [which was in the early 1990s]."

To confirm that the latest manufacturing practices keep this contamination at a minimum, SRRD adds, "the Agency is requiring that five recent batches of all technical products be analyzed for [dioxins and furans].... The Agency is specifying that the manufacturers use the most current state-of-the-art laboratory methods for measuring [dioxins and furans] at levels less than 1 part per trillion."

In response to activist concerns about weed-and-feed products containing 2,4-D, SRRD notes that the application rate has been reduced under the RED, and that this measure will ensure that exposures to toddlers playing on turf treated with the granular product will be within the safety margin – which was established with the 10X safety factor mandated by the Food Quality Protection Act to address data gaps.

In response to the Beyond Pesticides argument that 2,4-D reregistration should be delayed until all data gaps are filled, SRRD says "the generic data base ... has been reviewed and determined to be substantially complete."

### **ADDITIONAL STUDIES**

Nevertheless, OPP is requiring many more 2,4-D studies. Some of those studies, like oyster and mysid acute toxicity, are relatively minor; others, like the developmental neurotoxicity test (DNT) and a repetition of the rat two-generation reproduction study (with the addition of new endpoints), are major.

Hammond said that, "Now that we have the final RED, we can ramp up our planning for the [data call-in] that lies ahead. In some of the [previous] evaluation and assessment documents, there have been hints about which studies might be required, but with the issuance of the RED the list is getting better defined.

"The DNT," Hammond continued, "is a relatively recent study design that obviously attained a high profile with several classes of insecticides,

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but it is still a work in progress in many ways. There are questions about how to proceed, which means that we have more preliminary work to do. Likewise, the two-gen rat reproduction study [with the addition of] features such as endocrine and immunotoxicity endpoints has been the subject of considerable discussion regarding its validation and methodology. Things may be getting settled enough that the timing of a 2,4-D data requirement will be workable.

“The data call-in,” Hammond added, “will be sent to all 2,4-D registrants and we expect that it will be the members of the 2,4-D Task Force II who commit to generating the generic data.”

### RISK FINDINGS AND MITIGATION

The RED is based on the findings of a revised risk assessment which concluded that dietary risk (including drinking water exposures) from 2,4-D are not of concern. However, when the dietary exposures were added to acute residential exposures, OPP flagged an aggregate risk of concern. As a result, says the RED, “registrants agreed to reduce the maximum application rate to turf and residential lawns from 2.0 lbs [acid equivalent, or ae]/acre to 1.5 lbs.”

The only occupational risk of concern flagged by OPP arose from mixing-and-loading wettable powder. To mitigate that risk, registrants will be required to package wettable powder in self-disposing, water-soluble bags.

### COMMENTS ON MITIGATION

*Insider* asked Hammond to elaborate on this, and other, 2,4-D mitigation measures presented in the RED appendix on amended product labels.

*Insider:* What is your response to the wettable powder mitigation?

*Hammond:* 2,4-D, per se, is not currently packaged and sold in those water-soluble packages. We tried it back in ‘94 or ‘95 and it proved to be terribly inconvenient. I believe that packaging is only being used for some new products which are mixtures with a little 2,4-D. But, water soluble packets, when used correctly, will qualify as a closed loading system under the Worker Protection Standard.

*Insider:* The mitigation requires a label statement saying, ‘Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System permit...’ What type of effluent would contain 2,4-D? Are you aware of any NPDES permits for 2,4-D in effluent?

*Hammond:* Regardless of the active ingredient, all technical and manufacturing use pesticide products are required to have environmental hazard statements on their labels about effluent discharges and the

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potential need for NPDES permits. These statements come from the EPA Label Review Manual and are applicable to the production or use of the product in a manufacturing or formulation situation. We have not determined the status of NPDES permits for 2,4-D in effluents. The effluent and NPDES statements are not applicable to end-use products.

*Insider:* Is the precautionary groundwater statement something new? One applicator previously expressed a concern that the statement which says that product applications near a cistern or well could cause groundwater contamination would prompt state or local use restrictions.

*Hammond:* The precautionary statement on potential groundwater contamination has been on 2,4-D labels for approximately 15 years. The statement is based primarily on laboratory environmental chemistry studies that indicate a potential for groundwater contamination based on a combination of water solubility and soil adsorption characteristics. However, extensive field dissipation studies in which the soil profile was monitored until the virtual disappearance of 2,4-D did not find significant downward movement. The only exception was a site with deep sand topsoil and irrigation that far exceeded normal annual rainfall. Additionally, widespread well monitoring studies have found very few instances of 2,4-D in groundwater – the exceptions generally being where mixing/loading sites were located at wellheads or other, similarly vulnerable areas. We do not expect any major regulatory changes regarding 2,4-D in groundwater because the compound has been well characterized and has been monitored by various agencies over a number of years.

*Insider:* The mitigation directs aquatic applicators to proceed in outward bands of application. Does that significantly change established practice?

*Hammond:* Many aquatic applications are localized along shores, so working outward from the shore in bands should not be a change in most cases. There might be minor changes on a site-specific basis, but we do not expect a broad impact.

*Insider:* Are the 48-hour restricted entry intervals for 2,4-D salts and amines, and the 12-hour REI for salts and esters, new?

*Hammond:* No, the Worker Protection Standard guidelines issued in the early 1990s required that all labels contain re-entry guidance for agricultural use requirements. All current agricultural use labels contain re-entry guidance and the time periods are unchanged by the RED.

*Insider:* After the standard statement which says ‘do not allow this product to drift,’ there’s an additional statement which says, ‘Only protected handlers may be in the area during application.’ Is that additional statement new?

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*Hammond:* Possibly for a few products. However, products with use patterns subject to the Worker Protection Standard or uses considered to present occupational exposure already carry this statement on their labels.

*Insider:* Is the maximum ditchbank rate of 2.0 lbs ae/acre a reduction from the previous maximum?

*Hammond:* The maximum ditchbank rate of 2.0 lbs a.e. per acre is based on the maximum terrestrial application rate. Yes, it is a reduction since some current labels have higher rates – particularly for non-crop areas.

*Insider:* Is the maximum floating and emergent weed rate of 4.0 lbs ae/surface acre a reduction from the previous maximum?

*Hammond:* The maximum rate of 4.0 lbs. a.e. per surface acre has been maintained; no there's no reduction there.

*Insider:* Is the maximum submersed-weed rate of 10.8 lbs per acre a reduction from the previous maximum?

*Hammond:* The 4 part-per-million rate has been maintained for submersed aquatic weed control, with 10.8 lbs a.e. per acre-foot equaling a [resulting] 4 ppm concentration in water. However, a large majority of applications for submersed weed control target 1-to-2 ppm 2,4-D concentrations, and the revised labels will have a chart to assist the applicator to determine the amount of 2,4-D to apply for the target subsurface concentration.

*Insider:* Are the setback, waiting-period and other restrictions for applications around sources of irrigation water new?

*Hammond:* Existing 2,4-D aquatic labels contained setback restrictions [from irrigation water sources]. However, the RED labeling contains extensive new or revised instructions and restrictions. They are much more tailored to the type of application and rate applied than the information on current labels.

*Insider:* There are notification requirements triggered by treatments in drinking water sources, including a requirement for warning signs every 250 feet of shoreline, if the treatments occur within 600 feet of drinking water intakes. Do those requirements apply regardless of the treatment rates?

*Hammond:* The requirements depend on the type of aquatic application. For floating and emergent weeds, the drinking water setback distance from a functioning potable water intake is equal to or greater than 600 feet. For submersed weeds, the minimum setback distance varies from 600 feet for a 1 ppm 2,4-D concentration in water to 2,400 feet for a concentration of 4 ppm. A table provides the minimum distances for

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drinking water sources. If the aquatic application occurs at a distance from the water intake equal to or greater than setback distance, then notification is not required.

Conversely, if 2,4-D is applied closer to the drinking water intake than the minimum setback distance, the label will read, 'Notification to the party responsible for a public water supply or to individual private water users must be done in a manner to assure that the party is aware of the water use restrictions when this product is applied to potable water.' Posting is only one example of a notification. Other means such as letters may be appropriate as well.


There are no swimming restrictions for applications of 2,4-D acid or 2,4-D amine forms. The only swimming restriction is a 24-hour waiting time for 2,4-D butoxyethanol ester [2,4-D BEE], which also includes a notification requirement. Again, posting is only one example of notification.

Another new label statement indicates when no restrictions apply: 'Except as stated above [swimming information on 2,4-D BEE], there are no restrictions on using water from treated area for swimming, fishing, watering livestock or domestic animals.'

*Insider:* There is a great deal of crop-specific mitigation. Is any of this mitigation, as far as you know, going to be problematic for the growers?

*Hammond:* The mitigations are largely in the form of maximum rates per application, maximum rates per year and minimum retreatment intervals. The studies in support of 2,4-D reregistration were planned to fit usage practices wherever possible, so most users will not encounter limitations that are problematic. Some of the new maximum rates reflect typical practices rather than upper end practices, so there may be a relatively few users that have to make adjustments.

*Insider:* Is there anything new about the droplet size and wind-speed and wind-direction requirements?

*Hammond:* Nearly all labels presently have some type of spray drift precautions, but the 2,4-D RED wording brings changes. The 'Spray Drift Management' labeling includes sections on a variety of factors including weather conditions, equipment, application methods and susceptible plants. Current labels contain wind speed and droplet size; however, the RED refines drift parameters to include more details about ground and aerial applications. 

#### **Publisher's Statement**

#### **PESTICIDE.NET Insider eJournal**

ISSN 1553-8672

Published by:

Regulatory Compliance Systems, LLC  
P.O. Box 2784  
Woodbridge, VA 22195-2784  
U.S.A.  
Phone: +1-703-492-4328  
Fax: +1-703-491-9711

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