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M E M O R A N D U M

TO: Ann Prichard, Senior Environmental Research Scientist **HSM-03017**
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VIA: Joseph Frank, Senior Toxicologist
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FROM: Sheryl Beauvais, Staff Toxicologist (Specialist)
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DATE: June 16, 2003

SUBJECT: RESPONSE TO REGISTRANT COMMENTS ON DRAFT METHIDATHION RISK CHARACTERIZATION DOCUMENT (DATA PACKAGE 198309)

The draft occupational risk assessment for methidathion was distributed November 6 (Lewis, 2002). The draft occupational risk assessment is an addendum to the Risk Characterization Document (RCD). The portion of the RCD that assessed dietary and drinking water risks was finalized in June 2001 (Lewis, 2001). Gowan Company reviewed Lewis (2002) and sent a letter dated January 21, 2003. This memo responds to three comments in that letter, which address the exposure assessment. Carolyn Lewis has responded separately to the remaining comments.

Comment 1: Use of upper-bound PHED calculations are extremely conservative.

Upper-bound estimates were used for acute exposures (Beauvais, 2002). This is not conservative, and is in fact a recognized approach in risk assessment. The purpose of using an upper-bound estimate is to address all likely exposures, not simply average exposures. In contrast, averages were used for seasonal, annual and lifetime exposure estimates (Beauvais, 2002). Previous exposure assessments from DPR have used upper-bound estimates for acute exposure (e.g., Wang and Haskell, 1994; Sanborn, 1996).

Thus, the use of upper-bound estimates for acute exposure is not new. However, recently, DPR has made an effort to standardize and explicitly state how exposures are estimated. As part of this effort, a thoughtful approach to use of PHED data was instituted as explained in Powell (2002). Arithmetic means are used rather than geometric means, and a 90% upper confidence limit (UCL) is taken of both the upper-bound and mean values. Arithmetic means are considered by DPR to be the best estimate because, "[w]hile extremely high daily exposures are low-probability events, they do occur, and the arithmetic mean appropriately gives them weight in proportion to their probability. In contrast, the geometric mean gives decreasing weight as the value of the exposure increases..." (Powell, 2002). Additionally, DPR uses UCL as described in Powell (2002), "in order to increase confidence in the estimate by accounting for some of the uncertainty added by using surrogate data whose relevance to the target exposure scenario cannot be fully assessed. The 90% confidence level is used by statistical convention."

PHED data are not simply surrogate data; they are also poorly characterized for the user, confounding assessment of the match between any given subset and the exposure scenario it is intended to represent. UCL are not routinely applied to surrogate data, such as transfer coefficients (TCs), but are used to address concerns specific to PHED. DPR believes this approach is the most appropriate, and the fact that previous exposure assessments did not approach PHED this way is not in itself a reason for disregarding the approach now.

This comment closed with a request for the underlying statistical and validation methods. These are available in the enclosed memo (Powell, 2002). Incidentally, it should be noted that an earlier version of this memo was presented and discussed at a meeting of the Agricultural Reentry Task Force (ARTF) Joint Regulatory Committee in June 2002; discussion continued at the November 2002 task force meeting, and DPR participated in a teleconference on this issue in April 2003 with task force representatives, including a representative from Gowan Co.

Comment 3: The estimates of exposure duration and use rates are unrealistic.

The argument that the most recent use data for methidathion do not support the use estimates in the exposure assessment is somewhat persuasive, mainly because use of methidathion has been decreasing each year for the past several years. Methidathion use has decreased annually for most crops, but this may not be a permanent trend, nor is the data from a single year (2001) an "unequivocal negation" of assumptions used in the exposure assessment. In fact, even in the absence of an annual trend a single year's pesticide use data would provide an uncertain estimate of use patterns because in any year use may be affected by factors such as weather and pest pressure. In some crops, acres planted may also vary between years.

Because methidathion is an organophosphate, and because newer compounds are being registered to replace many uses of OPs, it is likely that methidathion use has decreased due to a shift to products in other pesticide classes. OPs have been under severe scrutiny in recent years, and this scrutiny will eventually be extended to many of the other pesticide classes as well. When this happens, there is no mechanism in place to prevent a shift back to OPs such as methidathion. Because of this, it is not possible to be certain that use of methidathion will not increase in the future. Exposure assessments are intended to estimate future exposure to a pesticide, using available information about pesticide use patterns and crop activities, and should not be overly influenced by use in a single year.

DPR has recently introduced a new website for public access to its Pesticide Use Report (PUR) data, which includes application dates (http://calpip.cdpr.ca.gov/cfdocs/calpip/prod/main.cfm). The PUR data summarized in the methidathion exposure assessment (Beauvais, 2002) were available on a monthly basis; with the new DPR website, data could be obtained with greater resolution. This was done, and the most recent five years of PUR data (1997 to 2001) were

examined to determine the best estimates of exposure duration. Numbers of sequential days with pesticide applications were totaled for an estimate of seasonal exposure duration, and numbers of days per year were totaled for annual exposure estimates. In both cases, days were rounded to the nearest month. Using this method, airblast applicator exposure estimates are unchanged, as is the seasonal exposure duration for aerial applicators. All other handler seasonal and annual exposure durations were changed. The annual exposure duration for handlers involved in aerial applications is 2 months; seasonal and annual exposure durations for handlers involved in groundboom applications are 4 months; seasonal and annual exposure durations for mixer/loader/applicators using backpacks or low pressure handwands are each one month. The revised exposure estimates are shown below in Table 1. Exposure durations for reentry workers are unchanged.

With regard to use rates, it is true that PUR data can be used to estimate average pounds/acre applied each year. And while it may seem like a ridiculous extreme to suggest that only 13 people applied methidathion using airblast in 2001, in reality DPR has no way of knowing how many individuals use methidathion. It is a crucial fact that DPR risk assessments must protect not only handlers applying pesticides at an average rate, but all users. Even if it were true that most users do not consistently apply methidathion at the maximum rate allowed on the label, there is nothing to prevent a user from doing so. For example, in the case of severe infestations in a region, a commercial pest control operator might treat multiple fields, all at the maximum application rate, and would be legally entitled to do so. DPR believes that it is appropriate to consider maximum application rates for long-term as well as short-term exposure assessments.

Comment 4: Inappropriate transfer coefficients have been used in the reentry assessments.

Two TCs were identified in this comment as being inappropriate; these were for thinning artichokes and harvesting/thinning citrus. We agree that the appropriate value for thinning artichokes should be 300 cm^2/hr rather than 1,000 cm^2/hr. Using 300 cm^2/hr as the TC, the Acute Absorbed Daily Dosage is 0.018 mg/kg/day; Seasonal, Annual, and Lifetime Average Daily Dosages are 0.0085, 0.0043, and 0.0023 mg/kg/day, respectively.

Until DPR has completed evaluations of studies submitted by the ARTF, exposure estimates rely on evaluations done by the US EPA. US EPA has reevaluated the TC for fruit thinning, and now supports 3,000 cm^2/hr rather than 8,000 cm^2/hr as the best estimate (Dawson, 2003). In light of this reassessment, we feel that an adjustment is appropriate. Using 3,000 cm^2/hr as the TC, the Acute Absorbed Daily Dosage is 0.0026 mg/kg/day; Seasonal, Annual, and Lifetime Average Daily Dosages are 0.0014, 0.0007, and 0.0004 mg/kg/day, respectively.

Table 1. Estimates of Pesticide Handler Exposure to Methidathion

Work Task	Acute ADD [a/] (mg/kg/day)	SADD [b/] (mg/kg/day)	AADD [c/] (mg/kg/day)	LADD [d/] (mg/kg/day)
Aerial [e/]				
M/L	0.844	0.422	0.070	0.038
Applicator	0.488	0.244	0.041	0.022
Flagger	0.638	0.319	0.053	0.028
Airblast [f/]				
M/L	0.096	0.042	0.021	0.011
Applicator	3.61	1.57	0.783	0.418
Groundboom [g/]				
M/L	0.116	0.050	0.017	0.009
Applicator	0.106	0.046	0.015	0.008
Backpack sprayer				
M/L/A [h/]	0.128	0.048	0.004	0.002
Low-pressure handwand				
M/L/A [i/]	0.0023	0.0009	0.00007	0.00004

[a/] Acute Absorbed Daily Dosage (acute ADD) is an upper-bound estimate of Total Absorbed Dosage given in Table 5 (95th percentile estimate used to increase confidence in estimate; see text).
[b/] Seasonal Average Daily Dosage is a 90% upper confidence estimate of Total Absorbed Dosage given in Table 5 (see text).
[c/] Annual Average Daily Dosage = SADD x (annual use months per year)/(12 months in a year).
[d/] Lifetime Average Daily Dosage = AADD x (40 years of work in a lifetime)/(75 years in a lifetime).
[e/] Estimated high-use season is 2 months; estimated annual use is 2 months.
[f/] Estimated high-use season is 3 months; estimated annual use is 6 months.
[g/] Estimated high-use season is 4 months; estimated annual use is 4 months.
[h/] Estimated high-use season is 1 month; estimated annual use is 1 month.
[i/] Estimated high-use season is 1 month; estimated annual use is 1 month.

References:

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