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HSM-02014

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445-4248

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SUBJECT: REVIEW OF U.S.EPA BYSTANDER RISK ESTIMATES FOR A PROPOSED BUFFER ZONE REDUCTION FOR TELONE PRODUCTS

DPR staff were asked to comment on the methodology used to estimate bystander inhalation exposure to 1,3-dichloropropene with reduced buffer zones ("Post-application Bystander Risk Estimates for Proposed Label Change from 300 to 100 foot Buffer Zone for Telone II, Telone C-17, and Telone C-35", memo dated March 22, 2002, from Steven Weiss, Health Effects Division/Reregistration Branch, to Karen Whitby, Chief, Health Effects Division/Registration Action Branch 1).

Bruce Johnson of the Environmental Monitoring Branch was invited to comment, but since his work on buffer zones for fumigants is so different from the approach used by Steven Weiss, he declined. Thomas Thongsinthusak and Sally Powell of the Worker Health and Safety Branch reviewed the document, and our comments are summarized here.

<u>Summary of method used to estimate exposure</u>

"Bystander" does not have an explicit definition as an exposure scenario, according to Steve Weiss, but is loosely defined as nonoccupational exposure to persons living near treated fields. In the context of evaluating different buffer-zone lengths, persons are assumed to reside in structures at the evaluated distances from the edge of treated fields, and to be exposed while at their residences.

Risk was assessed for acute, short/intermediate-term and lifetime (cancer) exposures. All exposure estimates were based on measured concentrations taken from 14 field studies monitoring 22 applications, with samplers at distances from 82 to 410 feet from field edge. No modeling of air concentrations was done.

Acute exposure was represented by the highest measured 4-hour concentration in any study. For short/intermediate-term and lifetime exposures, Weiss selected from each distance from each application, the sampler with the highest average concentration for the averaging period. This was assumed to represent the exposure to persons living "downwind" of that field. The averaging period for short/intermediate exposure was 7 days; for cancer, it was the total duration of monitoring in each study (7 to 21 days). Lifetime exposure was calculated assuming the average concentration was experienced for the number of days in the monitoring study, once a year for 30 years in a 70-year lifetime.

Margins of exposure (MOEs) and cancer risks were calculated for each monitored distance from each application under four exposure assumptions. These were the four combinations of two application rates (the actual rate used in the study and the maximum label rate) and two daily exposure durations (2 and 16 hours). NOAELs and cancer potency were expressed in terms of air concentrations, rather than dosages. The end-points were adjusted by Activity Factors (AF) reflecting the ratio of human-to-animal inhalation rates at different activity levels. An AF of 1.3 (in the sedentary activity range) was used for cancer risk. An AF of 2.0 was used for acute and short/intermediate-term MOEs.

Summary of conclusions

Weiss concluded that "Decreasing the buffer zone from 300 to100 feet will most likely result in short- and intermediate-term MOEs (non-cancer risk) above 100 provided daily exposure time is no more than a few hours per day. However, this decrease in buffer zone size may result in cancer risk estimates of greater than 1.0E-6. Furthermore, the existing buffer zone of 300 feet may also result in cancer risk estimates of greater than 1.0E-6 for some residents living near telone-treated fields." The MOE for acute exposure (using the highest measured 4-hr concentration at any distance) was 630, indicating an acceptable level of acute risk.

DPR's major comments

Overall, the risk assessment adequately answers, in the negative, the question whether buffer zones can be reduced safely. We concur with this conclusion and with the conclusion that the existing buffer zone of 300 feet may result in unacceptable cancer risks to residents. However, we disagree with Weiss' conclusion that MOEs for short/intermediate exposures are acceptable at 100 feet. For one-time exposures, the maximum application rate must be used. Further, we think that for exposures of only 7 days duration, only the 16-hr/day exposure should be considered. For this scenario, 12 applications have concentrations measured between 82 and 100 feet from the field; 3 have MOEs < 100, 5 are between 100 and 150, and all are less than 360. This does not seem to be strong evidence for the safety of the 100-ft buffer zone, especially if there is any consideration to providing extra protection for children. Moreover, inappropriate 7-day average air concentrations were used for this assessment. This MOE should have been calculated using the *highest* average concentration for any consecutive 7 days. Instead, it used the average concentration for the *first* 7 days of monitoring, which in almost all cases have lower concentrations than later days.

Our major concern is that the method of estimating lifetime exposure could easily be misunderstood, and we would prefer that the report be much more explicit about the fact that these are lower-bound estimates. Since screening or Tier 1 assessments are generally understood to represent worst cases, it needs to be very clear that these estimates represent "best cases", and that if any mitigation is contemplated, these are not the exposure levels that would need to be mitigated. We recommend the report explain the reasons these estimates are biased low. For example, they only reflect the exposure from a single field. We know from area air monitoring that multiple applications in an area contribute to "ambient" concentrations that will be experienced in addition to field-specific concentrations. In addition, the assumption that air concentrations are zero after the length of the monitoring period can only bias the estimates in the downward direction. Moreover, the field sizes in these monitoring studies are smaller than typical applications, and we know that off-site concentrations are positively related to the size of the treated area and the total mass applied. The mean application size in the monitoring studies appears to have been 14 acres. The largest field was 70 acres and all others were 20 acres or smaller. The average application in California in 2000 was 26 acres; 25 percent of applications were larger than 35 acres and the five largest ranged from 174 to 360 acres. Finally, no statistical analysis was done to predict potential concentrations higher than the highest measured ones.

The assumption of 30 years exposure in a 70-year lifetime is probably reasonable, being equivalent to assuming each field is treated once in every 3 of 7 years. Our examination of field treatment frequencies with 1,3-dichloropropene and with methyl bromide in California suggests that 3 out of 7 years is around the average.

Other DPR comments

Since drip applications are thought to have lower emissions, and since they already have a 100-ft buffer zone, the monitoring studies of drip applications should not have been included in this assessment.

As stated previously, the 16-hr/day exposure at maximum application rate is the most relevant for short-to-intermediate exposures. A suggested revision of Table 1, highlighting that column, is included here. In addition, we have ordered the studies by distance and MOE, and taken out the drip applications.

A brief description of the bystander exposure scenario would be helpful.

A brief explanation of the derivation of Activity Factors would be helpful.

For 16-hr per day exposures, might the AF of 2.0 be too high?

For cancer risk, the most appropriate exposure scenario is the 2-hr/day exposure with typical application rate. This column might be highlighted in Table 2.

Monitoring study number 20 had unexplained field spike recoveries from 785 – 2419%. This probably means it should not have been used. (It's also a drip application.)

The second paragraph under Short- and Intermediate-Term Exposure refers to "MOEs ranging from 43 to 440…" Table 1 has 450 as the maximum in that column.

In Table 1, the 2-hr and 16-hr MOEs are under the wrong labels.

cc: Thomas Thongsinthusak
Donna DiPaolo
Ruby Reed

Table 1. Non-Cancer Risk for Bystander Exposures at 82 to 200 feet From Field

#	Study Location/Date	MRID#	Formulation type	Application Method	Broadcast Rate		MOE for Direction with highest 7-Day TWA				Distance (ft)
					study rate (gal/A)	label max rate (gal/A)	duration =2 hrs, AF=2.0		duration =16 hrs, AF=2.0		
							study rate	max rate	study rate	max rate	
10	Harquahala Valley, AZ; 1993	427742-01	Telone II	Row	*	*	320		39	≤ *39*	82
9	Moses Lake, WA 1992	426973-01	Telone II	Broadcast	25	35	1,200	840	150	110	82
11	Hookerton, NC; 1993	428456-01	Telone C-17	Broadcast	20	42	1,800	848	220	110	82
17	Highlands County, FL; 1998 (TURF)	451207-01	Telone II	Broadcast	5.19	35	2,300	350	290	43	100
19	Naples, FL; 2001	454002-02	Telone II	Row	25.3	35	510	370	64	46	100
19	Immokalee, FL; 2001	454002-02	Telone II	Row	28.4	35	1,200	1,000	160	130	100
2	Imperial Valley, CA; 1989	422657-01	Telone II	Broadcast	12.1	35	6,000	2,100	750	260	100
16	Collier County, FL; 1999 (TURF)	451207-02	Telone II	Broadcast	5.12	35	14,000	2,100	1,800	260	100
3	Salinas Valley, CA; 1992	425451-01	Telone II	Broadcast	12.3	35	8,200	2,900	1,000	360	100
7	San Joaquin Valley,CA; 1995	442585-01	Telone II	Row	5.67	35	5,400	870	670	110	105
18	Waushara County, WA; 2001	454002-03	Telone II	Broadcast	26.8	35	4,600	3,600	580	450	200

* could not determine broadcast application rate from information provided in study report