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SUBJECT: EVALUATION OF THE NEED TO REVISE THE OCCUPATIONAL EXPOSURE ASSESSMENT FOR 1,3-DICHLOROPROPENE

This memorandum summarizes my evaluation of whether higher priority should be assigned to revising the exposure assessment for 1,3-dichloropropene (1,3-D) in consideration of several changes since the original risk characterization (DPR, 1997) was completed:

1) Additional products and uses introduced in California
2) Additional data on worker exposure
3) Lower acute No-Observed-Effect Level (NOEL) (Reed, 2001)
4) New Worker Health and Safety (WHS) Branch practice of using of the 95th percentile for daily exposure instead of the geometric mean
5) New WHS practice of using of the arithmetic instead of the geometric mean, and changes to method of estimating exposure frequency and duration for longer-term exposures

The last three factors would not in themselves necessitate revising either the exposure or risk assessments. The original margins of exposure (MOE) could simply be recalculated using the new NOEL and exposure statistics. However, in light of the first two factors, it was necessary to consider whether the whole exposure assessment needed to be revised.

This evaluation primarily considers short-term occupational exposure. Seasonal and longer occupational exposures are not expected to be affected as much by the changes in the Department of Pesticide Regulation (DPR) practice. Nonoccupational exposures are not addressed by this evaluation. DPR and Dow AgroSciences are addressing lifetime and seasonal nonoccupational exposures by modeling air concentrations associated with changes to the statewide management plan for 1,3-D. Short-term off-site exposure will be modeled by the Environmental Monitoring Branch. (It may be noted, however, that WHS recently reviewed off-site air monitoring data and modeling results for Telone applications, and concluded that a buffer zone of at least 300 feet should be maintained for protection against acute and lifetime risks [Worker Health and Safety Branch, 2004a, b and c].)

Conclusions: 1) There is not an urgent need to revise the occupational exposure assessment for 1,3-D; 2) Additional worker exposure data will be needed whenever the revision is done.

New acute NOEL

The 24-hr NOEL used in the original risk assessment was 54.8 mg kg^{-1} d^{-1} (DPR, 1997). Subsequently, that NOEL was changed to 10.4 mg kg^{-1} d^{-1} on the basis of a new toxicity study. (The new NOEL has not been formally adopted because it has not yet been peer-reviewed outside DPR.) Reed (2001) gives the corresponding reference concentration (RfC) as 200 μg m^{-3}, based on children's average breathing rate of 0.46 m^3 kg^{-1} d^{-1}. Based on the default adult breathing rate of 0.28 m^3 kg^{-1} d^{-1} (Andrews and Patterson, 2000), the RfC for adult one-day exposure would be 330 μg m^{-3}.

Changes in Worker Health and Safety Branch exposure assessment practices

The exposure assessment for 1,3-D was completed in 1994 (Sanborn and Powell, 1994). At that time, WHS practice was to calculate absorbed daily dose (ADD) using the geometric mean of measured daily exposures. Current WHS practice is to use the estimated 95th percentile of daily exposures as the basis for calculating ADD for any exposure duration less than seven days, with the percentile value estimated assuming exposures are lognormally distributed (Powell, 2002).

Additional differences between past and current WHS exposure assessment practice are that ADD is now typically based on 1) an 8-hr workday, rather than on varying durations based on the exposure assessor's judgment, and 2) the maximum label application rate.

Seasonal exposure is now estimated assuming that the arithmetic mean daily absorbed dose is received every day during the period of continuous peak use, which is determined from use reports. The value of the seasonal absorbed daily dose (SADD) is thus the unamortized average absorbed daily dose.

Products and uses

1994

In 1994, Dow had proposed one product, Telone® II, for reintroduction of 1,3-D in California. All applications were to be at 12 gallons of product per acre (GPA), the equivalent of 118 lbs a.i. per acre. Telone II is applied by soil injection, either broadcast or to rows. Dow proposed that all application rigs would have end-row spillage controls (automatic shut-off of product flow when the chisels are lifted from the soil, as they are when the rig turns at the end of a row). The 1994 occupational exposure assessment considered only this scenario.

Table 1. Application parameters for representative currently registered 1,3-D products applied by soil injection.

Equipment	Chisel (shank), offset wing shank, Nobel (sweep) plow, plow-sole
Injection depth	≥ 12" below final soil surface
Soil sealing	Break up chisel traces + compact surface (broadcast) or form beds (row)
Tarping	With or without plastic film
REI	7 d (permit conditions; 5 d on label)
Fumigation period	Leave soil undisturbed ≥ 7 d
Preplant interval	≥ 7 days per 10 gal/acre
PPE	All handlers: face shield or safety glasses; specified ½-face respirator (except with Yetter rig) Loaders: Coveralls; Chemical-resistant gloves, footwear, headgear, apron.
Engineering controls	Bulk containers must have dry-disconnect couplings. Soil injection equipment must have end-row spillage control.

Product	Crops	Broadcast appln rates (GPA)	Broadcast appln rates (lbs a.i/ac) [a]
Telone II (9.85 lbs a.i/gal)	veg, field fruit, nut nursery	9-12 (18, 25) [b] 27-35 42-55	89-118 (177, 246) [b] 266-345 414-542
Trilone II (9.49 lbs a.i/gal)	veg, field fruit, nut nursery	9-12 (18, 25) 27-35 42-55	85-114 (171, 237) 256-332 399-522
Telone C-17 (8.6 lbs a.i/gal)	veg, field fruit, nut nursery	10.8-21.6 (30) 32.4-42 50.4-66	93-186 (258) 279-361 433-568
Tri-Form 30 (7.5 lbs a.i/gal)	veg, field fruit, nut nursery	12-24 (34) 37-48 57.5-75.5	90-180 (255) 278-360 431-566
Telone C-35 (7.1 lbs a.i/gal)	veg, field fruit, nut & strawberries nursery	13-26 (36) 39-50 60.5-79	92-185 (256) 277-355 430-561
Pic-Clor 60 (4.7 lbs a.i/gal)	veg, field fruit, nut nursery	19.5-39 (55) 59.5-77 92.5-121.5	92-183 (259) 280-362 435-571
Tri-Form 40/60 (4.5 lbs a.i/gal)	veg, field fruit, nut nursery	19.5-39 (55) 59.5-77 92.5-121.5	88-176 (248) 268-347 416-547

a CA permit conditions set max at 332 lbs a.i/ac.
b Parenthesized values are higher rates allowed only in muck soils.

Current

As of this date, there are sixteen 1,3-D products registered in California. Four contain 1,3-D as the only a.i. (92 to 97.5% by weight), the rest contain 1,3-D in combination with from 15 to 60% chloropicrin. Two are drip-applied at label rates ranging from 85 to 252 lbs/ac. A secured tarp seal is required for all drip applications. The other products are soil-injected at label rates ranging from 85 to 568 lbs/ac; however, California permit conditions (DPR, 2002) restrict the maximum rate to 332 lbs/ac. Soil-injected applications may be broadcast or row, tarped or untarped, and must use spillage control. Table 1 summarizes application parameters for seven representative soil-injection products. Table 2 summarizes application parameters for the two drip-applied products.

The mean application rate of 1,3-D in California, based on the data reported by Crop Data Management Systems (CDMS) for 2001, was 200 lbs a.i./ac for soil-injection applications and 156 lbs a.i./ac for tarped drip applications.

Table 2. Application parameters for currently registered 1,3-D products for drip application.

Equipment	Drip
Depth	Surface or buried
Tarping	Secured tarp seal required
REI	7 d (permit conditions; 5 d on label)
Fumigation period	Leave undisturbed ≥ 14 d
Preplant interval	≥ 7 days per 10 gal/acre (min 14 d)
PPE	Closed systems: Chemical-resistant gloves, footwear; face-sealing goggles. Direct contact: Coveralls; Chemical-resistant gloves, footwear, headgear and apron; face shield or safety glasses; specified ½-face respirator.
Engin. controls	Bulk containers must have dry-disconnect couplings.

Product	**Crops**	**Broadcast appln rates (GPA)**	**Broadcast appln rates (lbs a.i/ac)**
Telone EC (9.45 lbs a.i/gal)	veg, field fruit	9-18 9-24	85-170 85-227
InLine (6.57 lbs a.i/gal)	veg, field strawberries	13-26 29-38.4	85-171 191-252

Updated risk estimates for handlers

In this section, the original estimates of handler exposure (Sanborn and Powell, 1994) and risk (DPR, 1997) are recalculated using current DPR exposure and risk assessment practices.

The 1994 assessment of handler exposure was based on data from one study (Houtman, 1993a). The Houtman study used shallow (16-18”), broadcast, untarped soil injections of Telone II at 246 lbs/ac under three levels of engineering controls. Air concentrations were monitored in the breathing zones of loaders and applicators. In addition, biomonitoring data were collected from the five loaders and five applicators working under the “no engineering controls” condition (enclosed cabs without filters; no spillage control). Only these biomonitoring results were used in the 1994 assessment. Applicators’ absorbed doses were considerably higher than loaders’, primarily because of the longer exposure durations. The applicator estimates, only, were updated for this memorandum.

Table 3 gives the biomonitoring results for the five applicators from Houtman (1993a), and compares the ADD, SADD and corresponding MOE from the original 1,3-D risk assessment (DPR, 1997) to those recalculated using current DPR exposure and risk assessment practices.

Short-term exposure

In the 1994 exposure assessment, geometric mean absorbed dose from Houtman was adjusted downward to account for: 1) the estimated 79% reduction that would be provided by spillage controls, 2) the 90% protection assumed for the half-face respirators required for applicators by the label, and 3) the higher application rate used in the study (246 lbs/ac) than that proposed for California (118 lbs/ac). It was assumed that an applicator worked 6.8 hrs/day. The ADD was 1.13 $\mu g\ kg^{-1}\ d^{-1}$. Based on the NOEL of 54.8 $mg\ kg^{-1}\ d^{-1}$, the acute MOE was 48,368.

I recalculated ADD using the 95th percentile absorbed dose from Houtman adjusted for: 1) 79% reduction from spillage controls, 2) 90% reduction from the half-face respirator, 3) the maximum permitted application rate of 332 lbs/ac, and 4) an 8-hr workday. The recalculated ADD was 57.5 $\mu g\ kg^{-1}\ d^{-1}$. Based on the new NOEL of 10.4 $mg\ kg^{-1}\ d^{-1}$, the acute MOE is 181.

Intermediate-term exposure

Seasonal applicator exposure was estimated in the 1994 exposure assessment assuming that an applicator worked 18 days during a 90-day season. The ADD of 1.13 $\mu g\ kg^{-1}\ d^{-1}$ (adjusted as described above for 6.8 work-hours/day, spillage controls, respirator and application rate of

118 lbs/ac) was amortized by 18/90 workdays to give the SADD of 0.23 μg kg^{-1} d^{-1}. With a subchronic NOEL of 7.1 mg kg^{-1} d^{-1} (DPR, 1997), the seasonal MOE for applicators was 31,000.

Table 3. Applicator exposure data and acute and seasonal MOEs as calculated in original risk assessment and recalculated using current methods and assumptions.

Biomonitoring results for 5 applicators from Houtman (1993a)				Adjustment factors [a] used in DPR exposure assessment (Sanborn & Powell, 1994)	
ID	absorbed μg	BW kg	absorbed μg kg^{-1}		
1	8997.15	80.5	111.8	Time: 6.8 /4 hrs =	1.7
2	4748.97	85.5	55.6	Spillage control	0.21
3	819.21	84.5	9.7	Respirator	0.1
4	5514.04	86.4	63.8	App rate:	
5	25393.75	77.3	328.6	118 /246 lbs/ac =	0.48
		Geometric mean	66.1		
		Arithmetic mean	113.9		
		Maximum	328.6		
		95th %ile [b]	1015		

	ADD μg kg^{-1} d^{-1}	Acute MOE
Sanborn & Powell (1994) [c]	1.13	48,368
DPR (1997) [d]	21.1	2,600
New DPR [e]	57.5	**181**

	SADD μg kg^{-1} d^{-1}	Seasonal MOE
DPR (1997)	0.23	31,000
New DPR [f]	3.89	**1,825**

a μg /kg was multiplied by each adjustment factor.
b Estimated assuming lognormal distribution.
c Used geometric mean μg /kg.
d The ADD reported in the risk assessment was said to be based on the highest exposure; however, using the maximum μg /kg, I calculated ADD = 5.63, MOE = 9,731.
e Using 95th %ile μg/kg, 8-hr day, maximum permitted application rate of 332 lbs/ac, and the new NOEL.
f Using arithmetic mean μg/kg, 8-hr day, and statewide mean application rate of 200 lbs/ac for soil-injection applications (based on 2001 CDMS data).

The new SADD, calculated from the arithmetic mean absorbed dose adjusted for 8 work-hours/day, spillage controls, respirator and the current mean application rate of 200 lbs/ac, is

3.89 μg kg^{-1} d^{-1}. Using the same subchronic NOEL as in 1997, the new seasonal MOE for applicators is 1,825.

Under current WHS practice, it is assumed that this dose is received every day of the peak work period. Using CDMS data for Tulare, Kern and Fresno Counties in 2001, I estimated that a 6-week period of continuous high use existed. During this peak period, there were between 24 and 49 soil-injection applications in the combined 3-county region each week.

Lifetime exposure

Lifetime applicator exposure was calculated in 1994 assuming 270 total career workdays in a 70-year lifetime (information provided by Dow indicated this was a maximum). Lifetime average daily dose (LADD) was estimated as 0.012 μg kg^{-1} d^{-1}. Lifetime cancer risk at the UCL potency (0.055 per mg kg^{-1} d^{-1}) was 6.6 x 10^{-7} (DPR, 1997).

Under current methods, LADD is calculated by estimating the total number of workdays per year and assuming that the SADD (in this case, 3.89 μg kg^{-1} d^{-1}) is received on each workday of a 40-yr career over a 75-year lifetime. It is difficult to estimate the number of days per year that an individual would apply 1,3-D. However, since almost all soil-injection applications of 1,3-D in California are made by one company, it is likely that each applicator is applying on many days. If each applicator applied on 8 days in addition to the 42 days assumed during the peak period each year (for a total of 2000 days in his lifetime), his lifetime cancer risk would be 1.5 x 10^{-5}. In order to have lifetime cancer risk no greater than 1.0 x 10^{-6}, an applicator could only work a total of 130 days in a lifetime, or 3.25 d/yr over a 40-yr career.

Additional worker exposure data

In this section, worker exposure data not available or not considered in the 1994 exposure assessment are examined. All of these data are from studies in which personal air was monitored. The analysis presented here consists of estimating the 95th percentile 24-hr average air concentration experienced by workers and comparing that to the 24-hr RfC of 330 μg m^{-3}.

Houtman *et al.* (1993) monitored personal air of loaders and applicators at Telone applications in Washington, Arizona and North Carolina under three different levels of engineering controls. I calculated the 95th percentile 24-hr air concentration for each site using the data from the medium control level (for loaders: dry disconnects but no vapor recovery; for applicators: spillage control and enclosed cab *without* organic vapor-removing filter), and using current WHS assumptions and methods. For loaders, four hrs/day exposure and 90% protection from half-face respirator (required by label) were assumed. For applicators, the assumptions were 8-hr workdays, 90% protection from half-face respirator (required by label unless air-filtered enclosed

cab is used) and the maximum application rate of 332 lbs/ac. The results are given in Tables 4 (applicators) and 5 (loaders).

Table 4. Applicator exposure calculated from data in Houtman *et al*.[a] (1993) using current DPR methods and assumptions.

Site	95th %ile 24-hr air concentration ($\mu g\ m^{-3}$) [b]
Custom, WA (n = 5) Telone II, Broadcast, 25 GPA (246 lbs a.i/ac) Depth 16-18”	38
Growers, AZ (n = 5) Telone II, Row, 12 GPA (118 lbs a.i/ac) Depth 14-16”	2383 (1004[c], 286[d])
Growers, NC (n = 5) Telone C-17, Broadcast, 20 GPA (172 lbs a.i/ac) Depth 10” [e]	343

a All applications were untarped soil injection using row-end spill controls.
b Estimated by adjusting measured $\mu g\ m^{-3}$ to reflect 8-hr work days, the maximum CA broadcast-equivalent application rate of 332 lbs/ac, and use of ½-face respirator with vapor-removing cartridge as required by the label.
c Percentile calculated excluding the lowest measured concentration.
d Based on highest measured concentration (6091 $\mu g\ m^{-3}$).
e The minimum injection depth required by current labels is 12”.

Table 5. Loader exposure calculated from data in Houtman *et al*.[a] (1993) using current DPR methods and assumptions.

Site	Assumptions	95th %ile 24-hr air concentration ($\mu g\ m^{-3}$)
Custom Loaders, WA (n=5) Broadcast 25 GPA (246 lbs a.i/ac) Depth 16-18 “	8-hr work day ½-face respirator with vapor-removing cartridge	47
Growers, AZ (n=5) Row 12 GPA (118 lbs a.i/ac) Depth 14-16 “	4-hr [b] work day ½-face respirator with vapor-removing cartridge	332

a Both applications were of Telone II using dry-disconnect couplings.
b A 4-hr work day was assumed for growers, since they would be unlikely to load fumigant continuously for a full day.

Applicator exposure exceeded the adult acute RfC of 330 $\mu g\ m^{-3}$ at two of three applications; loader exposure exceeded the RfC at one of two applications. Two of the exceedances were barely above the RfC, but applicator exposure at the Arizona site was much higher (the 95th percentile concentration was 2383 $\mu g\ m^{-3}$). This may be one of those cases where the lognormal percentile estimate is not appropriate. The lowest measured concentration was less than 1/50th of the mean, while the second lowest was 1/4th and the highest was less than 3 times the mean. The extremely low value makes the variance, and thus the estimated 95th percentile, much higher. Even without that observation, however, the 95th percentile is 1004 $\mu g\ m^{-3}$. Because this was the only site giving such a high estimate, and because the most appropriate analysis of the data is not entirely clear, I do not think this is cause for immediate alarm. However, this needs to be examined closely when the exposure assessment is revised.

Rotondaro (2001) monitored three bedded, tarped applications of Telone II in Florida. A Yetter rig injected Telone into flat soil at a depth of 12", then closed and packed the shank trace. Bed-forming equipment immediately followed the application equipment. Finally, tarp-laying machines were used to cover the beds with plastic. Actual (not broadcast) application rates were 139-150 lbs/ac. Personal air was monitored for drivers, operators and shovel men. Monitored concentrations were highest for the operators, whose job was to ride the tarp-laying machine and monitor the tarping operation. The 95th percentile 24-hr air concentrations for operators at the three sites assuming 8-hr workdays, the maximum broadcast-equivalent application rate of 332 lbs/ac, and no respiratory protection (respirators are not required when Yetter rigs are used) were 206, 15.0 and 2.2 $\mu g\ m^{-3}$.

I found no registrant data on worker exposure with drip applications. Since workers are not normally in the field during drip applications, these exposures are expected to be lower than with soil injection. However, the exposure of workers checking/adjusting/repairing the drip equipment and of tarp cutters/punchers/removers may be significant and should be monitored.

Information on handler exposure to MITC from metam-sodium applications indicates that tarp-removal is a relatively high-exposure activity. The worker exposure studies by Houtman (1993a) and Houtman *et al.* (1993) monitored untarped applications. Rotondaro (2001) did not monitor tarp cutters/punchers. Exposure data are needed for workers punching tarps and removing tarps after 1,3-D applications.

Houtman (1993b) monitored re-entry worker exposure after untarped applications of Telone II. Personal air was monitored for five workers performing each of three tasks: 1) forming beds 15-24 hrs post application, 2) picking rocks from soil 64-68 hrs post application, and 3) repairing irrigation equipment 85 hrs post application. The 95th percentile 24-hr air concentrations for the

three tasks, assuming 8-hr workdays, the maximum application rate of 332 lbs/ac and 90% protection from a respirator (required because these activities occurred within the REI), were 134, 9.0 and 5.7 $\mu g\ m^{-3}$, respectively.

Conclusions

1. The occupational exposure assessment for 1,3-D does not need to be revised immediately.

   Although there are now more products and application sites than when the original exposure assessment (Sanborn & Powell, 1994) was done, the uses are essentially the same. 1,3-D is still used only as a soil fumigant. It is not used in greenhouses. Most products are applied by soil injection, as they were in 1994. There now are two drip-applied products; exposures during drip applications should be addressed when the exposure assessment is revised, but these exposures are not expected to be high and do not need to be addressed immediately.

   There is a new, lower acute NOEL for 1,3-D and some of the exposure assessment methods and assumptions used by WHS have changed since 1994. Applying these changes to the data on which the 1994 occupational exposure assessment was based reduces the acute MOE for applicators from 2600 (DPR, 1997) to 181.

   The seasonal MOE for applicators was 31,000 (DPR, 1997). Applying the changes in WHS exposure assessment methods reduces the seasonal MOE for applicators to 1825.

   Lifetime exposure will have to be examined very carefully. Data on frequency and duration of exposure for handlers are critically needed. In the 1997 risk assessment, cancer risk for applicators was calculated assuming a total of only 270 application days per lifetime. This is probably unrealistically low. Using current WHS methods and assuming 50 workdays/yr, lifetime cancer risk for an applicator is 1.5×10^{-5}. (It should be noted that for ambient exposure to 1,3-D, which is modeled probabilistically, cancer risk is calculated for the 95th percentile lifetime exposure. In contrast, this applicator cancer risk is for the *average* lifetime exposure.)

   Several exposure studies have become available since 1994. Using current WHS methods and assumptions, 95th percentile 24-hr personal air concentrations were calculated. Most, but not all, were below the adult acute RfC of 330 $\mu g\ m^{-3}$. Re-entry workers were monitored at three sites performing three different tasks; 95th percentile concentrations ranged from 5.7 to 134 $\mu g\ m^{-3}$. Loaders were monitored at two applications, with 95th percentile concentrations of 47 and 332 $\mu g\ m^{-3}$. Applicators were monitored at six applications: for five, the 95th percentile concentrations ranged from 2.2 to 343 $\mu g\ m^{-3}$; at the sixth, the 95th percentile concentration was 2383 $\mu g\ m^{-3}$. There is some question in my mind about the validity of this high estimate, but it could indicate a problem and should be investigated when the assessment is revised.

2. Some additional occupational exposure data will be needed in order to revise the exposure assessment for 1,3-D.

   At least one additional worker exposure study is needed for a broadcast soil-injection application to a minimum of 20 acres, at the maximum permitted application rate, using all currently required PPE and engineering controls. Applicators should be monitored for at least eight hours of application work. This may be a tarped application

   No data are available for tarp removers following broadcast applications. This is expected to be a relatively high-exposure activity, therefore worker exposure data are needed.

   No data are available for drip applications. The highest exposures are anticipated to be those of handlers adjusting or repairing drip lines, and those of workers punching holes in the tarps at the end of the fumigation period. Worker exposure data are needed for these activities.

   Data on the frequency and duration of handler activities per individual handler are needed to assess seasonal and lifetime occupational exposures. These data should be readily available from Tri-Cal, Inc., which does almost all the 1,3-D applications in California.

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