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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

160

DATE:

SUBJECT: Exposure Analysis, 2,4,5-T

FROM: Chief, Chemistry Branch
Criteria and Evaluation Division (WH-568)

RECEIVED

TO: Project Manager
Office of Special Pesticide Reviews (WH-566)

THRU: Acting Director
Criteria and Evaluation Division (WH-568)

Attached please find a re-write by our chemists of the section entitled "Exposure Analysis for 2,4,5-T and TCDD" to be included in the PD #1 of the Working Group.

You will note please that the numbers in Table II for beef have changed slightly (lower) since we have excluded the kidney residues from the edible portion of the beef ingested by the average population.

The exposure levels for Tables 12 and 13 were calculated to be higher since we used higher dosages than in the original document.

We also added a section entitled (p.9) Aerial Application: Exposed Population Directly Beneath Spray Plane.

We have also added 5 additional references (164-168).

Based on discussion with Plant Studies, we have modified the Working Group's description of bikini-clad persons entering into spray areas. In general, aerial applicators of 2,4,5-T are very sensitive to releasing spray deposits in populated sections of either rights-of-way or forests. This is in part due to intense pressures which have been brought to bear by the private sector on public utilities and federal and state foresters.

The modified exposure estimate we have provided names no specific exposed population because in our opinion, identification of an exposed sub-population to 2,4,5-T spray, even under rangeland treatment situations where responsibility is more difficult to affix, is at the best, very difficult.

Mr. Collier or Mr. Boyd will be glad to attend your next Working Group Meeting and discuss our revisions.

Gunter Zweig, Ph.D.

cc: Mr. Collier
Mr. Boyd
Dr. Severn

Analysis
EXPOSURE FOR 2,4,5-T and TCDD

Prepared by: 2,4,5-T Working Group

Revised and Supplemented by:

Carroll W. Collier
Chemistry Branch
Criteria and Evaluation Division

January 20, 1977

(2) Exposure Analysis

In order to determine whether a rebuttable presumption should be issued based on reproductive and fetotoxic effects, pursuant to Section 162.11(a)(3)(ii)(B), the Working Group must determine whether or not an ample margin of safety exists between the levels of 2,4,5-T and/or 2,3,7,8 tetrachloro-dibenzo-p-dioxin (TCDD), which produce reproductive and fetotoxic effects, and the level to which humans can reasonably be anticipated to be exposed.

The cancellation of uses of 2,4,5-T on food crops intended for human consumption and for use around the home, recreation sites, aquatic areas, and ditch banks in 1970 was thought to have eliminated the potential exposure to that portion of the population at risk, i.e., women of child bearing age.

However, social changes over the last few years have given women the opportunity for employment in areas that once were considered open only to men. Since women of child-bearing age are now employed in occupations such as pesticide applicators, operators of highway construction and maintenance equipment, foresters, and chemical formulators, they have become part of the population at risk with potential exposure to 2,4,5-T and/or TCDD.

In order to determine whether an ample margin of safety exists, the Working Group must first determine how much 2,4,5-T a woman could be exposed to through oral, dermal, or inhalation exposure. For each of these analyses the Working Group assumes a woman to weigh 60 kg.

(a) Oral Exposure

For purposes of this analysis the Working Group considered currently registered uses where the possibility of oral exposure to 2,4,5-T and TCDD existed. Treatment of range and pasture land could result in oral exposure through ingestion of meat and milk from animals grazing on the treated area. Since actual data on residues of 2,4,5-T in animals grazing on treated rangeland is unavailable the Working Group, for purposes of the 2,4,5-T oral exposure analysis, used residue information obtained in a feeding study (37) in which cattle were fed considerably higher amounts of 2,4,5-T than they would normally be exposed in grazing on treated land. The following calculations are based on the average quantitites of food eaten per day (1.5 kg), as reported by Lehman (144, 168).

Table 11. 2,4,5-T Exposure Analysis

	Whole Milk	Meat (Beef)
No adverse effect level of 2,4,5-T for teratogenicity (mice)	20 mg/kg of body weight	20 mg/kg/ of body weight (Roll, 1971)
Average level of 2,4,5-T identified*	0.103 ppm	0.20 ppm
%of food item in total human diet	19.6%	4.6%
Average amount of food eaten per day	1.5 kg	1.5 kg
Exposure to 2,4,5-T per day	0.0005 mg/kg/day	0.0002 mg/kg/day

*Animals fed at level of 300 ppm 2,4,5-T in diet for 2-3 weeks. This is based upon a "worst case" situation for cows grazing on freshly-treated pasture without a withdrawal period and assumes that all milk and meat came from such cows. Meat (beef) includes muscle, fat, and liver tissues which constitute the major portion of edible meat.

To find the average daily intake of a single food item, multiply the average daily food intake by the percent of that item in the total diet: for milk, 1.5 kg X 19.6% =0.2940 kg; and for meat (beef) 1.5 kg x 4.6% = 0.069 kg.

The quantity of 2,4,5-T in the average daily diet equals the average daily intake of each food item multiplied by the level of 2,4,5-T in the food item: for milk, .294 kg X 0.103 ppm = 0.03 mg; and for meat (beef) .069 kg X 0.20 ppm = 0.014 mg.

The theoretical exposure of an average woman equals the amount in the diet divided by the weight of the average woman: for milk, .03 mg/60 kg = .0005 mg/kg; and for meat (beef) 0.014 mg/60 kg = 0.0002 mg/kg. Therefore, the total daily oral exposure based on consumption of whole milk and beef, could be .0007 mg/kg/day.

Existing data on TCDD residues in animals grazing on treated rangeland is too meager to use for an analysis of TCDD exposure to humans through ingestion of meat or milk from animals so exposed.

The Working Group considers that the difference between the no-adverse-effect level of 2,4,5-T for teratogenic effects (20 mg/kg) and the calculated oral exposure level for 2,4,5-T (.0007 mg/kg per day) does constitute an ample margin of safety. Since this risk criterion for other chronic adverse effects have not been met or exceeded, a rebuttable presumption does not arise.

(b) Dermal Exposure

(i) Spray-applicator: Back-pack Sprayer

For purposes of this analysis, the Working Group assumes the applicator to be a 60-kg woman of child-bearing age, and the site of application either a right-of-way or spot treatment of pasture or rangeland. The equipment is a back-pack sprayer (164). The following calculations of exposure are based on dilution

for spraying of one pint of formulated product per 32 pints of water. Typical 2,4,5-T formulations, based on inspection of a large number of registered labels, range from 4 to 6 lbs active ingredient (acid equivalent) per gallon. The product used in this exposure analysis has an assumed concentration of 4 lbs 2,4,5-T per gallon. Label recommendations vary from a recommended dilution rate of 0.094 to 4 lbs acid equivalent per 32 pints of water. A dilution rate of 1.6 lbs per 32 pints has been selected as "representative" of a typically used spray mixture.

Wolfe, et. al., 1974 (164) made a study of dermal exposure of fenthion during hand back-pack spraying for mosquitoes for 10 situations ranging from 0.1 to 6.3 mg/hour, with a mean value of 3.6 mg/hr. Method of application was a hand pressure sprayer using a .06% spray. Workers wore short-sleeved, open-necked shirts with no gloves or hat.

Based on Wolfe's data, a dermal exposure of approximately 0.177 pints/applicator/day can be calculated as follows:

$$\frac{6.3^{*}\ mg}{hour} \times \frac{8\ hours}{day} = \frac{50.4\ mg}{day} = \frac{0.050\ g}{day}\ \text{active ingredient}$$

1 liter spray X 0.0006 = 0.6 g a.i./liter

$$\frac{0.050}{0.6} = 0.084\ \text{liters per day};\ \frac{0.084\ liters}{day} \times 2.113\ pt/l = 0.177\ pt/day$$

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*Worst case observed exposure

In order to conduct these analyses, the Working Group must determine not only the amount of 2,4,5-T and/or TCDD which would come in contact with the skin but also the amount that would be absorbed.

For purposes of this analysis, the Working Group determined that 10% of the 2,4,5-T and or TCDD coming in contact with the skin of the applicators will be absorbed even after washing, based on absorption studies with other pesticides (145, 146, 163).

For example, pesticide absorption through the human forearm utilizing acetone as a solvent ranged from 0.4 to 73.9% for 13 various insecticides and herbicides. The herbicide 2,4-D, which is structurally very similar to 2,4,5-T, gave a value of 5.8% absorption, based on urinary excretion. DDT, which is similar to TCDD, is lipophillic and highly insoluble in water, gave a 15% absorption value under the same conditions (146).

Table 12. Back-pack Sprayer Dermal Exposure Data

	2,4,5-T	TCDD
Use dilution rate	3 pints (1.6 pounds 2,4,5-T per 32 pints of water)	3 pints (0.00000016 pounds TCDD per 32 pints of water)
Amount of diluted material on skin daily	.177 pint	.177 pint
% diluted material absorbed	10%	10%
Exposure level	402 mg	.0402 micrograms (ug)
Dose level*	6.7 mg/kg*	.00067 ug/kg*
No-Adverse-Effect level for teratogenic effects	20 mg/kg	0.03 ug/kg

*Based upon 60 kg weight woman

The following calculations (see Table 13 for mathematics) will give the daily dermal exposure for both 2,4,5-T and TCDD: 1) convert the dilution rate to grams; 2) multiply this figure by 1,000 (for 2,4,5-T) to convert to milligrams and by 1,000,000 (for TCDD) to convert to micrograms; 3) multiply this figure by the amount of diluted material gotten on skin daily; 4) multiply this figure by the amount absorbed; and 5) divide this figure by the weight of the applicator for the daily exposure to 2,4,5-T or TCDD per 8-hour working day.

Table 13.

2,4,5-T	TCDD
1) 1.6 pounds/32 pt X 454 g = 22.70 g/pt	1) 0.00000016 pounds/32 pt X 454 = 0.00000227 g/pt
2) 22.70 g/pt X 1000 = 22700 mg/pt	2) 0.00000227 g/pt X 1,000,000 = 2.27 ug/pt
3) 22700 mg/pt X .018 pt/day = 408 mg/day	3) 227 ug/pt X 0.018 pt/day = 0.041 ug/day
4) 408 mg/day X 10% = 41 mg/day	4) 0.041 ug/day X 10% = 0.0041 ug/day
5) 41.0 mg/day ÷ 60 kg = 0.68 mg/kg/day	5) 0.0041 ug/day ÷ 60 kg 0.00007 ug/kg/day

The Working Group considers that the difference between the no-adverse-effect level of 2,4,5-T for teratogenic effects (20 mg/kg) and this calculated dermal exposure level for 2,4,5-T (.68 mg/kg), as well as the difference between the no-adverse-effect level of TCDD for teratorgenic effects (0.03 ug/kg) and this calculated exposure level for TCDD (0.00007 ug/kg) does not constitute on ample margin of safety. The Working Group therefore recommends

issuance of a rebuttable presumption against pesticide products containing 2,4,5-T and/or TCDD pursuant to 40 CFR Section 162.11(a)(3)(ii)(B).

(ii) Spray applicator: Tractor-mounted Low-boom Spray Equipment

For the purpose of this analysis, the Working Group assumes the applicator to be a 60 kg female of child-bearing age clearing brush on either rangeland or rights-of-way. The same product cited above is being used, and the dilution rate is 1.6 lbs of 2,4,5-T to 32 pints with water (equal to 1 gal of 4 lbs 2,4,5-T/10 gallon of water). Based on exposure studies using similar equipment but a different herbicide (147), the Working Group determined that, during a eight-hour working day, the applicator would get 0.048 pints of diluted material on her skin. The Working Group determined that 10% of the pesticide on the skin would be absorbed (145, 146, 163).

Table 14. Dermal Exposure Data (Tractor-mounted Equipment)

	2,4,5-T	TCDD
Use dilution rate	1 gallon (4 pounds) per 10 gallons of water	1 gallon of 2,4,5-T (0.0000004 pounds TCDD) per 10 gallons of water
amount of diluted material on skin	0.048 pints	0.048 pints
% diluted material absorbed	10%	10%
Exposure level	109 mg	.0109 ug
Dose level	1.8 mg/kg	.00018 ug/kg
No-adverse-effect level for teratogenic effects	20 mg/kg	0.03 ug/kg

The following calculation (see Table 15 for mathematics) will give the daily dermal exposure for both 2,4,5-T and TCDD: 1) convert the dilution rate to grams; 2) multiply this figure by 1000 and divide by 8 (for 2,4,5-T)

to convert to mg/pt, and multiply by 1,000,000 and divide by 8 (for TCDD) to convert to ug/pt; 3) multiply this figure by the amount of diluted material gotten on skin daily; 4) multiply this figure by amount absorbed; and 5) divide this figure by the weight of the applicator for the daily exposure to 2,4,5-T or TCDD per 8-hour working day.

Table 15

2,4,5-T	TCDD
1) 4 pounds/10 gal. X 454 g = 182 g/gal.;	1) 0.0000004 pounds/ 10 gal. X 454 g = 0.0000182 g/gal.;
2) 182 g/gal. X 1,000 ÷ 8 = 22,750 mg/pt	2) 0.0000182 g/gal. X 1,000,000 ÷ 8 = 2.27 ug/pt;
3) 22,750 mg/pt X 0.048 pt = 1092 mg	3) 2.27 ug/pt X 0.048 pt = 0.109 ug;
4) 1092 mg X 10% = 109 mg	4) .109 ug X 10% = .011 ug
5) 109 mg/60 kg = 1.8 mg/kg per day	5) .011 ug/60kg = 0.00018 ug/kg per day

The Working Group considers that the difference between the no-adverse-effect level of 2,4,5-T for teratogenic effects (20 mg/kg) and this calculated dermal exposure level for 2,4,5-T (1.8 mg/kg), as well as the difference between the non-adverse-effect level of TCDD for teratogenic effects (0.03 ug/kg) and this calculated exposure level for TCDD (0.00018 ug/kg), do not consititute an ample margin of safety. The Working Group therefore recommends the issuance of a rebuttable presumption against pesticide products containing 2,4,5-T and/or TCDD pursuant to 40 CFR Section 162.11(a)(3)(ii)(b).

(iii) Aerial Application: Exposed Population Directly Beneath Spray Plane

Caplan et. al., 1956 (165) working with aerially applied malathion in oil sprays applied .46 lbs per .76 gallons (calculated from data) per acre and determined a dermal exposure for bare skin of 3.556 mg. At an application rate of 4 lbs acid equivalent 2,4,5-T per 10 gallons/acre, the above information can be used to calculate an equivalent dermal exposure to 2,4,5-T applied by aircraft.

$$\frac{3.556 \text{ mg dermal exposure}}{.46 \text{ lbs pesticide applied}} \times \frac{4 \text{ lbs pesticides}}{\text{acre}} = 31 \text{ mg/60 kg body wt.} = .51 \text{ mg/kg}$$

Using the 10% dermal absorption factor discussed in the earlier section, the final exposure would be .051 mg/kg body wt/treatment.

(c) Inhalation Exposure

(i) Aerial application

Caplan et. al., 1956 (165) working with aerially applied malathion in oil formulations has provided estimates of inhalation exposure to unprotected personnel standing on the ground, directly beneath the spray planes. At an application rate of .46 lbs a.i./gal/acre an average air concentration of .067 mg/m^3 of malathion was obtained. The authors considered the sampling to be equivalent to average inspiration through the nostrils. The collection period spanned the course of the actual application and for two hours afterwards. The mass medium diameter (= volume median diameter) reported by Caplan was 109 microns which compares almost exactly with the average volume median diameter of a postulated spray which can be interpolated exactly midpoint between a "coarse aerosol" and "fine spray" as described in (166) (Vmd for course aerosol = 86 microns; Vmd for fine spray = 130 microns) where $\frac{86 + 130}{2}$ = 108 microns = midpoint Vmd between a "coarse aerosol" and or "fine spray". Caplan further reports that the .067 mg/m^3 of "inspirable" malathion represents only 12% of the total impingable deposit striking horizontal ground surfaces. Inspection of Attachment I shows that this 12% volume would only be bracketed by a higher value for coarse aerosol and a lower value for fine spray at a drop size range of 40-60 microns. Therefore, we can arrive at an estimate of respirable particle as representing those being 40-60 microns or less.

Since 2,4,5-T would never be applied as a fine spray but either as "medium" or "coarse" sprays a "worst case" exposure to inspirable particles (particles 40-60 microns and lower) would on the basis of (166) be 2% of the total spray volume for a "medium" spray.

Thus, an exposure to "medium" sized sprays with a Vmd of 278 microns would only be 2/12 that of one having a Vmd of 109 u and the inhalable exposure would be 2/12 X .067 mg/m^3 = .011 mg/m^3 per aerial treatment assuming a complete dissipation of the pesticide aerosol by the end of a 2 hour post-spray period.

For the purpose of the 2,4,5-T exposure let us assume a treatment of 4 lbs acid equivalent 2,4,5-T/10 gallons/ acre. Over a similar 2 hour period , a person directly exposed to 2,4,5-T aerial sprays could inhale

$$2/12 \times \frac{.067 \text{ mg}}{m^3} \times \frac{1.8 \text{ } m^3}{hr} \times 2 \text{ hr} \times \frac{1}{60 \text{ kg}} = .0007 \text{ mg/kg/treatment}$$

Supplemental References

164. Wolfe, H. and W. F. Durham. 1974. Exposure of Mosquito Control Workers to Fenthion. Mosquito News, 34:263-267.

165. Caplan, B., D. Culver, and W. C. Thielan. 1956. Human Exposure of Populated Areas During Airplane Application of Malathion. AMA Arch. Ind. Health 14: 326-332.

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167. Roll, R., 1971 Studies of the teratogenic effect of 2,4,5-T in mice. Food Cosmetic Toxicology. 9: 671-76. Pergamon Press.

168. Lehman, A. J. 1965. Appraisal of the safety of chemicals in foods, drugs, and cosmetics. Ass'n. of Food and Drug Officials of the U.S. Topeka, KA.