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Description Notes Alvin L. Young filed these documents together with others under the label, "Agent Orange Exposure Project."

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20506

May 9, 1986

MEMORANDUM FOR AOWG SCIENCE SUBPANEL ON EXPOSURE ASSESSMENT

FROM:

Al Young
AL YOUNG

SUBJECT:

Recap of Action from 2 May 1986

1. Reports from Barnes and Kang (exposure scenarios), Christian (exposure assessment scores for 0.5 km and 1 day), and CDC (TCDD levels in adipose tissue) were received. The data were discussed as to completeness and it was determined that all Subpanel members needed to review the handouts and identify data gaps. However, the challenge now is to interpret the material within the mission outlined for the Subpanel.
2. Recap of Requested Action:
 - D. Barnes - Complete scenario on re-entry.
 - J. Murray - Complete Task Reports
 - J. Bricker - Complete document on "Agent Orange Exposure Probability Modeling."
 - A. Young - Draft proposed report.
3. Our next (and likely last) meeting is scheduled for 15 May 1986, 9:30 A.M. - 12:00 P.M., Room 5026, NEOB.

Thanks!

REQUEST FOR APPOINTMENTS

To: Officer-in-charge
Appointments Center
Room G-201, NEOB

Please admit the following appointments on Friday, May 2, 1986

for Dr. Alvin Young of OSTP
(NAME OF PERSON TO BE VISITED) (AGENCY)

BARNES, Donald

BLAIR, Aaron

BRICKER, Jerry

CHRISTIAN, Richard

FINGERHUT, Marilyn

KANG, Han

KELLER, Carl

LAYDE, Peter

MURRAY, John

SEVERN, David

SHEPARD, Barclay

MEETING LOCATION

Building NEOB

Room No. 5026

Time of Meeting 1:00-3:30 PM

Requested by Polly Thompson

Room No. _____ Telephone 3961

Date of request April 29, 1986

Additions and/or changes made by telephone should be limited to (4) names or less.

5/2/86

Barnes/Kang

D R A F T

REPORT ON RELEVANT EXPOSURE SCENARIOS

The following exposure scenarios were considered:

1. A soldier under the path of a Ranch Hand spraying operation.
2. A soldier entering an area recently sprayed during a Ranch Hand operation.
3. A perimeter spray applicator
 - a. A backpack sprayer
 - b. An operator of a power wagon ("buffalo sprayer")
4. A soldier in a camp whose perimeter was being sprayed.*

* No, not this!



[Note that analyses generated by Bricker are also relevant to several of these scenarios.]

SCENARIO 1 -- A soldier under the path of a Ranch Hand spraying operation.

Relative exposure potential -- High

Relative likelihood -- Low

See separate Kang analysis.

SCENARIO 2 -- A soldier entering an area recently sprayed by a Ranch Hand spray operation.
Relative exposure potential -- Moderate
Relative likelihood -- Moderate to High

This scenario is similar to the "re-entry problem" encountered in the use of agricultural pesticides in which an interval is established between the time of application of pesticide to a crop and the time of re-entry of farm workers to the fields (often for purposes of harvesting the crop.) Consideration is given to

- a. The level of pesticides residues on the crop/foilage.
- b. The "dislogability" of the pesticide residues from the crop during an encounter with the farm worker; usually from direct contact with the skin of the worker while picking.
- c. The dermal absorption of the pesticide residues through the skin of the worker.

From the above information, an estimate can be made of dose received, which, when coupled to the animal toxicity data, can be used to estimate human risk.

For point a in the case of a pesticide, the EPA requires studies on the residues of chemicals applied to a food crop. In the case of non-food use pesticides (e.g., 2,4,5-T), the level of residue on the crop/foilage can be estimated from the application rate (mass/area). For example, Lang (circa 1981) estimated the amount of 2,4,5-T that might be found on a berry in a forest as a result of a spray operation.

For point b, it has proven to be difficult to determine accurately the dislogable residue. A procedure has been developed and gained acceptance in the regulatory community to address this problem: the Popendorf correlation, which relates chemical formulation properties, application rates, and anticipated dislogable residues.

[The details of the Popendorf correlation are being gathered for application to our scenario.]

For point c, gaining an accurate estimate of dermal absorption is difficult. Many factors -- for example, chemical structure, vehicle, area of the body encountering the chemical, age of the subject, and presence or absence of perspiration -- affect the absorption process. In practice, the EPA uses a range of .1 - 100% absorption. In the case of 2,3,7,8-TCDD, related animal experimental data (Poiger and Schlatter) suggest that the dermal absorption rate is likely to be in the lower end of the range.

SCENARIO Ca -- A perimeter spray applicator: A backpack sprayer.
Relative exposure potential: High
Relative likelihood: High on an individual basis; Low on a population basis

In the case of 2,4,5-T, a study was conducted on backpack sprayer working in the forests of the Pacific Northwest in which workers were biomonitoring for exposure to the chemical (Lavy et al, 1980). These data (urinary excretion) were coupled with a pharmacokinetic model to estimate the doses to which the workers were exposed.

Exposure Estimate

The accompanying Table 1 from EPA's "Quantitative Exposure Assessment of 2,4,5-T, TCDD and Silvex", 1980, provides the results of this analysis. Note that forestry backpack sprayer has an averaged exposure of .02 mg (2,4,5-T)/kg-hr when applying the chemical at a rate of 1.6 lb/acre.

[Note that the EPA also employs a generic method of estimating exposure from field application of pesticides. This alternative approach relies on the Agency's growing body of information on a variety of pesticide applications and is expressed in the form of a composite "surrogate exposure" estimate. Typical data are presented in the accompanying table of "Preliminary Exposure Estimates", taken from EPA's "Amitrole: Pesticide Registration Standard and Guidance Document", March 1984. Note that in the case of the backpack sprayer, the surrogate data indicates exposure estimates are in the range .0006 to .01 mg/kg-hr, with a typical value of about .004 mg/kg-hr. Note that this is roughly an order of magnitude lower than estimate given above.]

Health Assessment

Making some additional assumptions, we can estimate the potential health significance of this information.

Assumptions for a backpack sprayer in Vietnam:

Apply 2,4,5-T at a rate of 1.6 lb/acre and obtained an exposure of less than .1 mg/kg-hr (cf. .02 mg/kg-hr average)

8 hrs a day

5 days a week

100 days per year

2 years

Conc. of 2,3,7,8-TCDD in 2,4,5-T taken as 2 ppm

Absorption and uptake of 2,3,7,8-TCDD is comparable to 2,4,5-T

Average lifetime of 70 years

Cancer Concerns from 2,3,7,8-TCDD

Under these assumptions, the lifetime average daily dose (LADD) for 2,3,7,8-TCDD is

$(.1 \text{ mg } 2,4,5\text{-T/kg-hr}) \times (2 \times 10^{-6} \text{ mg } 2,3,7,8\text{-TCDD/mg } 2,4,5\text{-T})$
 $\times (8 \text{ hr/day}) \times (100 \text{ days/year of application})$
 $\times (2 \text{ yr application/70 yr lifetime})$

FROM EPA'S "Quantitative Assessment of Exposure
to 2,4,5-T, Silvex and TCDD"; Sept 12, 1980

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TABLE 1

Estimated Exposure of Pesticide Applicators and Farmworkers to 2,4,5-T

| Use Pattern | Exposed Group | Application Rate ¹ (lb/A) | Estimated | | Average Exposure ² (mg/kg/hr) | | |
|----------------------|--------------------------|--------------------------------------|----------------------------------|--------------------------------|--|--------------------|-------|
| | | | No. Exposed Persons ¹ | Exposure ¹ (hrs/yr) | | | |
| <u>FORESTRY</u> | | | | | | | |
| 1. Aerial | Pilots | 2 | 73 | 200 | 0.015 | | |
| | Mixer/Loaders | 2 | 73-145 | 800 | 0.062 | | |
| | Flaggers | 2 | — 3 | 800 | 0.003 | | |
| | Supervisors | 2 | — 3 | 800 | 0.004 | | |
| 2. Ground Broadcast | a. Tractor | Mixer/Loader | 2 | 90-180 | 480 | 0.020 | |
| | | Mistblower | Tractor/operator/worker | 2 | 90 | 240 | 0.013 |
| | | Supervisor | 2 | — 3 | 480 | 0.006 | |
| | b. Backpack | Applicators | 1.6 | 300 | 800 | 0.021 | |
| | | Sprayer | Mixer/Supervisor | 1.6 | — 3 | 800 | 0.005 |
| | <u>RANGE AND PASTURE</u> | | | | | | |
| 1. Aerial | Pilots | 1.0 | 130 | 75 | 0.008 ⁴ | | |
| | Mixer/Loaders | 1.0 | 130-260 | 100 | 0.031 ⁴ | | |
| | Flaggers | 1.0 | 800 | 25 | 0.002 ⁴ | | |
| 2. Ground Backpack | Applicators | 0.6 | 20,000 | 80 | 0.008 ⁴ | | |
| <u>RICE</u> | | | | | | | |
| Aerial | Pilots | 1.0 | 307 | 12 | 0.008 ⁴ | | |
| | Mixer/Loader | 1.0 | 307 | 48 | 0.030 ⁴ | | |
| | Flaggers | 1.0 | 6500-9500 | 0.6 | 0.002 ⁴ | | |
| <u>RIGHTS-OF-WAY</u> | | | | | | | |
| 1. Aerial | Pilots | 8.0 | 25 | 400 | 0.060 ⁴ | | |
| | Mixer/Loaders | 8.0 | 25-50 | 400 | 0.240 ⁴ | | |
| 2. Ground | a. Selective | Applicators (hand) | 6.4 | 1380 | 1000 | 0.084 ⁴ | |
| | | Basal | | | | | |
| | b. Cut Stump | Applicators (hand) | 4.0 | 60 | 500 | 0.053 ⁴ | |
| | | | | | | | |
| | c. Mixed Brush | Applicators (hand) | 6.0 | 270 | 660 | 0.079 ⁴ | |
| | | Truck boom Applicators | 0.8 | 178 | 660 | 0.005 ⁴ | |
| | d. Railroad | Crew of Four | 5.(avg) | 114 | 264 | 0.066 ⁴ | |
| | e. Electric Power | Applicators (hand) | 6.(avg) | 400 | 660 | 0.080 ⁴ | |

1. See Table 1-A

2. Reference 19. Calculated dose levels; received by EPA on February 14, 1979; #16P [30,000/26]; See also Table 2-A for raw data.

3. (—) indicates that the number of individuals cannot be estimated.

4. These values were extrapolated as explained in the text.

FROM EPA's Pesticide Registration "Amitrole: Standard and Guidance Document", March, 1984

PRELIMINARY EXPOSURE ESTIMATES

lowest replicate

highest replicate

Based on 2.4 lbs amitrole/acre 40 to 90 minutes daily

| Exposure Situation | Minimum | Typical | Maximum |
|---------------------|--------------------|--------------------|--------------------|
| | (mg/kg/dy) | | |
| <u>Utility</u> | | | |
| Knapsack/Hand-Carry | | | |
| Applicator | 7x10 ⁻³ | 4x10 ⁻² | 9x10 ⁻² |
| Mixer/Loader | 2x10 ⁻³ | 9x10 ⁻³ | 2x10 ⁻² |
| Power Wagon | | | |
| Mixer/Loader/ | | | |
| Applicator | 3x10 ⁻² | 3x10 ⁻¹ | 8x10 ⁻¹ |
| <u>Industry</u> | | | |
| Knapsack/Hand-Carry | | | |
| Applicator | 5x10 ⁻³ | 3x10 ⁻² | 7x10 ⁻² |
| Mixer/Loader | 5x10 ⁻⁴ | 3x10 ⁻² | 1x10 ⁻¹ |
| Power Wagon | | | |
| Mixer/Loader/ | | | |
| Applicator | 3x10 ⁻² | 3x10 ⁻¹ | 8x10 ⁻¹ |
| <u>Railroad</u> | | | |
| Tanktrain | | | |
| Applicator | 4x10 ⁻⁵ | 2x10 ⁻⁴ | 5x10 ⁻⁴ |
| Mixer/Loader | 8x10 ⁻³ | 4x10 ⁻² | 9x10 ⁻² |
| Hy-Rail | | | |
| Applicator | 4x10 ⁻⁶ | 2x10 ⁻⁵ | 5x10 ⁻⁵ |
| Mixer/Loader | 1x10 ⁻⁴ | 4x10 ⁻³ | 1x10 ⁻² |
| <u>Forest</u> | | | |
| Knapsack/Hand-Carry | | | |
| Applicator | 4x10 ⁻⁴ | 3x10 ⁻³ | 5x10 ⁻³ |
| Mixer/Loader | 1x10 ⁻⁴ | 7x10 ⁻³ | 3x10 ⁻² |
| Helicopter | | | |
| Pilot | 2x10 ⁻⁴ | 3x10 ⁻⁴ | 4x10 ⁻⁴ |
| Mixer/Loader | 2x10 ⁻³ | 7x10 ⁻² | 3x10 ⁻¹ |
| <u>Highway</u> | | | |
| Tractor/Truck | | | |
| Applicator | 2x10 ⁻⁵ | 1x10 ⁻⁴ | 3x10 ⁻⁴ |
| Mixer/Loader | 5x10 ⁻³ | 3x10 ⁻² | 6x10 ⁻² |
| <u>Home</u> | | | |
| Aerosol Can | | | |
| Applicator | 3x10 ⁻⁷ | 1x10 ⁻⁵ | 2x10 ⁻⁵ |

16 word

*mg/kg/dy (Human Equivalents) = (dose/20)/3
 Lifetime Exposure = (mg/day) (days/yr) / (10kg) x 2 x (365)

In summary, the Agency has made a preliminary estimate that dermal exposure, especially from the hands, constitutes virtually all of the total amitrole exposure. The use of lightweight waterproof clothing (jumpsuit, gloves, hat and boots [or shoes]) is expected to reduce dermal exposure. Despite the minor contribution toward the total exposure, a respirator is required during mixing/loading operations until the effects of inhalation exposure can be better defined.

d. Risk Estimates

The Agency cannot, with the available data, accurately predict the risks involved with the use of amitrole. Quantitative risk assessments are normally based upon assumptions and,

$$\times (1 \text{ yr lifetime}/365 \text{ days})$$

$$\text{LADD} = 1 \times 10^{-8} \text{ mg/kg-d} (= 10 \text{ pg/kg-d})$$

Using EPA's conservative approach to assessing the upper limit of the cancer risk (that is, the risk of contracting cancer is not likely to be greater than the estimate), we obtain

$$\text{Upper Limit of the Risk} = \text{Potency} \times \text{Exposure (LADD)}$$

$$\text{where Potency} = 2 \times 10^5 \text{ (mg/kg-d)}^{-1} \text{ (EPA, Sept., 1985)}$$

$$\text{Upper Limit of the Risk} = (2 \times 10^5) \times (1 \times 10^{-8})$$

$$= 10^{-3}$$

Non-cancer Concerns from 2,4,5-T

The above assumptions can be used to estimate a one day exposure to 2,4,5-T

$(.1 \text{ mg/kg-hr}) \times 8 \text{ hr/day} = .8 \text{ mg/kg-day}$
 which can be compared to an EPA "Provisional Acceptable Daily Intake (PADI)" of .003 mg/kg-d. (As noted below, many regulatory toxicologists would be speaking of an ADI of .03 mg/kg-d at this point.)

That is, the one day exposure of the backpack sprayer is roughly 250 times higher than the PADI (25 times the ADI) for 2,4,5-T.

The significance of short term exposure is difficult to assess vis a vis the PADI/ADI, which is predicated on a lifetime exposure; in this case, of course, we have a much more limited exposure. The PADI/ADI in this case was derived from a 2 year rat study in which there was no effect seen at 3 mg/kg-d (NOEL). (At 10 mg/kg-d, increased liver metabolism to form coporphrins was observed.)

[Traditionally, the ADI would be derived by dividing the NOEL by 100 to get .03 mg/kg-d. Since the pesticide legislation authorizes EPA to require a full range of testing, the Agency takes a more conservative stance, until all of the data are received.]

[Note that the LADD for 2,4,5-T, which arguably relates to lifetime exposure, is below the ADI; i.e.,

$$\text{LADD } 2,4,5\text{-T} = \text{LADD } 2,3,7,8\text{-TCDD}$$

$$\times (\text{mg } 2,4,5\text{-T} / 2 \times 10^{-6} \text{ mg } 2,3,6,7,8\text{-TCDD})$$

$$= (1 \times 10^{-8} \text{ mg/kg-d}) / (2 \times 10^{-6})$$

$$= 5 \times 10^{-3} \text{ mg/kg-d}$$

$$= .005 \text{ mg/kg-d versus ADI} = .03 \text{ mg/kg-d}$$

Non-cancer Concerns from 2,3,7,8-TCDD

The one day exposure level of 2,3,7,8-TCDD can be derived from the 2,4,5-T value above:

$$2,3,7,8\text{-TCDD level} = 2,3,5\text{-T level} \times 2 \text{ ppm}$$

$$= .8 \text{ mg/kg-d} \times 2 \times 10^{-6}$$

$$= 1 \times 10^{-6} \text{ mg/kg-d} = 1000 \times \text{pg/kg-d}$$

This value can be compared to ADI values cited by various regulatory authorities which are on the order of 1 pg/kg-d; but, again, the interpretation of a single day exposure to a lifetime exposure criteria is difficult.

Again, to the degree that it is applicable, the LADD can be seen to be somewhat under the ADI:

LADD = 10 pg/kg-d versus ADI = 1 pg/kg-d.

Summary

The crude analysis above suggests that the field-based exposure estimates project cancer risk (using EPA potency estimates) not greater than 10^{-3} . Single day exposures are likely to exceed significantly the ADI levels of 2,4,5-T and 2,3,7,8-TCDD, although the toxicological significance of these data is unclear.

SCENARIO Cb -- An operator of a power wagon
Relative exposure potential: High
Relative likelihood: High on an individual basis; Low on a
population basis

There do not appear to be any field-based, biomonitoring data available on the exposure anticipated from power wagon use. However, the accompanying table of Preliminary Exposure Estimates shows the results of the "surrogate exposure" approach mentioned in Scenario Ca above. [Note these data are based on an application rate roughly 50% higher than the 1.6 lb/acre used in Ca and, therefore, they will overestimate the exposure a bit.] Note that the range of exposures anticipated for the power wagon operator are in the range of .03 -.8 mg/kg-d, with a typical value of .3 mg/kg-d, or .04 mg/kg-hr. That is, the exposure is estimated to be on the same order of magnitude as the exposure to the backpack sprayer used above (.02 mg/kg-hr). Therefore, the subsequent analysis will be comparable to Scenario Ca above.

SUMMARY

The risks experienced by the power wagon operator are expected to be comparable to that of the backpack sprayer.

SCENARIO 4 -- A soldier in a camp whose perimeter is being sprayed by a power wagon.

Relative exposure potential: Low
Relative likelihood: Moderate

In the professional opinion of EPA pesticide exposure assessors, spray from a power wagon is not likely to drift appreciably, given factors such as the large droplet size and ground level application.

SUMMARY

This scenario is not likely to be of concern.

D R A F T

SUMMARY

| <u>SCENARIO</u> | <u>Estimated Exposure Lifetime Ave. Daily Dose</u> | <u>Upper limit of Cancer Risk</u> | <u>Est. Expos. Single Day</u> | <u>ADI</u> |
|---|--|--|-----------------------------------|-------------|
| 1 Direct Ranch Hand spray | | SEE KANG | | |
| 2 Re-entry | | UNDER DEVELOPMENT (or is that "underdevelopment"?) | | |
| 3 Backpack sprayer or power wagon operator | | | | |
| 2,3,7,8-TCDD | 10 pg/kg-d | 10 ⁻³ | 1000 pg/kg-d | 1 pg/kg-d |
| 2,4,5-T | .005 mg/kg-d | --- | .8 mg/kg-d | .03 mg/kg-d |
| 4 Someone in camp | | JUDGED TO BE OF LOW CONCERN | | |