Estimating Risk for Unique Exposure Scenarios in Response to Illegal Pesticide Applications

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Pesticide Regulation

- EPA regulates pesticides so they are "safe" (no unreasonable risk) when used according to the label directions

- EPA approves a "registration" that permits a pesticide's distribution, sale, and use after the company meets the scientific and regulatory requirements

However…

- Misapplication or pesticide misuse can result in unique exposure scenarios

- The public can be exposed from drift, spills, or releases

- Pesticides are sometimes used in intentional poisonings

Resulting in…

- Exceedances of pesticide tolerances
- The need to assess risk to public health
- The need to establish action levels that are protective

Risk = Toxicity x Exposure

Rodenticide-Exposed Bison

- A rancher applied 40,000 pounds of Rozol prairie dog bait to the surface of rangeland

- Rozol (active: chlorophacinone) is only registered for below-ground use (at least 6 inches)

- According to the label, livestock are not permitted to graze in treated areas for 14 days after treatment and when any bait is above ground

- Bison (868) were released to graze on the rangeland soon after Rozol was applied

Treated wheat bait

Rodenticide-Exposed Bison

- There are no food tolerances for chlorophacinone because food crops and grazing animals should not be exposed

- U.S. Department of Agriculture (USDA), and Food and Drug Administration (FDA) were notified

- FDA regulates game animals (bison) but did not have jurisdiction until animals entered commerce

- There is no reference dose for chlorophacinone

- Approach consisted of calculating a reference dose and a screening level for chlorophacinone in bison tissue

Calculation of Reference Dose (RfD)

- No Observable Adverse Effect Level (NOAEL)=

5 µg/kg/day (rat sub-chronic,

Mally and Porret Blanc 1998)

- **RfD = NOAEL / (UF *MF)**

0.5 µg/kg/day/ (1000*1)

- Uncertainty Factors (UF)
  - 10H (interspecies)
  - 10A (intraspecies)
  - 10S subchronic to chronic
  - UF =H*A*S= 1000

- **RfD = 0.005 µg/kg/day**

- Modifying Factor (MF) =1

Plan A: Calculate screening level and test meat

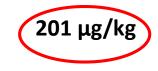|	
Cholorphacinone RfD	0.005 µg/kg/day
Total RfD for 80 kg adult	0.4 µg
Total RfD for 15 kg child	0.075 µg
Daily meat consumption adult	0.2 kg/day (FDA)
Daily meat consumption child	0.05 kg/day (EPA Exposure Factors Handbook)
Meat screening level (adult)	2 µg/kg
Meat screening level (child)	1.5 µg/kg
Reporting limit	10 µg/kg

Plan B: Model worst-case exposure scenario for bison to estimate meat concentration and determine a hold time

Total amount of Rozol used	17,778 kg
Concentration of chlorophacinone applied	0.005%
Amount of chlorophacinone applied	0.899 kg
Number of acres	5000 acres
Amount of chlorophacinone per acre	0.00018 kg/acre
Amount of grass per acre (North Dakota State University Extension Service, NDSUES)	900 kg
Amount of chlorophacinone per kg of grass	1.975E-7 kg
Bison grass consumption per day (NDSUES)	10 kg
Days of consumption (exposure duration)	51 days
Bison consumption of chlorophacinone	1.01E-4 kg
Bison weight	500 kg

Estimated chlorophacinone concentration in bison tissue **201 µg/kg**

Calculation of Hold Time

201.48 µg/kg predicted concentration in bison

70-day half-life

1.5 µg/kg screening level

70 days*log(201.48 /1.5)/log2= **495 day hold time**

Rodenticide-Exposed Bison

- Management practices were provided to prevent potentially exposed bison from being consumed (i.e., sent for slaughter/rendering), including a hold time of 495 days based on half-life studies in ruminants

- EPA approved the Chlorophacinone Testing and Management Plan and communicated the plan to FDA

Doom Pesticide Incident

- An unregistered pesticide, Doom (76% active ingredient dichlorvos), was sprayed on bedding, flooring, ceilings, and walls in rooms at the Knights Inn, Michigan City, Indiana, and at the Super 8 Motel, in Howe, Indiana

- The liquid formulation of dichlorvos is not currently registered by EPA for use in homes or other residential settings, such as motels

- EPA cancelled all indoor residential uses of dichlorvos with the exception of pest strips and required labeling modifications prohibiting the use of pest strips containing dichlorvos in occupied living areas

Calculation of Risk-based Surface Goals for Carcinogens

$$Risk-based\ Surface\ Goal_C\ (\mu g/cm^2) = \frac{Target\ risk}{Cancer\ risk_O + Cancer\ risk_D}$$

Cancer risk from oral exposures:

$$Cancer\ Risk_O = \frac{SF_O \times ED \times EF \times MCF \times STF \times UC \times MSA \times MF \times SE \times ET}{BW \times AT_C \times TCF}$$

Cancer risk from dermal exposures:

$$Cancer\ Risk_D = \frac{SF_D \times ED \times EF \times MCF \times STF \times UC \times CR \times ABS_D \times ET}{BW \times AT_C \times TCF}$$

Calculation of Risk-Based Surface Goals for Noncarcinogens

$$Risk-based\ Surface\ Goal_N\ (\mu g/cm^2) = \frac{Target\ hazard}{Noncancer\ hazard_O + Noncancer\ hazard_D}$$

Noncancer hazard from oral exposures

$$Noncancer\ Hazard_O = \frac{\frac{1}{RfD_O} \times ED \times EF \times MCF \times STF \times UC \times MSA \times MF \times SE \times ET}{BW \times AT_c \times TCF}$$

Noncancer hazard from dermal exposures:

$$Noncancer\ Hazard_D = \frac{\frac{1}{RfD_D} \times ED \times EF \times MCF \times STF \times UC \times CR \times ABS_D \times ET}{BW \times AT_N \times TCF}$$

Equation Parameters

Parameter	Definition	Industrial	Residential
ED	Exposure duration (years)	25	6 Child 24 Adult
EF	Exposure frequency (days/year)	250	350
MCF	Mass conversion factor (mg/µg)	0.001	0.001
STF	Skin transfer factor (unitless)	0.25 nonporous 0.05 porous	0.25 nonporous 0.05 porous
UC	Unit concentration (µg/cm^2)	1.0	1.0
MSA	Mouthing surface area (cm^2/event)	45	15 Child 45 Adult
MF	Mouthing frequency (events/hour)	2	9 Child 2 Adult
SE	Saliva extraction factor (unitless)	0.5	0.5
ET	Exposure time (hours/day)	8	16

Parameter	Definition	Industrial	Residential
BW	Body weight (kg)	70	15 Child 80 Adult
AT_C	Averaging time for carcinogens (years)	70	70
AT_N	Averaging time for noncarcinogens (years)	25	6 Child 24 Adult
TCF	Time conversion factor (days/year)	365	365
CR	Contact rate (cm^2/hour)	2000	2000
SF_O	Oral cancer slope factor ($[mg/kg\text{-}day]^{-1}$)	Chemical specific	Chemical specific
SF_D	Dermal cancer slope factor ($[mg/kg\text{-}day]^{-1}$) $SF_D = SF_O/ABS_{GI}$	Calculated	Calculated
ABS_{GI}	Gastrointestinal absorption factor (unitless)	Chemical specific	Chemical specific
ABS_D	Dermal absorption factor (unitless)	Chemical specific	Chemical specific
RfD_O	Oral reference dose (mg/kg-day)	Chemical specific	Chemical specific
RfD_D	Dermal reference dose (mg/kg-day) $RfD_D = RfD_O \times ABS_{GI}$	Calculated	Calculated

Risk-Based Surface Goals

Cancer

Target risk = 1.00E-4

Nonporous

Adult   5.71 µg/100cm^2

Child   **3.92 µg/100cm^2**

Porous

28.54 µg/100cm^2

19.60 µg/100cm^2

Noncancer

Target hazard = 1

Nonporous

Adult   8.28 µg/100cm^2

Child   7.60 µg/100cm^2

Porous

41.38 µg/100cm^2

38.01 µg/100cm^2

Results

- Knights Inn
    - 51 swab samples at Knights Inn ranged from nondetect to 27.6 $\mu g/100cm^2$
    - 21 samples exceeded the risk-based screening level of 3.9 $\mu g/100cm^2$
    - 29 rooms tested positive for dichlorvos

- Super 8 Motel
    - 42 swab samples ranged from nondetect to 48.8 $\mu g/100cm^2$
    - 3 samples exceeded the Risk-Based Screening Level of 3.9 $\mu g/100cm^2$
    - 26 rooms tested positive for dichlorvos

- Both motels were condemned by the local health department
- Remediated at a cost to the defendant of $92,000

In summary

- Although EPA registers pesticides so there is no unreasonable risk of harm when used according to the label, pesticide misuse, intentional poisonings, spills, or releases can result in environmental exposures that may threaten public health

- Action levels that are protective of public health can be determined for unique exposure scenarios using EPA Risk Assessment Guidelines

Questions?

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