Department of Pesticide Regulation

Mary-Ann Warmerdam
*Director*

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# MEMORANDUM

TO: Worker Health and Safety Branch Staff **HSM-09004**

FROM: Joseph P. Frank, D.Sc., Senior Toxicologist *(original signed by J. Frank)*
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APPROVED BY: Susan Edmiston, Chief *(original signed/approved by J. Frank for S. Edmiston)*
Worker Health and Safety Branch

DATE: February 13, 2009

SUBJECT: METHOD FOR CALCULATING SHORT-TERM EXPOSURE ESTIMATES

## Policy Memo

The purpose of this memorandum is to document and adopt methods to be utilized by Worker Health and Safety (WHS) staff for estimating short-term exposure. This memorandum presents the basic instructions for calculating the exposure estimates. The statistical basis and justification for the method are explained in the attached memorandum, (Powell to Frank 2009).

## Background

The Department of Pesticide Regulation (DPR) considers exposures of seven days or less in duration to be short-term exposures. In considering the potential risks associated with short-term exposures, single-day exposures are typically assessed. However, when dealing with compounds that may produce adverse effects very quickly, it is sometimes necessary to consider exposure durations considerably less than a day.

Higher-than-average short-term exposures do, by definition, occur in every monitored group of individuals. By legislative mandate, DPR has an obligation to protect any individual exposed to pesticides as a result of legal uses (California Food and Agriculture Code 12824). Protecting only those exposed at the "average" level would allow many individuals (anyone with above-average exposure) to be exposed to potentially acutely toxic concentrations. DPR therefore uses an upper-bound estimate of short-term exposure.

For the upper-bound estimate of short-term exposure, DPR normally estimates the 95th percentile of the population. The reason for estimating the $95^{th}$ percentile rather than the maximum of short-term exposure is that the exposures are considered to be lognormally distributed. In theory, the lognormal distribution has an infinitely large maximum. In practice of course, exposures must have a finite maximum value because a finite amount of active ingredient is applied. The $95^{th}$ percentile is recommended rather than a higher percentile (e.g., $99^{th}$

percentile), because the higher a percentile, the less reliably it can be estimated. Also, it is recognized that the assumed lognormal distribution may not exactly match the actual distribution of exposure values, and that any discrepancy from the lognormal distribution will be greatest at the upper extremes (Ott, 1990). Therefore, we consider the 95th percentile a realistic estimate of the highest exposure.

Calculation

The formula for computing the lognormal percentile is:

$$\text{95th percentile} = \exp\left\{\hat{\mu} + 1.645 \cdot \hat{\sigma}_P\right\}$$

where $\hat{\mu}$ and $\hat{\sigma}_P$ stand for the arithmetic mean and arithmetic standard deviation of the natural (base *e*) logarithms of measured short-term exposure, and 1.645 is the value (often called a Z value) corresponding to the 95th percentile of the standard normal distribution. The arithmetic standard deviation used in this formula is the "population" standard deviation, calculated by dividing the sum of squared deviations by N. This formula is implemented in Excel as:

= EXP(AVERAGE(*lns of exposure*) + NORMSINV(0.95)*STDEVP(*lns of exposure*)).

**Noted Exception:**
From time to time exposure assessors will find that the estimated 95th percentile is actually lower than the highest value found in the actual monitoring study. Unless values exceeding the 95th percentile are confirmed to be erroneous, the highest reported value should be used as the upper bound, rather than the 95th percentile.

**Alternative Approaches:**
Exposure assessors should consider the 95th percentile the default approach to address upper bound exposure estimates for short-term exposures. Any alternative approaches for estimating upper bound exposures will be justified and approved by the Senior Toxicologist.

**References**
Powell, S. 2009. Recommended Statistical Method for Calculating Estimates of Short-Term Exposure

Ott, W.R. 1990. A physical explanation of the lognormality of pollutant concentrations. *Journal of the Air and Waste Management Association* 40:1378-1383.

Attachment

Mary-Ann Warmerdam
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# Department of Pesticide Regulation

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## M E M O R A N D U M

TO: Joseph P. Frank, D.Sc., Senior Toxicologist
Worker Health and Safety Branch

FROM: Sally Powell, Senior Environmental Research Scientist
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(916) 324-6174

DATE: February 9, 2009

SUBJECT: RECOMMENDED STATISTICAL METHOD FOR CALCULATING ESTIMATES OF SHORT-TERM EXPOSURE

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Since 2001 (Powell, 2001), the Department of Pesticide Regulation (DPR) has generally used upper-bound estimates of short-term exposure when basing estimates on data from the Pesticide Handler Exposure Database (PHED). Upper-bound estimates should also be used for short-term exposure estimates calculated from other data.

This memorandum explains why upper-bound estimates should be used for short-term exposure, recommends an upper-bound statistic and shows how to calculate it. (The method given here cannot be used for estimates based on PHED; for that, exposure assessors should continue to use the method in Frank (2007).)

### Short-term exposure

Short-term exposures are important because, while an organism can generally tolerate a higher exposure for a short period than it can for a longer period, some adverse effects can be produced in a short period of time if the exposure is sufficient. DPR considers exposures of seven days or less in duration to be short-term exposures. In considering the potential risks associated with short-term exposures, single-day exposures are typically assessed. However, when dealing with compounds that may produce adverse effects very quickly, it is sometimes necessary to consider exposure durations considerably less than a day. For this reason, DPR may evaluate exposure for other time intervals, such as 1 hour or 8 hours. The 24-hour time period may be used to address residential exposure, the 8-hour time period may be used to assess worker exposure, and the 1-hour time period may be used to evaluate both worker and residential exposure.

### Upper-bound estimates

Higher-than-average daily exposures do, by definition, occur in every monitored group of individuals. By legislative mandate, DPR has an obligation to protect any individual exposed to pesticides as a result of legal uses (California Food and Agriculture Code 12824). Protecting only those exposed at the “average” level would allow many individuals (anyone with above-

average exposure) to be exposed to potentially acutely toxic concentrations. DPR therefore uses an upper-bound estimate of short-term exposure.

The recommended upper-bound value for short-term exposure is the estimated 95th percentile of the short-term exposure distribution, which is assumed to be lognormal. The 95th percentile is the value such that 95% of anticipated exposures would be lower and 5% would be higher. DPR's concern is for the highest exposure an individual may realistically experience while performing a label-permitted activity. The reason for estimating the 95th percentile of daily exposure rather than the maximum is that the lognormal distribution in theory has an infinitely large maximum. In practice of course, exposures must have a finite maximum value because a finite amount of active ingredient is applied. The 95th percentile is recommended rather than a higher percentile (e.g., 99th percentile), because the higher a percentile, the less reliably it can be estimated. Also, it is recognized that the assumed lognormal distribution may not exactly match the actual distribution of exposure values, and that any discrepancy from the lognormal distribution will be greatest at the upper extremes (Ott, 1990). Therefore, we consider the 95th percentile a realistic estimate of the highest exposure.

<u>Calculation of the upper-bound exposure estimate</u>

One formula for computing the lognormal percentile is:

$$\text{95th percentile} = \exp\left\{\hat{\mu} + 1.645 \cdot \hat{\sigma}_P\right\}$$

where $\hat{\mu}$ and $\hat{\sigma}_P$ stand for the arithmetic mean and arithmetic standard deviation of the natural (base *e*) logarithms of measured short-term exposure, and 1.645 is the value (often called a Z value) corresponding to the 95th percentile of the standard normal distribution. The arithmetic standard deviation used in this formula is the "population" standard deviation[1], calculated by dividing the sum of squared deviations by N. This formula is implemented in Excel as:

= EXP(AVERAGE(*lns of exposure*) + NORMSINV(0.95)*STDEVP(*lns of exposure*)).

An alternate formula that gives the same result is:

$$\text{95th percentile} = (GM) \cdot (GSD)^{1.645}$$

where GM and GSD stand for the geometric mean and geometric standard deviation of the untransformed exposure values.

[1] See the technical note at the end of this document for information on calculating the population standard deviation.

This 95th percentile estimate is a *parametric* estimate, because it uses assumptions about the distribution of the parent population in addition to the observed data values. The *sample* 95th percentile is simply the observed value that is greater than or equal to 95% of the observations. It can never be larger than the largest observed value. (The PERCENTILE function in Excel calculates the sample percentile.) DPR uses the parametric estimate of the percentile because samples of observations from lognormal distributions are unlikely to capture the very high values in the population.

Readers of exposure assessments are sometimes concerned when upper-bound estimates are considerably larger than the mean exposure. These readers may suggest that upper-bound estimates should not be used if they are much larger than the mean, and that large differences between the mean and upper-bound estimate indicate a problem with the upper-bound value. However, large differences between the mean and the upper percentiles are typical of many lognormal distributions and do not necessarily indicate a problem. Evaluation of individual exposure monitoring studies shows that ranges of exposure values can be quite broad, and can include values that are substantially higher than study means (e.g., Everhart and Holt, 1982; Grover *et al.*, 1986; Popendorf *et al.*, 1995; Vercruysse *et al*., 1999). Some studies have reported exposure ranges that span orders of magnitude (e.g., Wojeck *et al.*, 1981; Grover *et al.*, 1986; Hines *et al.*, 2001).

Readers of exposure assessments may also be concerned when an upper-bound estimate is larger than the highest observed exposure in a data set. Yet it is unreasonable to expect that any finite set of data will include the highest values that may occur. Especially with small samples from highly skewed distributions, it is very unlikely that a sample will capture the highest exposures that could occur in the population.

**References**

Everhart, L.P. and Holt, R.F. 1982. Potential benlate fungicide exposure during mixer/loader operations, crop harvest, and home use. *Journal of Agriculture and Food Chemistry* 30:222-227.

Frank, J. 2007. Method for Approximating Confidence Limits for Upper Bound and Mean Exposure Estimates from the Pesticide Handlers Exposure Database (PHED). Memo No. HSM-07005, September 20, 2007. Sacramento, CA: Worker Health and Safety Branch, Department of Pesticide Regulation.

Grover, R., Franklin, C.A., Muir, N.I., Cessna, A.J. and Riedel, D. 1986. Dermal exposure and urinary metabolite excretion in farmers repeatedly exposed to 2,4-D amine. *Toxicology Letters* 33:73-83.

Hines, C.J., Deddens, J.A., Tucker, S.P. and Hornung, R.W. 2001. Distributions and determinants of pre-emergent herbicide exposures among custom applicators. *Annals of Occupational Hygiene* 45:227-239.

Ott, W.R. 1990. A physical explanation of the lognormality of pollutant concentrations. *Journal of the Air and Waste Management Association* 40:1378-1383.

Popendorf, W., Selim, M. and Lewis M.Q. 1995. Exposure while applying industrial antimicrobial pesticides. *American Industrial Hygiene Association Journal* 56:993-1001.

Powell, S. 2001. Approximating the 95th Percentile and the 90 % Confidence Limit for Exposure Estimates from the Pesticide Handlers Exposure Database (PHED v1.1). Memo No. HSM-01010, August 23, 2001. Sacramento, CA: Worker Health and Safety Branch, Department of Pesticide Regulation.

Vercruysse, F., Drieghe, S., Steurbaut, W. and Dejonckeere. 1999. Exposure assessment of professional pesticide users during treatment of potato fields. *Pesticide Science* 55:467-473.

Wojeck, G.A., Nigg, H.N., Stamper, J.H. and Bradway, D.E. 1981. Worker exposure to ethion in Florida citrus. *Archives of Environmental Contamination and Toxicology* 10:725-735.

*Technical Note*
Calculating the population standard deviation

The estimate of the 95th percentile used by DPR,

$$95^{\text{th}} \text{ percentile} = \exp\left\{\hat{\mu} + 1.645 \cdot \hat{\sigma}_P\right\},$$

is called the Maximum Likelihood Estimate (MLE) of the percentile (Crow and Shimizu 1988). The standard deviation called for in this formula is the MLE of the standard deviation, also called the "population" standard deviation.

Using the individual exposure values, the population standard deviation is calculated as:

$$\hat{\sigma}_P = \sqrt{\frac{\sum_{i=1}^{n}(Y_i - \bar{Y})^2}{n}}$$

where $Y_i$ is the natural logarithm of an exposure value. This can be obtained in Excel by applying the STDEVP function to the natural logarithms of the exposure values.

If you have previously calculated the ordinary standard deviation of the natural logarithms of exposure, you can obtain the population standard deviation as:

$$\hat{\sigma}_P = \hat{\sigma} \cdot \sqrt{\frac{n-1}{n}}$$

where $\hat{\sigma}$ is the ordinary standard deviation of the natural logarithms.

Crow, E. L. and K. Shimizu (1988). Lognormal Distributions: Theory and Applications. New York, Marcel Dekker, Inc.