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Matching Exposure and Toxicity Averaging Times in Risk Assessment

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Introduction

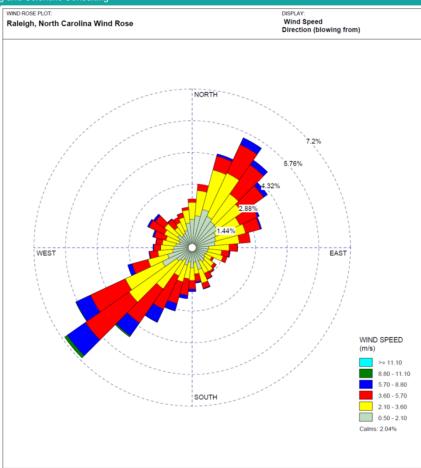
- The North Carolina Department of Environmental Quality (DEQ) proposes setting an Acceptable Ambient Level (AAL) of 5 µg/m³ for methyl bromide
 - AALs are intended for acute exposure (24-hour average) but NC DEQ based it on toxicity data for a chronic exposure
- Chronic exposures for log fumigations are likely to be significantly lower than acute exposures
 - Therefore, the basis for the toxicity level is a mismatch with the proposed exposure duration for the AAL

Sources of Daily Exposure Variability for Log Fumigations

- Meteorological conditions vary such that a unit of emission will result in different downwind concentrations
 - Wind directions vary from hour-to-hour and often have seasonal variability
 - Results in different locations for peak concentrations
 - Atmospheric stability varies with time of day and is more often stable during the winter
 - Greatly effects downwind concentrations
 - Affected by cloud cover and synoptic meteorological conditions
 - Longer winter days result in more hours with stable conditions

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Raleigh, North Carolina Wind Rose Shows Typical Wind Direction Variability

Sources of Daily Exposure Variability for Log Fumigations

- Operation hours
 - Fumigations are not continuous and there are peak periods throughout the year

Emissions

- Log fumigations include a treatment and aeration phase which vary in length and emission rate
- Treatment and aeration-related emissions may result in different locations for peak concentrations

General Risk Assessment Guidance

- Generally separately calculates risks for acute, subchronic, chronic, and lifetime durations (cancer only)
 - EPA's methyl bromide risk assessment calculates exposures for a 24-hour average, 4-week average, and a 6-month average
- Matches exposure estimates and toxicity studies to the appropriate durations

EPA Guidance on Calculation of RfCs

"The exposure-health relationship may be dependent on factors, including (1) the number of exposure hours per day; (2) the exposure scenario, that is, continuous versus interrupted (e.g., 1 week of exposure, 1 week of air, 1 week of exposure, etc.), versus intermittent (X hours per day, Y days per week) regimens; (3) the time of endpoint assessment (e.g., acute versus subchronic versus chronic studies or studies with recovery time before observation); (4) the endpoint(s); and (5) the mechanism of toxicity. (U.S. EPA 1994, p. 2-28)"

EPA's General Principles For Performing Aggregate Exposure and Risk Assessments

"In addition to the selection of an appropriate hazard endpoint for each route of exposure (e.g., oral, dermal, inhalation), an aggregate risk assessment should attempt to match the anticipated frequency and duration of exposure with toxicity studies that reflect comparable timing of exposure. For example, if an effect occurs only after several days of chemical dosing (of animals), it would be inappropriate to compare the estimated exposure over a single day with the exposure associated with an effect which requires multiple days to develop. (U.S. EPA, 2001; p. 17)."

EPA's Framework for Human Health Risk Assessment to Inform Decision Making

"The exposure assessment component of the analysis plan is developed by drawing on the information, considerations and decisions represented by the conceptual model for human health. Accordingly, the analysis plan describes the exposure assessment elements specified in the conceptual model, including the relevant routes and pathways, frequency and duration of exposures, populations and life stages, and assessment metrics. (U.S. EPA 2014, p. 31)."

EPA Guidelines for Exposure Assessment

"The frequency and duration of sample collection will depend on whether the risk assessor is concerned with acute or chronic exposures, how rapidly contamination patterns are changing, ways in which chemicals are released into the environment, and whether and to what degree physical conditions are expected to vary in the future."

EU's Children's Health and the Environment (CHEST)

"The method used to calculate HAs [Health Advisories] is similar to that for the RfD's using uncertainty factors. Data from toxicity studies with durations of length appropriate to the HA are being developed."

Conclusions

- One cannot assume that a short-term (acute) exposure will lead to a long-term (chronic) exposure of the same level.
 - There are several sources of variability that may result in the peak 24-hour concentration downwind of a log fumigation being higher than the longterm average concentration
- Authoritative bodies are clear that exposure and toxicity study duration need to be matched (acute→acute; chronic→chronic)
 - Most risk assessments consider different durations of exposure
- NC DEQ should not compare the EPA IRIS toxicity level to an exposure measurement over an acute duration