Bayer CropScience

Effect of Binning Processes for Obtaining Regional Distributions of Drinking Water Residues in Dietary Risk Assessements

Outline

- Introduction
- Introduction to WARP
- Binning Results

Introduction

- The acceptability of residues of a specific compound in drinking water in the U.S. is usually evaluated as part of an aggregate exposure assessment.
  - Considers food, drinking water, and residential uses
  - Overall exposure at a specified percentile (99.9) must have an acceptable margin of exposure (varies depending on the compound)
  - Assessment models can consider both the variability of residues and the variability in consumption

Introduction

- The acceptability of residues of a class of compounds with the same mode of action in drinking water in the U.S. is evaluated as part of a cumulative assessment.
  - Considers food, drinking water, and residential uses but may or may not be combined.
  - Residues converted to “equivalents”
  - Overall exposure at a specified percentile (usually 95 or 99) must have an acceptable margin of exposure (varies depending on the class)
  - Both the variability of residues and the variability in consumption are considered

Water Concentrations

- EPA's policy is to not use single value estimates of water concentrations except in Tier 1 assessments
- Surface water concentrations are now usually represented by 30-36 years of daily values estimated by modeling
- All high tier risk assessments by EPA use probabilistic distributions considering temporal variation

Introduction to WARP

- Regression model developed by the USGS for flowing streams
  - Based on NAWQA and other available monitoring data
  - Provides mean value and standard deviation as a function of variables for nine percentiles ranging from 5 to 95.
  - Important variables: use intensity, rainfall erosivity factor, soil erodibility factor, watershed area, Dunne overland flow, pesticide properties expressed as SWMI, and vapor pressure

Introduction to WARP

- Implementation in EPA risk assessment being undertaken by a cooperative effort
  - EPA
  - USGS
  - USDA
  - industry

WARP Associated Features

- Estimation of product use within a watershed
- Boundaries for 1600 flowing stream watersheds
- Routines for estimating daily values of drinking water for aggregate and cumulative dietary assessments
  - WARP-SIM-parent values generated statistically based on WARP estimates
  - Hybrid for metabolites and cumulative assessments
    - Values determined by WARP (includes variability)
    - Timing determined by PRZM/EXAMS

Surface Water

- In a regional assessment several hundred community water systems may need to be considered
- Developing 30 year daily concentrations for each of the water systems would require a lot of effort and the assessment models currently cannot handle this amount of data.
- Binning is an alternate approach
  - Especially appropriate since temporal variability is much greater than spatial variability

Example of Binning

- Case
  - Cumulative assessment for carbaryl and carbofuran
    - Example only since an arbitrary factor for relative potency was assumed
  - Northeastern U.S. (297 community water systems using surface water)
  - Performed by WARP Case Study Subgroup
    - Members from EPA, USGS, and Bayer CropScience
    - USGS conducted the WARP simulations
    - Bayer CropScience performed the PRZM/EXAMS and CARES runs

Procedure

- Generate WARP estimates for each watershed for carbaryl and carbofuran
- Rank estimates, specify bins, and select representative watershed from each bin
- Prepare 30-year sequence of daily concentrations for the representative watershed in each bin
- Evaluate overall concentration distribution using CARES

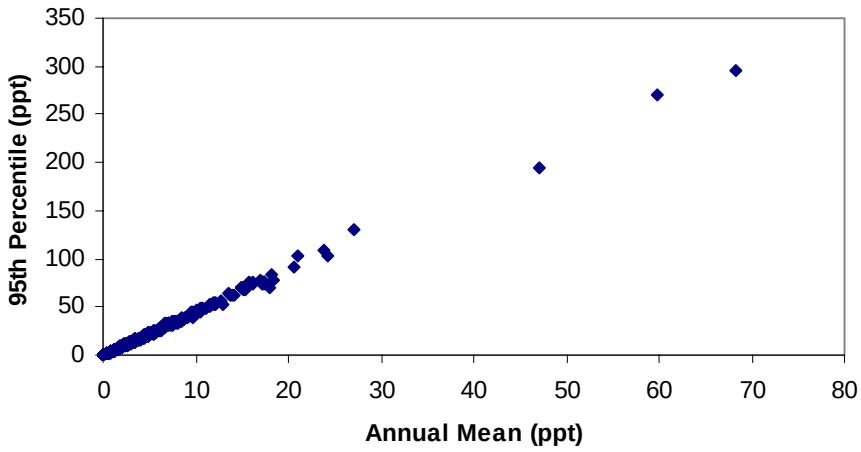
Advantages

- Since the same weather data is used for the PRZM/EXAMS simulations the correlation between the residues of the two different compounds is maintained
- Using CARES the temporal correlation between days of the year is maintained
  - Probably not so important for carbamate residues due to rapid reversibility

Ranking of Watersheds

- The 95th percentile concentration predicted by WARP was used to rank watersheds.
  - The WARP predicted percentiles and annual Time Weighted Average concentrations are highly correlated

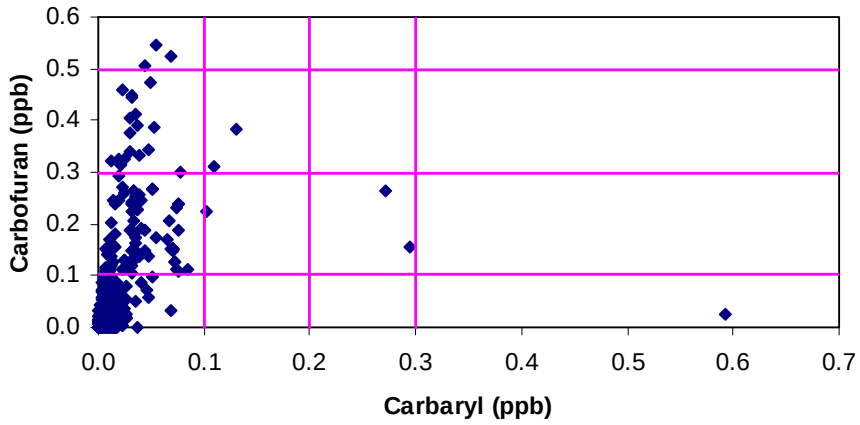
Correlation of 95th Percentile with TWA Mean



Binning Approaches

- Two dimensional
  - One dimension for each compound
  - Discarded due to complexity and additional work required for implementation
  - Use may be necessary under certain circumstances, for example, when use patterns for the two compounds are very different

Two Dimensional Binning



Binning Approaches

- One dimensional
  - Contribution of compounds summed by using the relative potency factor
  - Relatively easy to implement
  - Approaches
    - Bins of equal population
    - Bins of equal numbers of systems
    - Combination or other approaches

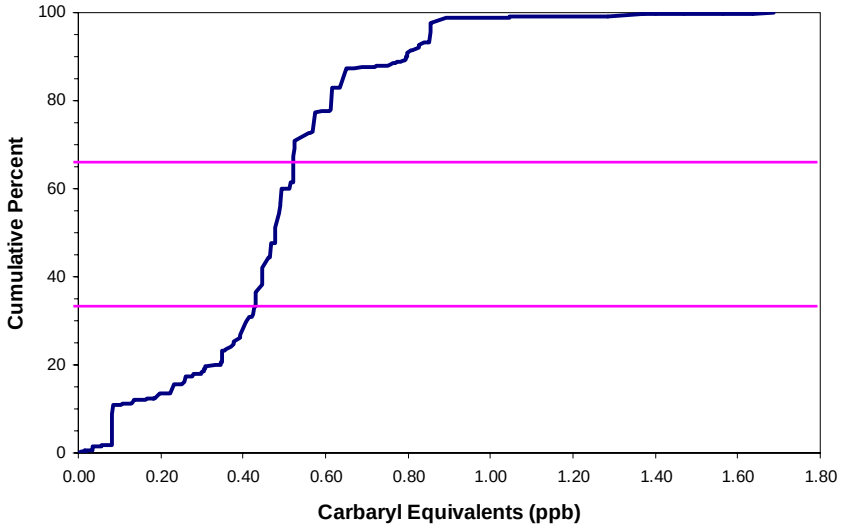
Advantages of Binning Approaches

- Bins of equal population
  - No population weighting required
  - Can be implemented on a variety assessment models
- Other approaches
  - Flexibility to include zero bin with no additional modeling effort
  - Selection of bin can be tailored to area of most importance

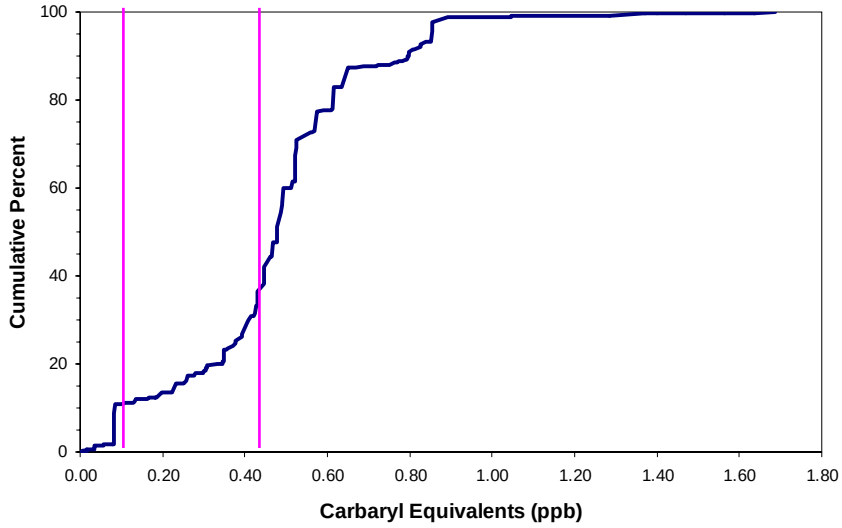
Binning Approaches evaluation

1. Three bins of equal population
2. Six bins of equal population
3. Three bins of equal numbers of community water systems plus zero bin
4. Six bins of equal numbers of community water systems plus zero bin

Three Bins of Equal Population



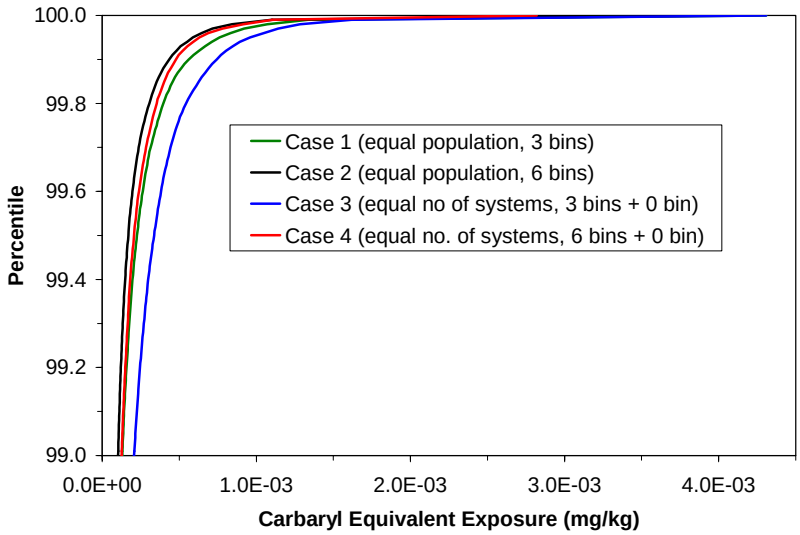
Three Bins Equal No. of CWS Plus Zero Bin



Bin Evaluation

- All bins evaluated assuming that the system with the highest concentration is representative of the entire bin
- Exposure calculated for population subgroup children 1-2
- Dietary assessment conducted using CARES version 2.0 (Build 7.8; 09/15/2005) which allows for statistical weighting of the yearly water profiles

Results of Evaluation



Conclusion: Binning Approaches

- Binning provides an acceptable procedure for deriving concentration distributions representative of several hundred community water systems.
- Initial evaluations indicate that 3-6 bins will be necessary to represent a regional distribution of concentrations

Conclusion: Binning Approaches

- The conservative approach of using the community water system with the highest concentration as representative of all bins means that increasing the number of bins will decrease the estimated residues.
- Binning approaches that keep the upper portion of the distribution into relatively small portions of the population will more closely approach the “true” concentration distributions especially at higher exposure percentiles.