



Pesticides: Science and Policy

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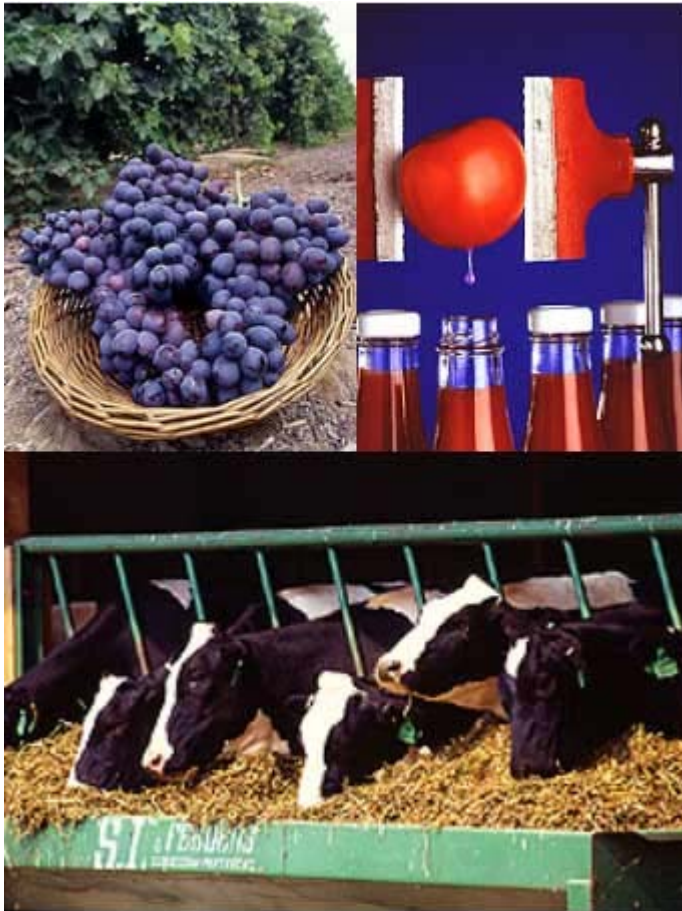
Dietary Risk Assessments in the United States and CARES

Scott Jackson and Patricia Rice
Exposure and Risk Assessment
October 4, 2004

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Dietary Risk



Potential for adverse health effects to occur as a result of consuming pesticide residues via food & water

Food

- Raw agricultural commodities
- Animal commodities (milk, meat, eggs)
- Processed commodities

Drinking water

- Monitoring
- Models

Dietary Risk Assessments Must Be Conducted For

- New Uses on
 - Food (must fit within the risk cup)
 - Animal feed commodities
 - Direct application to animals (i.e.. cows, poultry, swine)
- Changes in label, use pattern, or regions that may result in an increase of anticipated residues
- Tolerances: establishment and reassessment (FQPA 1996, FIFRA 88)

Dietary Risk

Dietary Risk = [(Amount Chemical Ingested)/(Amount Considered Safe [RfD])] x 100

Chemical Ingested: *Exposure* based on estimated quantity of chemical in food and quantity of food eaten
Exposure = Residue x Consumption

Amount Considered Safe: **Reference Dose [RfD]** based on toxicological data & uncertainty factor(s)

Exposure (Residue x Consumption)

Residue Data

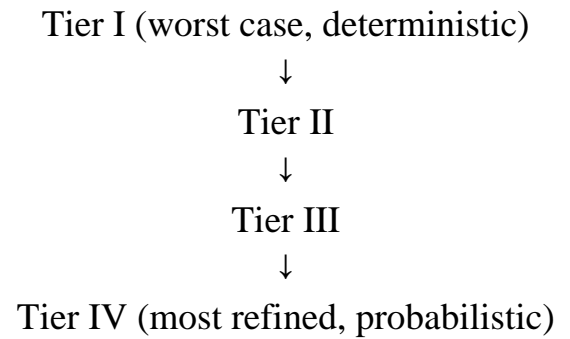
- Published or Proposed Tolerance Values
- Residue Field Trials (RACs)
- Food Processing Studies (commercial, consumer practices)
- Monitoring Data (PDP, CDPR)
- Market Basket Surveys

Consumption Data

- CSFII – USDA national food consumption survey (Continuing Food Survey of Intake of Individuals)
 - CDC – Center for Disease Control
 - NHANES – Nutrition Examination Surveys
 - NHEXAS – National Human Exposure Assessment Survey
-

Dietary Risk Assessment

- Total U.S. population and subpopulations
- Chronic (life time)
 - Cancer
- Acute (typically 1 day)
- Both chronic and acute assessments follow a tiered approach



The FQPA Challenge

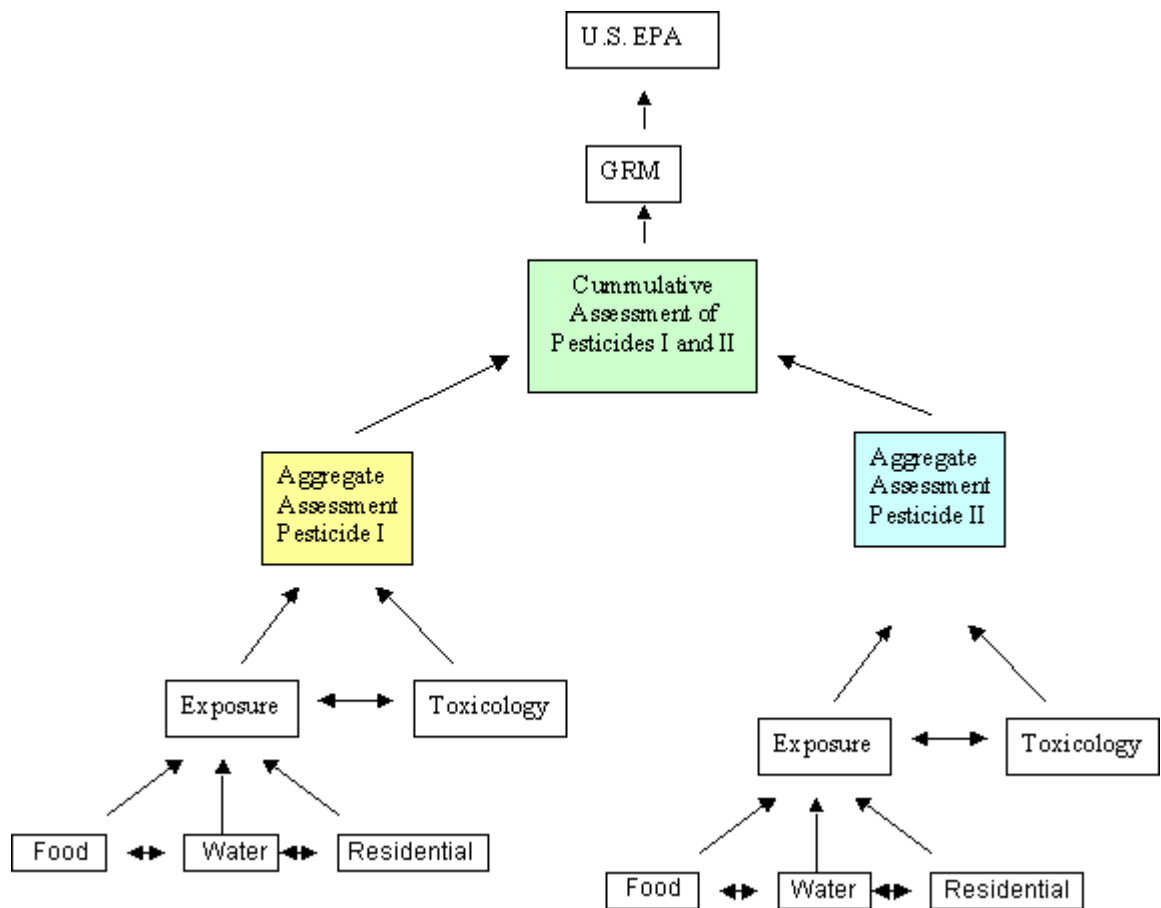
- 1996 Food Quality Protection Act (FQPA) changed data requirements and risk assessment standards
- EPA and stakeholders need outcome from several models in order to have confidence in exposure and risk calculations
- CARES – expert system to address FQPA standards for dietary, drinking water and residential exposure and risk
- Models evaluated by FIFRA Science Advisory Panel
 - Calendex (Novigen)
 - Lifeline (Hampshire Consulting/Lifeline Group)
 - CARES (ILSI)
 - SHEDS (ORD – TBA)

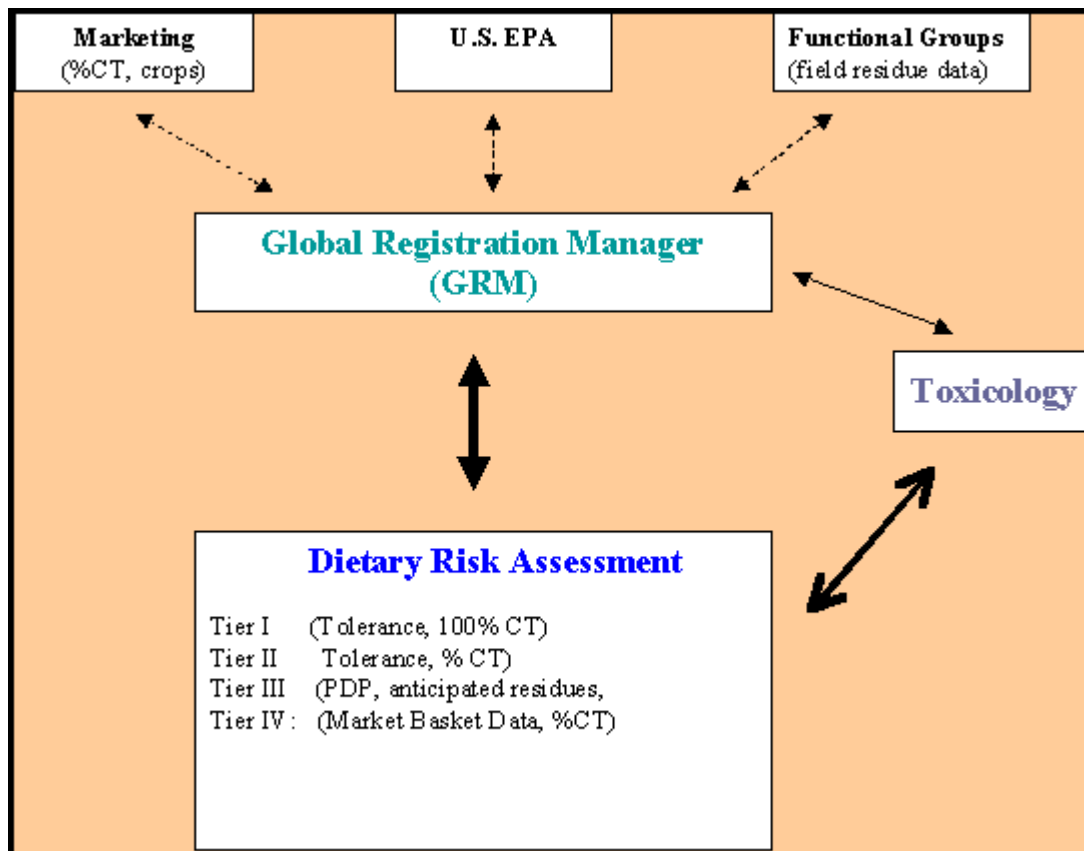
CARES Specifications & Key Features

- Open source code
- Calculations are transparent
- Notitia framework provides flexibility

- User friendly
 - Government, academics, public interest groups and industry have scientists successfully using CARES
 - Sensitivity analysis
 - What could makes a difference in the risk calculation
 - Utility
 - Current registrations and development candidates
-

Flow Diagram



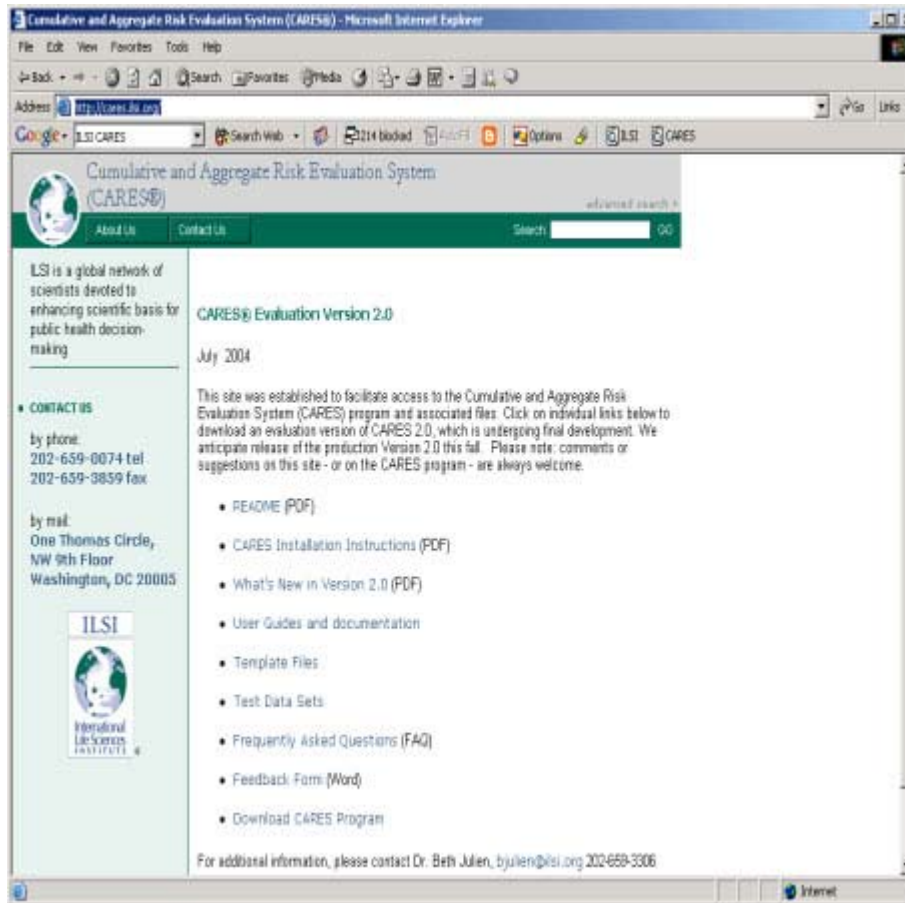


CARES

Cumulative and
Aggregate
Risk
Evaluation
System

Where can I find CARES?

- Public Web Site
Contains complete development documentation
EXIT Disclaimer <http://cares.ilsi.org/>



CARES SOFTWARE

What is CARES?

100,000 reference population

Population Generator

Stochastic exposure modules

Dietary | Residential | Water

Multiple sources & chemicals

Aggregate & Cumulate

Drill down and display

Contribution & Sensitivity

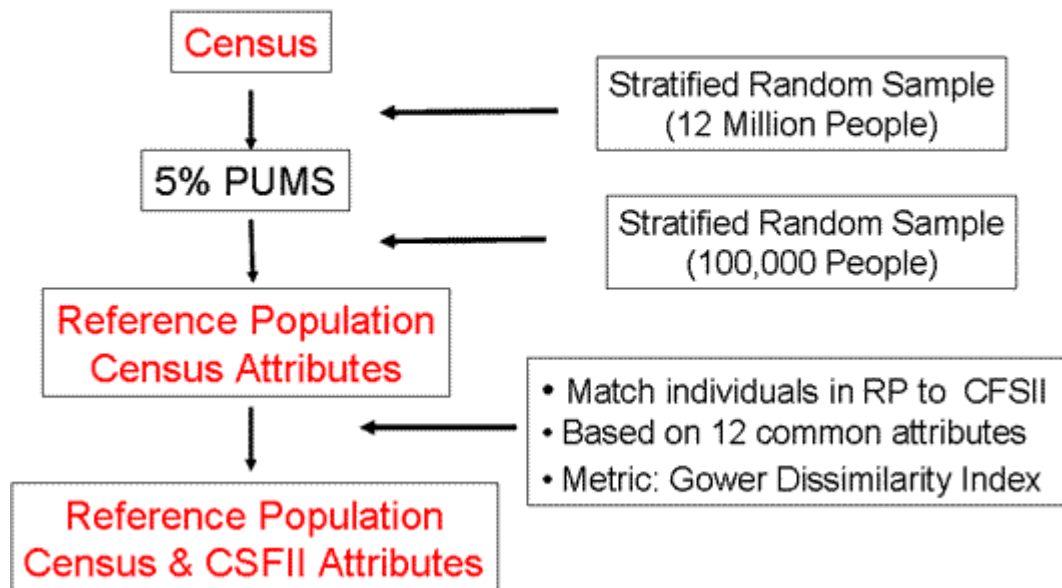
Reference Population Generator

- Generates 100,000 person Reference Population
- Real people with attributes
Gender, Age, Race, Location, \hat{A} ...
- 5000 subpopulation sample size



Total 1990 Census: 241,000,000
5% PUMS Population: 12,000,000
Reference Population: 100,000
 (0.04% of Census)

Basis of Reference Population

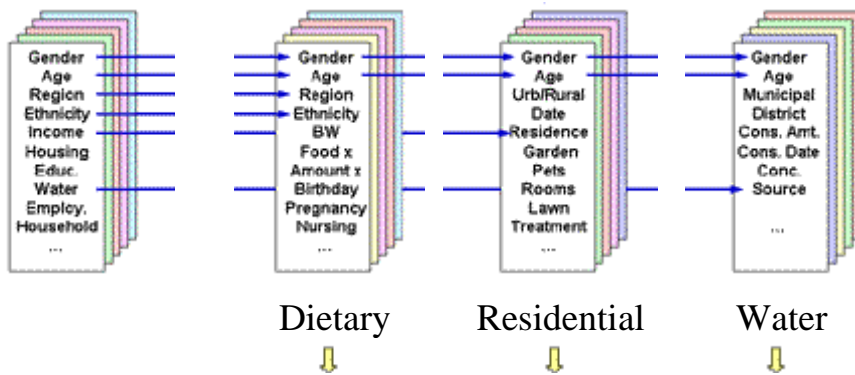


CARES POPULATION GENERATOR

- Matching attributes across databases to generate individual exposure data

| | | | |
|--|----------------|-----------------------|--------------|
| | Dietary | Residential | Water |
| Databases | Census/PUMS | CSFII/FCID NHAPS/REJV | Water |
| Matching characteristics across databases to establish daily profiles | | | |

for each of 100,000 individuals



Primary and Secondary Matching Attributes

12 Used in Primary Matching:

- Region
- MSA Status
- Household Size
- Gender
- Age
- Race/Ethnicity
- Household Income
- Percent of Poverty Level
- Poverty Category
- Employment Status
- Education Level
- Tenure (ownership status of residence)

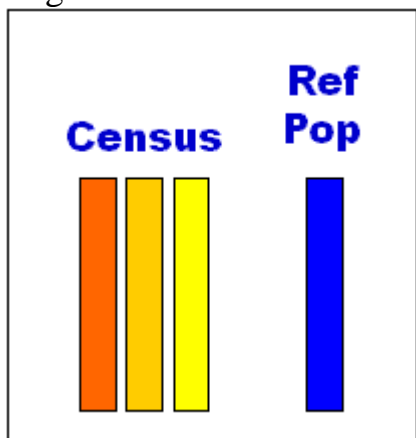
19 Additional Characteristics:

- Food Sufficiency
- Health Status
- Smoking Level
- Vegetarian
- Diabetic
- Low Calorie Diet
- Low Fat Diet
- Low Salt Diet
- Low Sugar Diet
- Diabetic Diet
- Milk Allergy
- Egg Allergy
- Fish/Shellfish Allergy
- Peanut Allergy
- Breastfeeding Status
- Lactation Status
- Pregnancy Status
- Age-in-Months
- Day-of-Week

Is the Reference Population Representative?

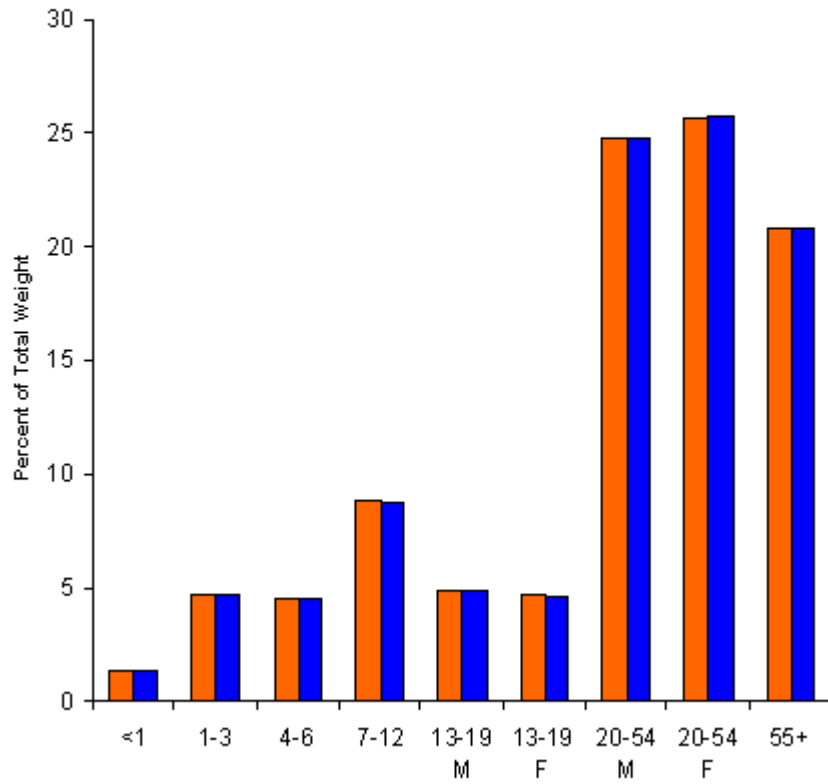
Comparison of US Census and the Reference Population of 100,000 individuals.

Legend



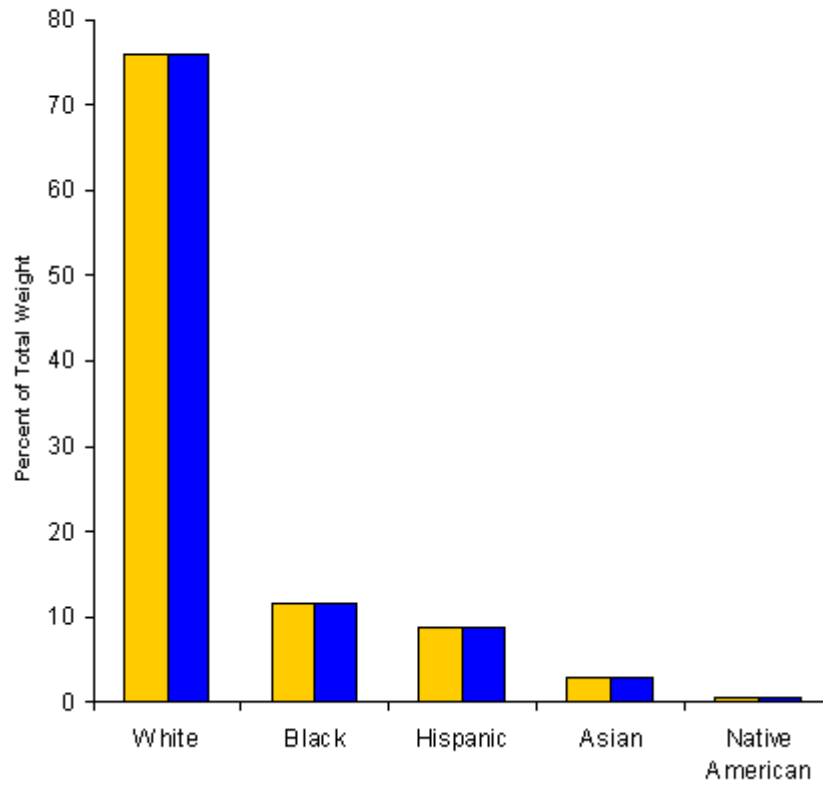
Percent of Total Weight

Age/Gender

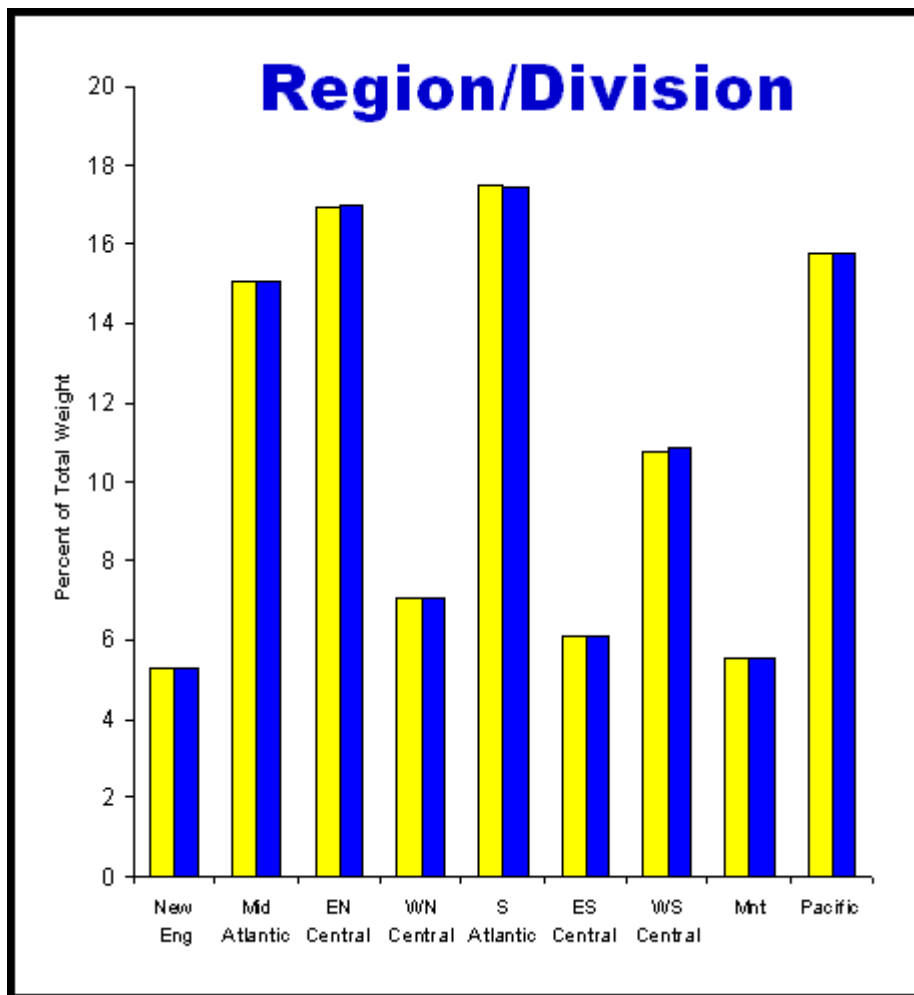


Percent of Total Weight

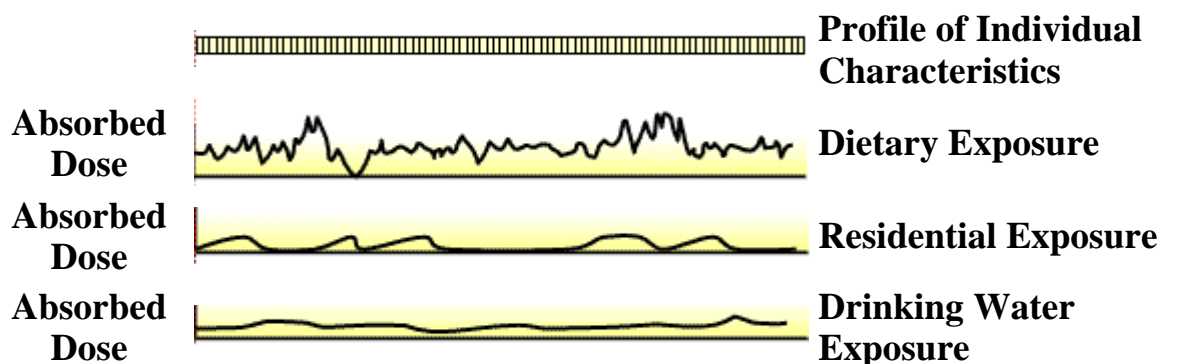
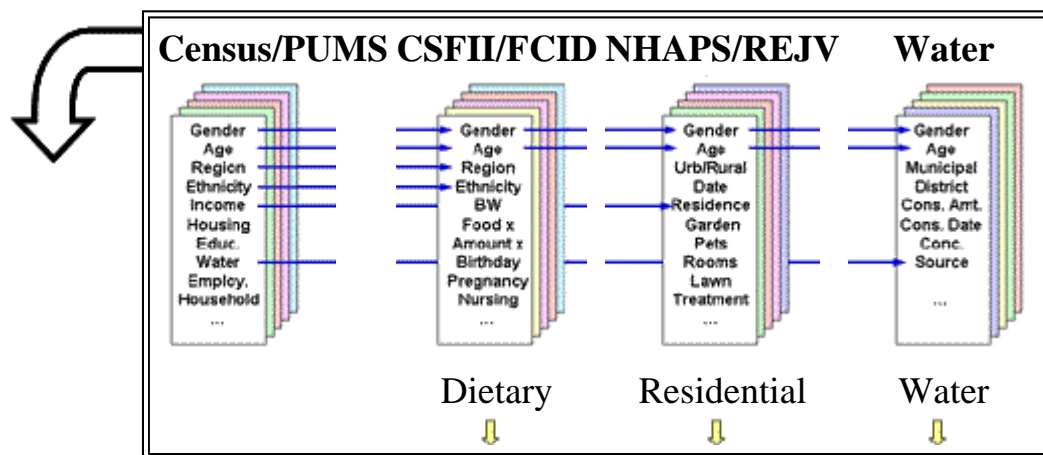
Race/Ethnicity



Percent of Total Weight



CARES SOFTWARE: Generates calendar year profile per person

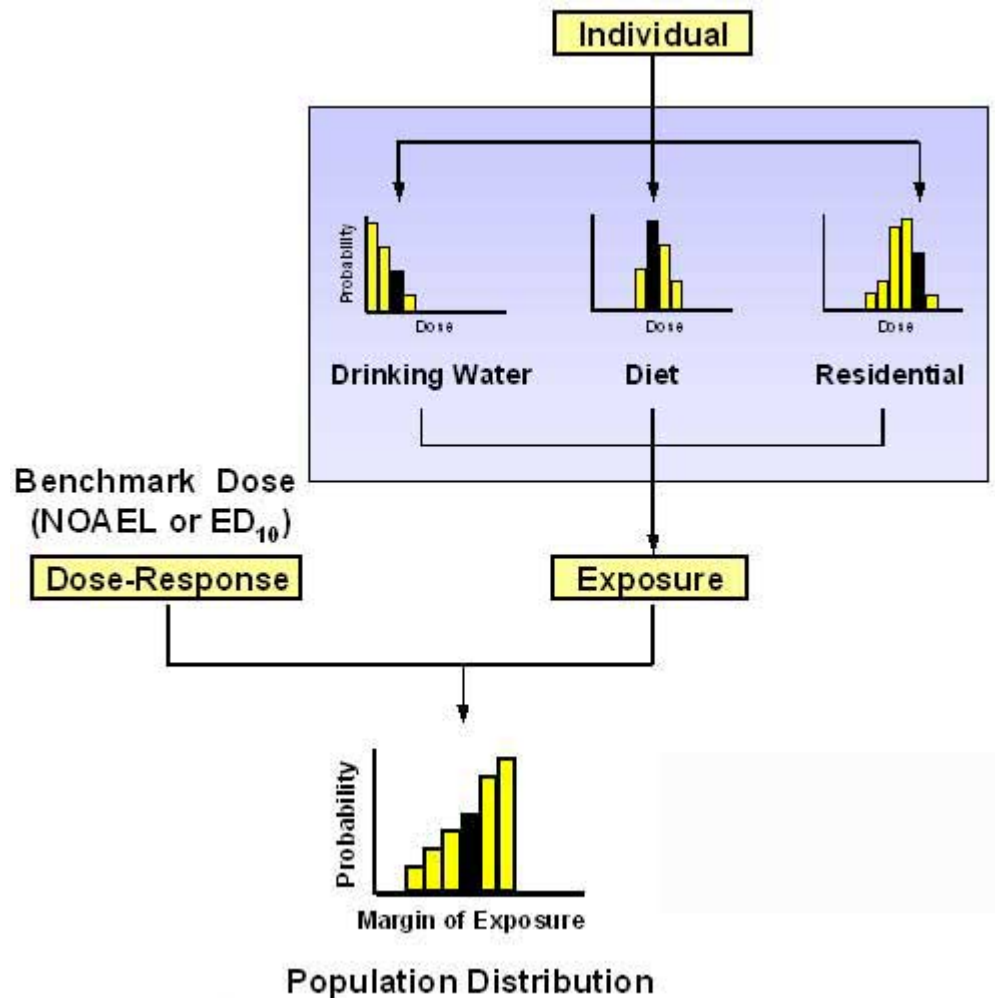


Aggregation

Aggregate an individual's source and route-specific dose profiles for a specified chemical to obtain a 365-day profile of Toxic Equivalent Doses (TEDs).

Determine distributions of TEDs and MOEs among individuals in the population.

Done for specified exposure durations (Acute, Short-Term, Intermediate, and Chronic)



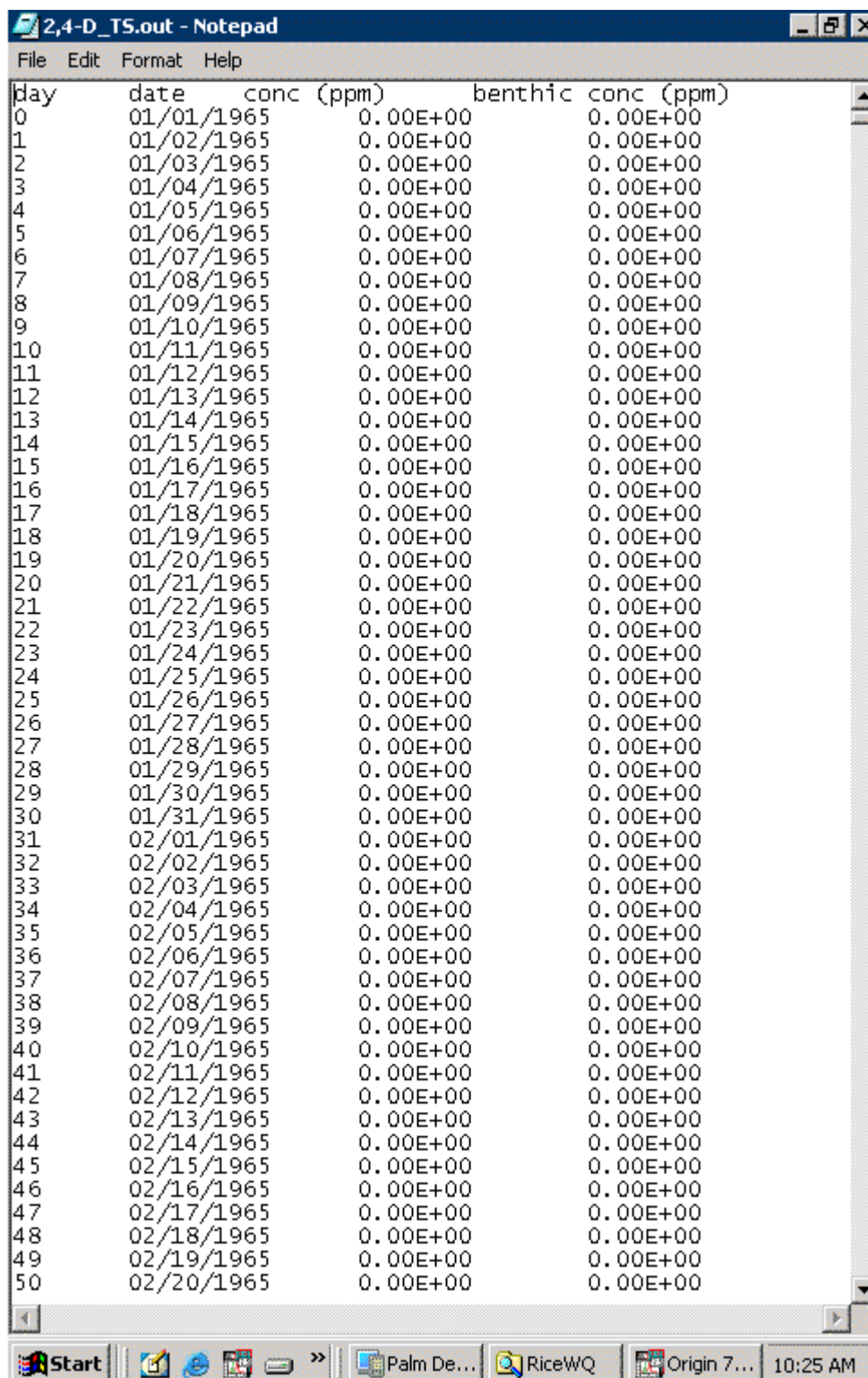
$$\text{Margin of Exposure} = (\text{NOAEL or ED}_{10}) / \text{Dose from Exposure}$$

Importing Water Data into CARES

CARES is flexible and will accept a variety of input formats and can handle linear interpolation with monitoring data

PE4 Output

Note the date in mm/dd/yyyy format



| day | date | conc (ppm) | benthic conc (ppm) |
|-----|------------|------------|--------------------|
| 0 | 01/01/1965 | 0.00E+00 | 0.00E+00 |
| 1 | 01/02/1965 | 0.00E+00 | 0.00E+00 |
| 2 | 01/03/1965 | 0.00E+00 | 0.00E+00 |
| 3 | 01/04/1965 | 0.00E+00 | 0.00E+00 |
| 4 | 01/05/1965 | 0.00E+00 | 0.00E+00 |
| 5 | 01/06/1965 | 0.00E+00 | 0.00E+00 |
| 6 | 01/07/1965 | 0.00E+00 | 0.00E+00 |
| 7 | 01/08/1965 | 0.00E+00 | 0.00E+00 |
| 8 | 01/09/1965 | 0.00E+00 | 0.00E+00 |
| 9 | 01/10/1965 | 0.00E+00 | 0.00E+00 |
| 10 | 01/11/1965 | 0.00E+00 | 0.00E+00 |
| 11 | 01/12/1965 | 0.00E+00 | 0.00E+00 |
| 12 | 01/13/1965 | 0.00E+00 | 0.00E+00 |
| 13 | 01/14/1965 | 0.00E+00 | 0.00E+00 |
| 14 | 01/15/1965 | 0.00E+00 | 0.00E+00 |
| 15 | 01/16/1965 | 0.00E+00 | 0.00E+00 |
| 16 | 01/17/1965 | 0.00E+00 | 0.00E+00 |
| 17 | 01/18/1965 | 0.00E+00 | 0.00E+00 |
| 18 | 01/19/1965 | 0.00E+00 | 0.00E+00 |
| 19 | 01/20/1965 | 0.00E+00 | 0.00E+00 |
| 20 | 01/21/1965 | 0.00E+00 | 0.00E+00 |
| 21 | 01/22/1965 | 0.00E+00 | 0.00E+00 |
| 22 | 01/23/1965 | 0.00E+00 | 0.00E+00 |
| 23 | 01/24/1965 | 0.00E+00 | 0.00E+00 |
| 24 | 01/25/1965 | 0.00E+00 | 0.00E+00 |
| 25 | 01/26/1965 | 0.00E+00 | 0.00E+00 |
| 26 | 01/27/1965 | 0.00E+00 | 0.00E+00 |
| 27 | 01/28/1965 | 0.00E+00 | 0.00E+00 |
| 28 | 01/29/1965 | 0.00E+00 | 0.00E+00 |
| 29 | 01/30/1965 | 0.00E+00 | 0.00E+00 |
| 30 | 01/31/1965 | 0.00E+00 | 0.00E+00 |
| 31 | 02/01/1965 | 0.00E+00 | 0.00E+00 |
| 32 | 02/02/1965 | 0.00E+00 | 0.00E+00 |
| 33 | 02/03/1965 | 0.00E+00 | 0.00E+00 |
| 34 | 02/04/1965 | 0.00E+00 | 0.00E+00 |
| 35 | 02/05/1965 | 0.00E+00 | 0.00E+00 |
| 36 | 02/06/1965 | 0.00E+00 | 0.00E+00 |
| 37 | 02/07/1965 | 0.00E+00 | 0.00E+00 |
| 38 | 02/08/1965 | 0.00E+00 | 0.00E+00 |
| 39 | 02/09/1965 | 0.00E+00 | 0.00E+00 |
| 40 | 02/10/1965 | 0.00E+00 | 0.00E+00 |
| 41 | 02/11/1965 | 0.00E+00 | 0.00E+00 |
| 42 | 02/12/1965 | 0.00E+00 | 0.00E+00 |
| 43 | 02/13/1965 | 0.00E+00 | 0.00E+00 |
| 44 | 02/14/1965 | 0.00E+00 | 0.00E+00 |
| 45 | 02/15/1965 | 0.00E+00 | 0.00E+00 |
| 46 | 02/16/1965 | 0.00E+00 | 0.00E+00 |
| 47 | 02/17/1965 | 0.00E+00 | 0.00E+00 |
| 48 | 02/18/1965 | 0.00E+00 | 0.00E+00 |
| 49 | 02/19/1965 | 0.00E+00 | 0.00E+00 |
| 50 | 02/20/1965 | 0.00E+00 | 0.00E+00 |

EXPRESS Output

Note the date in yyyy-mm-dd format



Consecutive numbering



Julian Date numbering (repeats each year)



mm/dd/yyyy numbering

Entering Monitoring Data into CARES



Input Monitoring Data



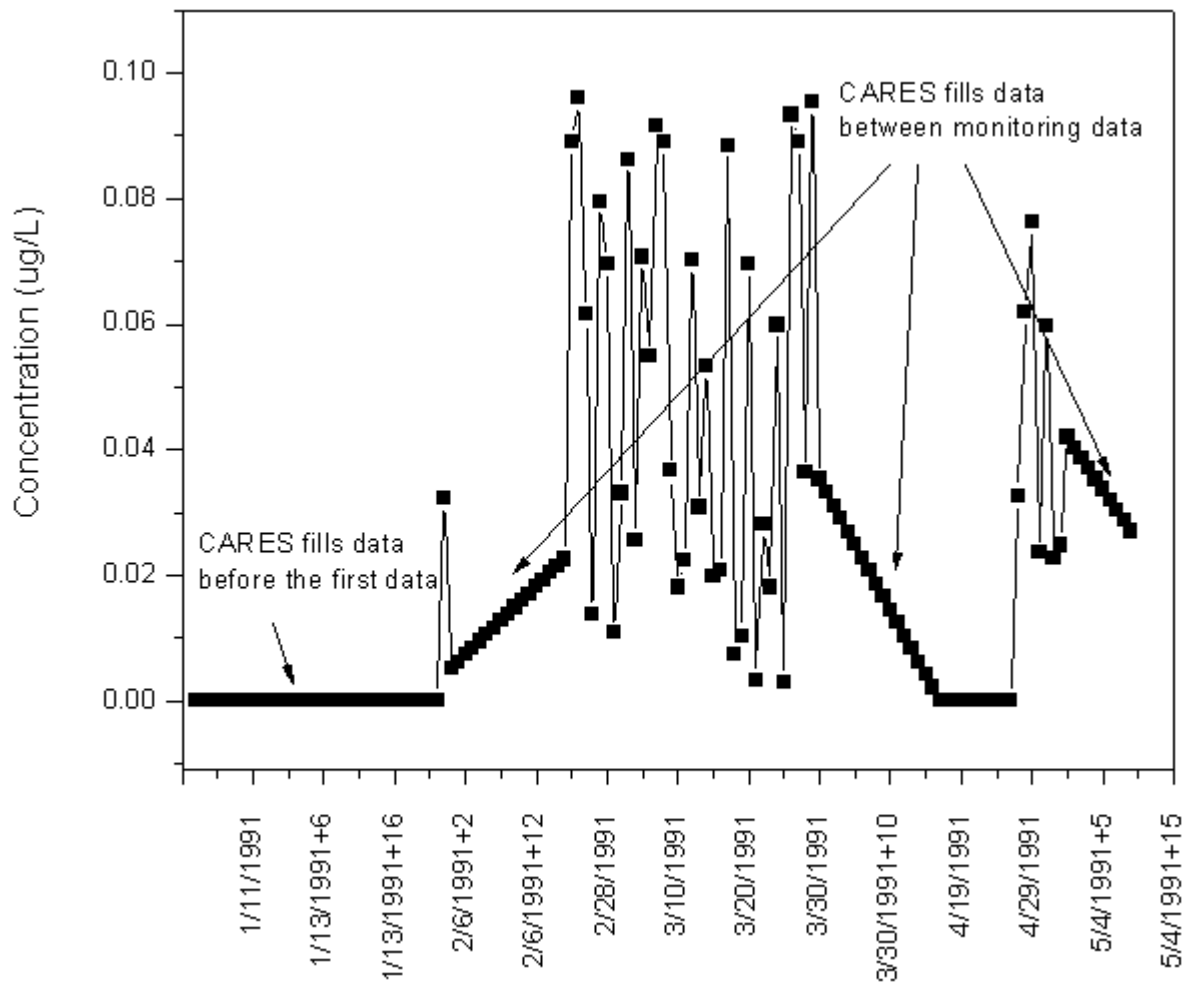
Input Monitoring Data after import

CARES and Monitoring Data

CARES uses

1. 1/2 LOD
2. Simple linear interpolation

Example of CARES calculating linear interpolation between monitoring data points



CARES Interface (NotitiaTM)

Explorer | **Tools** | **Canvas**

Data Explorer

Options Help

Familiar Objects

Help, Tools, Graphs

Windows Standards

User Aids

Objects

Helpful, Clear Design

Consistent Interface

104 Child Ingestion Hand-To-Mouth

104 Child Exposure

Added symbol ID 629159601 to Diagram
Symbol= (Demat1.F11104)

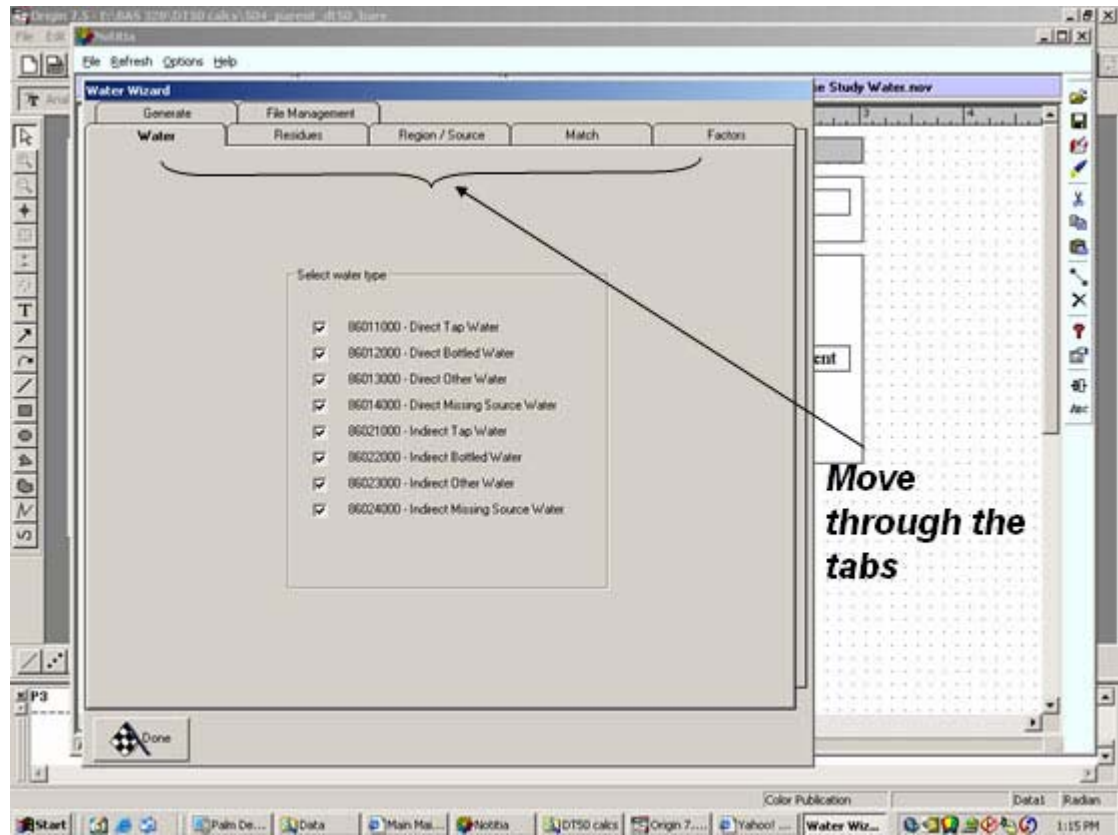
Added symbol ID 55851860 to Diagram
Symbol= (Ingestion1.F12104)

Water Selector Screen

First launch the water wizard Icon

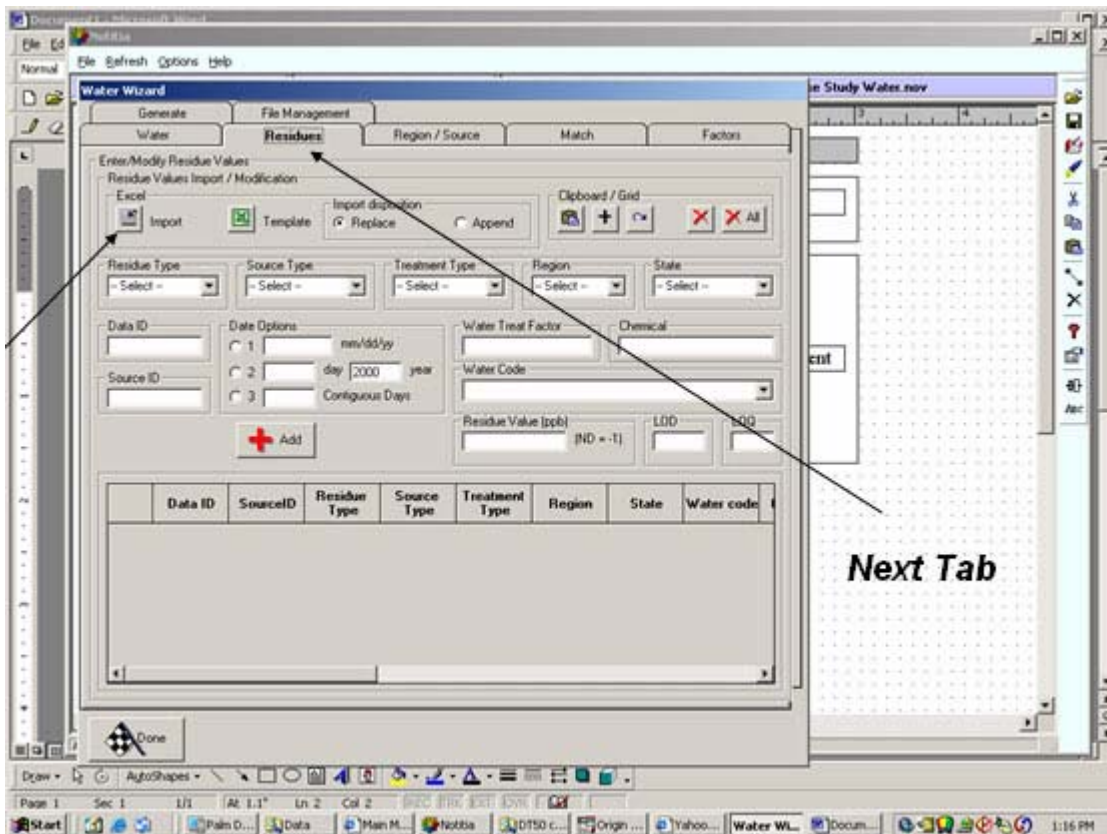
Select where contributions of residue will be used or go

Move through the tabs



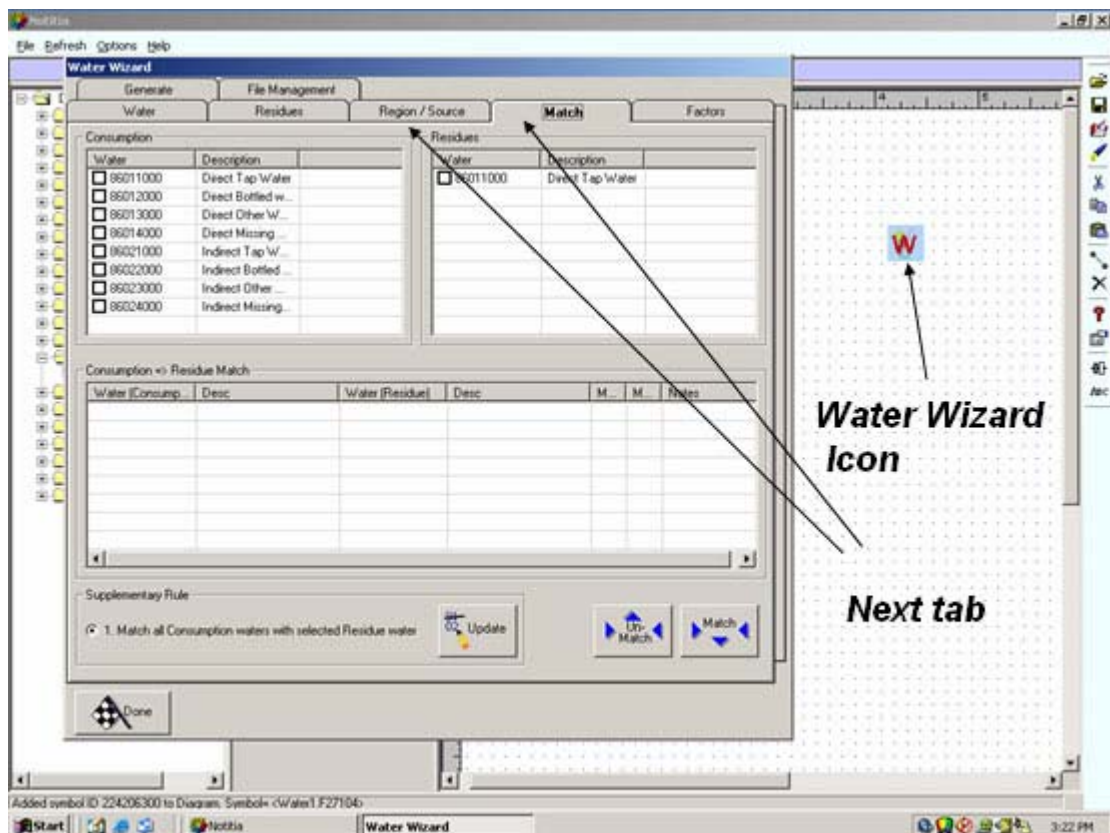
Import Data Screen

Import data screen. None of the features are used here if you are importing data.



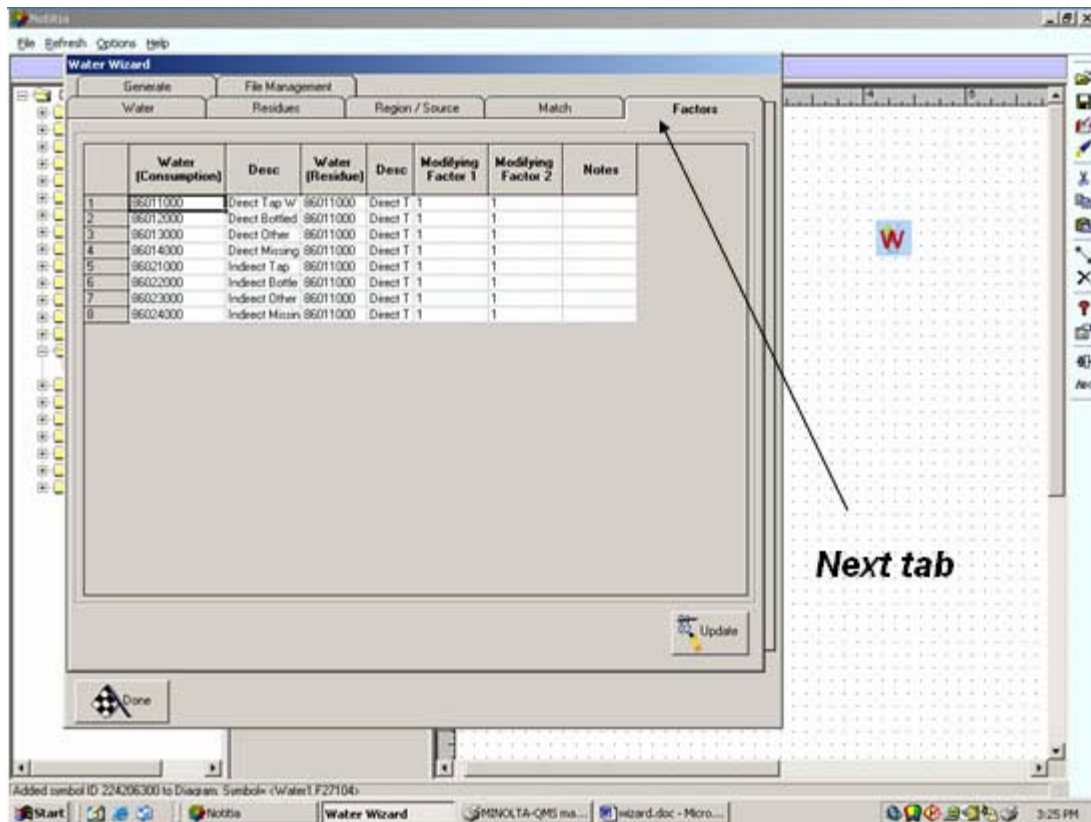
Water Match Screen

Again you would match residue source to water type



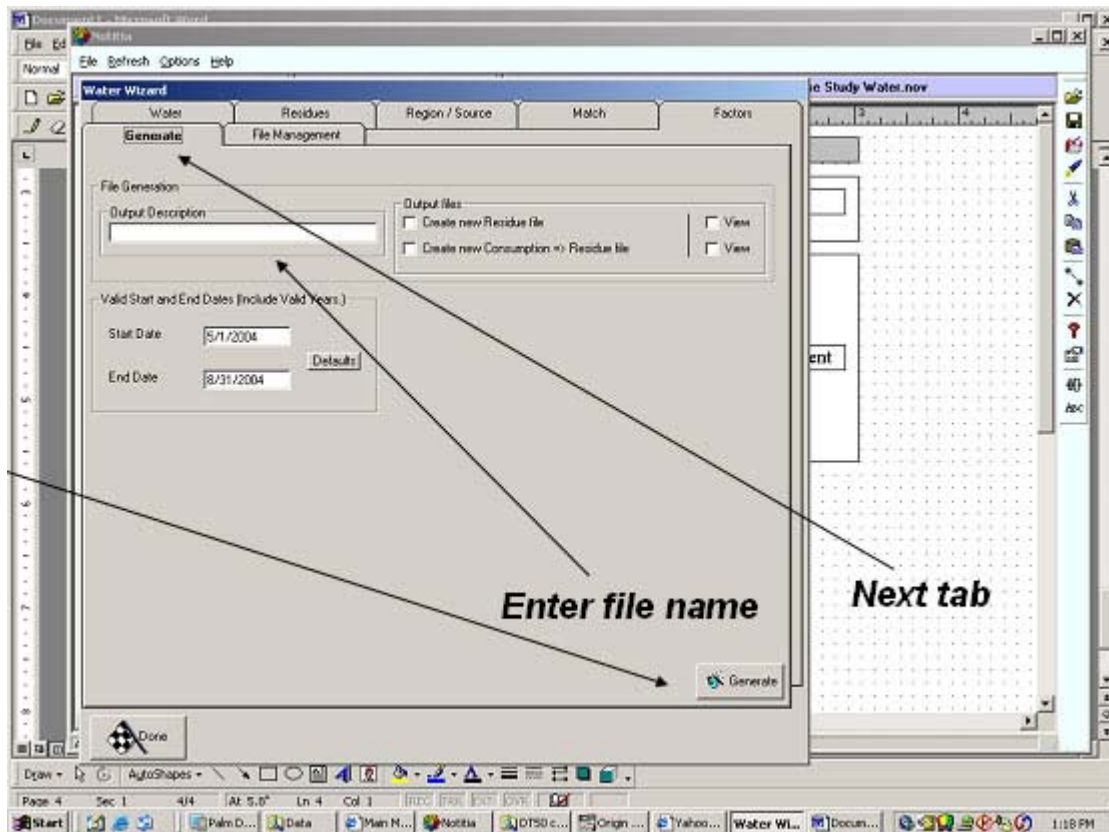
Water Factors Screen

It is possible to include water treatment factors here – However, it is better to handle this before data is brought in to CARES



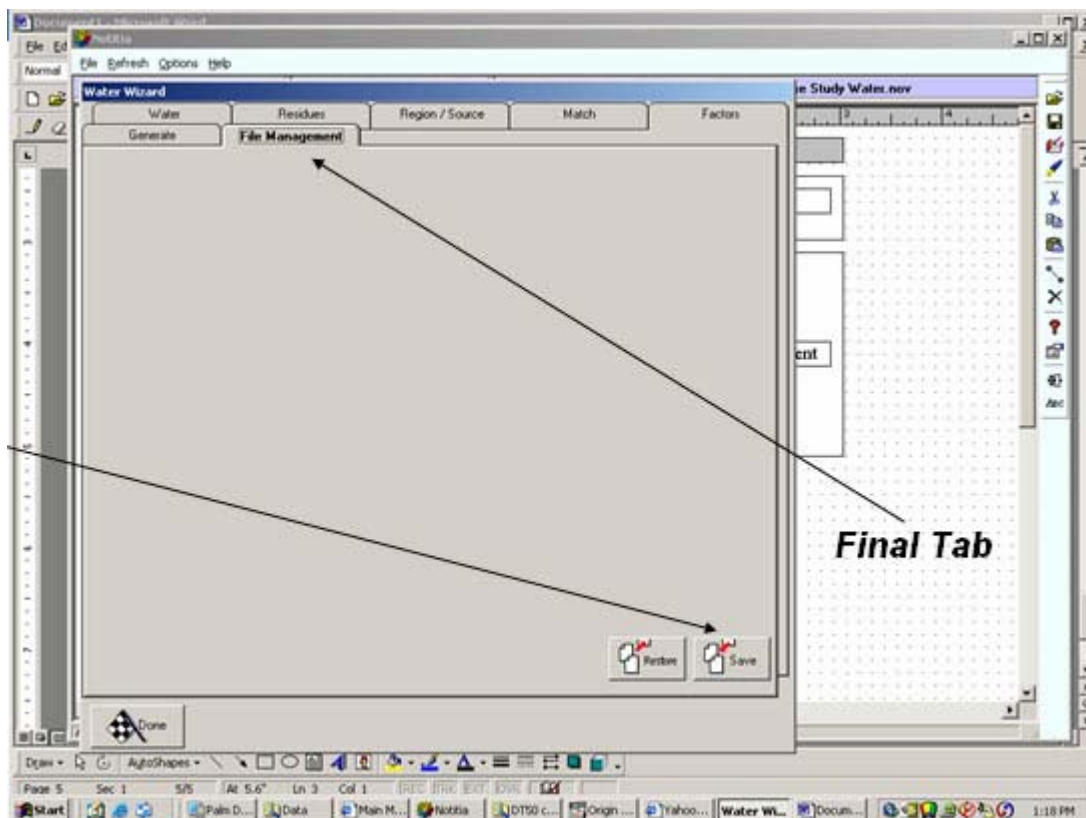
File Generation Screen

This screen is where the "transfer" files would be generated



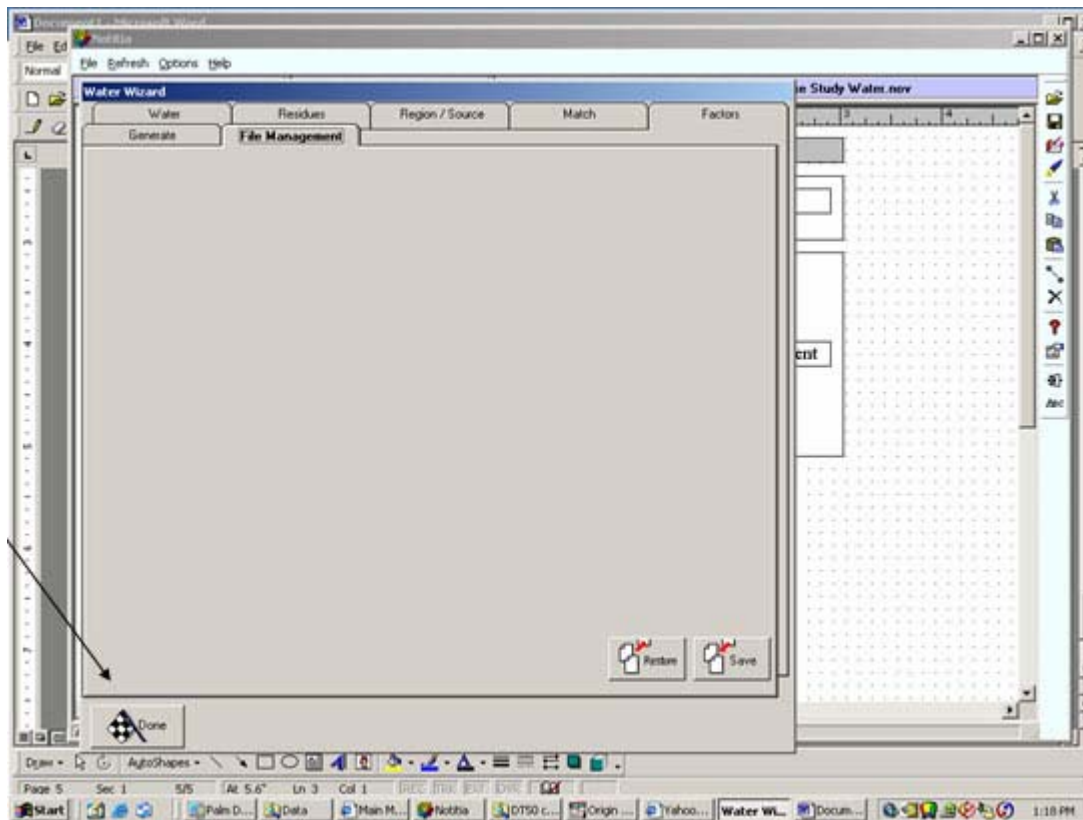
File Save Screen

This screen is an additionally required save screen



Exit Water Wizard

Select done to finish



Files Generated by the Water Wizard

After completion of the water wizard, two files will be generated.

These two files can be transferred to the person conducting the aggregation analysis.

Last Slide



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Last updated on Tuesday, July 24th, 2007

URL: http://www.epa.gov/oppefed1/models/water/cares_scott.htm