# U.S. Environmental Protection Agency



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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

**Dietary Risk** Dietary Risk Assessments Must Be Conducted For **Dietary Risk** Exposure (Residue x Consumption) **Dietary Risk Assessment** The FOPA Challenge **CARES Specifications & Key Features** Flow Diagram CARES Where can I find CARES? CARES SOFTWARE **Reference Population Generator Basis of Reference Population** CARES POPULATION GENERATOR Primary and Secondary Matching Attributes Is the Reference Population Representative? CARES SOFTWARE: Generates calendar year profile per person Aggregation Importing Water Data into CARES PE4 Output **EXPRESS** Output Entering Modeling Data into CARES Entering Monitoring Data into CARES **CARES** and Monitoring Data CARES Interface (Notitia $\frac{TM}{}$ ) Water Selector Screen Import Data Screen Water Match Screen Water Factors Screen File Generation Screen File Save Screen Exit Water Wizard Files Generated by the Water Wizard

#### Last Slide

#### **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	<i>Exposure</i> based on estimated quantity of chemical in food and quantity of food eaten
chemical ingestea.	<i>Exposure</i> = Residue x Consumption
<b>Amount Considered</b>	Reference Dose [RfD] based on toxicological data &
Safe:	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)

o Cancer

- Acute (typically 1 day)
- Both chronic and acute assessments follow a tiered approach



Tier I (worst case, deterministic) ↓ Tier II ↓ Tier III ↓ Tier IV (most refined, probabilistic)

# 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
  - o Calendex (Novigen)
  - Lifeline (Hampshire Consulting/Lifeline Group)
  - CARES (ILSI)
  - $\circ$  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
  - o Current registrations and development candidates



#### **Flow Diagram**



#### CARES

Cumulative and Aggregate **R**isk Evaluation System

#### Where can I find CARES?

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



# **CARES SOFTWARE**

#### What is CARES?



#### **Reference Population Generator**

- Generates 100,000 person Reference Population
- Real people with attributes Gender, Age, Race, Location, Â...
- 5000 subpopulation sample size



Total 1990 Census:241,000,0005% PUMS Population:12,000,000Reference 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/FCI	D NHAPS/REJV	Water
Matching			
characteristics			
across databases			
to establish daily			
profiles			



#### **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	MC11, Allowers
Health Status	Milk Allergy
Smoking Level	Egg Allergy
Vegetarian	Fish/Shellfish Allergy
Dishatia	Peanut Allergy
	Breastfeeding Status
Low Calorie Diet	Lactation Status
Low Fat Diet	Pregnancy Status
Low Salt Diet	Aga in Months
Low Sugar Diet	Age-III-IVIOIIUIS
Diabetic Diet	Day-oi-week

#### Is the Reference Population Representative?

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



Percent of Total Weight



Percent of Total Weight



Percent of Total Weight



**CARES SOFTWARE:** Generates calendar year profile per person



# Aggregation

Aggregate an individualÂ'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)



Margin of Exposure = (NOAEL or  $ED_{10}$ ) / 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

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# **EXPRESS** Output

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# **Entering Modeling Data into CARES**



Template Codes

How you "tell" CARES what you are entering



Microsoft Excel Worksheet Consecutive numbering



Microsoft Excel Worksheet Julian Date numbering (repeats each year)



Microsoft Excel Worksheet mm/dd/yyyy numbering

# **Entering Monitoring Data into CARES**



Microsoft Excel Worksheet Input Monitoring Data



Microsoft Excel Worksheet 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 (Notitia<sup>TM</sup>)



### 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.

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# Water Match Screen

Again you would match residue source to water type

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#### Water Factors Screen

It is possible to include water treatment factors here  $\hat{A}$ - However, it is better to handle this before data is brought in to CARES

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# **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

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### 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 conduction the aggregation analysis.

#### Last Slide



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