

Dietary Risk Assessment (Food Only)



Sheila Piper
EPA OPP/HED

Jennifer Lantz
Bayer CropScience

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Objectives

- Brief Overview of Dietary Assessment
 - What is a Dietary Assessment
 - What are the required inputs
 - What are the sources of inputs
- Workshop Dietary Example
- What's New
 - Chronic Capability
 - Dietary Minute Module

How Do We Assess Risk?

Four broad categories
of risk assessment:

Food

Aggregate

- Food
- Drinking water
- Residential

Cumulative

Occupational

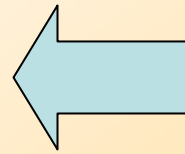
...each of which can be
evaluated over a
variety of time-
frames:

- ❖ Acute
- ❖ Short-term
- ❖ Intermediate Term
- ❖ Chronic
- ❖ Lifetime

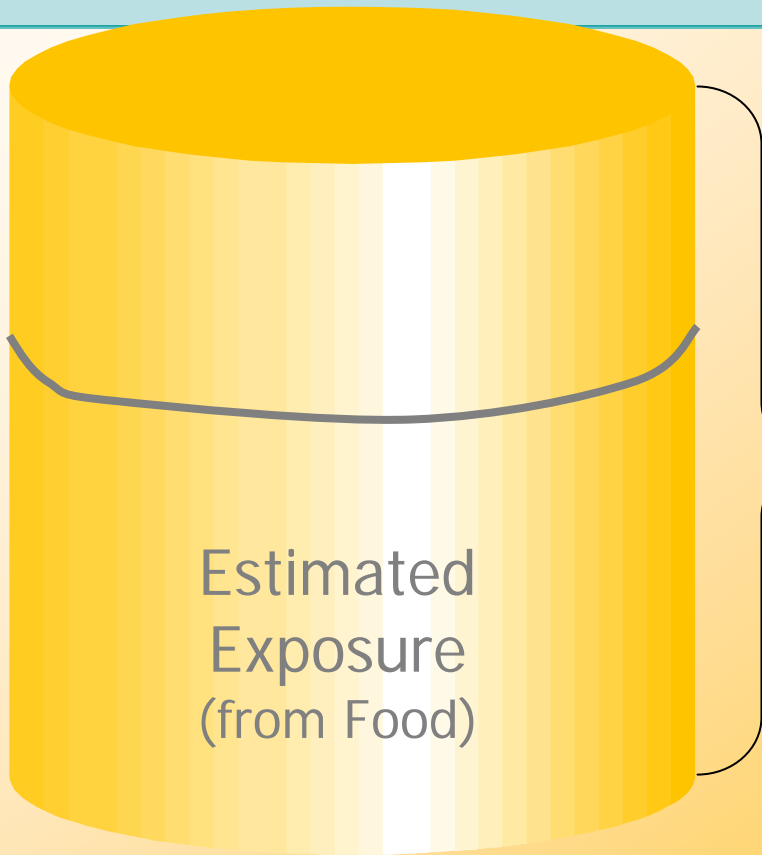
Dietary Risk Assessment

Risk = Hazard x Exposure

$$\text{Risk(\% PAD)} = \frac{\text{Exposure} \times 100}{\text{PAD}}$$



Risk calculated as a percent of a “safe dose” (percent of population adjusted dose (PAD))



FULL CUP

100% of the PAD is the threshold

Consumption Data-CSFII

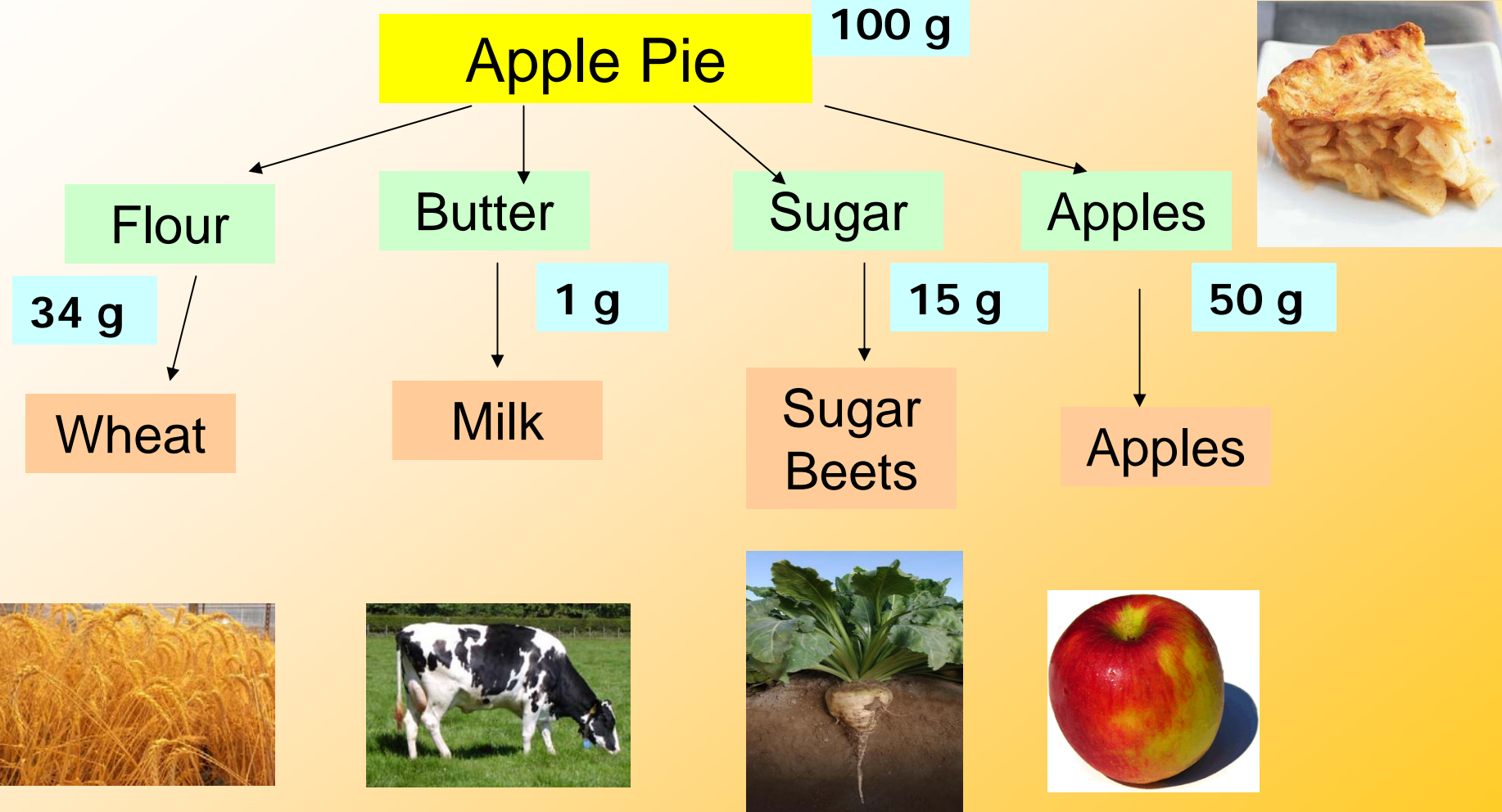
USDA's Continuing Survey of Food Intake by Individuals (CSFII) database which is designed to represent consumption practices of the U.S. population in terms of age, sex, race, season, income, etc.

CSFII-Continuing Survey of Food Intake by Individuals.

- 1994-1996 Statistically represents U.S. Population
 - 16,000 people x 2 days of intake = 32,000 records (person-days)
- 1998 Supplemental Children's Survey
 - 5,000 Age 0-9 x 2 days of intake = 10,000 records (person-days)
- The two surveys are combined for use in dietary risk models
- Publicly available at www.barc.usda.gov/bhnrc/foodsurvey

FCID-Food Commodity Intake Database

Converts foods as eaten to RACs using recipes



NHANES Data

National Health and Nutrition Examination Survey

- NHANES data provides a snapshot of the health and nutrition of the U.S. population
- 1999-2002 (food diary collected for only 1 day)
 - U.S. General Pop (N=18655, Total Diaries=18655)
 - Children 1-2 yrs old (Total Diaries=1077)
- 2003-2004 (2 day food diaries collected)
 - U.S. General Pop (N=9004, Total Diaries=17319)
 - Children 1-2 yrs old (N=570, Total Diaries=1083)
- 2005- 2006 data is not available
- **Publicly available at <http://www.cdc.gov/nhanes/>**

Residues



- Field Trial Data
- FDA Monitoring Data
- USDA/PDP Monitoring Data
- Market Basket Survey

Field Trial Data



- Required to register a food use (under FIFRA)
- Guidelines:
 - Residue Chemistry Data Requirements : 40 CFR 158.240
 - Residue Chemistry Test Guidelines: OPPTS 860.1500

http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/Series/860-1500.pdf



- To determine terminal residues in crops in the field for 2 purposes:
 - Establishing tolerances
 - Risk assessment

Monitoring Data



- **FDA/ Enforcement Monitoring**
 - Points of entry into USA
 - Regulatory focus
 - No preparation or peeling
- **USDA/PDP (Pesticide Data Program)**
 - Sampled at distribution centers
 - Focus on foods consumed by children
 - Food as consumed
- **Industry/Market Basket**
 - Grocery stores
 - Foods as consumed

Acute Assessments

- Risk resulting from 1-day exposure
- Residue level, food consumption, and endpoint all must represent 1-day exposure or dosing
- Assessments use:
 - Single high-end residue concentrations (deterministic)
 - The entire distribution of residues (probabilistic)

Chronic Assessments

- Risk resulting from exposure > 6 months
- Residue level, food consumption, and endpoint all must represent long term exposure or dosing
- Single average food residue/tolerance and consumption values
- Deterministic assessments, average exposure

Unrefined/Screening Level Acute Analysis

- Consumption:
 - USDA's CSFII Reported Consumptions

- Residues:
 - Tolerance level residue
 - 100% crop treated
 - Default Processing Factors

Highly Refined Acute Analysis

- Consumption:
 - Uses Full Distribution of CSFII Reported Consumptions
- Residues:
 - Incorporates *Distribution* of Percent Crop Treated
 - Uses “Best Available” *Distribution* of Residues
 - Market Basket Survey
 - PDP
 - FDA
 - Field Trial
 - Tolerance
 - Actual Processing Factors (if available)
 - Bridging Studies, Residue Decline/Degradation Studies, Cooking Studies, Processing Studies, etc.

Processing Factors

- A processing factor (PF) describes the concentration or reduction in residues from the processed commodity (PC) to the raw agricultural commodity (RAC)

$$PF = \frac{\text{Residue in PC}}{\text{Residue in RAC}}$$

- Washing, peeling, cooking, and trimming factors are also processing factors

Default Processing Factors

Commodity	Processing Factor	Commodity	Processing Factor
Apples - dried	8.0	Papayas - dried	1.8
Apples - juice/cider	1.3	Papayas - juice	1.5
Apricots - dried	6.0	Peaches - dried	7.0
Bananas - dried	3.9	Peanuts - butter	1.89
Beef - dried	1.92	Pears - dried	6.25
Cherries - juice	1.5	Pineapples - dried	5.0
Coconut - dried	2.1	Pineapples - juice	1.7
Corn grain - sugar/hfcs	1.5	Plantains - dried	3.9
Cranberries - juice	1.1	Plums - prunes (dried)	5.0
Grapefruit - juice	2.1	Plums - prunes (juice)	1.4
Grapes - juice	1.2	Potatoes/White - dry	6.5
Grapes - raisins	4.3	Tangerines - juice	2.3
Lemons - juice	2.0	Tomatoes - dried	14.3
Limes - juice	2.0	Tomatoes - juice	1.5
Lychee - dried	1.85	Tomatoes - paste	5.4
Onions - dehydrated or dried	9.0	Tomatoes - puree	3.3
Oranges – juice	1.8		

Percent Crop Treated

- Generated by BEAD using a variety of databases
- Percentage of acreage treated with a pesticide
- Average & maximum estimates
 - Estimates for single a.i.'s and agricultural sites only

Percent Crop Treated

Acute

- Probability of eating a treated commodity, single day
- Estimated Maximum PCT
- Residue Distribution File (RDF) format required
- 99.9th percentile of exposure

Chronic

- Long-term exposure
- Average PCT
- No RDFs, pt. estimate

Distribution of Field Trial Residues

– Typical Example

Sample Field Trial Residues (ppm)
45% CT; 0.05 LOQ

0.093	0.33
0.100	ND
0.074	ND
0.077	ND
0.41	

- There 9 FT residues with 3 non-detects

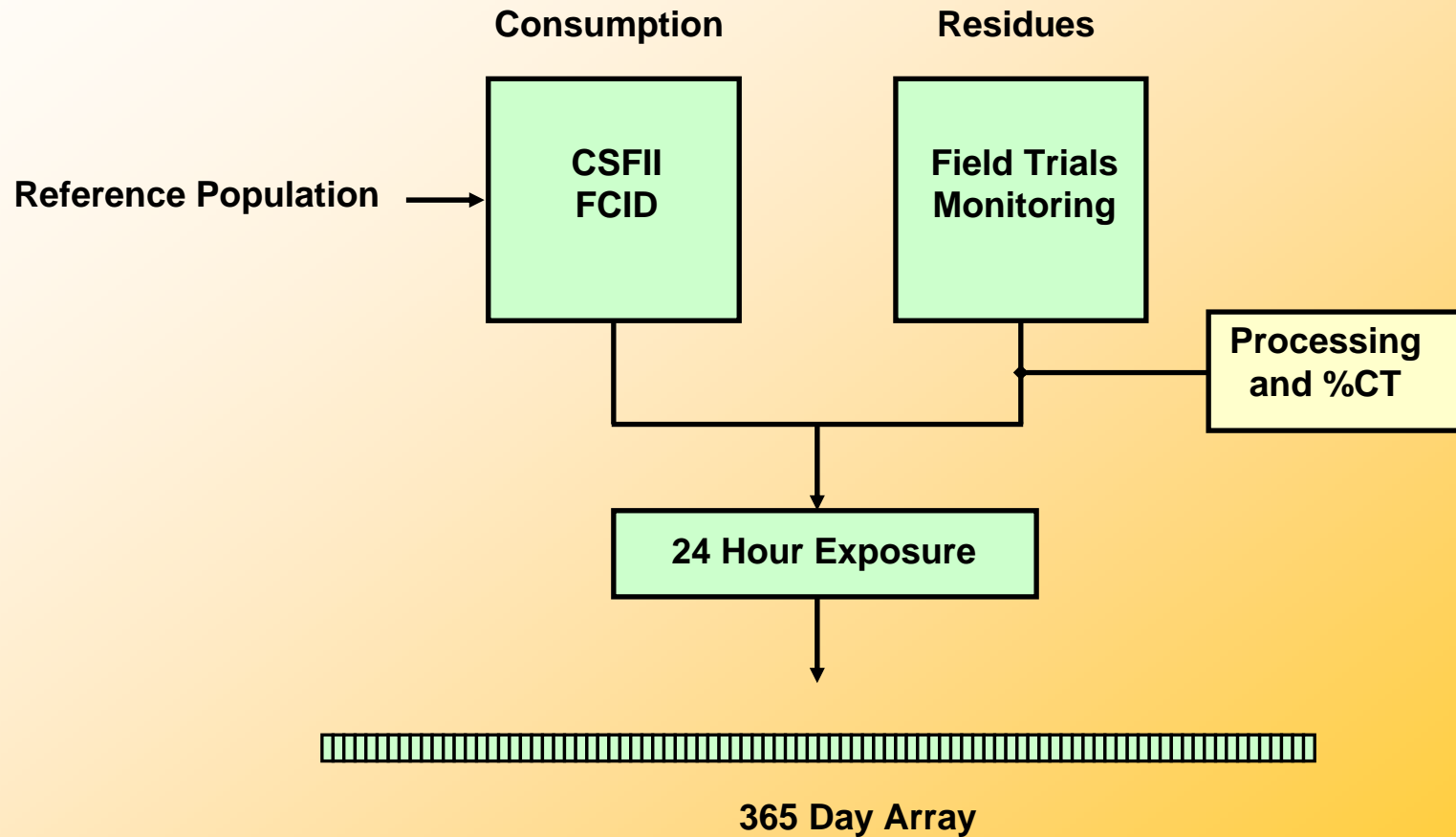
- To calculate zeros:

$$Z = \frac{[\# \text{ of samples} \times (100 - \text{PCT})]}{\text{PCT}}$$

$$Z = \frac{[9 \times (100 - 45)]}{45}$$

$$Z = 11 \text{ zeros}$$

CARES Dietary Module



Residue Distributions in CARES

- Residue distributions in CARES are constructed according to the EPA/OPP Memorandum 1/25/99 from the Chemistry Science Advisory Council:
- “ChemSAC decision re: calculation of anticipated residues.”
 - Except that non-blended and partially blended commodities are treated the same.
 - For tolerance data (T): The single value multiplied by the percent crop treated.
 - For field trial data (F): All values are used with ND’s at $\frac{1}{2}$ LOD (or LOQ). Zeroes are added to distribution according to percent crop treated.
 - For monitoring data (M): All values are used. The ND’s are assigned either $\frac{1}{2}$ LOD or a zero according to the percent crop treated value. No decomposition is incorporated for single serving items.

Workshop Dietary Example

- CHEMNAME on Carrots and Peaches
 - CHEMNAME: CAS#12-345-6 (prepared on Day 1)
 - Population: Children 1-2 (subset 100 with random seed 100)
 - All food forms for Carrots and Peaches
 - Residues:
 - New field trial data on peaches: 0.1, 0.05, 0.2 ppm
 - Previous field trial data on carrots in Dietary Template imported and appended (Values= 0.1, 0.2, 0.3, 0.4, 0.5, 5@ND with LOD=0.1 ppm).
 - Fraction Crop Treated:
 - Carrots: 0.2 (20%CT)
 - Peaches: 0.1 (10%CT)
 - Modifying Factors:
 - Carrot Juice: 0.1

Chronic Capability: Dietary Wizard

The screenshot shows the 'Dietary Wizard' application window. It has a blue title bar and a menu bar with 'Food / Food Form', 'Residues', 'Match', 'Factors', and 'Rules'. Below the menu bar are tabs for 'Averages', 'Generate', and 'File Mgmt'. The main area contains a table with the following data:

	Food (Residue)	Desc	Cooked Status (Residue)	Food Form (Residue)	Cooking Method (Residue)	Average	FCT
1	11000070	Apple, fruit with peel	Uncooked	Fresh	None or Not ap		
2	08003750	Tomato	Uncooked	Fresh	None or Not ap		
3	08003790	Tomato, juice	Uncooked	Fresh	None or Not ap		
4	95002280	Mushroom	Uncooked	Fresh	None or Not ap		
5	95003590	Strawberry	Uncooked	Fresh	None or Not ap		

At the bottom of the window are 'Done' and 'Cancel' buttons.

- Average Tab added to Dietary Wizard to override automatic average calculation from acute residue distribution and percent crop treated entered in Factors tab.
- The foods (and food forms) selected in the Food/Food Form tab will be displayed in the list. The data fields “Average” and “FCT” (Fraction Crop Treated) are data entry fields.

Chronic Capability: Dietary Wizard

- Leave Average and FCT fields blank – automatic calculation occurs using data entered for acute analysis.
- Enter average values for one or more food and food form combinations and leave FCTs blank – for those food and food form combinations where average values are entered, these average values are directly used; for the remaining food forms, automatic calculation occurs as above.
- Enter average and FCT values (range: 0.0 to 1.0) for one or more food and food form combinations; the average residue value used in chronic exposure calculations is the average value entered multiplied by the entered FCT value.
- Leave average values blank and enter FCTs for one or more food and food form combinations – the FCTS are ignored.

Chronic Capability: Options Tab

Run Parameters

Random Seed Limits Outputs Avg. Period

Sampling Percentiles **Options**

Automatically Estimate Exposure Limit to Exclude.

Percentile:

Number of People:

Fraction of Limiting Value for Excluding Data in "... by Food" Table:

Acute/Chronic

Acute (MOE) Route specific NOEL
 Systemic NOEL

Acute (aPAD)
 Chronic (MOE)
 Chronic (cPAD)
 Chronic (Cancer Risk)
 Chronic (CARES Percentiles)

Done Cancel

Chronic Capability: Options Tab

- Chronic (MOE)
 - Chronic Exposure, mg/kg/day = $1000 \times \Sigma$ (Average Consumption, mg/kg/day) x (Average Residue, ppm), summed across all foods
 - Chronic MOE = (Chronic NOEL, mg/kg/day) / (Chronic Exposure, mg/kg/day).
- Chronic (cPAD, expressed as a percentage)
 - Chronic Exposure, mg/kg/day = $1000 \times \Sigma$ (Average Consumption, mg/kg/day) x (Average Residue, ppm), summed across all foods
 - cPAD = (Chronic Exposure, mg/kg/day) x (Uncertainty Factor) x 100 / (Chronic NOEL, mg/kg/day)
- Chronic (Cancer Risk)
 - Chronic Exposure, mg/kg/day = $1000 \times \Sigma$ (Average Consumption, mg/kg/day) x (Average Residue, ppm), summed across all foods
 - Cancer Risk = (Chronic Exposure, mg/kg/day) x (Q*, (mg/kg/day)-1)
- Chronic (CARES Percentiles)
 - A CARES dietary assessment generates annual average exposure outputs for each individual in the selected subpopulation (when appropriate option is checked in the Outputs tab). These average exposure outputs are used in conjunction with individual weighting factors to summarize them as percentiles.

Dietary Minute Module - Objectives

- Refine the standard 24-hour dietary risk assessment approach in CARES to allow exposure and risk assessments for periods less than 1-day.
- Develop module to be user friendly, transparent and publicly available through ILSI.
- Develop module with the flexibility to be applied to other classes of chemical and as the basis for a cumulative DMM module.

CSFII, Recipe, and FCID Relationship

CSFII					
FCID HH	CSFII Food Code	Description	Consumed (g)	Body Weight (kg)	Consumption (g/kg)
20844-1-1	14620320	Pizza topping from meat pizza	84	11.8	7.119

Individual RACs for a meat pizza

Recipe File		
Food Code	Food	Gram Weight Consumed
8003770	Tomato, puree	20.11
8003750	Tomato	18.05
27012230	Milk, nonfat solids	16.40
27022240	Milk, water	8.46
27002220	Milk, fat	8.38
21000440	Beef, meat	5.32
25002930	Pork, fat	5.18
25002900	Pork, meat	4.87
21000470	Beef, fat	3.71
3002370	Onion, dry bulb	3.15
25002920	Pork, meat byproducts	1.36
6003500	Soybean, oil	1.36
21000460	Beef, meat byproducts	0.83

$g/kg * (g \text{ weight}/100)$

FCID Database	
Food Code	Consumption (g/kg)
8003770	1.432
8003750	1.285
27012230	1.167
27022240	0.602
27002220	0.597
21000440	0.379
25002930	0.369
25002900	0.347
21000470	0.264
3002370	0.224
25002920	0.097
6003500	0.096
21000460	0.059

- FCID needs to have Time food eaten added.

Food Consumption (FCID) Food Consumption (FCID) 28Mar05

File Data Statistics Graph Options Help

Σ

	FCID ID	Person #	Day #	Food Code	Cooked Status	Food Form	Cooking Method	Consumed Amount (g/kg)
1	10001	1	1	1010520	9	0	0	0.5046251
2	10001	1	1	3001640	2	1	0	0.0084277
3	10001	1	1	3001650	2	1	1	0.0045608
4	10001	1	1	3002370	2	1	0	0.2098495
5	10001	1	1	3002370	2	1	1	0.2187307
6	10001	1	1	6003500	9	0	0	0.100686
7	10001	1	1	8003750	2	1	1	1.946238
8	10001	1	1	8003760	2	1	0	0.693599
9	10001	1	1	8003760	2	1	1	0.4709692

Loaded Food Consumption (FCID) Records = 2516076

Food Consumption (FCID) Food Consumption (FCID) (Time) Aug04

File Data Statistics Graph Options Help

Σ

	FCID ID	Person #	Day #	Food Code	Cooked Status	Food Form	Cooking Method	Consumed Amount (g/kg)	Time (Minute)
1	10001	1	1	1010520	9	0	0	0.331316271186441	1260
2	10001	1	1	1010520	9	0	0	3.72213898305085E-03	1380
3	10001	1	1	1010520	9	0	0	0.134518347457627	450
4	10001	1	1	1010520	9	0	0	3.58459322033898E-02	720
5	10001	1	1	3001640	2	1	0	8.4406779661017E-03	720
6	10001	1	1	3001650	2	1	1	4.56779661016949E-03	1260
7	10001	1	1	3002370	2	1	0	0.210172881355932	720
8	10001	1	1	3002370	2	1	1	0.219067796610169	1260
9	10001	1	1	6003500	9	0	0	0.100064237288136	720
10	10001	1	1	6003500	9	0	0	7.76949152542373E-04	960
11	10001	1	1	8003750	2	1	1	1.94923728813559	1260
12	10001	1	1	8003760	2	1	0	0.69466779661017	720

Loaded Food Consumption (FCID) Records = 3444062 10001 Row: 1, Col: 1

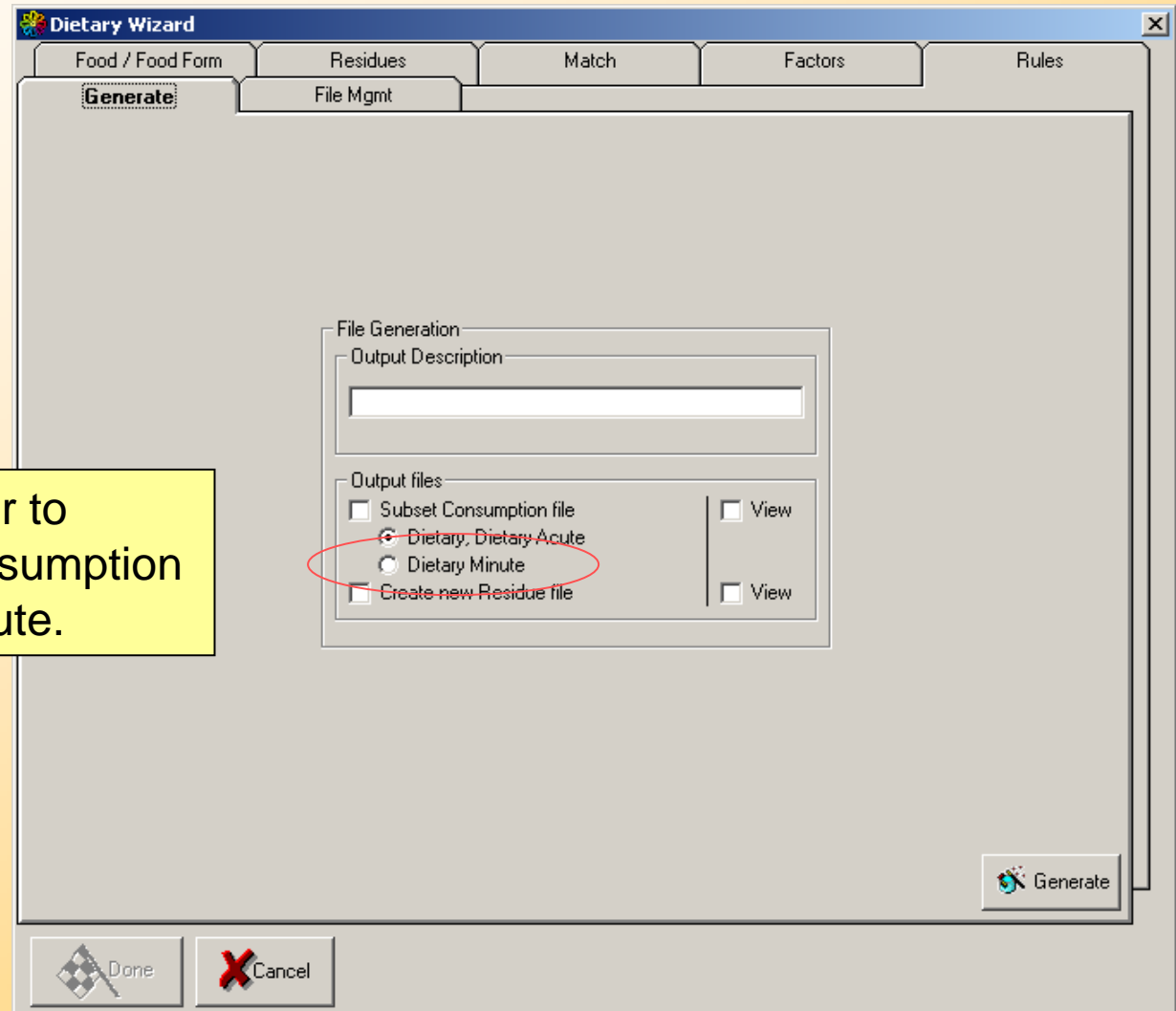
Eating Events at:
 9:00 PM
 11:00 PM
 7:30 AM
 12:00 AM

Sum to:
 0.50540269

Dietary Minute Module

- The DMM breaks down food consumption in the CSFII exposure events by time of day. Each exposure event is described as a single food or group of foods recorded by an individual as being consumed at a particular time of the day or at a named eating occasion (e.g. lunch).
- Exposure events are then grouped into exposure intervals according to the toxicology profile of the chemical.
- A distribution of exposure intervals is constructed which includes the exposure intervals where there is zero-exposure.
- The methods currently in CARES for constructing the DMM distribution to compare to the tox endpoint have not been reviewed or approved by EPA.

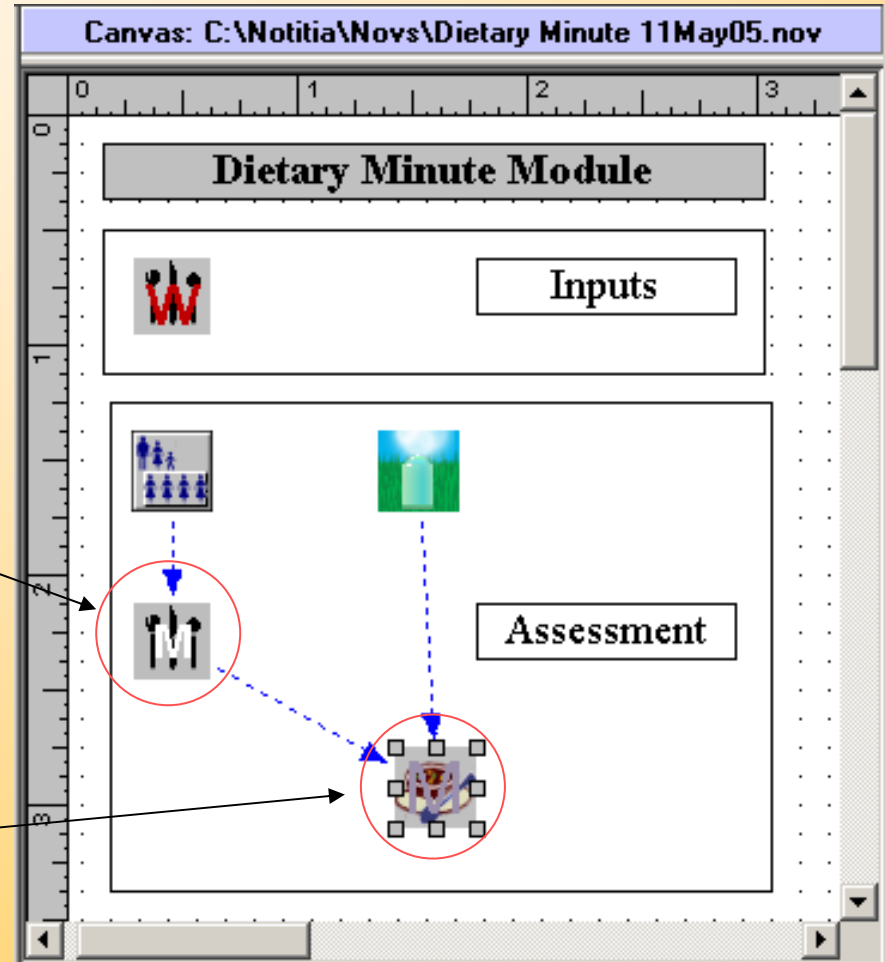
Dietary Wizard



The screenshot shows the 'Dietary Wizard' application window. It has a blue title bar and a tabbed interface with tabs for 'Food / Food Form', 'Residues', 'Match', 'Factors', and 'Rules'. The 'Generate' tab is active, showing a 'File Mgmt' sub-tab. The main area contains a 'File Generation' dialog box with an 'Output Description' text field and an 'Output files' section. The 'Output files' section has four options: 'Subset Consumption file', 'Dietary, Dietary Acute', 'Dietary Minute', and 'Create new Residue file'. The 'Dietary, Dietary Acute' option is selected and circled in red. There are 'View' checkboxes next to the 'Subset Consumption file' and 'Create new Residue file' options. A 'Generate' button is located in the bottom right corner of the main area. At the bottom of the window are 'Done' and 'Cancel' buttons.

Allows user to create consumption file by minute.

Dietary Minute Canvas



Food Selector

- Select consumption by minute
- Select residue file

Dietary Analysis

- Random Seed
- Sample technique actual or percentile

Dietary Minute Module Output – Exposures, By Food

Exposures, By Food

File Data Statistics Graph Options Help

Reversibility Tool

Residues randomly assigned for each Eating Event

	CARES ID	Day	Time Minutes	Food	Cooked Status	Food Form	Cooking Method	CAS	Consumption	Residue	Exposure
1	18-0001758-02	1	660	11000070	1	1	0	11-1111-1	1.015e+01	2.100e-01	2.131e-03
2	18-0001758-02	1	1080	15004020	2	1	0	11-1111-1	1.170e+00	3.611e-02	4.225e-05
3	18-0001758-02	1	900	15004020	2	1	0	11-1111-1	4.494e-01	3.611e-02	1.623e-05
4	18-0001758-02	1	780	8003750	2	1	2	11-1111-1	1.579e+00	1.005e+00	1.587e-03
5	18-0001758-02	1	1080	8003770	2	4	0	11-1111-1	4.054e+00	4.042e-01	1.639e-03
6	18-0001758-02	2	720	15004020	2	1	1	11-1111-1	6.965e-01	3.611e-02	2.515e-05
7	18-0001758-02	2	600	15004020	2	1	3	11-1111-1	7.757e-05	3.611e-02	2.801e-09
8	18-0001758-02	2	1140	15004020	2	1	4	11-1111-1	1.318e-01	3.611e-02	4.758e-06
9	18-0001758-02	2	960	15004020	2	3	2	11-1111-1	3.913e+00	3.611e-02	1.413e-04
10	18-0001758-02	2	720	8003750	2	1	1	11-1111-1	1.266e-01	1.300e+00	1.646e-04
11	18-0001758-02	2	960	8003760	2	1	0	11-1111-1	1.507e+00	4.042e-01	6.091e-04
12	18-0001758-02	2	960	8003770	2	1	0	11-1111-1	4.184e+00	4.042e-01	1.691e-03
13	18-0001758-02	2	960	8003770	2	1	1	11-1111-1	1.389e-01	4.042e-01	5.615e-05

Loaded Ex 001758-02 Row: 5, Col: 1

Time of eating occasions on each day and food form consumed.

Reversibility Tool

Dietary Minute - Analysis

Ready


Reversibility Interval (Hrs):


Methods

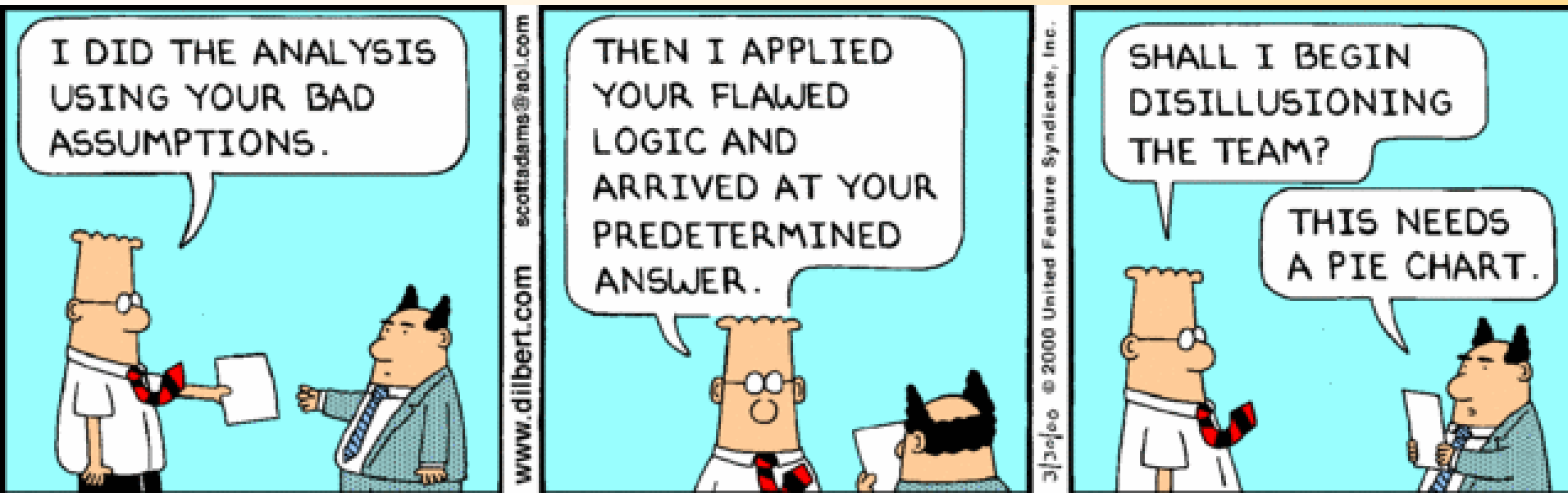
- Reversibility Interval (Cumulative)
- Reversibility Interval (Fixed)
- Reversibility Interval (Equivalent Exposure)

Reversibility Lag Interval (Hrs):

Elimination Coefficient (β_3):

 Done

 Calc



Questions?