Dietary Exposure Assessment at the Food and Drug Administration:

A comparison of exposure assessment methods used in the Total Diet Study and analyses of individual food products

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Exposure Assessments

- Point Estimates – “The Estimate is …”
  - Safety assessments for food additives
  - Evaluations using the TDS
- Probabilistic Estimates
  - Contaminants
    - Stochastic (from the Greek, stochastikos: to guess at)
    - Monte Carlo
    - Black box

Simplified Exposure Equation

$$EDI_x = \sum_{f=1}^{F} \frac{Freq_f \cdot Port_f \cdot Conc_{xf}}{N}$$

EDI_x = The Estimated Daily Intake of Substance x

F = Total no. of foods in which x can be found
$Freq_f$ = No. of eating occasions for food f over N survey days
$Port_f$ = Average portion size for food f
$Conc_{xf}$ = Concentration of the substance x in the food f
N = No. of survey days

Exposures for Individuals Combined

Acrylamide Exposure

- Data included in 2006 assessment
  - New data:
    - 2005 targeted data, Table 4, http://www.cfsan.fda.gov/~dms/acrydata.html
    - 2004 and 2005 Total Diet Study (TDS) data, Tables 2 and 3, http://www.cfsan.fda.gov/~dms/acrydat2.html
  - Previous data from 2003, 2004 assessments:
    - 2002-2004 targeted data, Tables 1-3, http://www.cfsan.fda.gov/~dms/acrydata.html
    - 2003 TDS data, http://www.cfsan.fda.gov/~dms/acrydat2.html
- 66 food categories evaluated
  - Ethnic, regional foods included

Acrylamide Intake Modeling

AA Intake = (Eaters$_{(yes\ or\ no)}$) x (Food Amt.) x (AA Level)

Eaters$_{(yes\ or\ no)}$ – Either 0 or 1 in Proportion to Percent Eaters

Food Amount – Food Consumption Value from Survey Data

Acrylamide Level – Value from Laboratory Data –
Each Value Equally Likely on Each Iteration

Results are Summed over Foods and Individuals

Acrylamide Intake Modeling

- Each Iteration is a Virtual Consumer
- 25,000 Iterations
- No Accounting for Correlations Between Food Choices
- Truncation of Distributions Removes Irrationally High Values
  - 13 L of Coffee Per Day – 100th Percentile

Acrylamide Model in Excel: Overview

Food	% eaters	Mean Intake (g/kg-bw-d)	ACM Conc (ug/kg)	Intake (ug/kg-bw-d)	Big Kahuna (ug/kg-bw-d)
Almonds	0.3	0.3	320.3	0.000	0.44
Nuts & Seeds	5.9	0.4	36.1	0.001	
Bagels	9.8	0.6	50.3	0.003	
Baked Beans	4.4	1.6	35.3	0.003	
Breaded Chicken	14.8	1.3	15.5	0.003	
Breaded Fish	5.3	1.3	11.6	0.001	
Breakfast Cereal	40.8	0.8	124.5	0.041	

Acrylamide Model in Excel: FC Data

Percentages	Almonds	Nuts&Seeds	Bagels
0.01	0.0	0.0	0.1
0.05	0.0	0.0	0.2
0.1	0.0	0.0	0.2
0.15	0.0	0.1	0.3
0.2	0.0	0.1	0.3
0.25	0.1	0.1	0.4
0.3	0.1	0.1	0.4
0.35	0.1	0.1	0.4
0.4	0.1	0.2	0.4
0.45	0.1	0.2	0.4
0.5	0.1	0.3	0.5
0.55	0.1	0.3	0.5
0.6	0.1	0.4	0.5
0.65	0.2	0.4	0.6
0.7	0.2	0.5	0.7
0.75	0.3	0.5	0.7
0.8	0.3	0.7	0.8
0.85	0.5	0.8	1.0
0.9	0.8	1.1	1.1
0.95	1.4	1.5	1.3
0.97	1.4	1.9	1.6
0.98	1.4	2.2	1.8
0.99	1.5	2.7	2.3

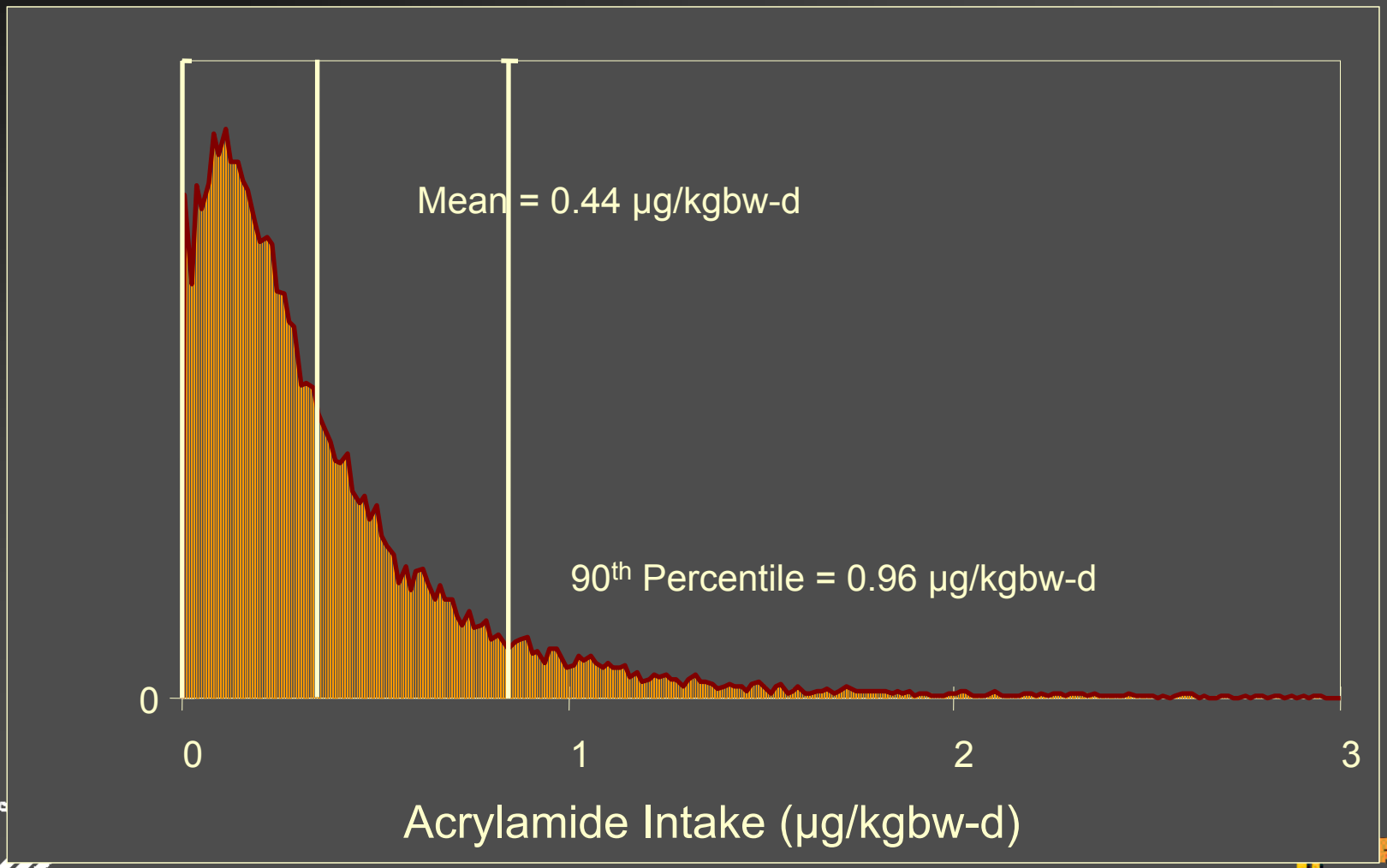
Acrylamide Model in Excel: Contaminant Data

Crisp Bread		Doughnuts		French Fries	
182	Streit's lightly salted matzos	24	Shoppers Food Warehouse, cake doughnut	252	Arby's french fries
504	Wasa original crispbread fiber rye	5	Shoppers Food Warehouse, french twirl doughnut	197	Burger King french fries, location 1
125	Indian flat bread (from local restaurant)	14	Shoppers Food Warehouse, plain doughnut	220	Burger King french fries, location 2
184	Wasa, Crisp 'n Light Crackerbread	26	Doughnut, Cake-Type, Any Flavor	369	Burger King french fries, location 3
208	Manischewitz, Matzos unsalted	19	Doughnut, Cake-Type, Any Flavor	257	Checkers french fries, location 1
620	Fat Free Natural, Rye Crisp	15	Doughnut, Cake-Type, Any Flavor	407	Checkers french fries, location 2
		18	Doughnut, Cake-Type, Any Flavor	389	Chick-fil-A french fries
		10	Krispy Kreme Doughnuts	452	Fuddruckers french fries, location 1
		22	Krispy Kreme Doughnuts	346	Fuddruckers french fries, location 2
		26	Doughnut, Cake-Type, Any Flavor	313	KFC french fries, location 1
		16	Doughnut, Cake-Type, Any Flavor	270	KFC french fries, location 2

Results – Feb. 2003

Survey used	Age Group	Exposure (mean)	90th %ile
MRCA	2+ years	0.48 µg/kgbw-day	0.91
CSFII (3-day)	2+ years	0.32	0.66
CSFII (2-day)	2+ years	0.37	0.81
MRCA	2-5 year olds	1.26	2.33
CSFII (3-day)	2-5 year olds	0.78	1.63
CSFII (2-day)	2-5 year olds	1.00	2.15

Acrylamide Intake Distribution
CFSII 1994-96, 1998; 2+ Population



Top 20 Foods by Mean Acrylamide Intake

Food	Mean AA intake (µg/kgbw-day)	Cumulative Percentile
French Fries (RF*)	0.070	0.16
French Fries (OB*)	0.051	0.28
Potato Chips	0.045	0.38
Breakfast Cereal	0.040	0.47
Cookies	0.028	0.53
Brewed Coffee	0.027	0.60
Toast	0.023	0.65
Pies and Cakes	0.018	0.69
Crackers	0.017	0.73
Soft Bread	0.014	0.77

Food	Mean AA intake (µg/kgbw-day)	Cumulative Percentile
Chile con Carne	0.014	0.80
Corn Snacks	0.011	0.82
Popcorn	0.007	0.84
Pretzels	0.007	0.86
Pizza	0.006	0.87
Burrito/Tostada	0.006	0.88
Peanut Butter	0.003	0.89
Breaded Chicken	0.003	0.90
Bagels	0.003	0.90
Soup Mix	0.003	0.91

* RF, restaurant fries; OB, oven baked

Top Eight Foods by Acrylamide Per Portion

Food	AA Conc (µg/kg)	Portion Size (g)*	AA (µg) Portion
Breakfast Cereal	124.6	55	6.9
Brewed Coffee	8.0	240	1.9
Postum	93	240	22.3
French Fries (RF)	401	70	28.1
French Fries (OB)	697.8	70	48.8
Potato Chips	608.1	30	20.4
Canned Black Olives	498.5	15	7.5
Prune Juice	206.3	140	28.8

Portion Sizes From 21 CFR 101.12, Table 2

What-If Scenarios
CSFII, 1994-96, 98, 2+ Population

- Mean= 0.44 µg/kgbw-d, 90th=0.96 µg/kgbw-d

- Remove AA from French Fries
  - Mean – 0.37 µg/kgbw-d; 90th Percentile – 0.78 µg/kgbw-d
- Remove AA from Snack Foods
  - Mean – 0.38 µg/kgbw-d; 90th Percentile – 0.85 µg/kgbw-d
- Remove AA from Breakfast Cereal
  - Mean – 0.38 µg/kgbw-d; 90th Percentile – 0.84 µg/kgbw-d
- Remove AA from Coffee
  - Mean – 0.40 µg/kgbw-d; 90th Percentile – 0.88 µg/kgbw-d

Perchlorate Exposure

- Multi-agency Investigation
- May be natural, may be anthropomorphic
  - Source isn't material
- Initial surveys completely inadequate
  - Milk
  - Vegetables thought to be irrigated with contaminated water
  - 5 vegs, milk, and bottled water

2004-5 Survey expansion

- 27 foods and beverage classes
  - Some seafood included
- 5 to >100 samples per food
- Consistently low, typically ≤ 10 ppb, with occasional outliers
- Spinach and greens much higher
  - >90 ppb
- Food consumption approx. 1/3 of the diet

Perchlorate Residue Data

Food Groups	Number of Data Points	Average Residue (ppb)
Lettuce	137	10.3
Milk	125	5.81
Tomatoes	73	13.7
Carrots	59	15.8
Spinach	36	115
Cantaloupes	48	28.6
Apples	9	0.15*
Grapes	12	8.58
Oranges	10	3.47
Strawberries	19	2.14
Watermelon	19	1.96
Fruit Juices (Apple & Orange)	14	2.31
Broccoli	14	8.49
Cabbage	13	8.80
Greens	14	92.4
Cucumber	20	6.64
Green Beans	19	6.12
Onions	12	0.53
Potatoes	6	0.15*
Sweet Potatoes	6	1.24
Corn Meal	22	1.16
Oatmeal	22	3.96
Rice (Brown & White)	19	0.50*
Whole Wheat Flour	19	4.27
Catfish	7	1.02
Salmon	11	1.06
Shrimp	5	19.83
Total	775	

Perchlorate Exposure

Population	Monte Carlo estimate using @Risk software with 5,000 iterations* (µg/kg-bw/d)	
	Mean	**90th Percentile**
All ages 2+ Years	0.053	0.12
Children, 2-5 Years	0.17	0.34
Females, 15-45 Years	0.037	0.074

Food Contributors

Food Groups	Mean Intake (µg/kg bw/day)	Cumulative Percentage
Milk	0.025	47
Tomatoes	0.005	56
Fruit Juices (Apple & Orange)	0.004	64
Spinach	0.004	72
Carrots	0.003	78
Lettuce	0.003	84
Cantaloupes	0.002	88
Greens	0.001	90
Broccoli	0.001	92
Green Beans	0.001	94
Grapes	0.001	96
Cucumbers	0.001	98
All other foods	<0.001	100
Total	0.053	100

Summary

- Simple distributional analyses allow data manipulation unavailable to point estimate methods
- All of the food consumption data come from one source
  - TDS use of data is different, but conclusions support methodology
- Contamination concentration data give clue to source or type of incident/ecology
- Model uncertainty not evaluated