

Market survey risk assessment of foods containing advisory labeling

From Start to Finish: Quantitative Risk Assessment of Foods Containing Peanut Advisory Labeling

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Peanut Risk Assessment

- **1 Part per million (ppm) is equivalent to:**
 - **1 $\mu\text{g/g}$**
 - **1 mg/kg**
 - **1 mg/L or $\mu\text{g/mL}$ (in water)**

2005		
% Positive	Lowest Levels	Highest Levels
7.3	3 ppm	4000 ppm

2009		
% Positive	Lowest Levels	Highest Levels
8.6	3 ppm	510 ppm

Hefle SL, Furlong TJ, Niemann L, Lemon-Mule H, Sicherer S, and Taylor SL. Consumer attitudes and risks associated with packaged foods having advisory labeling regarding the presence of peanuts. *J Allergy Clin Immunol* 2007;120:171-176.

Product Analysis

2005

<u>Product Category</u>	<u>No. Tested</u>	<u>No. Positive</u>	<u>PPM Whole Peanut</u>
Baked goods/mixes	15	0	-
Baking Ingredients	32	0	-
Candy/confectionary	36	7	3 - 206
Cereal/cereal bars	27	2	3 - 107
Frozen desserts	9	0	-
Instant meals	8	0	-
Nutrition/meal bars	28	4	14 - 4000
Snack foods	24	0	-
Total	179	13	3 - 4000

2009

<u>Product Category</u>	<u>No. Tested</u>	<u>No. Positive</u>	<u>PPM Whole Peanut</u>
Baked goods/mixes	43	1	8
Baking Ingredients	16	2	3 - 11
Candy/confectionary	32	4	3 - 24
Cereal/cereal bars	20	2	19 - 97
Frozen desserts	9	0	-
Instant meals	17	0	-
Nutrition/meal bars	24	6	3 - 510
Snack foods	25	1	3
Total	186	16	3 - 510

Peanut Risk Assessment

- **Assess allergic consumer risk of reaction when consuming products that contain voluntary advisory labels for peanuts**



Protein 2 Go™ Bar is available in 8 delicious flavours:



In 72g size.

Ingredients: (Coconut Cream)

Protein Blend (Whey Protein Concentrate, Milk Protein Isolate, Soy Protein Isolate), High Fructose Corn Syrup, Coating (Maltitol, Modified Palm Kernel Oil, Skim Milk Powder, Cocoa Powder, Soy Lecithin, Salt, Natural Flavour), Soy Protein Concentrate, Maltodextrin, Glycerine, Water, Soy Crisps (Soy Protein Isolate, Rice Flour, Malt and Salt), Shredded Coconut, Canola Oil, Soy Lecithin, Chicory Root Extract (inulin), Natural and Artificial Flavour.

May contain traces of peanuts and / or other nuts.



Protein 2 Go™ Bar is available in 8 delicious flavours:



*Double Chocolate
Supreme*



*Chocolate
Strawberry Dip*



*White Chocolate
Avalanche*



*Chewy
Caramel*



*Golden
Pecan*



*Pralines
& Cream*



*Fudgy Peanut
Butter Cup*



*Coconut
Cream*

Probabilistic Model for Risk Assessment

NHANES Survey

Product analyses

Clinical studies

Consumption Patterns (mg)

Levels (ppm)

Thresholds (mg)

Allergen intake (mg)

No Allergic Reaction

Allergic Reaction

Food Allergy Research & Resource Program

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Prevalence of Peanut Allergy

TABLE I. Prevalence of peanut and TN allergy in 2008 by age

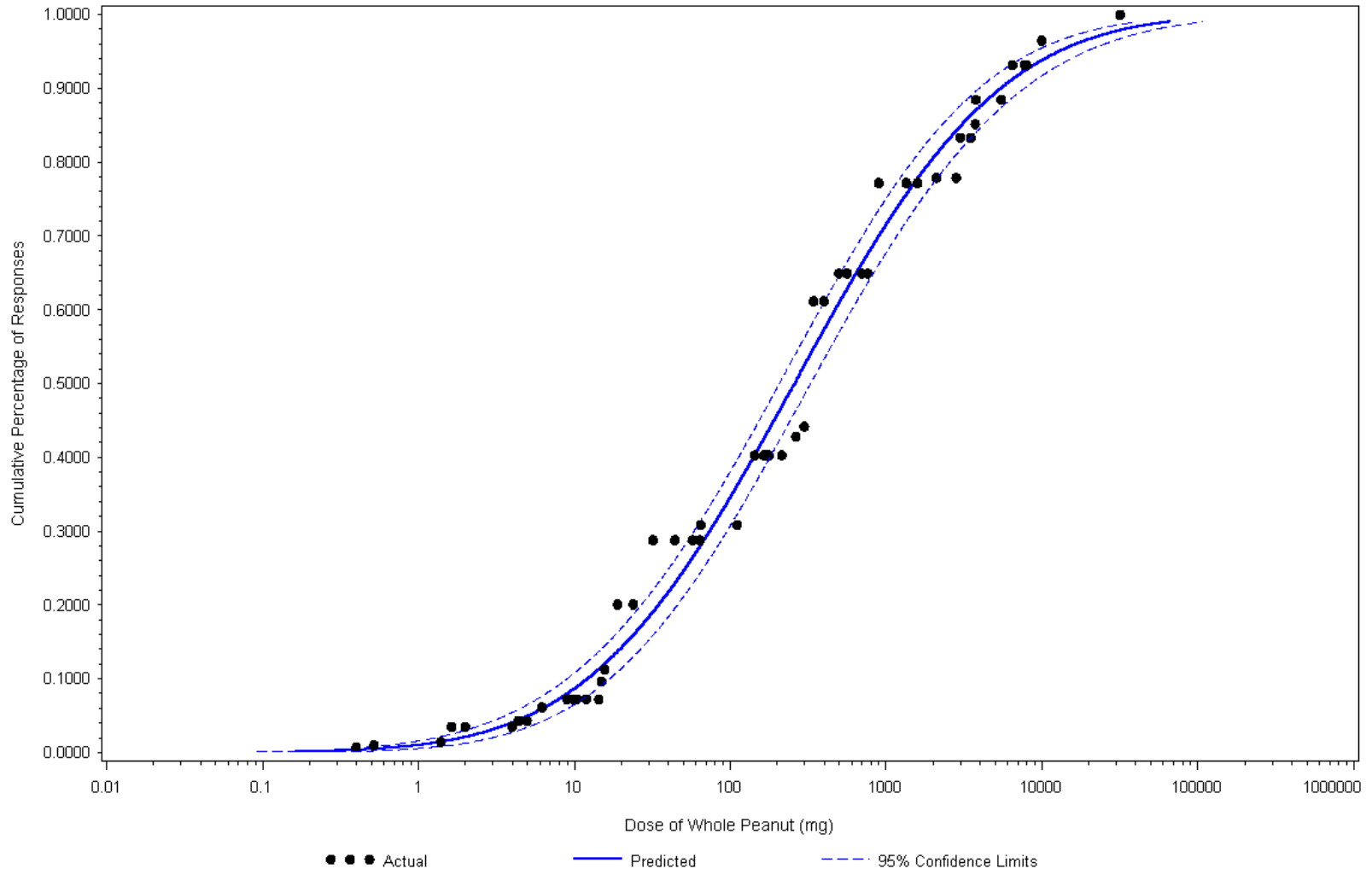
	Total sample population n = 13,534	Type of nut allergy							
		Any nut*		Both peanut and TN		Peanut only		TN only	
		No.	Percent (± 95% CI)	No.	Percent (± 95% CI)	No.	Percent (± 95% CI)	No.	Percent (± 95% CI)
Age (y)									
0-5									0.5 (0.1-1.2)
6-10									0.4 (0.1-1.2)
11-17									0.8 (0.4-1.5)
18-20									0.2 (0.0-1.2)
21-30									0.5 (0.2-1.1)
31-40									0.3 (0.1-0.8)
41-50	1,754	28	1.6 (1.1-2.3)	3	0.2 (0.0-0.5)	10	0.6 (0.3-1.1)	8	0.5 (0.2-0.9)
51-60	1,894	20	1.1 (0.7-1.6)	3	0.2 (0.0-0.5)	7	0.4 (0.2-0.8)	5	0.3 (0.1-0.6)
61-64	610	9	1.5 (0.7-2.8)	0	0.0 (NA)	2	0.3 (0.0-1.2)	5	0.8 (0.3-1.9)
≥65	2,481	32	1.3 (0.9-1.8)	1	0.0 (0.0-0.2)	18	0.7 (0.4-1.1)	11	0.4 (0.2-0.8)
Not reported (<18)	43	1	2.3 (0.1-12.3)	0	0.0 (NA)	0	0.0 (NA)	1	2.3 (0.1-12.3)
Not reported (>18)	518	2	0.4 (0.1-1.4)	0	0.0 (NA)	1	0.2 (0.0-1.1)	1	0.2 (0.0-1.1)
Overall	13,534	194	1.4 (1.2-1.7)	26	0.2 (0.1-0.3)	77	0.6 (0.5-0.7)	58	0.4 (0.3-0.6)

**Parameter estimate:
(26 + 77) ÷ 13,534 = 0.76%**

NA, Not applicable.

*"Any nut" is reported nut allergy including peanuts, TNs, or unspecified nut.

Log-Normal (expressed as peanut)



Allergen Threshold Studies

- **Use of existing peanut threshold dataset**

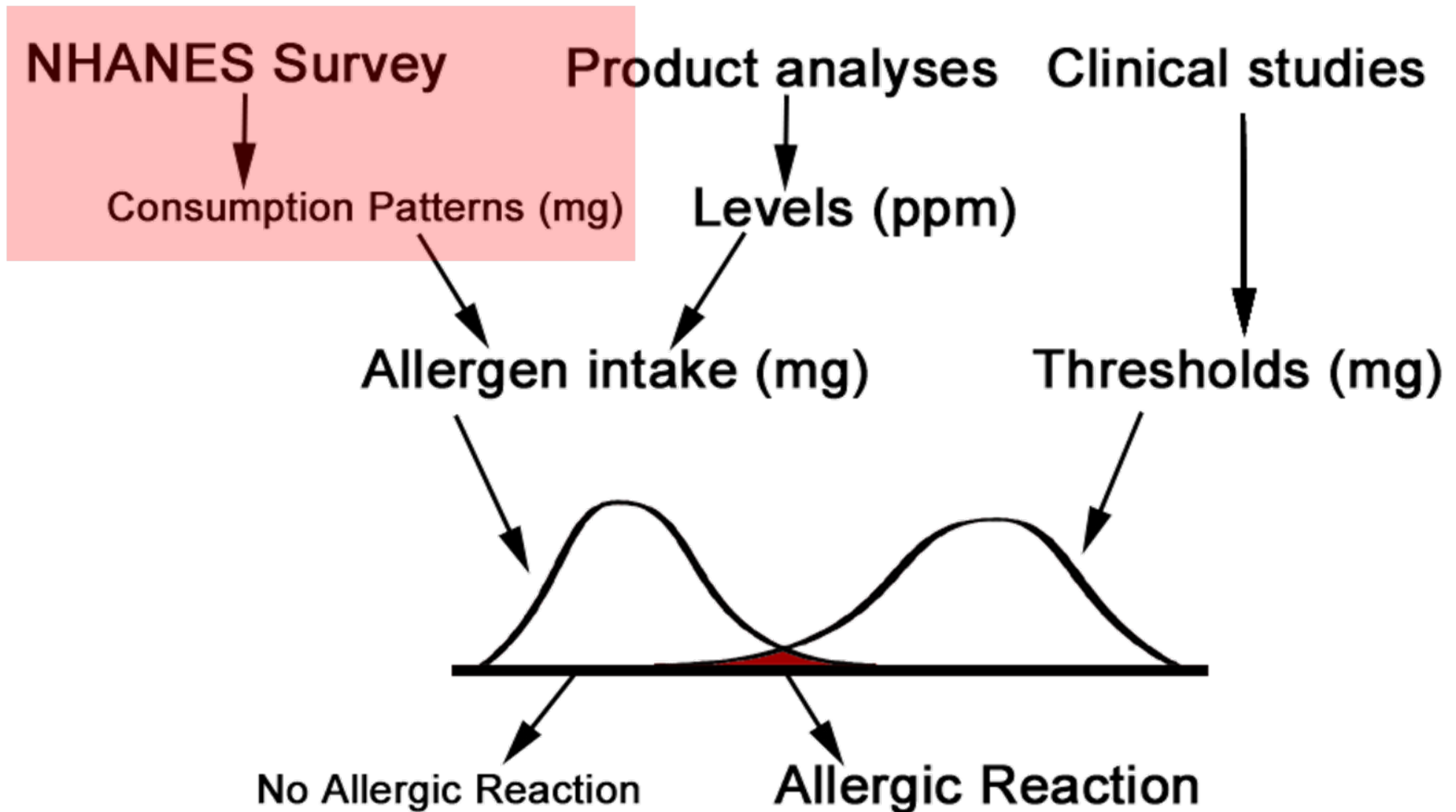
Source	Total No. of Peanut-Allergic Individuals	ED₁₀	95% CI	ED₀₅	95% CI
Nancy Data	286	14.4	10.7, 19.6	7.3	5.2, 10.4
Published Papers	164	14.1	6.6, 29.9	4.2	1.7, 10.1
Combined	450	12.3	9.0, 16.8	5.2	3.6, 7.4

All values reported in mg of whole peanut

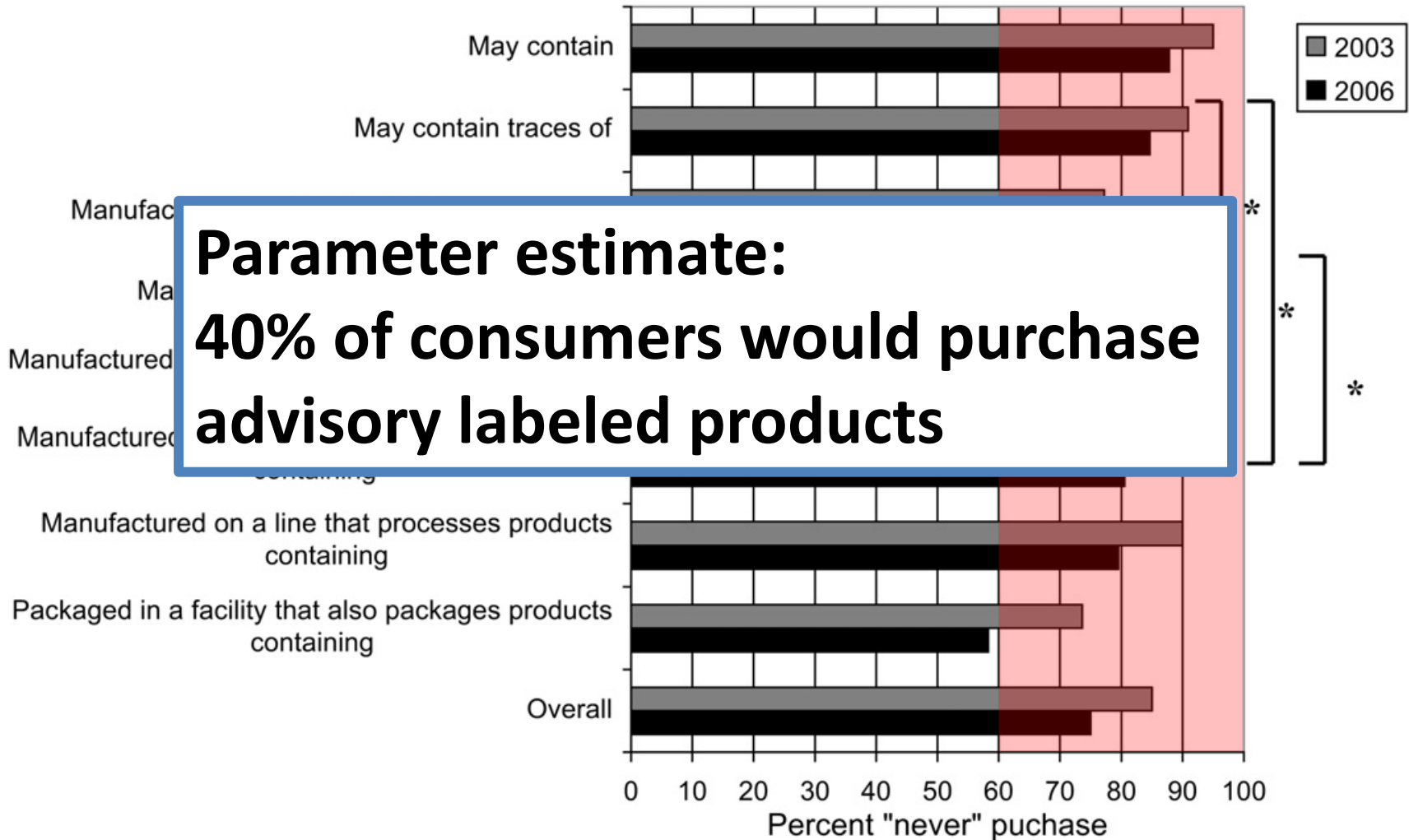
Allergen Threshold Studies

- **Have data on 450 peanut-allergic individuals to use in modeling dose-distribution**
- **Lowest doses observed to cause mild objective reactions were at 0.4 mg whole peanut (4 individuals)**
- **Model will predict the possibility that more sensitive individuals do exist**
- **Can set a population threshold if we can decide acceptable level of risk**

Probabilistic Model for Risk Assessment



Probability of Purchasing Advisory Labeled Products



NHANES Dataset

- **The National Health and Nutrition Examination Survey (NHANES)**
- **The survey examines a nationally representative sample of about 5,000 persons each year.**

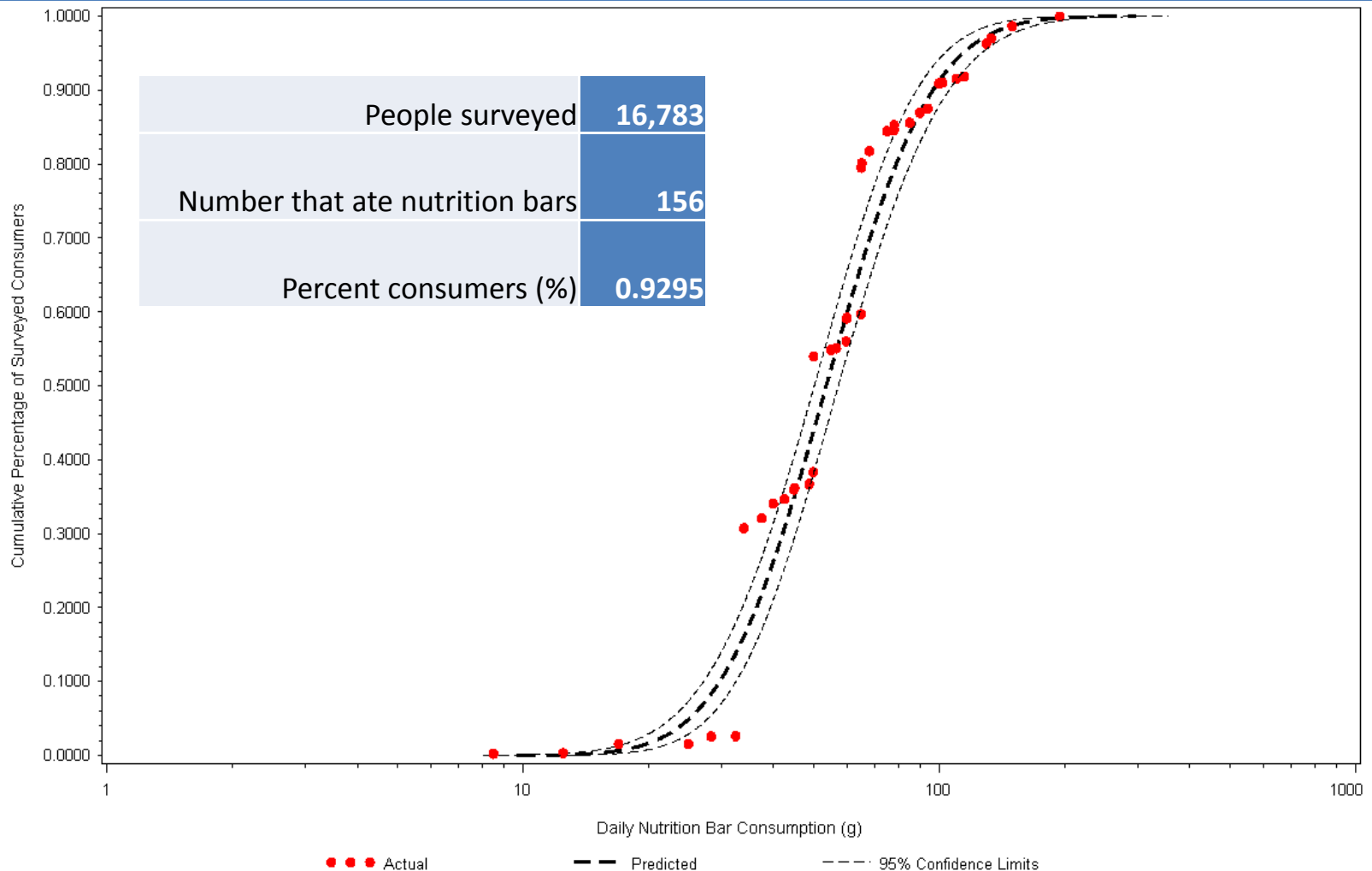
NHANES Dataset

- **The NHANES interview includes demographic, socioeconomic, dietary, and health-related questions.**
- **We are able to extract consumption data based on product category, age, and sex.**

Respondent sequence number	Gender - Adjudicated	Age at Screening Adjudicated - Recode	Number of days of intake	USDA food code	Dietary day one sample weight	Dietary two-day sample weight	Grams	day	year	Long Food Co
33809	2	14	2	94000100	10239.010495	10620.763295	192.56	2	2005-06	Water, tap
33810	2	13	2	11112110	19368.641266	21121.929528	213.5	1	2005-06	Milk, cow's, fluid, 2% fat
33810	2	13	2	11112110	19368.641266	21121.929528	228.75	1	2005-06	Milk, cow's, fluid, 2% fat
33810	2	13	2	11553100	19368.641266	21121.929528	277.75	1	2005-06	Fruit smoothie drink, N
33810	2	13	2	27450060	19368.641266	21121.929528	104	1	2005-06	Tuna salad
33810	2	13	2	27560300	19368.641266	21121.929528	88	1	2005-06	Corn dog (frankfurter or coating)
33810	2	13	2	53108100	19368.641266	21121.929528	29	1	2005-06	Cake, cupcake, chocolate filling
33810	2	13	2	54301000	19368.641266	21121.929528	12	1	2005-06	Cracker, snack
33810	2	13	2	58404010	19368.641266	21121.929528	180.75	1	2005-06	Chicken rice soup
33810	2	13	2	63141010	19368.641266	21121.929528	116.25	1	2005-06	Pineapple, raw
33810	2	13	2	64104010	19368.641266	21121.929528	232.5	1	2005-06	Apple juice
33810	2	13	2	71201010	19368.641266	21121.929528	10.75	1	2005-06	White potato, chips
33810	2	13	2	71401030	19368.641266	21121.929528	122	2	2005-06	White potato, french fried
33810	2	13	2	81102000	19368.641266	21121.929528	9.54	2	2005-06	Margarine, NFS
33810	2	13	2	92530610	19368.641266	21121.929528	494	2	2005-06	Fruit juice drink, with high fructose
33810	2	13	2	92530610	19368.641266	21121.929528	988	2	2005-06	Fruit juice drink, with high fructose
33810	2	13	2	94000100	19368.641266	21121.929528	237	2	2005-06	Water, tap
33812	1	80	1	12210400	14699.564117	.	5.88	1	2005-06	Cream substitute, powder
33812	1	80	1	22000100	14699.564117	.	6.28	1	2005-06	Pork, NS as to cut, cooked
33812	1	80	1	25210220	14699.564117	.	70	1	2005-06	Frankfurter or hot dog, beef
33812	1	80	1	26319140	14699.564117	.	96.75	1	2005-06	Shrimp, floured, breaded
33812	1	80	1	31105000	14699.564117	.	20	1	2005-06	Egg, whole, fried
33812	1	80	1	51101000	14699.564117	.	40	1	2005-06	Bread, white

Foodcode	Description
91781010	Snickers Marathon Protein bar
53544450	PowerBar (fortified high energy bar)
91780010	Snickers Marathon Energy bar
41435110	High protein bar, candy-like, soy and milk base
53541200	Meal replacement bar

NHANES Consumption Data Fit to a Log-Normal Curve



Peanut Risk Assessment

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Product Analysis

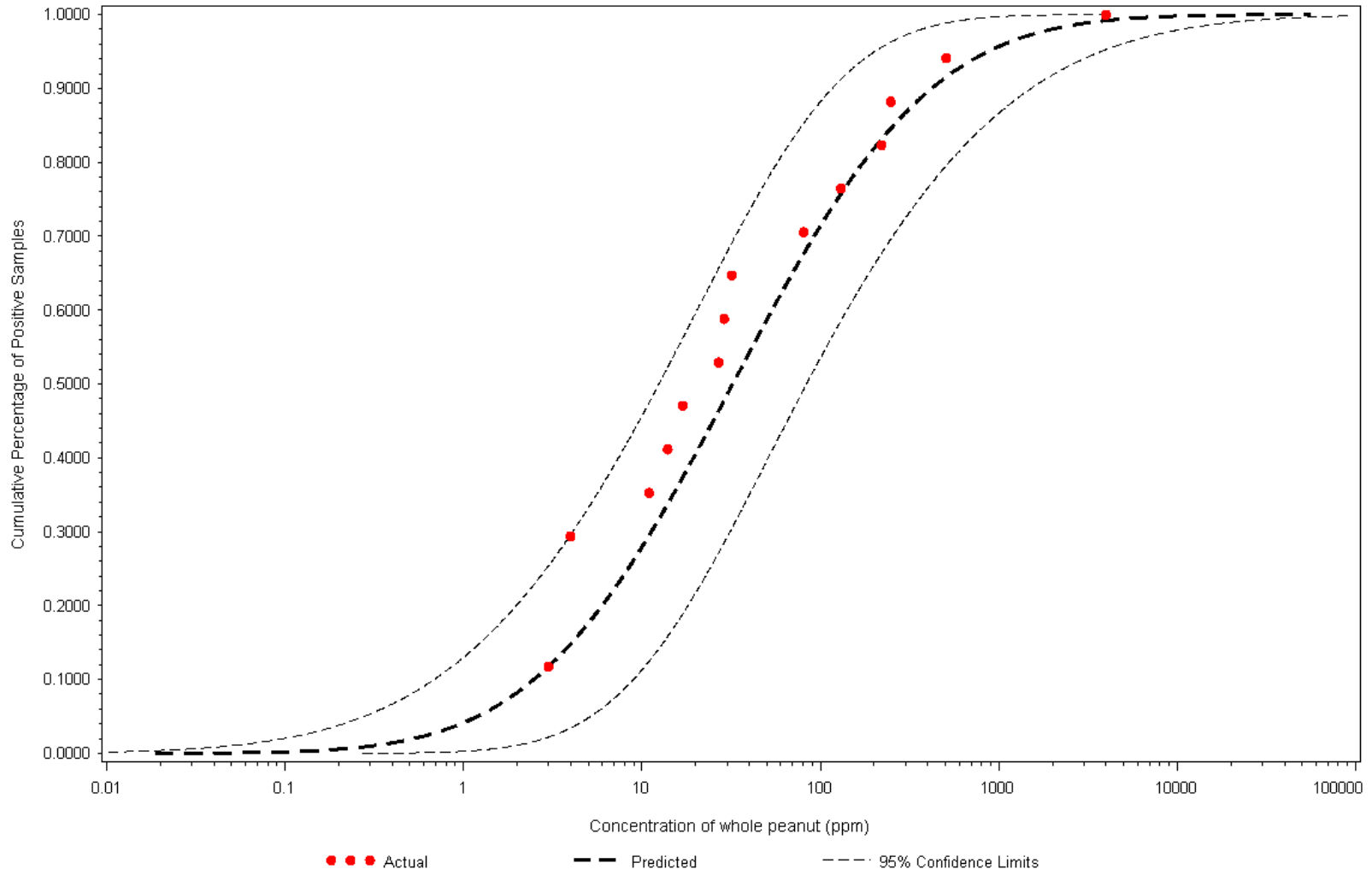
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2005+2009 Product Analysis Data Fit to a Log-Normal Curve



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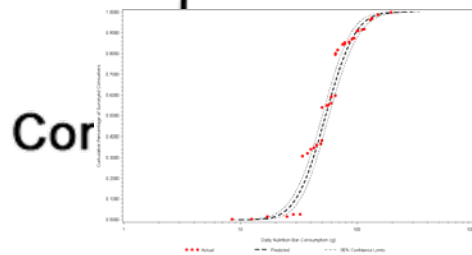
Probabilistic Model for Risk

0.93%
Consume

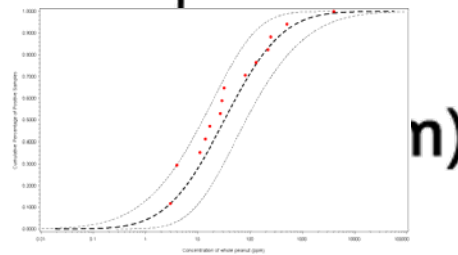
19.2%
Have Peanut

0.76%
Are Allergic

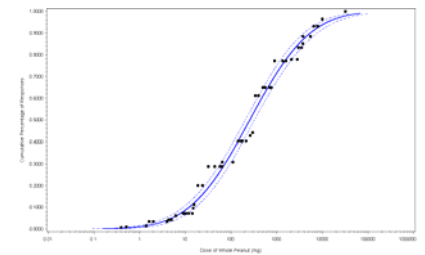
NHANES Survey



Product analyses



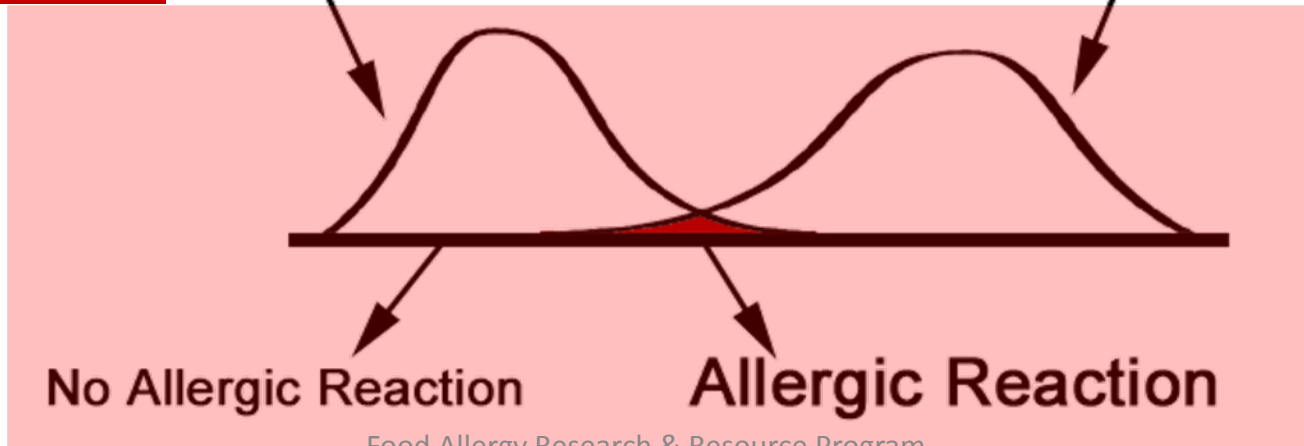
Clinical studies



40%
Purchase

Allergen intake (mg)

Thresholds (mg)



Initial Nutrition Bar Simulation Results

<u>Parameter Inputs</u>	<u>Average Value (%)</u>	<u>Distribution Shape</u>	<u>Source of Data</u>
Prevalence of Peanut Allergy	0.76	Beta	Sicherer et al. 2010
Alle			2010
Probability of Pu			2007
Co			abase
Co			abase
Probability of Peanut Being Present	19.2	Beta	Labeling Surveys
Level of Peanut Present		Lognormal	Labeling Surveys
<u>Simulation Results</u>		<u>Mean</u>	<u>Std. Dev.</u>
Reaction Probability in Users (%)		1.06	0.52
Reaction Probability in Peanut Allergic Population (%)		0.00420	0.00210
Reaction Probability in U.S. Population (%)		0.0000320	0.0000164

Reaction probability in peanut-allergic user population is 1 in 100

Initial Nutrition Bar Simulation Results

<u>Parameter Inputs</u>	<u>Average Value (%)</u>	<u>Distribution Shape</u>	<u>Source of Data</u>
Prevalence of Peanut Allergy	0.76	Beta	Sicherer et al. 2010
Probability of Peanut Allergy			2010
Reaction probability in the peanut-allergic population is 4 in 100,000 per day			
Probability of Peanut Being Present	19.2	Beta	Labeling Surveys
Level of Peanut Present		Lognormal	Labeling Surveys
<u>Simulation Results</u>		<u>Mean</u>	<u>Std. Dev.</u>
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Simulation Estimates 96 reactions per day in USA!!

Interpreting the results

- **We can confidently say that nutrition bars do not cause 96 peanut-allergic reactions per day in the USA.**
- **We are over-estimating the risk!**
- **Key reasons and assumptions for high results**
 - **Peanut-allergic consumers assumed equally likely to eat nutrition bars as general population**
 - **40% are assumed to ignore advisory labels**
 - **NHANES includes very high upper-level consumption estimates**
 - **The simulation is not brand specific while users may favor brands that have a lower likelihood of peanuts**
 - **The threshold curve could be skewed to more sensitive side**

Interpreting the results

- **Of course, a key conclusion is that nutrition bars are risky and peanut-allergic consumers should not eat them if have advisory labels**
- **Other food categories showed lower risks from analytical survey**

Acknowledgements

- Steve L. Taylor, Ph.D.
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