Sensitivity Analysis of Food Safety Process Risk Models: An Introduction and Simple Example

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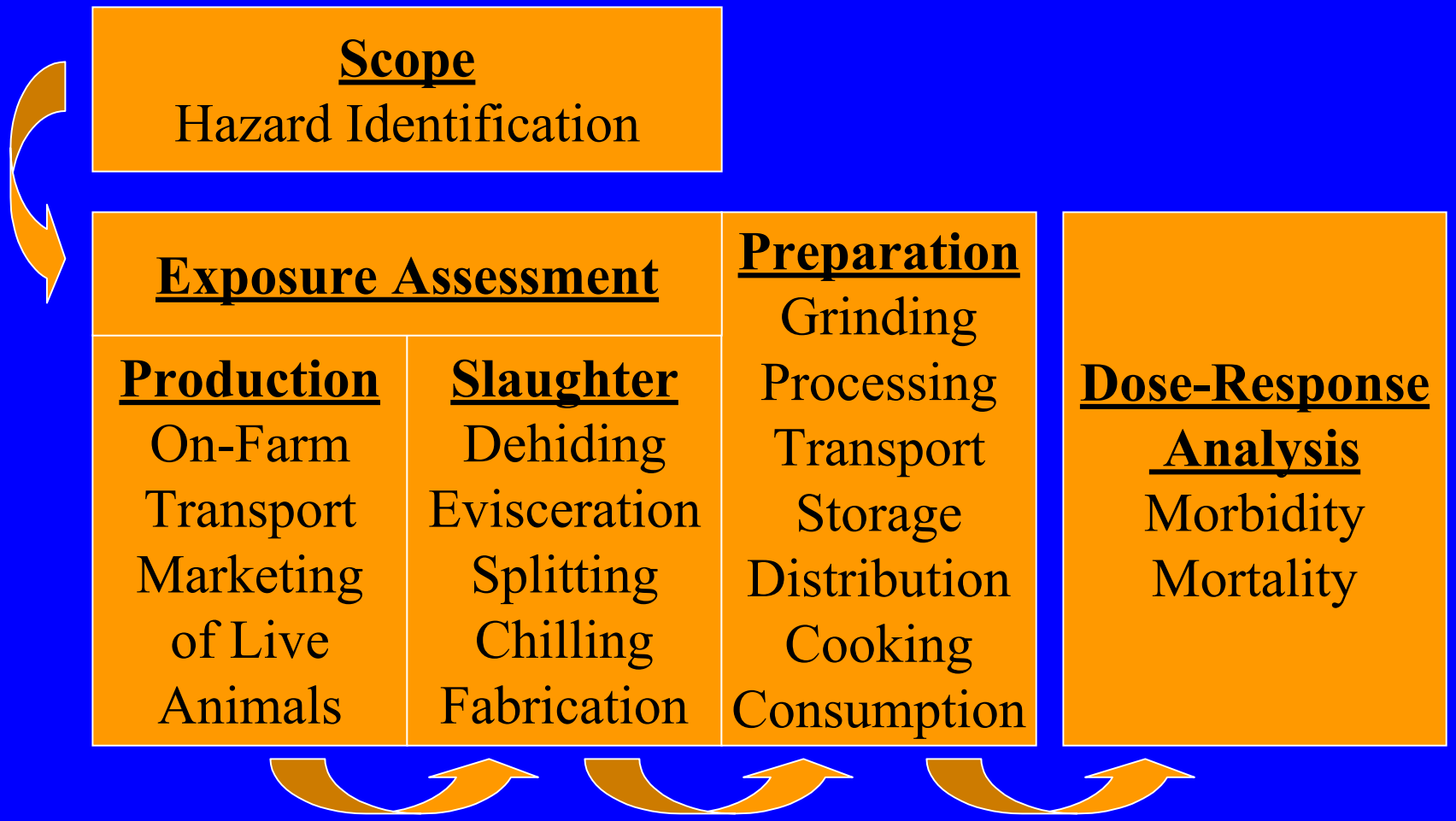
Food Safety HACCP Principles

Hazard Analysis and Critical Control Points

1. Conduct Hazard Analysis
2. Identify Critical Control Points (CCPs)
3. Establish Critical Limits
4. Establish CCP Monitoring
5. Establish Corrective Actions
6. Document HACCP Plan
7. Establish Verification Procedures

E. coli O157:H7 Farm-to-Table Process Risk Model



USDA-NCSU Sensitivity Analysis Cooperative Agreement

- 2001
  - Workshop of Experts and Practitioners
- 2002
  - Application & Evaluation of Methods
- 2003
  - Comprehensive Reference for Practitioners
- Project Website: www.ce.ncsu.edu/risk

Sensitivity Analysis Criteria for Identifying Potential CCPs

- Nonlinearities and Thresholds
  - Microbial Growth and Inactivation
- Interactions
  - Time x Temperature (Lag Phase)
- Discrete Random Variables
  - Animals, Micro-organisms

Other Sensitivity Analysis Considerations

- Ability to Discriminate Among the Importance of Inputs
- Variety of Approaches
  - Analyze Sensitivity Locally/Globally
  - Vary Inputs Jointly/Individually
  - Assess Modular/Continuous Model Setups
  - Evaluate Outputs in Region of Concern
  - Apportion Variance/Evaluate Position Shifts
  - Consider Model and Scenario Uncertainties

Limitations of Sensitivity Analysis

- Level of analysis should be commensurate to the decision.
- Sensitivity analysis can only identify *potential* CCPs.
- Other relevant decisional criteria include legal, economic, technical, administrative, and equity considerations.

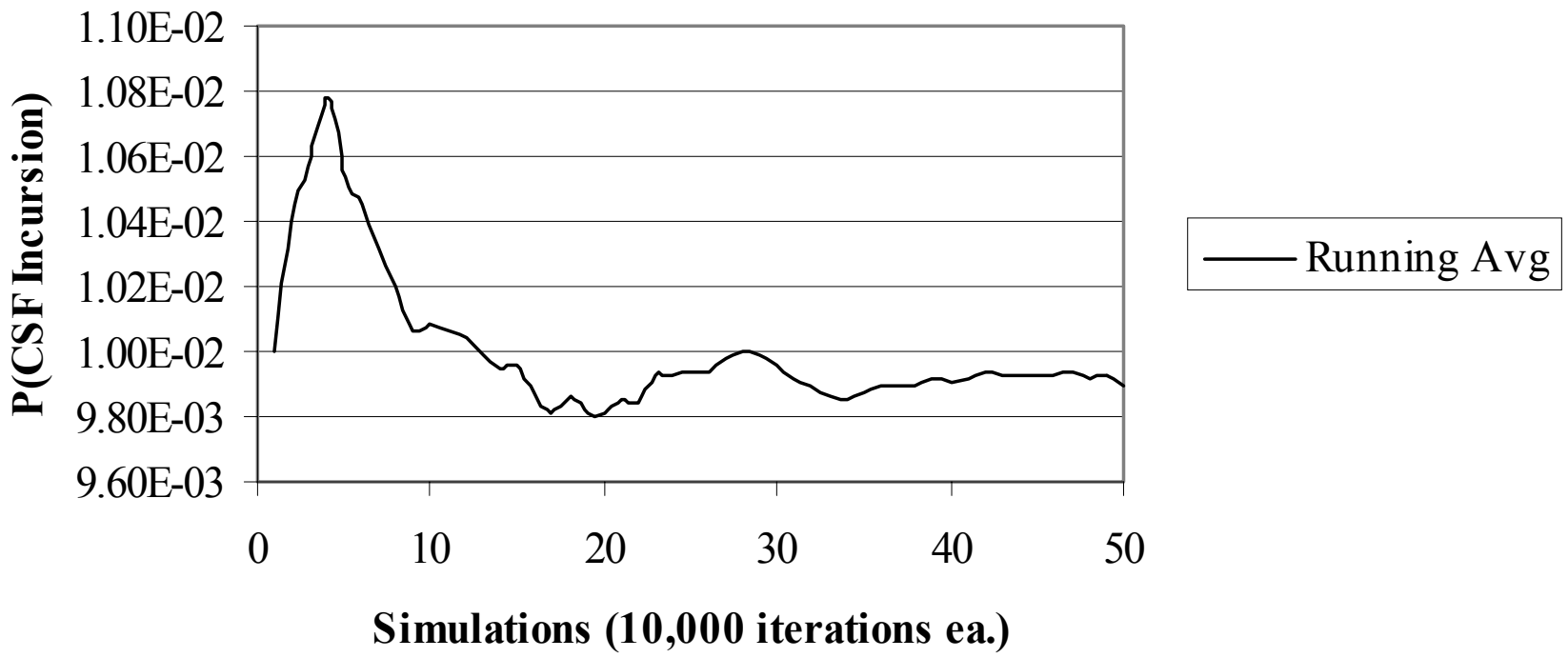
Hypothetical Animal Health Example: Risk of Exporting Chronic Salmon Fever (CSF) via Salmon Semen Pathway

- Monte Carlo Simulation Model
- MCSM output represents simulated experiment generating a set of matched observations
- Response surface modeling approach used to summarize and perform sensitivity analysis

Hypothetical Animal Health Example: Risk of Exporting Chronic Salmon Fever (CSF) via Salmon Semen Pathway

Monte Carlo Simulation Model	
X1 (RISKY PERIOD)	TEXPON(1,3,52) (wks)
X2 (DOSES/YR)	MIN = 0 MAX = 1800 MLV = 800
X3 (DOSES/SHIPMENT)	UNIF(10,30)
X4 (SHIPMENTS DURING X1)	BIN(SHIPMENTS/YR, X1/52 (yr))
X5 (CTR PREV)	1 of 276 ctr-yrs ~ BETA(2,276)
X6 (W/IN CTR PREV MLV)	UNIF(15%,30%)
X7 (W/IN CTR PREV)	MIN = 5% MAX = 100% MLV = X6
X8 (DONORS/SHIPMENT)	P(X8=1) = 0.75 P(X8=2) = 0.25
Y (CSF INCURSION DURING YR)	BINARY OUTCOME (0,1)

Figure 1. Convergence of Annual Risk of CSF Incursion

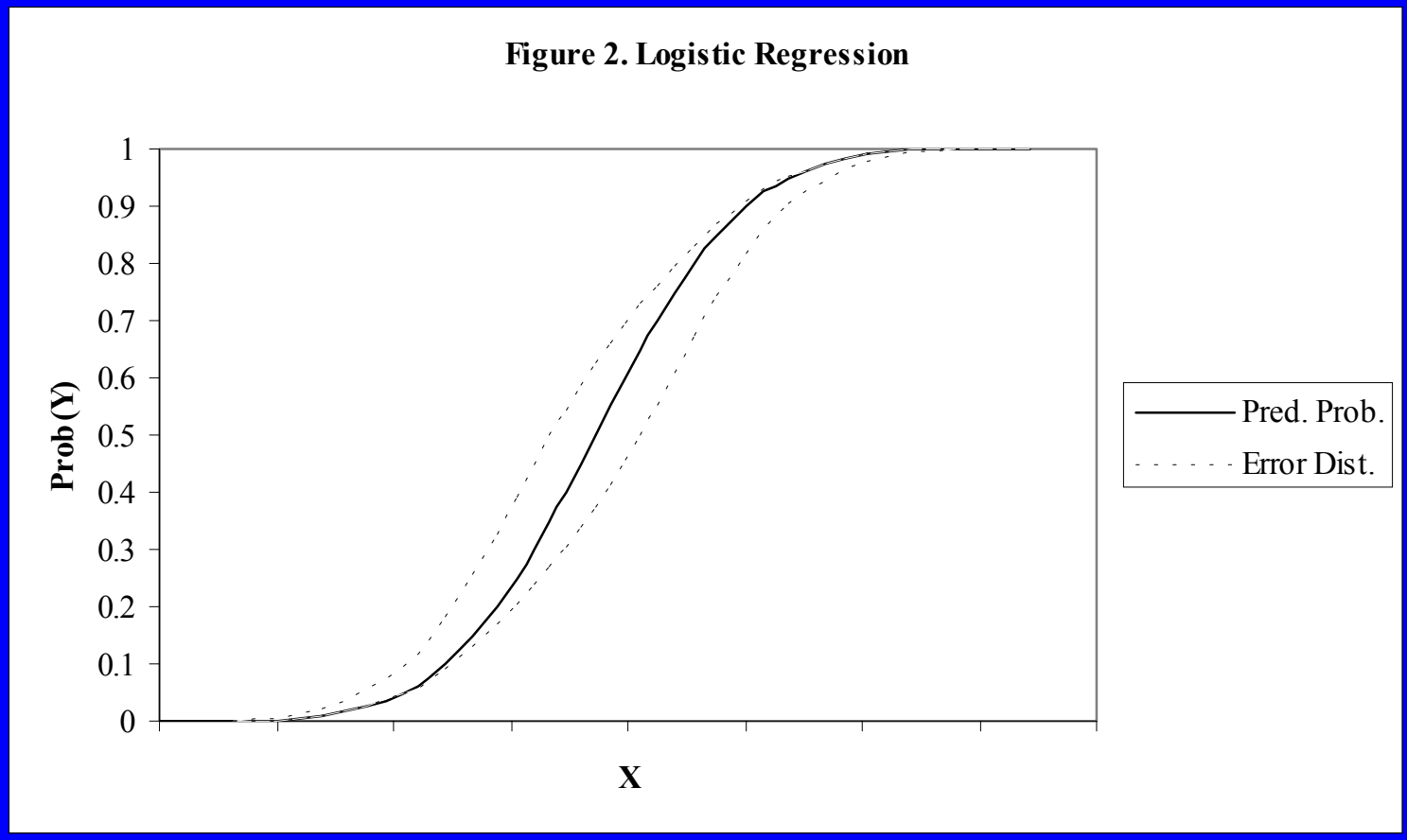


Results: Approximately 1 in 100 (9.9×10^{-3})

annual risk of CSF-incursion

(95% credible interval of $2.3 \times 10^{-4} – 3.7 \times 10^{-2}$)

Response Surface Modeling



$$\ln(p) = \ln\left(\frac{p}{1-p}\right) = \beta_0 + \beta_1 X_1 + \ldots + \beta_n X_n,$$

Identification of Important Input Variables

- Variable Selection Procedure
  - Backward stepwise variable selection (with a significance level of 0.001 for staying in the model)
- Standardized Regression Coefficients
  - Indicator, normalized for scale and spread, of relative importance

Sensitivity to Multicollinearity

Table 1. Summarized Results of Logistic Regression Analysis on Ten Simulations – Misidentified Model										
Model Term	SIM 1	SIM 2	SIM 3	SIM 4	SIM 5	SIM 6	SIM 7	SIM 8	SIM 9	SIM 10
	Standardized Regression Coefficient (Sign of Regression Coefficient for Interaction Terms)									
X1	**0.2769**					**-0.5165**		**0.2156**	**0.2140**	
X2					**0.3117**					
X3				**-0.1813**		**-0.2662**				
X4	**0.4882**	**0.2307**	**0.2541**	**-0.1514**	**0.7204**	**0.3637**	**0.2747**	**0.5977**	**0.5268**	**0.3165**
X5	**0.2762**	**0.2377**	**0.2667**	**0.2314**	**0.2930**	**0.2528**	**0.2784**	**0.3009**	**0.2284**	**0.2849**
X6										
X7	**0.2716**	**0.2182**	**0.2544**	**0.2463**	**0.3150**	**0.2125**	**0.3083**	**0.2495**	**0.2786**	**0.2413**
X8	**0.1725**					**0.1709**				
X1*X3						**+**				
X1*X4	**-**							**-**	**-**	
X2*X4					**-**					
X3*X4				**+**						

Alternative Model Specifications

Table 2. Summarized Results of Logistic Regression Analysis on Five Simulations – Omitting X1, X2 & X3 from the Model

Model Term	SIM 1		SIM 2		SIM 3		SIM 4		SIM 5	
	b_i	std b_i	b_i	std b_i	b_i	std b_i	b_i	std b_i	b_i	std b_i
b_0	-8.1648	-	-6.7305	-	-7.0821	-	-6.8689	-	-7.4155	-
X4	0.1168	0.2719	0.1000	0.2307	0.1068	0.2541	0.0997	0.2287	0.1175	0.2696
X5	99.8821	0.2786	85.1629	0.2377	95.6126	0.2667	82.5814	0.2302	106.300	0.2965
X6	-	-	-	-	-	-	-	-	-	-
X7	2.9113	0.2651	2.4029	0.2182	2.7945	0.2544	2.6511	0.2409	3.3995	0.3094
X8	0.7493	0.1789	-	-	-	-	-	-	-	-
mean risk	0.0098		0.0095		0.0091		0.0089		0.0101	
2.5 %ile	0.0014		0.0023		0.0017		0.0020		0.0014	
97.5 %ile	0.0433		0.0345		0.0363		0.0324		0.0452	

Alternative Model Specifications

Table 3. Summarized Results of Logistic Regression Analysis on Five Simulations – Omitting X4 from the Model

Model Term	SIM 1		SIM 2		SIM 3		SIM 4		SIM 5	
	b_i	std b_i	b_i	std b_i	b_i	std b_i	b_i	std b_i	b_i	std b_i
b_0	-9.497	-	-5.1496	-	-8.3974	-	-8.4737	-	-7.2091	-
X1	0.1597	0.2824	0.1166	0.2062	0.1258	0.2230	0.1321	0.2339	0.1282	0.2270
X2	0.00116	0.2168	-	-	0.00136	0.2548	0.00154	0.2888	0.00132	0.2477
X3	-	-	-0.0894	-2.845	-	-	-	-	-0.073	-0.2323
X5	100.5	0.2803	83.632	0.2334	92.7011	0.2586	81.5046	0.2272	102.1	0.2848
X6	-	-	-	-	-	-	-	-	-	-
X7	2.9816	0.2715	2.4631	0.2236	2.8827	0.2625	2.7154	0.2467	3.3248	0.3026
X8	0.7752	0.1851	-	-	-	-	-	-	-	-
mean risk	9.96E-03		9.58E-03		9.33E-03		8.96E-03		9.95E-03	
2.5 %ile	9.94E-04		1.39E-03		1.21E-03		1.16E-03		8.30E-04	
97.5 %ile	4.93E-02		3.87E-02		3.99E-02		3.87E-02		4.92E-02	

Considering Scenario Uncertainty

- Uncertainty about actual prevalence of CSF-infected salmon semen centers
  - Uncertainty due to bounding the problem

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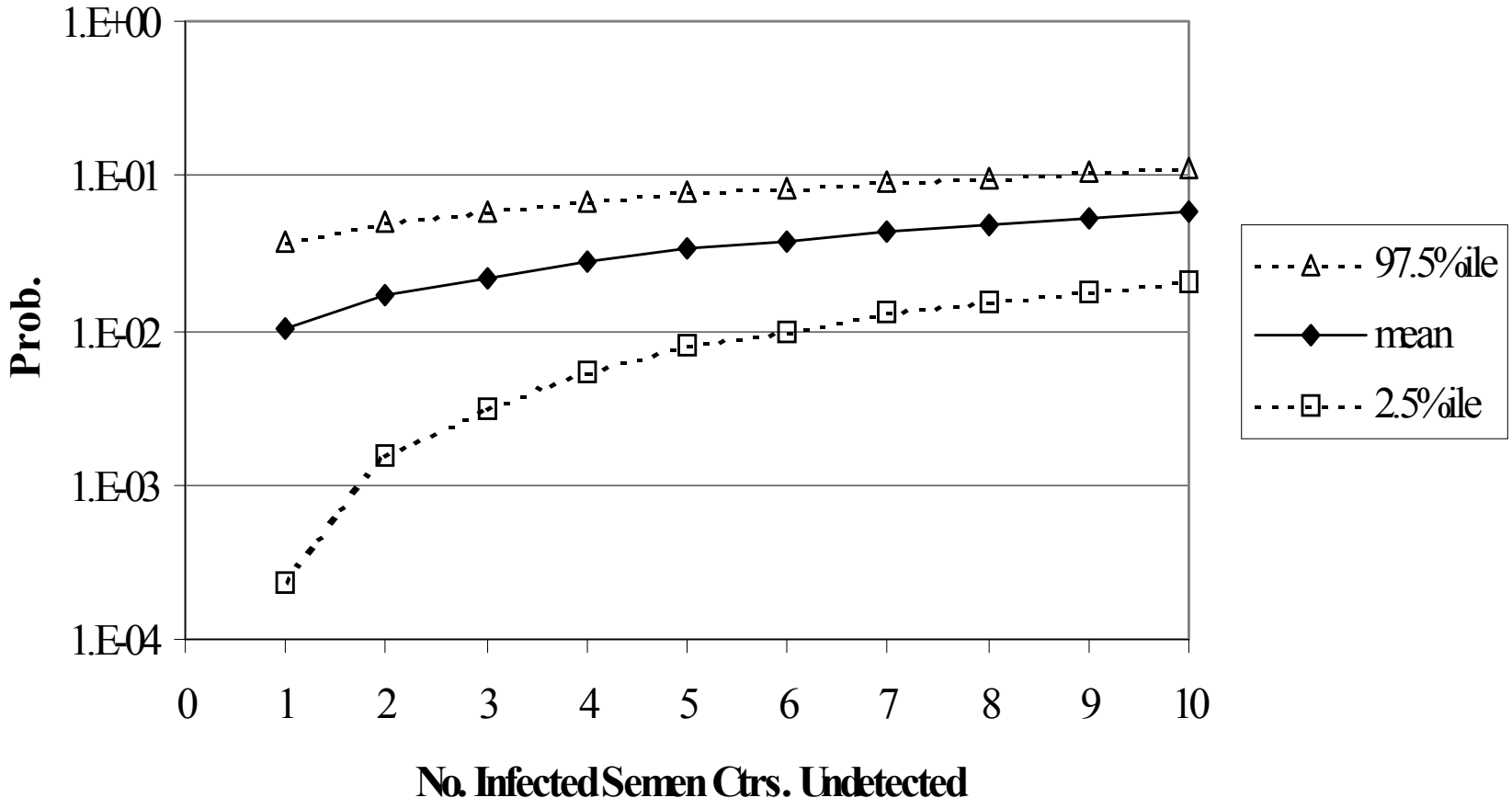
- Uncertainty about actual prevalence of CSF-infected salmon semen centers
  - Uncertainty due to bounding the problem
  - Uncertainty due to under-reporting

Figure 3. Annual Risk of CSF Incusion via Salmon Semen Pathway



Discussion

- Different sensitivity analysis approaches may arrive at different conclusions.

Conclusion

- Precautionary tale of the hazards of applying sensitivity analysis in a formulaic fashion.
- No simple replicable formula for regulatory development.
- Uncertainty is the norm, not the exception.