

RISK ASSESSMENT AND RISK MANAGEMENT FOR SAFE FOODS

Assessment needs inclusion of variability and uncertainty,
management needs discrete decisions

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安全な食品のためのリスク評価とリスク管理

評価においては変動と不確実性が必要

管理においては個別的な判断が必要

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History



Process criteria ($F_{121}=3$ min, T-t pasteurisation)

Microbial testing and criteria

HACCP

QM QRA

FSO

development

legislation



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食品安全管理の歴史



食品加工基準($F_{121}=3$ min, T-t 低温殺菌)

微生物検査と基準

ハサップ

QM QRA

摂取時安全目標値

手法の開発

法制化



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History QM/QRA



Bigelow D value F value



QM

QRA

variability/ uncertainty

QM = Quantitative Microbiology
QRA = Quantitative risk assessment / risk analysis



QM /QRA の歴史



ビゲロウモデルにおける D値 F値



QM

QRA

変動 / 不確実性

QM = 定量微生物学
QRA = 定量的リスク評価 / リスク分析



Risk assessment

Hazard identification
potential danger

Exposure assessment
 N

Hazard Characterisation
 $P(N)$ +severity

Risk Characterisation
Probability and severity including variability
and uncertainty

リスク評価

ハザードの同定
ヒトの健康に危害を与える可能性

ばく露評価
 N (微生物の濃度)

ハザードの特性解析
健康危害の発生確率
+
重篤度

リスクの特性解析
変動と不確実性を含めて、健康危害の発生確率と
重篤度を特徴づける

Risk assessment

Hazard identification

Objective procedure

Exposure assessment

Initial contamination
Kinetics

Hazard Characterisation

dose-response
(disease probability/
severity as function of dose)

Risk Characterisation

probability/severity 50.000.000 products

リスク評価 (Codexの定義による)

ハザードの同定

客観的な手順

ばく露評価

初期汚染
体内動態

ハザードの特性解析

用量-反応関係
(用量の関数として表す
疾患の確率と重篤度)

リスクの特性解析

発生確率と重篤度
50.000.000 製品

Advice for Legislation / Management

LEGISLATION = LINE IN THE SAND



SCIENCE = VARIABILITY
(HETEROGENEITY)

法制化と管理に向けたアドバイス

法制化 = 砂に書いた直線



科学 = 変動
(多様性)

1.4	Minced meat and meat preparations intended to be eaten raw	<i>Salmonella</i>	5	0
1.5	Minced meat and meat preparations made from poultry meat intended to be eaten cooked	<i>Salmonella</i>	5	0

Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
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LEGISLATION = LINE IN THE SAND



1.4	生食用ひき肉及び肉製品	サルモネラ菌	5	0
1.5	調理用鶏肉のひき肉及び肉製品	サルモネラ菌	5	0

(サンプル)

25 g 中に検出されず	EN/ISO 6579 検出方法	製品の保存期間中に市場に出回った製品
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法制化 = 砂に書いた直線

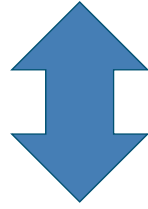


Zero risk – Control – Variability – Heterogeneity - Biology

CONSUMERS, THE GOVERNMENT,
THE INDUSTRY:

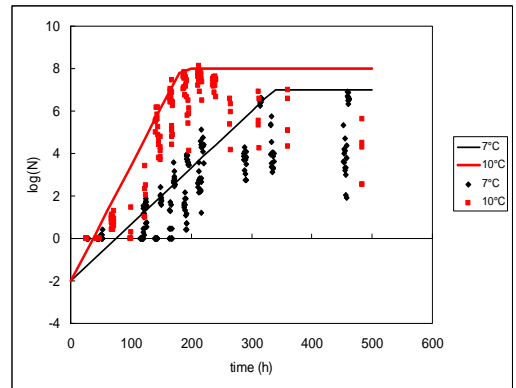
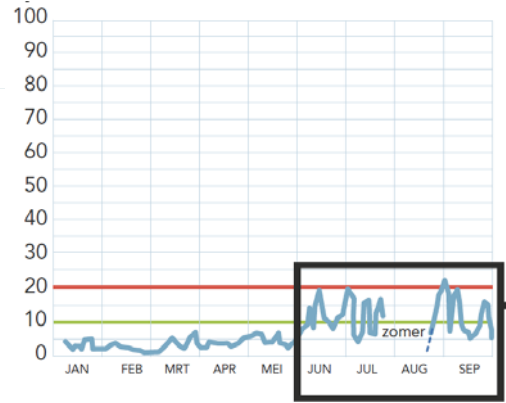
ZERO RISK

CONTROL



BIOLOGY

VARIABILITY
(HETEROGENEITY)

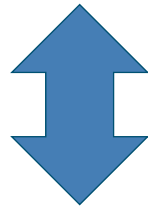


ゼロリスクーコントロールー変動ー多様性ー生物学

消費者、政府、生産業者：

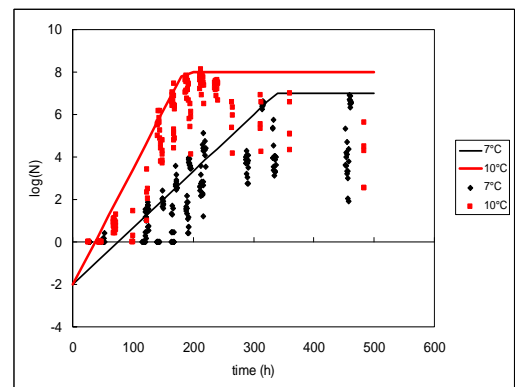
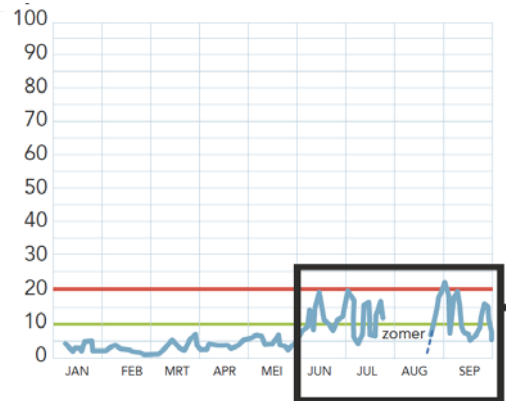
ゼロリスク

コントロール



生物学

変動
(多様性)



Variability in contamination

VARIABILITY AT MOMENT OF CONSUMPTION:

TIME TEMPERATURE OF STORAGE
HYGIENE AT THE FARM
VARIABILITY IN PROCESSING
VARIABILITY IN ORGANISMS

汚染における変動

摂食時点における変動：

貯蔵の時間と温度
生産ファームの衛生状態
処理工程における変動
微生物の変動

Sources of variability / heterogeneity

Experimental error
Biological variability
Cell history, physiological state
Genetic variability
Strain variability

Product specific effects
Variability in controlling factors, environment, humans, etc

QUANTIFY: REALISTIC PREDICTIONS
DETERMINE SOURCES
RANK IMPORTANCE
CONTROL WHERE POSSIBLE
BIOLOGICAL INSIGHT



変動／多様性の原因

実験誤差
生物学的な変動
細胞の背景、生理学的状態
遺伝的変動、
株間の変動

製品特異的な影響
コントロール要因、環境、人間《ホスト》等における変動

定量化: 現実的な予測
感染源の特定
重要性のランク付け
可能な範囲でのコントロール
生物学的な洞察



Variability in level at constant temperature

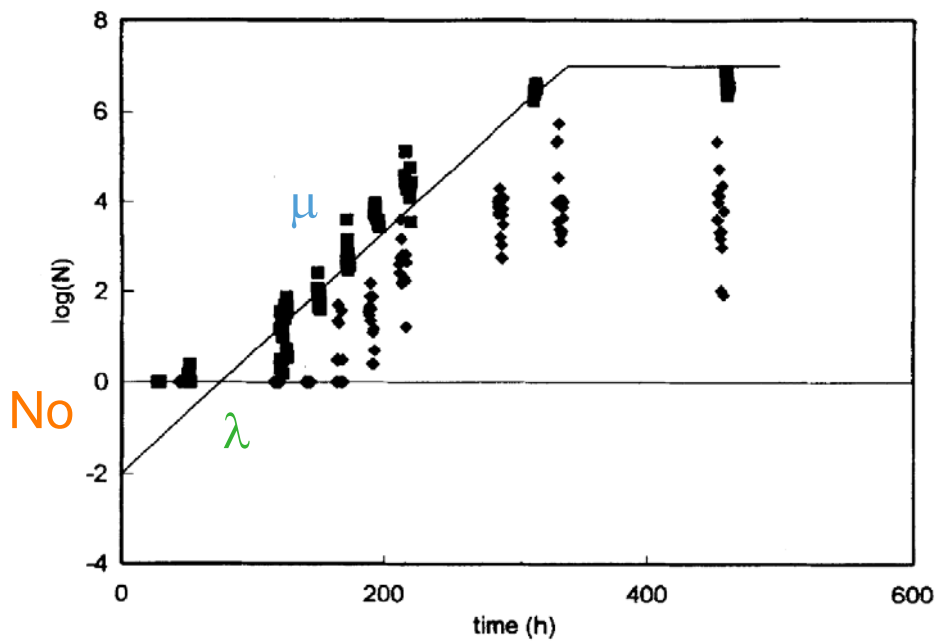


Fig. 4. Comparison of the predicted number of organisms and the measured number at 7°C. ■ Series 1 (lab 1); ◆ Series 2 (lab 1); — Model prediction.

一定の温度下における微生物増殖の変動

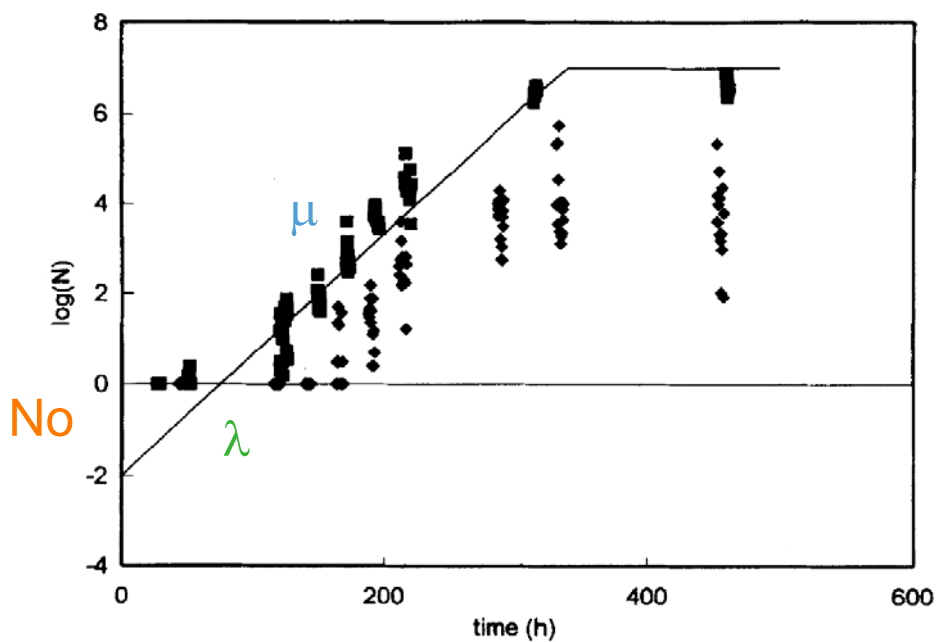


図 - 4. 7°Cにおける増殖：実測値（◆、■）とモデル予測（—）の比較

Initial number, growth, lag and infectivity

Variability in contamination

Consumer variability

$$P_{ill} = N_o e^{\mu(t-\lambda)} \cdot r$$

$$\mu = b \cdot (T - T_{min})^2$$

Fridge variability
seasonal variability

Biological variability

初期値、増殖、遅滞および感染

汚染における変動

消費者における変動

$$P_{ill} = N_o e^{\mu(t-\lambda)} \cdot r$$

$$\mu = b \cdot (T - T_{min})^2$$

冷蔵庫に由来する変動
季節的な変動

生物学的な変動

Dose-Response: Large uncertainty

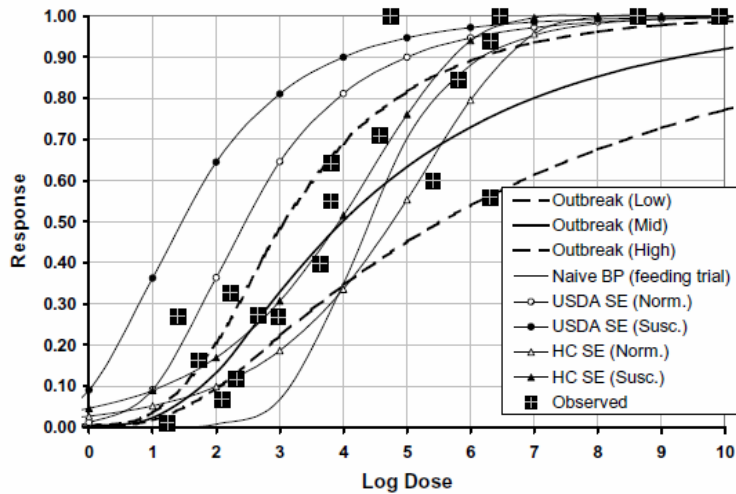
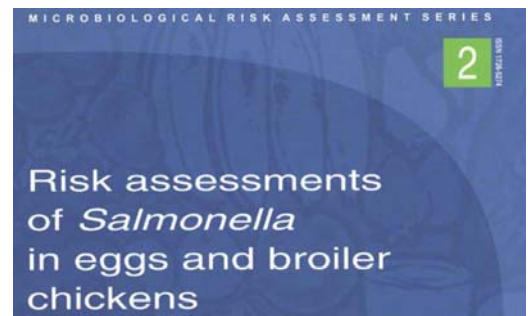
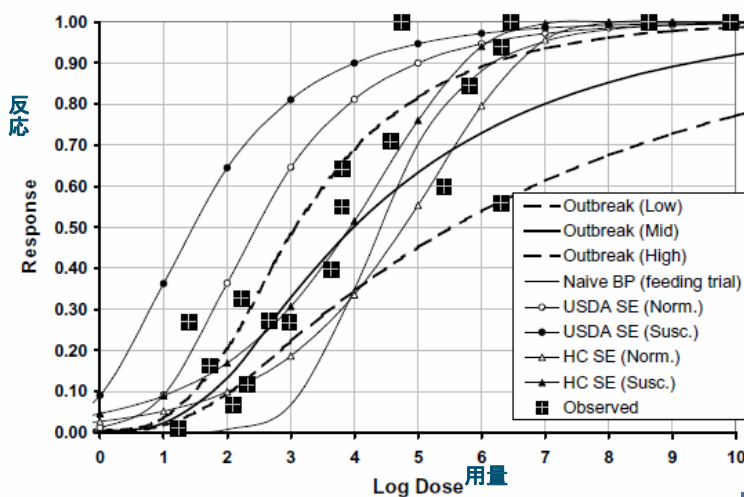


Figure 3.19. Comparison of all dose-response models with reported outbreak data.

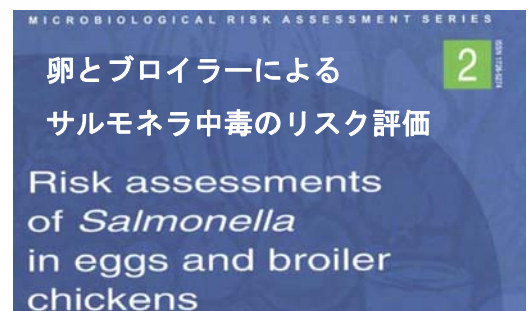


用量－反応関係：不確実性は大きい

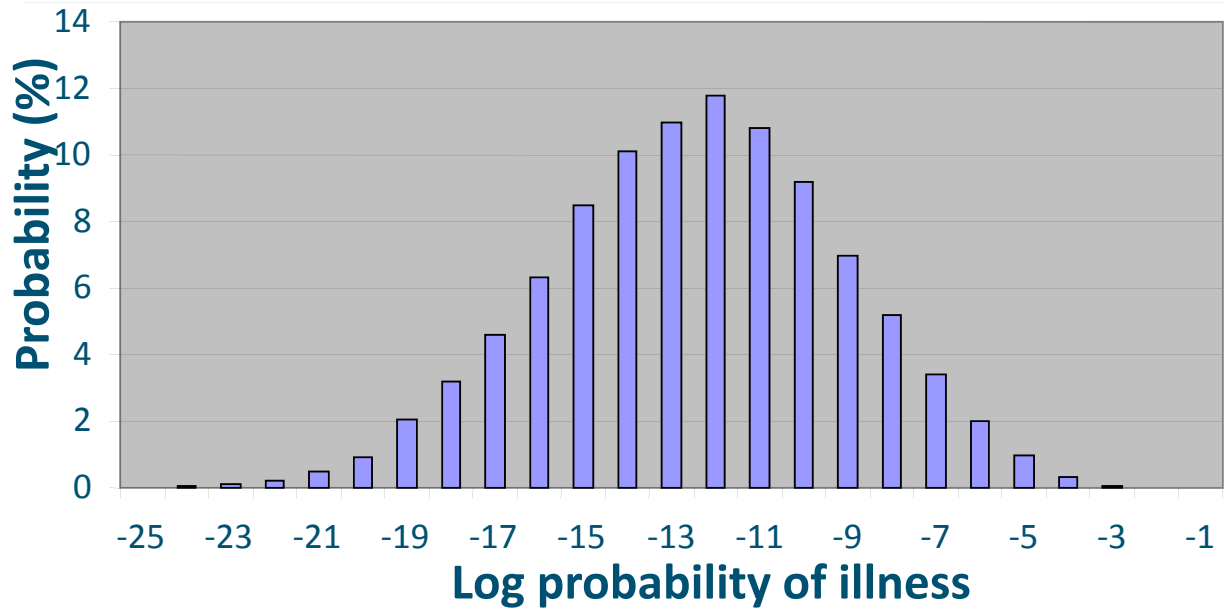


— モデル予測値
■ 報告値

用量－反応モデル値と報告された食中毒データとの比較



Probability distribution illness from a single hamburger for *E. coli* O157:H7 (Cassin et al. 1998)



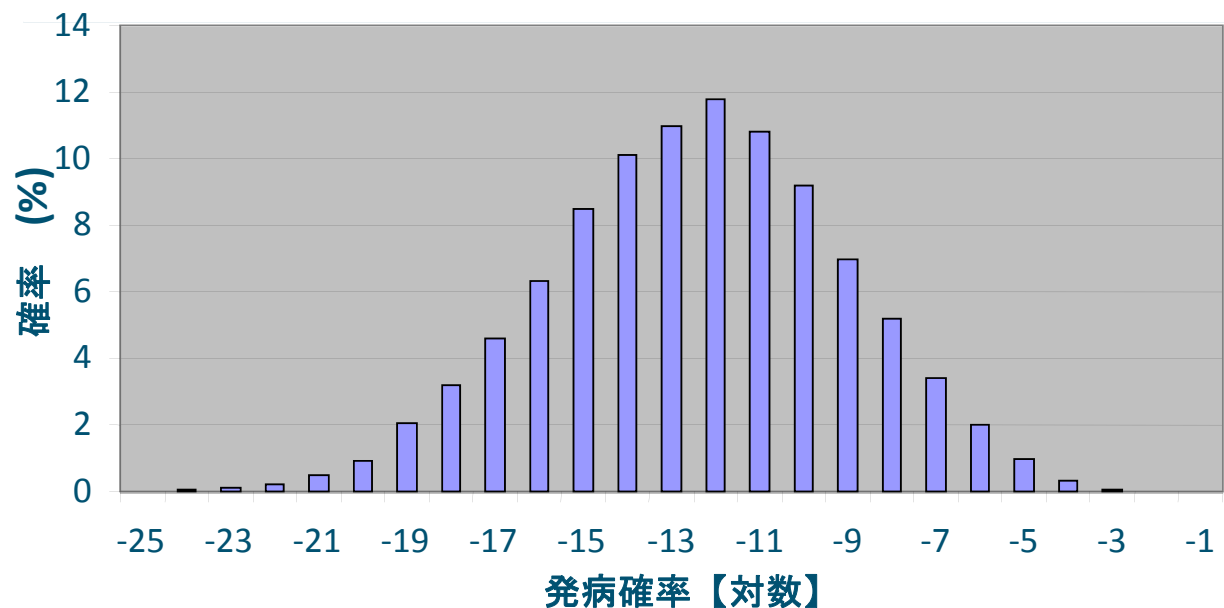
Exposure / dose response models with 44 parameters with their statistical distribution that can all be criticised



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Quantitative risk assessment for *Escherichia coli* O157:H7 in ground beef hamburgers. Michael H. Cassin, Anna M. Lammerding, 1998. Ewen C.D. Todd, William Ross, R. Stephen McColl. International Journal of Food Microbiology 41: 21-44

1個のハンバーガーによる大腸菌O157:H7 食中毒の発病確率分布 (Cassin et al. 1998)



44パラメータを用いた評価可能な統計学的分布によるばく露・用量反応モデル



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The uncertainty and variability of the cumulative probability of the prevalence !

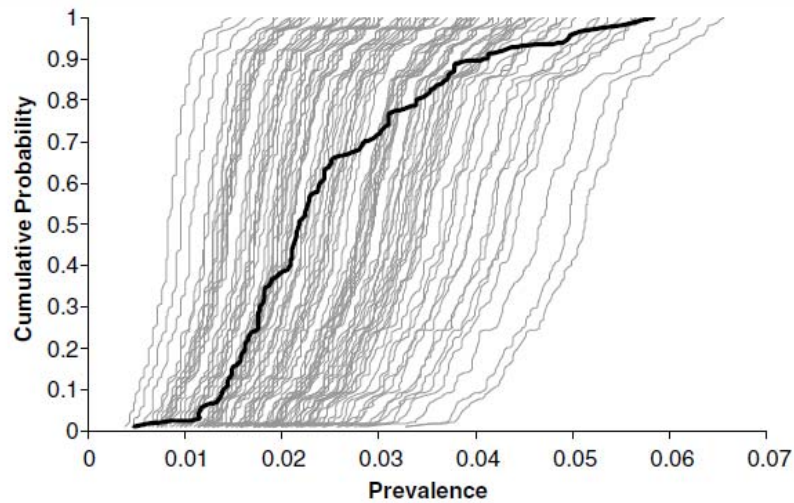


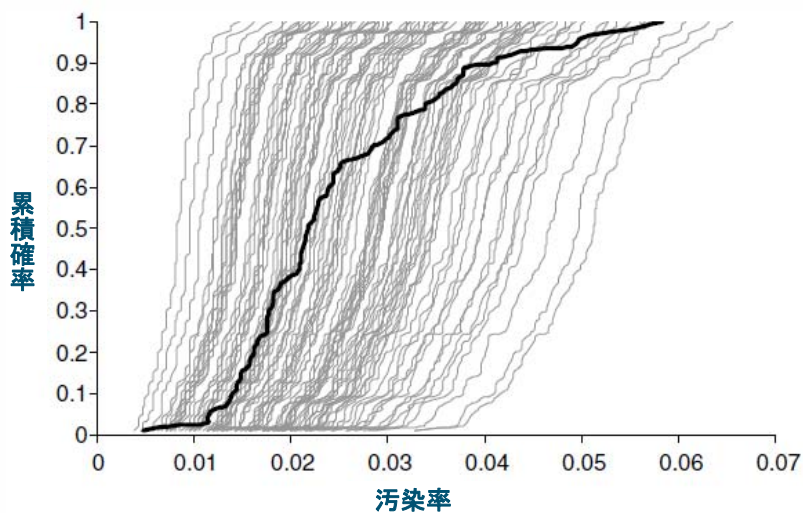
Fig. 8. Second-order cumulative probability for the prevalence of *E. coli* O157:H7 on beef trimmings. (Heavy line represents no separation of uncertainty and variability; thin lines represent successive simulations with separation of uncertainty and variability).

Development and validation of a probabilistic second-order exposure assessment model for *Escherichia coli* O157:H7 contamination of beef trimmings from Irish meat plants

E. Cummins ^{a,*}, P. Nally ^a, F. Butler ^a, G. Duffy ^b, S. O'Brien ^b



大腸菌汚染の累積確率における不確実性と変動



牛トリミング上の大腸菌O157:H7汚染の二次累積確率

太い線：不確実性と変動を分離しない場合

細い線：不確実性と変動を分離してシミュレートした場合

出典：Development and validation of a probabilistic second-order exposure assessment model for *Escherichia coli* O157:H7 contamination of beef trimmings from Irish meat plants

E. Cummins ^{a,*}, P. Nally ^a, F. Butler ^a, G. Duffy ^b, S. O'Brien ^b



■ Decision support !

法制化と管理に向けたアドバイス

■ 判 断 の 支 援 !

A. SUSCEPTIBILITY AND SEVERITY		C. PROBABILITY OF FOOD CONTAINING AN INFECTIOUS DOSE	
1 Hazard Severity SEVERE hazard - causes death to most victims MODERATE hazard - requires medical intervention in most cases MILD hazard - sometimes requires medical attention MINOR hazard - patient rarely seeks medical attention		6 Probability of Contamination of Raw Product per Serving Rare (1 in a 1000) Infrequent (1 per cent) Sometimes (10 per cent) Common (50 per cent) All (100 per cent) OTHER	
2 How susceptible is the population of interest ? GENERAL - all members of the population SLIGHT - e.g., infants, aged VERY - e.g., neonates, very young, diabetes, cancer, alcoholic etc EXTREME - e.g., AIDS, transplant recipients, etc.		10 What increase in the post-processing contamination level would cause infection or intoxication to the average consumer? none slight (10 fold increase) moderate (100-fold increase) significant (10,000-fold increase) OTHER	
B. PROBABILITY OF EXPOSURE TO FOOD		7 Effect of Processing The process RELIABLY ELIMINATES hazards The process USUALLY (90% of cases) ELIMINATES hazards The process SLIGHTLY (50% of cases) REDUCES hazards The process has NO EFFECT on the hazards The process INCREASES (10 x) the hazards The process GREATLY INCREASES (1000 x) the hazards OTHER	
3 Frequency of Consumption daily weekly monthly a few times per year OTHER		11 Effect of preparation before eating Meal Preparation RELIABLY ELIMINATES hazards Meal Preparation USUALLY ELIMINATES (90%) hazards Meal Preparation SLIGHTLY REDUCES (50%) hazards Meal Preparation has NO EFFECT on the hazards OTHER	
4 Proportion of Population Consuming the Product all (100%) most (75%) some (25%) very few (5%)		8 Is there potential for recontamination after processing ? NO YES - minor (1% frequency) YES - major (50% frequency) OTHER	
5 Size of Consuming Population Australia ACT New South Wales Northern Territory Queensland South Australia Tasmania Victoria Western Australia OTHER		9 How effective is the post-processing control system? WELL CONTROLLED - reliable, effective, systems in place (no increase in risk) CONTROLLED - mostly reliable systems in place (3-fold increase) NOT CONTROLLED - no systems, untrained staff (10-fold increase) GROSS ABUSE OCCURS - (e.g. 1000-fold increase) NOT RELEVANT - level of risk agent does not change	
If "OTHER" enter "number of days between a 100g" 10		If "OTHER" enter a percentage value between 0 (none) and 100 0.0001%	
Population considered: 16,489,032 specify: 16,489,032		indicates the extent of risk increase 1.00E-03 If "other", enter a value that indicates the extent of risk increase 1.00E-02	
		RISK ESTIMATES probability of illness per day per consumer of interest 1.42E-05 total predicted illnesses/annum in population of interest 2.14E+04 RISK RANKING (0 to 100) 58	

Risk Ranger

A simple, spreadsheet-based, food safety risk assessment tool

Thomas Ross*, John Sumner



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リスクリンジャー

A simple, spreadsheet-based, food safety risk assessment tool

Thomas Ross*, John Sumner



	Pathogen	Sporigen	Population exposure	Dose-1% value ^a	P1 value ^b
Growth in food may not be needed to cause illness	Norovirus	—	no growth in food is possible, highly infectious (probability of infection for a single particle of 0.5)		
	Parasites	—	no growth in food is possible, ingestion of a few parasites may cause infection		
	<i>Salmonella</i> (salmonellosis)	—	any exposed people	4.1	$2.5 \cdot 10^{-3}$
	<i>Shigella</i>	—	any exposed people	8.8	$1.2 \cdot 10^{-3}$
	<i>Campylobacter jejuni</i> (diarrheal disease)	—	adults	2.9	$3.5 \cdot 10^{-3}$
	EHEC (e.g. <i>E. coli</i> O157) (haemolytic uremic syndrome)	—	children < 6 years	8.4	$1.2 \cdot 10^{-3}$
			children 6–10 years	41.9	$2.4 \cdot 10^{-4}$
	<i>Yersinia enterocolitica</i>	—	no dose–response model available, involved in water-borne infections and growth in water does not seem possible		

microbiological safety of foods: A new tool and its application to composite products

Pietro Stella^{a,*}, Olivier Cerf^d,
Marta Hugas^a,
Kostas P. Koutsoumanis^c,
Christophe Nguyen-The^{d,e},
John N. Sofos^f, Antonio Valero^g
and Marcel H. Zwietering^h

病原菌の分類	病原菌	芽胞形成性	ばく露集団	Dose-1% value ^a	P1 value ^b
食品中で増殖しなくても、食中毒を引き起こす	ノロウイルス	—	食品中の増殖なしの可能性あり、感染性が高い (一個による感染確率 : 0.5)		
	寄生虫	—	食品中の増殖なしの可能性あり、数匹の摂取で感染する場合もある		
	サルモネラ属菌 (サルモネラ症)	—	全ての集団	4.1	2.5×10^{-3}
	赤痢菌	—	全ての集団	8.8	1.2×10^{-3}
	カンピロバクター・ ジェジュニ (下痢症状)	—	成人	2.9	3.5×10^{-3}
	EHEC (例 ; 大腸菌O157) (溶血性尿毒症)	—	6歳未満の小児	8.4	1.2×10^{-3}
			6~10歳の小児	41.9	2.4×10^{-4}
	エルシニア・ エンテロコリチカ	—	用量–反応モデルは無い 飲料水による感染に関与するが、水中での増殖は考えにくい		

Ranking the microbiological safety of foods: A new tool and its application to composite products

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Growth in food is usually needed to cause illness	<i>Listeria monocytogenes</i> (severe listeriosis)	–	more susceptible sub-population	$9.5 \cdot 10^9$	$1.1 \cdot 10^{-12}$
			less susceptible sub-population	$4.2 \cdot 10^{11}$	$2.4 \cdot 10^{-14}$
	<i>Vibrio parahaemolyticus</i> (enterocolitis)	–	adults	$2.2 \cdot 10^4$	$4.6 \cdot 10^{-7}$
	<i>Clostridium perfringens</i>	+		$1.5 \cdot 10^6$	$6.9 \cdot 10^{-9}$
	<i>Bacillus cereus</i> (diarrhoeic)	+	no dose–response model available, at least 10^5 – 10^6 cells per serving of foods causing illness		

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病原菌の分類	病原菌	芽胞形成性	ばく露集団	Dose-1% value ^a	P1 value ^b
通常、食中毒の発症には食品中での細菌の増殖が必要	リステリアモノサイトゲネス (重症リステリア症)	–	高感受性集団	9.5×10^9	1.1×10^{-12}
			低感受性集団	4.2×10^{11}	2.4×10^{-14}
	腸炎ビブリオ (腸炎)	–	成人	2.2×10^4	4.6×10^{-7}
	ウェルシュ菌	+		1.5×10^6	6.9×10^{-9}
	セレウス菌 (下痢)	+	用量–反応モデルは無い。一食当たり最低 10^5 – 10^6 個の細胞があれば発症する		

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Growth in food is needed for production of toxins or toxic metabolites that may cause illness ^f	<i>Clostridium botulinum</i>	+	no data available
	<i>Staphylococcus aureus</i>	-	no data available
	<i>Bacillus cereus</i> (emetic)	+	no data available
	Bacteria producing biogenic amines	-	no data available

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病原菌の分類	病原菌	芽胞形成性	
食中毒を引き起こす毒素または有毒代謝物を産生するには食品中での増殖が必要	ボツリヌス菌	+	データなし
	黄色ブドウ球菌	-	データなし
	セレウス菌 (嘔吐)	+	データなし
	生体アミンを産生する細菌	-	データなし

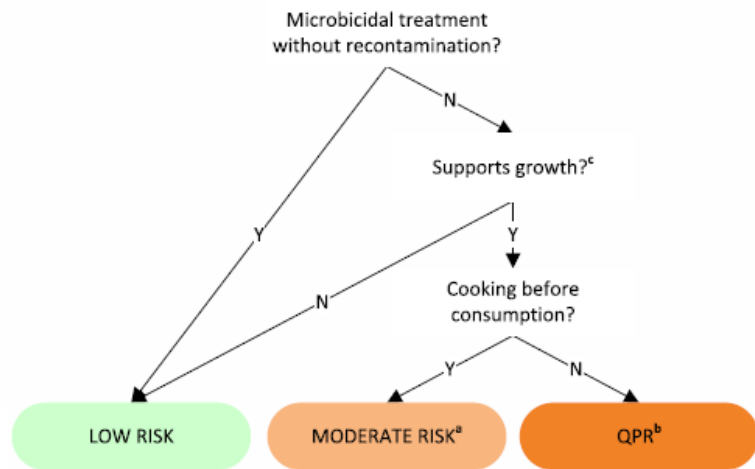
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Christophe Nguyen-The^{d,e},
John N. Sofos^f, Antonio Valero^g
and Marcel H. Zwietering^h

Tree 2
Hazards for which growth in food is usually needed to cause illness

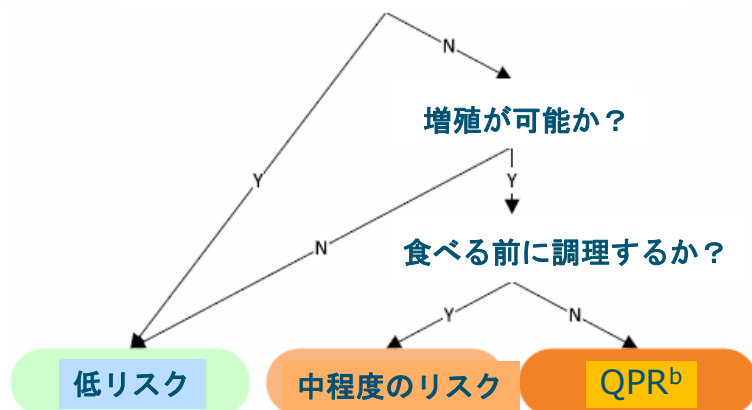


Ranking the microbiological safety of foods: A new tool and its application to composite products

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食中毒の発症に通常は食品中での細菌の増殖が必要なハザード

再汚染させないような殺微生物処理か？



SCIENTIFIC OPINION

Scientific Opinion on the risk posed by pathogens in food of non-animal origin. Part 1 (outbreak data analysis and risk ranking of food/pathogen combinations)¹

EFSA Panel on Biological Hazards (BIOHAZ)^{2,3}

科学的意見

非動物起源の食品中の病原体によるリスクに関する科学的意見

1. 集団発生のデータ解析と食品／病原菌の組み合わせによるリスクランキング

EFSA 生物学的ハザードに関するパネル (BIOHAZ)

EFSA Panel on Biological Hazards (BIOHAZ)^{2,3}

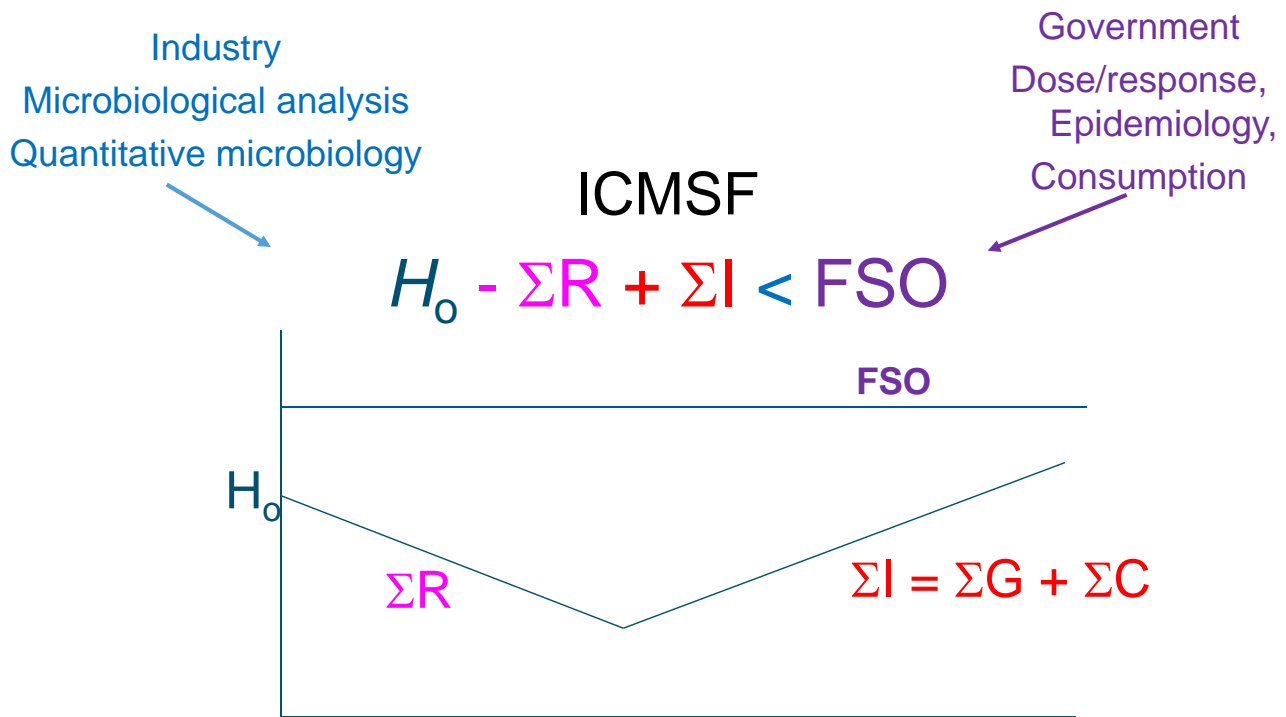
Ranking position Pathogen FoNAO category

5

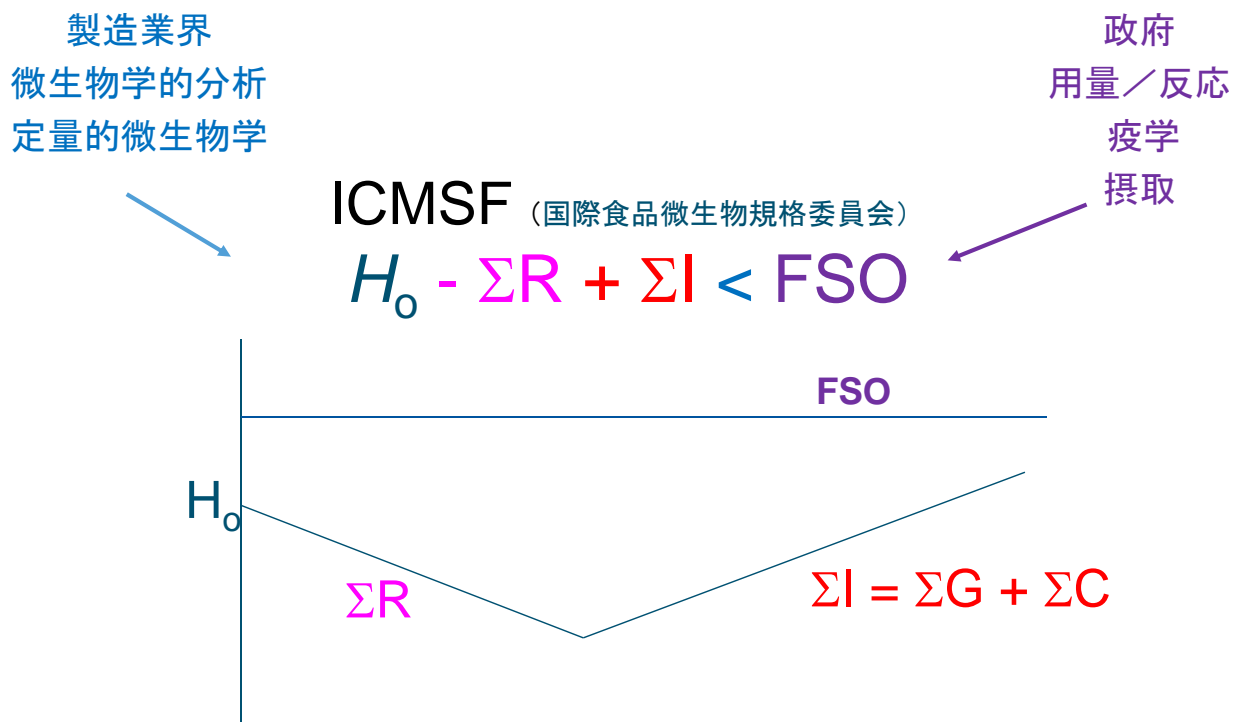
First	<i>Salmonella</i> spp.	Leafy greens eaten raw as salads
	<i>Salmonella</i> spp.	Bulb and stem vegetables
Second	<i>Salmonella</i> spp.	Tomatoes
	<i>Salmonella</i> spp.	Melons
	Pathogenic <i>E. coli</i>	Fresh pods, legumes and grain
Third	Norovirus	Leafy greens eaten raw as salads
	<i>Salmonella</i> spp.	Sprouted seeds
	<i>Shigella</i> spp.	Fresh pods, legumes or grain
Fourth	<i>Bacillus</i> spp.	Spices and dry powdered herbs
	Norovirus	Bulb and stem vegetables
	Norovirus	Raspberries
	<i>Salmonella</i> spp.	Raspberries
	<i>Salmonella</i> spp.	Spices and dry powdered herbs
	<i>Salmonella</i> spp.	Leafy greens mixed with other fresh FoNAO
	<i>Shigella</i> spp.	Fresh herbs
	Pathogenic <i>E. coli</i>	Sprouted seeds
	<i>Yersinia</i> spp.	Carrots
Fifth	Norovirus	Tomatoes
	Norovirus	Carrots
	<i>Salmonella</i> spp.	Nuts and nut products
	<i>Shigella</i> spp.	Carrots

リスク・ランキング	病原菌	FoNAO（非動物起源食品）カテゴリー
1 位	サルモネラ属菌	サラダ用の生食葉野菜
2 位	サルモネラ属菌	根菜および茎野菜
	サルモネラ属菌	トマト
	サルモネラ属菌	メロン
	病原性大腸菌	生さやえんどう、マメ、穀類
	ノロウィルス	サラダ用の生食葉野菜
3 位	サルモネラ属菌	発芽種子
	赤痢属菌	生さやえんどう、マメ、穀類
	バチルス属菌	スパイス、乾燥薬草粉末
4 位	ノロウィルス	根菜および茎野菜
	ノロウィルス	ラズベリー
	サルモネラ属菌	ラズベリー
	サルモネラ属菌	スパイス、乾燥薬草粉末
	サルモネラ属菌	生食用の葉野菜と他の生野菜のミックス
	赤痢属菌	生薬草
	エルシニア	ニンジン
	ノロウィルス	ニンジン
5 位	ノロウィルス	トマト
	ノロウィルス	ニンジン
	サルモネラ属菌	ナッツおよびナッツ製品
	赤痢菌	ニンジン

FSO: Food Safety Objective: norm set by government



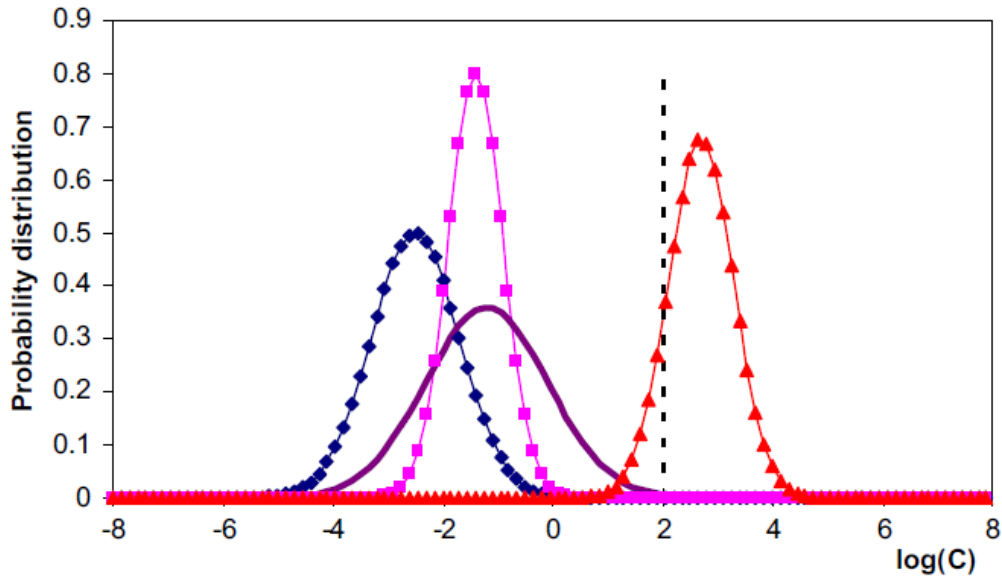
FSO: 摂取時安全目標値：政府の設定による目標値



Validation of control measures in a food chain using the FSO concept

M.H. Zwietering^{a,*}, C.M. Stewart^b, R.C. Whiting^c, International Commission on Microbiological Specifications for Foods (ICMSF)

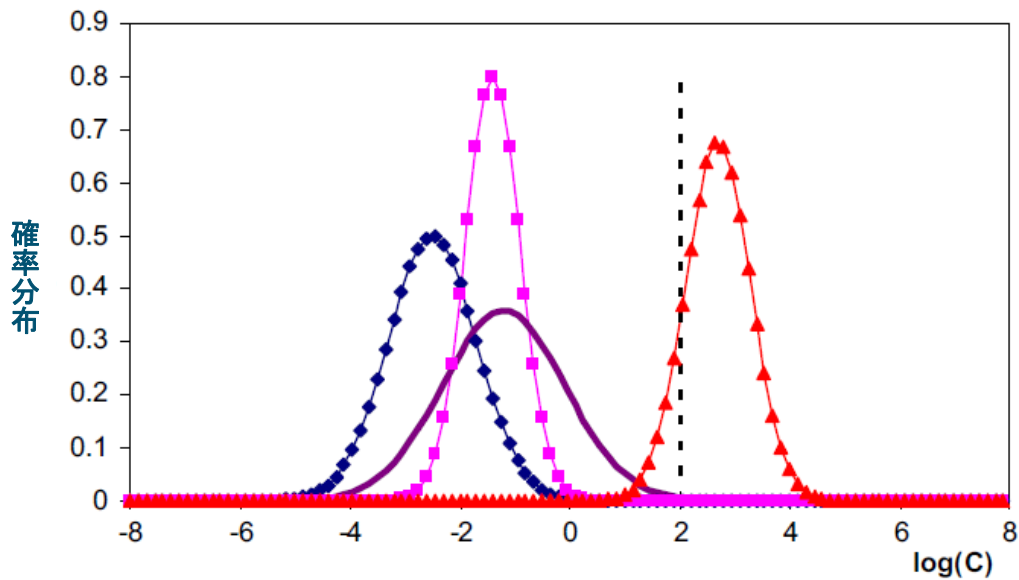
$$H_0 - \Sigma R + \Sigma I < FSO$$



FSO 概念によるフード・チェーンに関する規制措置の妥当性の検証

M.H. Zwietering^{a,*}, C.M. Stewart^b, R.C. Whiting^c, International Commission on Microbiological Specifications for Foods (ICMSF)

$$H_0 - \Sigma R + \Sigma I < FSO$$



$$\mathcal{L}(\mathbf{z}_k) = \frac{1}{R} \sum_{r=1}^R \|\mathbf{y}(\mathbf{z}_k)_r - \mathbf{FSO}\|_{L_1} \mathbb{I}_{\{\mathbf{y}(\mathbf{z}_k) < \mathbf{FSO}\}}, \quad (1)$$

where $\|\mathbf{y}(\mathbf{z}_k)_r - \mathbf{FSO}\|_{L_1} = \sum_{t=1}^T |y(\mathbf{z}_k, t)_r - FSO|$ is the sum over time of the absolute difference between the model output at time t and a FSO. The function $\mathbb{I}_{\{\mathbf{y}(\mathbf{z}_k) < \mathbf{FSO}\}}$ is equal to 1 for inputs with all desirable replications and 0 otherwise.

$$\mathcal{L}(\mathbf{z}_k) = \frac{1}{R} \sum_{r=1}^R \|\mathbf{y}(\mathbf{z}_k)_r - \mathbf{FSO}\|_{L_1} \mathbb{I}_{\{\mathbf{y}(\mathbf{z}_k) < \mathbf{FSO}\}},$$

ここで (1)

$$\|\mathbf{y}(\mathbf{z}_k)_r - \mathbf{FSO}\|_{L_1} = \sum_{t=1}^T |y(\mathbf{z}_k, t)_r - FSO|$$

は、時間 t におけるモデルアウトプットとFSOとの差の総和である。全てに望ましいレプリケーションが代入されると、関数 $\mathbb{I}_{\{\mathbf{y}(\mathbf{z}_k) < \mathbf{FSO}\}}$ の値は1となり、それ以外では0となる。

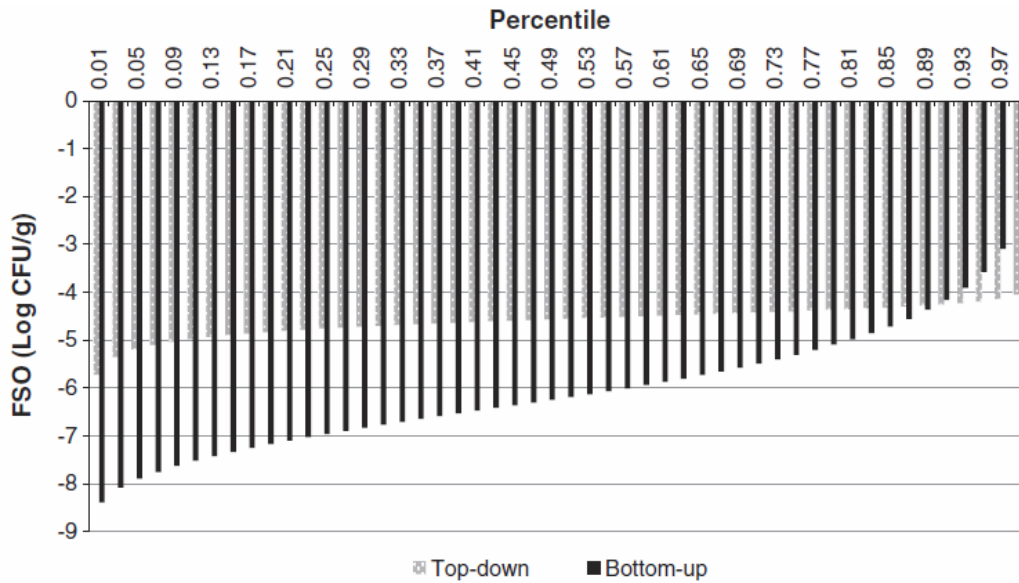


Fig. 5. Detailed characteristics of the FSO output distributions for chicken meat as obtained with the top-down model (grey bars) and the bottom-up model approach (black bars).



Risk assessment strategies as a tool in the application of the Appropriate Level of Protection (ALOP) and Food Safety Objective (FSO) by risk managers

E. Gkogka ^{a,b,1}, M.W. Reij ^{a,*}, L.G.M. Gorris ^{a,b}, M.H. Zwietering ^a

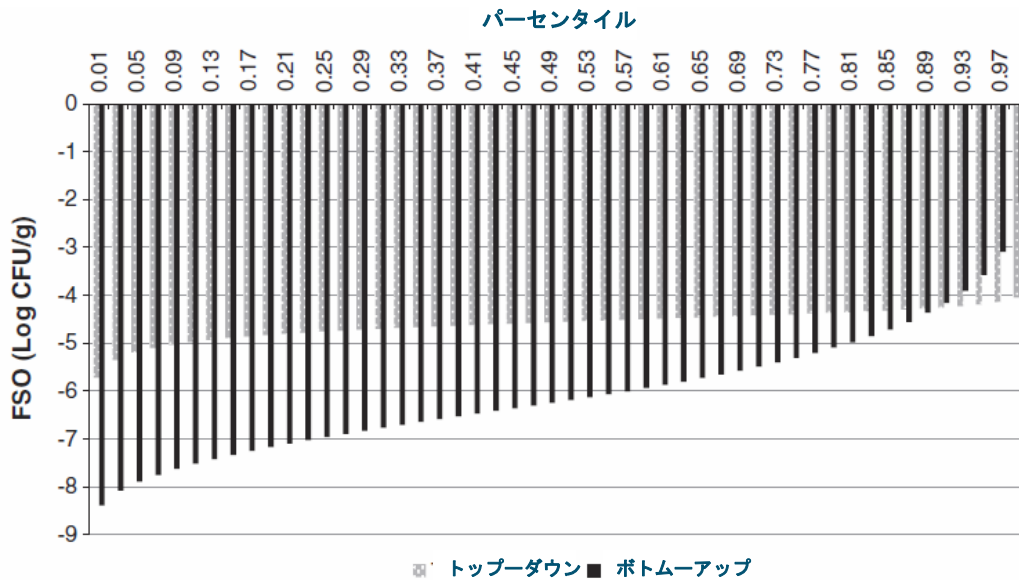


図-5. 鶏肉についてトップダウン・モデルおよびボトムアップ・モデルによるアプローチから得られるFSO値分布の特徴

出典:

Risk assessment strategies as a tool in the application of the Appropriate Level of Protection (ALOP) and Food Safety Objective (FSO) by risk managers

E. Gkogka ^{a,b,1}, M.W. Reij ^{a,*}, L.G.M. Gorris ^{a,b}, M.H. Zwietering ^a



ANALYSIS of the risk analysis

- Variability of factors: better control
- Uncertainty of factors: more research
- Level of factors: changes in chain

リスク分析の分析

- 要因の変動：より良いコントロール
- 要因の不確実性：さらなる研究
- 要因のレベル：チェーンにおける変化

Conclusions

- Variability / Uncertainty / Complexity
- There is a need to go in that direction
- There is also a need to link this to decisions
- Go deep but get back to the surface

結論

- 変動／不確実性／複雑性
- その方向に進む必要がある
- これを決定にリンクする必要もある
- 深く進んで、時には表面に戻る。

Thank you



Thank you

