資料2 - 5

Listeria monocytogenes International Workshop
Food Safety Commission, Japan
March 2012

Methodology for Risk Assessment of *Listeria monocytogenes*

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TIA is a joint venture of the University of Tasmania and the Tasmanian Government

食品安全委員会セミナー
リステリア
2012年3月

リステリア・モノサイトゲネスのリスク評価の方法論

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TIA is a joint venture of the University of Tasmania and the Tasmanian Government

overview

- outbreaks of *L. monocytogenes* in Australia and New Zealand and risk management
- risk assessments of *L. monocytogenes* in ready-to-eat foods
- elements of risk assessment
- data sources and approaches for microbial food safety risk assessment

概要

- オーストラリア、ニュージーランドにおけるリステリア・モノサイトゲネス（以下、LM）感染症の発生とそのリスク管理
- 非加熱喫食調理済み食品（Ready-to-eat 食品）におけるLMのリスク評価
- リスク評価の構成要素
- 食品の微生物学的リスク評価に必要なデータと評価アプローチ

outbreaks of *L. monocytogenes* in Australia and New Zealand and risk management

オーストラリア、ニュージーランドにおけるLM感染症の発生とそのリスク管理

outbreaks in Australia

- 1990
  - 6 mother-infant pairs, maternity ward, no fatalities (chicken liver paté?)
- 1991
  - 2-3 cases, mild gastroenteritis, NZ smoked mussels
- 1998/99
  - 6 cases, aged-care facility, fruit salad
- 2009
  - ~13 invasive cases, 3 miscarriages; 26 cases febrile gastro-enteritis, chicken wraps and other cooked chicken products

オーストラリアでの発生事例

- 1990年
  - 6組の母子、死亡者なし （鶏肝臓パテ）
- 1991年
  - ２～3症例、軽度の胃腸炎、ﾆｭｰｼﾞｰﾗﾝﾄﾞ産燻製イガイ
- 1998/99年
  - 6症例、老人介護施設、フルーツサラダ
- 2009年
  - 3例の流産例, 多くとも13例の非侵襲症例;
    26例の熱性胃腸炎、およびその他の調理済み鶏肉

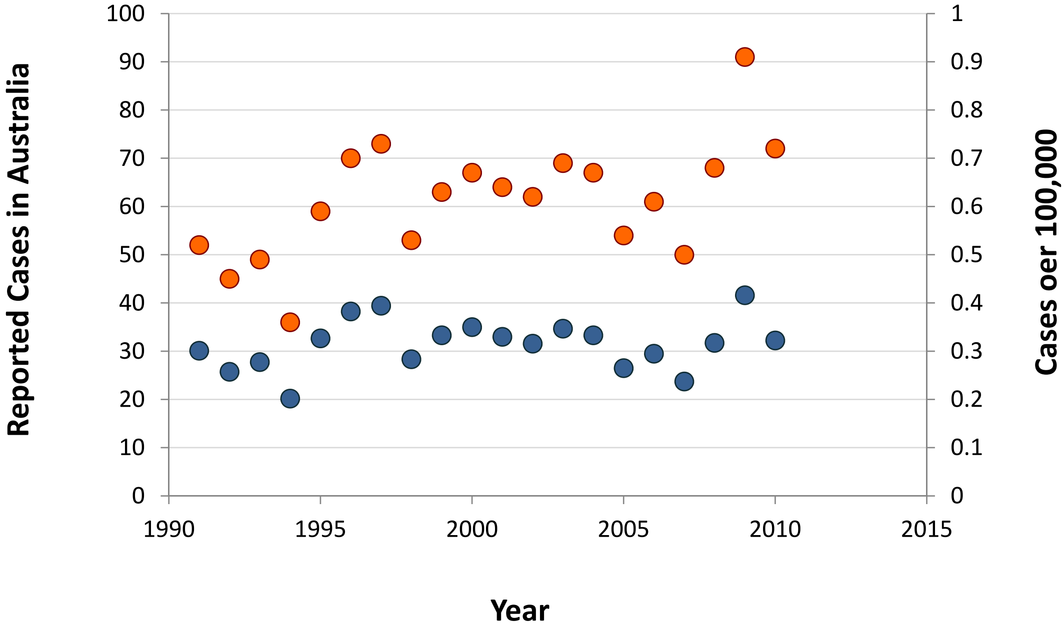
L. monocytogenes epidemiology in Australia

- mostly sporadic cases or very small outbreaks (2 – 3 people)
- mostly in elderly (since 1990)
- foods most often implicated are
  - cooked, diced chicken
  - processed meats, paté

オーストラリアにおけるLMの疫学

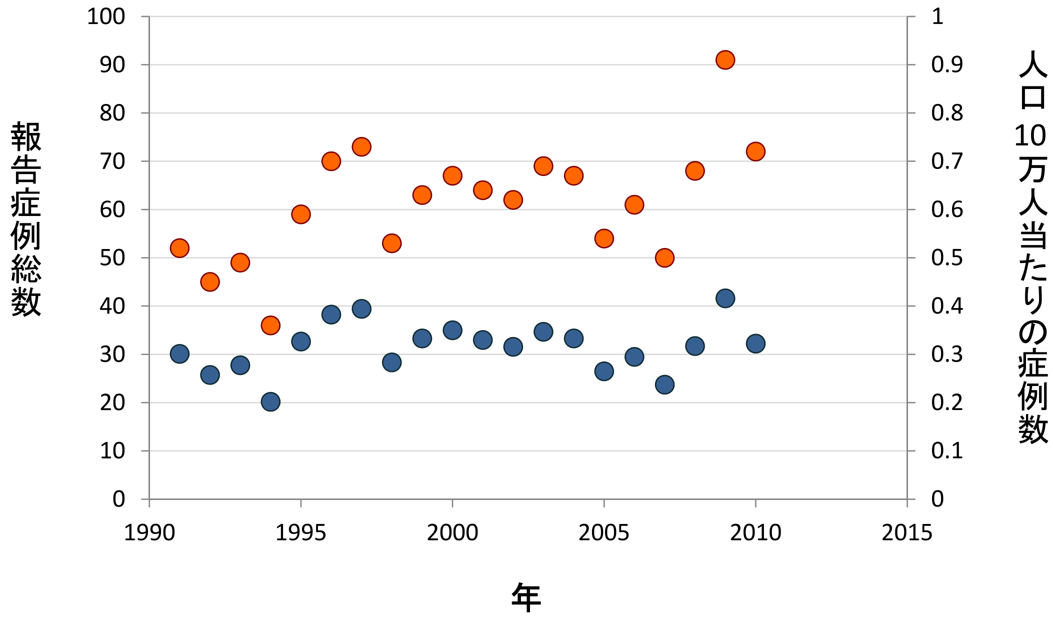
- ほとんどが散発性のものか、あるいは非常に小規模（2～3人）の発生
- ほとんどが高齢者 （1990年以降）
- 原因食品と考えられるのは、ほとんどが
  - 調理済みの、角切り鶏肉
  - 処理済み食肉、パテ

Listeriosis in Australia



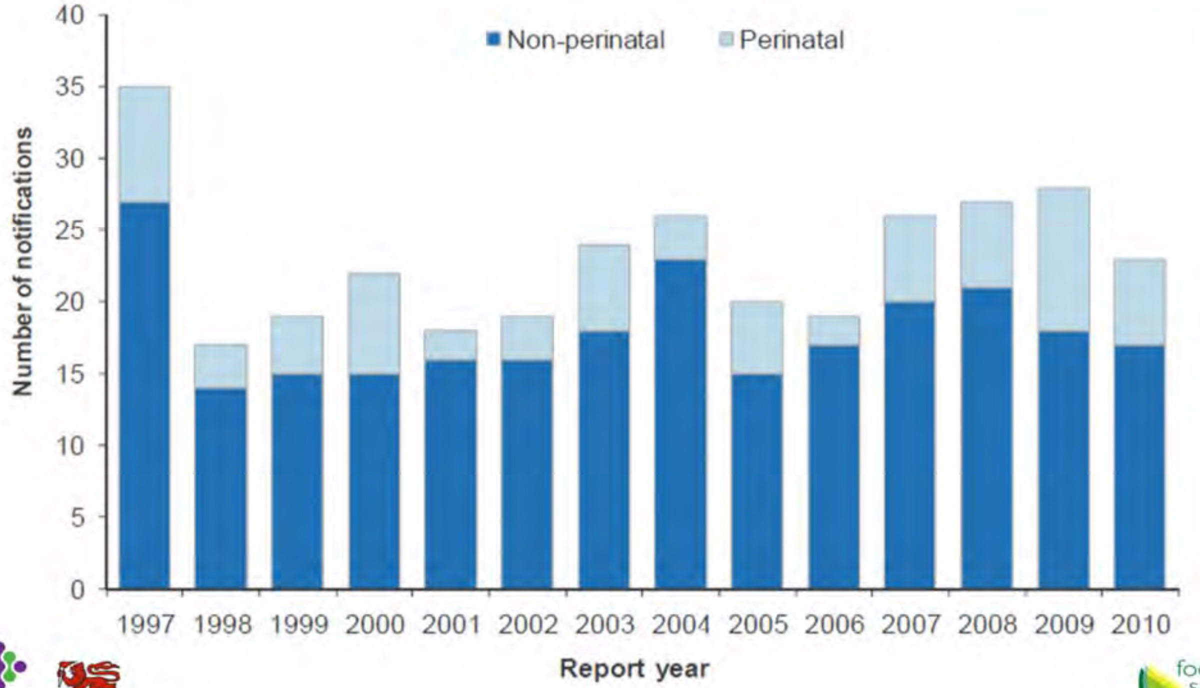
Communicable Diseases Intelligence (2012)

オーストラリアにおけるリステリア症



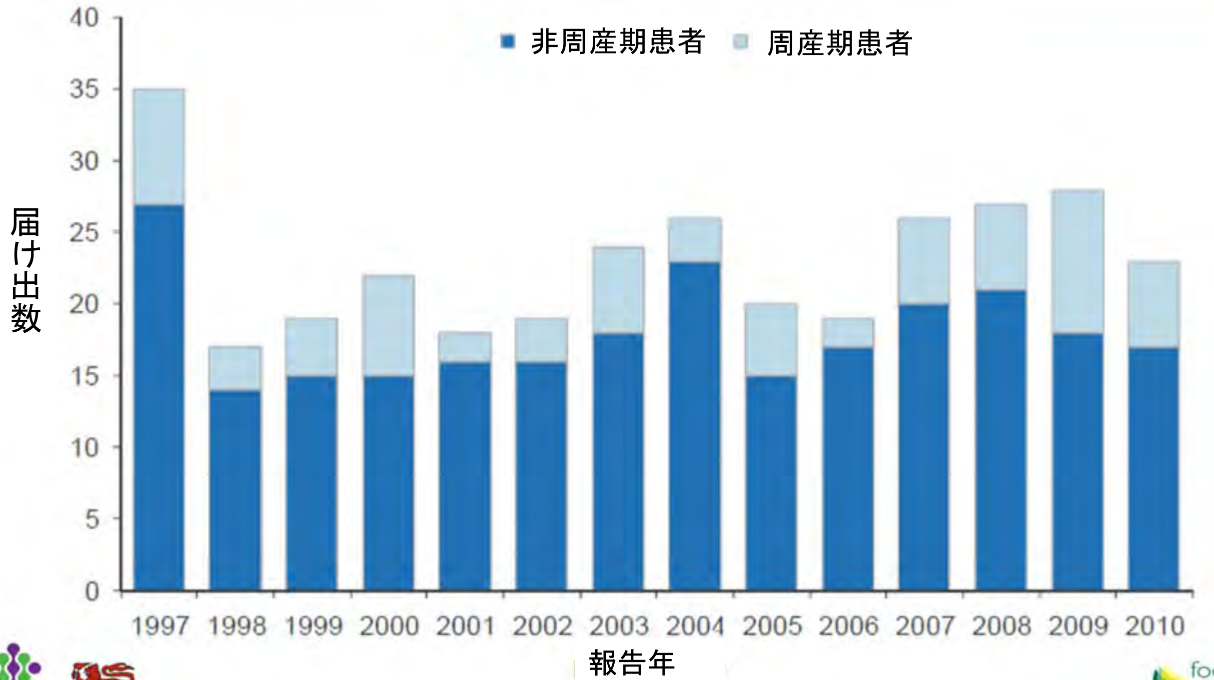
Communicable Diseases Intelligence (2012)

L. monocytogenes epidemiology in New Zealand



Population in 1997: 3.8 M; in 2011: 4.4 M

ニュージーランドにおけるLMの疫学



1997年の国人口：380万人　　2011年の国人口：440万人

outbreaks in New Zealand

- only one outbreak reported since 2001, occurred in 2009 but source is unknown
- smoked mussels involved in one earlier outbreak

ニュージーランドにおける発生

- 2001年以降の報告は、1例のみ。
  2009年に発生したが原因食品は不明。
- 最初の1例では、燻製イガイが関与。

Conclusions: *Listeria Epidemiology in Oceania*

- Listeriosis incidence, and case-fatality ratio, in Australia and New Zealand is similar to other Western nations
- Listeriosis in Australia has lower prevalence in the very young (compared to many other nations)
  - most cases are among the elderly (possibly due to active consumer education)

結論：*オセアニアにおけるリステリアの疫学*

- オーストラリアとニュージーランドにおける
  リステリア症の発生と致死率は
  西欧諸国のケースとよく似ている。
- オーストラリアのリステリア症は、若年層では罹患率が低くなっている。（他国との比較）
  - ほとんどの症例は高齢者。（おそらく（若年層では）活発な消費者教育が行われている）

Risk management

- “zero tolerance” is applied
- Australia considering Codex, or EFSA, type regulations (i.e., up to 100 cfu.g^{-1} in foods that prevent growth; predictive models to identify ‘non-growth’ foods
  - based on relatively high LD_{50} for *L. monocytogenes*
- Australian recall guidelines recognise ‘non-growth’ foods

リスク管理

- 「ゼロ・トレランス」を適用
- オーストラリアは、LMが増殖しない食品において、Codexあるいは EFSA、および型による規制（すなわち、最大100 cfu.g^{-1}）に配慮している。すなわちLMが増殖しない食品を特定するための予測モデルである。
  - LMの比較的高いLD_{50} に基づく
- オーストラリア人は、LMが増殖しない食品を認めたガイドラインを想起する。

risk assessments of *L. monocytogenes* in ready-to-eat foods

非加熱喫食調理済み食品（ Ready-to-eat 食品）におけるLMのリスク評価

WHO | Risk assessment of <i>Listeria monocytogenes</i> in ready-to-eat foods, MRA Series 4 & 5

http://www.who.int/foodsafety/publications/micro/mra_listeria/en/index.html

- Food Safety
- Zoonoses
- Microbiological risks
- Chemical risks
- Biotechnology and nanotechnology
- Food standards (Codex Alimentarius)
- Foodborne disease
- Food production to consumption
- Capacity building
- Consumer education

Risk assessment of *Listeria monocytogenes* in ready-to-eat foods, MRA Series 4 & 5

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Microbiological Risk Assessment Series, No. 4, Interpretive Summary
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- Chinese pdf, 9.27Mb

Summary: This volume contains an overview of the risk assessment with a particular focus on information that would be relevant to risk managers faced with addressing problems posed by *Listeria monocytogenes* in ready-to-eat foods. This document has been prepared and reviewed by an international team of scientists. During their preparation input was received from several international fora including expert consultations and Codex Alimentarius committee meetings as well as via public and peer review.

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WHO | Risk assessment of <i>Listeria monocytogenes</i> in ready-to-eat foods, MRA Series 4 & 5

http://www.who.int/foodsafety/publications/micro/mra_listeria/en/index.html

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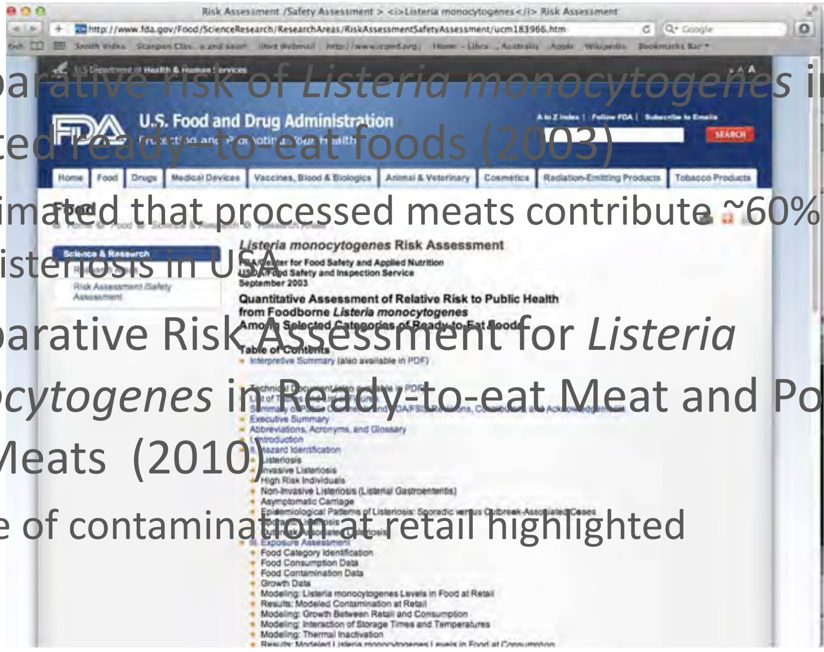
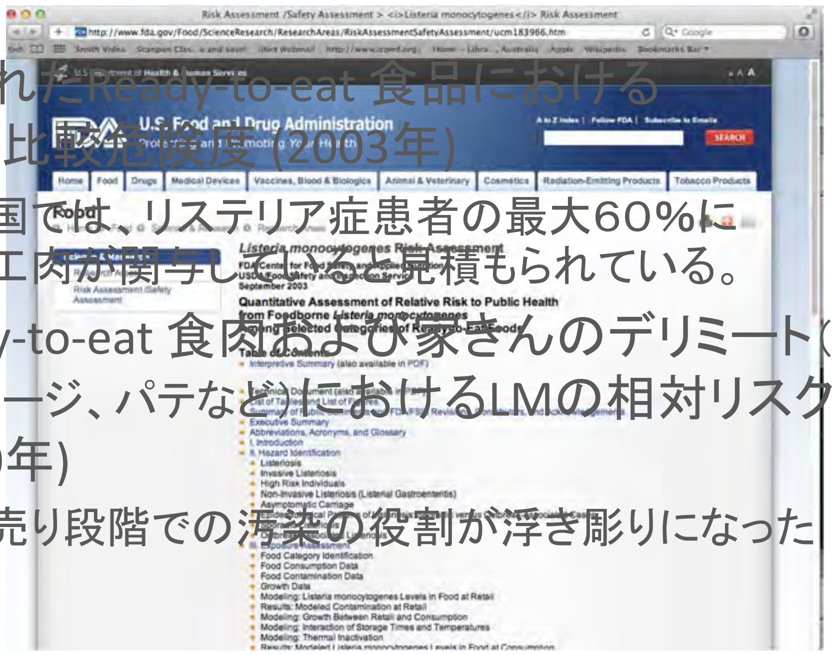
USDA (FSIS); USFDA



- Comparative risk of *Listeria monocytogenes* in selected ready-to-eat foods (2003)
  - estimated that processed meats contribute ~60% of cases of listerosis in USA
- Comparative Risk Assessment for *Listeria monocytogenes* in Ready-to-eat Meat and Poultry Deli Meats (2010)
  - role of contamination at retail highlighted

USDA (FSIS); USFDA



- 選ばれたReady-to-eat 食品における LMの比較危険度 (2003年)
  - 米国では、リステリア症患者の最大60%に加工肉が関与していると見積もられている。
- Ready-to-eat 食肉および家きんのデリミート(ハム、ソーセージ、パテなど)におけるLMの相対リスク評価 (2010年)
  - 小売り段階での汚染の役割が浮き彫りになった

Meat and Livestock Australia

- *Listeria monocytogenes in ready-to-eat meat products: risks and their management (2004).* 248pp
- estimated that processed meats contribute ~50% of cases of listeriosis in Australia
- available on request, including model; summary in:
  - Ross *et al*., (2009). Int. J. Food Microbiol., **131**:128-137)


mla
Final report
FOOD SAFETY

Meat & Livestock Australia
Locked Bag 991
North Sydney, NSW 2059

October 2004

ISBN – 1 74036 599 2

Listeria monocytogenes in ready-to-eat meat products: risks and management

PRMS.012

報告書:『オーストラリアにおける食肉と家畜』

- *ready-to-eat 食肉製品中のLM: リスクとその管理（2004）。248ページ*
- オーストラリアでは、最大50%のリステリア症患者に加工肉が関与していると見積もられている。
- モデルを含む資料の請求可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NZFSA Risk profiles

- http://www.foodsafety.govt.nz/science-risk/risk-assessment/risk-profiles/

- *Listeria monocytogenes* in:
  - ice cream
  - low moisture cheeses
  - processed ready-to-eat meats
  - ready-to-eat salads
  - soft cheeses

NZFSA リスクプロファイル

- http://www.foodsafety.govt.nz/science-risk/risk-assessment/risk-profiles/

- *下記製品の中のLM*:
  - アイスクリーム
  - 低水分チーズ
  - 加工済みの ready-to-eat 食肉
  - ready-to-eat サラダ
  - ソフトチーズ

Other *L. monocytogenes* risk assessments

- several others in published literature, e.g.,
  - Peeler and Bunning (1994) Pasteurised milk
  - Bemrah *et al*., (1998) Camembert cheeses
  - Mataragas *et al*., (2010) processed pork

その他の、LMリスク評価

- 公表文献で報告された事例
  - Peeler and Bunning (1994年)　低温殺菌ミルク
  - Bemrah *et al*., (1998年)　カマンベールチーズ
  - Mataragas *et al*., (2010年)　加工豚肉

elements of risk assessment

リスク評価の構成要素

risks and hazards

- ***hazard***
  - something that *could* cause harm
- ***risk***
  - the ***likelihood*** that harm will occur (i.e. that the hazard will be manifest)

  together with
  - the ***severity*** of harm, i.e., how many affected, how sick they become

リスクとハザード

- ***ハザード***
  - *危害を与え得る何か*
- ***リスク***
  - 危害が発生する可能性（すなわち、ハザードが顕在化する可能性）

  とともに
  - 危害の程度　　すなわち、どれだけ影響を受けるのか、どれくらいひどくなるのか

“Risk”

- differentiates trivial or unlikely hazards from those that are likely to have greater and more serious consequences
- *i.e.*, it quantifies the ***importance*** of hazards

“リスク”

- 小さなあるいは起こりそうもないハザードと、より大規模で深刻な結果が予想されるハザードを区別する。
- すなわち、ハザードの重要性を定量化する。

microbial food safety risk assessment

- origins in WTO (GATT) Uruguay Round (1995)
  - to facilitate trade between nations
  - SPS and TBT provisions require
    - protection of health and natural resources as only reasons for import restrictions
    - (i.e. *not* protection of local industries)
    - any restrictions must be “science-based”
- US regulations requiring cost-benefit assessment of new laws
- can be applied to many kinds of ‘hazards’

食品の微生物学的リスク評価

- WTO (GATT) のウルグアイラウンド (1995年)が起源
  - 国家間の貿易を促進する
  - SPSおよびTBT協定では次のことが規定されている
    - 輸入制限の理由として、健康と自然資源を保護すること
    - (すなわち、現地の産業は保護しない)
    - どの制限項目も、科学的根拠に基づいたものであること
- 米国の規制は、新法のコスト-ベネフィット評価を要求している
- さまざまなハザードに適用し得る

SPS協定： 衛生植物検疫措置の適用に関する協定
TBT協定： 貿易の技術的障害に関する協定

risk assessment

- framework for systematic synthesis of knowledge and data, *to gain new insights*

to

- provide support/insight for (‘risk management’) decisions

- epidemiology can be just as good for estimating food safety risk but not as useful for risk management

リスク評価

- 知見、データを系統的に総合して、新しい見識を得るための枠組み

その目的は

- リスク管理に関する意思決定をより良いものにするためのサポートを行うためである

- 疫学は、食品安全リスクを推定するためには適しているが、リスク管理には有効ではない

other applications

- allocation of resources
- identification of optimal food management strategies, involving all stage of the food chain from “farm to fork”
- attribution of sources of food-borne illness
- augmenting HACCP

その他の用途

- 資源配分
- 最適な食品管理戦略の明確化
  その戦略には、「農場から食卓まで」のフードチェーンのすべての段階がふくまれている。
- 食品媒介疾患の原因の特定
- HACCPの強化

Benefits of risk assessment for risk management

- structured approach aids critical thinking and understanding
- a database of knowledge is established
- a powerful decision support tool
  - the bases of decisions are documented
  - it is progressive and is both a framework and a data repository which can be built upon and improved continuously
- agreed framework for demonstration of “equivalence” in international trade
- identifies ‘date gaps’, i.e. *research* needs.

リスク評価の利点

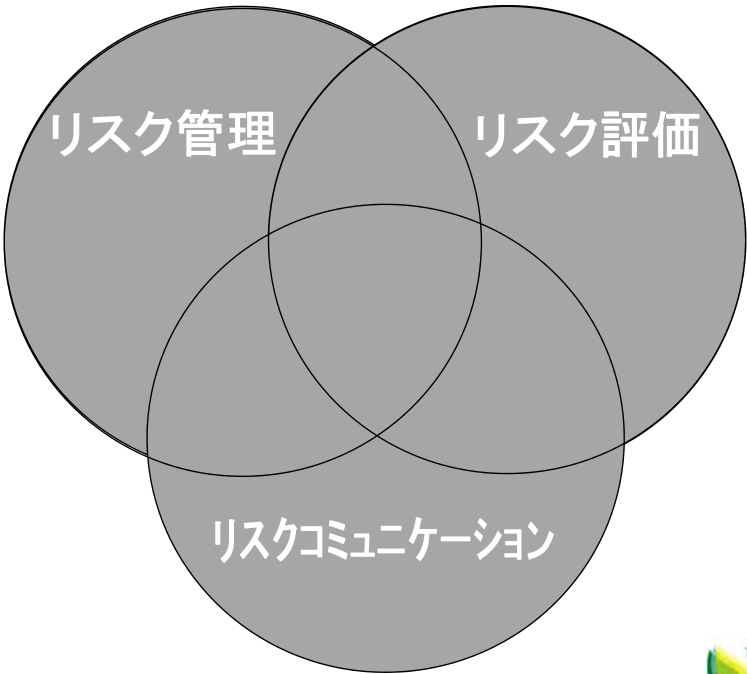
- 構造化されたアプローチが論理的な思考と理解を助ける
- 知識のデータベースが構築される
- 強力な意思決定支援ツールとなる
  - 決定の根拠は記録される
  - そのツールは進歩的であり、枠組みでもあり構築され絶えず整備されていくデータの宝庫でもある
- 国際貿易において「同等」を証明する、合意された枠組みである
- 「時の隔たり」を明らかにする, すなわち、研究ニーズ

risk analysis framework

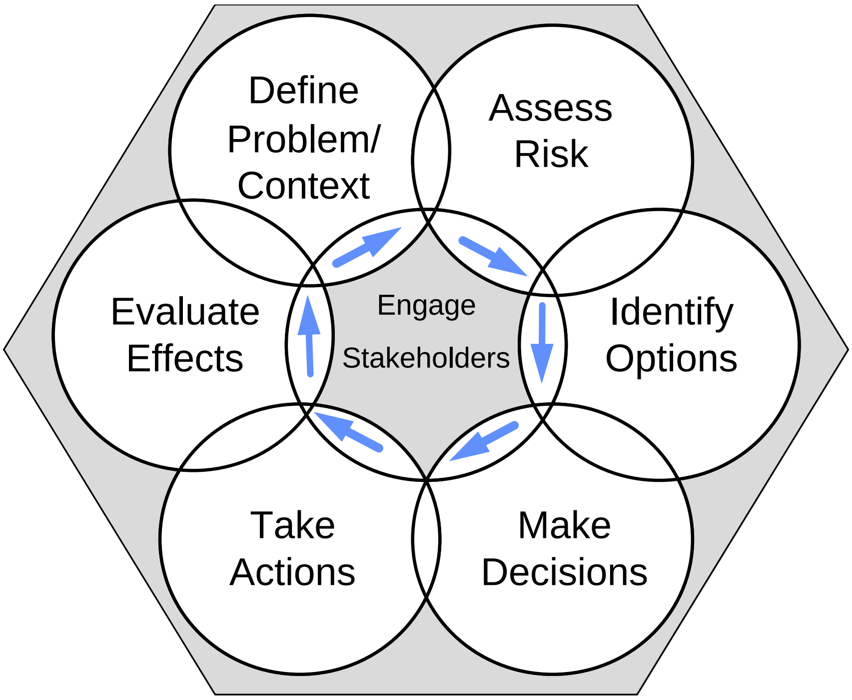
three integrated activities

リスク分析

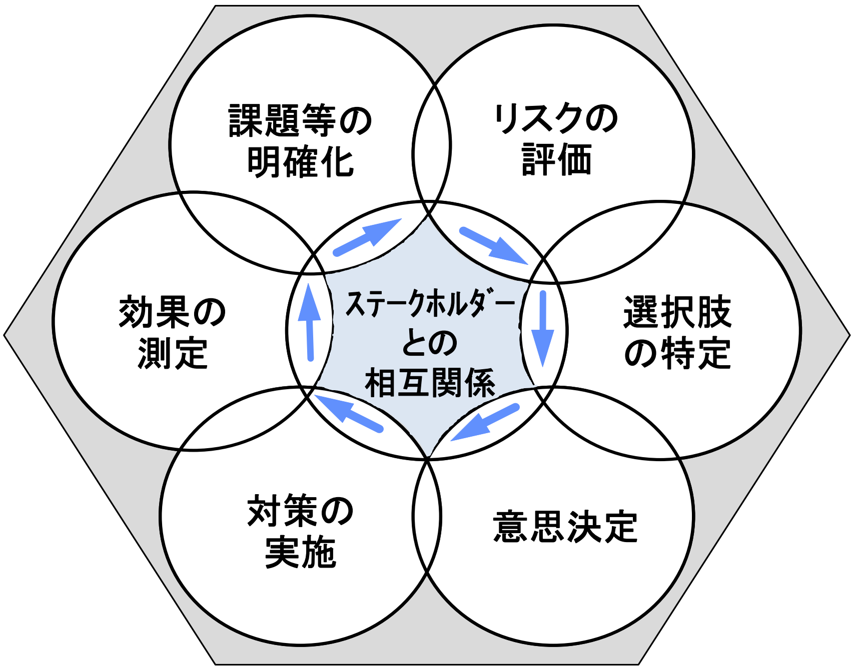
3要素が
一体となって
活動する

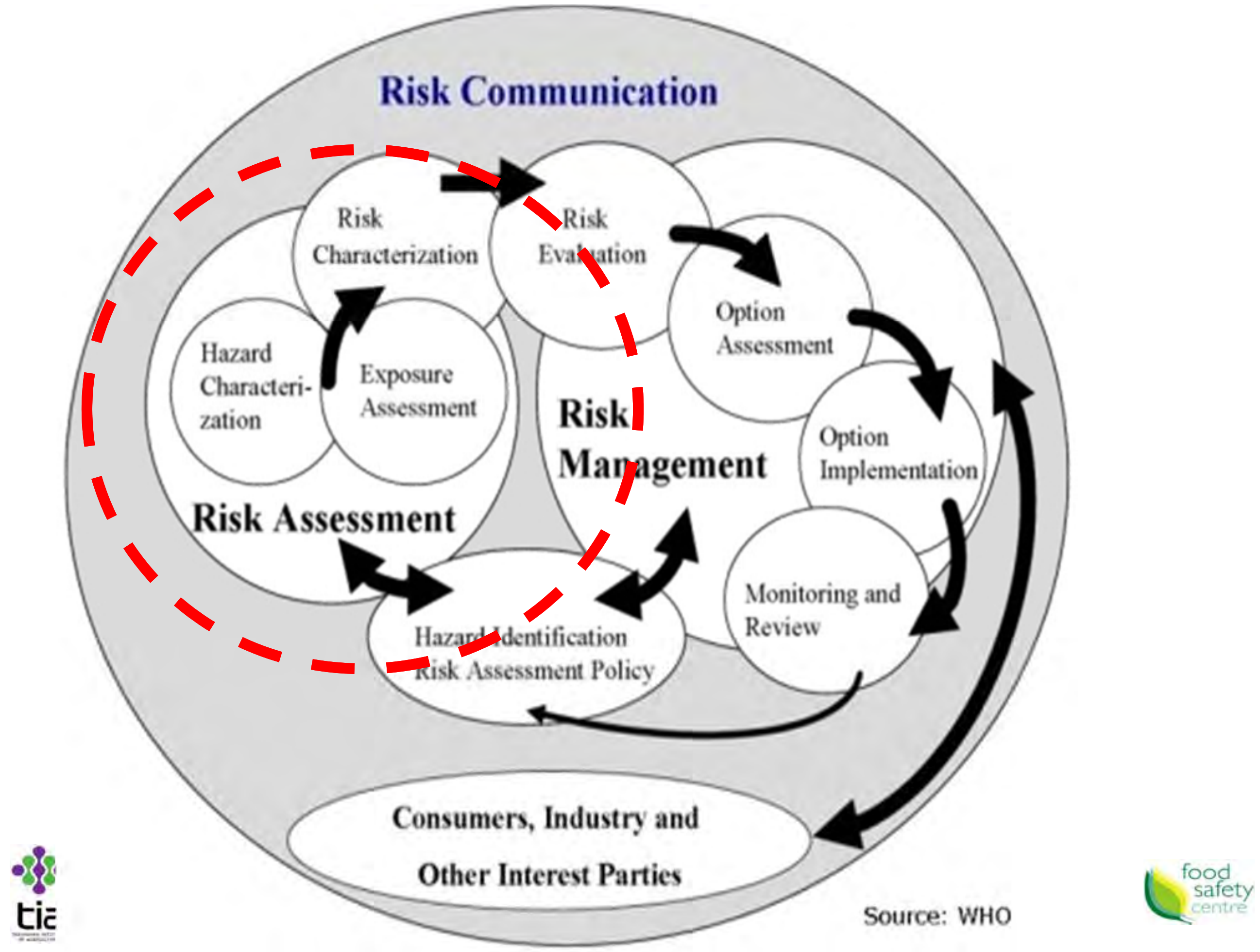


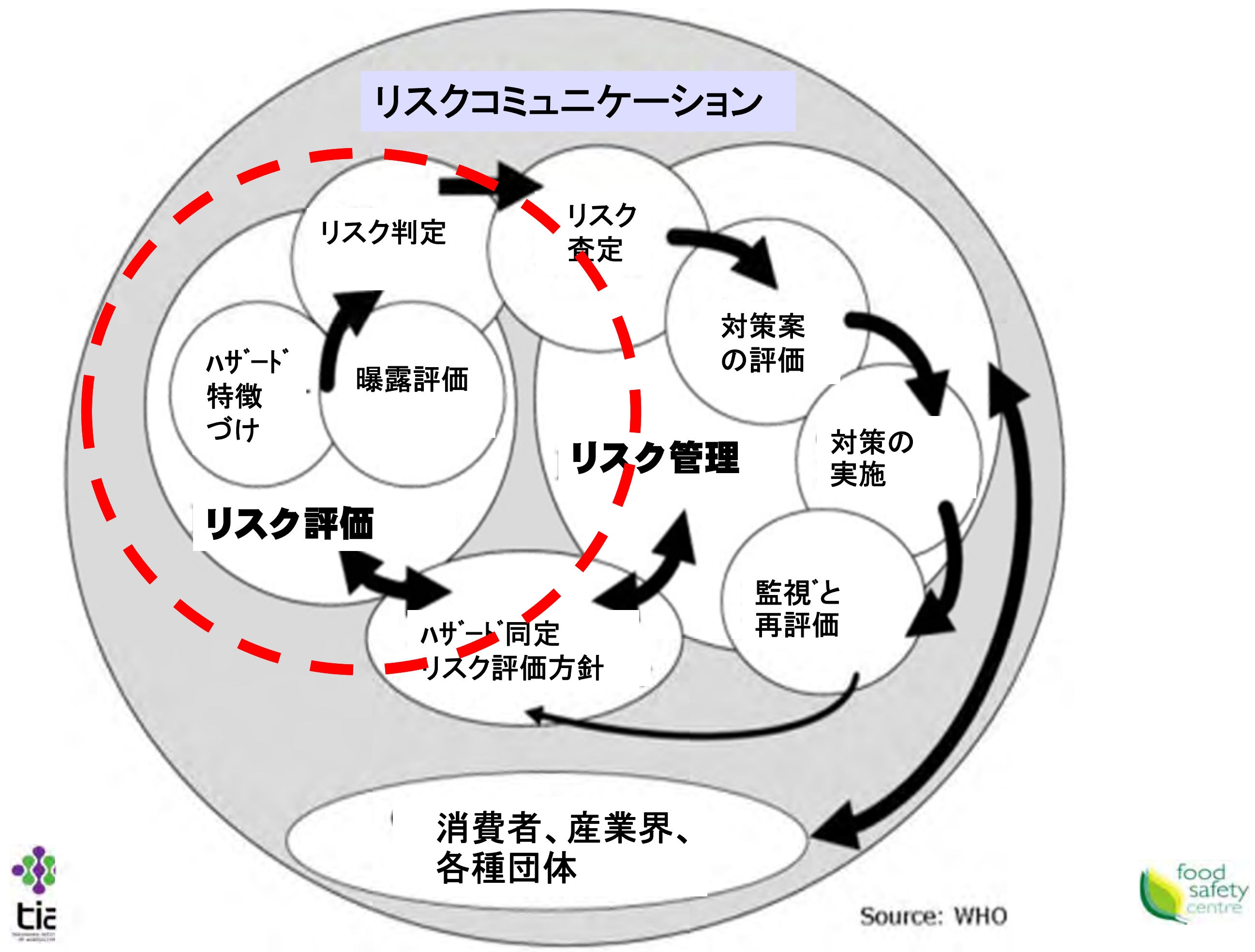
US risk analysis framework



米国のリスク分析の枠組み




Risk Communication
Risk Characterization
Risk Evaluation
Option Assessment
Hazard Characteri-zation
Exposure Assessment
Risk Management
Option Implementation
Risk Assessment
Monitoring and Review
Hazard Identification
Risk Assessment Policy
Consumers, Industry and Other Interest Parties
Source: WHO
food safety centre


リスクコミュニケーション
リスク判定
リスク査定
対策案の評価
ハザード特徴づけ
曝露評価
リスク管理
対策の実施
リスク評価
監視と再評価
ハザード同定
リスク評価方針
消費者、産業界、各種団体
Source: WHO
food safety centre

Risk management process

- identify that a food safety problem requiring management exists
- conduct a risk assessment to:
  - determine the relationship between the hazard and human health
  - potential control/management options
- establish criteria consistent with protection of public health

リスク管理のプロセス

- 実際の管理を必要とする食品安全上の問題を特定する
- リスク評価は次の目的で実施する:
  - ハザードと人の健康との関連をつき止める
  - 潜在的な管理を行う
- 公衆衛生の維持に合致した基準の設定

data sources and approaches for microbial food safety risk assessment

食品の微生物学的リスク評価に必要なデータと評価アプローチ

microbial food safety risk assessment

- techniques not well established
- Codex Alimentarius Commission gave remit for establishment of approaches to FAO/WHO
- series of 'expert consultations'
- CAC/GL 30 (1999)
- JEMRA reports
  - http://www.codexalimentarius.net/web/jemra.jsp

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食品の微生物学的リスク評価

- 手法は確立されたものではない
- コーデックス委員会がFAO/WHOに付託
- 一連の「専門家への諮問」
- CAC/GL 30* (1999年) *PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESSMENT
- JEMRA*報告書 *FAO/WHO 合同微生物学的リスク評価専門家会議
  - http://www.codexalimentarius.net/web/jemra.jsp

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PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESSMENT

CAC/GL-30 (1999)

Table of Contents

INTRODUCTION

Risks from microbiological hazards are of immediate and serious concern to human health. Microbiological Risk Analysis is a process consisting of three components: Risk Assessment, Risk Management, and Risk Communication, which has the overall objective to ensure public health protection. This document deals with Risk Assessment which is a key element in assuring that sound science is used to establish standards,

CODEX STAN Page 1 of 6

PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESSMENT

CAC/GL-30 (1999)

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INTRODUCTION

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rules of “good” risk assessment

1. Microbiological Risk Assessment should be soundly based upon science

…

5. The conduct of a Microbiological Risk Assessment should be transparent

…

9. A Microbiological Risk Assessment should explicitly consider the dynamics of microbiological growth, survival, and death in foods and …

「適切な」リスク評価のルール

1. 微生物学的リスク評価は、科学の健全な基盤の上で行われなければならない

…

5. 微生物学的リスク評価の実施には、透明性が確保されなければならない

…

9. 微生物学的リスク評価は、食品中における微生物の増殖、生存、死滅といった動態を積極的に考慮しなければならない …

microbial food safety risk

- function of **probability** and **severity** of illness(es)

- ***probability*** of illness depend on **exposure**:
  – how often the food is consumed
  – how much is consumed per meal
  – prevalence of pathogen in food
  – concentration of pathogen in food
  – virulence of the pathogen
  – susceptibility of the host

- ***severity*** of consequence depends on pathogen

微生物の食品安全リスク

- 健康被害をこうむる**確率**と**程度**の関数

- ***健康被害をこうむる確率****は暴露量に依存する*:
  – 当該食品が食べられた頻度
  – 一食当たりの当該食品の量
  – 食品中の病原菌の比率
  – 食品中の病原菌数
  – 病原菌の毒性
  – 宿主の感受性

- *危害の****程度****は病原菌に依存する*

Food Safety Risk Assessment: *components*

Hazard Identification

Exposure Assessment

Dose-Response Assessment

Risk Characterisation

Uncertainty/Variability Analysis

what do we still need to know?; how much confidence do we have in our estimate?

食品安全分野のリスク評価: 構成要素

ハザード同定

暴露評価

用量ー反応 評価

リスク判定

不確実性/変動性 分析

我々はさらに何を知る必要があるのか; 我々は評価にどれくらい自信を持つことができるか

Risk assessment process

HAZARD IDENTIFICATION

EXPOSURE ASSESSMENT

DOSE~RESPONSE ASSESSMENT

RISK CHARACTERISATION

tia UTAS

food safety centre

リスク評価のプロセス

ハザード同定

暴露評価

用量ー反応 評価

リスク判定

tia UTAS

food safety centre

hazard identification

ハザード同定

Hazard Identification

definition of the problem, including evidence for a problem, hazard and food involved, etc.

often based on epidemiological data, food survey data, etc.

infection reports (clinical experience)

ハザード同定

問題の確定
（問題、ハザード、関与食品の証拠を含む）

しばしば、疫学データや食品調査データ等も使用

感染症報告書（臨床経験）

exposure assessment

暴露評価

Exposure Assessment

- *estimation of how often people are exposed to the hazard/food combination and*
- *the amount of the hazard they are exposed to*
- *routes of exposure*

暴露評価

- *ヒトがどのくらいの頻度でハザード付着食品に暴露するのかという推定*
- 人が暴露されるハザードの量
- *暴露の経路*

Exposure assessment: *Conceptual model and data sources*

exposure:

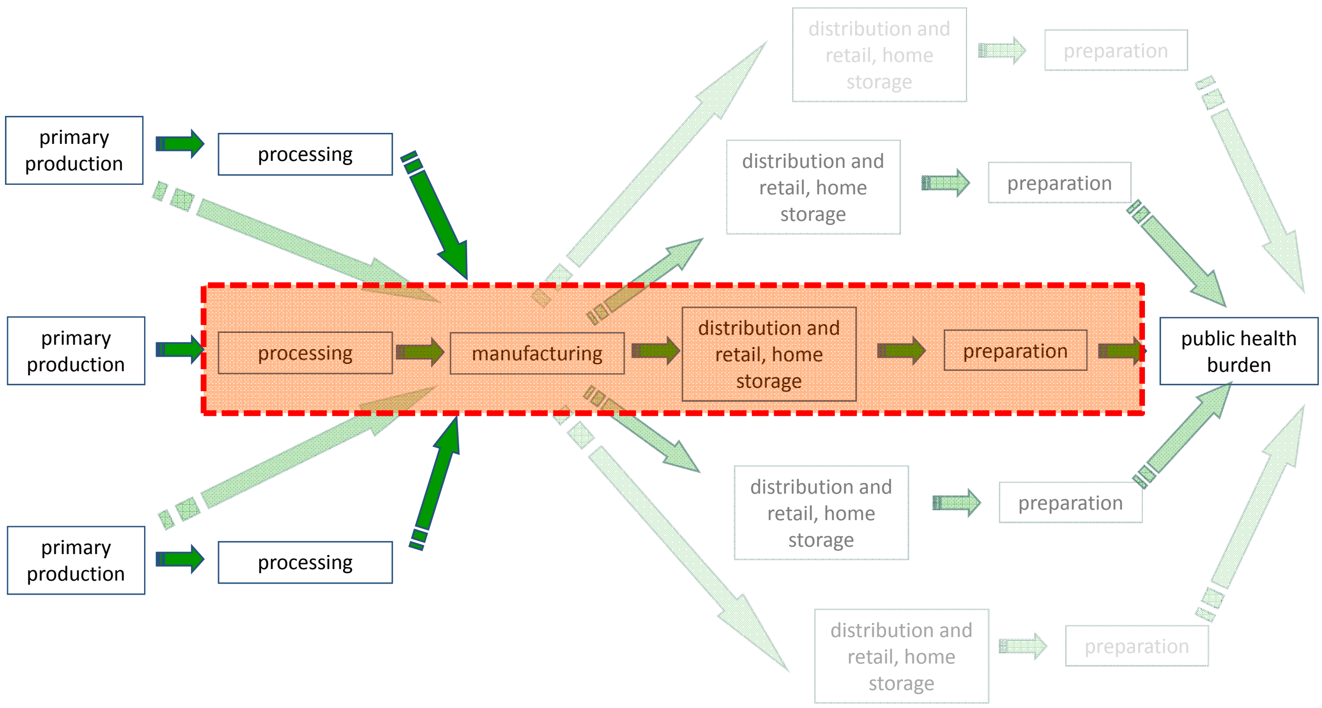
- how often eaten, how much eaten, and by whom?
- how often contaminated, how heavily contaminated?
- how did the contamination arise?
- how did the hazard level change?

暴露評価: 概念モデルとデータソース

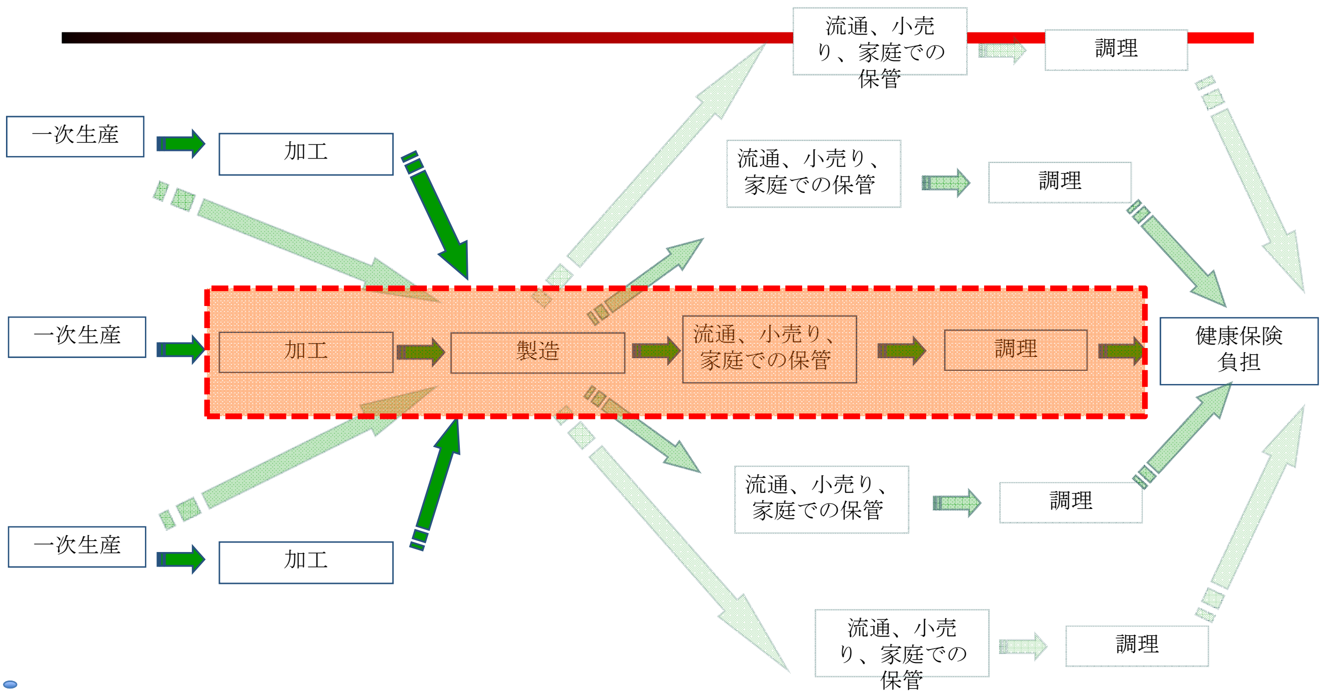
暴露

- どれくらいの頻度で、どれくらいの量が、誰によって食べられたのか？
- どれくらいの頻度で、どれくらいひどく汚染されたのか？
- どのように汚染は起きたのか？
- どのようにハザードレベルが変化したのか？

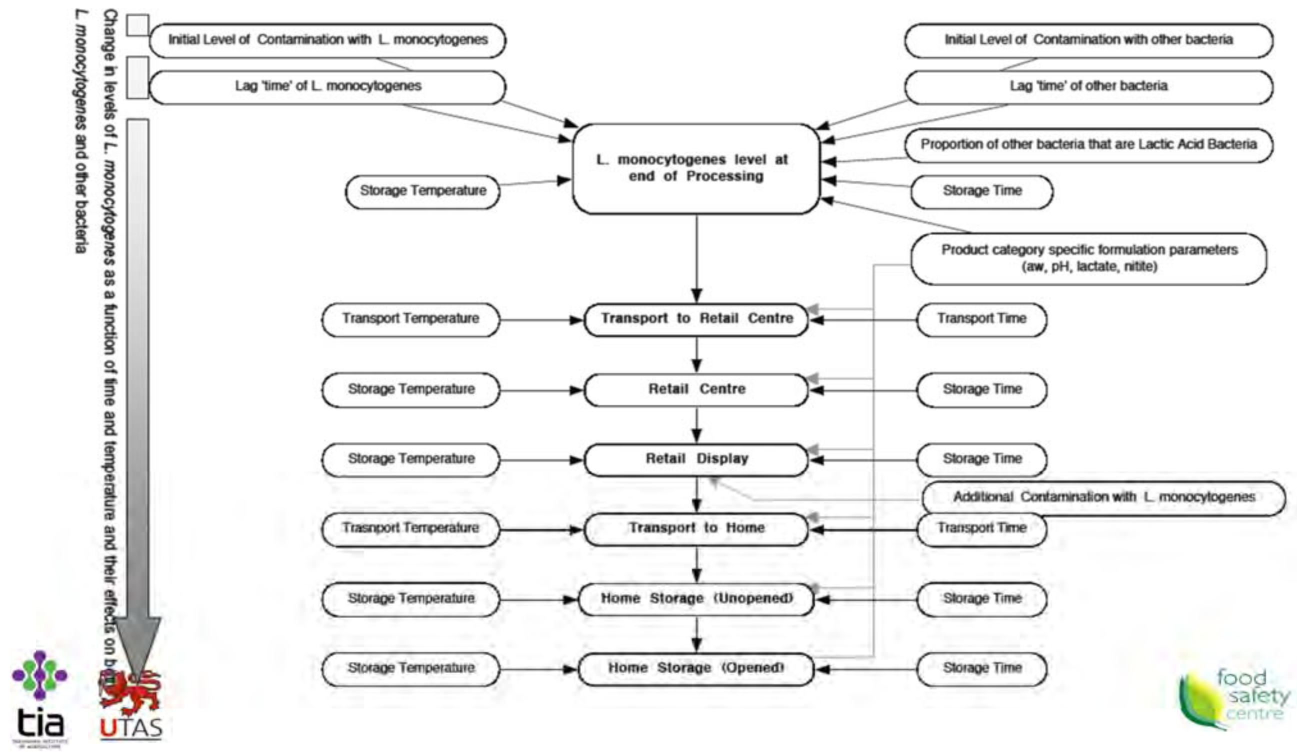
Complex/Variable Food Chains



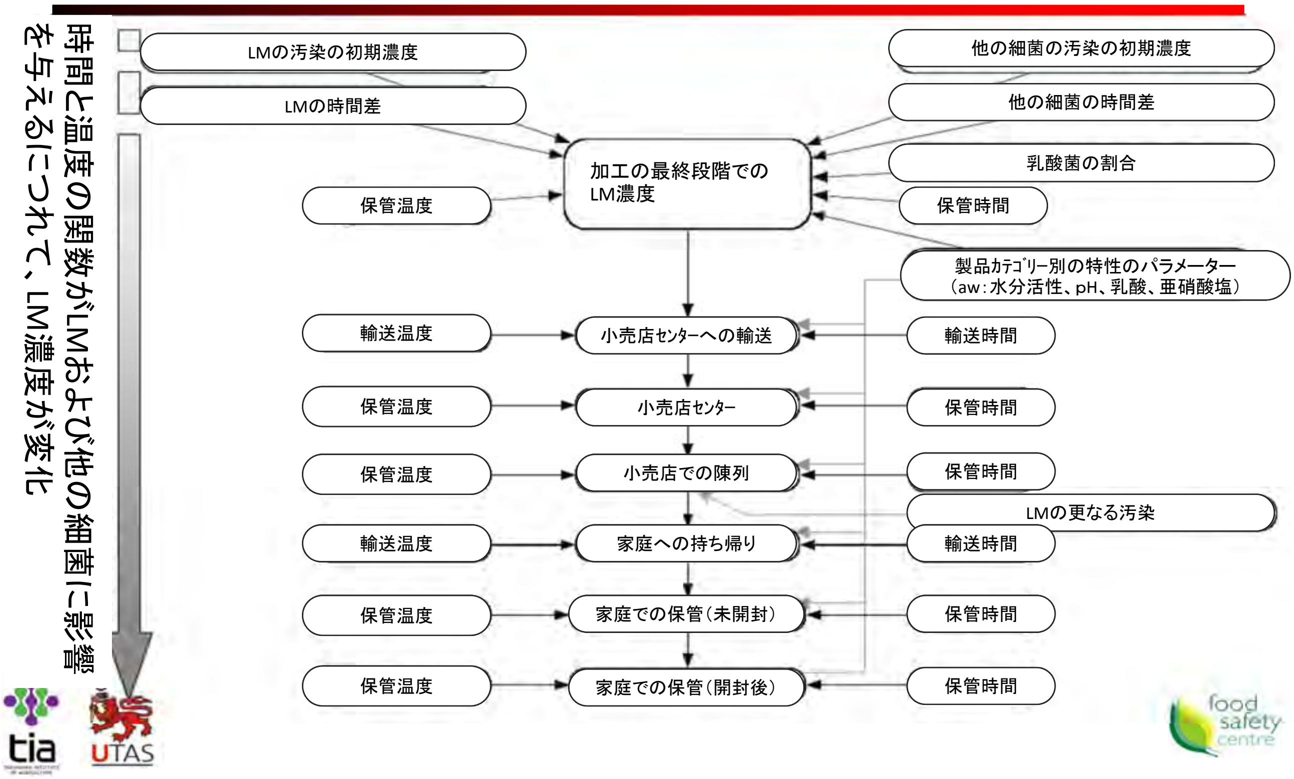
複雑で変化しやすいフードチェーン



Conceptual Model for Exposure to *L. mono* in Australian processed meats



オーストラリアの加工肉におけるLM暴露の概念モデル



Development of the Model

- conducted in parallel with FAO/WHO risk assessment of *L. monocytogenes* in RTE foods - mutual benefits
- model is microbial ecology “rich”, e.g.

  temperature affects on shelf life/spoilage modelled

  interaction between lactic acid bacteria and *L. monocytogenes* modelled

モデルの開発

- FAO/WHOによるRTE食品中のLMに関するリスク評価と並行して開発された – 相互の利益
- モデルは微生物生態学が豊富に採用されている　たとえば、

  保管期間/腐敗に影響を及ぼす温度がモデル化された

  乳酸菌とLMとの相互作用がモデル化された

Conceptual Model

- detailed steps from production to consumption
- allowed mitigation options to be simulated
- 'fudge' factors not used, defensible assumptions
- outputs:
  - risk of listeriosis *per* serving
  - total predicted cases in Australia, from processed meats, *per year*

概念モデル

- 生産から消費までの段階を詳しく述べた
- 軽減策のシミュレーションを可能にした
- 誤差は用いられない、予防可能な仮説
- 出力:
  - 一食当たりのリステリア症のリスク
  - オーストラリアにおける年間の予想総患者数、加工食肉を発生源として

Model Outputs

	Total volume (*t*)	Mean serving size (g)	Servings (per year)	Predicted number of cases per year (95% CI)
Processed meats	194,600	45.34	4.29 billion[a]	43 (54.5 to 31.2)
Pâtés/liverwursts	8,400	53.01	0.16 billion	0.36 (0.48 to 0.25)
Cooked sausages[b]	60,400	87.50	0.69 billion	0.24 (0.32 to 0.17)
Total				44 (55 to 31)

a i.e. 1000 million

b For the estimate of the risk of cooked sausages, 95% were assumed to be eaten after normal cooking (immersion in boiling water for several minutes) which is listericidal

(*reported* cases in Australia = ~60 per year; total *estimated* ~ 120 per year)

MLA: L. monocytogenes Symposium,June 2011

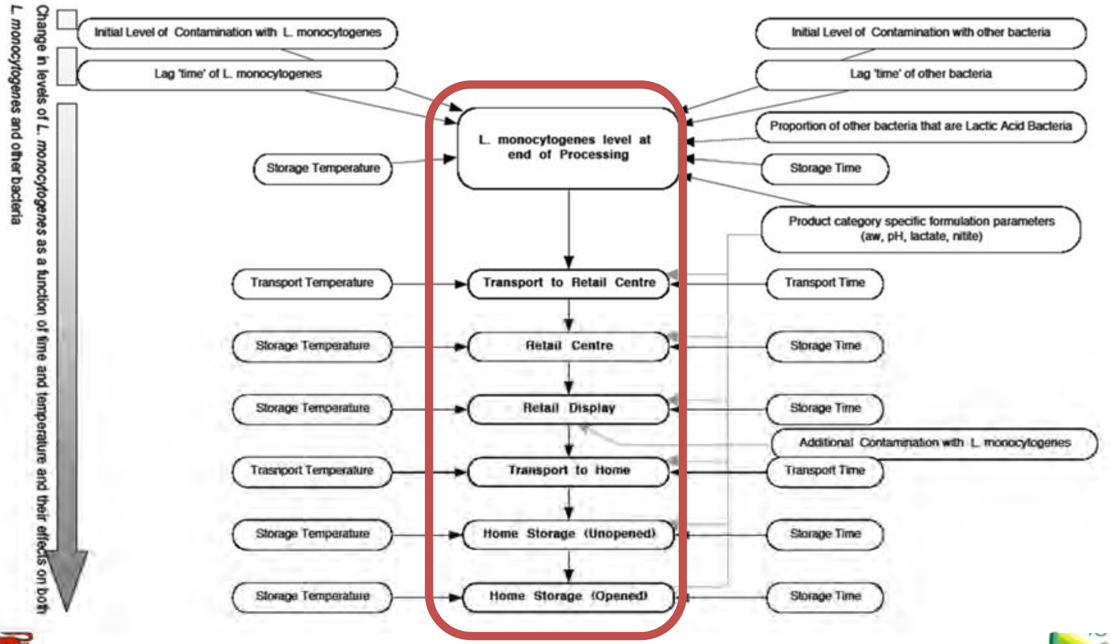
モデルのアウトプット

	総量 (*t*)	一食当たりの平均量 (g)	総摂食量 (年)	年間予想患者数 (95% CI :信頼区間)
加工肉	194,600	45.34	42億9千万	43 (54.5 to 31.2)
パテ/レバーブルスト (レバーソーセージ)	8,400	53.01	1億6千万	0.36 (0.48 to 0.25)
調理済みソーセージ＊	60,400	87.50	6億9千万	0.24 (0.32 to 0.17)
合計				44 (55 to 31)

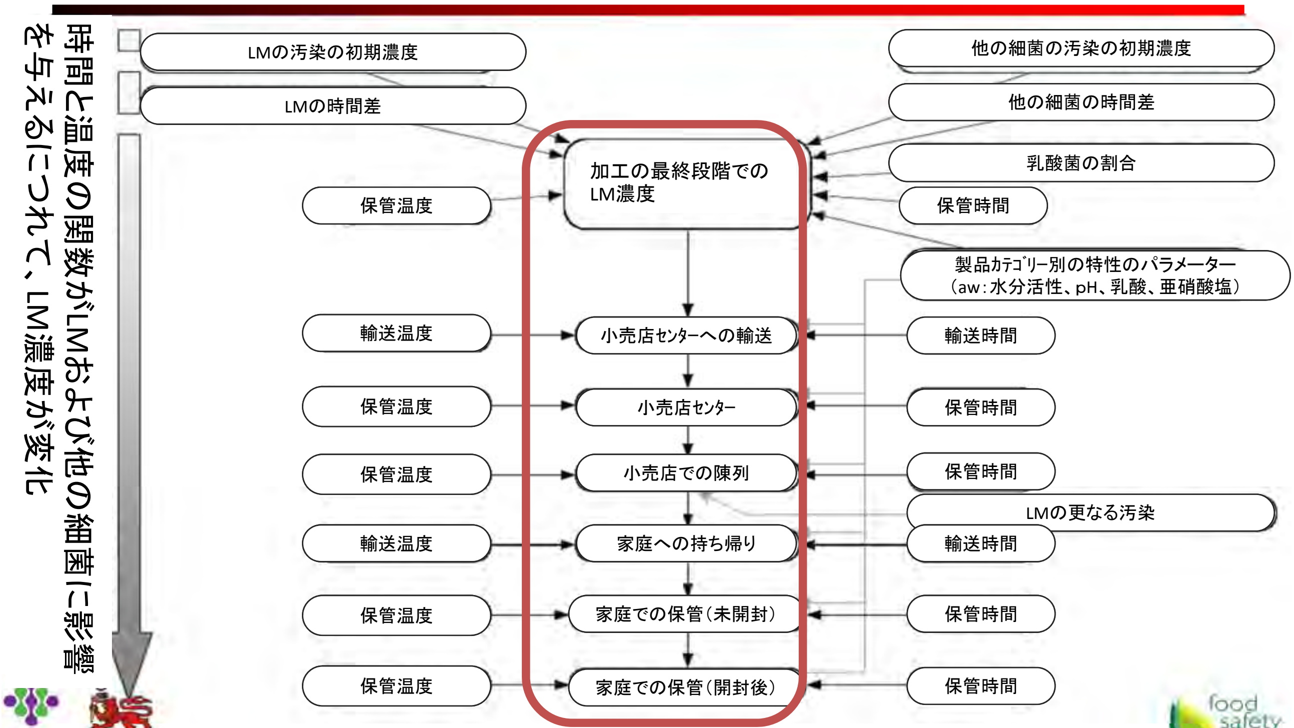
＊ 調理済みソーセージのリスクの推定に関しては、95%は通常の調理(熱湯に数分間浸ける)の後に食べられるとみなされた。

オーストラリアにおける報告症例＝年間60名以下、推定総数は年間120名以下

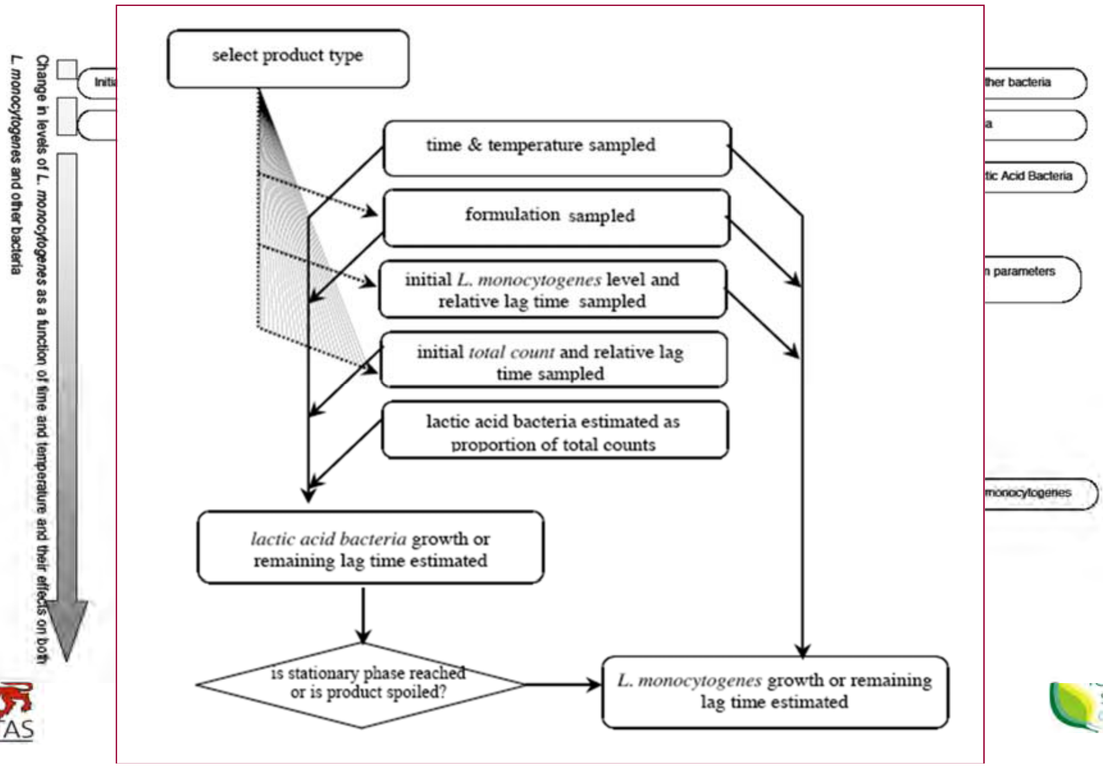
Conceptual Model: *Predictive microbiology*



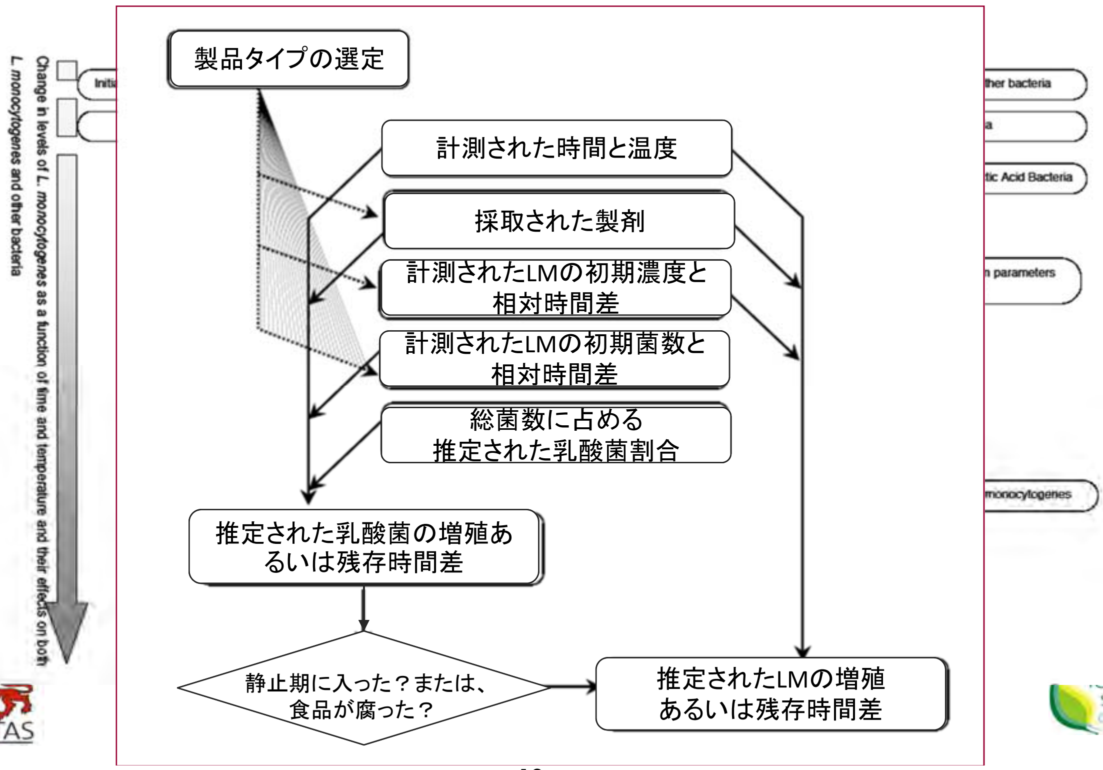
概念モデル: 予測微生物学



Conceptual Model: *Predictive microbiology*



概念モデル: *予測微生物学*



Predictive microbiology

- "quantitative microbial ecology of foods"
- relates food formulation, processing/storage conditions, and time to expected changes in microbial numbers
- very good models exist for *L. monocytogenes* growth and growth limits (e.g., Mejholm and Dalgaard, 2009*)
- links many steps/inputs in the conceptual model

予測微生物学

- 食品の定量微生物生態学
- 食品特性、加工/保管状態、および菌数の予想される変化に要する時間に関係する
- LMの増殖および増殖限界のための非常によいモデルが存在する (たとえば、Mejholm and Dalgaard, 2009)
- 概念モデル中の多様な段階や入力に関わっている

modelling Listeria monocytogenes growth rates and growth limits

- regulations for *L. monocytogenes* risk management differentiate food that do or *do not* support growth
- options to decide this are:
  - pH < 4.4 OR aw < 0.92
  - challenge testing
  - predictive microbiology

LMの増殖率と増殖限界をモデル化する

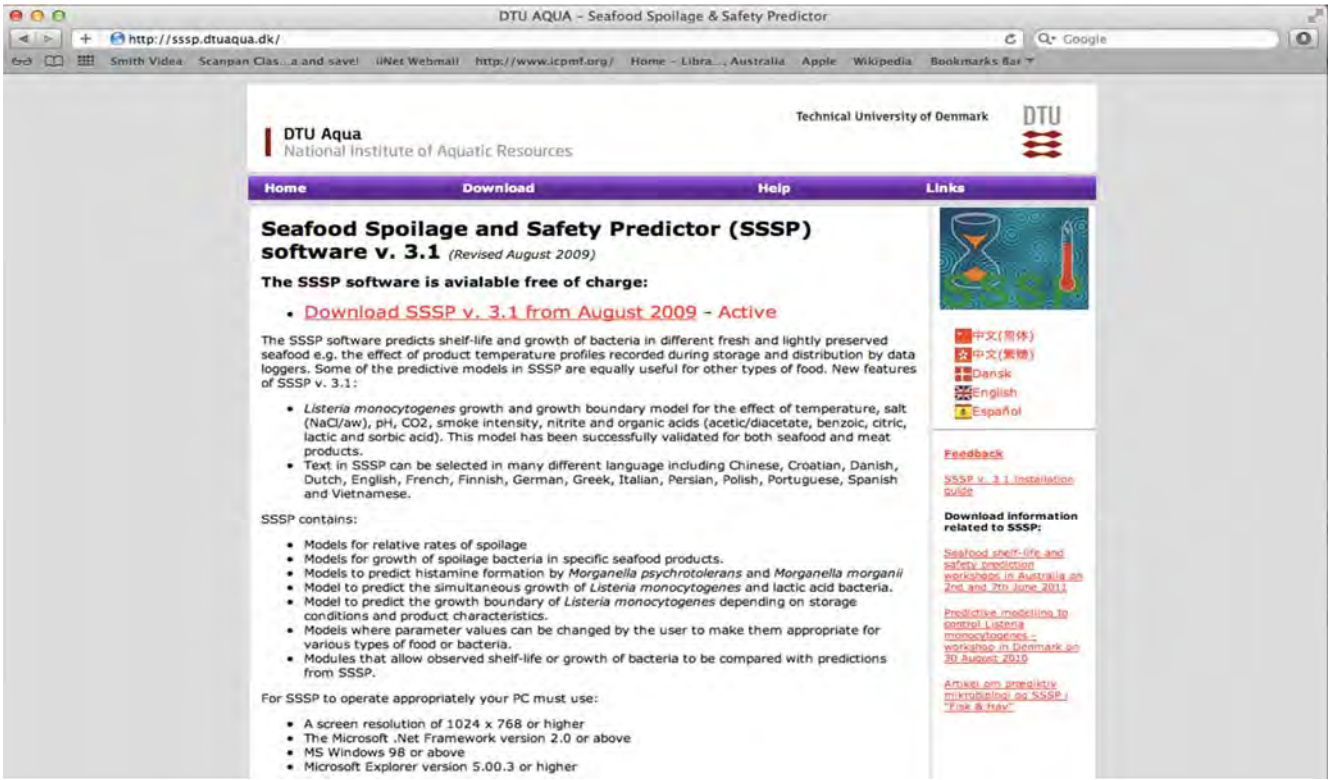
- LMのリスク管規制によって、LMが増殖する食品と増殖しない食品を区別する
- これを決定するのは:
  - pH < 4.4　または　aw（水分活性）< 0.92
  - チャレンジテスト
  - 予測微生物学

Mejholm and Dalgaard (2009)

- best model available
  - most comprehensive (12 factors)
  - most well-validated
  - most accurate
  - most accessible
- predicts growth rate and growth limits (for specified levels of confidence)
- free for download

Mejholm and Dalgaard (2009年)

- 有効な最適モデル
  - 最も包括的なモデル (12の要素)
  - 最もよく検証されたモデル
  - 最も精密なモデル
  - 最も利用しやすいモデル
- 増殖率と増殖限界を推定する（特定の信頼水準で）
- ダウンロードが自由


DTU AQUA - Seafood Spoilage & Safety Predictor

http://sssp.dtuaqua.dk/

DTU Aqua
National Institute of Aquatic Resources

Technical University of Denmark

DTU

Home | Download | Help | Links

Seafood Spoilage and Safety Predictor (SSSP) software v. 3.1 *(Revised August 2009)*

The SSSP software is avialable free of charge:

- Download SSSP v. 3.1 from August 2009 - Active

The SSSP software predicts shelf-life and growth of bacteria in different fresh and lightly preserved seafood e.g. the effect of product temperature profiles recorded during storage and distribution by data loggers. Some of the predictive models in SSSP are equally useful for other types of food. New features of SSSP v. 3.1:

- *Listeria monocytogenes* growth and growth boundary model for the effect of temperature, salt (NaCl/aw), pH, CO2, smoke intensity, nitrite and organic acids (acetic/diacetate, benzoic, citric, lactic and sorbic acid). This model has been successfully validated for both seafood and meat products.
- Text in SSSP can be selected in many different language including Chinese, Croatian, Danish, Dutch, English, French, Finnish, German, Greek, Italian, Persian, Polish, Portuguese, Spanish and Vietnamese.

SSSP contains:

- Models for relative rates of spoilage
- Models for growth of spoilage bacteria in specific seafood products.
- Models to predict histamine formation by *Morganella psychrotolerans* and *Morganella morganii*
- Model to predict the simultaneous growth of *Listeria monocytogenes* and lactic acid bacteria.
- Model to predict the growth boundary of *Listeria monocytogenes* depending on storage conditions and product characteristics.
- Models where parameter values can be changed by the user to make them appropriate for various types of food or bacteria.
- Modules that allow observed shelf-life or growth of bacteria to be compared with predictions from SSSP.

For SSSP to operate appropriately your PC must use:

- A screen resolution of 1024 x 768 or higher
- The Microsoft .Net Framework version 2.0 or above
- MS Windows 98 or above
- Microsoft Explorer version 5.00.3 or higher

中文(简体)
中文(繁體)
Dansk
English
Español

Feedback

SSSP v. 3.1 Installation guide

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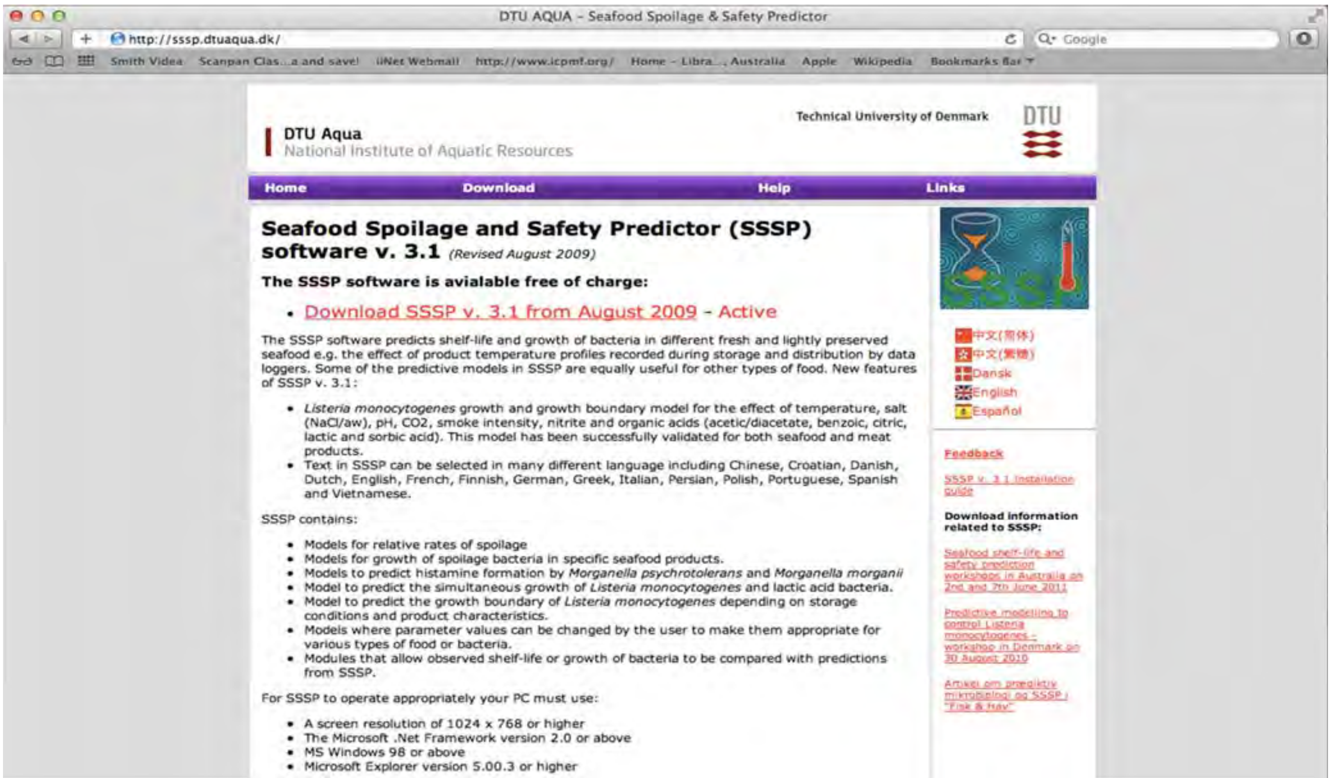
Seafood shelf-life and safety prediction workshops in Australia on 2nd and 7th June 2011

Predictive modelling to control Listeria monocytogenes - workshop in Denmark on 30 August 2010

Artikel om prædiktiv mikrobiologi og SSSP i "Fisk & Hav"

http://sssp.dtuaqua.dk/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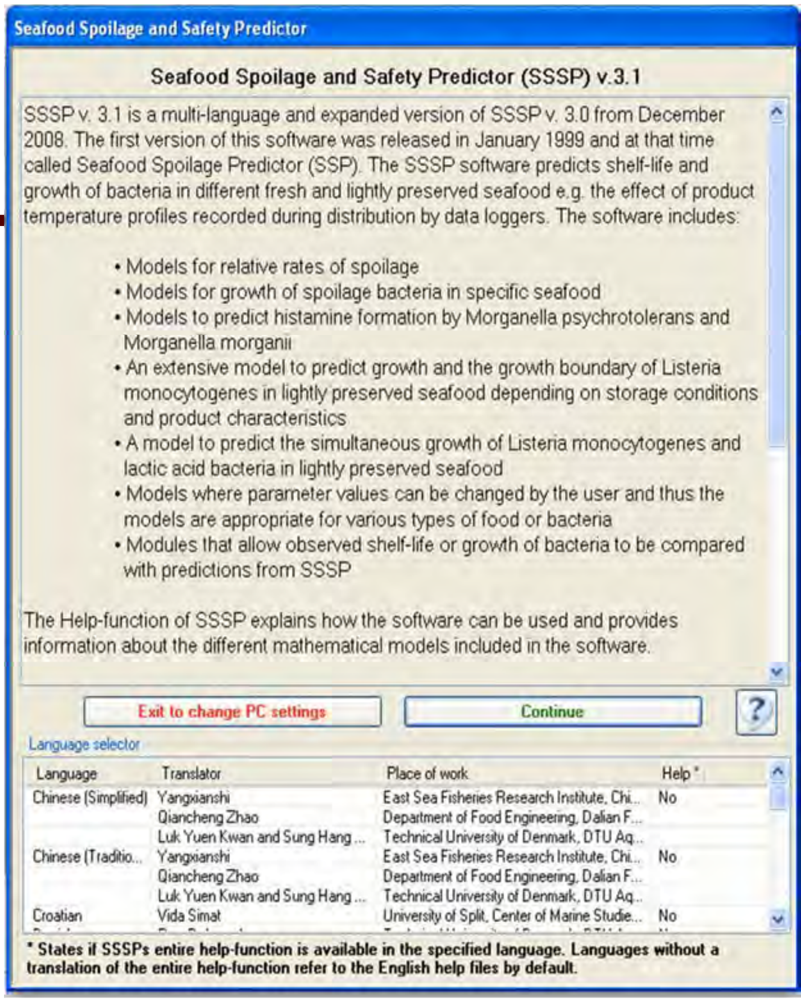
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• An extensive model to predict growth and the growth boundary of Listeria monocytogenes in lightly preserved seafood depending on storage conditions and product characteristics
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The Help-function of SSSP explains how the software can be used and provides information about the different mathematical models included in the software.
Exit to change PC settings
Continue
?
Language selector
Language | Translator | Place of work | Help *
Chinese (Simplified) | Yangxianshi | East Sea Fisheries Research Institute, Chi... | No
Qiancheng Zhao | Department of Food Engineering, Dalian F...
Luk Yuen Kwan and Sung Hang ... | Technical University of Denmark, DTU Aq...
Chinese (Traditio... | Yangxianshi | East Sea Fisheries Research Institute, Chi... | No
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Luk Yuen Kwan and Sung Hang ... | Technical University of Denmark, DTU Aq...
Croatian | Vida Simat | University of Split, Center of Marine Studie... | No
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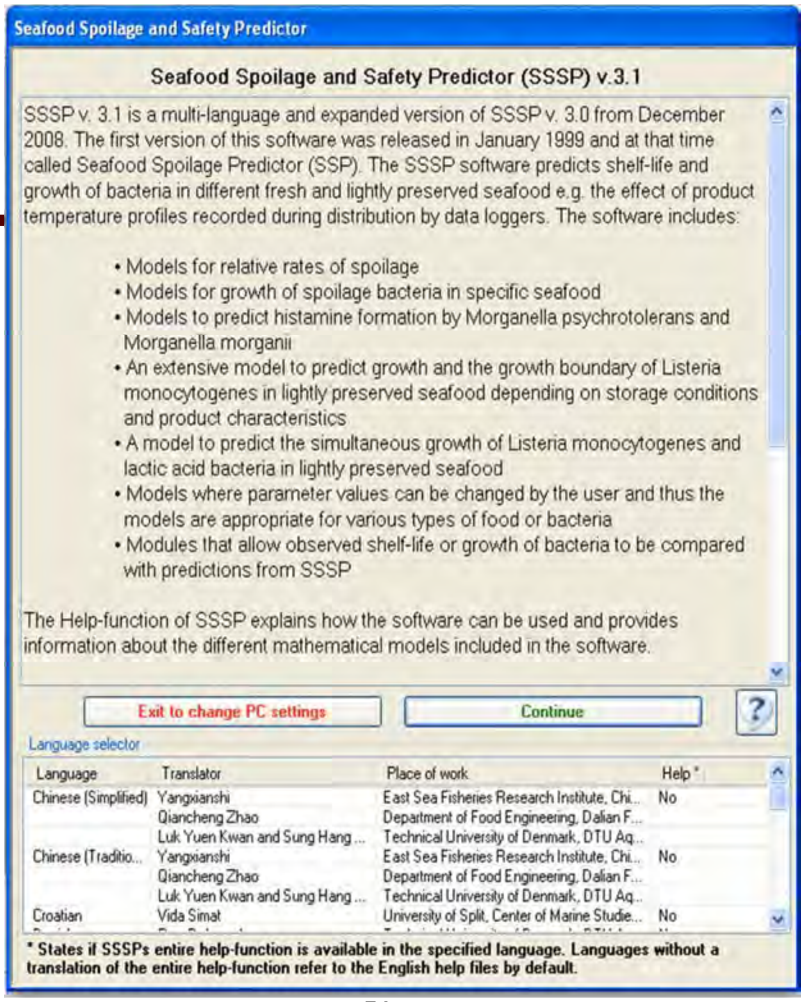
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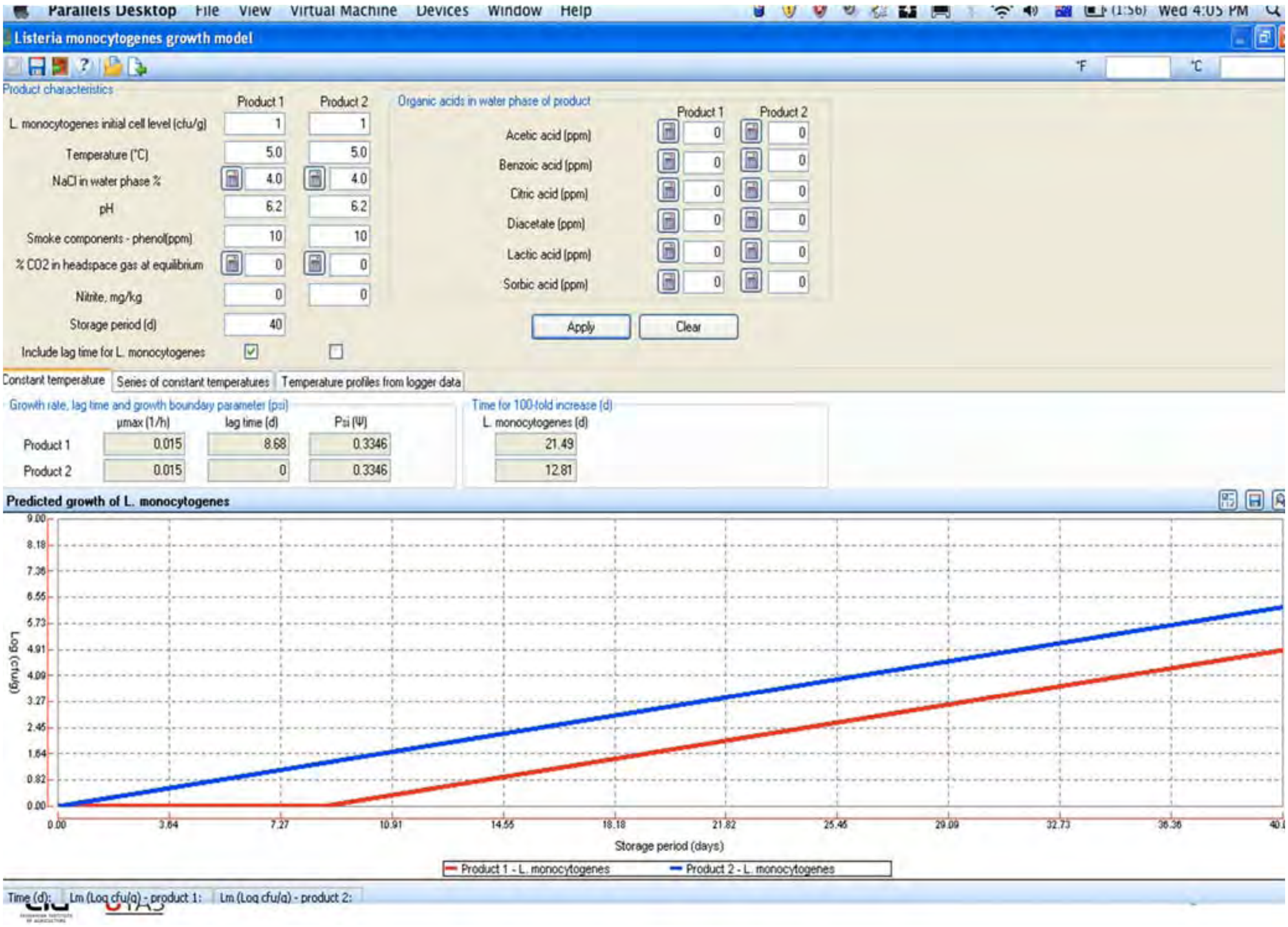
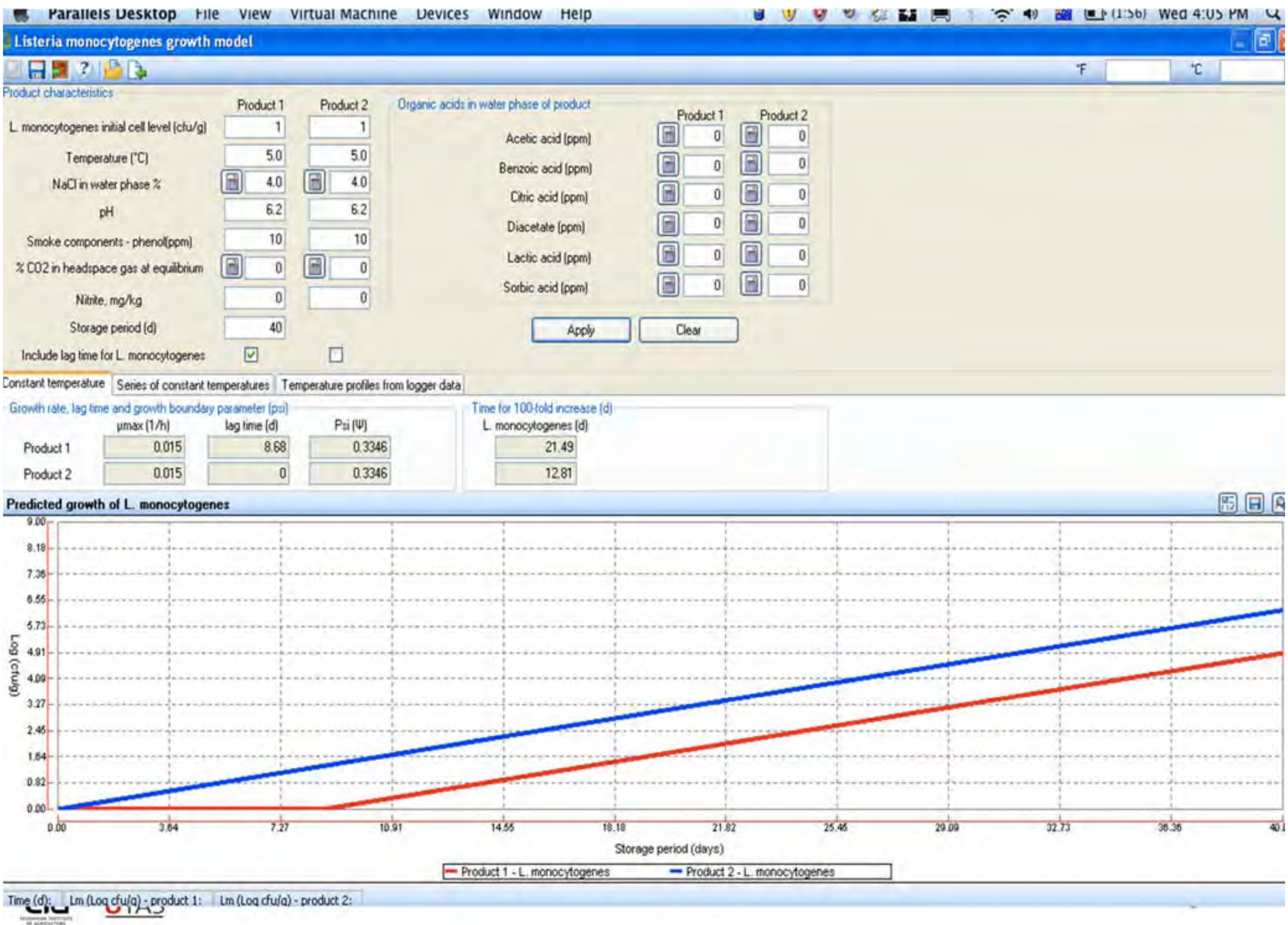

Parallels Desktop File View Virtual Machine Devices Window Help
Wed 4:05 PM
Listeria monocytogenes growth model
Product characteristics
Product 1
Product 2
L. monocytogenes initial cell level (cfu/g) 1 1
Temperature (°C) 5.0 5.0
NaCl in water phase % 4.0 4.0
pH 6.2 6.2
Smoke components - phenol(ppm) 10 10
% CO2 in headspace gas at equilibrium 0 0
Nitrite, mg/kg 0 0
Storage period (d) 40
Include lag time for L. monocytogenes
Organic acids in water phase of product
Acetic acid (ppm) 0 0
Benzoic acid (ppm) 0 0
Citric acid (ppm) 0 0
Diacetate (ppm) 0 0
Lactic acid (ppm) 0 0
Sorbic acid (ppm) 0 0
Apply
Clear
Constant temperature
Series of constant temperatures
Temperature profiles from logger data
Growth rate, lag time and growth boundary parameter (psi)
μmax (1/h)
lag time (d)
Psi (Ψ)
Product 1 0.015 8.68 0.3346
Product 2 0.015 0 0.3346
Time for 100-fold increase (d)
L. monocytogenes (d)
21.49
12.81
Predicted growth of L. monocytogenes
Log (cfu/g)
9.00
8.18
7.36
6.55
5.73
4.91
4.09
3.27
2.45
1.64
0.82
0.00
0.00
3.64
7.27
10.91
14.55
18.18
21.82
25.45
29.09
32.73
36.36
Storage period (days)
Product 1 - L. monocytogenes
Product 2 - L. monocytogenes
Time (d):
Lm (Log cfu/g) - product 1:
Lm (Log cfu/g) - product 2: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pH 6.2 6.2
Smoke components - phenol(ppm) 10 10
% CO2 in headspace gas at equilibrium 0 0
Nitrite, mg/kg 0 0
Storage period (d) 40
Include lag time for L. monocytogenes
Organic acids in water phase of product
Acetic acid (ppm) 0 0
Benzoic acid (ppm) 0 0
Citric acid (ppm) 0 0
Diacetate (ppm) 0 0
Lactic acid (ppm) 0 0
Sorbic acid (ppm) 0 0
Apply
Clear
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μmax (1/h)
lag time (d)
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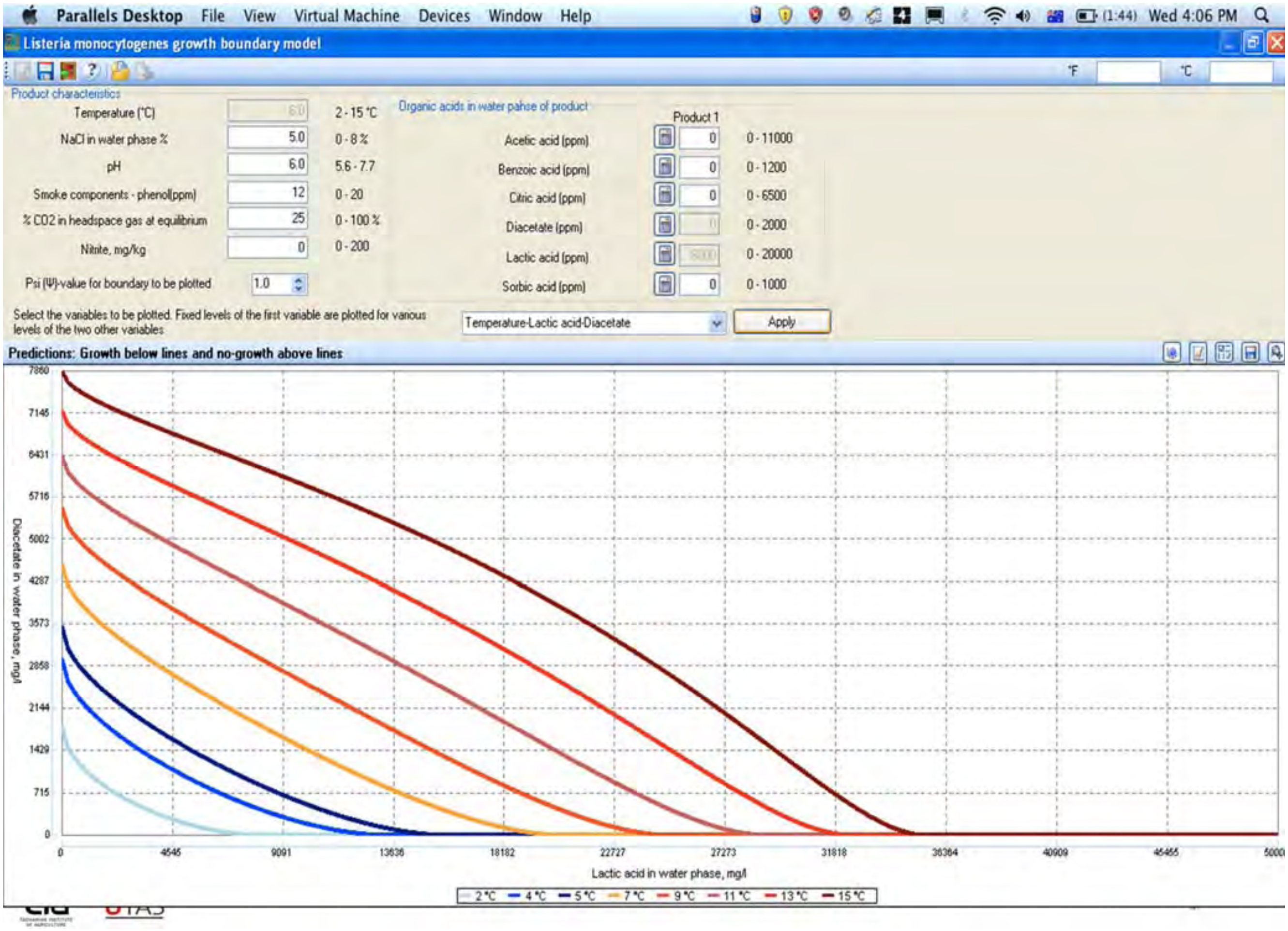
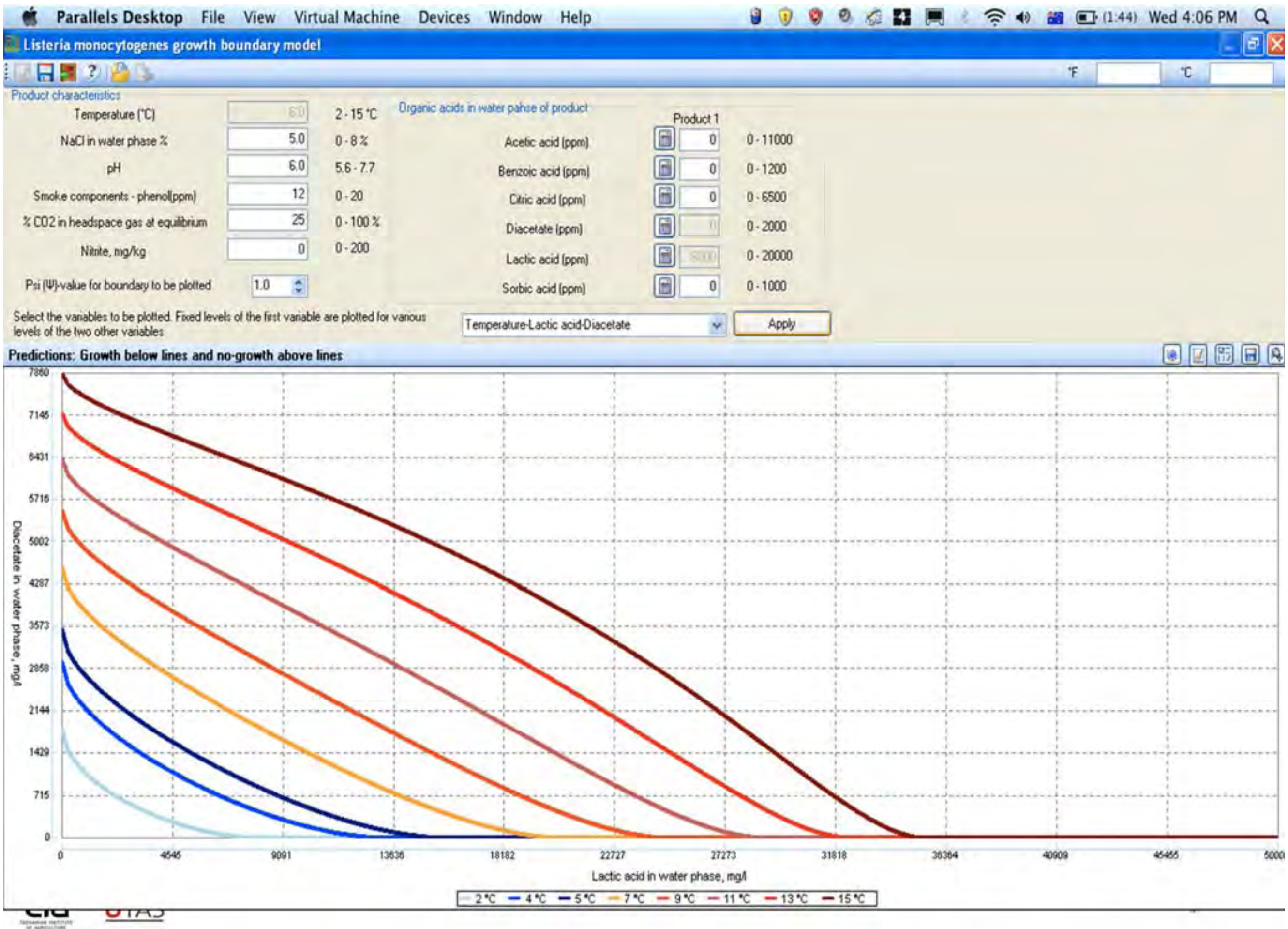
Log (cfu/g)
Storage period (days)
Product 1 - L. monocytogenes
Product 2 - L. monocytogenes
Time (d):
Lm (Log cfu/g) - product 1:
Lm (Log cfu/g) - product 2:




Parallels Desktop File View Virtual Machine Devices Window Help
Wed 4:06 PM
Listeria monocytogenes growth boundary model
Product characteristics
Temperature (°C) 6.0 2 - 15 °C
NaCl in water phase % 5.0 0 - 8 %
pH 6.0 5.6 - 7.7
Smoke components - phenol(ppm) 12 0 - 20
% CO2 in headspace gas at equilibrium 25 0 - 100 %
Nitrite, mg/kg 0 0 - 200
Psi (Ψ)-value for boundary to be plotted 1.0
Organic acids in water pahse of product
Product 1
Acetic acid (ppm) 0 0 - 11000
Benzoic acid (ppm) 0 0 - 1200
Citric acid (ppm) 0 0 - 6500
Diacetate (ppm) 0 0 - 2000
Lactic acid (ppm) 0 - 20000
Sorbic acid (ppm) 0 0 - 1000
Select the variables to be plotted. Fixed levels of the first variable are plotted for various levels of the two other variables
Temperature-Lactic acid-Diacetate
Apply
Predictions: Growth below lines and no-growth above lines
Diacetate in water phase, mg/l
Lactic acid in water phase, mg/l
2 °C 4 °C 5 °C 7 °C 9 °C 11 °C 13 °C 15 °C

hazard characterisation
(dose-response assessment)

ハザード特徴づけ
(用量-反応 評価)

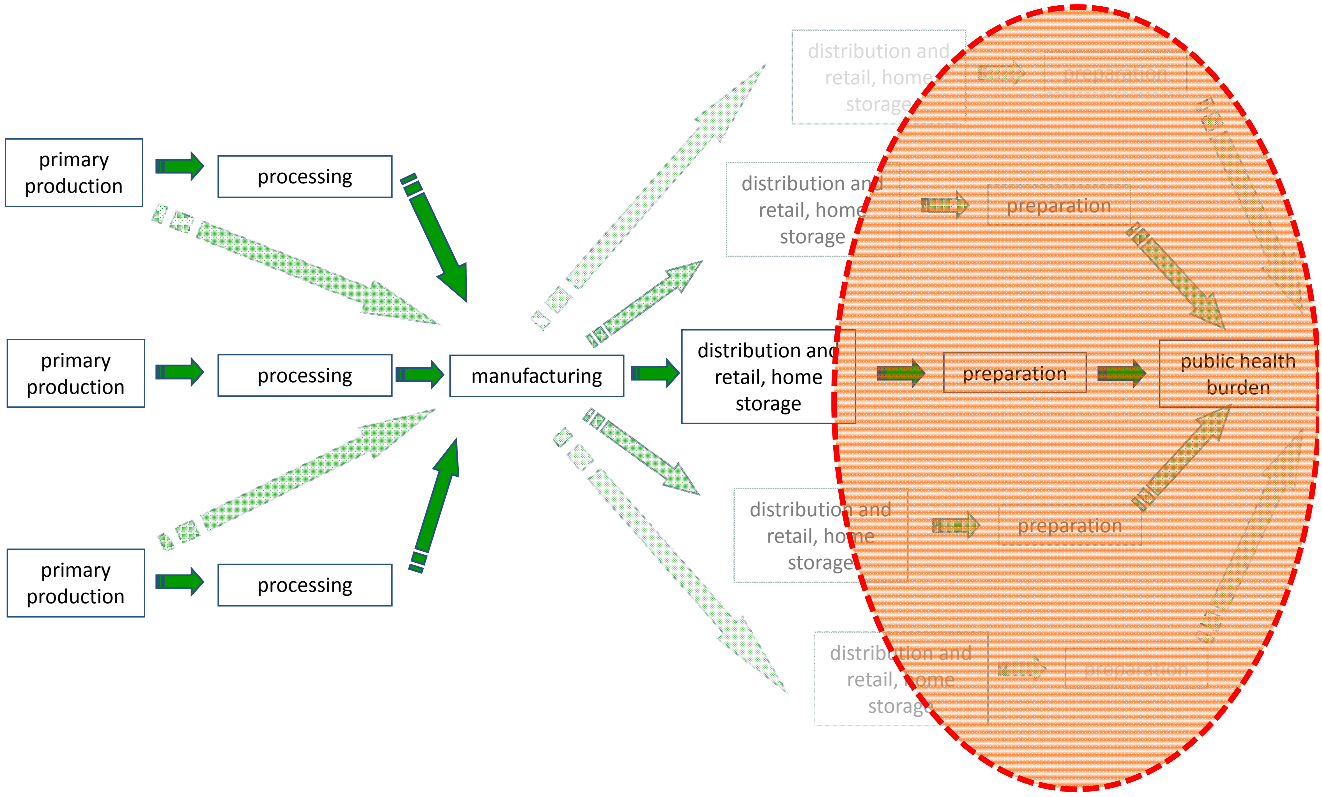
Dose-Response Assessment

the relationship between the amount ingested and probability, and severity, of illness caused

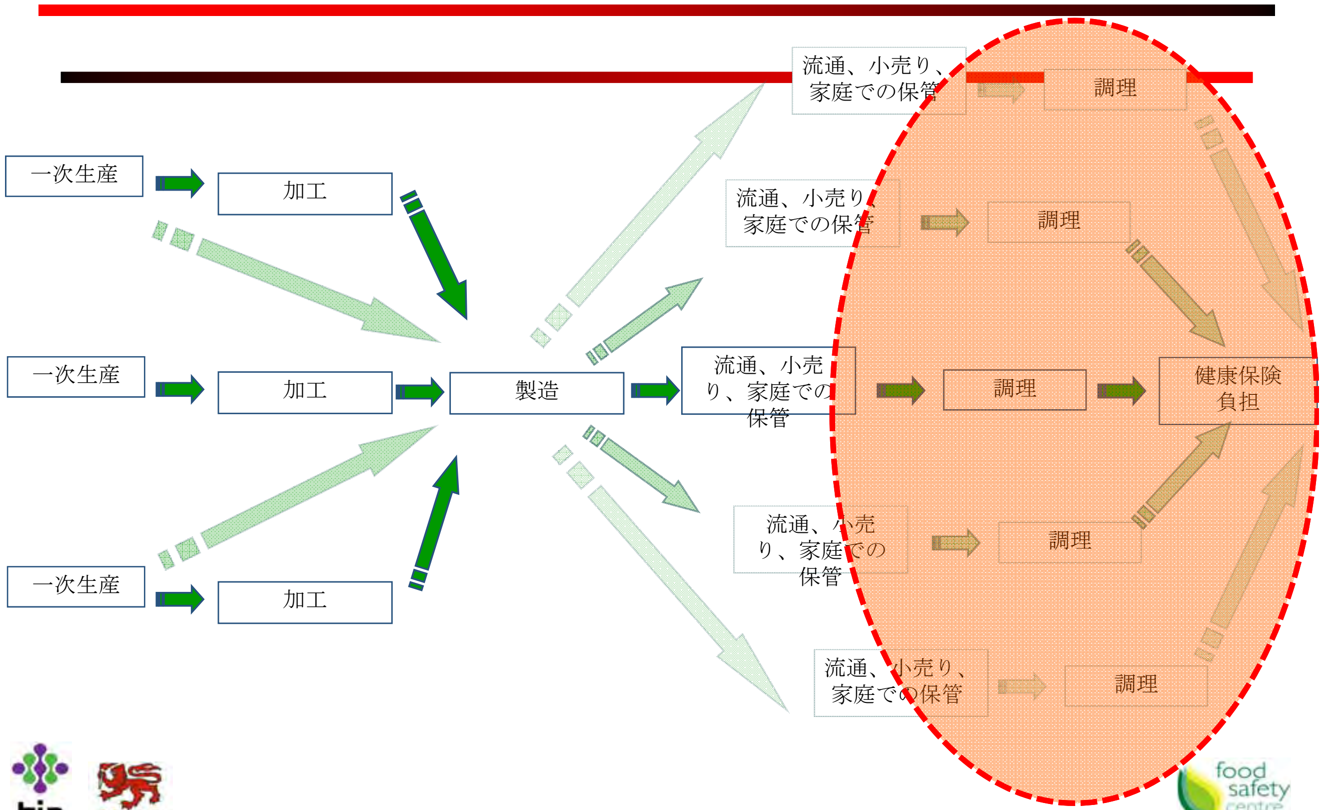
用量-反応 評価

摂取量と、引き起こされた健康被害の発症確率と重症度との関連

Complex/Variable Food Chains



複雑で変化しやすいフードチェーン



Dose ingested in serving → Dose Probability-of-Infection Model → Probability of Illness per Serving

食事での摂取量 → 菌量・感染確率モデル → 一食当たりの健康被害発生確率

Dose response relationships-data problems

For *known hazards*, unethical to do feeding trials, so:

rely on old, human feeding trials

(but were mostly healthy, adult, males)

epidemiological data

dose data often very poor, long delay between exposure and recognition of outbreak

animal models

uncertain relationship to human response

relevant animal models very expensive

用量反応相関ー データの問題

既知のハザードに関しては、摂食試験は非倫理的：それゆえ、

旧来の摂食試験に依存

(しかし、その大部分は、男子の健常成人)

疫学データ

用量データは、しばしば質が悪く、暴露と発生確認との間に大きな時間的ずれが生じる

動物モデル

ヒトでの反応との関連が不明確

関連する動物モデルは非常に高価

modelling ‘dose-response’

- assume that each organism has an equal probability of causing infection
  - *(agrees with single-hit theory, endorsed by JEMRA)*
- there is an upper limit beyond which increased dose does not increase risk of infection
- these characteristics described by ‘exponential’ or ‘Beta-Poisson’ models
- relationship is dose *vs* probability (i.e., not dose *vs* response)
- can choose different responses, e.g., *infection*, *morbidity*, or *mortality*

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‘用量-反応’のモデル化

- 各生物が感染する確率は等しいと仮定する
  - *(JEMRAにおいて支持されているシングルヒット説に沿っている)*
- 感染リスクを高めない菌量を越えた上限
- それらの特徴は、‘指数関数’ あるいは ‘ポアソンベータ分布’モデルによって説明される
- 相関関係は、菌量 対 確率　(菌量 対 反応　ではない)
- 異なった反応を選ぶことができる。
  たとえば、感染、罹患率、死亡率

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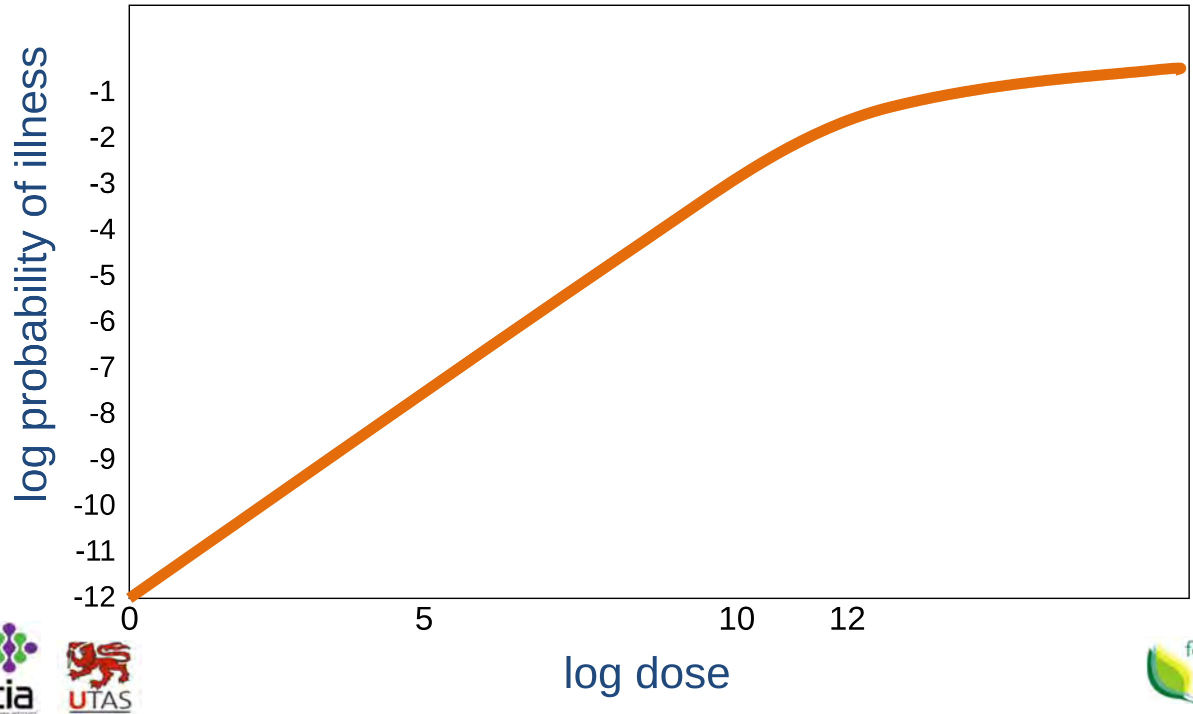
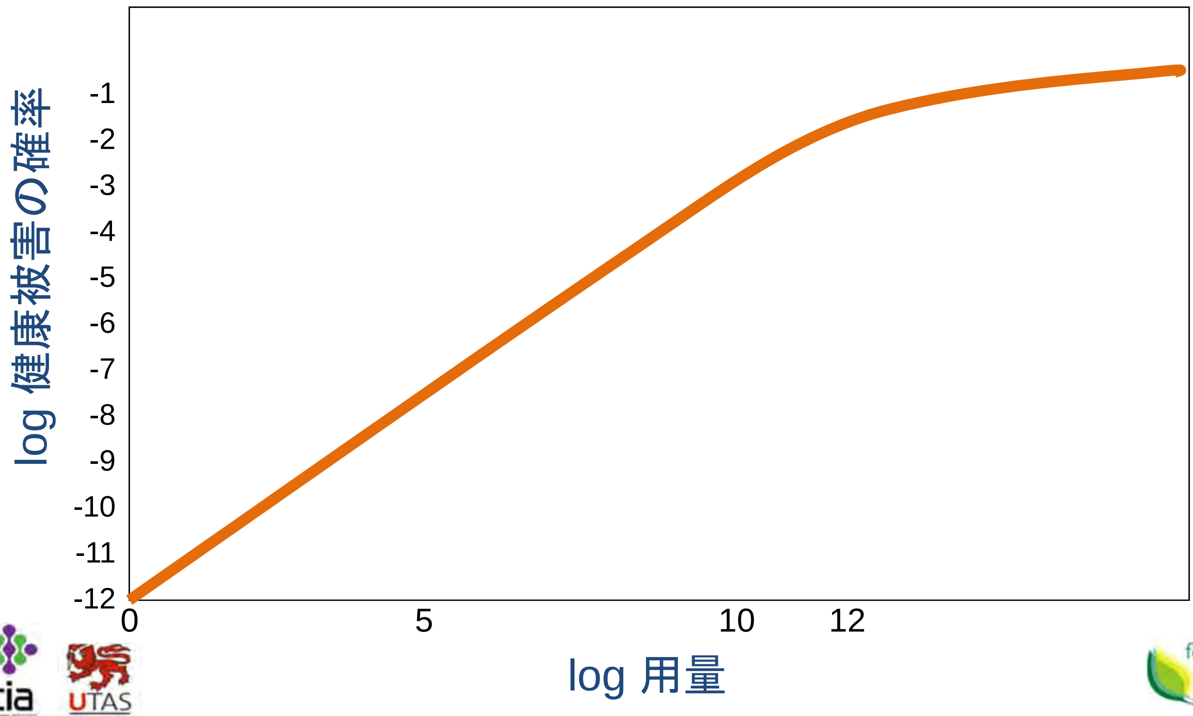
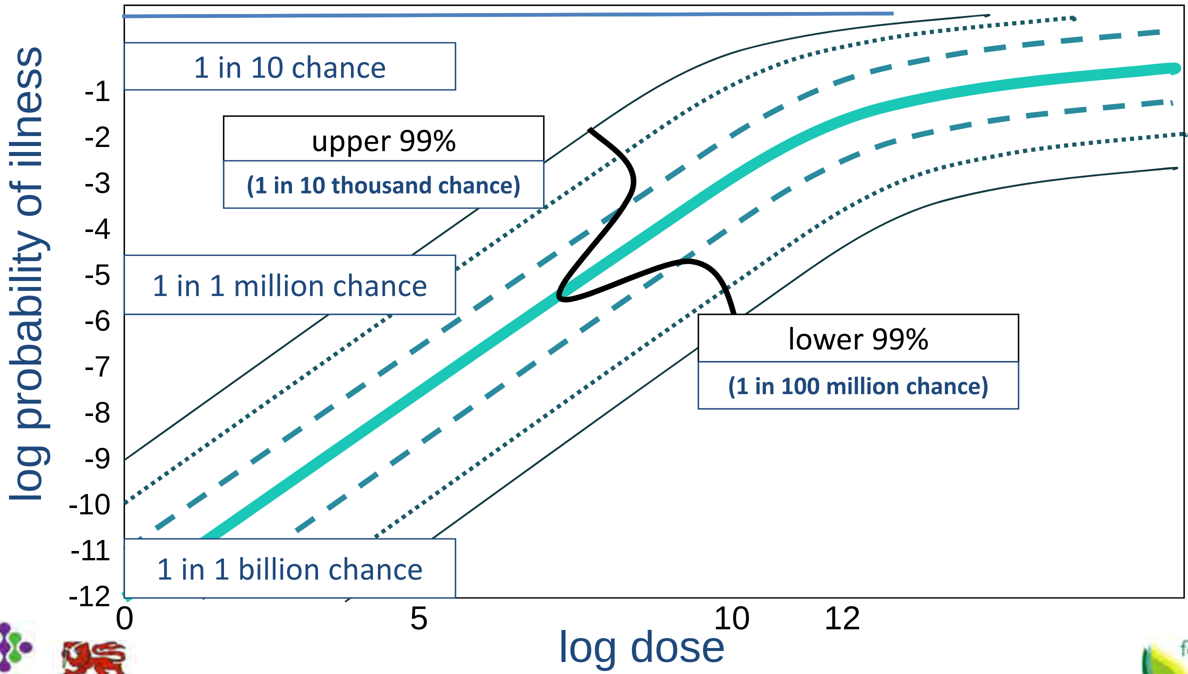
Dose-$P_{infection}$ exponential model



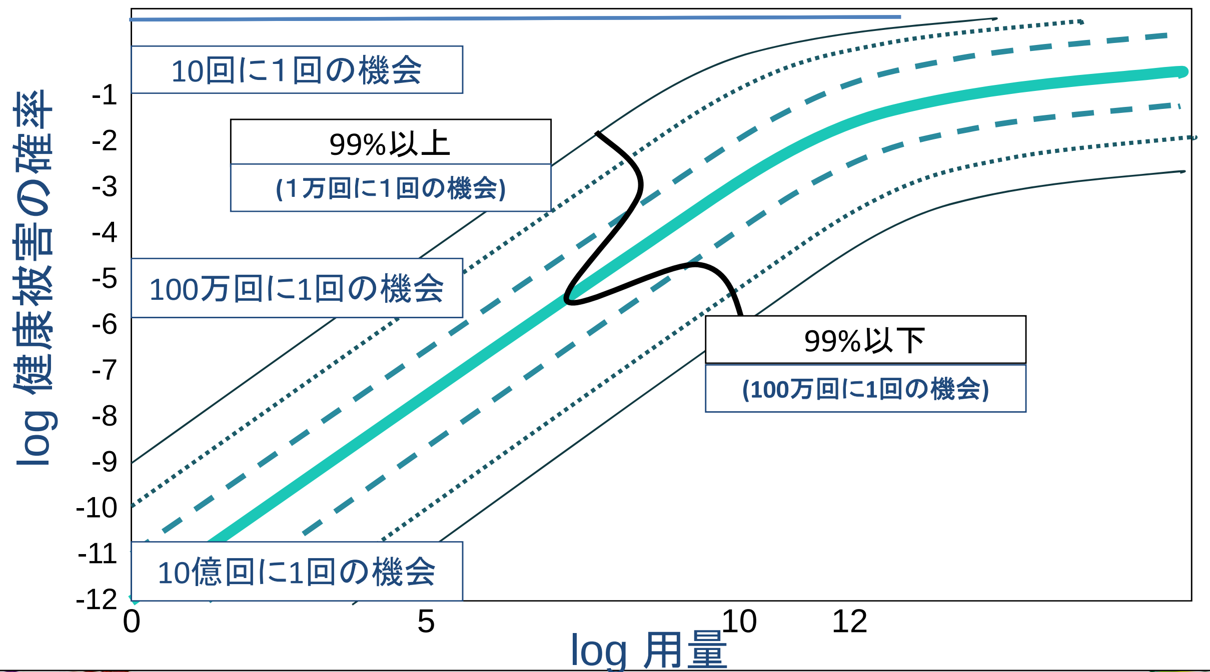
用量-確率$_{感染}$ 指数関数モデル



Variability in Dose-$P_{infection}$ Relationships



用量-確率$_{感染}$の相関



risk characterisation

リスク判定

Risk Characterisation

synthesis of the exposure assessment and the dose-response assessment to estimate the risk (probability of illness, severity of illness) to public health;

may also include definition of factors that most affect the risk and ways to minimise the risk

リスク判定

公衆衛生へのリスク（健康被害の発症確率と重症度）を見積もるための暴露評価と用量-反応相関の統合；

リスク判定は、リスクおよびそれを最小化する方法に最も影響を及ぼす要素の定義を含み得る

Risk Characterisation

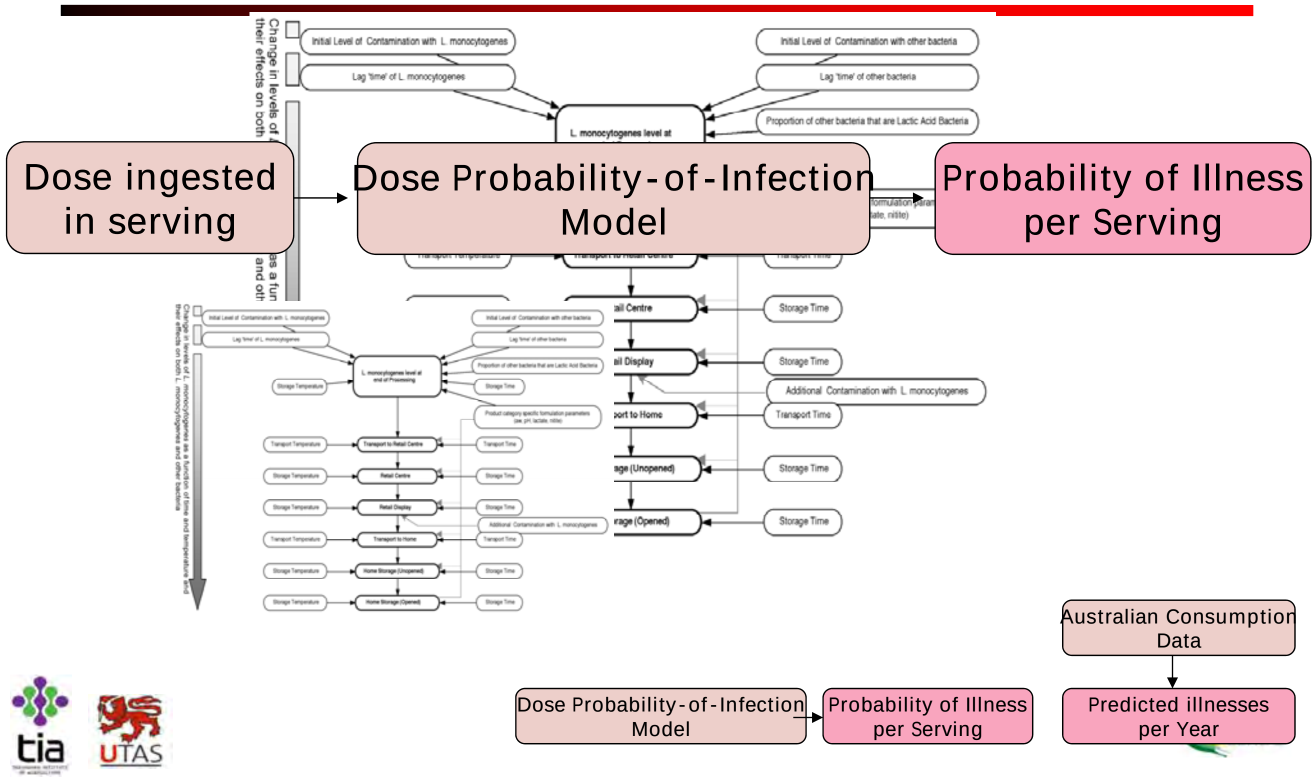
synthesis of exposure assessment and hazard characterisation within a 'conceptual model' of the whole food chain

– commonly not enough information
– commonly rests on many assumptions
– often very mathematical
– semi-quantitative methods also sought

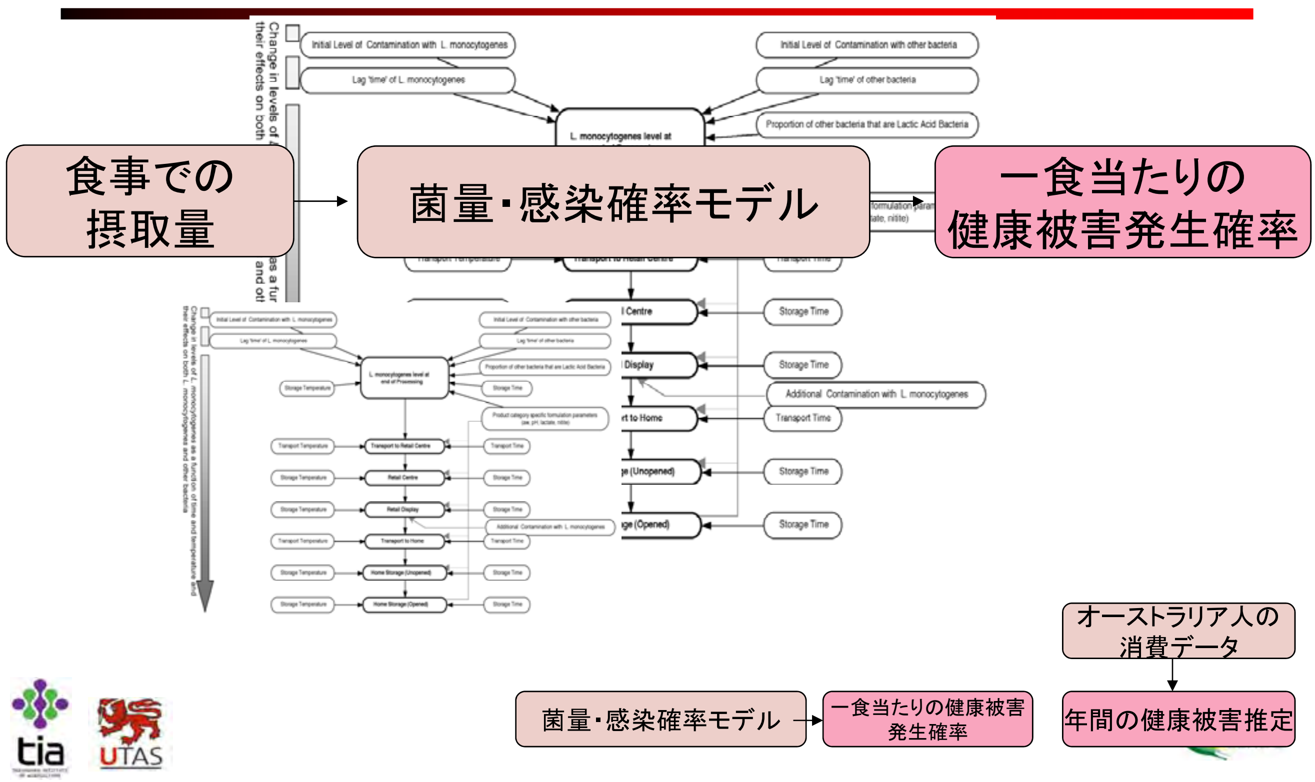
リスク判定

フードチェーン全体の概念モデルの中での暴露評価とハザードの統合

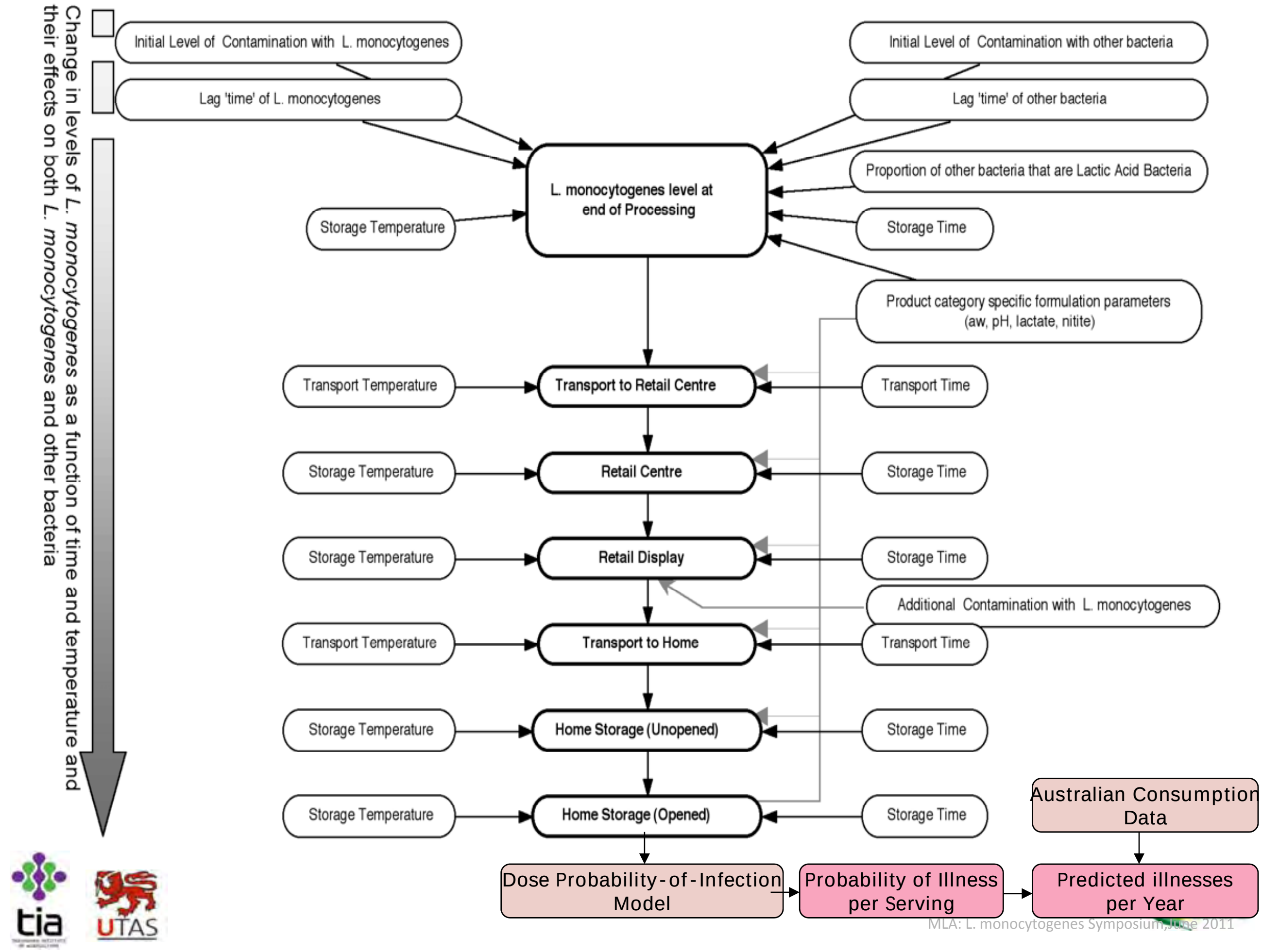
– 一般には、十分な情報はない
– 一般には、多くの仮説に基づいている
– しばしば数学的である
– 必要とされる半定量分析



Dose ingested in serving
Dose Probability-of-Infection Model
Probability of Illness per Serving
Initial Level of Contamination with L. monocytogenes
Lag 'time' of L. monocytogenes
Initial Level of Contamination with other bacteria
Lag 'time' of other bacteria
Proportion of other bacteria that are Lactic Acid Bacteria
L. monocytogenes level at
Storage Time
Additional Contamination with L. monocytogenes
Transport Time
Australian Consumption Data
Dose Probability-of-Infection Model
Probability of Illness per Serving
Predicted illnesses per Year



食事での摂取量
菌量・感染確率モデル
一食当たりの健康被害発生確率
Initial Level of Contamination with L. monocytogenes
Lag 'time' of L. monocytogenes
Initial Level of Contamination with other bacteria
Lag 'time' of other bacteria
Proportion of other bacteria that are Lactic Acid Bacteria
L. monocytogenes level at
Storage Time
Additional Contamination with L. monocytogenes
Transport Time
オーストラリア人の消費データ
菌量・感染確率モデル
一食当たりの健康被害発生確率
年間の健康被害推定


Change in levels of L. monocytogenes as a function of time and temperature and their effects on both L. monocytogenes and other bacteria
Initial Level of Contamination with L. monocytogenes
Lag 'time' of L. monocytogenes
Initial Level of Contamination with other bacteria
Lag 'time' of other bacteria
Proportion of other bacteria that are Lactic Acid Bacteria
Storage Temperature
L. monocytogenes level at end of Processing
Storage Time
Product category specific formulation parameters (aw, pH, lactate, nitite)
Transport Temperature
Transport to Retail Centre
Transport Time
Storage Temperature
Retail Centre
Storage Time
Storage Temperature
Retail Display
Storage Time
Additional Contamination with L. monocytogenes
Transport Temperature
Transport to Home
Transport Time
Storage Temperature
Home Storage (Unopened)
Storage Time
Storage Temperature
Home Storage (Opened)
Storage Time
Australian Consumption Data
Dose Probability-of-Infection Model
Probability of Illness per Serving
Predicted illnesses per Year
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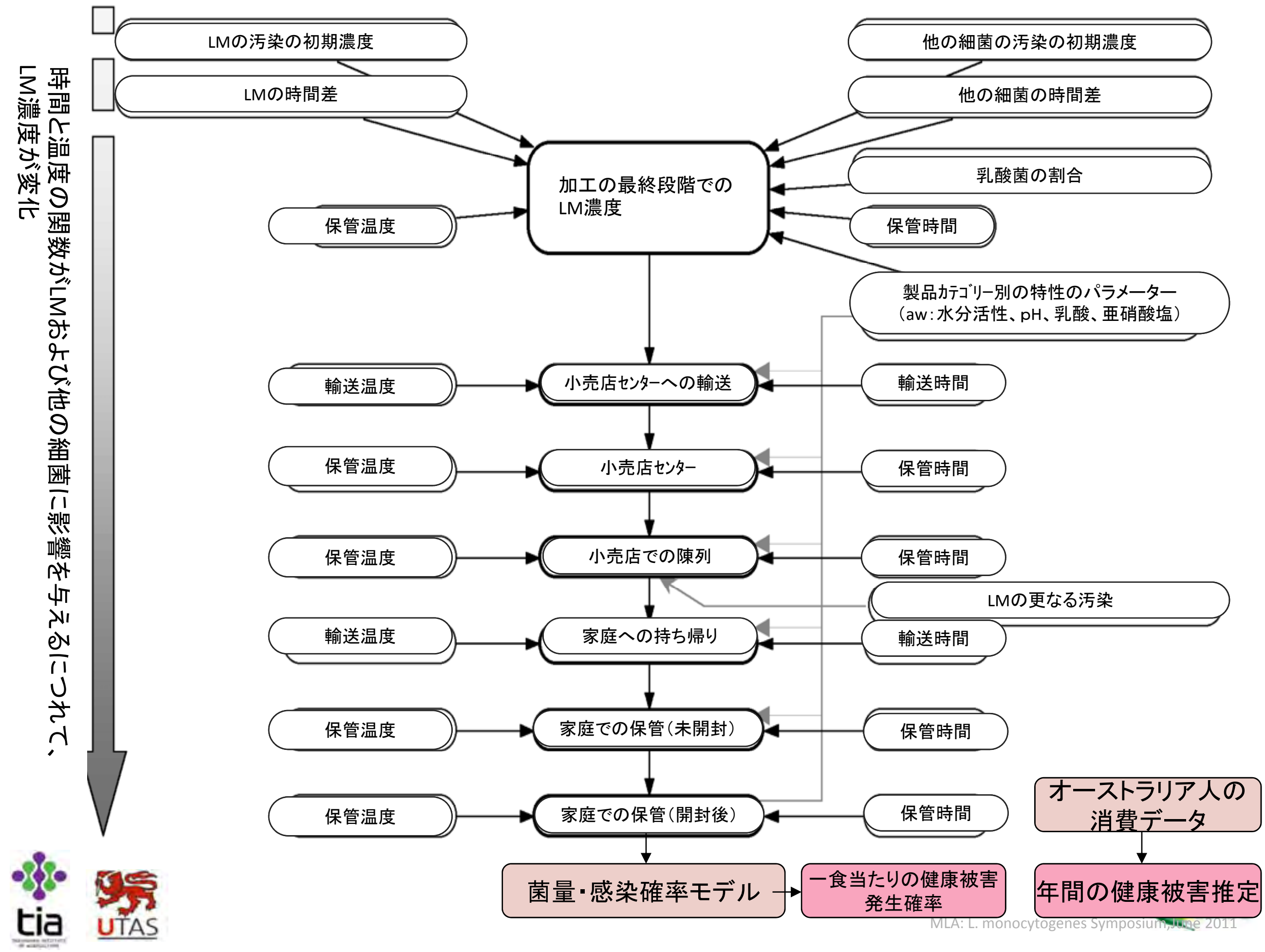
MLA: L. monocytogenes Symposium, June 2011


時間と温度の関数がLMおよび他の細菌に影響を与えるにつれて、LM濃度が変化
LMの汚染の初期濃度
LMの時間差
他の細菌の汚染の初期濃度
他の細菌の時間差
乳酸菌の割合
保管温度
加工の最終段階でのLM濃度
保管時間
製品ｶﾃｺﾞﾘｰ別の特性のパラメーター（aw：水分活性、pH、乳酸、亜硝酸塩）
輸送温度
小売店ｾﾝﾀｰへの輸送
輸送時間
保管温度
小売店ｾﾝﾀｰ
保管時間
保管温度
小売店での陳列
保管時間
LMの更なる汚染
輸送温度
家庭への持ち帰り
輸送時間
保管温度
家庭での保管（未開封）
保管時間
保管温度
家庭での保管（開封後）
保管時間
オーストラリア人の消費データ
菌量・感染確率モデル
一食当たりの健康被害発生確率
年間の健康被害推定
tia
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MLA: L. monocytogenes Symposium, June 2011

MFSRA: Risk char’n approaches

qualitative ⇦⇨ quantitative
(descriptive) (mathematical)

deterministic ⇦⇨ stochastic
(fixed values) (distributions of values)

approach taken depends on data available, resources available, importance of the risk questions

食品の微生物学的リスク評価のアプローチ

定性的 ⇦⇨ 定量的
（記述的） （数学的）

決定論的 ⇦⇨ 確率論的
（固定値） (値の分布)

有効なデータ、有効な資源、リスク課題の重要性によってとられるアプローチ

risk assessment approaches

can be

- qualitative
  - but limited inference
- deterministic
  - averages don't always characterise the most important sources of risk
  - worst case scenarios can vastly exaggerate risk
- stochastic
  - explicitly considers the effects of variability in system
  - characterises the full range of possible levels of risk – most common, worst etc.

リスク評価のアプローチ

- 定性的
  - しかし、限定的な推定
- 決定論的
  - 平均値からは、必ずしもリスクの最も重要な原因を特定できない
  - ワーストケース・シナリオは、リスクを過大に強調し得る
- 確率論的
  - システム変動の影響を積極的に考慮する
  - 予想され得るすべてのリスク水準の特徴を明らかにする

  —「最も一般的な」、「最悪の」 など

Risk assessment matrices

- decision trees
- use a matrix of hazard levels and probability levels
- assume that both are known
- subjective decisions have to be made
- basis of those decisions is not transparent

リスク評価のマトリックス

- ディシジョンツリー　（意思決定を導き出すための樹形図）
- ハザード水準と確率水準のマトリックスを使用
- 両方の水準が既知のものである仮定
- 主観的判断がなされなければならない
- それらの決定のベースに透明性はない

RA Tools: *ICMSF (1986) Matrix*

- designed for determining sampling intensity related to product risk

Type of Hazard	Conditions under which the food is expected to be handled and consumed are sampling, in the usual course of events		
	Conditions reduce hazard levels (e.g. kill pathogens)	No change in risk (refrigeration)	may increase risk (e.g. conditions allowing pathogen growth)
"utility" (e.g. reduced shelf life, spoilage)	**1**	**2**	**3**
indicator organisms detected (low, indirect hazard)	**4**	**5**	**6**
moderate hazard - not usually life threatening (ie. usually no sequelae, illness normally of short duraction, symptoms are self-limiting but can cause severe discomfort)	**7**	**8**	**9**
serious hazard - incapacitating but not usually life threatening, sequelae rare, moderate duration	**10**	**11**	**12**
severe hazard for all consumers sensitive sub-populations (e.g. causing life threatening illness or sbstantial chronic sequelae or illness of long duration)	**13**	**14**	**15**

リスク評価ツール: *国際食品微生物規格委員会(1986年)のマトリックス*

- 製品リスクに関連した抽出比を決定するために設計された

Type of Hazard	Conditions under which the food is expected to be handled and consumed are sampling, in the usual course of events		
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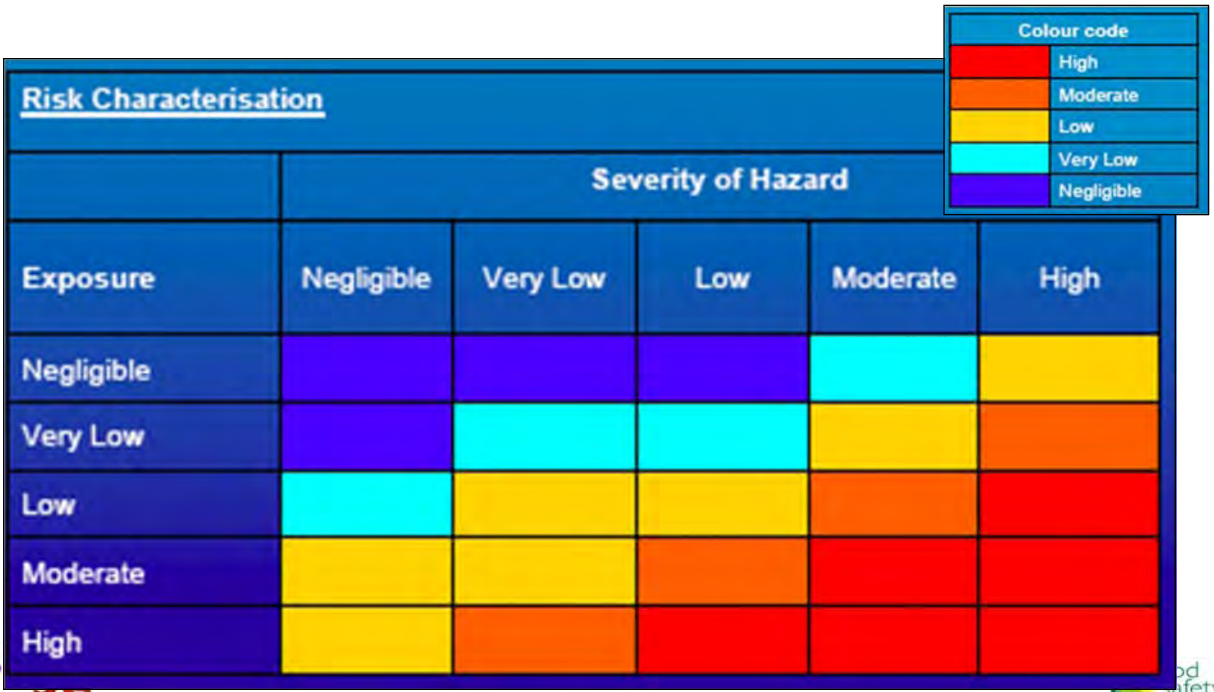
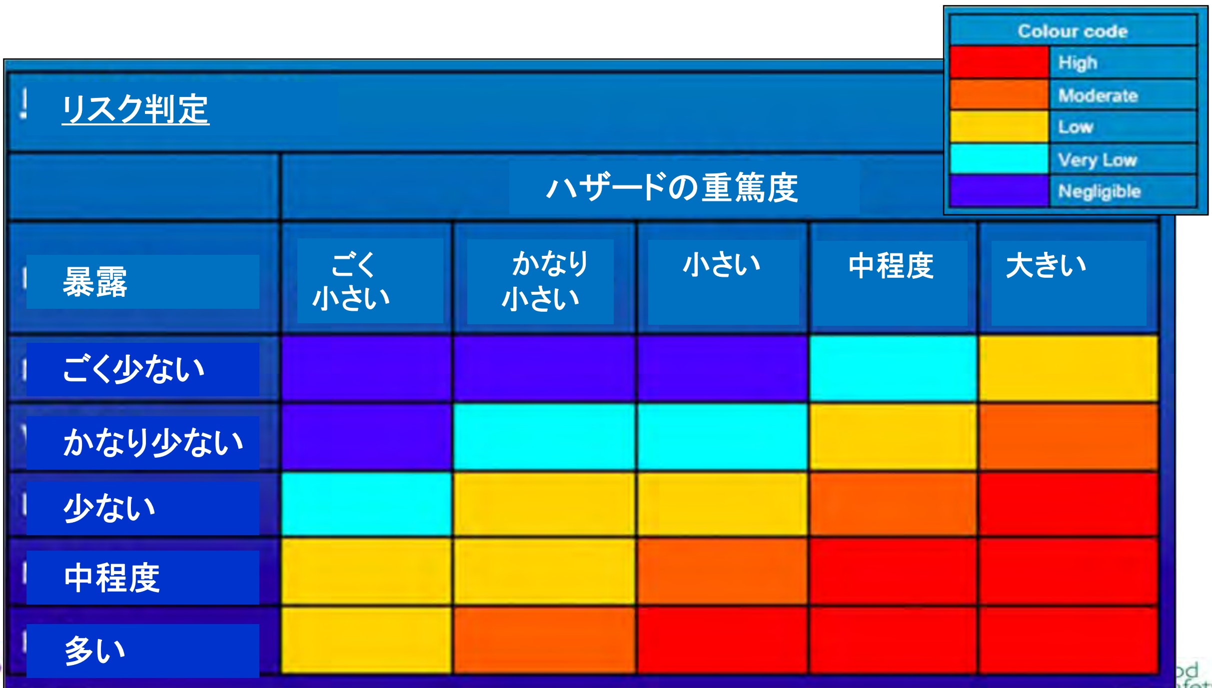
qualitative: risk matrices

定性的: リスクマトリックス

Risk matrices



リスクマトリックス



RA tools: *"Risk Ranger" spreadsheet*

based on Codex food safety risk assessment principles (but no details of uncertainty/variability)

many steps modelled discretely

their relative effect can be gauged,
risks can rise and fall within a single assessment

uses spreadsheet to automate calculations, including logical tests

relative risk calculated on a continuous scale of 1 - 100; avoids limited and subjective categories

still many assumptions, simplifications, need for knowledge

a good teaching tool for risk assessment

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リスク評価ツール: *表計算ソフト"Risk Ranger"*

コーデックス食品安全リスク評価の原則に基づく
（ただし、不確実性/変動性についての詳細はない）

多くの段階が個別に作られた

それらの比較影響が評価され、
単一評価の中でリスクが増減し得る

計算（論理テスト含む）を自動化するため、表計算ソフトを活用する

相対リスクは1-100の連続スケールで計算；
限定された主観的カテゴリーは使わない

多くの想定、単純化、知識欲求

リスク評価のよい教材

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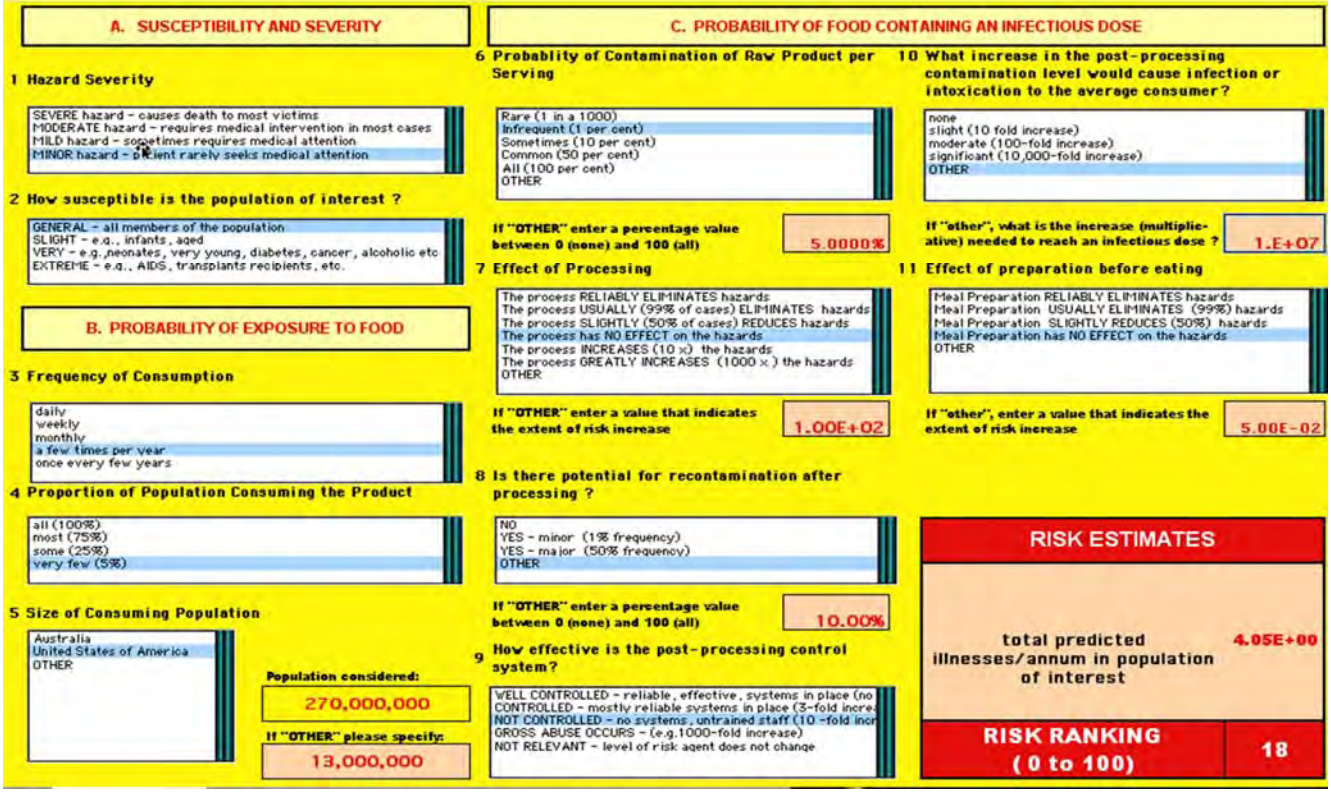

A. SUSCEPTIBILITY AND SEVERITY

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

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, transplants recipients, etc.

B. PROBABILITY OF EXPOSURE TO FOOD

3 Frequency of Consumption

daily
weekly
monthly
a few times per year
once every few years

4 Proportion of Population Consuming the Product

all (100%)
most (75%)
some (25%)
very few (5%)

5 Size of Consuming Population

Australia
United States of America
OTHER

Population considered: 270,000,000

If "OTHER" please specify: 13,000,000

C. PROBABILITY OF FOOD CONTAINING AN INFECTIOUS DOSE

6 Probablity 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

If "OTHER" enter a percentage value between 0 (none) and 100 (all) 5.0000%

7 Effect of Processing

The process RELIABLY ELIMINATES hazards
The process USUALLY (99% 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

If "OTHER" enter a value that indicates the extent of risk increase 1.00E+02

8 Is there potential for recontamination after processing ?

NO
YES - minor (1% frequency)
YES - major (50% frequency)
OTHER

If "OTHER" enter a percentage value between 0 (none) and 100 (all) 10.00%

9 How effective is the post-processing control system?

WELL CONTROLLED - reliable, effective, systems in place (no
CONTROLLED - mostly reliable systems in place (3-fold incre
NOT CONTROLLED - no systems, untrained staff (10 -fold incr
GROSS ABUSE OCCURS - (e.g.1000-fold increase)
NOT RELEVANT - level of risk agent does not change

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

If "other", what is the increase (multiplicative) needed to reach an infectious dose ? 1.E+07

11 Effect of preparation before eating

Meal Preparation RELIABLY ELIMINATES hazards
Meal Preparation USUALLY ELIMINATES (99%) hazards
Meal Preparation SLIGHTLY REDUCES (50%) hazards
Meal Preparation has NO EFFECT on the hazards
OTHER

If "other", enter a value that indicates the extent of risk increase 5.00E-02

RISK ESTIMATES

total predicted illnesses/annum in population of interest 4.05E+00

RISK RANKING (0 to 100) 18

free for download: http://www.foodsafetycentre.com.au/**riskranger**.php

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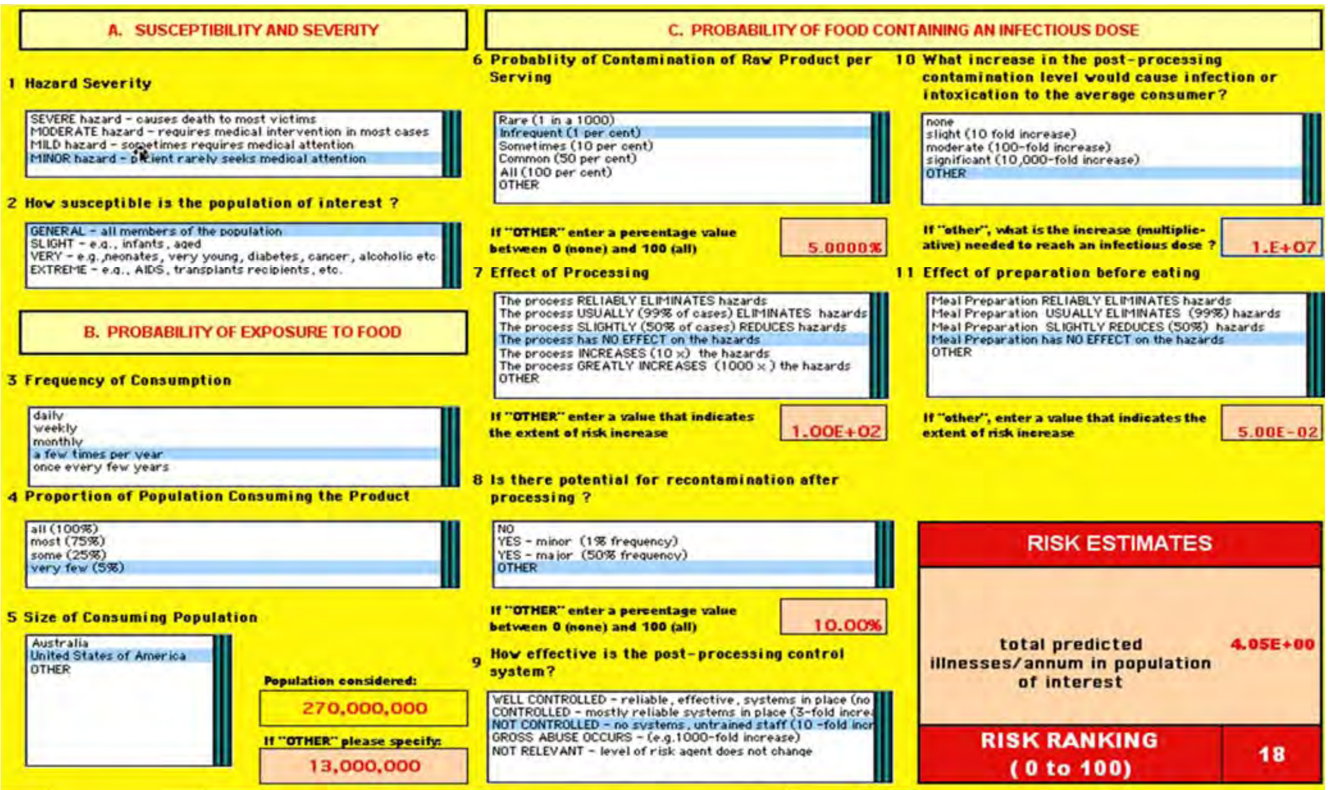

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RISK ESTIMATES

total predicted illnesses/annum in population of interest 4.05E+00

RISK RANKING (0 to 100) 18

free for download: http://www.foodsafetycentre.com.au/**riskranger**.php

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stochastic modeling

確率論的モデリング

risk assessment

will typically rely heavily on:

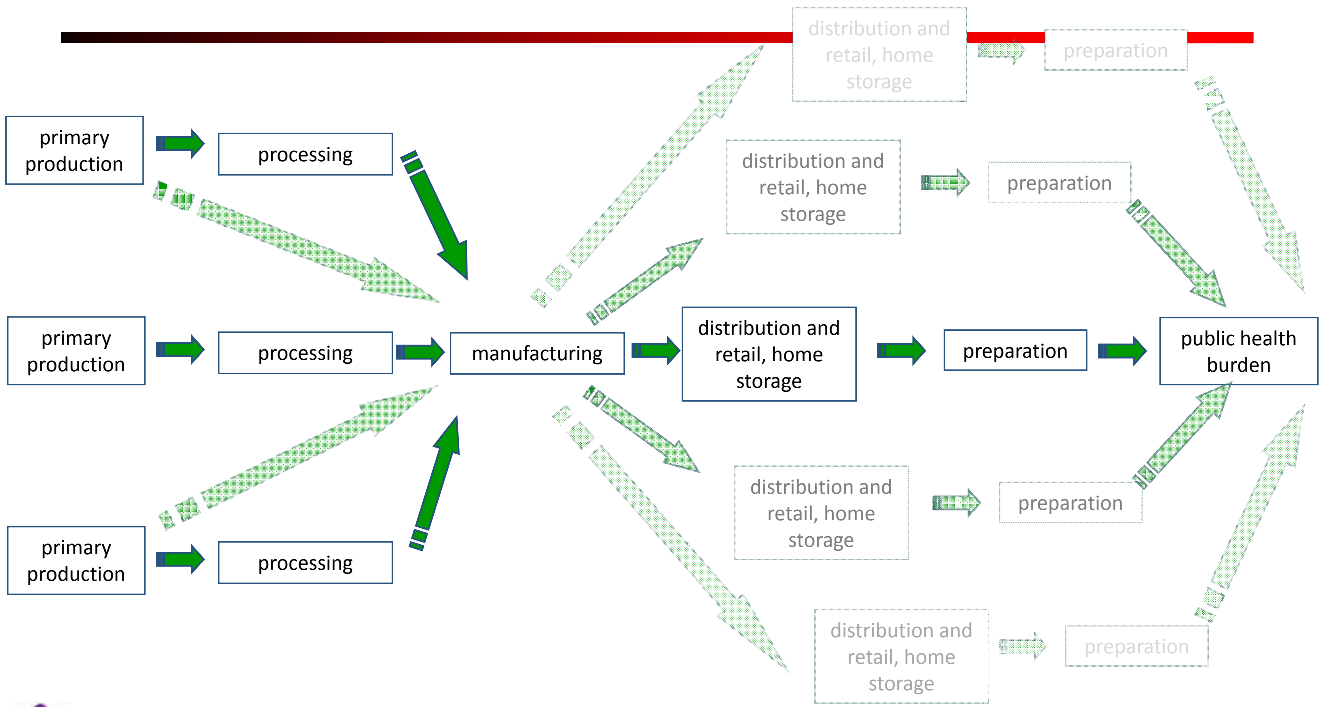
- mathematical modelling techniques
- computational power
- scientific knowledge and data
  - e.g., predictive microbiology models, markers of virulence, virulence mechanisms

リスク評価

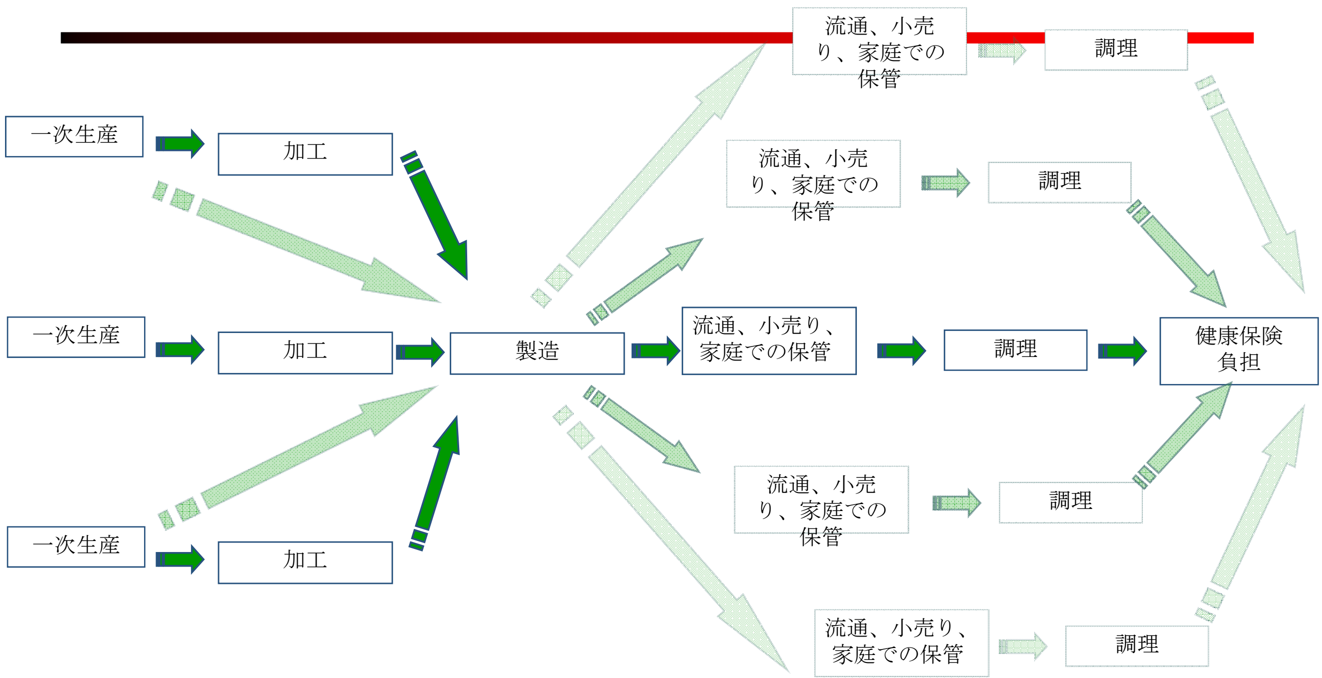
リスク評価は、次の点に依存するところが大きい:

- 数学的モデリング技法
- コンピュータの力
- 科学的知見とデータ
  - たとえば、予測微生物学モデル、毒性マーカー、毒性メカニズム

Complex/Variable Food Chains



複雑で変化しやすいフードチェーン



Risk Assessment

- now widely applied in all areas of business and formal decision processes

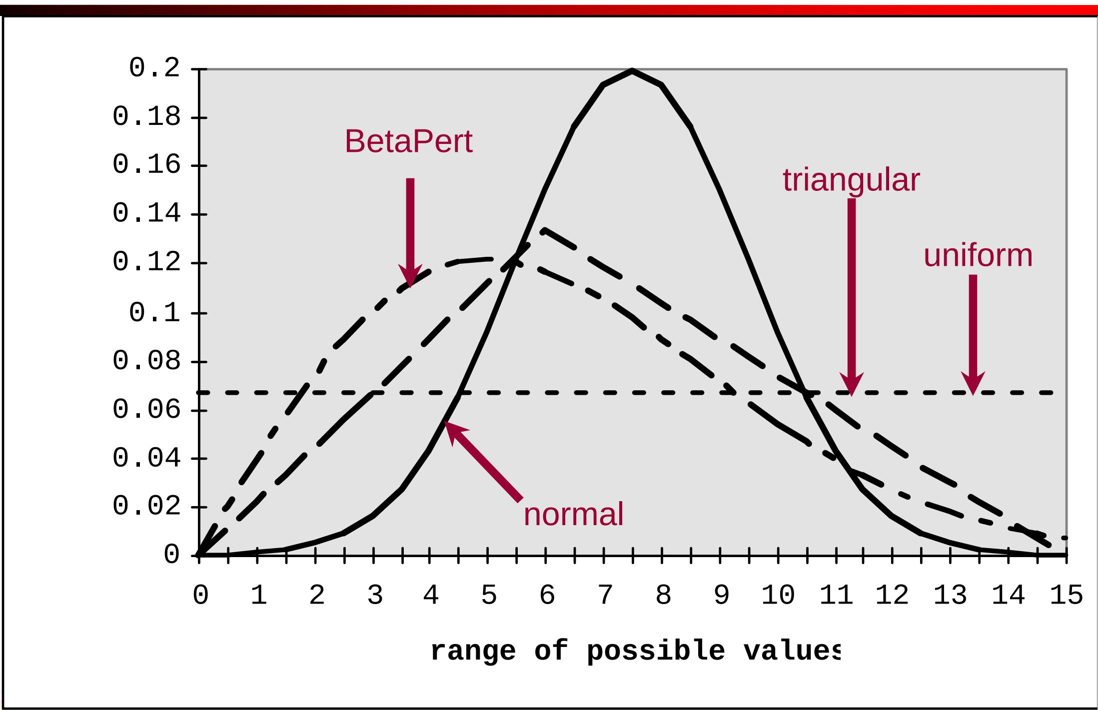
- usually highly mathematical - often using *stochastic simulation modelling* (relies on computer power to simulate all possible combinations of circumstances, as well as their likelihood)

リスク評価

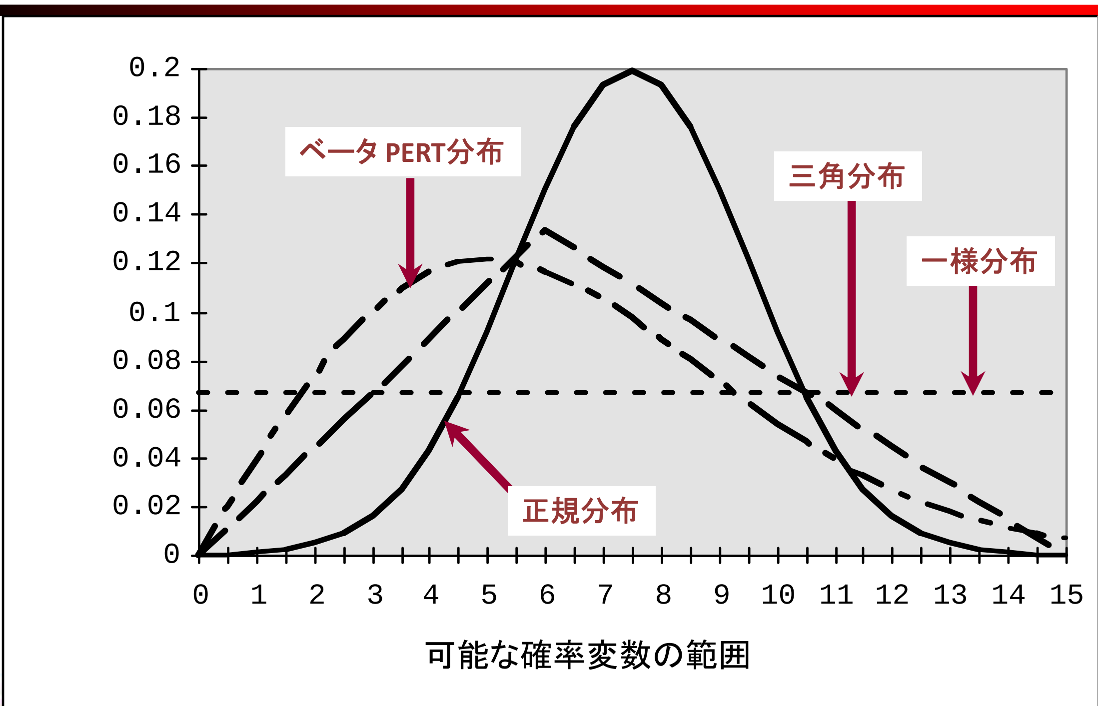
- 現在では、あらゆるビジネス分野と正式な意思決定プロセスに広く応用されている

- 通常はかなり数学的 – しばしば、確率論的シミュレーションモデリングを使用（考えられるあらゆる状況をシミュレーションするためにコンピュータの力に依存）

Distributions



分布



Approaches: *Monte Carlo simulation*

Use probability distributions for inputs

- Randomly "samples" from the specified distributions of each input in the model.
- Repeated sampling generates a distribution for the output
- effectively uses computing power to do hundreds of thousands of "what-if" examples to generate an overall representation of the risk under a wide range of circumstances

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アプローチ: モンテカルロシミュレーション

入力のために確率分布を適用

- モデルの中で、各入力の特定の分布からランダムに抽出する
- 反復抽出により出力の分布が形成される
- あらゆる広範な状況下でリスクの全体的な説明をするため、おびただしい仮説を処理するために、コンピュータの力を効果的に活用する

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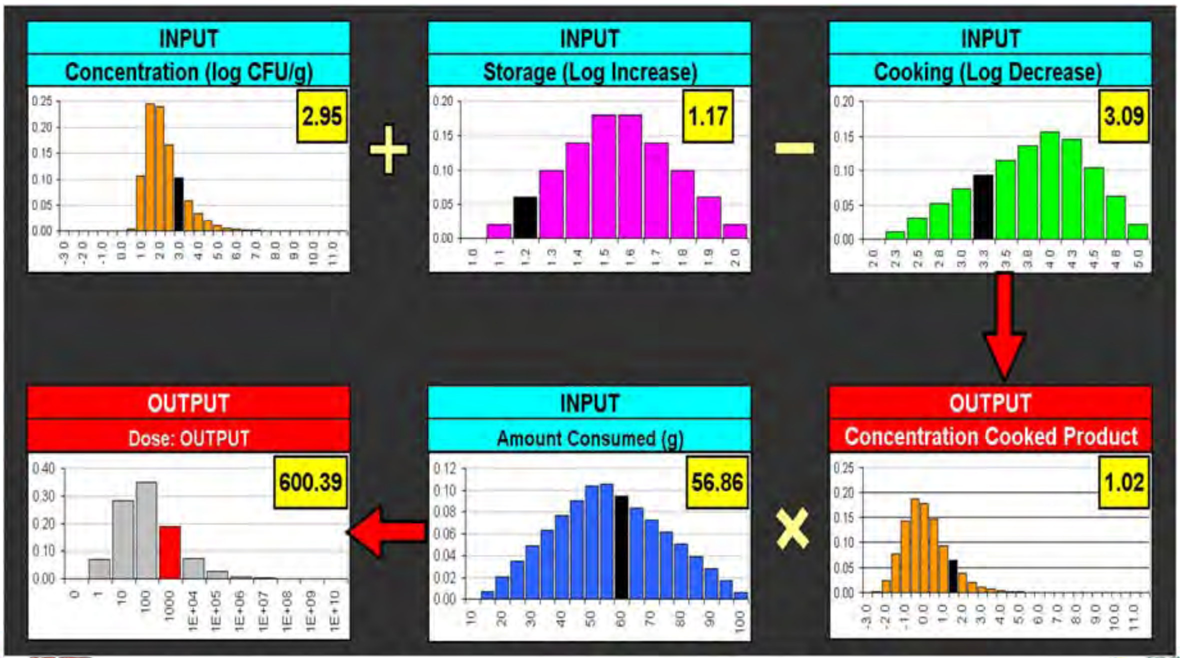
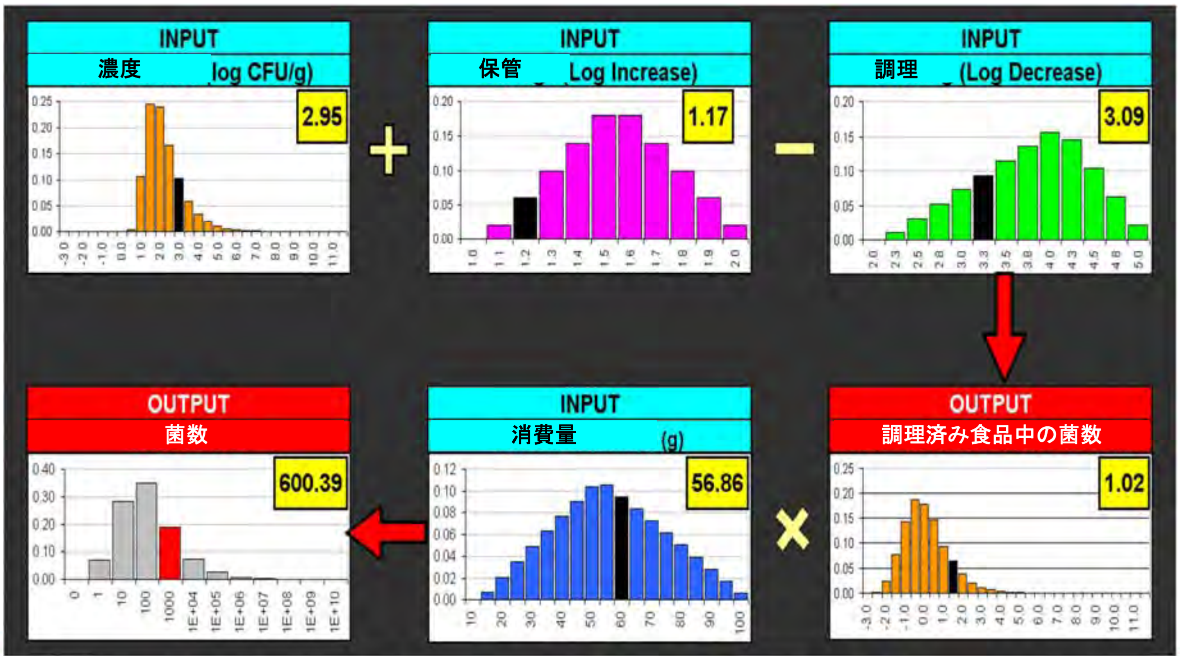
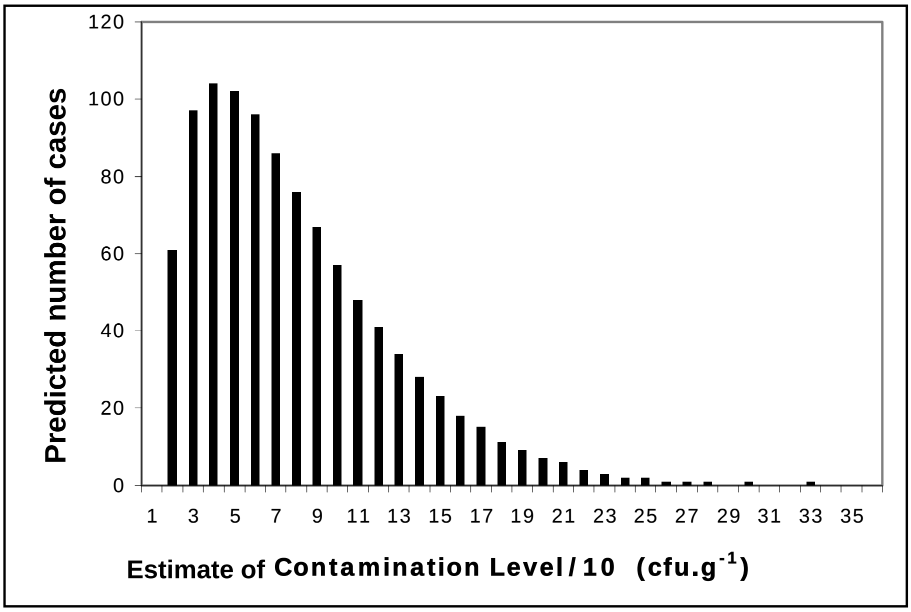
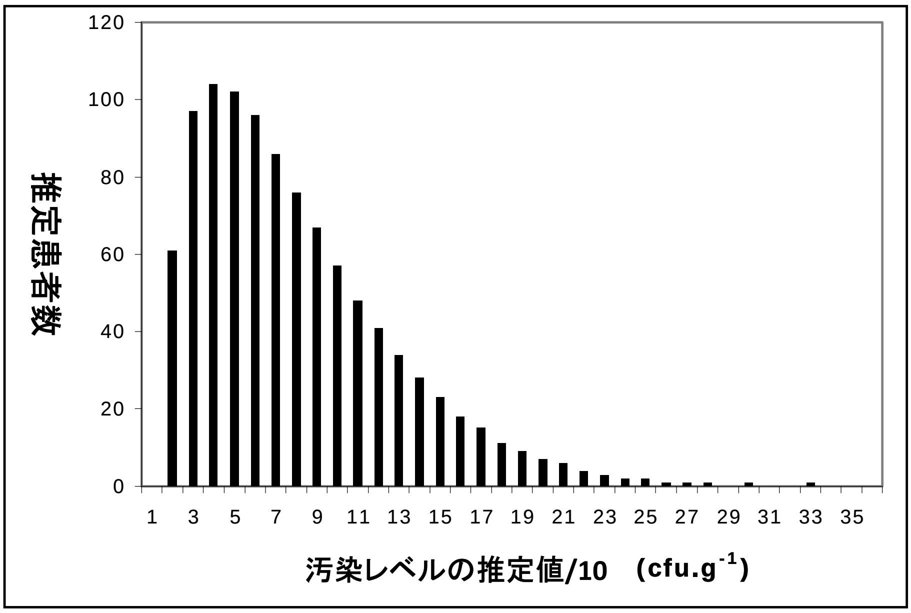

INPUT
Concentration (log CFU/g)
2.95
INPUT
Storage (Log Increase)
1.17
INPUT
Cooking (Log Decrease)
3.09
OUTPUT
Dose: OUTPUT
600.39
INPUT
Amount Consumed (g)
56.86
OUTPUT
Concentration Cooked Product
1.02


INPUT
濃度 log CFU/g)
2.95
INPUT
保管 Log Increase)
1.17
INPUT
調理 (Log Decrease)
3.09
OUTPUT
菌数
600.39
INPUT
消費量 (g)
56.86
OUTPUT
調理済み食品中の菌数
1.02

Stochastic modelling



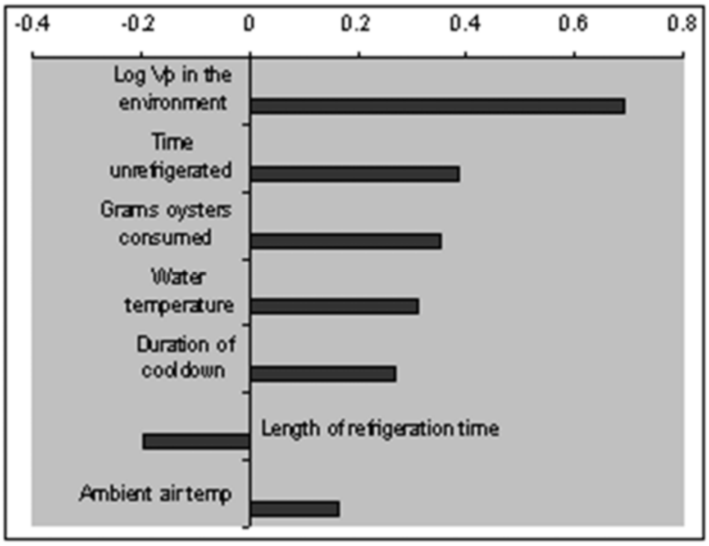
Stochastic modelling



Sensitivity analysis

Sensitivity analysis

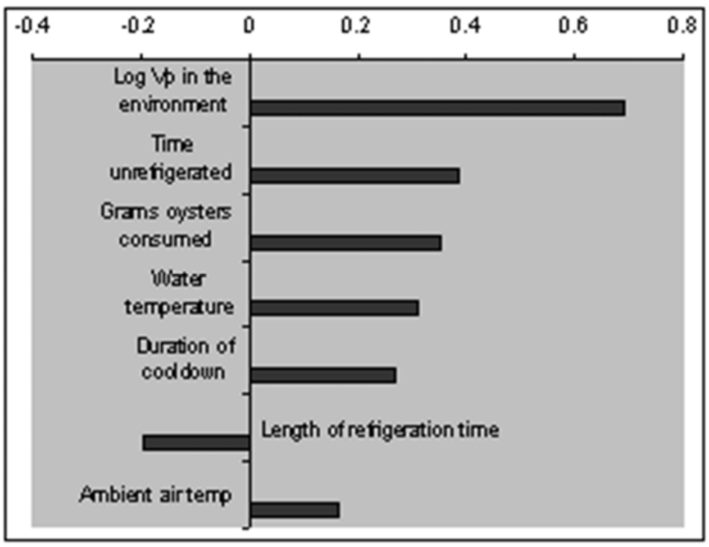
- inputs that have most influence on the predicted outcome are identified
- Tornado plots, as shown opposite, often used
- use this insight to identify potential risk management options



感度分析

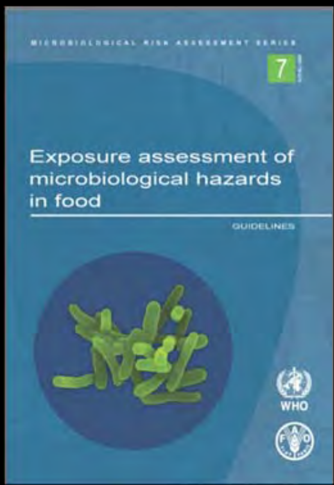
感度分析

- 予想される結果に最も影響を及ぼす入力が特定される
- トルネードプロットもしばしば使用される
- この分析結果を、将来的なリスク管理の選択肢を特定するために利用する



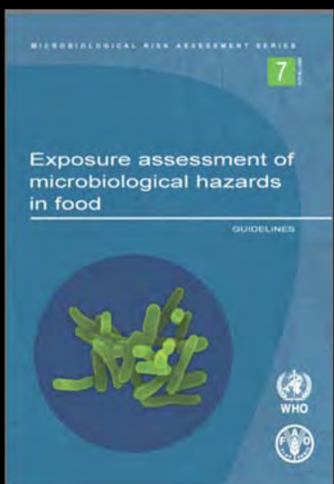
WHO/FAO MFSRA Guidelines

http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/guidelines1/en/



WHO/FAO 食品の微生物学的リスク評価のガイドライン

http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/guidelines1/en/



summary

まとめ

MFSRA: summary

- risk is a product of hazard, probability of exposure and severity of adverse effects
  - requires exposure assessment and
  - dose-response assessment
- needed to support risk management
- must be objective, science/data-based, ‘transparent’

食品の微生物学的リスク評価: まとめ

- リスクとはハザードの産物であり、暴露の確率と被害の重篤度である
  - 暴露評価、および
  - 用量-反応評価　　を必要とする
- リスク管理をサポートするために必要である
- 客観的で、科学/データに基づき、透明性が確保されていなければならない

MFSRA: summary

- internationally endorsed *principles* now established
- various methods available
  – stochastic simulation methods preferred if data is available
- many risk assessments/risk profiles available for *L. monocytogenies* in ready-to-eat foods

食品の微生物学的リスク評価: まとめ

- 国際的に承認された原則が制定された
- 有効な種々の方法
  – 確率論的シミュレーション手法（データが入手できれば）
- Ready-to-eat食品における、LMのための多数のリスク評価/リスクプロファイル

thank you for your attention,
and questions

ご静聴ありがとうございました。