資料


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and the Environment
Microbial risk assessment in the Netherlands and internationally
Prof. Arie Havelaar, RIVM, Bilthoven, NL
Japan Food Safety Commission
Tokyo, 17 October 2008


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オランダ及び国際的な
微生物のリスク評価
アリー・ハベラー博士，国立健康環境研究所，オランダ
食品安全委員会
2008年10月17日　東京
食品安全委員会事務局仮訳

Outline

- Organization of food safety risk assessment in Europe
  - The Netherlands
  - European Commission – EFSA
  - Risk assessment by EFSA
- Integrated approaches to support food safety decision making
  - Priority setting: disease burden and cost of illness
  - WHO Foodborne Epidemiology Reference Group
  - Risk assessment and risk management of Campylobacter on poultry meat in the Netherlands

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概要

- 欧州における食品安全リスク評価のための機関
  - オランダ
  - 欧州委員会 – 欧州食品安全機関（EFSA）
  - EFSA によるリスク評価
- 食の安全に関する意思決定を支える統合的アプローチ
  - 優先順位の設定：疾病負担および疾病によって生じる費用
  - WHO 食品由来疾患疫学調査グループ
  - オランダでの食鳥肉におけるカンピロバクターのリスク評価およびリスク管理

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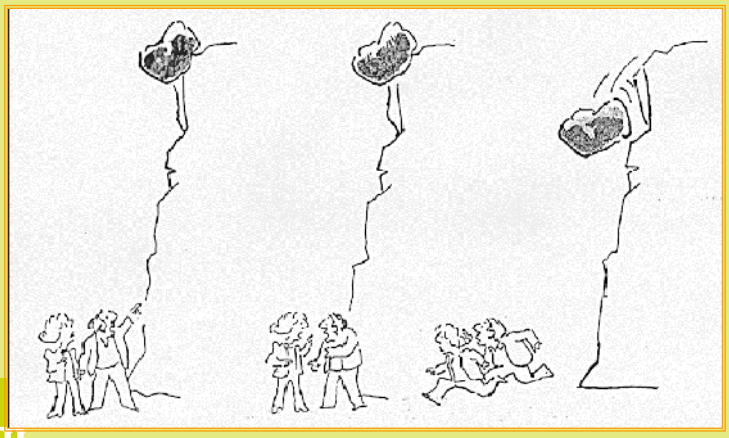
Risk analysis

A process consisting of 3 components *(WHO/FAO, 1995)*:

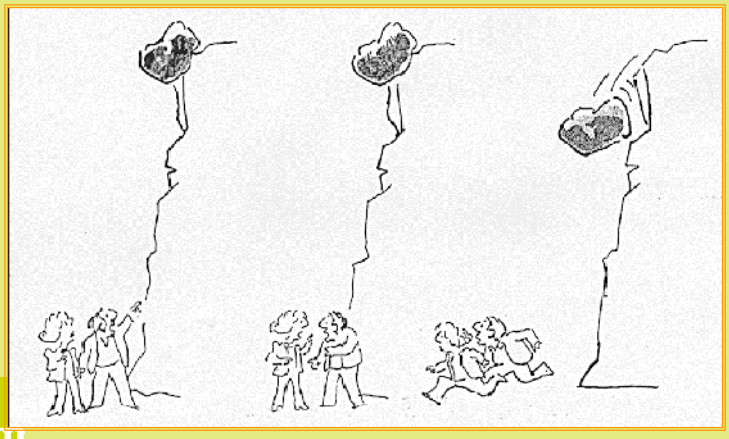
Risk assessment Risk communication Risk management



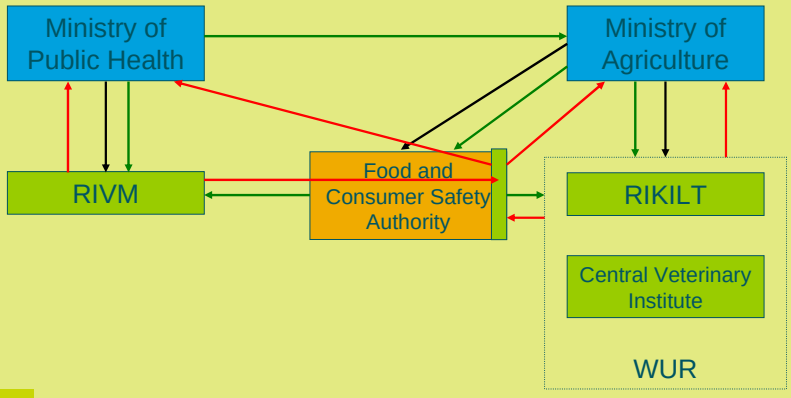
リスク分析

プロセスは3要素からなる *(WHO/FAO, 1995)*:

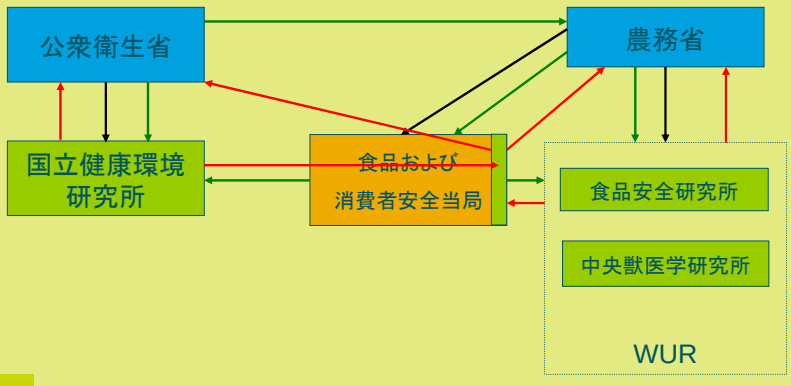
リスク評価 リスクコミュニケーション リスク管理



Food safety risk analysis in the Netherlands



オランダにおける食品の安全性に関するリスク分析



RIVM is scientifically independent

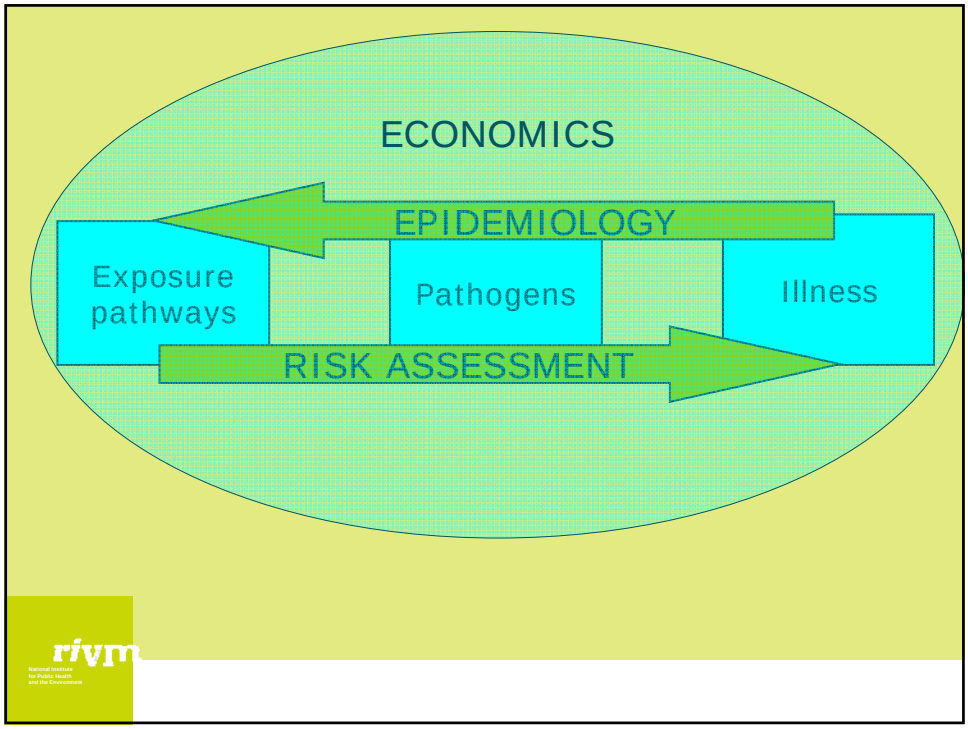
- Law on RIVM (21 October 1996)

  "Our Minister does not give instruction to the director-general (of RIVM) with regard to the methods according to which the research is carried out and how results are reported"

国立健康環境研究所（RIVM）は科学的に独立した機関である

- 国立健康環境研究所に関する法律 (1996年10月21日)

  「大臣は（RIVM）の局長に対して、調査の手法や結果の報告方法に関して、いかなる指示も与えない。」


ECONOMICS
EPIDEMIOLOGY
Exposure pathways
Pathogens
Illness
RISK ASSESSMENT
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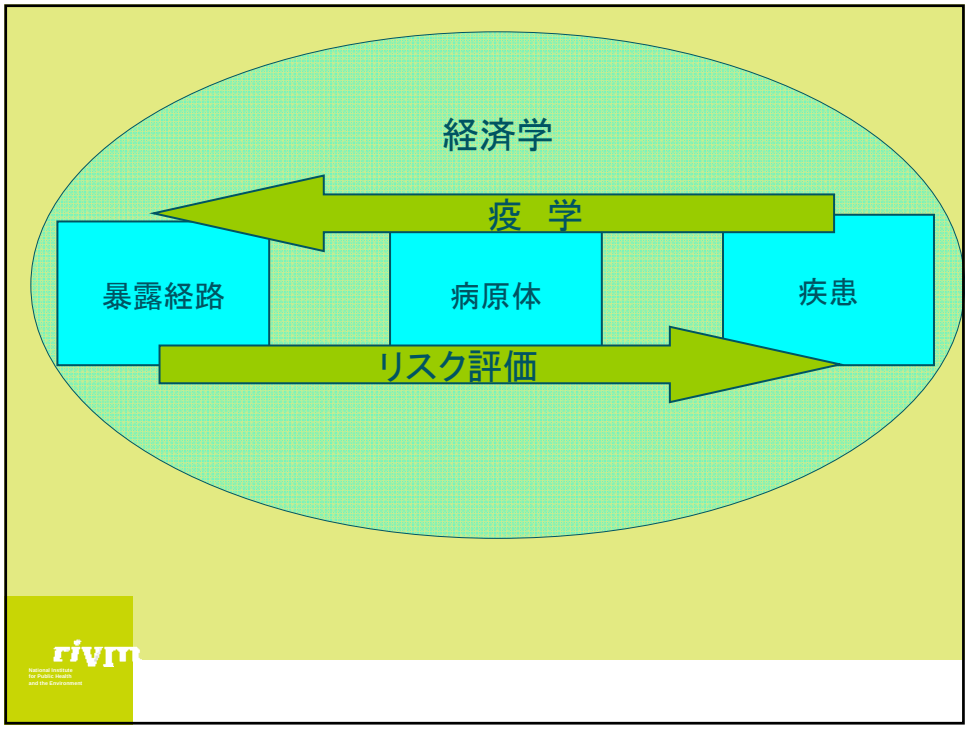
経済学
疫　学
暴露経路
病原体
疾患
リスク評価
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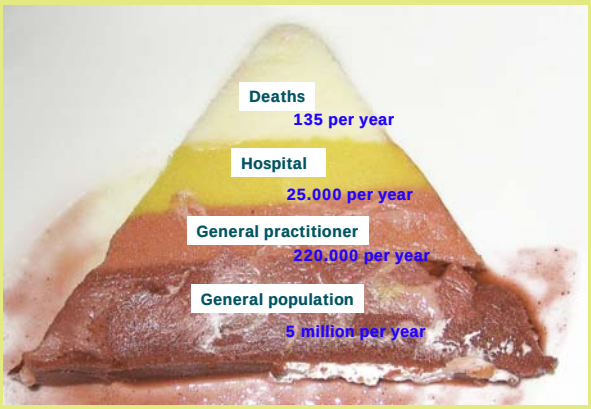
Surveillance pyramid for gastro-enteritis in the Netherlands



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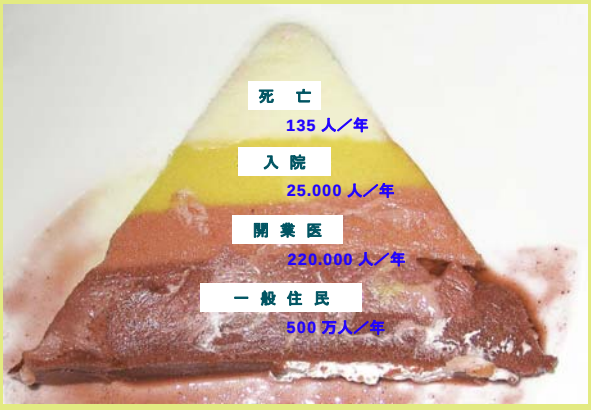
オランダにおける胃腸炎の サーベイランスピラミッド



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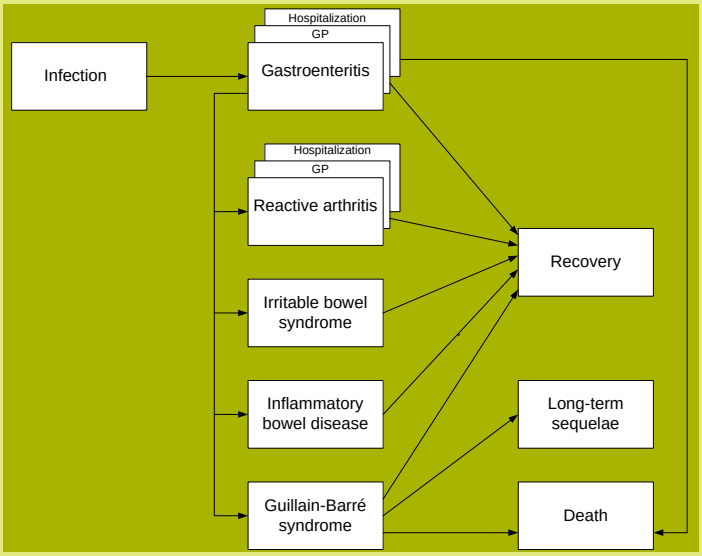
What are the priorities?

Outcome	Norovirus	Rotavirus	Campylo-bacter	Salmonella
Gastro-enteritis	470,000	190,000	59,000	35,000
GE – visit to GP	10,000	11,000	14,000	5,400
GE – hospital	1,000	3,000	570	640
GE – death	5	1	25	39
Reactive arthrititis	-	-	1,000	460
Guillain-Barré s	-	-	59	-
Infl. Bowel Disease	-	-	22	9

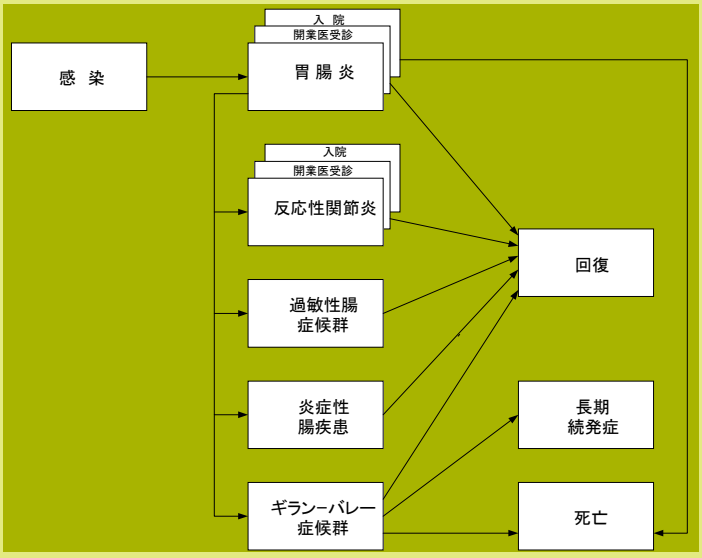
何を優先すべきか

転　帰	ノロウイルス	ロタウイルス	カンピロバクター	サルモネラ
胃腸炎	470,000	190,000	59,000	35,000
胃腸炎－開業医受診	10,000	11,000	14,000	5,400
胃腸炎ー病院受診	1,000	3,000	570	640
胃腸炎−死亡	5	1	25	39
反応性関節炎	-	-	1,000	460
ギラン−バレー症候群	-	-	59	-
炎症性腸疾患	-	-	22	9

Outcome tree for *Campylobacter* spp.



カンピロバクター属による感染の転帰



YLD - Years Lived with Disability

YLD = Incidence of cases/sequelae
x
average duration
x
disability weight

DALY = YLL + YLD

YLD - 障害による損失余命年数

YLD = 発症例／続発症
×
平均罹病期間
×
障害の重みづけ(傷害の重篤度)

障害調整生命年（DALY）= YLL + YLD

YLL - Years of Life Lost (mortality)

YLL_x = Number of deaths
x
standard years of life lost

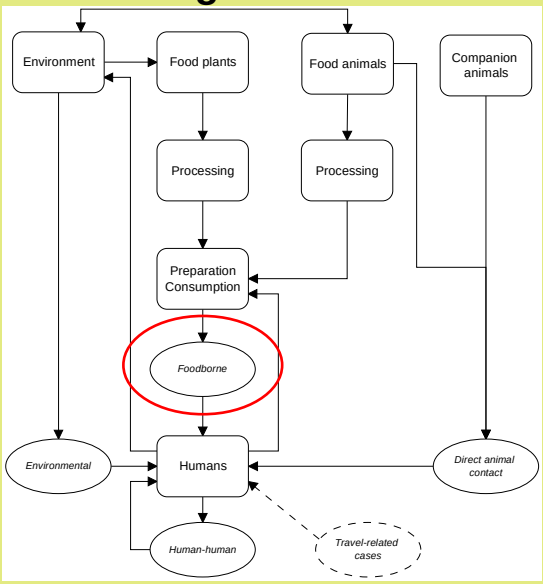
DALY = YLL + YLD

YLL - 早期死亡による余命損失年数

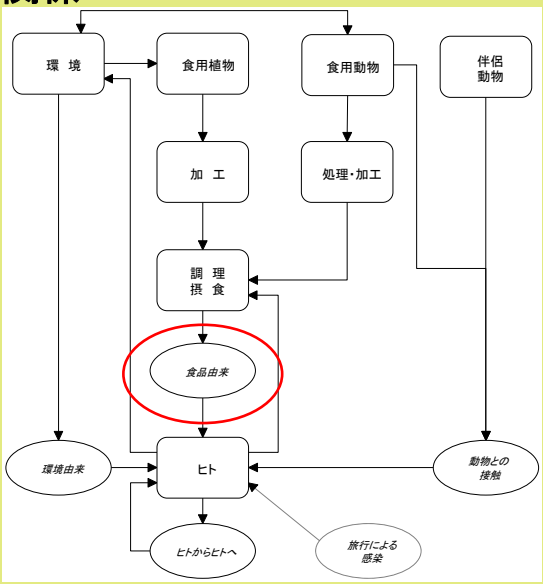
YLL_x = 死亡例数
×
標準損失余命年数

DALY = YLL + YLD

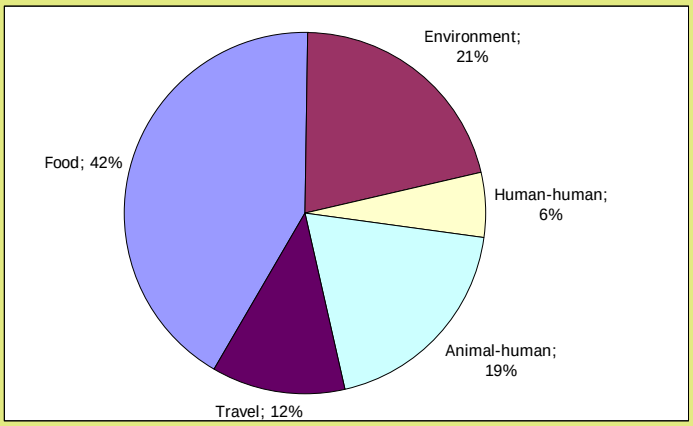
Attribution diagram



因果関係

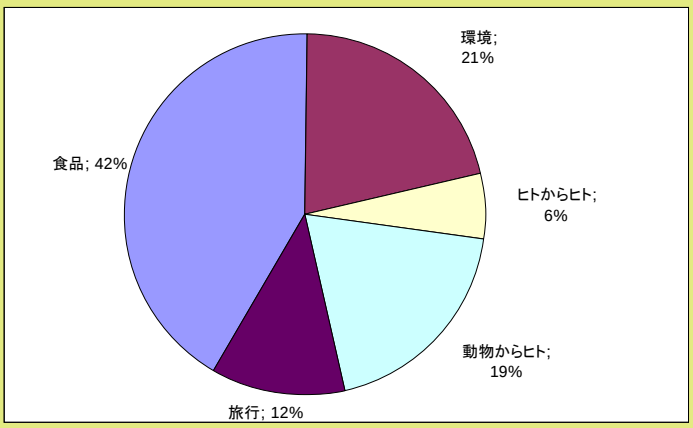


Main exposure pathways for Campylobacter



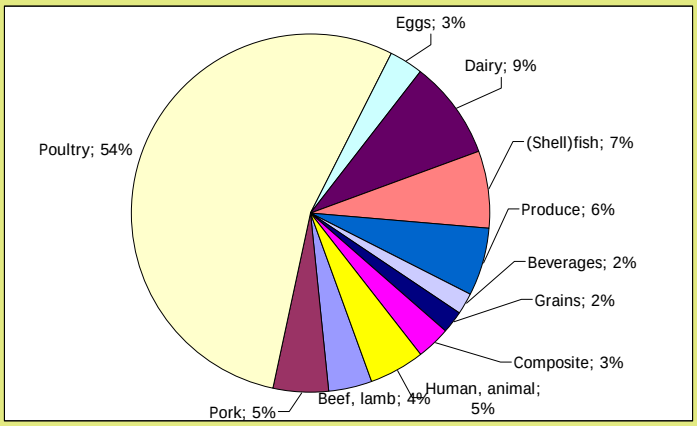
Expert survey; Havelaar et al. Foodborne Path Dis 2008

カンピロバクターの主な暴露経路



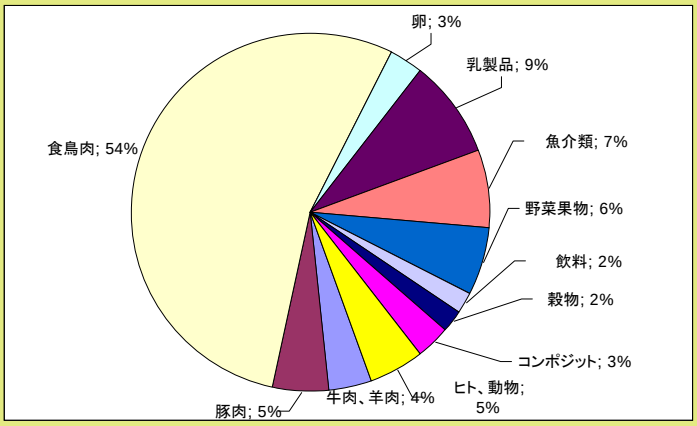
専門家調査、Havelaar et al. Foodborne Path Dis 2008

Food pathways for Campylobacter



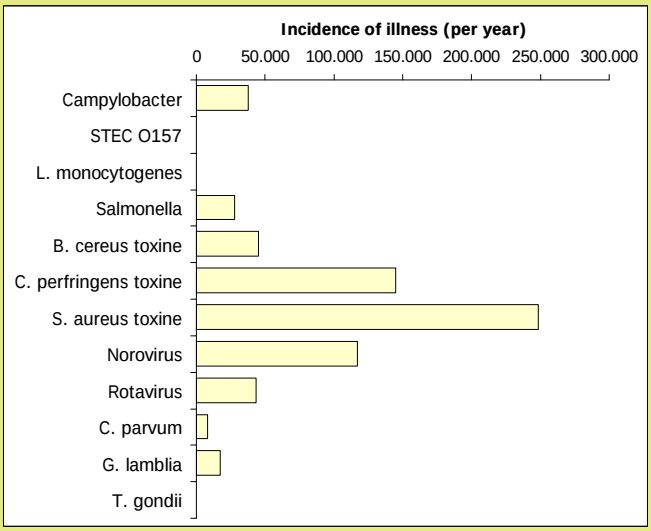
Expert survey; Havelaar et al. Foodborne Path Dis 2008

カンピロバクターの食品媒介経路

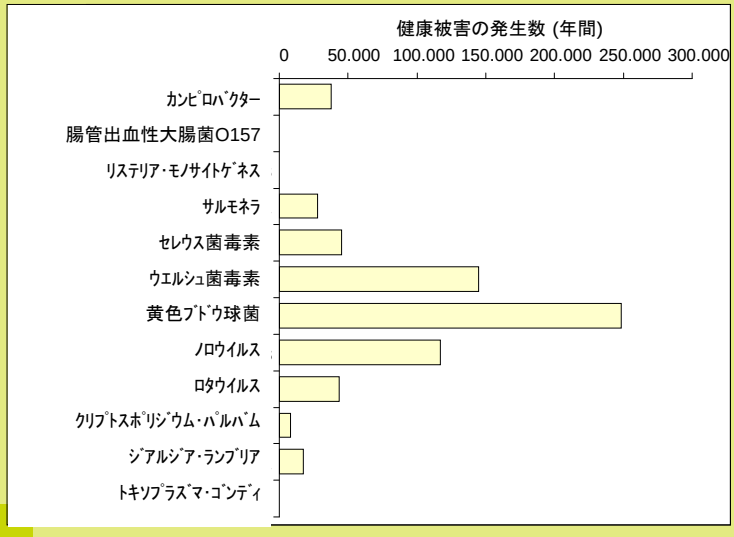


専門家調査、Havelaar et al. Foodborne Path Dis 2008

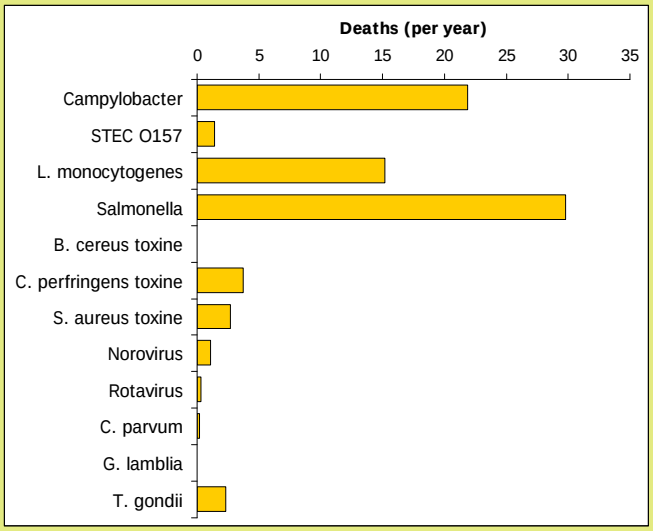
Illness by contaminated food



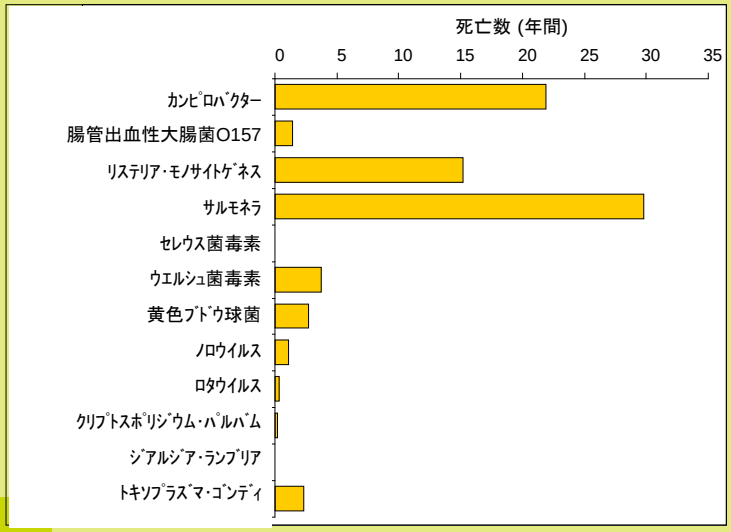
汚染食品による健康被害



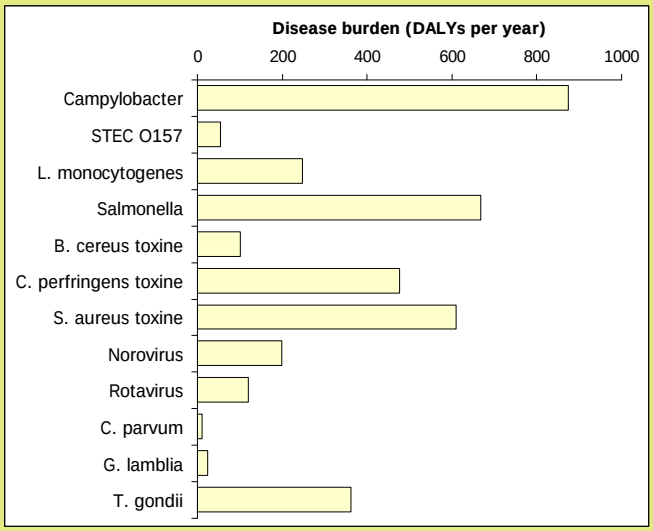
Mortality by contaminated food



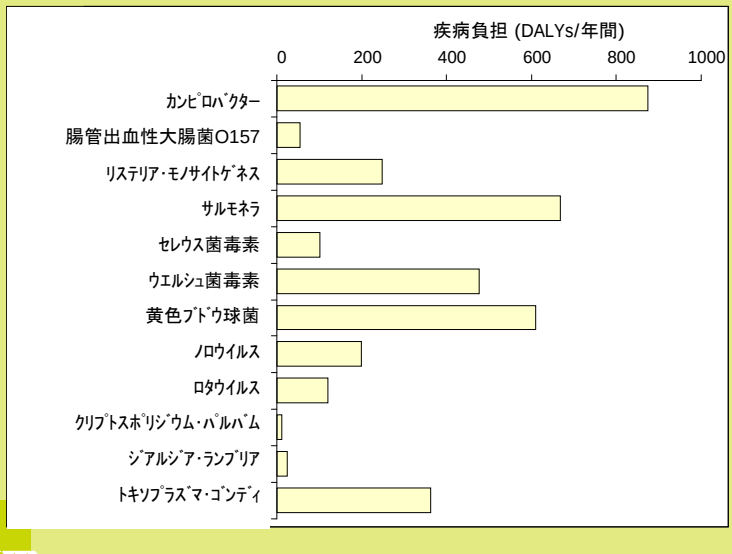
汚染食品による死亡



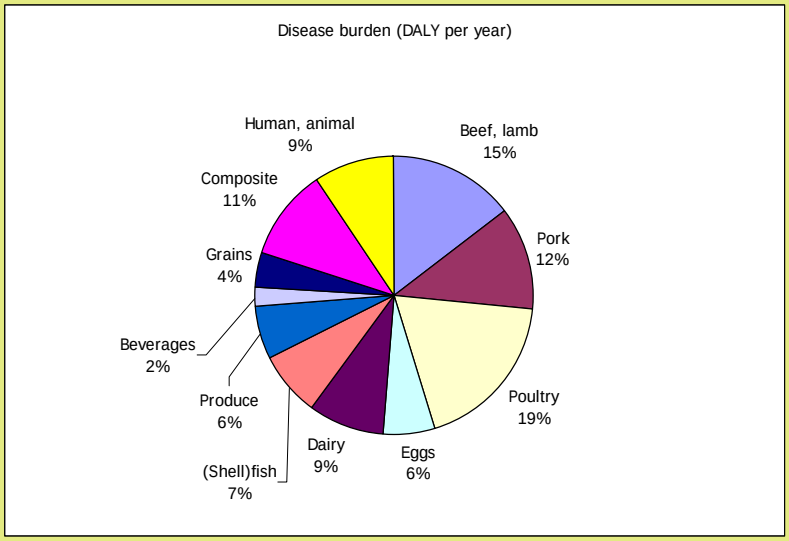
Disease burden by contaminated food



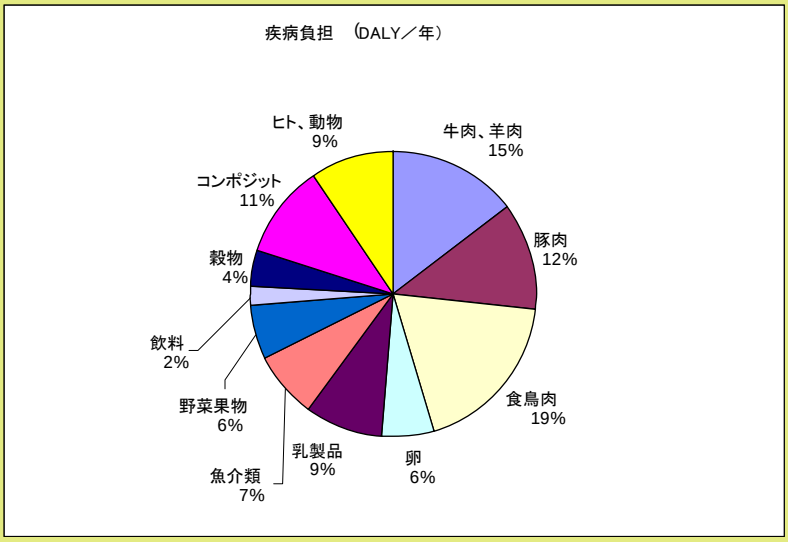
汚染食品による疾病負担

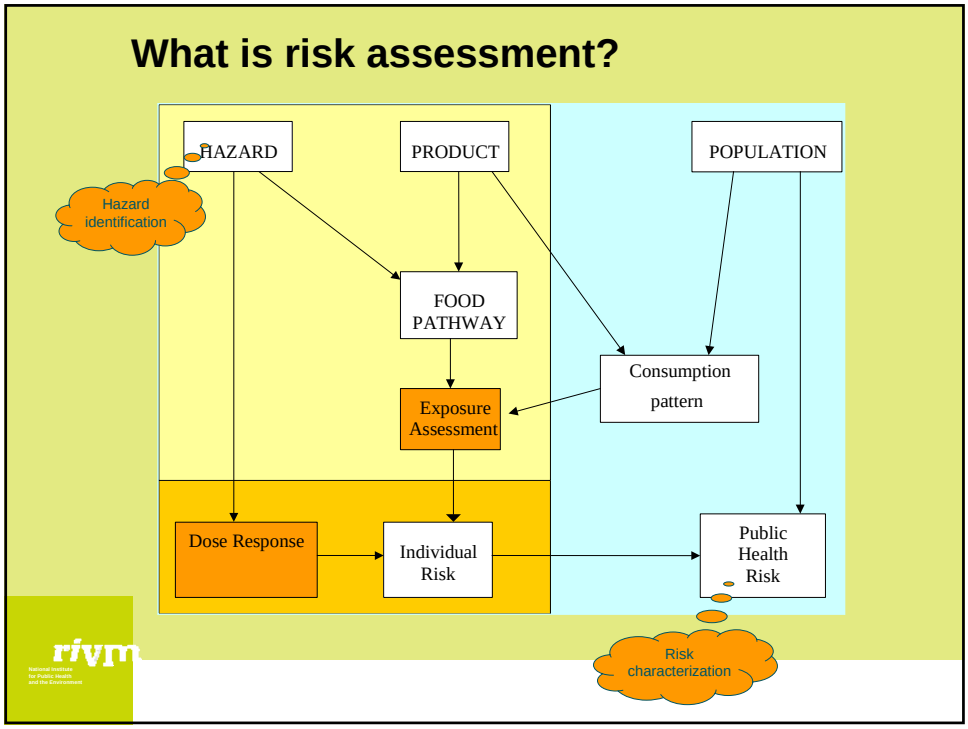


Disease burden per food group



食品群別の疾病負担




What is risk assessment?
HAZARD
PRODUCT
POPULATION
Hazard identification
FOOD PATHWAY
Consumption pattern
Exposure Assessment
Dose Response
Individual Risk
Public Health Risk
Risk characterization
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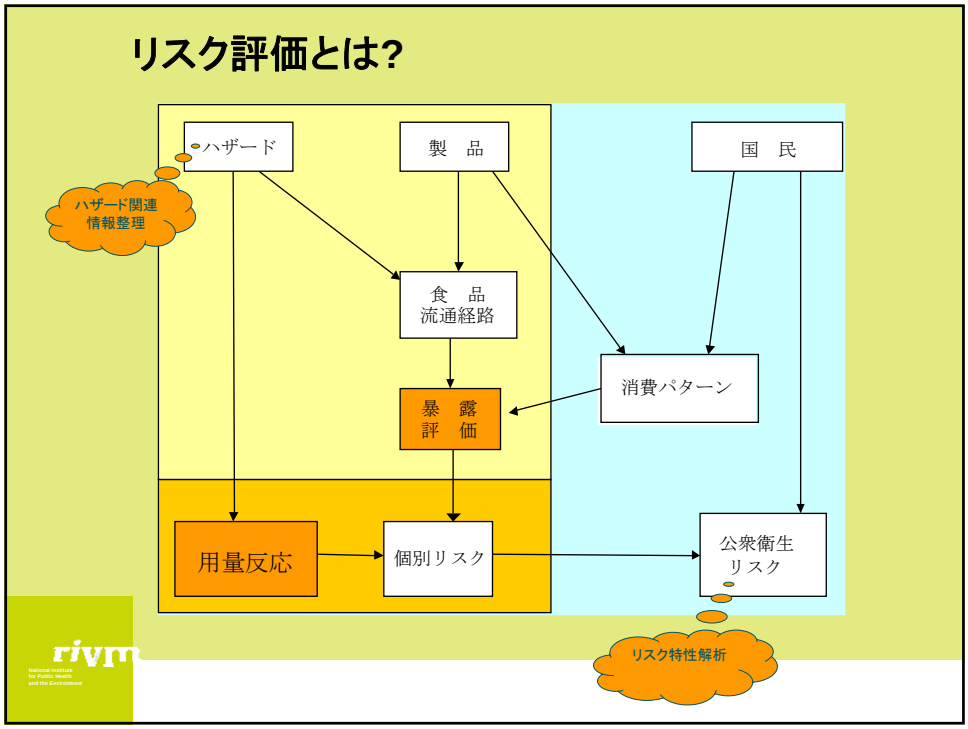
リスク評価とは?
ハザード
製　品
国　民
ハザード関連情報整理
食　品流通経路
消費パターン
暴　露評　価
用量反応
個別リスク
公衆衛生リスク
リスク特性解析
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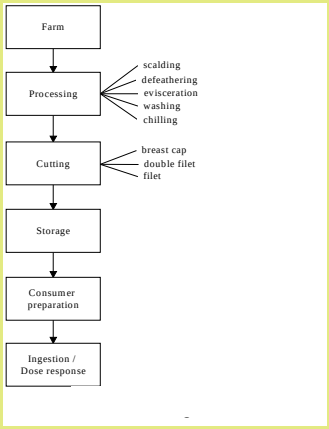
CARMA Farm to Fork risk model for Campylobacter in the broiler meat chain



- Model transmission of Campylobacter through the food chain (prevalence and numbers)
- Assess consumer exposure and compare alternative scenarios due to interventions
- Combine with dose response models to estimate risk reduction due to intervention
- Combine with epidemiological data to estimate reduced incidence of illness due to interventions

Nauta et al., Risk Anal 2007;27:845-861

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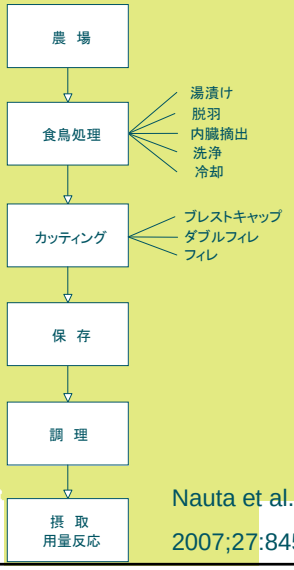
CAMPYLOBACTER RISK MANAGEMENT AND ASSESSMENT CARMA

CARMA（カンピロバクターのリスク管理および評価）農場から食卓に至るブロイラー肉のフードチェーンにおけるカンピロバクターリスクモデル



- フードチェーン全体にわたるカンピロバクター伝播モデルを構築（保菌率及び保菌数）
- 消費者の暴露を評価し、介入による各種シナリオを比較
- 用量反応モデルを適用し、介入によるリスク低減を推定
- 疫学データを適用し、介入による発症率の低下を推定

Nauta et al., Risk Anal 2007;27:845-861

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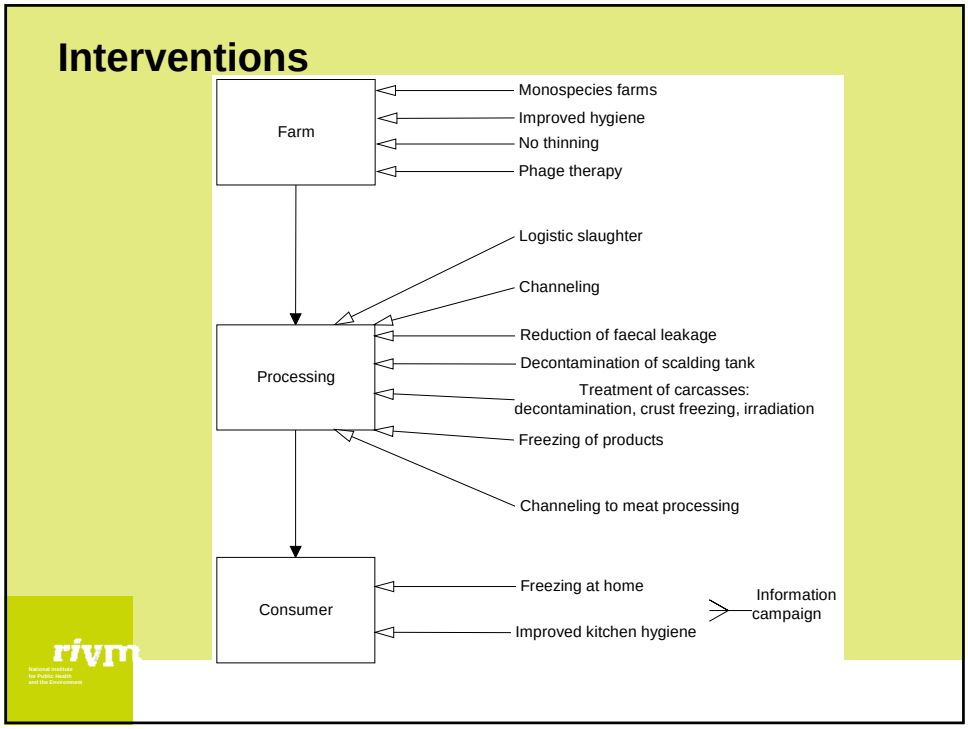
CAMPYLOBACTER RISK MANAGEMENT AND ASSESSMENT CARMA


Interventions
Farm
Monospecies farms
Improved hygiene
No thinning
Phage therapy
Logistic slaughter
Channeling
Processing
Reduction of faecal leakage
Decontamination of scalding tank
Treatment of carcasses:
decontamination, crust freezing, irradiation
Freezing of products
Channeling to meat processing
Consumer
Freezing at home
Improved kitchen hygiene
Information
campaign
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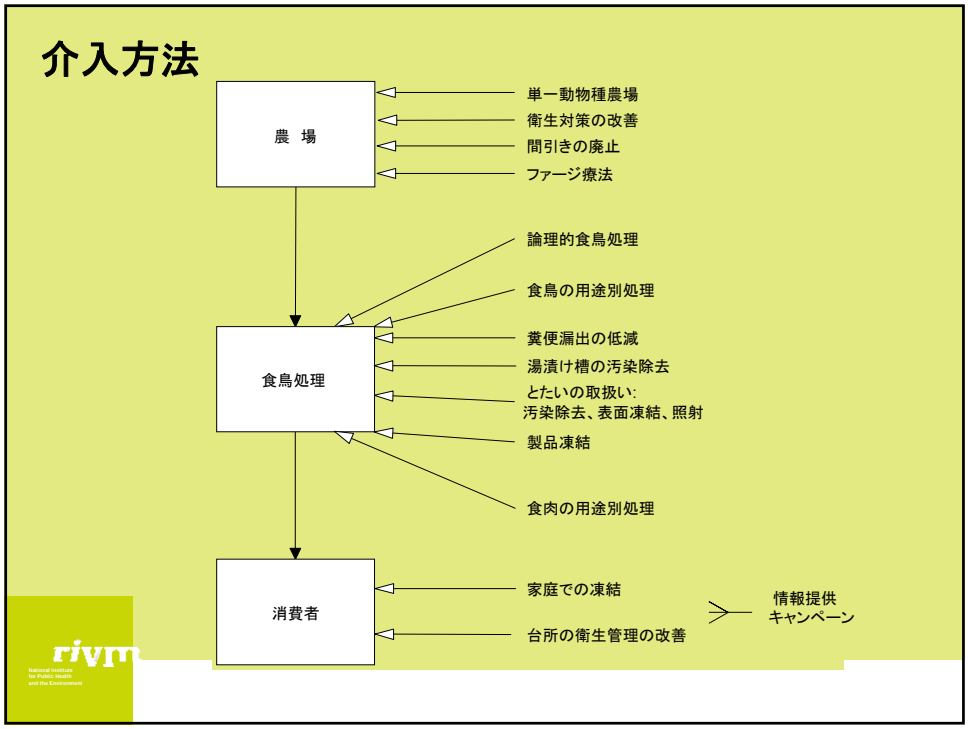
介入方法
農　場
単一動物種農場
衛生対策の改善
間引きの廃止
ファージ療法
論理的食鳥処理
食鳥の用途別処理
食鳥処理
糞便漏出の低減
湯漬け槽の汚染除去
とたいの取扱い:
汚染除去、表面凍結、照射
製品凍結
食肉の用途別処理
消費者
家庭での凍結
台所の衛生管理の改善
情報提供
キャンペーン
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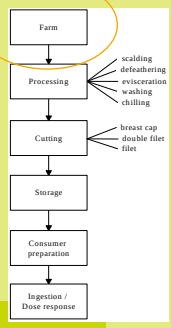
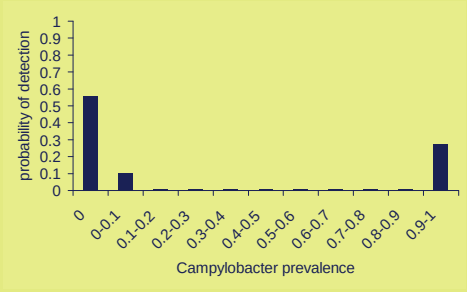
Farm

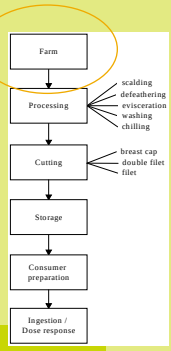
- Model for dynamics of infection within a flock (Katsma et al. Risk Anal. 2007;27(4)863-876.)
- Results:
  - Distribution of animal prevalence in flocks

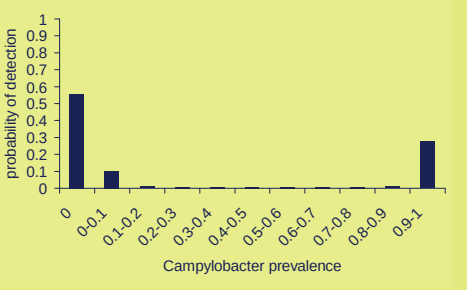




農場

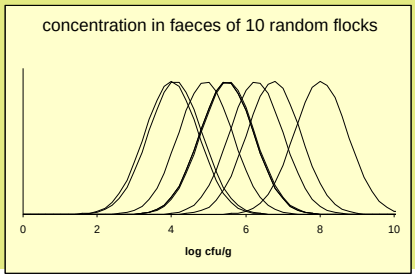
- 鶏群内感染に関する動態把握モデル (Katsma et al. Risk Anal. 2007;27(4)863-876.)
- 結果:
  - 鶏群内の感染率分布





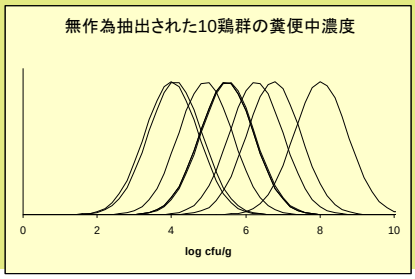
Input data for slaughter model

- Concentration in faeces leaking during processing
  - variable within flocks: mean 6.0 , sd 0.73 log cfu/g
    and between flocks: sd 1.52
- Contamination of bird exterior
  - variable within flocks: mean 7.30 , sd 0.56 log cfu/bird
    and between flocks: sd 0.83



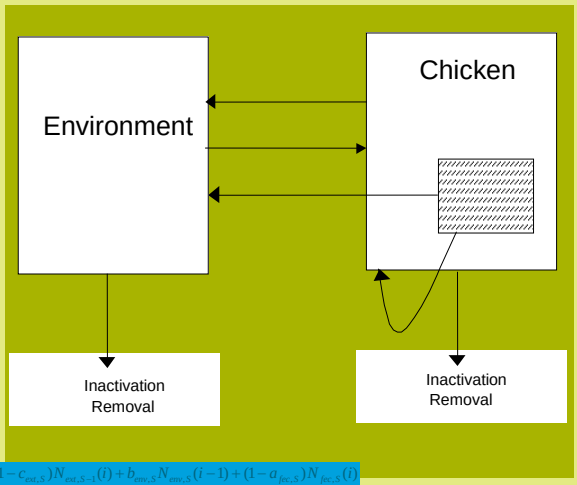
食鳥処理モデルの入力データ

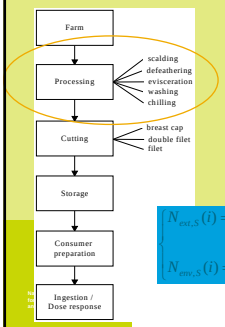
- 処理中の漏出糞便中の濃度
  - 鶏群内の変動: 平均 6.0 , 標準偏差 0.73 log cfu/g
    鶏群間の変動: 標準偏差 1.52
- 食鳥体表汚染
  - 鶏群内の変動: 平均 7.30 ,標準偏差 0.56 log cfu/bird
    鶏群間の変動: 標準偏差 0.83



Processing: non-linear dynamics

cross - contamination, inactivation and removal



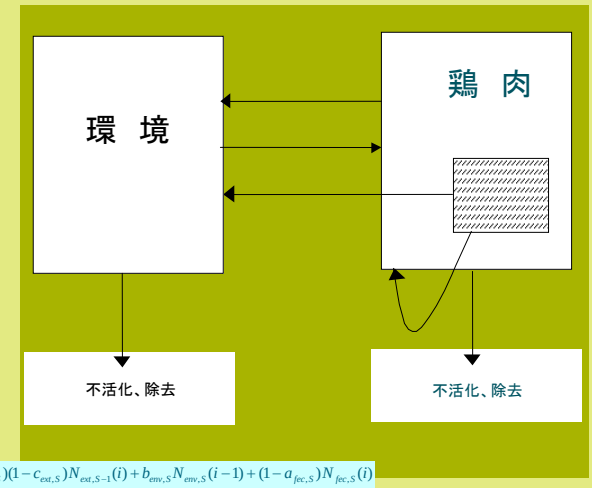


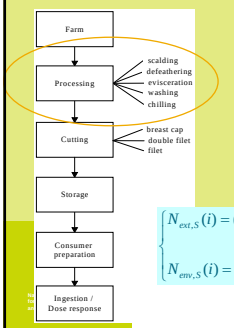
$$\begin{cases} N_{ext,S}(i) = (1-a_{ext,S})(1-c_{ext,S})N_{ext,S-1}(i) + b_{env,S}N_{env,S}(i-1) + (1-a_{fec,S})N_{fec,S}(i) \\ N_{env,S}(i) = a_{ext,S}N_{ext,S-1}(i) + (1-b_{env,S})(1-c_{env,S})N_{env,S}(i-1) + a_{fec,S}N_{fec,S}(i) \end{cases}$$

Nauta et al. Risk Analysis 2005;25(1): 85-98

食鳥処理: 非線形ダイナミクス

交差汚染、不活化と除去

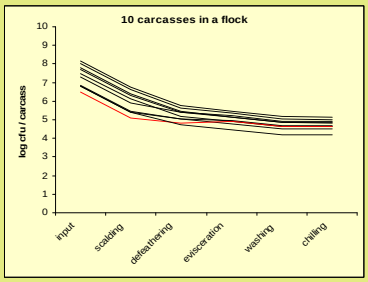


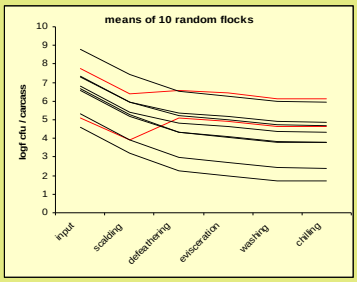


$$\begin{cases} N_{ext,S}(i) = (1-a_{ext,S})(1-c_{ext,S})N_{ext,S-1}(i) + b_{env,S}N_{env,S}(i-1) + (1-a_{fec,S})N_{fec,S}(i) \\ N_{env,S}(i) = a_{ext,S}N_{ext,S-1}(i) + (1-b_{env,S})(1-c_{env,S})N_{env,S}(i-1) + a_{fec,S}N_{fec,S}(i) \end{cases}$$

Nauta et al. Risk Analysis 2005;25(1): 85-98

Variability between (products from) different flocks is larger than variability within flocks





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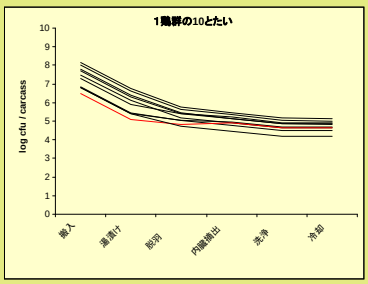
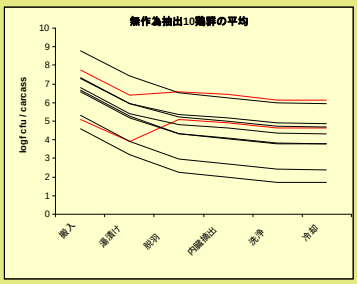
異なる鶏群由来の製品間のばらつきは、鶏群内におけるばらつきより大きい





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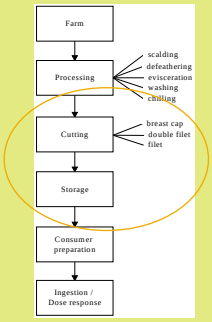
Cutting and storage



- Cutting carcasses to breast fillets
  - partitioning to smaller food unit:
    decrease in cfu per unit
  - cross-contamination:
    decrease in cfu per unit and
    decrease in variability between products
  - Storage
  - Inactivation: limited survival of *Campylobacter* during chilled storage:
    decrease in cfu per fillet

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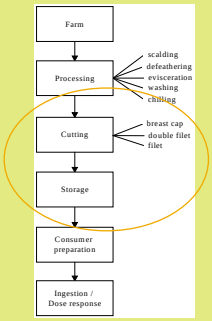
カッティングと保存



- とたいからササミへ
  - より小さな食品単位への分割:
    食品単位当たりの菌量(cfu)の減少
  - 交差汚染:
    食品単位当たりの菌量(cfu)の減少　と
    製品間のばらつきの減少
  - 保存
  - 不活化: 冷蔵保存中のカンピロバクター生残の制限:
    ササミ当たりの菌量(cfu)の減少

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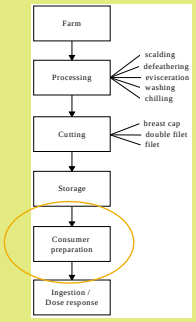
Consumer phase model

Quantifying the cross contamination to salad

- Transfers (*microbiology*):
  - chicken to hand
  - handwashing (?)
  - hand to salad
- Frequency of handling *(observations)*
  - eating chicken breast with salad
  - washing hands, board, salad
  - use other board
  - chicken cut before salad
- Consumption data

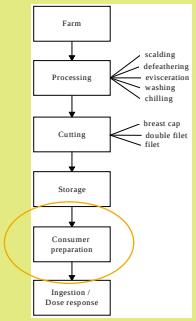


Mylius et al. Risk Anal 2007;27:803-813.

消費者段階モデル

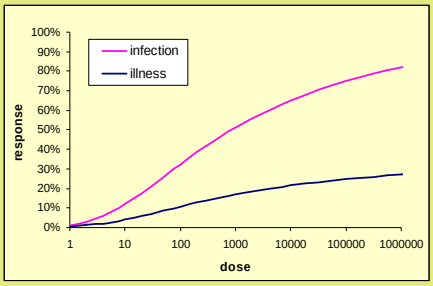
サラダへの交差汚染の定量化

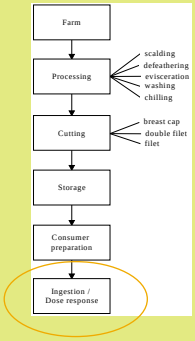
- 移行 (*微生物学*):
  - 鶏肉から手指へ
  - 手洗い (?)
  - 手指からサラダへ
- 取扱い頻度 *(観察)*
  - サラダとともに鶏肉を喫食
  - 手指、まな板、サラダ野菜の洗浄
  - まな板の使い分け
  - サラダの調理前に鶏肉を分割
- 消費データ(喫食量)



Mylius et al. Risk Anal 2007;27:803-813.

Dose Response

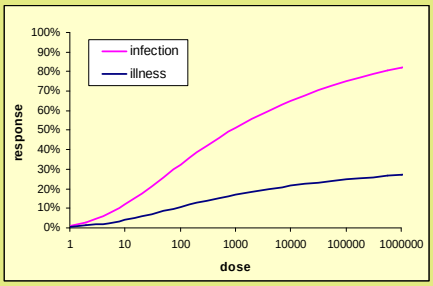


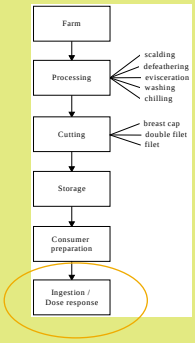


- Beta-Poisson model
- probability of infection from 1 cfu campylobacter : 1.9%
- probability of illness given infection 33%
- Uncertain! There are alternatives!

Teunis & Havelaar Risk Analysis 2000;20:513-520

用量反応



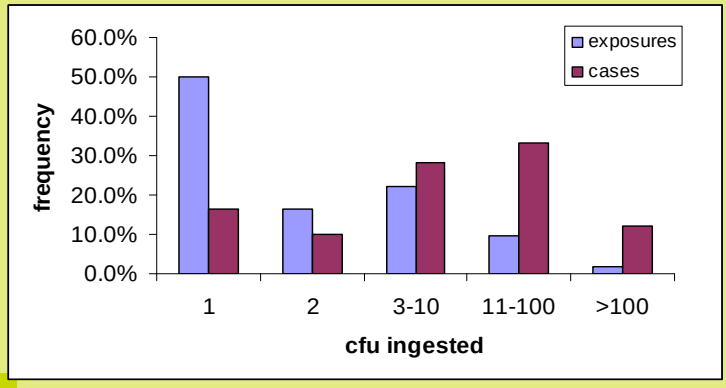


- ベータ-ポアソン・モデル
- 1 cfuのカンピロバクター摂取による感染確率 : 1.9%
- 感染した場合の発症確率 33%
- 不確実!　代替の存在!

Teunis & Havelaar Risk Analysis 2000;20:513-520

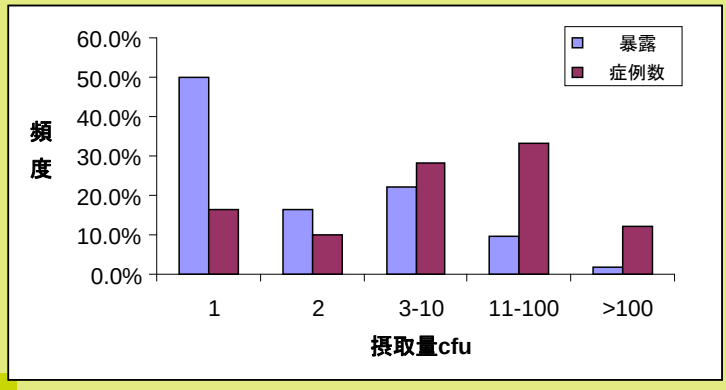
Exposure and illness, baseline scenario

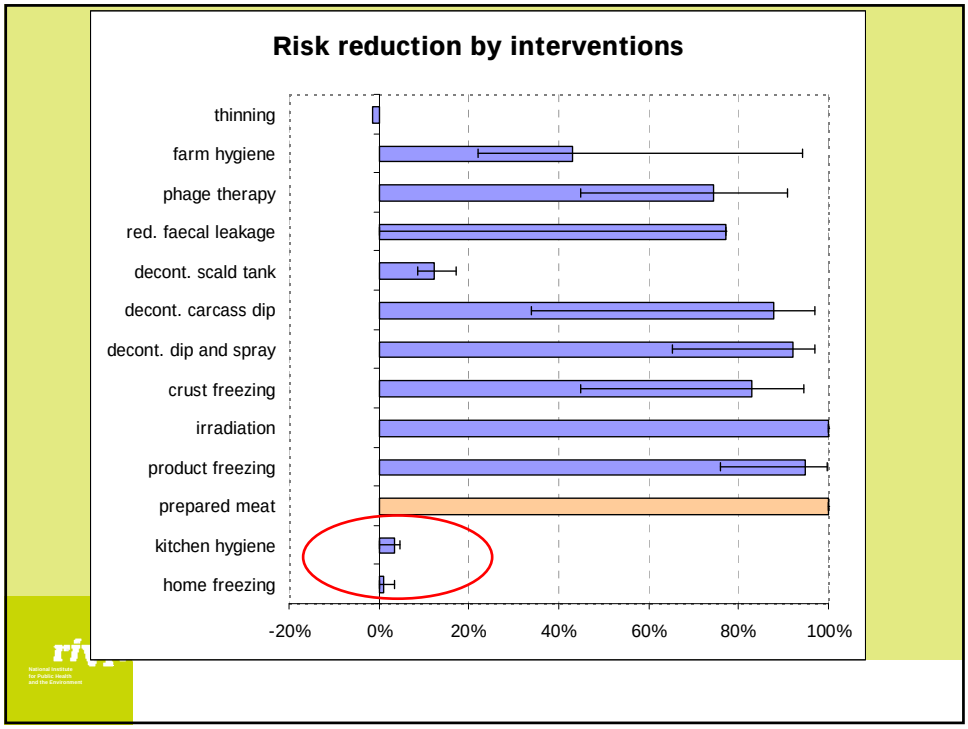
- Cross-contamination from fillet to salad; the Netherlands, 2000
- 0.8% of salads is contaminated; yearly 12000 cases of GE

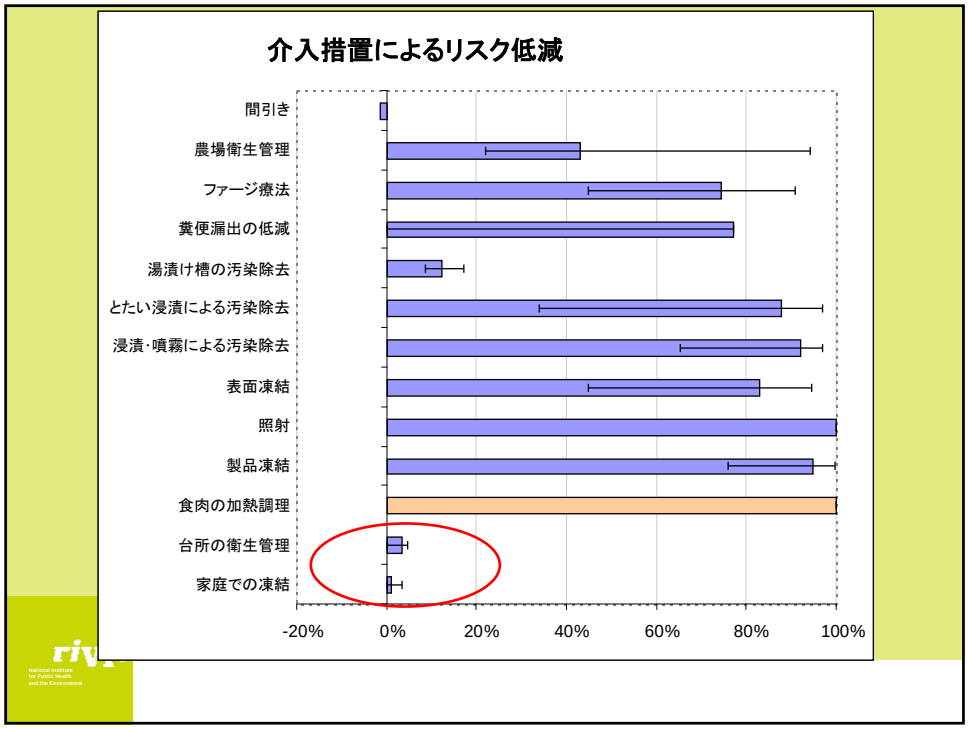


暴露と発症, ベースライン･シナリオ

- ササミからサラダへの交差汚染; オランダ, 2000
- サラダの0.8%が汚染されている; 年間 12,000 の胃腸炎例




Risk reduction by interventions
thinning
farm hygiene
phage therapy
red. faecal leakage
decont. scald tank
decont. carcass dip
decont. dip and spray
crust freezing
irradiation
product freezing
prepared meat
kitchen hygiene
home freezing
-20%
0%
20%
40%
60%
80%
100%


介入措置によるリスク低減
間引き
農場衛生管理
ファージ療法
糞便漏出の低減
湯漬け槽の汚染除去
とたい浸漬による汚染除去
浸漬･噴霧による汚染除去
表面凍結
照射
製品凍結
食肉の加熱調理
台所の衛生管理
家庭での凍結
-20%
0%
20%
40%
60%
80%
100%

Estimating the efficiency of an intervention

- (Direct) costs of an intervention
  - Investments and variable costs *K (in euros)*
- Benefits of an intervention
  - Reduced human disease burden *Z (in DALYs)*
  - Reduced cost of human illness *W (in euros)*
  - No benefits for animal health

- Cost-utility ratio $\frac{K-W}{Z}$ € / averted DALY

- All costs and benefits are discounted at a rate of 4%

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介入効率の推定

- 介入の（直接的）費用
  - 投資及び各種費用 *K（ユーロ）*
- 介入によるメリット
  - ヒトにおける疾病負担の低下 *Z（DALY）*
  - ヒト疾患にかかる費用の低減 *W（ユーロ）*
  - 動物の健康に対するメリットなし

- 費用対効果率 $\frac{K-W}{Z}$ € / 回避できたDALY

- 費用とメリットはすべて 4% 割り引かれる

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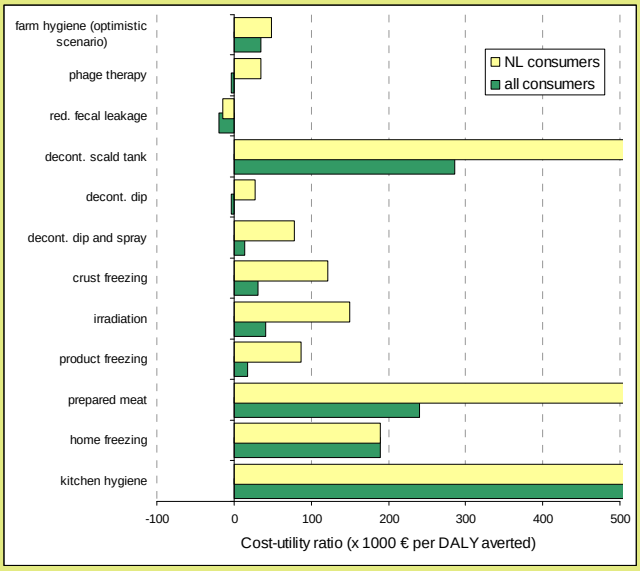
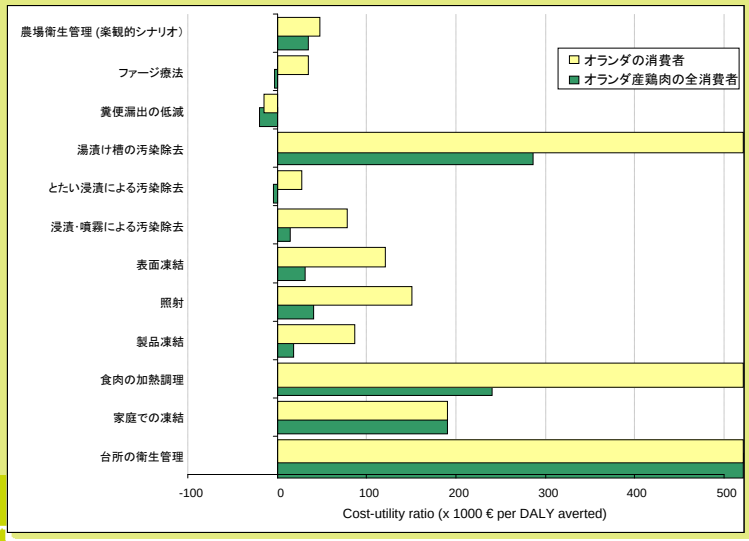
Cost-effectiveness of interventions



Havelaar et al., Risk Anal 2007;27:831-844

介入による費用対効果



Havelaar et al., Risk Anal 2007;27:831-844

Public education campaigns

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国民啓発キャンペーン

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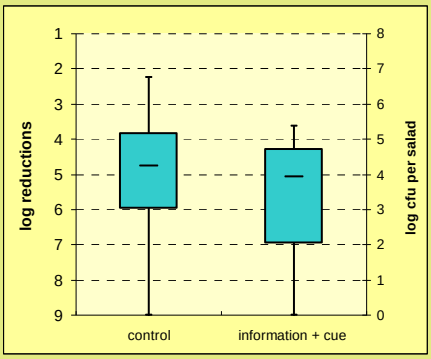
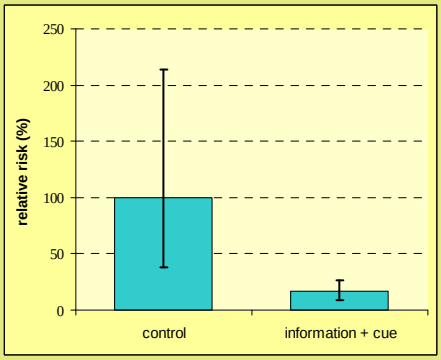
Exposure

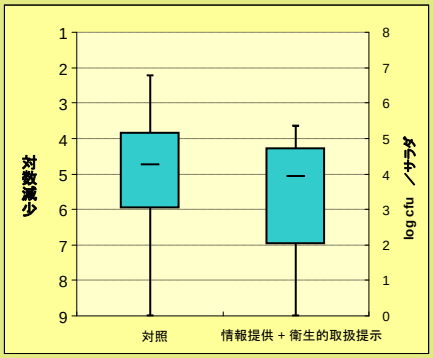


Risk

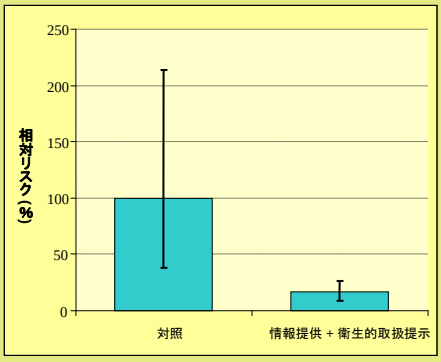


Nauta et al., Risk Anal 2008;28:179-192

暴　露



リスク



Nauta et al., Risk Anal 2008;28:179-192

Recommendations from the CARMA project

- Address multiple sources of Campylobacter
- To reduce exposure by chicken meat
  - Promote a consistently high level of farm hygiene
  - Get ready for scheduling
  - Consider and optimise decontamination and reduce faecal leakage during slaughtering
  - Maintain hygiene education for consumers
  - Develop compensation mechanisms to recover costs
  - Increase chain transparency
  - Take measures at the European level
  - **Do not aim for zero-tolerance but consider risk-based Food Safety Objectives and Performance Objectives**

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CARMA プロジェクトからの勧告

- 複数のカンピロバクター感染源に対処する
- 鶏肉による暴露を減らすには
  - 農場の衛生レベルを一貫して高い状態に保つよう努力する
  - スケジューリングを積極的に行う
  - 汚染除去の検討・最適化を行い、とさつ時の糞便漏出を低減させる
  - 消費者への衛生教育を継続的に行う
  - コスト回収のための補償システムを開発する
  - フードチェーンの透明性を高める
  - 欧州レベルでの対策を実施する
  - **ゼロ・トレランス（違反を一切認めない）を目指すのではなく、リスクに基づく摂食時安全目標値及び達成目標値を検討する**

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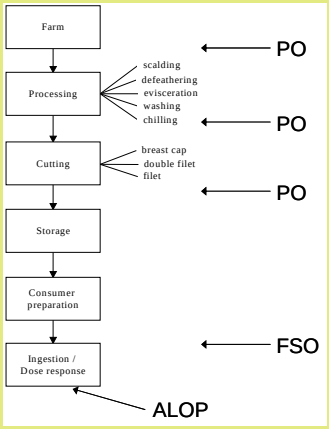
Risk-based food safety management: the new perspective (CCFH)

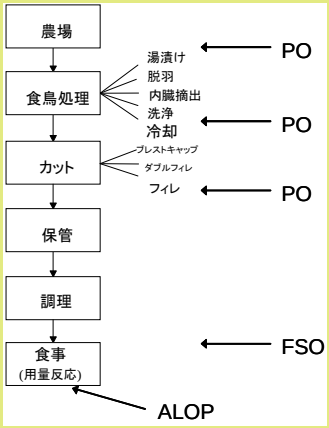
- Appropriate Level of Protection (ALOP)
  consumer health risk
- Food Safety Objective (FSO)
  hazard level at the moment of consumption
- Performance Objective (PO)
  hazard level in the food chain
- Performance Criterion (PC)
  effect of a process
- Product, process or microbiological criteria
- Implementation in practice

- QMRA provides the link between hazard control and consumer risk

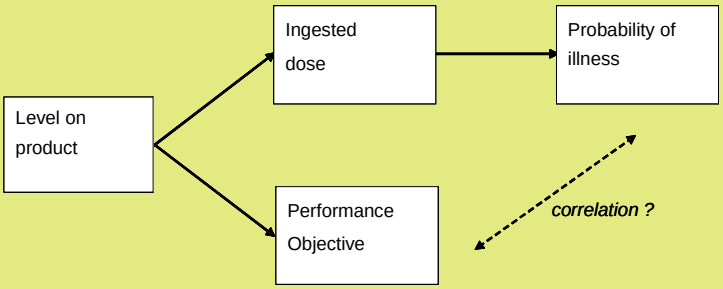


リスクに基づく食品安全管理：新たな展望 (CODEX食品衛生部会)

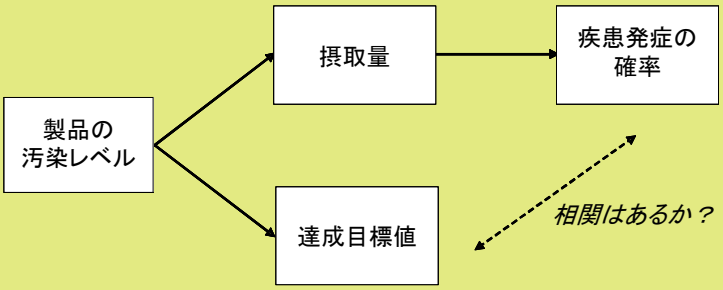
- 適切な衛生健康保護水準 (ALOP)
  消費者の健康リスク
- 摂食時安全目標値 (FSO)
  消費段階でのハザードレベル
- 達成目標値 (PO)
  フードチェーンでのハザードレベル
- 達成基準 (PC)
  ある過程の影響
- 製品、過程、もしくは微生物学的基準
- 現場で実施する
- 定量的微生物リスク評価（QMRA）はハザード管理と消費者リスクを結びつける



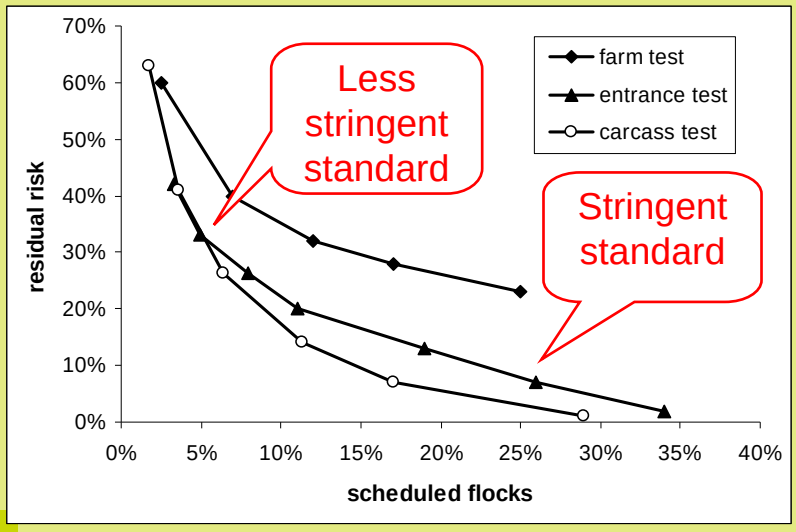
Risk-based evaluation of a Performance Objective



リスクに基づく達成目標値の評価

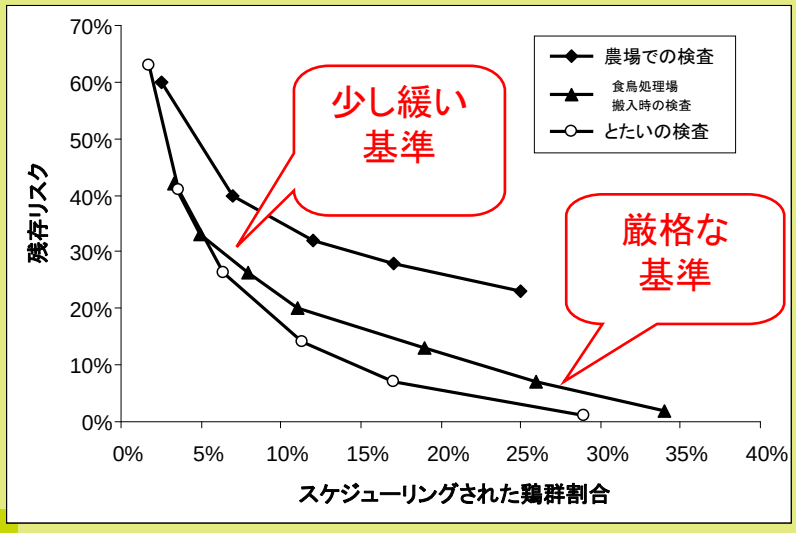


Dillemmas for policy makers



Nauta and Havelaar; Food Control 2008;19:372-381.

政策立案者のジレンマ



Nauta and Havelaar; Food Control 2008;19:372-381.

Requirements for a succesful scheduling strategy

- Variation between flocks larger than within flocks
- Correlation between contamination level in some stage of the food chain and consumer risk
  - Correlation between number of bacteria in caeca and on carcesses
- Requirements not confirmed in susbsequent research in the Netherlands; broiler processing is very complex
- Counting Campylobacter in the food chain is difficult
- Additional data collection agreed with industry
- European Commission is developing plans to set targets and criteria for Campylobacter in broiler meat

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スケジューリング戦略成功の要件

- 鶏群内よりも鶏群間の変動が大きい
- フードチェーンのある段階の汚染レベルと消費者リスクとの間に相関性がある
  - 盲腸内の菌数と、とたい上の菌数の間に相関性がある
- オランダにおけるその後の研究では、種々の要件について確認は行われていない。ブロイラーの加工は非常に複雑である
- フードチェーンにおけるカンピロバクター数の計測は難しい
- さらなるデータ収集について産業界と合意した
- EC では、ブロイラー肉におけるカンピロバクターの目標値及び基準を設定する計画を進めている

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Conclusions

- Quantitative approaches to support food safety policy are gaining more acceptance to support policy making, in the Netherlands as well as at the European and global level
- Integrated approaches are necessary
- Successful implementation requires long term commitment
- QMRA methodology is increasingly applied but efforts are necessary to further improve the methodology and its availability

結論

- 食品安全政策を支援する定量的アプローチは、政策立案を裏付けるものとして、オランダ、欧州、また世界レベルで次第に認識されるようになっている
- 統合的アプローチが必要である
- 効果的な実施には、長期的な努力を傾注することが必要である
- QMRA の方法を適用する機会は増えているが、さらに方法を改善し、利用しやすくするための努力も必要である