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Ministry for Primary Industries
Manatū Ahu Matua

Risk assessment as an input to regulatory decision-making

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FSS conference, 27 March, Edinburgh

www.mpi.govt.nz

Overview

- Introduction
- Trends and challenges
- Risk assessment
- *Salmonella* and *Campylobacter*
- Concluding comments

Common ground between Scotland and New Zealand

- Small island populations
- Food production/processing are important from an economic perspective
- Food processing is largely the same
- Shared heritage

- → Many challenges will be in common

themselves Scottish

(The Scotsman, 17 May, 2016) … with 2 from

Larnach Castle, Otago Peninsula, Dunedin, New Zealand

Dunedin, known as the Edinburgh of the South in New Zealand.

Scotland or New Zealand?

2016 notification rates for selected diseases in New Zealand

Disease	Rates per 100,000 population
Campylobacteriosis	158.9 (~135 if waterborne outbreak excluded)
Salmonellosis	23.2
Yersiniosis	18.3
VTEC/STEC infection	8.9
Listeriosis	0.8
Etc.	

Notification rates & Trends

- Limitations of using notification rates without context
  - Include various pathways (e.g. foodborne, occupational)
  - Severity of disease
  - Under-reporting
  - Different systems for some foodborne diseases (e.g. norovirus)

- Major trends influencing risk management priorities
  - Increased international trade
  - Cost-effectiveness food safety requirements
  - Public perceptions

- Use of risk assessment to assist risk management process

Changes in the international trade enviroment

- Animal Biosecurity protection based on science rather than island fortress attitude
- Trade agreements:
  - Bilateral
  - The Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement") the World Trade Organization on 1 January 1995

Consequences

- Trade with new trading partners
- Increased trade volumes of foods
- ‘New’ products
  - Unusual tissues
  - Multi-ingredient products
  - New preservation methods

→ A challenge for those involved in food safety to protect the public, especially so for small nations with more limited resources (experts & funds)

Cost-effectiveness topics

- Changes to meat inspection
  - Historically a poor cost-benefit pay-off
  - At times detrimental rather than beneficial (cross-contamination)
  - Difficult to convince export markets to achieve food safety differently/equivalence

- Cost to small operators (artisan producers, small slaughterhouses, retail)
  - Due to small scale of operation → relatively costly
  - Regardless of size → product must be fit for purpose
  - Some accommodation is possible but there are limits, not different from any other product (e. g. cars, electrical equipment)

Public perceptions

- Unease/aversion to change:
  - Examples: use of chemicals, irradiation, growth promoters
  - The issues may differ between countries
  - Need to ensure consumers' convictions are respected and that they feel so
- Strong belief systems:
  - Examples: natural is always better, raw better than cooked
  - Small vocal groups, especially a risk to the health of vulnerable groups
  - Unfounded claims

Risk assessment in New Zealand

- Risk assessment (RA) is used to assist decision making including in the areas that were just explained
- 'Classical' Codex/WHO/FAO Quantitative Microbiological Risk Assessment (QMRA) has been used at times:
  - hazard identification
  - hazard characterisation
  - exposure
  - risk characterisation
- Important to use the most cost-effective approach, which can be a simplified version of the classical QMRA → Qualitative Microbiological Risk Assessment
- RA assists decision making but does not make risk managers redundant!

Why carry out a risk assessment?

- To clarify the risk decision process and make informed, justifiable decisions
- To identify the unknown
- To acquire an understanding of the uncertainty
- To evaluate risk management options
- To meet Codex / SPS / WTO expectations

Disadvantages of a classical QMRA

- Labour intensive
- May take much time to complete
- Can be costly to collect information, e.g. surveys
- If gaps in the pathways, RA may be inconclusive
- Requires specialised expertise
- Corroboration of estimates is required at intermediate steps of the RA
- Uncertainty remains
- Examples
  - MPI developed a number of risk profiles as initial evaluations, but also because of data gaps and costs
  - Currently a “compact” meat import risk assessment is under development

Scale of uncertainty

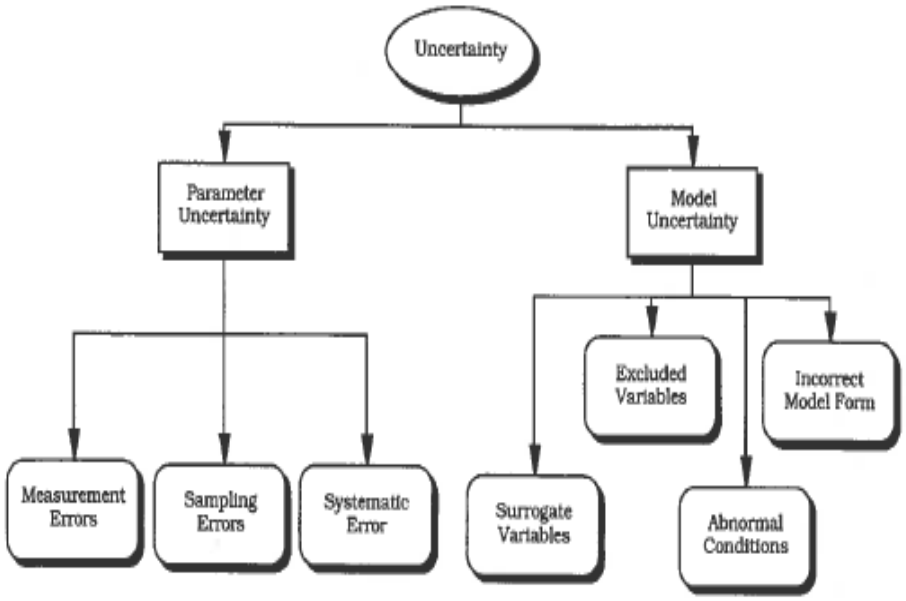
TABLE 1. *Risk estimates of human infections with* T. saginata *per year resulting from consumption of beef produced in New Zealand*

Risk estimates	Export market			Domestic market		
	Mean	Min.	Max.	Mean	Min.	Max.
Number of infections per year	0.50	0	5	1.10	0	11
Probability of infection per edible portion	4.89×10^{-10}	0	4.38×10^{-9}	5.00×10^{-9}	0	4.52×10^{-8}

Uncertainty in beef measles estimates, a typical example how uncertainty is conveyed

Illustration of the true extent of uncertainty

From Haas, Rose & Gerba (1990), based on Finkel (1990)



Alternatives to assist science-based decision making

- Need to keep the risk management question in mind
- Other options for decision-making can be more appropriate, depending on the circumstances:
  - RA with limited scope (e.g. draft import risk assessment)
  - Surveys (e.g. retail surveys)
  - Molecular biology (e.g. source attribution, whole genome sequencing)
  - Literature (e.g. experiences by food standard authorities abroad)
- However classical QMRA brings together the various pieces of information

Additional considerations for decision making by risk manager

- Legal requirements and government policy
- Judgement must still be exercised
  - Risk of acting versus risk of not acting
  - Benefit-risk assessment
- Deal with uncertainty
  - Identify what is unknown
  - Quantify to the degree possible, note it is uncertainty after all
- General public preferences

Advertisement by raw milk vendor

MPI Warning: Raw milk may contain Microorganisms that can cause serious illness. To reduce the risk of illness, the raw milk should be heated to at least 70 degrees celcius for at least one minute. This is critical for infants, young children, the elderly, pregnant women and people with weakened immune systems.

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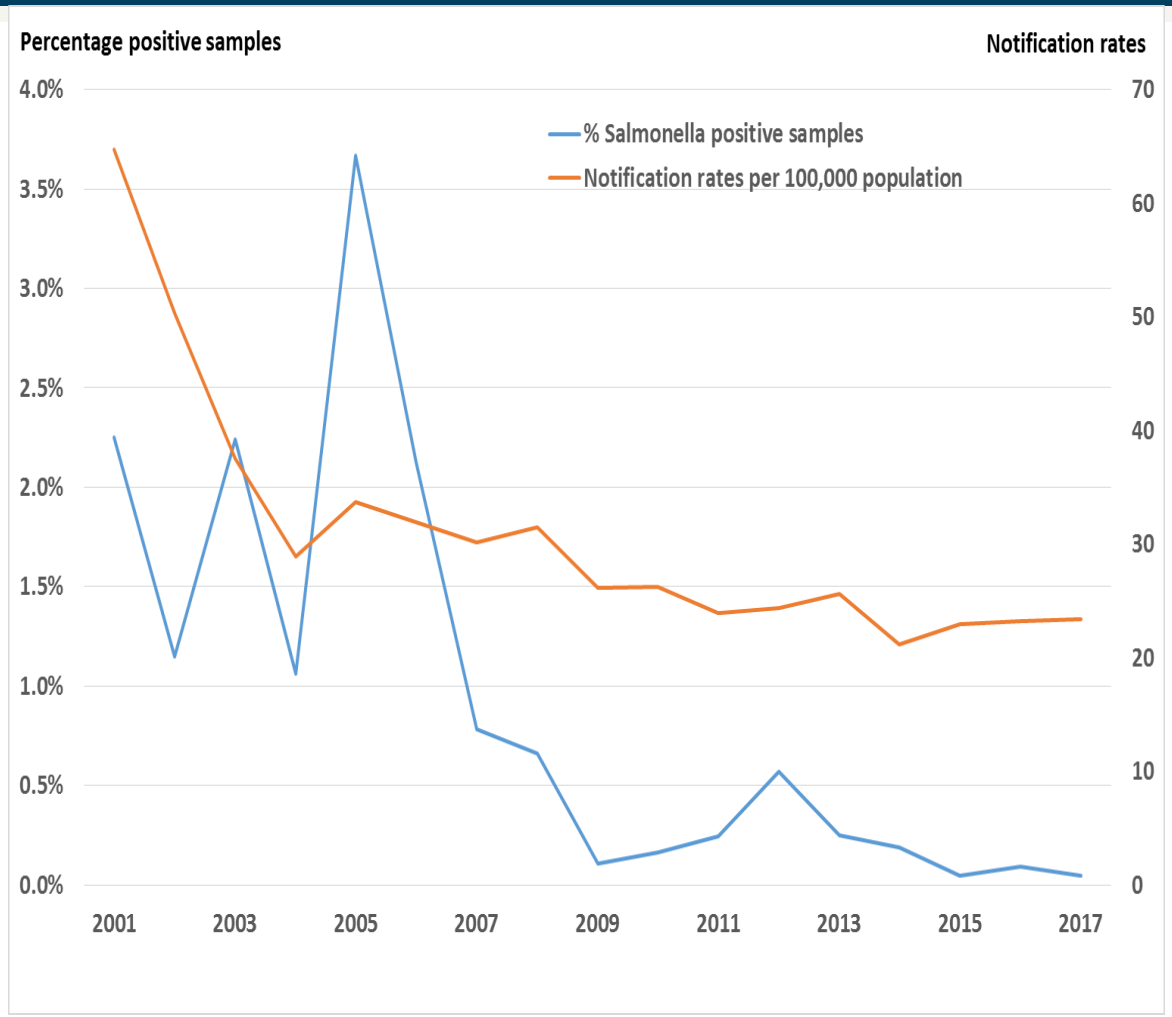
A New Zealand case study of foodborne illness associated with poultry

Salmonella & *Campylobacter* in poultry*:* what worked and wat didn't?

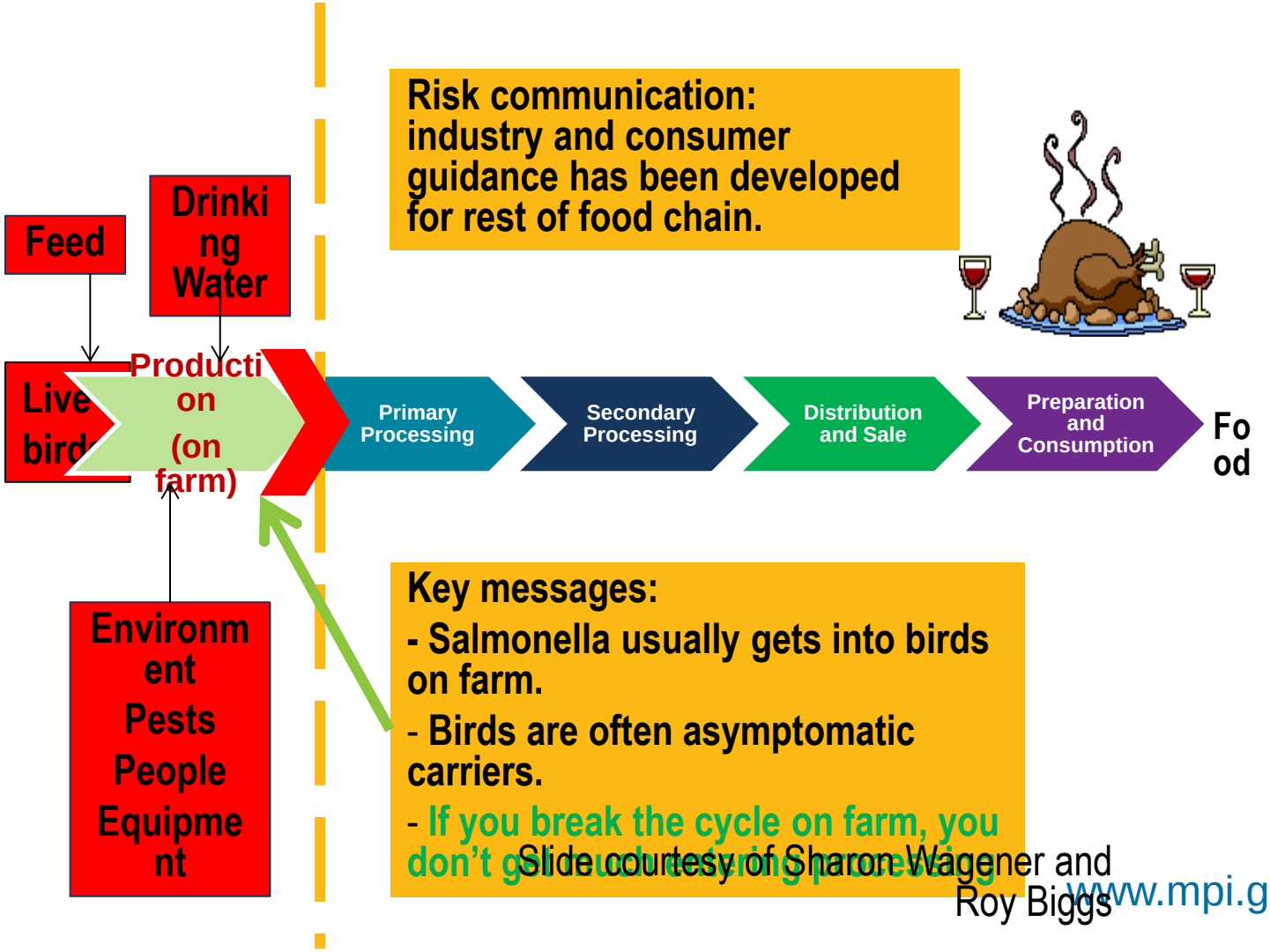
Risk assessment & risk management interaction: Salmonella and *Campylobacter*

- Mid-2001 Industry voluntarily introduced *Salmonella* NMD testing of broilers:
  - whole carcass rinse samples (trained samplers)
  - specified methods for generic *E. coli,* and *Salmonella*
  - analysis by approved laboratories
  - results reported to NZFSA
  - national results reported back to participants, comparing their performance against rest
  - corrective action for those failing limit
- Mid-2004: NZFSA required HACCP-based Risk Management Programmes including mandated NMD

Human illness and percentage positive broiler samples



Main sources of *Salmonella* in NZ Poultry



Slide courtesy of Sharon Wagener and Roy Biggs

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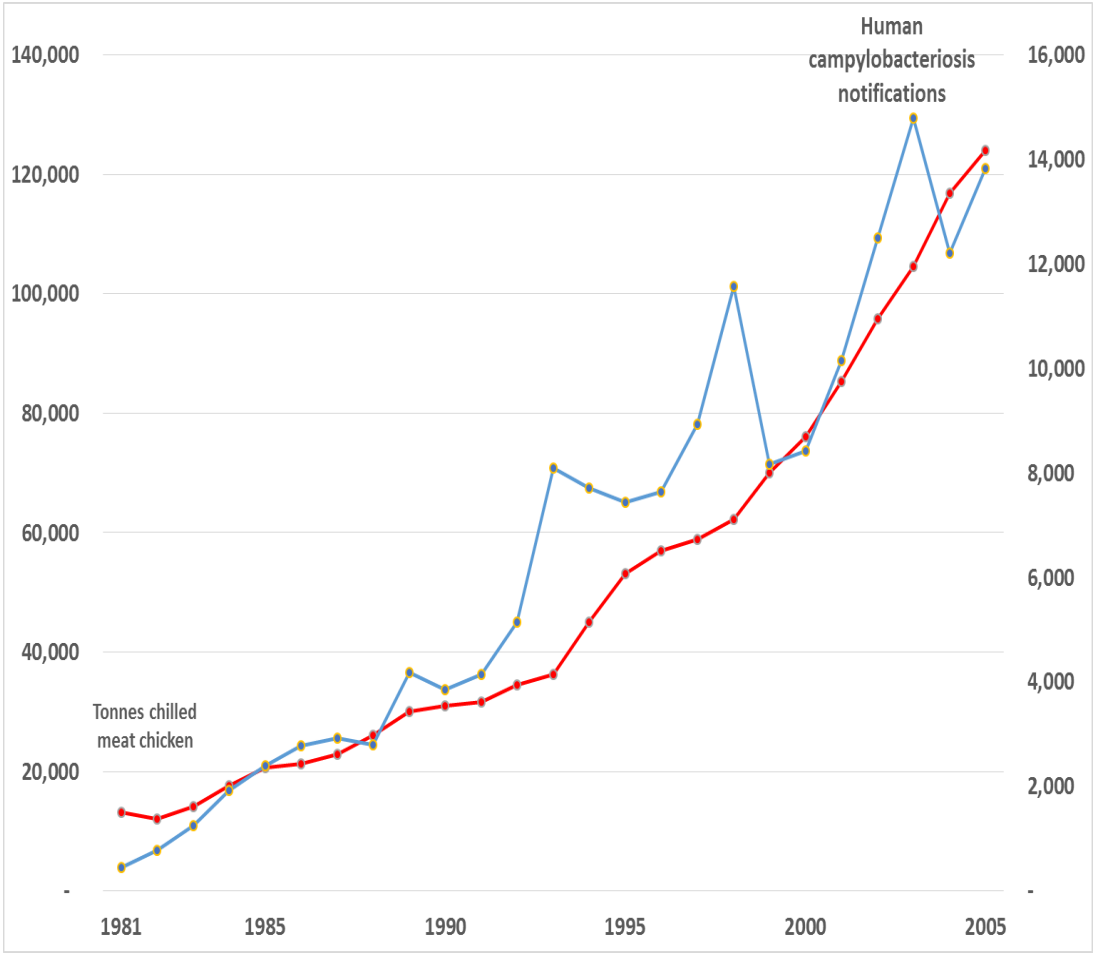
Salmonella vs *Campylobacter* in broilers

- On farm controls were very effective to reduce *Salmonella* infections
- What happened to *Campylobacter* until 2006? A different situation!

Is there a campylobacteriosis problem? And if so, whose?



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NZFSA's (now MPI) perspectives

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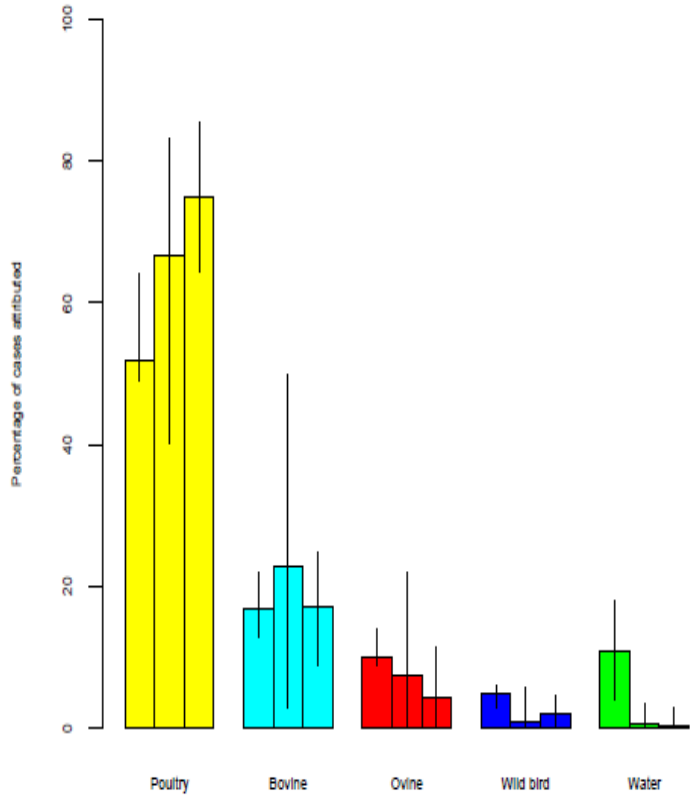
Poultry industry's perspective

In 2004/2005, the poultry industry surveyed the *Campylobacter* incidence rate in flocks over a 15-month period and discovered that 74% of flocks were positive. An enumeration trial conducted in the last six months of 2003 indicated however, that only 6% of carcasses ready for the market had counts of >100 per gram. In comparison, although the results were obviously not available until later, smaller surveys showed similar results: the European Union baseline survey in 2008 showed >40% of broiler chickens recording 100 or more per gram, and 5.8% with 10,000 or more per gram. At this point, the New Zealand poultry industry concluded that the high level of human Campylobacteriosis in New Zealand could not be attributed to higher than normal levels of the bacteria on chicken.

Roy Biggs, 2012

Risk assessment with source attribution estimates around the start of the *Campylobacter* strategy



Work commissioned by NZFSA:

Enhancing Surveillance of potentially foodborne enteric diseases in New Zealand: human campylobacteriosis in the Manawatu. Nigel French and the Molecular Epidemiology and Veterinary Public Health Group, 2008.

Key components for the *Campylobacter* strategy

- Bring together an NZFSA (now MPI) *Campylobacter* Strategy Working Group
- Have regular formal and informal meetings with poultry industry

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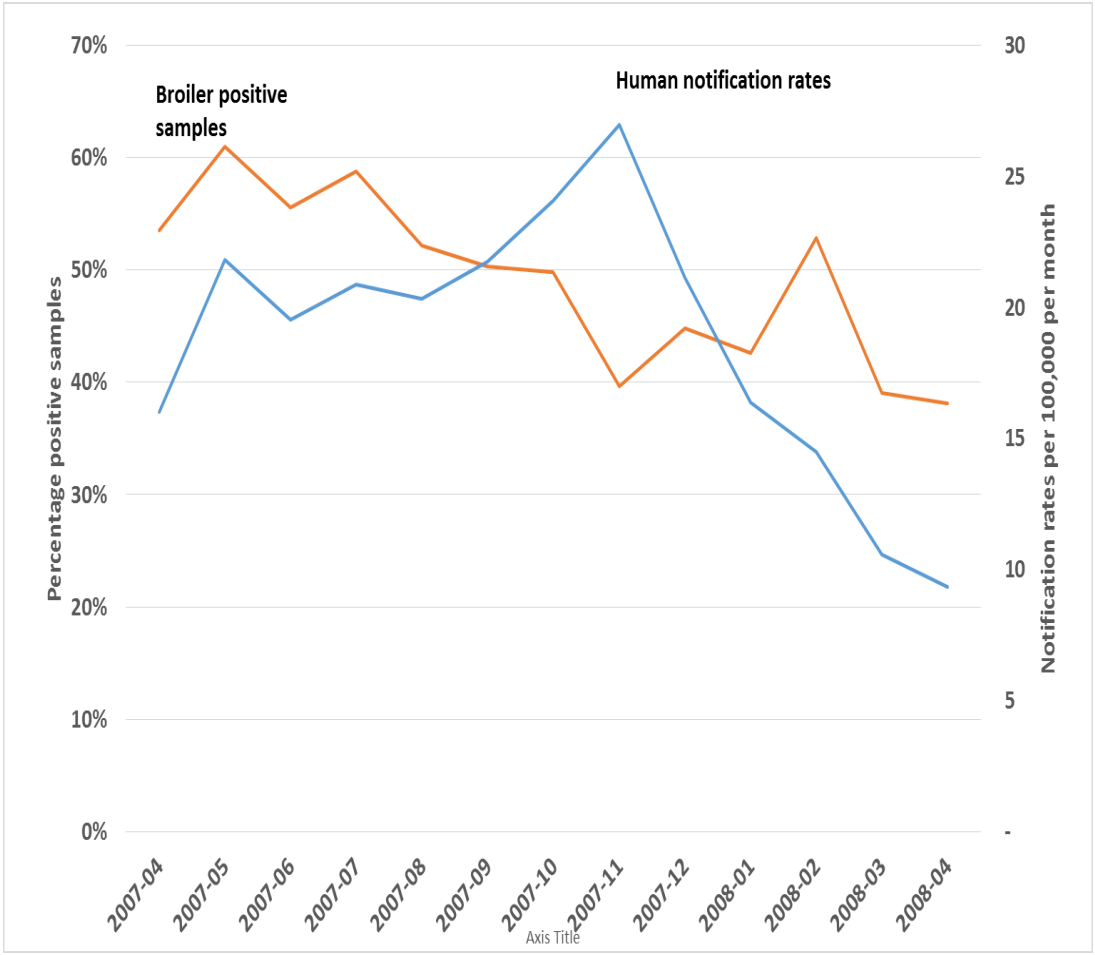
- Agree on a course of action; document in a formal strategy
- Get improvement quickly!

National Microbiological Database

- Already mandatory for *E. coli* and *Salmonella*
- Formally include *Campylobacter*
- In brief, for standard throughput premises:
  - Three carcass rinse samples per day
  - Each working day
  - Caecal sampling (discontinued after two years)

Risk management approach:
Voluntary vs mandated

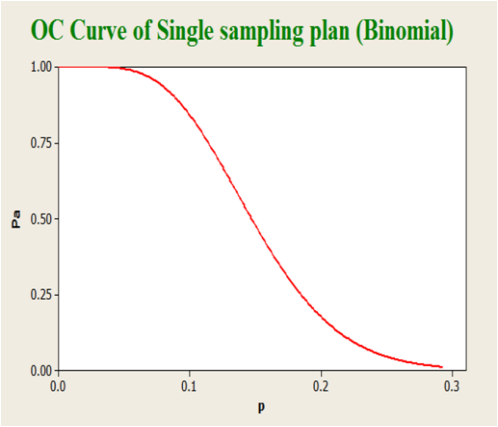


Options to bring about improvement: Interventions or Microbiological Limits

- Interventions
  - Few practical options
  - Not necessarily cost-effective
  - Validation required
- Microbiological Limits
  - To be achievable but challenging
  - Allows operators to establish cost-effective options
  - Requires a sound microbiological testing system

Initial target setting, explain uncertainty to industry

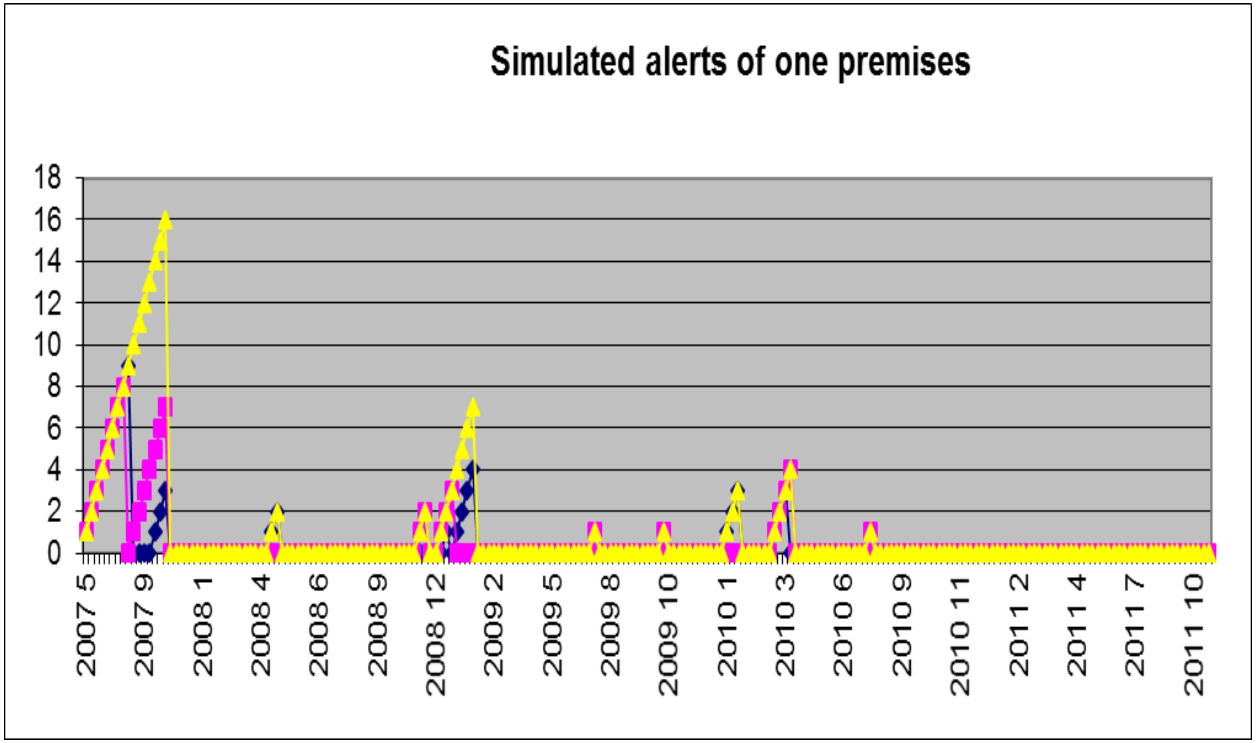
- Agreement with industry on 1 $\log_{10}$ reduction
- Used 90th percentile 4.78 → 3.78 $\log_{10}$ CFU
- Operating Characteristic curves explain uncertainty→ decision
  - sample size: 45
  - acceptance number: 6



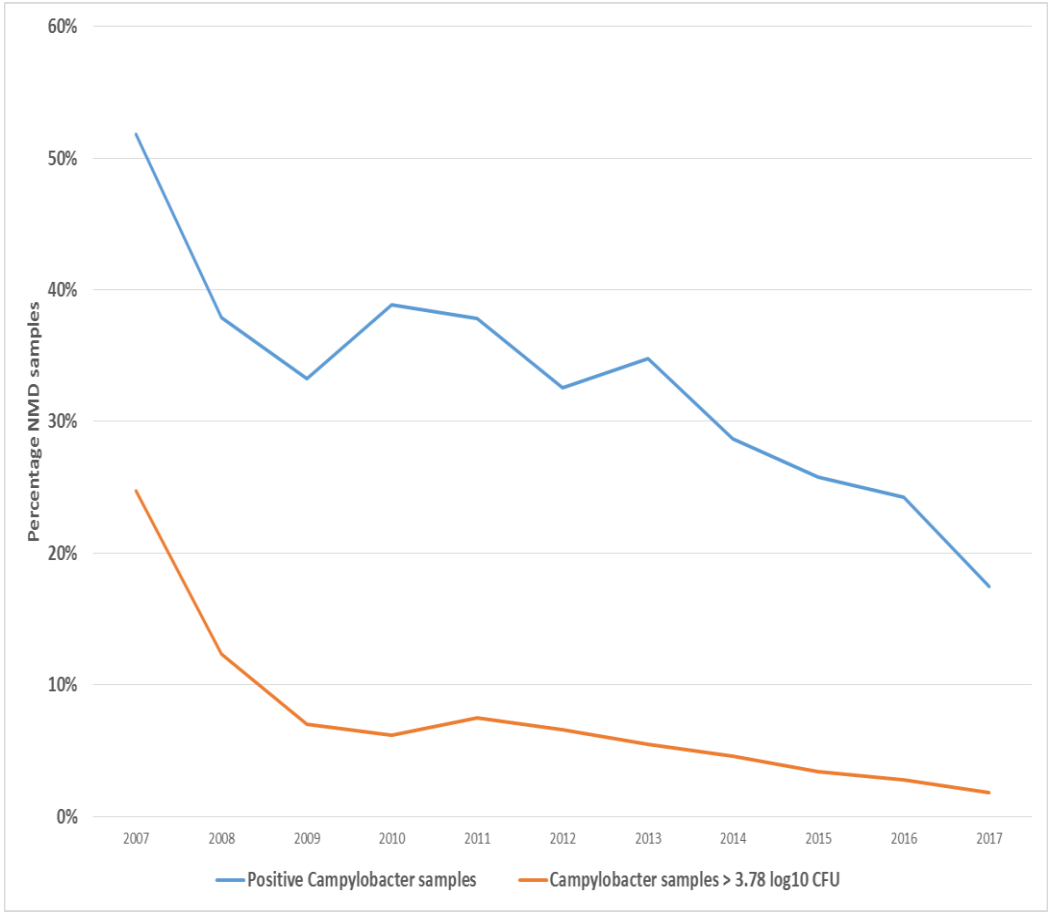
Premises specific tool to evaluate impact (2013)

Acceptance numbers (sample size = 45)

29	6
Number of positives samples	Number of samples >3.78 $\log_{10}$ CFU



Progress to date



- Only part year for 2007

Where did the success come from?

- Differed per premises
- Attention to detail / “Campy champions”
- Improvement washing steps
- Improvement / replacement evisceration equipment
- Improvement operation of immersion chillers
- Improvement / replacement crate washing equipment

Feasibility of better control of barn-raised poultry

- There was much emphasis on biosecurity while controlling *Salmonella*, was not adequate for *Campylobacter*
- 13/18 breeder flocks were positive for *Campylobacter* (MPI/ESR/PIANZ survey)
- Use of fly-screens?
- More than 20% of broilers are free-range

- NZ industry concentrated on processing since that was more likely to lead to a reduction

- More research is required as to feasibility under practical conditions

Poultry contamination has been reduced, what is the proportionality of further public health gains vs costs?

- In any case: keep up current limits (or equivalent)
- More knowledge of other sources is required
- Can more progress be made?
  - Comparison of premises
  - Comparison of countries
- Use of various models to estimate illness due to poultry
  - Source attribution (Massey)
  - Model based on attribution due to other sources being unchanged
  - NMD regression models

Attribution model, contribution by other sources unchanged

Year	Notification	Assumed attributed to poultry Percentage	Assumed attributed to poultry Notifications	Then attributed to other sources Notifications	
2006	379	80%	303	76	
					Unchanged
2015	135	44%	59	76	

If poultry attributed in 2006	Estimated attributed to poultry in 2015 Percentages	Number of notifications
60%	-12%	-16
65%	2%	3
70%	16%	22
75%	30%	41
80%	44%	59
85%	58%	78
90%	72%	97

The use of multiple models

- Similar results from models that differ with regard to:
  - Structure
  - Data sets
  - Assumptions

strengthen confidence.

- Example: What if dressing hygiene improves by 10% compared with 2015?

  The estimated reduction of notifications per 100,000 per year:

  - MLST source attribution model: 6 – 9 notifications
  - Small attribution model: 4 – 8 notifications
  - Regression model: ~ 6 notifications

Campylobacter strategy in a nutshell

- The regulator's predicament: how much proof is required?
- A formal strategy was required to reduce human campylobacteriosis
- Important to run strategies as appropriate for the circumstances
- Transparency to get acceptance by affected parties
- Use of various approaches such as surveys and models with different assumptions
  - For a better informed strategy
  - To give all stakeholders confidence of practical feasibility

Concluding comments

- Scotland and New Zealand face similar challenges
- Risk assessment underpins science and risk-based policies
- Working with the industry to protect the public health has been successful in New Zealand
- Further improvement of public health is still pursued

Acknowledgements

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