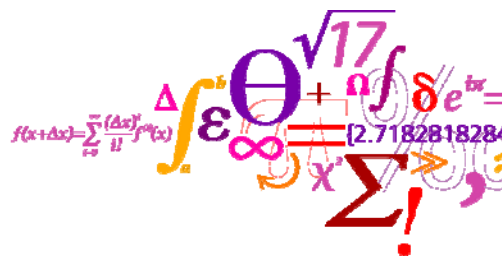




From microbial analysis to decision: the use of risk assessment

Maarten Nauta,
Division of Microbiology and Risk Assessment

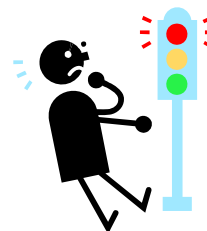


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This presentation: Microbiology

- Microbiological food safety
 - problem
 - microbiological analysis
 - microbiological criteria
- Microbiological risk assessment
 - dose response
 - exposure assessment
- Risk based decision making





Special challenges of microbiology

- Microbial pathogens in food are a continuous problem
 - bacteria, viruses, protozoa
- Detection and identification
 - Variability between strains
 - Adaptation: different states
 - Selection of the pathogens you are looking for
 - Low numbers, hidden in the food
- Low numbers need not imply safety
 - Microbes can multiply
 - One single bacterium may make you ill



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Microbiological food safety

- How to get food without pathogens?
 - kill and reduce amount of pathogens
 - sterilization, pasteurization
 - other preservation techniques
 - good food hygiene
 - but...
 - we cannot get rid of them

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Microbiological food safety(2)

- Food pathogens are "natural"
 - excreted by (domestic and wild) animals
 - contaminate meat during slaughter
 - manure used for crops



- Consumer demand for fresh and minimally processed foods
- 100% safe food is not possible
 - the risk should be "sufficiently low"

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What is "sufficiently low?"

Traditional approach

- The prevalence should be low
- The concentration should be low
- The number of people getting ill should be low

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Data: microbiological analysis

- We need to know:
 1. Whether a pathogen is present
 - presence/absence tests (PREVALENCE)
 2. How much of the pathogen is present
 - quantitative, enumeration (CONCENTRATION)

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We need a sampling plan

- Where to sample
 - *e.g.* at retail
- How much to sample
 - *e.g.* 5 x 25 g minced meat
- How often to sample
 - *e.g.* one food lot per week

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Presence/Absence

- Find out whether the pathogen is present in the food

- Different methods
 - enrichment
 - molecular methods

- Interpret results:
 - sensitivity
 - specificity
 - sample size

- ⊗ false negatives: underestimate the risk
- ⊗ false positives: may cost money

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Quantitative methods

- Count CFU's (colony forming units)

- Estimate MPN (most probable numbers)

- Extract ng DNA
 - what you see is what you count
 - depends on experimental conditions, growth medium, etc..
 - should have a relation to the "true" amount of living cells

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Microbiological criteria

- Define a test for "safe food":
 - how many samples from a set of n samples at a predefined point in the food chain may
 - be positive
 - exceed c cfu/g of product, with sample size x
 - well defined test protocol
- For example
 - *Salmonella* should be absent in 5 samples of 25 g in minced meat
 - *Listeria*: no more than 100 cfu/g in 5 samples ready to eat foods

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Microbiological criteria(2)

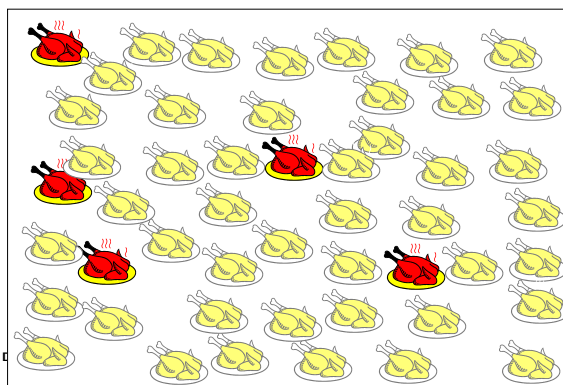
- Why are they formulated the way they are?
 - what is feasible testing?
 - tradition
- Development of test protocol
 - How do I need to sample to be confident that food in a food lot at a specified point in the food chain is not too much contaminated?

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Example (1)

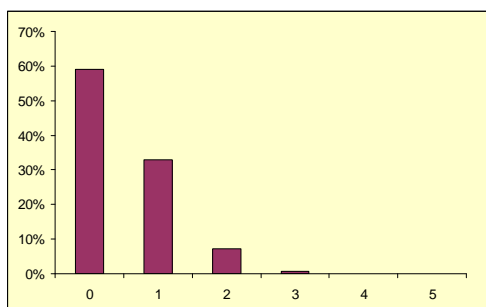
- Suppose a batch of chicken carcasses of which 10% is contaminated with more than a critical level of 100 cfu/g skin ("positive").
- If I take 5 samples, in how many will I find positive?



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Example (2)



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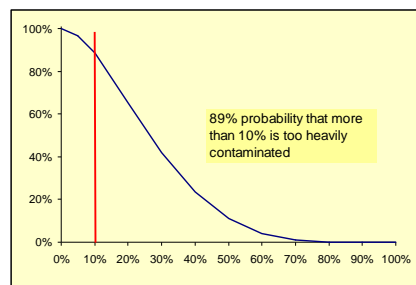


Example (3)

- But I don't know how many are positive...

so the question should be

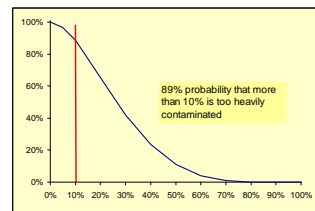
- If I find 1 or more positives when I take 5 samples, what is the probability that more than 10% is (too heavily) contaminated? ?



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Example (4)

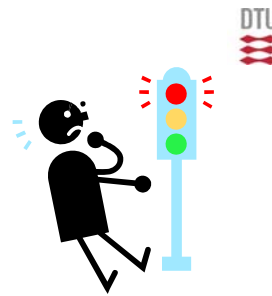
- This may be a fair test, but...
- We may draw a wrong conclusion
 - reject a batch which is not heavily contaminated
 - accept a batch that is heavily contaminated
- The more you test, the more you know
 - the more you test, the more it costs
- You are NEVER certain



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This presentation

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We have various testing protocols, but there is always uncertainty

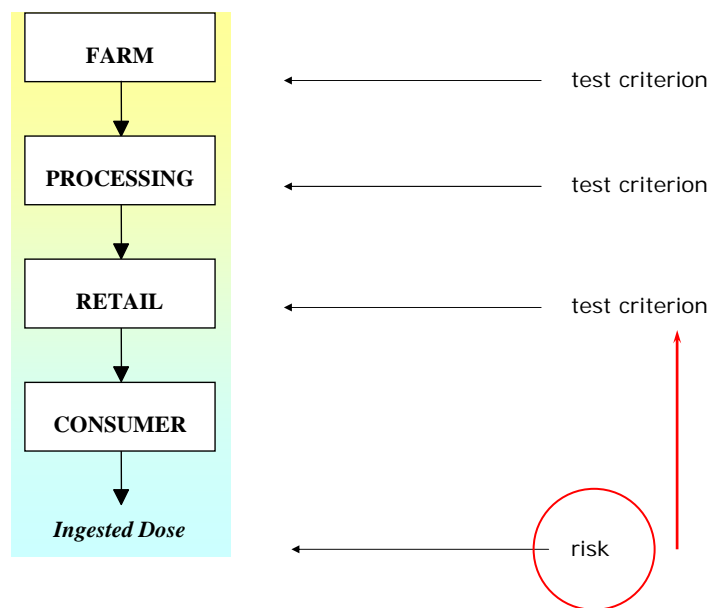
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What is sufficiently low?

Remember that for safe food

- The prevalence should be low
- The concentration should be low **Risk based approach**
- The number of people getting ill should be low

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Microbiological risk assessment

- Developed since the 1990's
- Requested by WTO and Codex Alimentarius
 - Is food safe enough to import it?
 - Decision should be transparent and science based
- First drinking water, later food
- AIM:
Evaluate the human health effects of pathogens in food products

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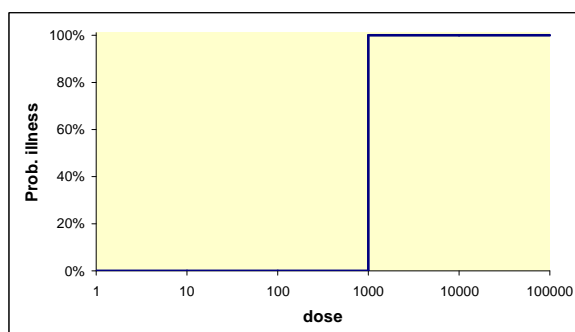
Is it safe to drink bathing water?



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How feasible is a minimum infectious dose (MID)?



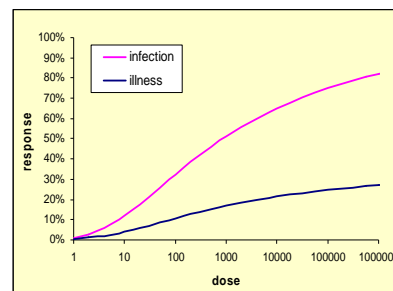
- MID is NOT feasible in microbiology

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Dose response relationship

- Relation between ingested dose and probability of illness
- Single hit models:
 - Each cell can lead to infection, but with low probability
 - No minimum infectious dose
- At least 1 cfu must be ingested
- The more you ingest, the more likely you get ill

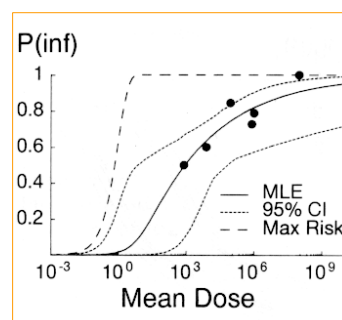


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How to know the dose response relationship?

- "Volunteer" studies
- Outbreak data
- Animal studies



- In general we are highly uncertain: studies are usually not representative for all people, all strains and all food products

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Next question: How much is ingested?

- We need an "amount of pathogens" ingested as the input of the dose response relation:

Exposure assessment

- Difficult to measure at point of exposure
 - count pathogens in meals?
 - microorganisms may die and multiply during food preparation and storage

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Predictive modelling

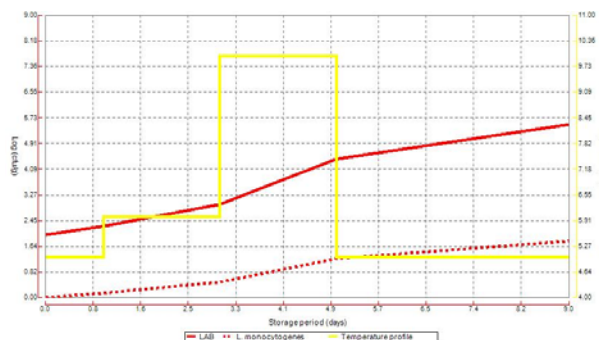
- If we cannot measure exposure, we have to estimate it based on somewhere else where we CAN.
 - for example:
 - measure at retail
- Predictive models predict growth and inactivation of bacteria during food processing
 - for example:
 - measure at retail
 - predict growth during storage (at x °C)
 - predict inactivation during heating (at y °C)

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Example

- Food with *Listeria monocytogenes* stored at 5, 6, 10 and again 5 °C.
- Growth from 0 to 1.7 log cfu/g

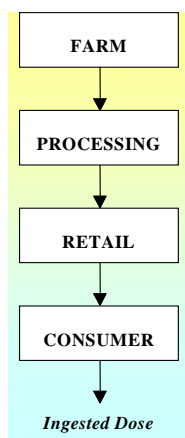


Source: SSSP model, Paw Dalgaard

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Farm to Fork exposure modelling...



- Large and complex food chain
- Describe the transmission of a microbial hazard
 - quantitative
 - mathematical model
- Assess exposure
 - probability of exposure
 - amount of exposure

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Exposure assessment + Dose response = Risk assessment



- Exposure assessment gives the ingested dose as a function of
 - concentration and prevalence somewhere in the food chain
 - what happens until exposure
- Dose-response gives the probability of illness given an ingested dose
- Risk assessment provides the probability of illness given concentration and prevalence

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So



- Risks cannot always be eliminated
 - We have to REDUCE them
 - We have to ASSESS them
- Risk depends on numbers of pathogens ingested
 - exposure assessment
 - dose response relations
- Usually we cannot measure at the point of exposure
 - predict growth and inactivation after point of microbiological data collection

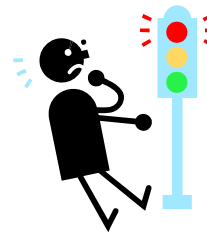
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Risk assessment uses models to link food chain data with probability of illness by consumption

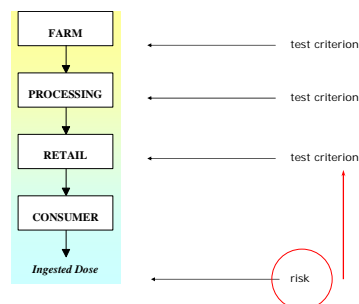


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Required for a risk based approach

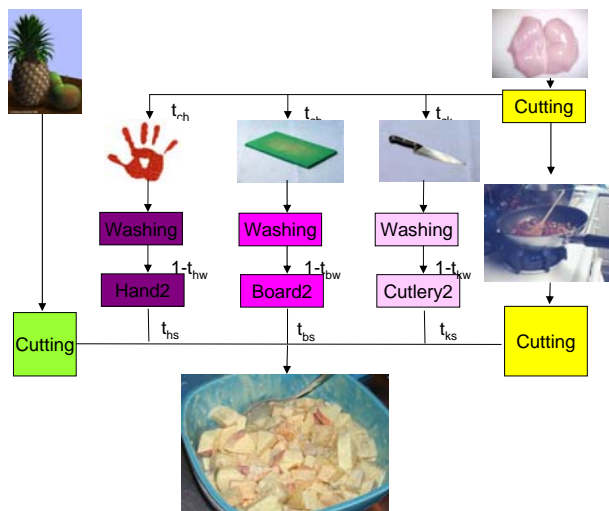
- You need to know
 - how pathogens behave
 - how food handlers behave (!)
- Often this is in the hands of consumers
 - No legislation
 - No control
 - Little data



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May require a complex model ...

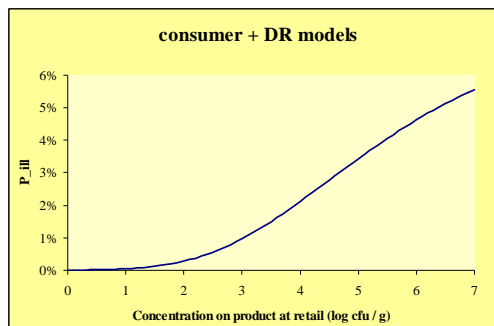
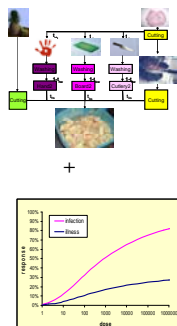


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But we can do it

- Relate concentration at retail to probability of illness
 - using models for exposure assessment and dose response

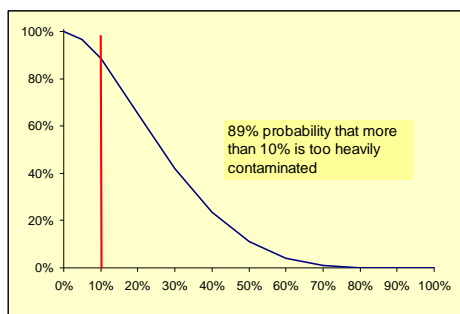


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But we can do it (2)

- Relate test result to likely concentrations at retail
– as shown before

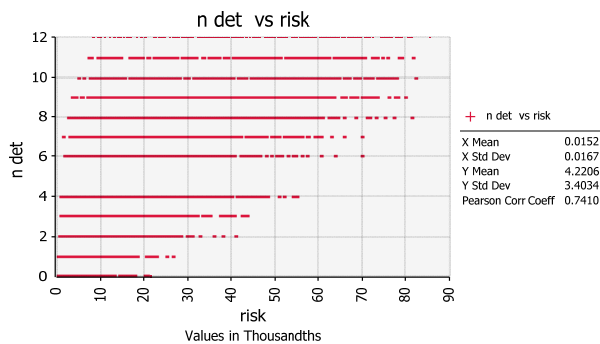


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But we can do it (3)

- And combine test results to risks...



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Uncertainty!!

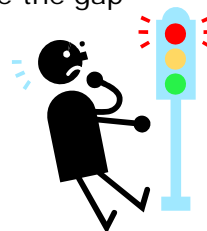
- Using a risk based approach provides best estimates given
 - a selection of assumptions
 - representative data
- Due to uncertainty we may be wrong
 - assumptions later prove to be wrong
 - stochastic variation (chance....)
 - e.g. sampling uncertainty
- We give the decision maker the best knowledge we have...

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Conclusions

- Microbiology is embedded in uncertainty
- Good microbiological analysis is essential
- Things may change between testing and exposure
- Developing risk based criteria can bridge the gap



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