Food safety risk and principles of sampling and testing of microorganisms in foods.

Marcel Zwietering

Laboratory of Food Microbiology

Wageningen University

Chairperson ICMSF

Since 1962

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We want to have zero risk in our food !

The consumer wants zero risk for sure
The company wants to have zero risk
The Food Safety Authority wants zero risk

Zero risk does not exist… !

Just like zero traffic accidents: zero deaths in traffic is impossible

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ELSEVIER
Available online at www.sciencedirect.com
ScienceDirect
Current Opinion in Food Science

All food processes have a residual risk, some are small, some very small and some are extremely small: zero risk does not exist

Marcel H Zwietering[1], Alberto Garre[1], Martin Wiedmann[2] and Robert L Buchanan[3,4]

Check for updates

Inactivation is never absolute (OK almost never)

- **Misconception 1:**
  - “if the level in the raw material is maximally 10^3 cfu/ml, a >3D reduction would kill all organisms”
  - In 100 ml there would be 10^5 cfu so still 100 left !

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Inactivation is never absolute

- **Misconception 2:**
  - "So for a product with maximally 10^3 cfu/ml and for a 100 ml amount (10^5 cfu total), a >5D reduction would kill all organisms"
  - So for a 6D reduction 10^5 cfu would reduce to 0.1 cfu/100 ml
  - Fractional cells do not exist so the product is "sterile"
  - No: in every 10 products 1 survivor is present (that could grow and make someone ill

Inactivation is never absolute

- So for a 12D reduction 10^5 cfu would reduce to 10^{-7} cfu
- This is 1 in 10 million products… still not zero, but OK, this could be an ALOP (Appropriate Level of Protection; WTO term)

- Zero risk does not exist. But how low a risk do we want to achieve
  - as a society: government, consumers; food industry ?
  - per serving / per year / per lifetime

Inactivation is never absolute

- in 100 billion cans worldwide yearly, with No=1 spore per can,
- D_{121}=0.21 min, z=10°C

2.5 min 121°C = 12D; $10^{11}\cdot 1\cdot 10^{-12}$=0.1 cases per year

one case worldwide every 10 years

3.0 min 121°C = 14.3D; $10^{11}\cdot 1\cdot 10^{-14.3}$=0.00052 cases per year

one case worldwide every 1930 years

Often F_0>3 min to reduce spoiling spores…. so almost absolute

Inactivation of *Salmonella* at 121°C for 3 min (3145545 D reduction !) is really virtually zero so "almost never" a consumer risk

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Testing is never absolute

Misconception 3: We tested 5 samples and they were negative so the organism is absent !

- 100 000 chocolate bars of 25 g a day with 1 in 10 000 containing 1 *Salmonella*
- 5 samples of 25 g tested per day

- how many detects per year ?
- probability of a case per year ?

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Testing is never absolute

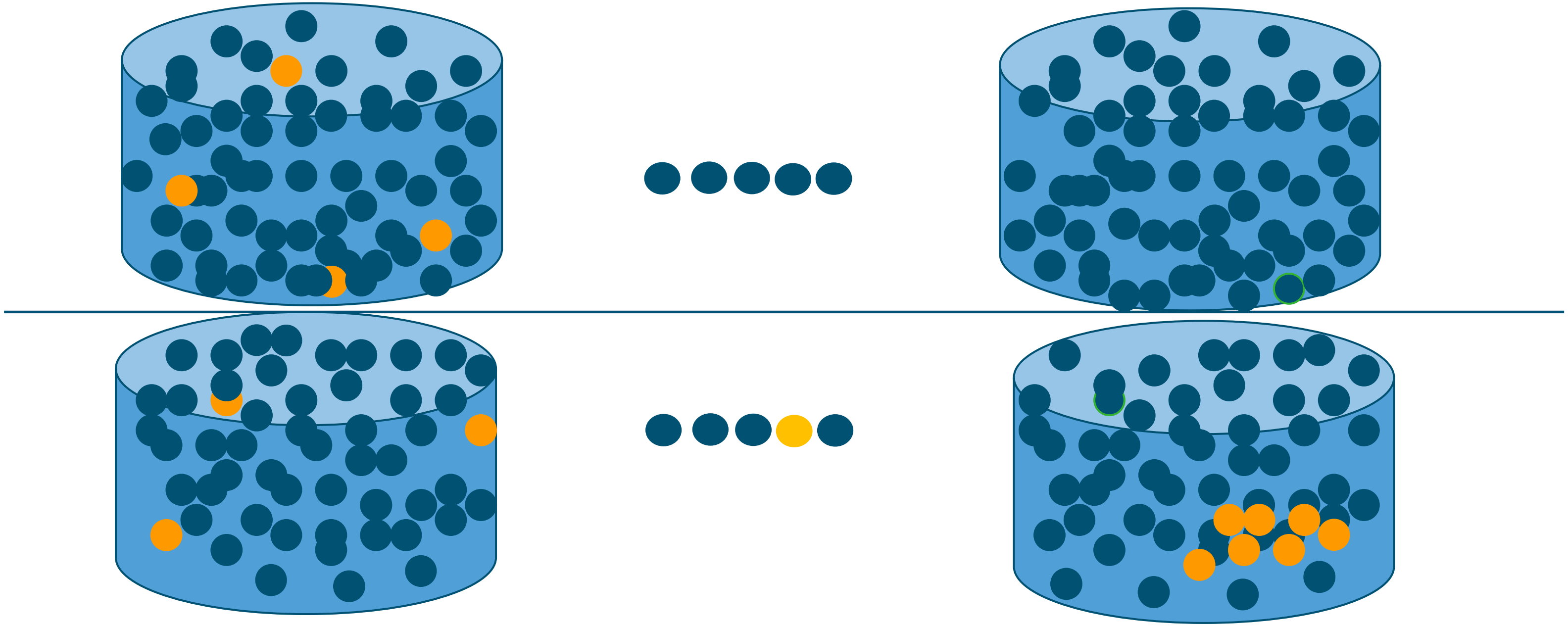
- 5 samples tested per day, 1 in 10 000 containing 1 *Salmonella*
- P_{detect}=5/10 000=0.0005 per day (1-(1-0.0001)^5)
- =0.1825 per year
- = 1 detect every 5.5 years !

- so that is under control ?

Testing is never absolute

- 100 000 chocolate bars of 25 g a day with 1 in 10 000 containing 1 *Salmonella* = 10 *Salmonella* per day
- 1 *Salmonella* has 1:400 probability of illness
- 10 per day is 3650 *Salmonella* per year
- 3650/400=9.1 illness per year
- under control ? 9.1 cases ! ….. “outbreak‟ ?
- but risk per serving=9.1/36 500 000 = 1 per 4 000 000

End product testing useful or lottery ?



Positives mean something, negatives are no guarantee

MISCONCEPTION 3

If the tested sample units are negative, the batch is free of the pathogen.

Verification
e.g. MicroCrit

Monitor Critical Limits

Validated CCPs

set up HACCP

PRP (GMP, GHP, ...)

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verification
by MicroCrit

Only testing is not solid

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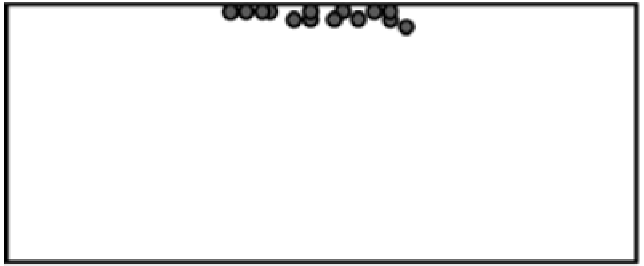
Not homogeneously distributed

- Microorganisms can be heterogeneously distributed
- Taking a sample is a stochastic process
- Performing a sampling plan (n=10) is a stochastic process
- Testing methods are not perfect

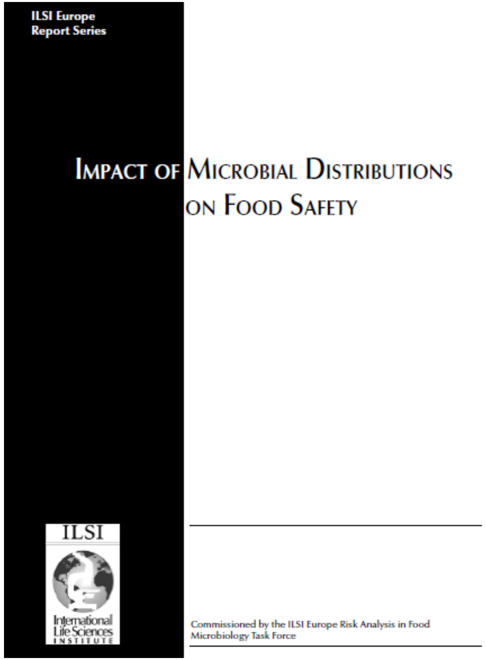
Testing is no control but can be used for verification

Distribution of microorganisms in foods

Contamination site: often on surface



- animals (skin, faeces)
- plants (soil, water, manure)
- equipment, utensils
- humans
- water, air, aerosols, dust
- packaging material
- vermin


ILSI Europe
Report Series

IMPACT OF MICROBIAL DISTRIBUTIONS ON FOOD SAFETY

ILSI
International Life Sciences Institute

Commissioned by the ILSI Europe Risk Analysis in Food Microbiology Task Force

Impact of Microbial Distributions on Food Safety
http://ilsi.eu/wp-content/uploads/sites/3/2016/06/Microbial-Distribution-2010.pdf

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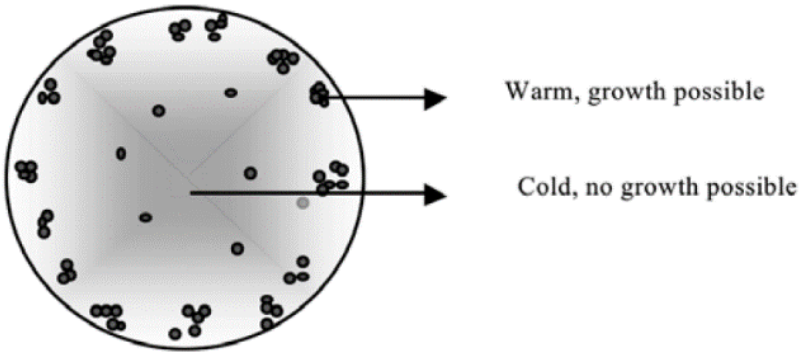
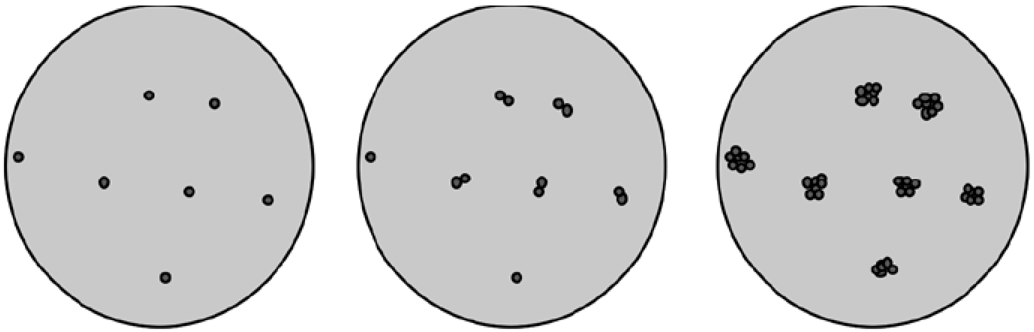
Distribution of microorganisms in foods

Dynamic levels (1)

- Growth



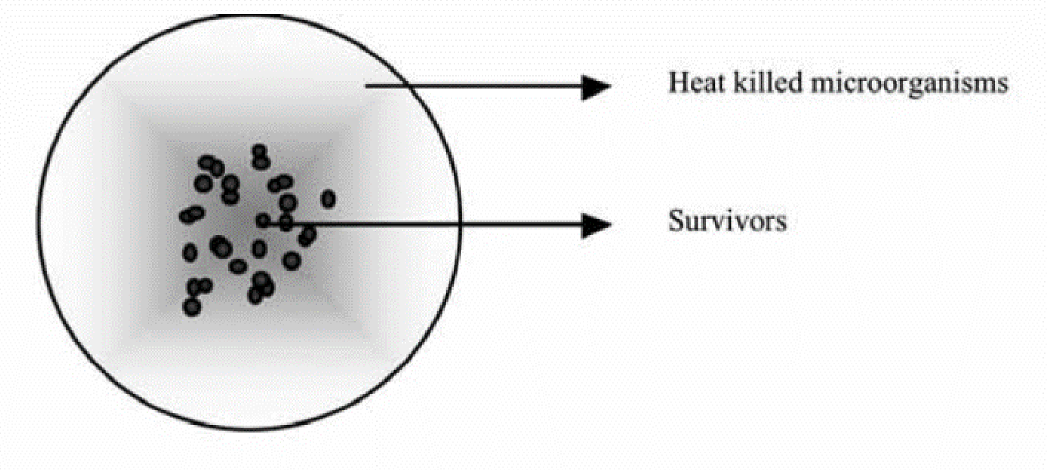
- Local clustering



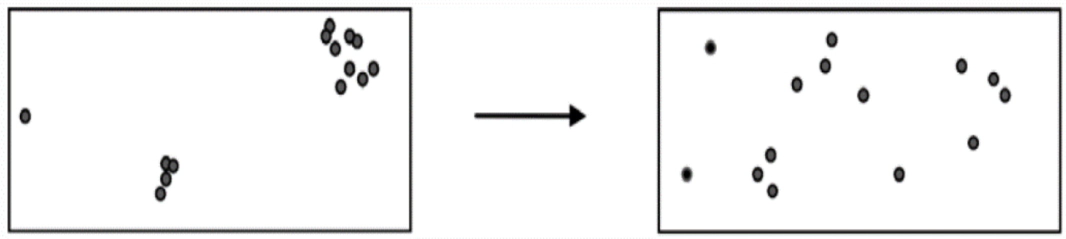
Distribution of microorganisms in foods

Dynamic levels (2)

- Death



- Mixing

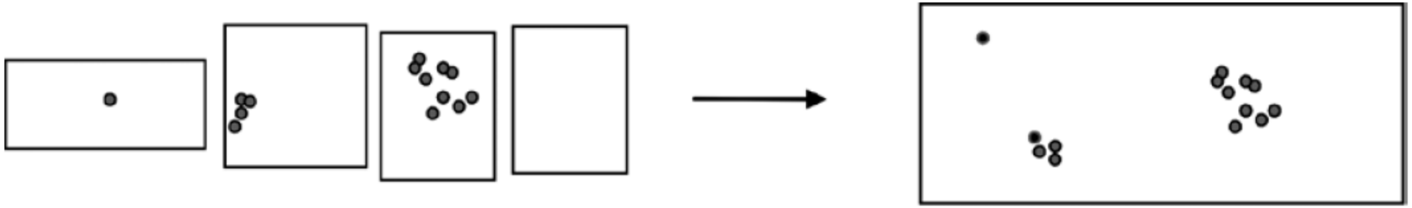


Impact of Microbial Distributions on Food Safety
http://ilsi.eu/wp-content/uploads/sites/3/2016/06/ Microbial-Distribution-2010.pdf

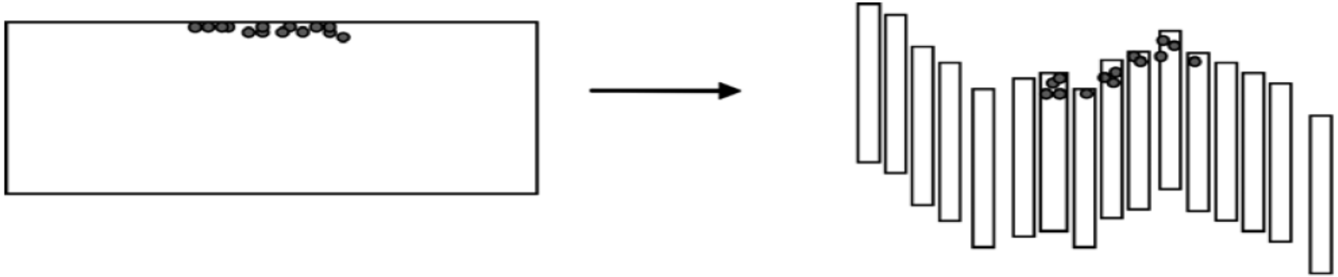
Distribution of microorganisms in foods

Dynamic levels 3

- Joining



- Fractioning



Impact of Microbial Distributions on Food Safety
http://ilsi.eu/wp-content/uploads/sites/3/2016/06/ Microbial-Distribution-2010.pdf

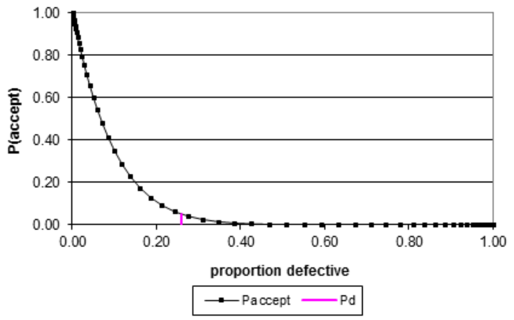
Sampling is a stochastic process

- Microorganisms can be heterogeneously distributed
- Taking a sample is a stochastic process
- Performing a sampling plan (n=10) is a stochastic process

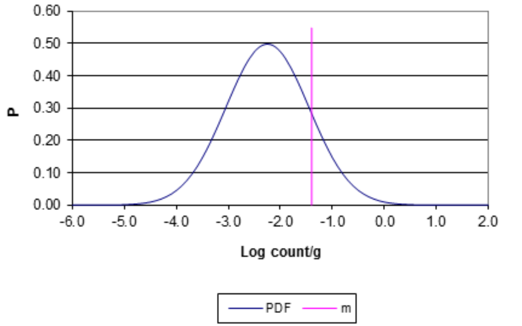
- Tools exist !

http://www.icmsf.org

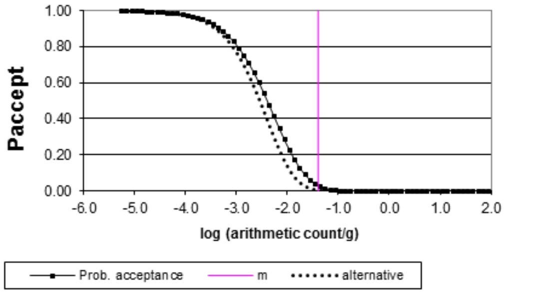
Operating characteristic curve for proportion defective, with n=10 and c=0



Probability density function (PDF) for log counts. Distribution mean = -2.25 and sigma = 0.80



Operating characteristic curve scaled to relate log arithmetic mean count to m



Batch acceptance for Pd			
		P(accept)	
Pd	20 %	10.7	%
actualPd	25.9 %	5.00	%

INPUTS		
mean	-2.25	
sigma	0.80	
m	-1.40	
n	10	
c	0	
amount	25	g

P(accept)		
Computed	5.00	%
Desired	5	%

Find mean that gives desired P(accept)

Find n that gives desired P(accept) or better (less)

Preject	95.00

ALTERNATIVE n AND c		
mean	-2.25	
sigma	0.80	
m	-0.98	
n	30	
c	0	
amount	9.6	g

P(accept)		
Computed	0.91	%
Target, left	5.00	%

For any value of n and c imputed find the m that gives the same P(accept) as the model on the left

Sandbox: for your own calculations

Means and median					
	Arithmetic			Geometric=median	
	0.0307	cfu/g		0.0056	cfu/g
one cfu in	32.6	grams	one cfu in	177.7	grams
	-1.51	log cfu/g		-2.25	log cfu/g

Implied Acceptance level		
Percentile	z-score	Concentration at this percentile
99.9	3.10	0.23

This sampling plan would provide 95 % confidence that a lot of food containing a median concentration of 1 organism in 177.7 g and an average concentration of 1 organism in 32.6 g (and having a standard deviation of 0.80 log cfu/g), would be rejected (i.e. more than 0 out of 10 samples of 25 grams giving detection of the organism)

Scale of the risk

- risk per serving
- risk per person per year
- risk per person per lifetime
- cases per year
- cases per million population

Consumer: risk per serving	1 per 4 000 000
Consumer: risk per person per year	1 per 80 000 (50 bars per year)
Consumer: risk per life-time	1 per 1 000 (80 years life expectancy)
Producer: cases per year	9.1 cases per 36.5 million bars
Government: cases per million people	12.5 cases per million people

Table 2

Examples of risk per serving of several diseases from RTE foods, risk per person per year, cases per year and cases per million population

Food product	Hazard	Region	Risk per serving	Risk per year per person	Cases per year	Cases/million population	Source
Deli meat	*L. monocytogenes*	USA[a]	$7.7 \cdot 10^{-8}$	$5.5 \cdot 10^{-6}$	1599	5.5	[23]
Unpasteurised milk	*L. monocytogenes*	USA[a]	$7.1 \cdot 10^{-9}$	$1.1 \cdot 10^{-8}$	3.1	0.011	[23]
Smoked seafood	*L. monocytogenes*	USA[a]	$6.27 \cdot 10^{-9}$	$4.5 \cdot 10^{-9}$	1.3	0.0045	[23]
Pasteurised milk	*L. monocytogenes*	USA[a]	$1.0 \cdot 10^{-9}$	$3.1 \cdot 10^{-7}$	90.8	0.31	[23]
Vegetables	*L. monocytogenes*	USA[a]	$2.8 \cdot 10^{-12}$	$6.9 \cdot 10^{-10}$	0.2	0.00069	[23]
Hard Cheese	*L. monocytogenes*	USA[a]	$4.5 \cdot 10^{-15}$	$1.4 \cdot 10^{-13}$	<0.1	<0.00035	[23]
Fermented meats	*L. monocytogenes*	Worldwide[b]	$2.5 \cdot 10^{-12}$	$6.6 \cdot 10^{-8}$	514.8	0.000066	[24]
Beef	*L. monocytogenes*	Brazil[c]	$8.1 \cdot 10^{-6}$	$1.2 \cdot 10^{-6}$	252	0.0000012	[25]
Beef	*Salmonella*	Brazil[c]	$4.7 \cdot 10^{-3}$	$8.6 \cdot 10^{-4}$	179,496	0.00086	[25]
Leafy green vegetable salad	*Salmonella*	The Netherlands[d]	$6.83 \cdot 10^{-6}$	$1.1 \cdot 10^{-5}$	187	10.82	[26]
Oysters	*Vibrio*	USA[a]	$4.5 \cdot 10^{-4}$ to $8.1 \cdot 10^{-1}$	$9.7 \cdot 10^{-6}$	2826	8.6	[27]
Oysters	*Vibrio*	Taiwan[e]	$8.56 \cdot 10^{-5}$	$2.8 \cdot 10^{-6}$	67	2.8	[28]
Shrimps	*Vibrio*	Malaysia[f]	$4.80 \cdot 10^{-6}$	$3.9 \cdot 10^{-6}$	123	12	[29]

All food processes have a residual risk, some are small, some very small and some are extremely small: zero risk does not exist

Marcel H Zwietering[1], Alberto Garre[1], Martin Wiedmann[2] and Robert L Buchanan[3,4]

$1.5 \cdot 10^{-7}$ $1.25 \cdot 10^{-5}$

Analysis of a quantitative risk assessment of listeriosis from pasteurized milk: The combinations of which factors cause listeriosis in this low-risk food?

Hiroki Abe [a,b,**], Alberto Garre [a], Shige Koseki [b], Heidy M.W. den Besten [a], Marcel H. Zwietering [a,*]

Food Control 152 (2023) 109831

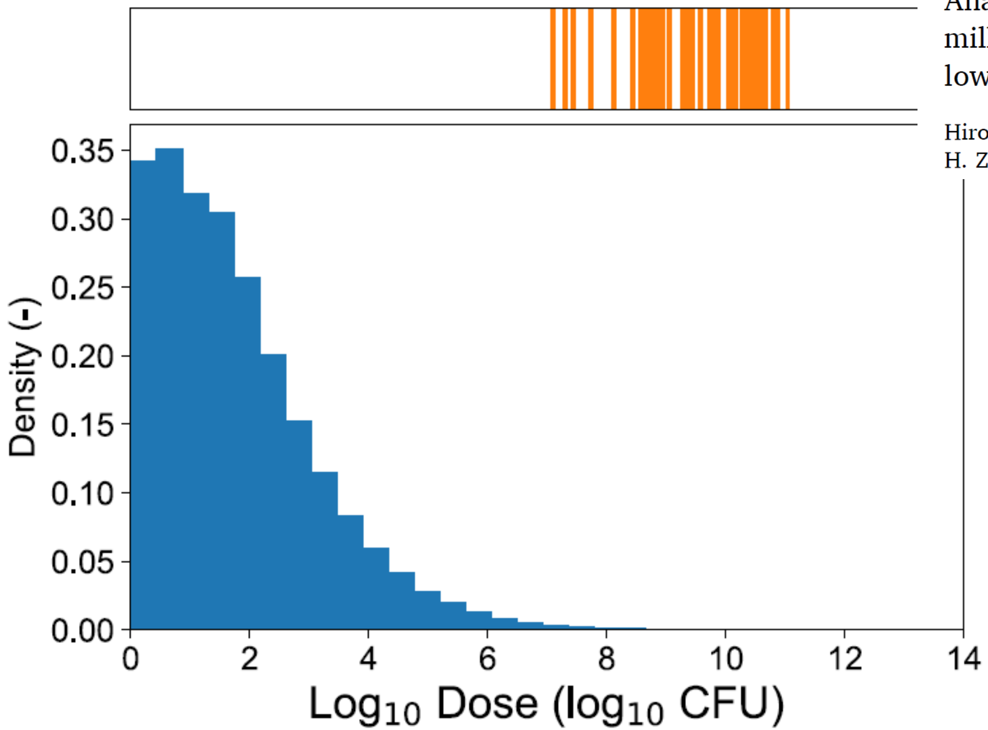
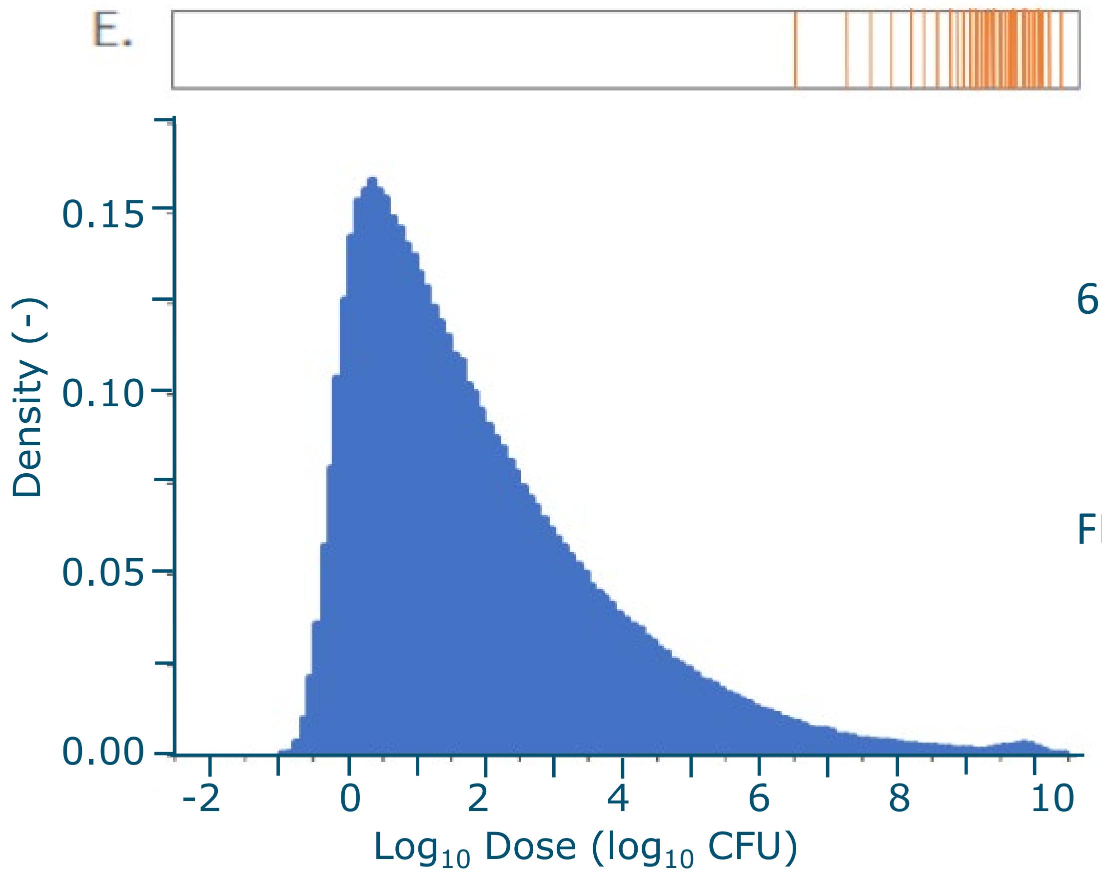


Fig. 3. The distribution of the estimated *L. monocytogenes* dose from contaminated pasteurized milk (blue distribution) and its location in scenarios with illness (orange bar above; barcode chart). The scale and x-axis grid of the above orange barcode chart is same as that of the below blue distribution of Log dose of contaminated dose scenario. The contaminated dose scenario was 0.04% of all scenarios: the doses of the 99.96% of all simulated scenarios were zero.

6.1 cases per 1 billion servings

FDA/FSIS: : 1 cases per 1 billion servings

WHO: : 5 cases per 1 billion servings



ELSEVIER
International Journal of Food Microbiology
Available online 8 December 2023, 110516
In Press, Journal Pre-proof What's this?

Temperature status of domestic refrigerators and its effect on the risk of listeriosis from ready-to-eat (RTE) cooked meat products

Wieke P. van der Vossen-Wijmenga [a b], Heidy M.W. den Besten [a], Marcel H. Zwietering [a]

65 cases per 1 billion servings

FDA/FSIS: : 77 cases per 1 billion servings

It is a matter of probability, of low probability

US estimates microbiological food borne illnesses per year (Scallan et al. 2011)
(31 pathogens)

Pill = 1:32	9 400 000 cases	31 000 per million	2.5 times per lifetime
Pdeath=1:220 000	1351 deaths	4.5 per million	0.00036 per lifetime

NL estimates microbiological food borne illnesses per year (RIVM)
(14 pathogens)

Pill = 1:25	680 000 cases	40 000 per million	3.2 times per lifetime
Pdeath=1:220 000	80 deaths	4.6 per million	0.00037 per lifetime

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In perspective .....

700 000 cases per year in the NL ….. that is dangerous !

That is 17M/700 000= 1 times in 25 years …. 3 times per lifetime

Prevention paradox ! with all controls

Conclusions

- 6D or 12D are not absolutes, but reduce risk with a factor million or trillion
- All samples being negative is no guarantee of safety
- A positive sample is indicating unsafety
- Control of safety is only to a very limited extend supported by end-product testing (verification only)
- Tools to determine performance do exist
- With large production volumes very low probabilities can give illness cases

there is a small residual risk	…. live with it
there is negligence	…. prevent it
there is stupidity	…..prevent it

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