Risk Based Performance Standards

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A definition?

- Inst Medicine & National Research Council Committee. Review on use of Scientific criteria & performance standards. 2003.

- Zero Tolerance is:

- **“A Lay audience perception of the absence of a hazard that cannot be scientifically assured, but is operationally defined as the absence of a hazard in a specified amount of food as determined by a specific method”**

- Some people think zero tolerance means absence of a hazard
- Hazard absence cannot be scientifically assured but regulatory practice means absence in a specified amount of food as determined by a specific method & sampling protocol.

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Zero tolerance vs Performance standards

- Performance Standards- where does this leave us.
  - 1) Performance standards – via microbiological criteria
  - 2) Performance standards- via process criteria/product criteria
- 3 examples

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Microbiological Criteria

- An example
  - *Campylobacter--UK*

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Example - *Campylobacter* in Poultry-UK example

- Background
- UK- biggest single cause of Infectious Intestinal Disease- 60 to 65,000 reports /yr
- Main cause—fresh poultry

	2005	2008	2014/15
Fresh Chicken. Prevalence *Campylobacter*	70%	76%	73%

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Next Moves?

- How to create an environment to reduce *Campylobacter* on raw chicken?
- Not feasible to introduce a “zero” requirement
- Way forward: Introduce criteria
- Not standards- not introduced into legislation
- Encourage producers/retailers to take action to reduce prevalence/levels.

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Campylobacter in UK

- UK Food Standards Agency View
- Create 3 criteria

<100/g	100 to <1000/g	>1000/g

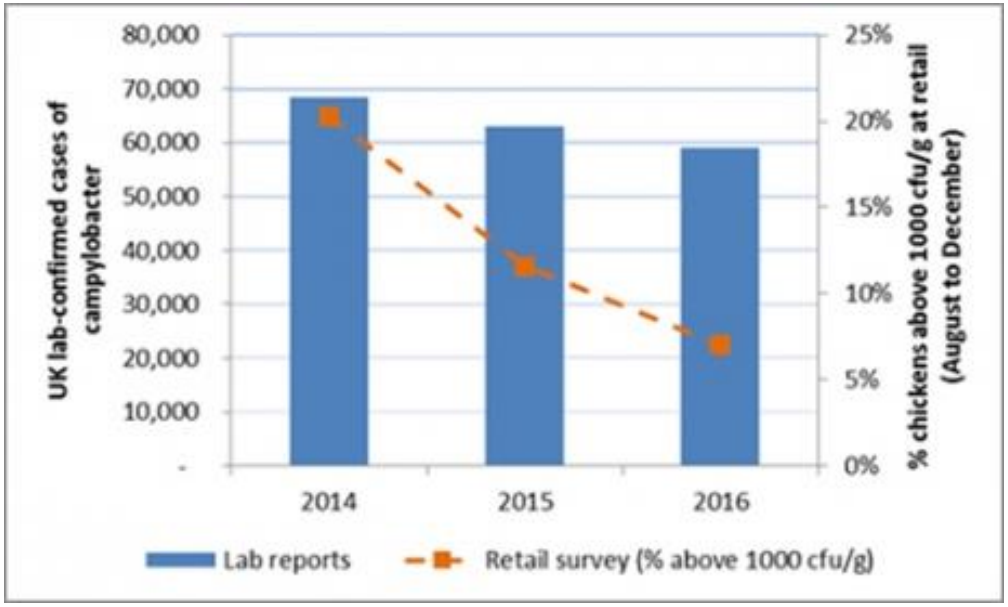
- Reduce number in highest criteria set (>1000/g)
- The “standard” is set:
  - reduce the number contaminated post slaughter at >1000/g from 27% (2008) to 10%.
  - Considered to be equivalent to a 7% level at retail
  - Models indicate reduction in illnesses of 50%

How to do it?

- Surveillance at retail level
- Annual results published
- Names of retailers given in reports (“name and shame policy”)
- Results:
  - Lots of work
  - Retailers/producers develop large research projects with their suppliers

Current data (March 2017)

	% >1000/g	Presence of Campy
2014	20%	78%
2015	12%	66%
2016	7%	56%



Graph from UK FSA web 14/3/17)

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Levels of Illness Reduction

- Reduction in reported cases 10,000
- Ratio reported to actual cases—1:9.3
- Calculated reduction in actual cases : 93,000

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Power of the *Campylobacter* performance standard?

- Its not a standard
- The reporting method has great effect (publicity)
- Generated research on reducing levels on retail whole chicken
- Alternative benefits
  - Makes public aware
  - Cook in bag chicken

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The Standard moves on:

Food category	Micro-organisms	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
"2.1.9 Carcases of broilers	*Campylobacter* spp.	50 (5)	c=20 From 1.1.2020 c=15; From 1.1.2025 c=10	1000 cfu/g		EN ISO 10272-2	Carcases after chilling	Improvements in slaughter hygiene, review of process controls, of animals origin and of the biosecurity measures in the farms of origin

EC Regulation 2073/2005- Amendment into force Jan 2018

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Process/Product criteria-standards

- Systems which can be shown to reduce/maintain a pathogen to/at an acceptable level.
- Acceptable level– The Food Safety Objective
- By knowing the acceptable level and the potential amount in the material– criteria can be produced
- Process standard- application of an external process (e.g. heat/time)
- Product Standard- attaining a parameter within the food (e.g. pH)

What needs to be known

- The acceptable level of hazard in the product
- The maximum level that may be found in the ingredient/product (with some consideration of dose)

- The required Process/Product criteria/standard can be devised.

Examples

- 12D reduction process for *C.botulinum* in canned foods
- FDA 5 log reduction process for juice (21 CFR 120.24)
- FDA Food Code 155F(68.33C) for 15 sec for Burgers (5D kill)
- Various milk pasteurisation requirements
- FSIS(2012) *Salmonella* compliance guidelines pertaining to Fermented meat products—validated 5 log reduction

Issues to consider

- The level of hazard reduction may differ
  - USA- 5 log reduction
  - Europe- 6 log reduction
- Parameters relation to the hazard

Core Temperature (ºC)	Cook Time (min) *L.mono*	Cook time (min) *E.coli* O157
60	43.48	93
65	9.3	13.6
70 ref	2	2
75	0.43	0.3
80	0.09	0.05

z=7.5 Cº L.mono
z=6.0 Cº E.coli

- Parameters related to the food
  - aW affects D value
    - BHIB 62C D=24sec
    - Wheat flour 62C D= 14.6h

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Things to note

- Some criteria are specified as the process to be given:
  - XºC for y min
  - Time/temperature validation is needed
- Some criteria are specified as a required log reduction
  - Full microbiological validation required.

STEC

- EU Working Group on Microbiological criteria.
- Guidance on actions if STEC detected.
- EU Guidance now stopped as Members States failed to agree actions
- UK Guidance moving forwards

Format of the Guidance

- Foods split into 2 “risk” profiles
  - RTE foods & those likely to be consumed less than thoroughly cooked
  - Foods to be consumed after a process that will remove an STEC risk

Food profile 1- RTE

- Confirmed detection of STX producing E.coli
  - Withdraw from the market

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Food profile 2- non-RTE

- Confirmed presence of STEC: O157, O26, O103, O145, O111, O104 .
- Is product sufficiently labelled for a cooking/treatment procedure befor consumption, that will remove the STEC risk
  - Yes- could be left on the market
  - No- do not place on the market or withdraw.
  - In either case investigate source-put in place controls

Some Conclusions

- Zero tolerance may be an overused term- that means very different things to different groups
- But it does not mean zero risk
- The use of well defined microbiological criteria (standards) can drive improvements in food safety
  - But end product testing alone, is a very basic tool that never assures safety
- Process/Product criteria- are good tools
  - Requires knowledge and validation
  - Requires an understanding that good hygiene after application is required.
- It is possible to mix performance standard types to achieve a desired outcome.