

Harmonizing International Regulations for *Listeria monocytogenes* in Ready-to-Eat Foods

Use of Risk Assessment for Helping Make Science-Based Decisions

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Listeriosis

- Australia: 3 cases/million 23% mortality
- New Zealand: 5 cases/million 17% mortality
- European countries: 0.3-7.5 cases/million
- United States: 3.4 –4.4/million 20-30% mortality
- Note: rate about the same, independent of the policies in place
- Estimated number of cases in US
 - 1800- 2500 with up to 500 deaths
 - Costs for 2,298 cases (77 newborn/fetal plus 422 adult deaths) = \$2.3 billion/year (ERS, 2000)

Listeriosis Foodborne Outbreaks

- Dairy
 - Hispanic-style soft cheeses; soft, semi-soft and mold-ripened cheeses; pasteurized chocolate flavored milk; pasteurized and unpasteurized milk; butter
- Meat
 - hot dogs; pork tongue jelly; processed meats; pate; salami;
- Fish and Shellfish
 - cooked shrimp; smoked salmon; smoked roe and mussels
- Vegetables
 - maize and rice salad; maize and tuna salad; potato salad; raw vegetables; and coleslaw
- Lm grows slowly at refrigeration temperatures

Regulation of Lm

- For trade purposes limits to the burden of the microbial load in foods is often required and this applies particularly to Lm in RTE foods
- Currently there is no international agreement on what numbers of Lm in foods are acceptable to protect the consumer
- In several countries, different criteria or recommendations for tolerable levels of Lm in RTE foods have been established over many years
- Rationale for these not always clear (expert opinion)

US Policy of Zero Tolerance

- Major outbreak in 1985 when Mexican-style soft cheese in Los Angeles, California caused over 142 cases with 48 fatalities
- Surveys done the same year by FDA found Lm in both imported and domestic soft cheeses
- It was recognized that Lm has caused foodborne disease from food products regulated by FDA and USDA, or had the potential to do so
- Therefore, the FDA established a policy of zero tolerance for Lm in RTE foods

Canadian Criteria for Lm in Foods

- 1. Soft cheese, pâté, jellied pork tongue, hot dogs, cold smoked rainbow trout and processed deli turkey meat. Detected in 50 g
- 2. All other RTE foods supporting growth of Lm with refrigerated shelf-life >10 days. Detected in 25 g
- 3. RTE foods supporting growth of Lm with refrigerated shelf-life <10 days and all RTE foods not supporting growth ≤ 100 cfu/g (also depends on adequacy of GMPs)

2006 EU Criteria for *L. monocytogenes* in Foods

Category of Food	Sampling plan	Limits	Where criterion applies
RTE foods intended for infants and SMP	n=10 c=0	Absence in 25 g	Products in the market
RTE foods able to support the growth of Lm, other than those intended for infants and SMP	n=5 c=0 n=5 c=0	100 cfu/g Absence in 25 g	Products in the market Before it has left the processor
RTE foods unable to support the growth of Lm, other than those intended for infants and SMP	n=5 c=0	100 cfu/g	Products in the market

SMP = special medical purposes

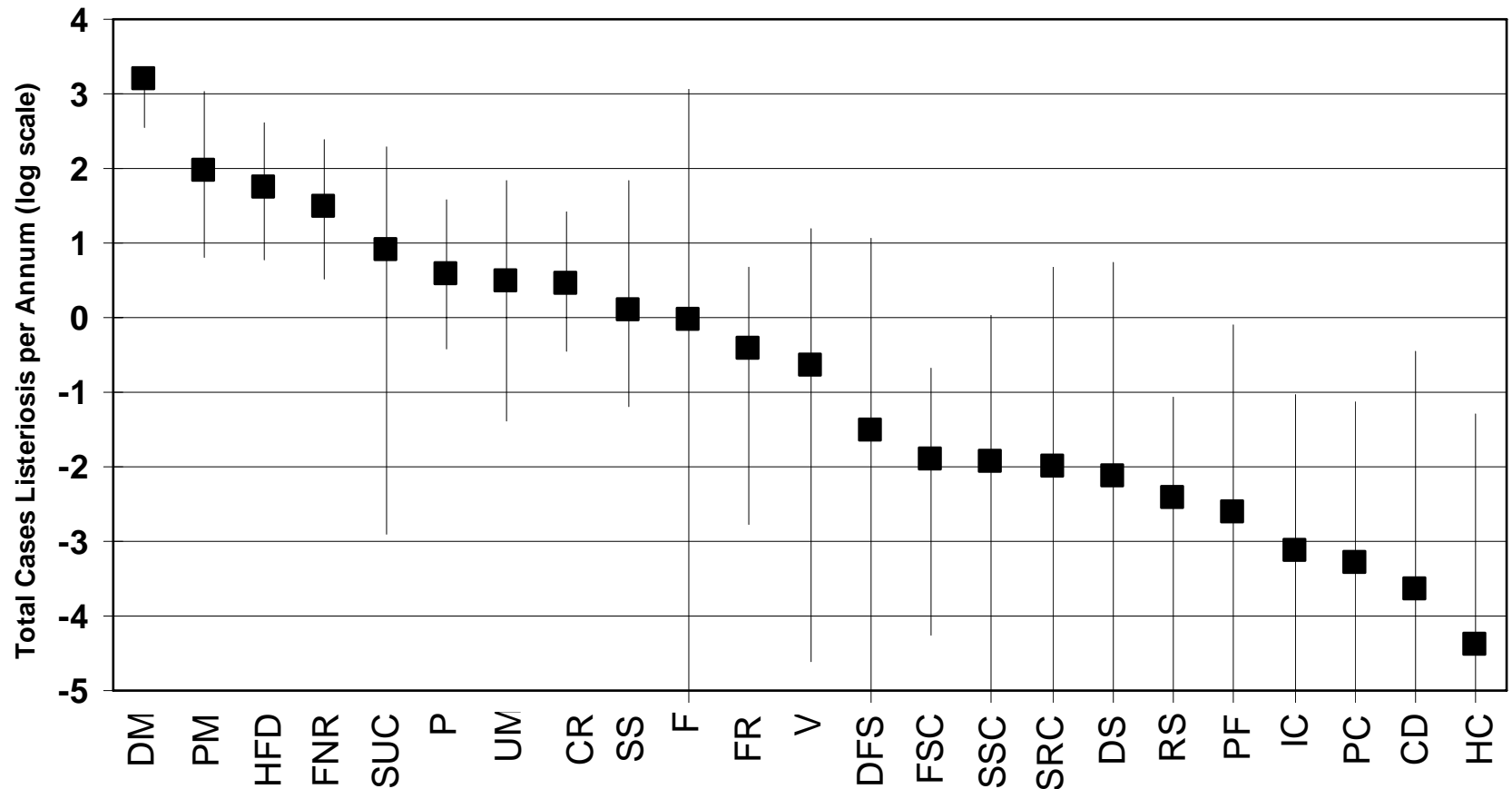
Growth and Survival Limits for *L. monocytogenes*

Parameter	Minimum	Maximum	Optimal	Survives (but no growth)
Temperature (°C)	-1.5 to +3	45	30 to 37	-18°C
pH	4.2 to 4.3	9.4 to 9.5	7.0	3.3 to 4.2
Water activity	0.90 to 0.93	> 0.99	0.97	< 0.90
Salt (%)	< 0.5	12 to 16	N/A	≥ 20

Risk Assessments for Lm in Ready-to-eat Foods

- FDA (2003) has done a risk ranking of these: risk per serving vs. risk per population
- USDA (2003) has a QRA for Lm in meats and poultry
- FAO/WHO (2004) has determined the risks of listeriosis from consumption of 4 RTE foods internationally and used “what if” scenarios

Predicted Cases of Listeriosis Associated with Foods for USA on a Yearly Basis (FDA/FSIS, 2003)



USDA QRA for *L. monocytogenes* in Meat and Poultry (2003) - Some Conclusions

- Increased frequency of food contact surface testing and sanitation is estimated to lead to a proportionally lower risk of listeriosis
- Combinations of interventions (e.g., micro testing and sanitation of food contact surfaces, pre-and post-packaging interventions, and the use of growth inhibitors/product reformulation) appear to be much more effective than any single intervention
- Example: no. of annual deaths in elderly would drop from 250 to <100 (median prediction) if industry used growth inhibitors and used post-packaging pasteurization

Final Rule on *L. monocytogenes* in RTE Meat & Poultry Products

- ALTERNATIVE 1. Use a post-lethality treatment that reduces or eliminates LM AND an antimicrobial agent or process that suppresses or limits LM growth throughout shelf-life
- ALTERNATIVE 2. Use either a post-lethality treatment that reduces or eliminates LM OR an antimicrobial agent or process that suppresses or limits LM growth throughout shelf-life
 - program of testing food contact surfaces in the post-lethality processing environment for Lm or indicator organisms
- ALTERNATIVE 3. Use only sanitation measures to prevent LM contamination
 - program of testing food contact surfaces in the post-lethality processing environment for Lm or indicator organisms
 - Plants using Alternative 3 will get the most frequent verification testing attention from government regulators

Filling a Data Gap -Transfer Coefficients for *Listeria monocytogenes* in Deli Meats

- Develop a series of *Listeria* transfer coefficients that can be incorporated into risk assessment calculations to determine the likelihood of cross-contamination between foods marketed by retail foodservice establishments and delicatessens
- Transfer coefficient = $\frac{\text{CFUs recovered from contact surfaces}}{\text{CFUs from RTE food}} \times 100$

Twelve Product, Environmental and Blade Variables Affecting Outcome of Model

- 1. Product fat content – high fat (salami) vs. low fat (turkey)
- 2. Product moisture content – high moisture (turkey) vs. low moisture (salami)
- 3. Product composition – homogeneous (bologna) vs. heterogeneous (salami)
- 4. Product temperature – frozen ($< 0^{\circ}\text{C}$) vs. refrigerated ($< 0-7^{\circ}\text{C}$) or abusive ($7-23^{\circ}\text{C}$)
- 5. Environment – low ($< 50\%$) versus high ($> 50\%$) relative humidity
- 6. Blade stainless steel grade – 304 vs. 316
- 7. Blade sharpness – sharp vs. dull or broken
- 8. Blade thickness – thin vs. medium or thick
- 9. Blade cutting speed/force – slow vs. fast
- 10. Blade age – changes in surface roughness, wear, scoring, and pitting over time
- 11. Blade surface finish – 2B vs. electropolished
- 12. Blade/knife edge – serrated vs. smooth

Transfer Coefficient Work Findings

- Slicing a contaminated product will lead to contamination of all slicer components
- > 90% of *Listeria* transfer from the blade to the product occurs during the first 10-15 slices of delicatessen meats after mechanical or knife slicing
- Deli meats will “clean” the slicer blade, but with varying effectiveness
- Depending on the original contamination load and the likelihood of growth in the newly contaminated product, this may increase the risk of listeriosis
- Do opened packages of non-recalled product pose a significant risk?

Comparing Risk Estimates for Listeriosis in Milk and Smoked Fish (FAO/WHO, 2004)

- Milk:
 - the risk per serving was low (5.0×10^{-9} cases per serving), but the very high frequency of consumption (almost 300 servings/year) resulted in milk making 9.1 cases/10 million/year = 250 cases in the USA)
- Smoked fish:
 - the risk per serving was estimated to be high (2.1×10^{-8} cases per serving).
 - However, consumption of this product is modest (1 to 18 servings/year), and consequently the total number of cases of listeriosis was moderate (0.46/ cases/10 million/year = 13 cases in the USA)

The Effect of Defective Servings on Number of Listeriosis Cases Using Two Standards (FAO/WHO, 2004)

Assumed percentage of defective servings	Predicted no. of listeriosis cases at 0.04 cfu/g	Predicted no. of listeriosis cases at 100 cfu/g
0	0.5	5.7
0.00001	1.7	6.9
0.0001	12.3	17.4
0.001	119	124
0.01	1185	1191
0.018	2133	2133
0.1	11,837	11,848
1	117,300	117,363

Defective servings assumed to contain 10^6 cfu/g

Relative Susceptibilities for Non-pregnant Sub-Populations Based on the Incidences of Listeriosis

Condition	Relative susceptibility
Transplant	2584
Cancer of the blood	1364
AIDS patients	865
Dialysis patients	476
Pulmonary cancer	229
GI and liver cancer	211
Non-cancer liver disease	143
Bladder and prostate cancer	112
Gynecological cancer	66
Diabetes, insulin dependent	30
Diabetes, non-insulin dependent	25
Alcoholism	19
Over 65 years old	7.5

Australian Approach to Managing Risky Food

- FSANZ is coordinating a *Listeria* risk assessment management strategy project

Listeria monocytogenes in Cooked Shrimp (FSANZ)

- Potential for rapid growth of *Listeria*
 - Linked with outbreaks of foodborne illness
 - 8% prevalence in cooked peeled shrimp
 - Shrimp may be exposed to temperature abuse
- FSANZ conducted a microbiological survey and a quantitative microbial risk assessment
- For susceptible population
 - One case of listeriosis per annum – where shrimp are stored for 3 days prior to consumption; or
 - One case every 1,600 years – if shrimp is consumed immediately after purchase

Listeria monocytogenes In Roquefort Cheese (FSANZ)

- Request for French Roquefort cheese to be sold in Australia
- French regulatory system for raw milk and Roquefort cheese manufacture was considered comprehensive and adequate and all exported product needs to comply
 - Raw milk tested for *L. monocytogenes*
 - Monitor pH, salt concentration and moisture
 - Minimum storage period no less than 90 days
 - Existing limits indicate no detectable levels of *L. monocytogenes* and *Salmonella* at retail ($<10^{-5}$ Lm cfu/ml)
- A qualitative risk assessment was undertaken by Food Science Australia to categorize the risk from each potential pathogen in Roquefort cheese showed negligible to low risk for 7 pathogens

Listeria monocytogenes In Roquefort Cheese (FSANZ)

- Based on a qualitative risk assessment, the sale of Roquefort is permitted in Australia
 - Very low/negligible risk if *L. monocytogenes* is not present in raw milk and there is effective control over cheese making and ripening operations
 - *L. monocytogenes* is unlikely to grow in Roquefort cheese during maturation and subsequent storage because of low pH and a_w
 - Relatively low consumption rates in Australia
 - 3 cases a year predicted from immunocompromized persons
- Labeling: Made from unpasteurised ewe milk

Petition to Change the FDA Regulations

- Fifteen trade associations submitted a citizen petition on December 24, 2003
- FDA should amend the regulations to establish a regulatory limit of 100 Lm CFU/g in foods that do not support the growth of the microorganism
- Limit would establish a science-based standard for the presence of Lm in such foods based on:
 - new and emerging evidence that consumer protection is a function of the organism's cell numbers in food, and not its mere presence
 - that low levels of Lm are not uncommon in the food supply and that such low levels are regularly consumed without apparent harm

Have Improvements Occurred in the US?

- US set its goal of 50% reduction of listeriosis cases from 1997 to 2005 but, although close, did not achieve this; other countries claim fewer cases
- So, some actions are working, probably more industry interventions and pregnant women aware of the risks of eating the riskier foods

Is Harmonization of Policies for Lm in RTE Foods Possible?

- Harmonization can only be done through agreements between governments
- Codex Alimentarius Commission is one logical international member country representation that this can be achieved
- Discussions have already occurred and continue with many subgroups and commissioned studies, such the FAO/WHO assessments (2004)
- Science –based criteria may be agreed to, e.g., 100 cfu/g at the time of consumption presents little risk to the healthy population

Is Harmonization of Policies for Lm in RTE Foods Possible?

- It may not matter how governments ask the industries and the consumers to achieve this – these can differ
 - Some foods can have industry interventions, such as added organic acid and pasteurization of packaged product (works for deli meat but not for cheese or some vegetables and fruits)
 - Culture has to be taken into consideration and may play a role in that certain foods are culturally important, such as raw milk cheeses in European countries
 - A zero tolerance regulation may not have an effect and a social science awareness study may need to be done

Is Harmonization of Policies for Lm in RTE Foods Possible?

- Consumer education and labeling have had limited success but do influence some people, and research into risk communication should continue
- There are certain populations that may need to be treated separately
 - AIDS, transplant patients, cancer therapy patients
 - Possible recommendations are just now being considered for these, e.g., EU more stringent conditions for medical purposes, but most policies will be internal ones by institutions housing these populations rather than governments imposing national levels for Lm in food served to these people



An Aggregate of Assessors (FAO WHO)



Thank you for your attention