



Food Industry Perspective on Non-O157 STEC

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Industry wants food to be safe

- Industry is concerned about any microorganism in foods that can cause illness.
- We know that some, but not all, non-O157 STEC can cause illness.



Industry assessment

- If an organism presents a significant risk, companies will have to address it their HACCP plans.
- Currently we have insufficient information to identify non-O157 STEC as a “hazard reasonably likely to occur” for most foods.

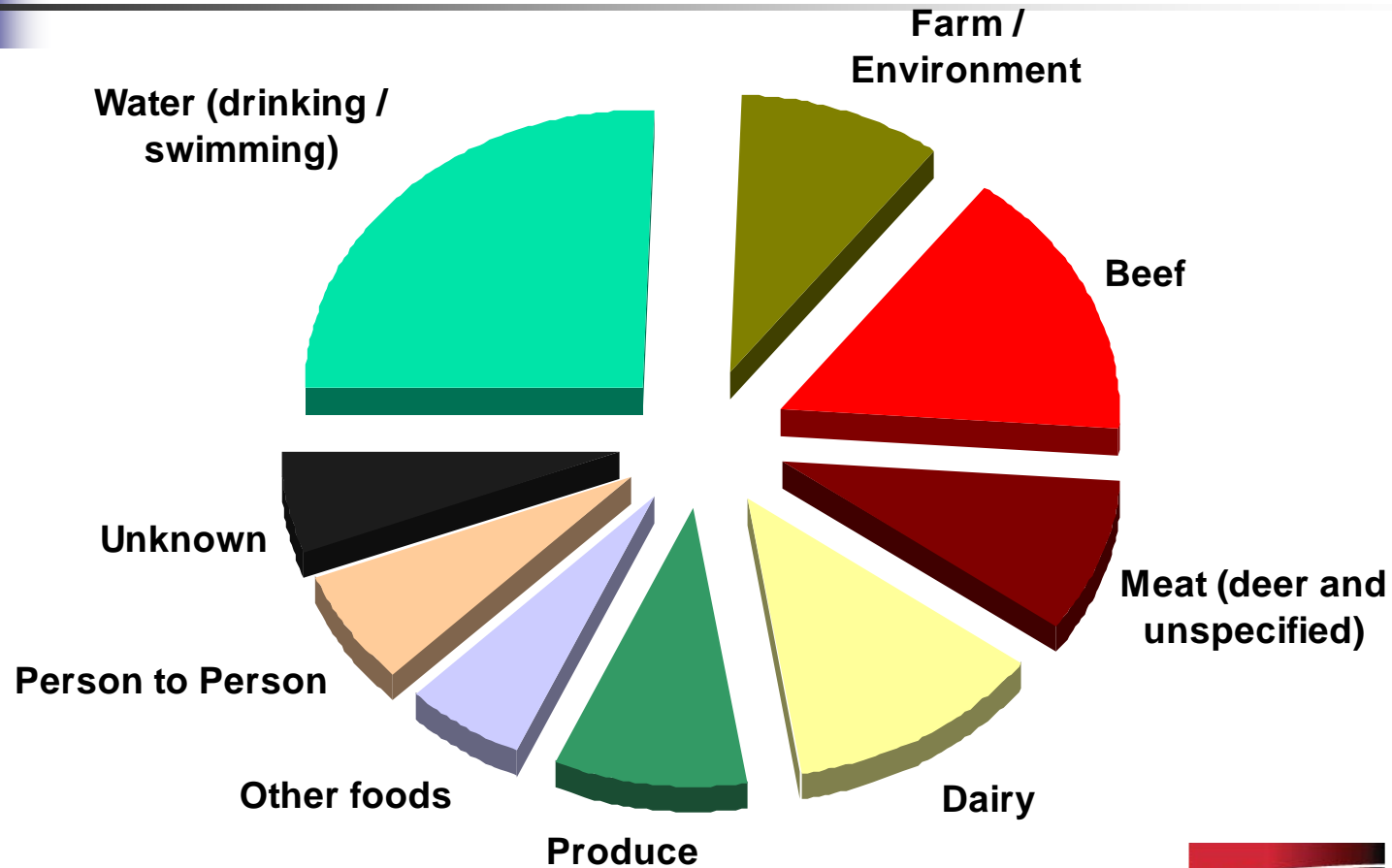


Industry needs answers

- What foods are these organisms associated with?
- Which of these foods have been associated with illness from these organisms?

E. coli O157:H7 Outbreaks Worldwide 1982 - 2006

207 total outbreaks reported in published scientific and government literature



Source: adapted from M. Ellin Doyle et al., 2006 Food Research Institute, University of Wisconsin



Food Sources of Non-O157 STEC

- Foods of animal origin - > 100 serotypes
 - beef, lamb, pork, chicken
 - Milk, cheese
- Foods cross contaminated by animal products
 - Produce may be a source

WHO, 1998 Zoonotic Non-O157 STEC





Food Sources of Non-O157 STEC Illnesses

- 1994, Montana, O104:H21 **milk**
- 1995, Australia O111:NM, uncooked, semidry fermented **sausage**
- 1996, Japan, O118:H2, salads

Epidemiologically linked



Pradel et al. 2000

- Prevalence and characterization of Shiga-toxin producing *Escherichia coli* isolated from cattle, food, and children during a one-year prospective study in France. J Clin. Microbiol. 38(3): 1023–1031.



Pradel et al. 2000

- 2143 samples – PCR for Shiga toxin-encoding genes
 - 60/603 cheese samples (+) for *stx*
- STEC isolated from 5/603 cheese samples
- 32/220 STEC isolates were not cytotoxic
- *eae* gene was found in 12/220 strains
- Concluded that majority of STEC isolates from cattle, beef and cheese were not likely to be pathogenic for humans.



Perelle et al. 2007

- Screening food raw materials for the presence of the world's most frequent clinical cases of Shiga toxin-encoding *Escherichia coli* O26, O103, O111, O145, O157. Int. J. Food Micro. 113: 284-288.

Perelle et al. 2007– prevalence of STEC

- Positives by PCR-ELISA for *stx*
 - Raw milk 43/205 (21%)
 - Minced beef 45/300 (15%)
- 74/88 (+) confirmed positive by *stx*-typing with 5'-nuclease PCR assay
- Multiplex real-time PCR for O26, O103, O111, O145, O157 confirmed 18/74

Perelle et al. 2007– more results

- Contamination by the main pathogenic *E. coli* O-serogroups of major public health concern:
 - 2.6% minced meat
 - 4.8% raw milk
- MPN: 1-2 STEC cells of the highly pathogenic serogroups/kg

Perelle et al. 2007– Conclusions

- “Contamination of beef meat and raw milk by the highly pathogenic serogroups of STEC is very low”
- “Risk of consumer infection by human pathogenic strains of STEC present in these samples is probably very minor”

Perelle et al. 2007– also of note

- Both toxigenic (*stx*-positive) and non-toxigenic (*stx*-negative) strains are present within each O-serogroup.
- When both *stx* and O-serogroup gene sequences were detected in food there was no evidence that these signals were displayed by a pathogenic *E. coli* strain.
- Isolation from food with confirmation is necessary but problematic and time consuming

NZ Fact Sheet on Non-O157 STEC

- “An isolate possessing the ability to produce either STX in the absence of other virulence determinants is unlikely to be a major pathogen.”

Ministry of Health, May 2001



Industry needs answers

- How do we detect the pathogenic strains of non-O157 STEC?
 - Food businesses need rapid tests for short shelf life products for verification and validation of interventions



Industry needs answers

- Currently we have no reason to believe that interventions that address *E. coli* O157 or *Salmonella* would not be effective against non-O157 STEC.
 - Are there unique properties/resistances of these organisms that suggest otherwise?
 - Are there foods unique to non-O157 STEC, such that these organisms need to be specifically targeted in a HACCP plan?

What makes a pathogen an adulterant?

- A food is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health.
- If the substance is not an added substance, a food is not adulterated if the quantity of the substance does not ordinarily render it injurious to health.

USC § 601 (m) (1)



What makes a pathogen an adulterant?

- *Salmonella* in raw meat is not an adulterant – ordinary methods of cooking and preparing the food kills *Salmonella*.
- *E. coli* O157:H7 in ground beef is an adulterant – *E. coli*-containing ground beef may be injurious to health when properly cooked according to many Americans.

US Court Decisions





Industry Assessment

- FDA will continue to take action against ready-to-eat foods containing pathogens.
- We need to be able to assess which strains are pathogens, and at what level.
- There is no reason to believe current practices for other pathogens in FDA-regulated products would not also address pathogenic non-O157 STEC.
- There are insufficient data to warrant a change in industry practices or regulatory requirements with respect to non-O157 STEC.





Crisis – the trigger for change

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Conclusions

- We don't have a crisis.
- We do have a "danger."
- This leads to many "opportunities."
- We need good methods to rapidly detect pathogenic strains of non-O157 STEC.
- We need to better assess the risk from non-O157 STEC to determine if changes are warranted.
- We don't want to wait for the crisis.