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May 6, 2004

FSIS Docket Clerk  
U.S. Department of Agriculture  
Food Safety and Inspection Service  
300 12th Street, SW.  
Room 102 Cotton Annex  
Washington, DC 20250

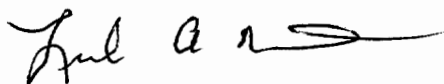
**RE: DEPARTMENT OF AGRICULTURE  
Food Safety and Inspection Service**

**[Docket No. 03-025N]**

**9 CFR Parts 301, 309, 310, 311, 313, 318, 319 and 320**

**Prohibition of the Use of Specified Risk Materials for Human Food  
and Requirements for the Disposition of Non-Ambulatory Disabled Cattle;  
Meat Produced by Advanced Meat/Bone Separation Machinery and Meat  
Recovery (AMR) Systems; Prohibition of the Use of Certain Stunning  
Devices Used To Immobilize Cattle During Slaughter; Bovine Spongiform  
Encephalopathy (BSE) Surveillance Program**

The USDA's Food Safety Inspection Service requested any additional comments or information on practices which would reduce or eliminate cross contamination between SRMs and edible product. I am submitting a CD with a presentation I have given at several meetings including the National Food Processors Association conference on prion inactivation. This presentation outlines suggestions and practices to reduce cross contamination during slaughter. The information was gathered from slaughterplants throughout Europe and a few in the United States. I have also included a procedure used in the United Kingdom to harvest the tongue. This was kindly provided by the Meat Hygiene Service.



Linda A. Detwiler, DVM

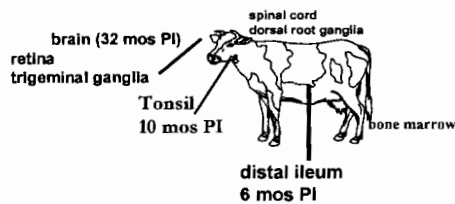
# A Guide to Cross Contamination: BSE

Linda A. Detwiler, DVM  
Washington, DC  
April 9, 2004

## What poses a risk: SRMs (to date)

- Brain
- Spinal Cord
- Trigeminal Ganglia
- Dorsal Root Ganglia
- Distal Ileum (Intestine)
- Vertebral Column
- Skull
- Tonsil
- Eye
- 3<sup>rd</sup> eyelid (Nictitating membrane)

## Distribution of Infectivity: Experimental

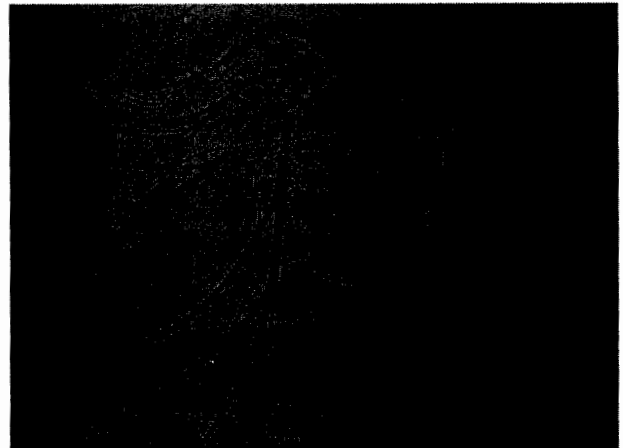
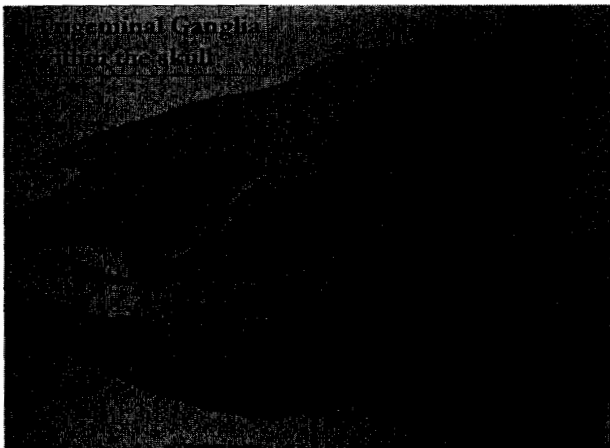


## CITATION

- All of the illustrations are taken from:

**Bovine Anatomy: An Illustrated Text**  
By Klaus-Dieter Budras, Robert E. Habel,  
Gisela Jahrmarker, Renate Richter, Diemut  
Starke

Blackwell Publishing



## DRG - Infectivity

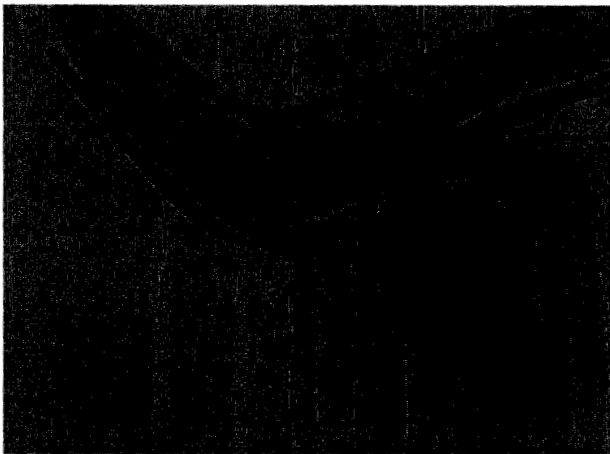
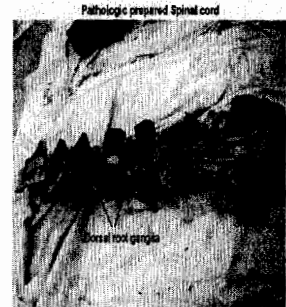
- Pathogenesis Study\*
- Oral challenge of 100 gr brain given at 4 months of age
- Sequential Sitr - 2, 6, 10, 14, 18, 22, 26, 32, 36, 38, 40 months
- Over 40 tissues collected
- DRG - infectivity at 32, 36, 38 and 40 months



Wells G.A.H., Hawkins, S.A.C., Green R. B., Austin A. R., Dexter I., Spencer, Y. I., Chaplin, M. J., Stack, M. J., & Dawson, M. (1998) Preliminary observations on the pathogenesis of experimental bovine spongiform encephalopathy (BSE): an update. *Vet. Rec.*, 142, 103-106.

## Dorsal Root Ganglia (DRG)

- Dorsal root ganglia are located at the outcoming spinal cord nerves and are surrounded by a taut connective tissue covering



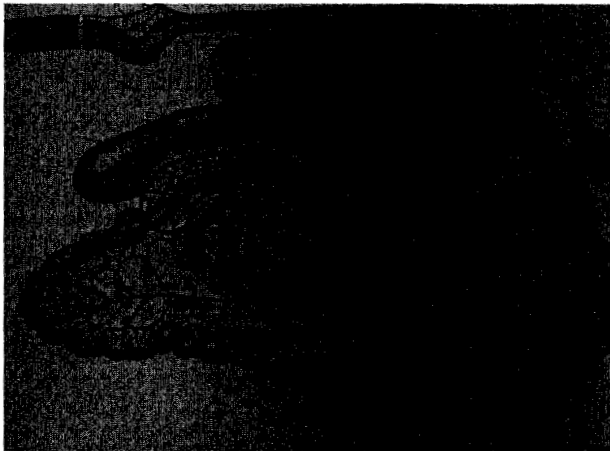
## SRMs: INTESTINES (Distal Ileum)

- 6-18 mos PI infectivity
- 18-31 mos PI no infectivity detected
- > 31 months PI infectivity

Wells G.A.H., Hawkins, S.A.C., Green R. B., Austin A. R., Dexter I., Spencer, Y. I., Chaplin, M. J., Stack, M. J., & Dawson, M. (1998) Preliminary observations on the pathogenesis of experimental bovine spongiform encephalopathy (BSE): an update. *Vet. Rec.*, 142, 103-106.

Wells G.A.H., Dawson M., Hawkins, S.A.C., Green R. B., Dexter I., Francis M. E., Simmons M. M., Austin A. R., & Horgan M. W. (1994) Infectivity in the ileum of cattle challenged orally with bovine spongiform encephalopathy. *Vet. Rec.*, 135, 40-41.

**\* Immunostaining throughout length of intestine**

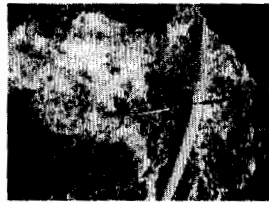


## Cross Contamination: Food and Feed

- Methods of processing can theoretically increase the risk to products via cross contamination
- Feed: throughout processing chain: rendering, feed manufacturer, transport, on farm mills, equipment
- Food: slaughter and processing: kill floor and fab floor
- Alterations in practices can reduce cross contamination

## Cross Contamination: Why risks are difficult if not impossible to eliminate

- Attack rate study
- Inactivation of agent



## BSE Transmission: Attack Rate

- studies underway: .1 gr; .01 gr; .001 gr raw brain orally to cattle
- .1 gr – 3 of 15 affected
- .01 gr – 1 of 15 (50+ mos incubation)
- .001 gr – 1 of 15 (71 mos)
- Ref: Presentation by Dr. Danny Matthews, UK VLA at the TAFS Workshop, Washington, DC; April 6, 2004



## TSE Inactivation

- “TSE agents are unusually resistant to disinfection and sterilization by most of the physical and chemical methods in common use for decontamination of infectious pathogens.”

WHO Infection Control Guidelines for the TSEs (1999)

## WHO Guidelines: Disinfectants Ineffective vs. TSEs

- |  |   |
|--|---|
| <ul style="list-style-type: none"> <li>■ Ineffective</li> <li>■ alcohol</li> <li>■ ammonia</li> <li>■ β-propiolactone</li> <li>■ formalin</li> <li>■ hydrochloric acid</li> <li>■ hydrogen peroxide</li> <li>■ peracetic acid</li> <li>■ phenolics</li> <li>■ sodium dodecyl sulfate (SDS) (5%)</li> <li>■ ethylene oxide</li> <li>■ formaldehyde</li> </ul> | <ul style="list-style-type: none"> <li>■ Ineffective</li> <li>■ boiling</li> <li>■ dry heat (&lt;600°C)</li> <li>■ ionising, UV or microwave radiation</li> <li>■ Variably or partially effective</li> <li>■ autoclaving at 121°C for 15 minutes</li> <li>■ boiling in 3% sodium dodecyl sulfate (SDS)</li> </ul> |
|--|---|

## WHO Guidelines

**“The safest and most unambiguous method for ensuring that there is no risk of residual infectivity on contaminated instruments and other materials is to discard and destroy them by incineration”**

## FDA Validation

- Dipping in water – TSE contaminated surfaces
- Soak and dip
- Beginning and endpoint titrations virtually identical
- That is: the exposure to water did virtually nothing to reduce infectivity
- Prion is sticky



Ref: Presentation by David Asher, CBER  
National Food Processors Association  
Conference on Prion Inactivation  
April 1, 2004

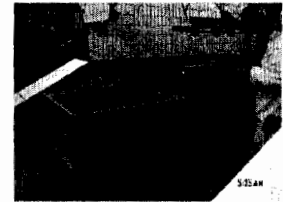
## WHO Guidelines

- Immerse in sodium hypochlorite 20,000 ppm available chlorine (preferred) or NaOH 1 N (alternative) at ambient temperature for 1 hr; clean; rinse in water and subject to routine sterilization.



## SRMs: Best practices

- Keep separate
- Avoid cross contamination
- Use separate equipment (knives, bins, etc)
- Different colors for visual standout in plant
- Training of plant personnel

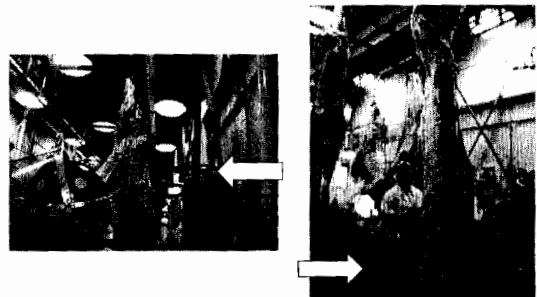


## SRMs: Dedicated Equipment

- Dedicated equipment for SRM removal
- e.g. 2 knife system
- Dedicated personnel also helps



## SRMs: Visual Differentiation



## SRMs: Training of Personnel

- Explain:
  - the disease
  - the agent and resistance
  - Cross contamination
  - Public health significance
- Take the necessary time
- Commitment starts at the top!!!



## Cross Contamination: Food

- Slaughter OR
- Processing
  - Entire Carcass
  - Head (head and cheek meat, tongue)
  - Split
  - Meat – contamination in fab



## Cross Contamination: Food

- Stun – may result in micro or macro emboli
- Carcass – potential due to circulation
- Air-injected stunning has been shown to produce macro emboli
- Industry discontinued
- USDA – Interim final rule
- References: Anil et al, 1999; Anil, et al, 2001a & b; Anil et al, 2002; Love, et al, 2000; Mackey and Derrick, 1979; Garland, et al, 1996; Garland, 1996; Munro, 1997; Taylor, 1996

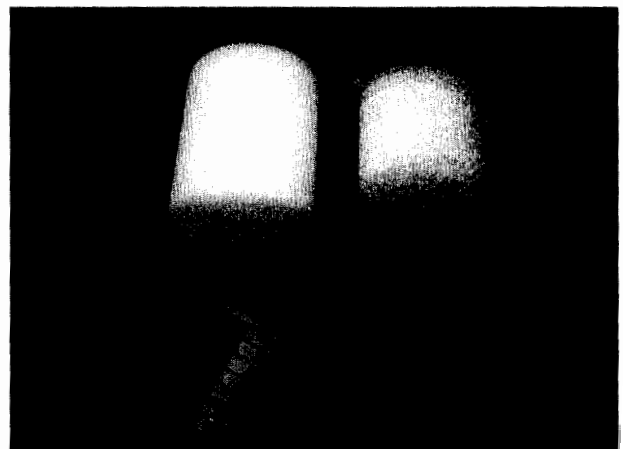
## Cross Contamination: Head

- Stun hole leakage
- Disarticulation
- Foramen magnum leakage
- CSF
- Deboning on table



## SRMs: Skull

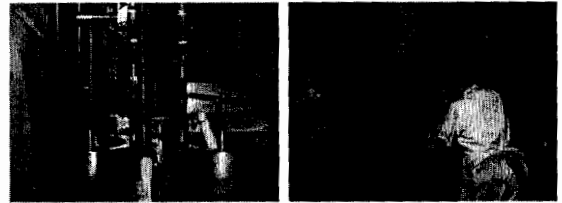
- Stunning – captive bolt leaves a hole
- Brain drip – can contaminate cheek and head meat
- Options – changes stunners: electrical or mushroom
- Cap hole



**Cork**



**Disarticulation**



**Double Knife**



**Foramen Magnum**



**CSF contamination**



**Head Processing: Cross Contamination**

- External
- Table contamination
- Transport



## SRMs: Tonsil

- If removing tonsil use separate knife (2 knife system)
- Take care not to cross contaminate tongue on cut

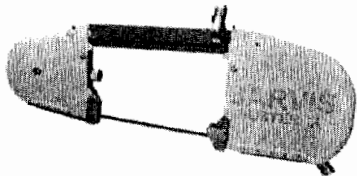


## Split

- Will have spinal cord spray on cut surface of carcass
- Keep saw clean and prevent buildup

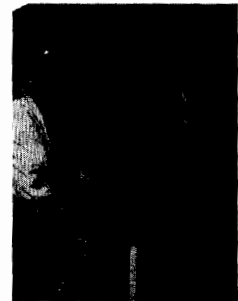


## Keep the Saw Clean



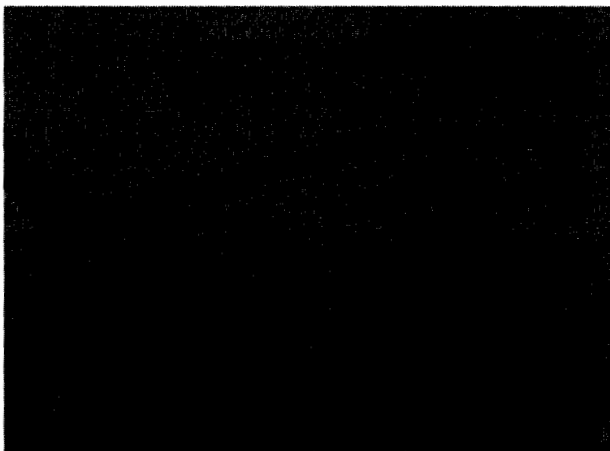
[www.jarviscanada.com](http://www.jarviscanada.com)

## Methodology to avoid Cross Contamination on Split



## Best Practices: Spinal Cord Removal

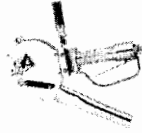
- Needs more attention to detail industry wide
- May need high and low station for cord removal
- Removal of both cord and sheath (dura)



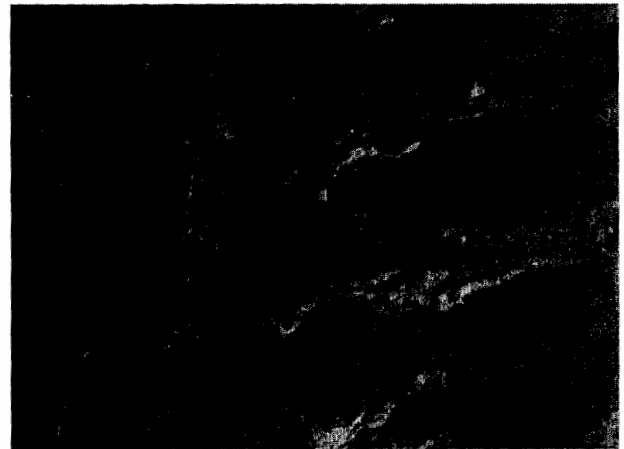
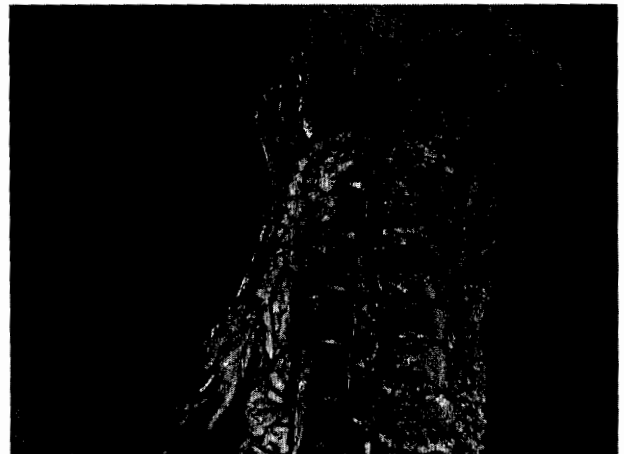
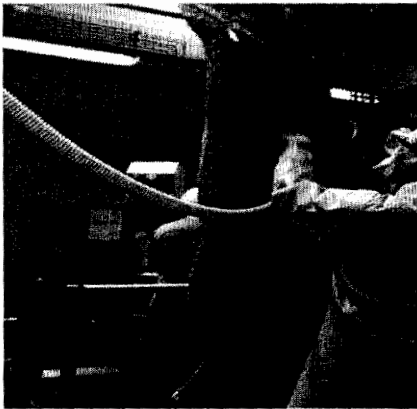


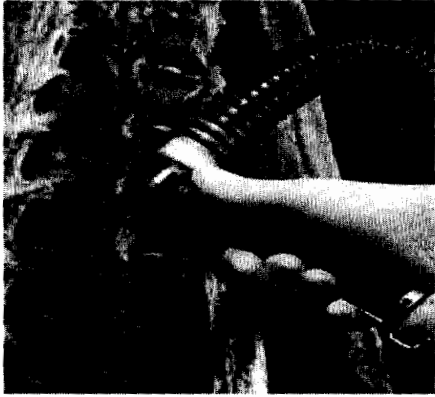
## Best Practices: Spinal Cord Removal

- Do not remove cord and trim carcass with same equipment
- Spinal cord and sheath out on kill floor
- Take care of missplits on kill floor

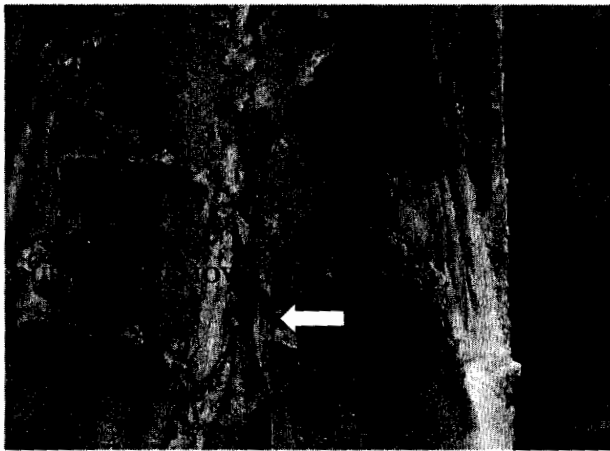


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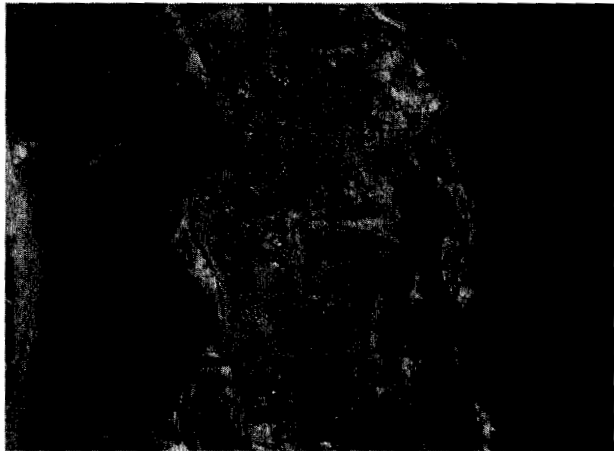


[www.bettcher.com](http://www.bettcher.com)

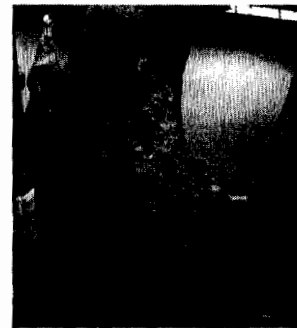
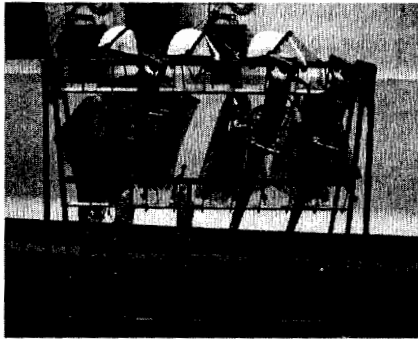


**Missplit**

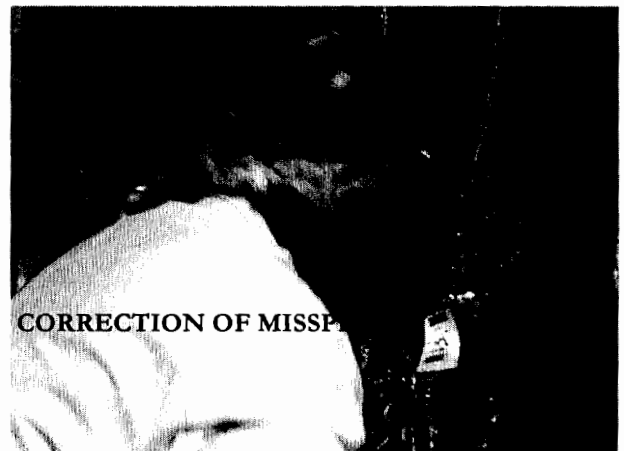




**Take care of Missplits on Kill Floor**



**Missplit Identified**



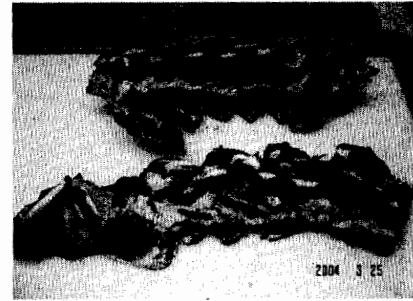
## DORSAL ROOT GANGLIA

*What are the best practices in the industry globally for the removal of dorsal root ganglia?*

*OR*

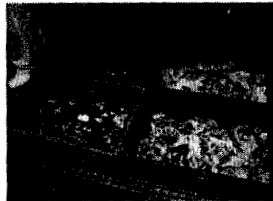
*How to avoid contamination if DRG are not removed?*

## DRGs: Its all in the cut



## Cross Contamination: Lessons

- Cannot eliminate all risks
- MAY NOT BE TOTALLY POSSIBLE
- Reduce risks by sourcing
- Reduce risks by best practices



## Cross Contamination: Lessons

IT IS ALL  
ABOUT RISK  
REDUCTION