Pre-Harvest Food Safety for Cattle Public Meeting
Notes from the Flip Charts for the Round Table Discussions

The United States Department of Agriculture's Food Safety and Inspection Service (FSIS), Animal and Plant Health Inspection Service (APHIS), and Agricultural Research Service (ARS) hosted the Pre-harvest Food Safety for Cattle Public Meeting on November 9, 2011, in Riverdale, MD. The agencies sought input on pre-harvest pathogen control strategies designed to reduce the likelihood that beef will be contaminated with pathogens of public health concern such as Shiga toxin-producing *E. coli* (STEC) and *Salmonella* during the slaughter process.

Three break-out sessions, or round table discussions, were held during the meeting, one in the morning and two in the afternoon. The agencies asked meeting participants to respond to three questions. For each main question, suggested supplementary questions were also provided to facilitate the discussion. The three main questions were:

1. What factors influence the shedding of *Salmonella* and *Escherichia coli* 0157:H7 and other Shiga toxin-producing *E. coli* (e.g., age of cattle, stress conditions)?
2. What effective and practical mitigations are available to reduce the pathogen load in general, and *Salmonella* and STECs specifically, in cattle prior to slaughter?
3. How can producers, processors, and government work together to promote adoption of pre-harvest food safety mitigations?

Meeting participants were seated at 10 tables. Each table responded to each question and reported out to the larger audience. At each table, a scribe recorded notes on a flip chart. The notes from the flip charts are provided below. The reports made to the larger audience are included in the meeting transcript that is available at the following URL: http://www.fsis.usda.gov/News_&_Events/2011_Events/index.asp.

Question 1

What factors influence the shedding of *Salmonella* and *Escherichia coli* 0157:H7 and other Shiga toxin-producing *E. coli* (e.g., age of cattle, stress conditions)?

Suggested Questions to Guide Discussions

- What are the gaps and barriers that exist to identify factors that influence the shedding of pathogens of human health concern?
- Can cattle likely to shed high quantities of pathogens ("high shedders") be identified and, if so, should high-shedding cattle be handled differently than other cattle prior to and during slaughter?
- How should a "high shedder" be defined? Are there economical and rapid tests to identify these "high shedders" in the field?
- What is the level of shedding that could overwhelm an establishment's intervention measures?
- Does confinement versus free-range rearing have an impact on shedding?
- How does the class of cattle (e.g., veal, market, dairy, cull dairy/bull) affect shedding?

TABLE 1

* **High Shedders**

1. What studies have been done to identify shedders?
2. Risk assessment models could help define the impact and how to define a high shedder.
3. Potential barriers for managing high-shedders are the turn-around time of diagnostic test.

* **Level of Shedding**

    - Quantitative modeling assuming current processing interventions could also help.

TABLE 2

Factors

1. Geography
2. Diet
3. Seasonality (Vectors)

Super Shedders

- Yes – if rapidly indentified (not for life).
- Identified by level shed.

No variation based on class of cattle

TABLE 3 – NA

TABLE 4

Factors Influencing Shedding

- Seasonality
- Geography

Temperature (Humidity)

- Is there a 'gap' in research relative to factors?
- Feedstuffs?
  - DDS (distillers' dried solubles) ↑ *E. coli*
- Change in Ruminal PH?
- Stress?
- Super shedder?
  - ↳ Do they exist?
  - ↳ Are they relevant?
  - ↳ What to do with them (if they can be identified)?

OBS

Subsidies to Support Prevention

Getting more complex Non-0157 STECs and *Salmonella*

Not an infection,

it's a colonization!

TABLE 5

- Complex chain – Barrier to ID factors
- Lack Real-time Quantities tests to ID and manage high shedders
- Cause of high shedders unknown – all/most shedder sometime
- Unsure of level of shedding that overwhelms establishment interventions
- Intermittent shedding – barriers
- Can't test your way out of the problem – barrier
- Population issue vs. "shedder" issue
- It's like "vaccinating the sick kids" vs. vaccinate population

- Factors – environment, temp, season
- Grass fed = confinement
  Smith – UNL – Research

TABLE 6

- Agreement on definition of "super-shedder"?
- Do they exist? Impact?
- Even less data on *Salmonella*
- Variation animal to animal and within the animal's lifespan
- Prevalence vs. levels per animal

Class of cattle as well as region/climate impact is different for different pathogens and can be greater for climate and geography than classification

TABLE 7

Research

- Colonization/shedding
- Genetics/genomics
  ⇩ Needed to identify Shedders/"Super Shedders"

Look more to "cut of cattle" than "class" of cattle

TABLE 8

<u>Research Gaps</u>

Commensals vs. pathogens

- interactions with environment
- genetics

*What is causing shedding?

Does all the funding go here?

- How is 1° determined?

- Coordination/Communication amongst federal/industry/academic researchers
- No rapid methods
  *no way to test at slaughter establishment
  *Even if we have a test – when do we test?

- No consistent definition for super shedder –

  E. coli O157
  STEC
  Salmonella

*Strain of *E. coli* vs. genetics of cow – which is more critical???

TABLE 9

- Definition of "pathogen" of human health concern
- Seasonality
- Region (Humidity, Ambient temperature, etc.)
- Genetics
- Understanding rumen microbiology
- Asymptomatic Carriers – identification
- Basic vs. applied research
- Reduce government food safety budget for research
- Inconsistency of research results
  - Meta-analysis
  - Consistency of parameters
- No rapid tests available
- When to identify a super shedder
- What is the "load" threshold
  Plant vs. plant differences
  What is the load a plant can handle
  →Reducing the peaks

→ Prevalence vs. load

→ Why do pathogens come and go without any explanation

→ Understanding microbial ecology

- Consistency of identification methodologies
  →Companies study results/numbers
- Risk/benefit analysis

- What is the appropriate end point Public health measurement
  →Healthy People 2020
  →Company testing
  →Centers for Disease Control and Prevention data

TABLE 10

VS – who are the shedders?

No practical means to identify problem animals.

- Timing of tests (needs to be < 1 hour)
- Variable shedding patterns
- 6 million head

Salmonella – cull dairy cows

What are environmental factors moving *E. coli* from farm to other areas (produce)?

Question 2

What effective and practical mitigations are available to reduce the pathogen load in general, and *Salmonella* and STECs specifically, in cattle prior to slaughter?

Suggested Questions to Guide Discussions

- How and when should effectiveness be defined and measured prior to slaughter?
- Is a qualitative (negative/positive) test sufficient for assessing the effectiveness of mitigation or is a quantitative (enumeration) test necessary? Should we also consider "semi-quantitative" measures or other options to find significant effectiveness of the measures?
- Are the measures cost effective?

TABLE 1

- Role of farming system, transportation time, cleanliness of animal leaving the farm, time at feedlot.
- Who's going to pay for a mitigation measure?
- Key role of fecal contamination.
- Preventive steps should be implemented at several points.
- Are these studies which determine the prevalence of pathogens at different points in supply chain?
- International partners say decrease transport time = decrease hide contamination.
- Consider both qualitative and quantitative tests. Quantitative is especially useful in a research setting.
- Human health outcomes should be gold standard when we are measuring cost effectiveness.
- Importance of consumer education and communication of risk.

TABLE 2

Mitigations

1. Vaccine
2. Probiotics
3. Best Practices

Cost Effectiveness

↳ How to define (Reduction of days of product diversion)

Quantitative is best for increased understanding and risk assessment (know load)

Semi –Quantitative better than yes/no.

TABLE 3

1. **How/when should effect be defined and measured prior to slaughter?**

When

- Sale barn?
- Direct from MA/PA?

→ 7/14 days prior to leaving feedlot.

So if the Law of the Land said we had to then we could test

Issues: • Logistics of testing • Number of tests/How/What test/Etc. • What do you do with results • Should you test unless you have a remedy • Never test unless you have a plan • Dealing with "lot" of cattle (Animal ID) • Need to define efficacy • Mitigation need to address internal/external • Numeration increases prevalence	• # of tests • Rapid Results • Cost • Lab capabilities • Data Management • Cattle Management • Logistics of Live World to Test/Read/Treat/Verify

Fecal pads

How → hide/rectum/environment – all as a system review

→ Then you have to take action **=WHAT??**

With Current System Knowledge	Cost effective => no Practical => no Available => no	Maybe PSTEL Sal Other	•Chlorates •Vaccine •Probiotics •GMP's/SOPs •Phage

Integration issues => **Extremely variable supply system**

2. Is a qualitative test sufficient/Should we consider (makes no sense)

→ To react you need accurate solid DATA

→ Needs to be uniform for all parties

→ Quantitative does not work 80+% positive

→ How do you qualitate?

3. Cost

Cannot answer this • factors are many

- # of tests
- Type of test system
- Where test is done
- Where sample is taken
- How you measure results
- Time of results
- Actions to results
- People/staffing/lab costs
- Variable customer/USDA expectations

How will regulatory agencies use this DATA =) Lost

TABLE 4

Reducing Pre-harvest Prevalence

- Vaccine
- DFM (Probiotics)
- Biosecurity?
- Phages
- Best management practices

→ No "Silver Bullet" but should be incorporated into a <u>system</u>.

<u>OBS</u>

Not all *Salmonella* are pathogenic!

↓

- Testing plus eliminating?
  – 70% Prevalence

Need virulence pathogenicity markers for *Salmonella*

-**<u>Qualitative vs. Quantitative</u>**

- Quantitative is important!
- Need to define "efficacy" Standards for new product approval.
  - ⇩ Current USDA Standard is too high → Dr. Dean's talk: 50% reduction is good enough!
  - ⇩ Let the market decide whether to use it

TABLE 5

- Phage – not "on farm"
- Vaccine
- DFM (Dose volume)
- Feed – DDG ↑ pathogen – blender credit
- Pen condition
- Water
- Pest management

How to measure effectiveness?

- Practicality
- Pathogen reduction
- Fecal

Measure

- Prior to commingle
- Over time
- Population (not individual)
- On Farm

Testing

- Qualitative
  For "real time" → Both can have value
  Day to day ←
- Quantitative
  Measure for impact
  Periodical
- Liability

Cost

7^{00}/head .01/lb. $.01-$2^{00}$

TABLE 6

-Measure pathogens at point closest to slaughter but must use common sampling protocol

-May need sequential sampling (with ability to direct response/treatment)

-Testing

E. coli +/-
Salmonella Both are Qualitative and Quantitative

TABLE 7

•Marketplace determines "efficacy" level

- Transparency

to

•Faster approval process → marketplace

•"Teat" dip model

TABLE 8

Consider what's available/approved

* Probiotics (Bovamine®) (certain feeds)
* Vaccine (conditional approval)
  - (3 doses)
  - 60-day withdrawal (0157, *Salmonella* (dairy)

↑ animal handling…

* Phage – at lairage (seasonal)
- Discussed CARROT – STICK –
- Practical/effective
* What are we measuring?
* How do we measure?

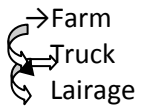
– May reduce load

–Need common understanding of effectiveness

–Approval process should not include economics → market should dictate adoption

–Discussion on learning from other country models and how they could apply

TABLE 9



Variable
What is the target and how do you know you got there

→ *Need to have a rapid test
→ Pre-Harvest GMP's
  → not really a test
→ What interventions work or don't work well together
→ Test to support GMP's
→ Population evaluation
→ Qualitative vs. Quantitative
  - Need both
  - Comparisons?
→ Cost of investing in interventions and staying with them when new technology is available
→ Practicality of interventions
→ FSIS needs to work w/other Government agencies for intervention approvals
→ Let the market decide on interventions
→ Consistent availability of interventions
→ Ongoing surveillance

TABLE 10

For *Salmonella*

1) Epitopixs *Salmonella* vaccine.
2) Antibiotic therapy – worried about antibiotic resistance

} only 2 choices on farm?

STECs

USDA - CVB needs field control studies

1) 2 vaccines <u>not</u> <u>approved</u>
2) Phage
3) Na Chlorate

Vaccine in Canada –licensed but not widely adopted.

Effectiveness

– USDA wants high level of effectiveness

- Breed cattle for ↓ disease susceptibility?

Cost effectiveness-

Yes, quantitative/semi-quantitative testing important. (For registration)

Question 3

How can producers, processors, and government work together to promote adoption of pre-harvest food safety mitigations?

Suggested Questions to Guide Discussions

- What barriers exist, real or perceived, that inhibit or prevent the development and use of mitigations?
- How can the government and industry foster innovation in this area?

TABLE 1

- Incentivize good behavior rather than punishing bad (i.e., clean animals at slaughter).
- Mitigation is an absolute cost to the producer.
- Develop industry (not government) standards for best practices and mitigation.
- Barriers: Approval process (moving target for approvals), conditional vs. full licensure, cost
- Do we have to experience an outbreak for producers to adopt new, costly mitigation techniques?
- Want producer and consumer to be winners
- Solutions: Best management practices which could help pay for mitigation techniques, build trust, foster interaction

TABLE 2

Barriers

1. Regulator Hurdles (efficacy)
2. Non-integrated industry (hourglass shape)
3. Funding of intervention (who pays)

Fostering Innovation

1. Results oriented
   - License the technologies
   - Don't classify pathogens as adulterants
2. Continue industry government communication

3. Fund research

TABLE 3

Mandate by Government (Specify interventions)

Fund by Government

- Give some sort of incentive to producers
- No clear direction – Approved intention
- USDA reaction to (positive)
- Discourages discovery and innovation
- Complexity of the livestock industry
- Live animal margins
- 3rd party data depository to share data for discovery without negative impact on data collector

FSIS Access

TABLE 4

Producers, Processors and Government working together

1. Decouple efficacy and safety. Any approved product must not have negative human health implications.
2. Let market place determine value.
3. Barriers
   - Cost
   - Regulatory approval
   - Conditional license for vaccine
4. Retailers can drive

Examples of Government Interference

1. GIPSA – Providing incentive
2. Vaccine approval – how effective is effective enough?
3. Chlorate – FDA

Phage – tight regulatory usage - location

TABLE 5 – NA

TABLE 6

Conflicting Agency Goals

- GIPSA adoption & implementation
- FDA/APHIS – vaccine & compound approval
- EPA/State, DNR/EPD at Farm
- Marketplace conditions: cost sharing/benefit recipient
- Perception contamination a plant issue
- Foster innovation by reducing governmental hurdles above

TABLE 7

Government Involvement:

→ Research (continued funding)
→ Streamline regulatory approval process
→ Larger proof of studies
  - Slaughter

→ Safety – efficacy: reduce
'Government focus needs to move from efficacy to safety
→ Regulatory inefficiencies impact innovation

Government confusing consumers?

→ USDA: promotes organic and natural and local
→ *E. coli* a natural organism
→ USDA wants industry to use vaccine?

Government/Producer Innovation

→ Take $ away from organic/local promotion & instead direct to producer awareness

TABLE 8

Barriers to Adoption and Development of Mitigations

Development	Application
*Approval { FDA, EPA, APHIS } Streamline process *Conditional approval ≠ freemarket *Field trials vs. challenge models to collect data *Need more tools in the tool box (as more approved, more to market) *Phage approval at the feedyard *Research versus application in commercial setting * How is effectiveness measured? * pH testing? *trim? *human illness reduction?	*Application Method e.g. – vaccines require animal handling –human -animal safety – feed and water *Cost – incentives 1) promote as safer 2) pay more to producer –packer –government ?tax incentives Other 3) mandate –producer (pull through) –packer –government –retail 4) producer needs to see benefit –add to BQA programs

TABLE 9

→ Timely approvals

→ Understanding what an Agency (all) wants to see in the DATA

→ Streamlined process animal + human health benefits

→ Consistency of efficacy across all production types

→ Increase money for funding across all sectors

→ What happens when you get a positive on an animal

→ **IMPLEMENT A PRODUCER PRE-HARVEST SYSTEM NOW**

→ Apply DFM and/or vaccine

Surveillance
Group/lot tracking
Pay/reimburse producer

→ Collaboration between Government and Industry

→ Data sharing mechanism

TABLE 10

Promoting adoption

USDA/CVB is a barrier – pre-market

Structure of industry – post-approval

Non-integrated supply line

•Missing value for user/cattleman

Producers/processors

Sales/supply agreements

Get an influential buyer

- Closer to buyer

Have to balance value to consumer while not competing with regard to safety

→added attributes to brand

Government – mandated program vs. direct customer information/practices

No artificial regulatory barriers

(Food Safety vs. Animal Disease)

- Especially when products have a known safety record

Conditional approval is viewed negatively

(why not fully approved?)

Provide premium paid by consumer → producer

↑ Consistency among regulator → Alignment