AUTOMATIC MILKING: FDA Issues

Douglas J. Reinemann, Ph.D.
University of Wisconsin
Milking Research and Instruction Lab
Madison, Wisconsin, USA
Appendix Q to the Pasteurized Milk Ordinance (PMO)

AMI for the Production of Grade "A" Raw Milk approved in 2003

- AMI shall identify and discard milk with abnormalities.
- Points of contact with abnormal milk will be cleaned and sanitized after milking such an animal.
- Box shall be kept as clean as any milking and equipment cleaning area.
- All ventilation air must come from outside the cattle housing area.
The Issue

- Allowing cleaning of tank valve and t-piece connection assembly and bleed valve (pick up or outer valve).
- Screened outlet to prevent contamination is difficult to verify automatically - outlet could be plugged by operator or failure.
- Supply specific proof that milk in the tank is not at risk of product contamination (public health) with single-seal separation (inner valve).
DeLaval VMS Valve Package
Inner milk tank shutoff
BLOCK Valve against
milk in storage
(IN)

Tank T-Piece close
coupled connection for
Block-Bleed-Block
valve assembly

Incoming Milk

Line to tank valve
(TV) BLOCK Valve
controls milk line
from VMS, light off
& stem out-open

CIP Recirculate

Cleaning Valve
(CV) CIP back to
VMS, light ON
& stem IN-closed

Pinch Valve Drain
(DV) Normally-open
low point drain for
line & valves outside
tank T-Piece, closed
during recirculation

(PV) Pick-Up / Outer
BLEED Valve
drains and vents
T-Piece connection
in Block-Bleed-Block
operation

Perforated drain / vent
cover when in automatic
operation
Lely Configuration
Horizontal
On the right are the block bleed block valves on the milk transfer line for protection from waste milk.
Proposal accepted in 2009 NCIMS

Un-link the raw milk language in Appendix Q Item 14R with pasteurized / processing Item 15P(b) as requirement basis of safety separation

Deviation from pasteurized / processing Block+Bleed required only for robotic milking

Providing protection equivalent to blok+bleed as defined in PMO 15P(b)
The Situation

FDA is asking the industry to present a proposal to NCIMS addressing equivalency.

Steve Sims

- each manufacturer might make their own proposal
- Better to get a consensus proposal
- Method to test and confirm
Challenges

Proposal for non-traditional Block+Bleed should be supported by data
- historic data based on stem operated dairy plant compression valves

AMS industry is using 2 single-seat valves in combination
- equivalent in terms of safety and sanitation?
- dead-leg distance requirement considered
Lely configuration
Vertical
Questions from Harrisburg FDA meeting

Can single-seat valves in a block+bleed meet the intent of 15P(b)?

- Challenge pressures when valves are nearly closed or just becoming open? ("Water hammer" over-pressure)
- Cleaning flow during tank cleaning
- Valve/seal impingement/pressure concern
- What is the proof of equivalency claim?
- Differences between compression valves versus non-traditional (15P(b): butterfly, disc, ball) valves?
Suggestions from Harrisburg FDA Meeting

- Substitute “seat lift” with “seat pulsing” to deliver a specific pressure
  - lifting the seat is interpreted as “out-of-position”
Manufacturers Response

- Seat pulsing duration or displacement (distance) tests did not produce uniform cleaning volume or pressure
  - Difficult to adjust and verify
- Can evidence (data) with a proprietary valve assembly be used as proof of concept for other configurations?
Industry consensus on generic construction and operation

Manufacturers individually responsible for validating their construction and operation method.

Consider the history of the non-mix, double-seat, double-lift valves

shows there can be “ratcheting” progress upwards towards compliance
VMS Test Guide
Tank Block-Bleed-Block
Flow Control Cooling (FCC)

1. Milk Tank in cooling mode
2. Milk Station in cleaning mode
   - Milk tank in separation mode
   - B-B-B valves in ‘fail-safe’ position
3. Identify valves and their position
4. Identify testing override switches
5. FAILURE MODE TEST
   - VMS milks tation cleaning stops, opens alld rains, milkpump and vacuum stop
   - VMS milk station ‘touch screen’ displays STOP alarm: “TANK VALVE IN WRONG POSITION”
Validation of a method is a 3-legged stool

- Design Criteria
- Performance Criteria
- Testing Criteria

Individual “Scope of Proposal” should also include the separations at milking stations
Other Issues

- Jeter and teat cup protection
  - In process component
  - Cover, Shielding, Location, Self cleaning
Other Issues

- Well Water backflow prevention
  - Central point well protection
  - Cross contamination between AMS units
  - Hot/Cold separation within AMS unit
- Cover for AMS stall when not in dedicated milking area
  - Positive pressure ventilation requirement
- Conversion from EU standard components to US FDA approved
Teatcups / jetters must be covered during the prep procedure.
AUTOMATIC MILKING: FDA Issues

Douglas J. Reinemann, Ph.D.
University of Wisconsin
Milking Research and Instruction Lab
Madison, Wisconsin, USA