

Residue Control in a HACCP Environment

Barb Masters, DVM

OFW Law

NIAA

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FSIS Residue Control - Background

- 2010 Office of Inspector General (OIG) Report

Key findings included:

- The need for FSIS to ensure establishments slaughtering animals at higher risks for residues (dairy and veal) are following HACCP principles.
- The need for FSIS to ensure product that has been tested for an adulterant does not receive the mark of inspection until negative test results are received.
- The regulatory agencies (FSIS, FDA and EPA) need to work more in harmony to better implement the National Residue program.

National Residue Program

- FSIS began reacting to “**same source suppliers**”
 - Same source suppliers were suppliers with more than one violative finding by FSIS
 - confirmed repeat violators (have been confirmed by FDA)
- FSIS issued FSIS Notice 41-12 re-emphasizing policies on residue violators
- FSIS has also issued a Compliance Guideline for Preventing Residues
 - [http://www.fsis.usda.gov/PDF/Residue Prevention Compliance Guide 042512.pdf](http://www.fsis.usda.gov/PDF/Residue_Prevention_Compliance_Guide_042512.pdf)

FSIS Notice 41-12

- Federal Register addressed the 2000 policy position of the Agency:

<http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/00-043N.htm>

- FSIS has determined that certain establishments have multiple residue violations because they repeatedly purchase animals from the same sources and do not use the information to reassess the adequacy of their hazard analysis.
- FSIS considers that these establishments do not have an adequate HACCP plan with respect to a potential residue hazard that may be reasonably likely to occur.

FSIS Notice 41-12

- If an establishment purchases animals from a confirmed laboratory residue violator the Public Health Veterinarian (PHV) is notified.
- FSIS determines if other establishments are purchasing animals from the same supplier.
 - If so, the PHV is to notify the establishment and document the discussion in an Memorandum of Interview (MOI).

FSIS Notice 41-12

- When a PHV is notified that an establishment has more than one FSIS laboratory-confirmed residue violation from animals purchased from the **same source supplier**, he/she is to discuss this finding with the establishment at the next weekly meeting

Same Source Supplier

- A **same source supplier** is defined as **person, farm, livestock market or other firm** from which the establishment has received or purchased animals with confirmed violative residue levels (from more than one production date)

Same Source Suppliers

- Upon notification of a “**same source supplier**”, the establishment should ensure that supplier of the animals is notified and is aware of the establishments concern that animals are not presented with residue violations (e.g., the establishment should follow “best practices”)

Same Source Suppliers

- PHV will increase testing of animals that the establishment receives from this same source supplier
 - 2 or more animals up to 100% based on professional judgment
 - Increased testing is to continue until four consecutive, separate shipments from the supplier are negative (verification that the best preventive practices are effective)

Same Source Suppliers

- If the establishment has a FSIS violative residue result in a “same source supplier” FSIS will issue an NR citing 9 CFR 318.20 to document the establishment’s failure to prevent animals with violative residue levels from entering slaughter as indicated by the multiple residue violations reported from the same source supplier (**third or more within a reasonable time span**)
 - Further violations will be documented and NRs linked
 - This NR will be documented even if the establishment has a program to address residue control (basis is failure to prevent violations)

Same Source Suppliers

FSIS RESIDUE VIOLATION INFORMATION SYSTEM

Part III: Source Violations Collected Since 12/16/2009

Source	Name	By State	Plant/ID Collected/Tags	Sample ID/Date	Tissue	Residue Value	---ppm--- Tolerance
John Doe, DVM, MASTERS PACKING John Doe VET SERVICES 928 EAST SEPTEMBER 1010 N. JEFFERSON ST. STORM LAKE, IA 00038M 502-902-84703 VETERINARIAN		TROY, KS	512654	09/28/10	KIDNEY	PENICILLIN	1.86 .05

FSIS Notice 41-12

- With multiple or recurring noncompliances, the PHV is to assess whether the establishment's HACCP system is inadequate under 9 CFR 417.6.
 - For any violative residue the establishment receives, they are expected to reassess their hazard analysis.
 - With repeated violations it will become increasingly difficult to support the decision that drug residues are not reasonably likely to occur.....



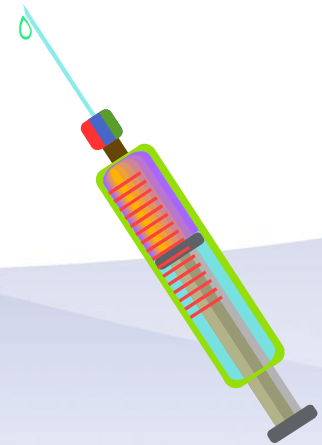
What Actions is FSIS Looking For?

- Best Available Preventive Practices!
 - Identification of all animals received at slaughter (traceback to **producers**)
 - Provide traceback information to FSIS at the time testing is conducted
 - Establishment contacting producers when there is a violation to educate them and expressing concern regarding violations
 - Notification to producer that establishment will not continue to purchase animals from repeat violators

What Actions is FSIS Looking For?

- Encourage suppliers to engage in recordkeeping for use of medications
- Encourage producers to engage in “Residue Avoidance Programs” (e.g., PQA+)
- Explore live animal testing
- Market/Dealer Certification such as an “Evergreen Certificate” attesting that the livestock being purchased are not from owners on the repeat residue list

What other actions has FSIS taken to improve residue control?



Residue Control

- FSIS has begun utilizing the KIS™ test as the in-plant screen at all livestock establishments
- FSIS has re-structured the overall National Residue Program
 - All monitoring samples (collected randomly on sows and market hogs are run through “multi-residue screens”
 - This is a surveillance program in which FSIS determines whether certain veterinary drugs and pesticides are present, and if so, at what level in a given sample.

Residue Control

- In-plant directed sampling
 - FSIS public health veterinarians will select animals based on disease conditions (-itis and -emias) and if are screen positive on KIS™ these samples will also be run thru the multi residue screen
 - If there is an in-plant “positive”, samples are sent to FSIS laboratory for confirmation (using the multi-residue methods) and then a confirmatory method

FSIS Re-structured Program

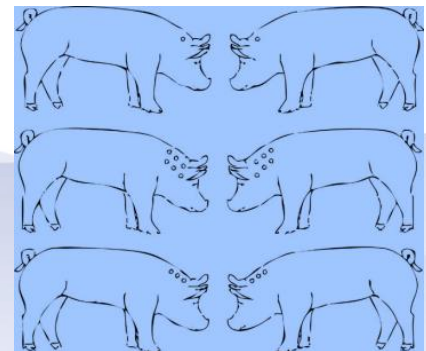
- The multi-residue method analyzes for:
 - Fluoroquinolones
 - Hormones
 - Macrolides/Lincosamides
 - Analgesics/Anti-inflammatories
 - Tetracyclines
 - Phenolics
 - Sulfonimides
 - B-agonist
 - B-Lactam/Cephalosporin

FSIS Re-structured program

- Impacts
 - Multiple compounds vs. single (e.g., antibiotics and anti-inflammatories)
 - Lower detection limits (in effect resulting in a new tolerance for some compounds)
 - If a compound is found that has no muscle tolerance in a species (e.g., penicillin in swine) then this is considered a violation, therefore, may lower detection capability
 - in effect lower levels are triggering violations

FSIS Re-structured Program

- Case Example.....
 - We saw an increase in penicillin violations in sows
 - Even though there was not evidence of misuse
 - Kudos to the National Pork Board for partnering with the regulated industry in addressing this concern...



What has FDA documented as the primary causes of residue violations?

- Treatment records not maintained
- Withdrawal time not followed
- Approved dosage exceeded
- Drugs given or fed by mistake
- Extra label usage by laymen



Summary

- FSIS Expects Establishments to Implement the Best Available Preventive Practices!
 - Use of FSIS same source supplier list in purchase decisions
 - Be aware of FDA injunctions and enforcement actions as well
 - Visiting Supplier, if appropriate (e.g., large producers) to ensure practices are followed
- Producers have a role in meeting these “best practices” when marketing animals for slaughter

Challenges

- Understanding Best Available Practices – with good communication between producer and establishments
- Validated live animal tests not available (so unable to pre-screen animals for slaughter)
- FSIS program updates has led to “different” withdrawals being needed for some compounds without any notification to producers

Questions

We are up to the challenge!

