Wagner, Scott - FSIS

From: Sarah De Los Santos [redacted]yahoo.com]
Sent: Wednesday, June 13, 2012 10:47 AM
To: Gallegos, Anna - FSIS
Cc: Wagner, Scott - FSIS
Subject: Fw: Request for third party review

Hello,

Anna this is the email that had the drug residue guidelines from Dr. Holterman and the Omaha, NE office that I told you I would send. It appears that you may already have this copy from them also.

Thanks again.

Sarah De Los Santos

--- On **Mon, 5/7/12, Arnold, Ilene - FSIS** <*Ilene.Arnold@fsis.usda.gov*> wrote:

From: Arnold, Ilene - FSIS <Ilene.Arnold@fsis.usda.gov>
Subject: Request for third party review
To: "[redacted]yahoo.com" <[redacted]yahoo.com>
Cc: "Holterman, James - FSIS" <James.Holterman@fsis.usda.gov>, "Hulsey, Laura - FSIS" <Laura.Hulsey@fsis.usda.gov>, "Seebohm, Scott - FSIS" <Scott.Seebohm@fsis.usda.gov>, "Edelstein, Rachel - FSIS" <Rachel.Edelstein@fsis.usda.gov>, "Gallegos, Anna - FSIS" <Anna.Gallegos@fsis.usda.gov>, "[redacted] - FSIS" <[redacted]fsis.usda.gov>
Date: Monday, May 7, 2012, 2:44 PM

As requested, Dr. Hulsey asked Dr. Holterman and Dr. Arnold to review the documents sent to OPPD PDD for review.

Dr. Hulsey requested that I send you our combined recommendation related to the Sanitation SOP, HACCP plan, and residue prevention.

In reviewing the Sanitation SOP for compliance with the regulation, the recommendations are as follows:

1) Identify what the abbreviation means the first time it is used. There is a definition section, but it is still not clear what KF or PR means on the first page of the plan.

2) Page 2 identify what these procedures are as they appear to be cleaning occurring at either the end of production or the beginning of production

3) Page identified as Pre-Operational Sanitation/Slaughter Floor reads more like monitoring than the cleaning

procedures which goes along with the above comment in 2).

4) Page 2 of the Pre-Operational Sanitation/Slaughter Floor appears to be in conflict with page one since that page indicates [redacted] Need to clarify the purpose of this random selection of days as monitoring needs to be daily to meet the regulatory requirement in 9 CFR 416.13(c). Additionally it mentions in the last sentence of Page 2 that the results will be initialed by the verifier but makes no mention of the requirement for a date on the daily record.

5) Page 1 of Operational Sanitation Procedures Slaughter Floor has a similar issue in that it appears monitoring will only take place once a month rather than daily as required by regulation. It is not clear if this activity in the second paragraph is a separate or additional to the daily monitoring or not.

6) This document has multiple sections and pages and it would be helpful to have some type of numbering system to keep all the pages in order and make them easy to reference.

Since I have no idea what the facilities look like, the OFO inspection team still will need to make a final determination as to the adequacy of the written Sanitation SOP.

In reviewing the HACCP plan for compliance with the regulation, the recommendations are as follows:

1) Signature Page – It is unclear why this page only mentions CCP document to be signed and dated as the regulation requires all entries on the HACCP records to be initialed or signed and dated, so we did not know if this document is the pre-shipment review or that the establishment only sign and date this document which would then not be in compliance.

2) Page 2 Process flow – this will need the OFO inspection team to verify that all the steps in the process are being addressed.

3) Pages 4-11 It is not clear if the 'Basis' mentioned has written procedures or programs that will be monitored on an ongoing basis to support their conclusion of the food safety hazard not being reasonably likely to occur. There are steps where 'No' is entered but no 'Basis' is provided. Written decision-making documents are not included. OFO EIAO will need to assess the documents and make the final compliance determinations as to the design and then execution of the plan.

4) Missing page numbers on several pages; all pages should be appropriately labeled to make it easier to follow the document. There also appears to be pages missing as the numbers jump.

5) Page 7 Splitting Saw step and Trim Station both mention antimicrobial spray but it is not clear if something is applied at this step or later in the process. The steps on this page need further clarification. Since there are no supporting documents, it is not possible to discern how the design is supported.

6) Page 11 *E. coli* O157:H7 is the proper way to express this pathogen in the first column when it is included in decisions associated with a pathogen of concern. Verification activities require recording verification activity performed, the results, initial, and date. For Corrective Actions a designation of the responsible employee is needed.

7) Page 13 Monitoring records require an initial or signature, date, and time to be in compliance. What does 'correct application' mean in terms of a procedure? For Corrective Actions the same comment as on Page 11 above.

8) Page 16 Critical limit states [redacted] unclear how this is supported in the design of the CL. For Corrective Actions the same comment as on Page 11 above.

Since there is no supporting documentation and pages appear to be missing, the OFO inspection team and/or EIAO will

still need to make the final determination as to the adequacy of the written hazard analysis and HACCP Plan design and execution.

Residue Prevention recommendation:

Since there are no medications, wormers, or fly treatments approved for use in the United States for horses intended for food and horses are frequently subjected to treatment with a variety of chemicals we recommend you implement a very robust residue prevention program. In addition to obtaining a signed affidavit from the owner we recommend you employ all 5 recommendations found in the Compliance Guide For Residue Prevention

1. Confirm producer history

2. Buy residue-free animals

3. Ensure animals are adequately identified

4. Supply the producer information to FSIS at ante-mortem

5. Notify Producers of Violative Animals

Detailed information on each of the recommendations can be found at this link: Compliance Guide For Residue Prevention

The final determination of the acceptability of your HACCP plan will be made by your District Office.

FSIS recently issued this information on equine slaughter in the Constituent Update

Equine Slaughter Restarts

Currently there are no facilities approved for horse slaughter in the United States.

Following a decision by Congress in November 2011 to lift the ban on horse slaughter, one establishment, located in New Mexico, recently applied for a grant of inspection exclusively for equine and USDA's Food Safety and Inspection Service is reviewing the application.

However, given that the agency last conducted a horse inspection six years ago, FSIS has determined that despite the congressional decision to lift the ban, the agency will require a significant amount of time to update its testing and inspection processes and methods before it is fully able to develop a future inspection regimen.

I noticed that currently do not appear to have an askFSIS account. The askFSIS application is used to address inspection related questions. You can access askFSIS at http://askFSIS.custhelp.com to search for answers to common questions. If you would like to set up an account and need assistance you are welcome to call me and I will walk you through the process of setting up an account and then how to search and submit questions.

I hope the information provided is helpful to you.

Ilene D. Arnold, MS, VMD *for* Dr. Laura Hulsey PDD Director

Senior Staff Officer

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Policy is my passion.

Have you searched askFSIS?

From: Hulsey, Laura - FSIS
Sent: Friday, May 04, 2012 4:02 PM
To: [redacted]yahoo.com
Cc: Seebohm, Scott - FSIS; Holterman, James - FSIS

Subject: RE: RE: FW: Update

Hello,

We are having a couple of staff officers review these and they will be in touch with you next week. The most scrutiny will be on the support for residues, which is Dr. Holterman's area of expertise. We can provide a review and comment of the material submitted, but it will still be up to the District Office to make the final determination of compliance.

I am also sharing these documents with the Small Plant Outreach group. We plan to have discussion with them on equine slaughter policies in the next couple of weeks.

Thanks for sending, and Dr. Holterman will be in touch with any follow-up questions.

Laura Hulsey, DVM

Director, Policy Development Division

USDA/FSIS/OPPD

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From: Sarah De Los Santos [mailto:[redacted]yahoo.com]
Sent: Friday, May 04, 2012 3:22 PM
To: Hulsey, Laura - FSIS
Subject: Fw: RE: FW: Update

Ms Hulsey,

Please see attached the FSIS findings on the second FSIS walkthrough...I am sending my original HACCP and

SSOP for third party review and possible conclusions.

Email attachments will follow.

Thank You,

Ricardo De Los Santos

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