s.(b)(6)
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U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
FIELD OPERATIONS

ADMINISTRATIVE ENFORCEMENT REPORT

1. REPORT NO. 25-08-N008

2. EST. NO. 19336 M

3. EST. ID. 3493

4. NON-COMPLIANCE *(Check all applicable boxes)*
☐ SPS ☐ SSOP ☒ HACCP ☐ HUMANE TREATMENT ☐ THREAT, INTIMIDATION, ASSAULT ☐ OTHER

5(a). NAME OF BUSINESS: Nebraska Beef, Est 19336 M
5(b). ADDRESS OR P.O. BOX: 4501 S. 36th Street
5(c). CITY, STATE, ZIP CODE: Omaha, Ne 68107
☐ Check if the business type is a non-federally inspected facility.)

6. TYPE OF NON-FEDERALLY INSPECTED BUSINESS
☐ Broker/Distributor
☐ Retail/Restaurant
☐ Other _____ *(Describe)*

7. PLANT SIZE
☐ Large
☐ Small
☐ Very Small

8. HACCP PROCESSING CATEGORIES *(If non-compliance type shown in block 2 is HACCP, check all that apply to the NOIE/Suspension letter issued)*
☒ Slaughter - all species
☐ Raw Product - ground
☒ Raw Product - not ground
☐ Thermally Processed - commercially sterile
☐ Not Heat Treated - shelf stable
☐ Heat Treated - shelf stable
☐ Fully Cooked - not shelf stable
☐ Heat Treated But Not Fully Cooked - not shelf stable
☐ Product With Secondary Inhibitors - not shelf

9. PRODUCT TYPE
☒ Meat ☐ Poultry
☐ Meat/Poultry ☐ Eggs

10. LABORATORY FINDINGS (Check if applicable to case)
☐ Listeria monocytogenes ☐ Salmonella ☒ E. Coli O157:H7
☐ Other _____

11. REPORT TYPE AND DATE OF ACTIONS
NOIE 06/27/08 DEFERRAL 07/08/08 SUSPENSION _____ ABEYANCE _____
REINSTATEMENT _____ WITHHOLDING OF LABELS _____
(Dates the establishment provided written notice of these actions)
CUSTOM (1) _____ *(Date LOW)* CUSTOM (2) _____ *(Date LOW)* CUSTOM (3) _____ *(Date LOW)*
DETENTION _____ TERMINATION _____
(Date product detained, and if applicable, terminated by FSIS personnel)
RECALL (1) _____ *(Date product was recalled by producing firm)*
RECALL (2) _____ *(Date of final recall effectiveness report to RMD)*
RECALL (FSIS Recall Number) _____
PROHIBITED ACTIVITY _____ *(Date establishment/business provided written notice of this action)*
APPEAL (1) _____ *(Date of appeal to DM.)* APPEAL (2) _____ *(Date of appeal to EARO)* APPEAL (3) _____ *(Date of EARO decision)*
ILLNESS OUTBREAK (1) _____ *(Date investigation closed with no enforcement action)*
ILLNESS OUTBREAK (2) _____ *(Date enforcement action initiated)*
NON ROUTINE INCIDENT _____ *(Date incident reported to OFSEP)*
OTHER (Specify): _____ *(Date of action)*

12. COMPREHENSIVE ASSESSMENT OF THE EXECUTION AND DESIGN OF AN ESTABLISHMENT'S FOOD SAFETY SYSTEMS
FROM: _____ TO: _____

13. OTHER SPECIAL REVIEW (e.g. IDV, Epidemiological Review, etc.) _____
FROM: _____ TO: _____

14. REFERRED TO OPEER FOR: *(Provide date of referral)*
COMPLAINT _____ *(Date)* SEIZURE _____ *(Date)*
TERMINATE CUSTOM _____ *(Date)* CRIMINAL INVESTIGATION _____ *(Date)*
OTHER (Specify): _____ *(Date)*

15. LIST PAST/RELATED REPORTS

16. COMPLETE WHEN CASE IS CLOSED
LOI DATE _____ LOW DATE _____ OTHER (Specify): _____ DATE _____

17. SIGNATURE OF ENFORCEMENT INVESTIGATION AND ANALYSIS OFFICER

18. SIGNATURE OF CASE SPECIALIST
CMS

19. DATE 07/09/08

FSIS FORM 5400-9 (4/14/2005) PDF

PREVIOUS EDITIONS ARE OBSOLETE.

A0002219_1-000000

LIST OF EXHIBITS

NAME/ADDRESS OF ESTABLISHMENT	REPORT NO.
Nebraska Beef LTD 4501 South 36th St Omaha NE, 68107	25-08-N008

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

EXHIBIT NUMBER	DESCRIPTION
1	A signed copy of the Notice of Intended Enforcement dated June 27, 2008. Document was given to subject firm because there is reason to believe that Nebraska Beef continues to produce beef trim positive for E. Coli O157:H7, and that the microbiological testing procedure in place at this establishment is not detecting positive sample lots, i.e. is not functioning properly.
2	A copy of Nebraska Beefs' E-coli O157:H7 testing procedure which appears that the establishment is following USDA FSIS sampling techniques for trim collection (N=60 sample size with 5 combos or less as a lot), and test 375g of the collected sample using th testing procedure (
3	A copy of ' test user guide. Document insert states that the intended use is to analyze 25g samples only, however the method has been validated to work using a 374g sample, through this use has not bee AOACC approved. Therefore this method if performed correctly is theoretically capable of detecting very low levels of E.coli O157:H7 contamination. However as with all microbiological methods, the procedures as describe must be followed precisely or there is a high risk of getting false negative results.
4	Copies of Nebraska Beefs' "in house" E.Coli O157:H7 testing results July 2006 to June 2008. Documents depict that subject firm has being doing "in house" testing of trim and never had a positive when the national prevalence of E.coli O157: H7 in trim is less than or equal to 1% so positives, while rare, should be found. Nebraska Beef does not use a positive control and so no verification that the testing methods as performed by the in house technician can in fact detect positives if present at low levels.
5	Copies of] E.coli O157:H7 test results which were performed as verification of the firms "in house" laboratory using 65 and 25 gram sample size and appears to validate firms sampling methods.
6	Copies of lab results from Nebraska Beef of product shipped to another establishment on 6/19/2008. Also included with exhibit are combo labels and a e-mail message. Documents depict that subject firm shipped into commerce product that was presumptive positive for E.coli O157:H7.
7	Copies of Nebraska Beefs' for beef trimmings destined for Raw Ground use for the time period of 6-2-2008 thru 6-22-2008. Documents depict that on June 17 , 2008 the pre-shipment review was signed for all beef trim prior to receiving the Certificate of Analysis showing that by signing the pre-shipment review prior to receiving the COA firm produced and on 6-19-2008 shipped adulterated product into commerce.
8	Copy of "STEPS" notification for subject firm. Documents state that subject firm is listed as a supplier in a E.coli positive case under ILN(s) MF 84733, MF64555, MF51918, and MF64470.
9	Copies of 4 "STEPS" notification e-mails provided to QA manager at Nebraska Beef. Documents notifying subject firm of being listed as a supplier of beef used to produce ground beef products that was found to be positive for E. coli O157:H7.

LIST OF EXHIBITS

NAME/ADDRESS OF ESTABLISHMENT	REPORT NO.
Nebraska Beef LTD **4501 South 36th St** **Omaha NE, 68107**	**25-08-N008**

EXHIBIT NUMBER	DESCRIPTION
10	**Copy of firm [redacted] Document describes the HACCP system in place at subject firm.**
11	**Copies of [redacted] Documents depict six presumptive positives for E.coli O157:H7 for beef trim derived from animals slaughtered for [redacted] on June 14, June 16, June 21 and June 23 2008. This information contains the 19 combos of trim tested and as mentioned in the NOIE plus the addition of 6 combos that comprised another 2 presumptive positives for E.coli O157:H7 for a total of 6 presumptive positives for the month of June which were found after the NOIE was issued.**

s.(b)(4)

LIST OF EXHIBITS

NAME/ADDRESS OF ESTABLISHMENT	REPORT NO.
Nebraska Beef, Est 19336 M 4501 S. 36th Street Omaha, Ne 68107	25-08-N008

EXHIBIT NUMBER	DESCRIPTION
12	Copy of Nebraska Beef's first response to the NOIE, dated July 2, 2008. The document includes the intial response and 13 attachments (150 pgs).
13	Copy of a submission from Nebraska Beef containing an analysis from consultant microbiologist an audit rating analysis from nd a memorandum addressing sanitation issues at Nebraska Beef.
14	Copy of Nebraska Beef's second response to the NOIE dated 7/3/2008, which contains the second response, a protocol for an in-plant validation study o revised Test and Hold Procedure, and a protocol for comprehensive assessment of sanitary conditions in the slaughter process.
15	Copy of additions to Nebraska Beef's second response, dated 7/7/2008, which includes utilizing for all trim samples, revised Test and Hold Procedures, revised comprehensive slaughter re-assessment protocol, and a copy of the form to be used for continuous monitoring of the slaughter area.
16	Copy of a Memorandum of Information from EIAO dated 7/3/2008, detailing a meeting held with a Nebraska Beef representative regarding clarifications with the company's response to the NOIE issued on 6/27/2008.
17	A copy of an Addendum to the NOIE responses from Nebraska Beef, received on 7/7/2008. Addendum includes the following , a scientific article regarding Employee and Slaughter Process Monitoring form, and a daily documentation of discussions form.
18	Copy of a Memorandum of Information from EIAO dated 7/7/2008, detailing a meeting held with Nebraska Beef representatives regarding further clarification of responses proffered by Nebraska Beef to the NOIE issued on 6/27/2008.
19	A signed copy of the Notice of Deferral hand delivered to Nebraska Beef on 7/8/2008, and Verification Plan hand delivered on 7/9/2008.
20	Copy of the final submission NOIE response from Nebraska Beef received and accepted on 7/8/2008. Submission includes the company response and eleven attachments including clarifications proffered in previous addendums.
21	E-mail request from of Nebraska Beef requesting that the statement in the Test and Hold procedure submitted on 7/10/2008, be recognized as the one that will be implemented during the verification period. Revised Test and Hold Procedure also included.
22	Letter from District Manager Dr. Dawn Sprouls to Nebraska Beef Food Safety Director, accepting the revised Test and Hold procedure as the procedures to be implemented during the verification and revised Verification Plan, dated 7/10/2008.

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 1

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-1

s.(b)(6)
s.(b)(7)(C)

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

☑ COPY ☐ ORIGINAL	1. DESCRIPTION OF EVIDENCE A signed copy of the Notice of Intended Enforcement dated June 27, 2008. Document was given to subject firm because there is reason to believe that Nebraska Beef continues to produce beef trim positive for E. Coli O157:H7, and that the microbiological testing procedure in place at this establishment is not detecting positive sample lots, i.e. is not functioning properly.

2. EVIDENCE OBTAINED FROM (Name, address, etc.) USDA FSIS OFO DO Des Moines District Office 210 Walnut St Ste 985 Des Moines, IA 50309	3. NAME OF PERSON OBTAINING EVIDENCE [redacted] DVM
	4. TITLE Enforcement Investigative Analysis Officer
	5. BADGE NO.
	6. DATE EVIDENCE OBTAINED 06/27/2008

7. LOCATION OF ORIGINAL(S) (If not attached)

Nebraska Beef
4501 South 36th St
Omaha, NE 68107

8. EXHIBIT NO. 1

United States Department of Agriculture
Food Safety and Inspection Service
Field Operations
Des Moines District Office
Federal Building
210 Walnut, Room 985
Des Moines, IA 50309-2123

Hand Delivered

June 27, 2008

Bill Hughes, President
Nebraska Beef, Establishment 19336
4501 South 36th St.
Omaha, NE 68107

NOTICE OF INTENDED ENFORCEMENT
(NOIE)

Dear Mr. Hughes,

This serves as official notification by the Food Safety and Inspection Service (FSIS) of our intent to withhold the marks of inspection and suspend the assignment of inspection program personnel at Nebraska Beef, 4501 South 36th St., Omaha, Nebraska 68107.

Background/Authority

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) provide that it is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. These Acts give FSIS the authority, as designated by the Secretary of the Department of Agriculture, to prescribe rules and regulations describing sanitation requirements for inspected establishments. They also provide FSIS program personnel the authority to refuse to allow meat or meat food products to be labeled, marked, stamped, or tagged as "inspected and passed" and to prevent the entry of products into commerce when the sanitary conditions of any such establishment are rendered adulterated and provide definitions for the term "adulterated". Furthermore, the Acts provide FSIS the authority to appoint inspectors from time to time to examine and inspect products, including the sanitary conditions of facilities. They also give FSIS program personnel the right to examine and inspect all carcasses and parts of carcasses that are further treated and prepared and the right to access and examine establishment records.

When the sanitary conditions of a facility are not properly maintained, FSIS can refuse to render inspection and indefinitely withdraw inspection from an establishment provided the establishment is afforded the right to an administrative hearing.

Under the authorities of the Acts, FSIS has prescribed rules and regulations required for establishments producing meat and poultry products, including the requirements pertaining to sanitation and Hazard Analysis and Critical Control Point (HACCP) (9 CFR §§ 416 and 417) and other matters. FSIS has developed Rules of Practice (9 CFR § 500) regarding enforcement. The Rules of Practice describe the

types of enforcement action that FSIS may take and include procedures for taking a withholding action and/or suspension, with or without prior notification, and for filing a complaint to withdraw a grant of Federal inspection.

Findings/Basis for Action

The following information is provided to support this Notification of Intended Enforcement (NOIE) for your facility:

There is reason to believe that Nebraska Beef continues to produce beef trim positive for *E. coli* O157, and that the microbiological testing procedure in place at this establishment is not detecting positive sample lots, *i.e.* is not functioning appropriately.

It appears that the establishment is following USDA-FSIS sampling techniques for trim collection (N-60 sample size with 5 combos or less as a lot), and test 375g of the collected sample using the testing procedure). The package insert states that the intended use is to analyze 25g samples only, however, the method has been validated to work using a 375g sample, though this use has not been AOAC approved. Therefore, this method, if performed correctly, is theoretically capable of detecting very low levels of *E. coli* O157:H7 contamination. However, as with all microbiological methods, the procedure as described must be followed precisely, or there is a high risk of getting false negative results.
Therefore it is reasonable to suggest the testing methodology is not being performed correctly, as supported by the following facts:

- In the two years that Nebraska Beef has been doing in-house testing of trim for *E. coli* O157:H7, they have never had a positive. The nationwide prevalence of *E. coli* O157:H7 in trim is below ≤1%, so positives, while rare, should be found occasionally.
- Nebraska Beef does not use a positive control and so has no verification that the test method, as performed by the in-house technician, can in fact detect positives if present at low levels.
- Samples from trim produced from animals custom slaughtered and processed at Nebraska Beef were sent to an outside lab (for *E. coli* O157 testing in June of 2008, where 19/326 combos were found positive, a percent positive rate of 5.8%. In the same period (June 2008), all trim produced from animals slaughtered and processed at Nebraska Beef but tested in-house (approx. 1493 combos) tested negative.
- Nebraska Beef has been identified as a supplier to grinders where raw ground beef tested positive for *E. coli* O157:H7 four times in 2008.

We also believe that Nebraska Beef continues to produce beef trim positive for *E. coli* O157 because on 6/19/2008 Nebraska Beef shipped into commerce product that was presumptive positive for *E. coli* O157:H7. This is supported by the following events:
Establishment 19336 produced 5 combos of beef trim intended for grinding that were packed on 6/17/2008 and were labeled as Beef Round Trim, combo ID #9 net wt #11 net wt. 1 #12 net wt. #13 net wt. ,#14 net wt. These 5 combos, along with 2 other combos were sent to Est. where it was ground prior to Es receiving a copy of the COA

(Certificate of Analysis). Once the COA's had been received it was determined that the 5 previously identified combos were presumptive positive for *E. coli* O157:H7. The pre-shipment review on this product was signed on 6/17/2008, prior to receiving the COA for this product from According to Est. 19336 Verification and Recordkeeping summary sheet in their plan for CCP the pre-shipment review of records conducted before shipment indicates the release of combos destined for raw ground use. Therefore by signing the pre-shipment review on 6/17/08, prior to getting the COA results, you produced and on 6/19/08 shipped adulterated product into commerce which was ground by Est. . **This is a non- compliance with 9 CFR 417.5(c).** By not properly implementing the pre-shipment review you lost control of the product and were not able to take corrective actions including the proper disposition of product. **This is a non-compliance with 9 CFR 417.3.** The fact that you lost control of the product is further evidenced by other product produced that same day (6/17/08) tested presumptive positive for *E. coli* O157:H7 and was initially shipped to Est , then re-routed to Est. who rejected the shipment and sent it back to Est. , where it was placed under retention by FSIS. It was then sent under seal to an Establishment in on 6/24/08, which rejected the product and sent it back to Est. on 6/25/08. At that time the documentation provided stated that it was being sent back to Est. In transit it was re-routed, with no paperwork to provide any notification of the change in destination. The product was eventually found in at Est on 6/27/08.

The sampling of trim combos that you perform daily is in fact a defacto verification of the trim portion and CCP In light of the 19 combos in the month of June, 2008 that have tested positive by an outside lab you have not re-assessed your hazard analysis or HACCP plan and at this point cannot support the decisions made in your hazard analysis that CCP reducing or preventing *E. coli* O157:H7 from occurring. **This is a non-compliance with 9 CFR 417.4(a)(3), 417.4(b), 417.5(a)(2).**

By not re-assessing your HACCP plan in a timely manner in response to the positive test results that were received on trim product that was produced in June 2008 you are no longer able to support the decisions that you have made in your plan that the CCPs in place will reduce, prevent or eliminate *E. coli* O157:H7 from occurring. Also because you have not been able to support the decisions you have made about the testing methodology used in your in-house lab the results produced from this testing do not adequately verify and in fact do not give you or us any assurance that your system is working as designed, in light of the test results obtained by the outside lab. **This is a non-compliance with 9 CFR 417.2(a)(c) & 417.5(a).**

The HACCP system in place at Est. 19336 is deemed to be inadequate according to 9 CFR 417.6(a) as the establishment, in light of the 19 presumptive positives for *E. coli* O157:H7 on combos of trim, has not re-assessed its' HACCP plan or hazard analysis and has not taken any corrective actions.

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The HACCP system in place at Est. 19336 is deemed to be inadequate according to 9 CFR 417.6(b) as establishment personnel are not performing an adequate pre-shipment review prior to shipping product as they are not reviewing all records (COAs) associated with the production of trim product prior to product being shipped.

The HACCP system in place at Est. 19336 is deemed to be inadequate according to 9 CFR 417.6(c) as the establishment is not taking all parts of corrective action by not doing a proper disposition on presumptive positive product and not maintaining control of the product.

The HACCP system in place at Est. 19336 is deemed to be inadequate according to 9 CFR 417.6(e) as the establishment has produced (on 6/17/08) and shipped (on 6/19/08) adulterated product into commerce. The public health consequences of shipping product adulterated with *E. coli* O157:H7 to an unsuspecting public for consumption is significant, as it is a known fact that severe human illness and death is caused by the consumption of beef meat product adulterated with *E. coli* O157:H7 (Economic Cost of Illness Due to *E. coli* O157 Infections in the United States, Paul D. Frenzen, et.al., Journal of Food Protection, Vol. 68, No. 12, 2005, pp. 2623-2630), (Foodnet Surveillance Report for 2004, CDC).

The above cited deficiencies leave the Agency without assurance that your system is adequate to produce product that is not adulterated or injurious to health, as defined in the FMIA, 21 USC 601 (m)(1), 602 & 610(c)(1)(B).

In accordance with FSIS' Rules of Practice, 9 CFR 500.4 we are notifying you of our intent to withhold the marks of inspection and suspend the assignment of inspectors at your facility. Please provide this office with a written response concerning this notice of intended enforcement (NOIE) within three (3) working days from the date of your receipt of this letter. We will determine further action, if any, based upon your response.

If you have questions regarding this matter, please feel free to contact [redacted] EIAO/PHV at (402) 437-[redacted]

Sincerely,

Dr. Dawn Sprouls
Des Moines District Manager

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 2

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-2

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

☑ COPY ☐ ORIGINAL	1. DESCRIPTION OF EVIDENCE A copy of Nebraska Beefs' E-coli O157:H7 testing procedure which appears that the establishment is following USDA FSIS sampling techniques for trim collection (N=60 sample size with 5 combos or less as a lot), and test 375g of the collected sample using the [redacted] testing procedure [redacted].

2. EVIDENCE OBTAINED FROM (Name, address, etc.) Nebraska Beef 4501 South 36th St Omaha, NE 68107	3. NAME OF PERSON OBTAINING EVIDENCE [redacted] DVM
	4. TITLE Enforcement Investigative Analysis Officer
	5. BADGE NO.
	6. DATE EVIDENCE OBTAINED 06/27/2008

7. LOCATION OF ORIGINAL(S) (If not attached)

Nebraska Beef
4501 South 36th St
Omaha, NE 68107

8. EXHIBIT NO. 2

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 3

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-3

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

☑ COPY
☐ ORIGINAL

1. DESCRIPTION OF EVIDENCE

A copy of [redacted] test user guide. Document insert states that the intended use is to analyze 25g samples only, however the method has been validated to work using a 374g sample, through this use has not bee AOACC approved. Therefore this method if performed correctly is theoretically capable of detecting very low levels of E.coli O157:H7 contamination. However as with all microbiological methods, the procedures as describe must be followed precisely or there is a high risk of getting false negative results.

2. EVIDENCE OBTAINED FROM (Name, address, etc.)

Nebraska Beef
4501 South 36th St
Omaha, NE 68107

3. NAME OF PERSON OBTAINING EVIDENCE

[redacted] DVM

4. TITLE

Enforcement Investigative Analysis Officer

5. BADGE NO.

6. DATE EVIDENCE OBTAINED

06/27/2008

7. LOCATION OF ORIGINAL(S) (If not attached)

Nebraska Beef
4501 South 36th St
Omaha, NE 68107

8. EXHIBIT NO. 3

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 5

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-5

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

☑ COPY
☐ ORIGINAL

1. DESCRIPTION OF EVIDENCE

Copies of [redacted] E.coli O157:H7 test results which were performed as verification of the firms "in house" laboratory using [redacted] and [redacted] gram sample size and appears to validate firms sampling methods.

2. EVIDENCE OBTAINED FROM (Name, address, etc.)

Nebraska Beef
4501 South 36th St
Omaha, NE 68107

3. NAME OF PERSON OBTAINING EVIDENCE

[redacted] DVM

4. TITLE

Enforcement Investigative Analysis Officer

5. BADGE NO.

6. DATE EVIDENCE OBTAINED

06/27/2008

7. LOCATION OF ORIGINAL(S) (If not attached)

Nebraska Beef
4501 South 36th St
Omaha, NE 68107

8. EXHIBIT NO. 5

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 6

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-6

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

☑ COPY ☐ ORIGINAL	1. DESCRIPTION OF EVIDENCE Copies of [redacted]ab results from Nebraska Beef of product shipped to another establishment on 6/19/2008. Also included with exhibit are combo labels and a e-mail message. Documents depict that subject firm shipped into commerce product that was presumptive positive for E.coli O157:H7.

2. EVIDENCE OBTAINED FROM (Name, address, etc.) Nebraska Beef 4501 South 36th St Omaha, NE 68107	3. NAME OF PERSON OBTAINING EVIDENCE [redacted] DVM
	4. TITLE Enforcement Investigative Analysis Officer
	5. BADGE NO.
	6. DATE EVIDENCE OBTAINED 06/27/2008

7. LOCATION OF ORIGINAL(S) (If not attached)

Nebraska Beef
4501 South 36th St
Omaha, NE 68107

8. EXHIBIT NO. 6

COA OK 08:45

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A0002221_136-000000

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 7

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-7

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

s.(b)(6)
s.(b)(7)(C)

☑ COPY ☐ ORIGINAL	1. DESCRIPTION OF EVIDENCE Copies of Nebraska Beefs' "Fabrication Pre-Shipment Review" for beef trimmings destined for Raw Ground use for the time period of 6-2-2008 thru 6-22-2008. Documents depict that on June 17 , 2008 the pre-shipment review was signed for all beef trim prior to receiving the Certificate of Analysis showing that by signing the pre-shipment review prior to receiving the COA firm produced and on 6-19-2008 shipped adulterated product into commerce.

2. EVIDENCE OBTAINED FROM (Name, address, etc.) Nebraska Beef 4501 South 36th St Omaha, NE 68107	3. NAME OF PERSON OBTAINING EVIDENCE [redacted] DVM
	4. TITLE Enforcement Investigative Analysis Officer
	5. BADGE NO.
	6. DATE EVIDENCE OBTAINED 06/27/2008

7. LOCATION OF ORIGINAL(S) (If not attached)

Nebraska Beef
4501 South 36th St
Omaha, NE 68107

8. EXHIBIT NO. 7

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 8

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-8

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

s.(b)(6)
s.(b)(7)(C)

☑ COPY ☐ ORIGINAL	1. DESCRIPTION OF EVIDENCE Copy of "STEPS" notification for subject firm. Documents state that subject firm is listed as a supplier in a E.coli positive case under ILN(s) MF 84733, MF64555, MF51918, and MF64470.

2. EVIDENCE OBTAINED FROM (Name, address, etc.) USDA FSIS OFO DO Des Moines District Office 210 Walnut St Ste 985 Des Moines, IA 50309	3. NAME OF PERSON OBTAINING EVIDENCE [redacted]	
	4. TITLE District Analyst	
	5. BADGE NO.	6. DATE EVIDENCE OBTAINED 06/27/2008

7. LOCATION OF ORIGINAL(S) (If not attached)
USDA FSIS OFO DO
Des Moines District Office
210 Walnut St Ste 985
Des Moines, IA 50309

8. EXHIBIT NO. 8

[redacted]

From: [redacted]@fsis.usda.gov **s.(b)(6)**
Sent: Saturday, June 07, 2008 7:31 PM **s.(b)(7)(C)**
To: [redacted]
Subject: Notification of Ecoli-Positive Result

The following establishment (**19336 M**) is listed as a supplier in the Ecoli-positive case under ILN: **MF64470** and LabCode: **2902**.
Upon receipt of this email, please contact the Supplier establishment and make the required oral notification for the Agency.
Also, please access STEPS and complete/edit the supplier profile (**STEPS Instructions: "Edit Case", "Supplier Est. No."**) to accurately reflect the facts of the oral notification.
Finally, complete the process by sending (through STEPS) email notification to the supplying firm or Office of International Affairs when applicable.
Thank you.

From: [redacted]@fsis.usda.gov
Sent: Thursday, June 19, 2008 1:43 PM
To: [redacted]
Subject: Notification of Ecoli-Positive Result

The following establishment (**19336 M**) is listed as a supplier in the Ecoli-positive case under ILN: **MF84733** and LabCode: **1302**.
Upon receipt of this email, please contact the Supplier establishment and make the required oral notification for the Agency.
Also, please access STEPS and complete/edit the supplier profile (**STEPS Instructions: "Edit Case", "Supplier Est. No."**) to accurately reflect the facts of the oral notification.
Finally, complete the process by sending (through STEPS) email notification to the supplying firm or Office of International Affairs when applicable.
Thank you.

s.(b)(6)
s.(b)(7)(C)

s.(b)(6)
s.(b)(7)(C)

From: [redacted]@fsis.usda.gov
Sent: Wednesday, June 18, 2008 11:49 AM
To: [redacted]
Subject: Notification of Ecoli-Positive Result

The following establishment (**19336 M**) is listed as a supplier in the Ecoli-positive case under ILN: **MF64555** and LabCode: **2902**.
Upon receipt of this email, please contact the Supplier establishment and make the required oral notification for the Agency.
Also, please access STEPS and complete/edit the supplier profile (**STEPS Instructions: "Edit Case", "Supplier Est. No."**) to accurately reflect the facts of the oral notification.
Finally, complete the process by sending (through STEPS) email notification to the supplying firm or Office of International Affairs when applicable.
Thank you.

From: [redacted]@fsis.usda.gov
Sent: Tuesday, June 17, 2008 2:59 PM
To: [redacted]
Subject: Notification of Ecoli-Positive Result

The following establishment (**19336 M**) is listed as a supplier in the Ecoli-positive case under ILN: **MF51918** and LabCode: **602**.
Upon receipt of this email, please contact the Supplier establishment and make the required oral notification for the Agency.
Also, please access STEPS and complete/edit the supplier profile (**STEPS Instructions: "Edit Case", "Supplier Est. No."**) to accurately reflect the facts of the oral notification.
Finally, complete the process by sending (through STEPS) email notification to the supplying firm or Office of International Affairs when applicable.
Thank you.

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 9

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-9

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

s.(b)(6)
s.(b)(7)(C)

☑ COPY ☐ ORIGINAL	1. DESCRIPTION OF EVIDENCE Copies of 4 "STEPS" notification e-mails provided to [redacted] QA manager at Nebraska Beef. Documents notifying subject firm of being listed as a supplier of beef used to produce ground beef products that was found to be positive for E. coli O157:H7.

2. EVIDENCE OBTAINED FROM (Name, address, etc.) USDA FSIS OFO DO Des Moines District Office 210 Walnut St Ste 985 Des Moines, IA 50309	3. NAME OF PERSON OBTAINING EVIDENCE [redacted] 4. TITLE District Analyst	
	5. BADGE NO.	6. DATE EVIDENCE OBTAINED 06/27/2008

7. LOCATION OF ORIGINAL(S) (If not attached)
USDA FSIS OFO DO
Des Moines District Office
210 Walnut St Ste 985
Des Moines, IA 50309

8. EXHIBIT NO. 9

[redacted]

From: [redacted]@fsis.usda.gov
Sent: Thursday, June 19, 2008 2:35 PM
To: [redacted]@nebraska-beef.com
Cc: FSIS RecallNotification; [redacted]
Subject: Notification of Ecoli O157:H7-positive Result

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

[redacted] Quality Assurance Manager
Nebraska Beef, Ltd.
Omaha, NE

This message is issued as a follow-up to your telephone conversation with the FSIS Des Moines District Office on 06/19/2008.

Your establishment, Nebraska Beef, Ltd., establishment 19336 M, has been listed as a supplier of beef used to produce ground beef products at establishment [redacted] The product produced at that establishment was sampled by FSIS and returned a positive result for *Escherichia coli* O157:H7 in a FSIS laboratory on 06/19/2008.

Material from your establishment was not the only raw material used in the sampled product.

The material from your establishment was identified as:
Product Name - Nebraska Clods & Nebrasks Knuckles Supplied these products to [redacted] thru [redacted] Est [redacted] This material was received by [redacted] on 6/9/2008 No lot # or Production date is available

If you have any questions you may contact Thomas Beck in the Des Moines District Office.

Des Moines District Office
Office of Field Operations
Food Safety & Inspection Service

Fax 515-727-8991

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

From: @fsis.usda.gov [mailto:l @fsis.usda.gov]
Sent: Wednesday, June 18, 2008 3:57 PM
To: @nebraska-beef.com
Cc: FSIS RecallNotification;
Subject: Notification of Ecoli O157:H7-positive Result

Food Safety Director
Nebraska Beef, Ltd.
Omaha, NE

This message is issued as a follow-up to your telephone conversation with the FSIS Des Moines District Office on 06/18/2008.

Your establishment, Nebraska Beef, Ltd., establishment 19336 M, has been listed as a supplier of beef used to produce ground beef products at establishment The product produced at that establishment was sampled by FSIS and returned a positive result for *Escherichia coli* O157:H7 in a FSIS laboratory on 06/11/2008.

Material from your establishment was not the only raw material used in the sampled product.

The material from your establishment was identified as:
Nebraska Beef Ltd. Est.19336 M supplied the following: 56660 Special Trim, 58860 Rose Meat, 67100 Front Shank, and 67200 Hind Shank All with a production date of 05/16/2008

If you have any questions you may contact in the Des Moines District Office.

Des Moines District Office
Office of Field Operations
Food Safety & Inspection Service

From: [redacted]@fsis.usda.gov
Sent: Tuesday, June 17, 2008 3:08 PM
To: [redacted]@nebraska-beef.com
Cc: FSIS RecallNotification; [redacted]
Subject: Notification of Ecoli O157:H7-positive Result

[redacted]ood Safety Director
Nebraska Beef, Ltd.
Omaha, NE

This message is issued as a follow-up to your telephone conversation with the FSIS Des Moines District Office on 06/17/2008.

Your establishment, Nebraska Beef, Ltd., establishment 19336 M, has been listed as a supplier of beef used to produce ground beef products at establishment [redacted]he product produced at that establishment was sampled by FSIS and returned a positive result for *Escherichia coli* O157:H7 in a FSIS laboratory on 06/15/2008.

Material from your establishment was not the only raw material used in the sampled product.

The material from your establishment was identified as:
Product code 67200 Front Shank Meat with production date 6/9/2008.

If you have any questions you may contact [redacted] in the Des Moines District Office.

Des Moines District Office
Office of Field Operations
Food Safety & Inspection Service

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

From: @fsis.usda.gov
Sent: Monday, June 09, 2008 8:48 AM
To: @nebraska-beef.com
Cc: FSIS RecallNotification
Subject: Notification of Ecoli O157:H7-positive Result

Bill Hughes
Nebraska Beef, Ltd.
Omaha, NE

This message is issued as a follow-up to your telephone conversation with the FSIS Des Moines District Office on 06/09/2008.

Your establishment, Nebraska Beef, Ltd., establishment 19336 M, has been listed as a supplier of beef used to produce ground beef products at establishment The product produced at that establishment was sampled by FSIS and returned a positive result for *Escherichia coli* O157:H7 in a FSIS laboratory on 06/04/2008.

Material from your establishment was not the only raw material used in the sampled product.

The material from your establishment was identified as:
Source MaterialBeef Chuck- Nebraska Beef Inc. Est. 19336 production date 5/19/08

If you have any questions you may contact Jeff Enlow in the Des Moines District Office.

Des Moines District Office
Office of Field Operations
Food Safety & Inspection Service

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 10

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-10

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

s.(b)(4)
s.(b)(6)
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☑ COPY ☐ ORIGINAL	1. DESCRIPTION OF EVIDENCE Copy of firms " HACCP plan" Document describes the HACCP system in place at subject firm.

2. EVIDENCE OBTAINED FROM (Name, address, etc.) Nebraska Beef 4501 South 36th St Omaha, NE 68107	3. NAME OF PERSON OBTAINING EVIDENCE F DVM 4. TITLE Enforcement Investigative Analysis Officer 5. BADGE NO. 6. DATE EVIDENCE OBTAINED 06/27/2008

7. LOCATION OF ORIGINAL(S) (If not attached)
Nebraska Beef
4501 South 36th St
Omaha, NE 68107

8. EXHIBIT NO. 10

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 11

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-11

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

s.(b)(6)
s.(b)(7)(C)

☑ COPY ☐ ORIGINAL	1. DESCRIPTION OF EVIDENCE Copies of Midwest Laboratories "Report of Analysis" #08-170-2112, 08-170-2112B, 08-177-2104A, 08-177-2105, and 08-177-2103A. Documents depict six presumptive positives for E.coli O157:H7 for beef trim derived from animals slaughtered for Coleman/Meyer on June 14, June 16, June 21 and June 23 2008. This information contains the 19 combos of trim tested and as mentioned in the NOIE plus the addition of 6 combos that comprised another 2 presumptive positives for E.coli O157:H7 for a total of 6 presumptive positives for the month of June which were found after the NOIE was issued.

2. EVIDENCE OBTAINED FROM (Name, address, etc.) Nebraska Beef 4501 South 36th St Omaha, NE 68107	3. NAME OF PERSON OBTAINING EVIDENCE DVM
	4. TITLE Enforcement Investigative Analysis Officer
	5. BADGE NO.
	6. DATE EVIDENCE OBTAINED 06/27/2008

7. LOCATION OF ORIGINAL(S) (If not attached)

Nebraska Beef
4501 South 36th St
Omaha, NE 68107

8. EXHIBIT NO. 226

A0002221_226-000000

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 12

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-12

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

s.(b)(6)
s.(b)(7)(C)

☑ COPY ☐ ORIGINAL	1. DESCRIPTION OF EVIDENCE Copy of Nebraska Beef's first response to the NOIE, dated July 2, 2008. The document includes the intial response and 13 attachments (150 pgs).

2. EVIDENCE OBTAINED FROM (Name, address, etc.) Nebraska Beef, Est 19336 M 4501 S. 36th Street Omaha, Ne 68107	3. NAME OF PERSON OBTAINING EVIDENCE DVM
	4. TITLE Enforcement Investigations Analysis Officer
	5. BADGE NO.
	6. DATE EVIDENCE OBTAINED 07/02/2008

7. LOCATION OF ORIGINAL(S) (If not attached)

USDA FSIS OFO
Des Moines District Office
210 Walnut Street, Suite 985
Des Moines, IA 50309

8. EXHIBIT NO. 12

NEBRASKA BEEF, LTD
4501 S. 36th Street
Omaha, Nebraska 68107
(402) 733-7000
Fax: (402) 733-1624

July 2, 2008

Dr. Dawn Sprouls
Des Moines District Manager
210 Walnut Street, Room 985
Des Moines, IA 50309-2123

Dear Dr. Sprouls:

s.(b)(4)

On June 27, 2008, Nebraska Beef was issued a Notice of Intended Enforcement (NOIE) in accordance with the Rules of Practice, 9 CFR 500.4. The following Action Plan is submitted in response to the NOIE.

(1) There is reason to believe that Nebraska Beef continues to produce beef trim positive for *E. coli* O157:H7, and that the microbiological testing procedure in place at this establishment is not detecting positive sample lots, i.e. is not functioning appropriately (No regulation cited). The ® package insert states that the intended use is to analyze 25g samples only, however, the method has been validated to work using a 375g sample, though this use has not been AOAC approved.

(2) It is reasonable to suggest the testing methodology is not being performed correctly as supported by the following facts: In the two years that Nebraska Beef has been doing in-house testing of trim for *E. coli* O157:H7, they have never had a positive. The nationwide prevalence of *E. coli* O157:H7 in trim is below = 1%, so positives, while rare, should be found occasionally.

(3) It is reasonable to suggest the testing methodology is not being performed correctly as supported by the following facts: Samples from trim produced from animals custom slaughtered and processed at Nebraska Beef were sent to an outside lab (Midwest) for *E. coli* testing in June 2008, where 19/326 combos were found positive, a percent positive rate of 5.8%. In the same period (June 2008), all trim produced from animals slaughtered and

combined the pproach combined with direct plating onto id/or

Throughout 2007 and the winter of 2008 not a single sample collected from a carcass in the cooler was positive for *E. coli* O157:H7 using all three methods. Additionally, testing at the other two facilities revealed that up to 20% of the samples collected from the carcasses in the other plants were positive for this pathogen.

The implementation of the targeted interventions was effective controlling *E. coli* O157:H7 in our facility which was indicated by their testing using three separate methods and by additionally testing done by the facility itself with negative results on the final product using AOAC approved methods internally and by an external laboratory all using AOAC approved methods (See Attachment 3)

As additional support for the validity of our microbiological programs, during the past 7 months, our company has been subjected to two Comprehensive Food Safety Reviews by FSIS, one in December 07 and another in May 08. Those audit reports contained information relating to thorough direct observations and records review of our micro sampling and testing programs, and in each case the decision was that we were in compliance with all regulatory requirements (See Attachment 4).

(4) It is reasonable to suggest the testing methodology is not being performed correctly as supported by the following facts: Nebraska Beef does not use a positive control and so has no verification that the Rapid Chek® test method, as performed by the in-house technician, can in fact detect positives if present at low levels.

Th

(See Attachment 5).

(5) It is reasonable to suggest the testing methodology is not being performed correctly as supported by the following facts: Nebraska Beef has been identified as a supplier to grinders where raw ground beef tested positive for *E. coli* O157:H7 four times in 2008.

The notifications from FSIS revealed that our establishment was not the only raw material used in the sampled product (See Attachment 6). While our company takes very

seriously anytime our products are implicated as a raw material supplier of non-intact products that test positive for *E. coli* O157:H7, the fact that we were not the only supplier does call into question whether our raw materials were a definitive source of the adulteration.

In all of the aforementioned incidents, the establishments of record received boxed, cryo-vaced beef sub-primals that they converted for non-intact use. Our HACCP program clearly identifies that beef primals and sub-primals are not intended for non-intact use and our understanding of existing agency policy is as follows;

1.

2.

3.

Once notified, our quality control department reviewed all records associated with the production dates supplied by FSIS and no deficiencies were found. Because we considered this record review outside the scope of the regulatory mandate relating to Reassessment (417.4), no record of these reviews were documented. However, effectively immediately, Nebraska Beef has instituted a reassessment procedure whereby

* In conclusion to items 2 through 5, beginning Monday June 30, 2008 and until further notice, all microbiological samples collected by Nebraska Beef will be submitted for pathogen testing to our outside contractor, Our contract laboratory has immediately implemented the method of testing which is considered by the industry to be a more sensitive test than the method, which was previously used (See Attachment 1). We feel that the utilization of outside laboratories and a more sensitive testing method will provide the agency with sufficient confidence in the testing methodology performance of Nebraska Beef's food products.

(6) Prior to getting the Certificate of Analysis (COA) results, Nebraska Beef produced and on 6/19/08 shipped adulterated product into commerce which was ground by establishment 4215 (Non-compliance w/ 9 CFR 417.5 (c)).

As stated in the text of the NOIE, Nebraska Beef shipped 7 combos of beef trimmings to prior to them receiving a copy of the COA.

Nebraska Beef normally ships all beef trimmings intended for non-intact use to customer, Since s located in an

adjacent section of our plant, operating under the same roof, we always tested and held the product within our facility. As standard in our process, we sign a pre-shipment review once all critical control points have been completed for a specific lot of production. We had previously never considered the product "shipped", only that the critical control points had been met. However, in this isolated incident the particular product was purchased by a new customer in which we custom slaughter, process, pack, and ship. Since the incident, our company has written and implemented a "

(7) By not properly implementing the pre-shipment review, you lost control of the product and were not able to take corrective actions including the proper disposition of product (Non-compliance w/ 9 CFR 417.3).

As mentioned previously above, our normal policy of
waived on this one occasion when the customer assured us that they just wanted the product at their facility so they could start the process as quickly as possible, once the results were received. Our company was assured more than once that the seal would not be broken nor would the product be removed from the trailer until they had received word from us stating the product was confirmed negative for *E.coli* 0157:H7. We denied their request several times during the day until it was finally determined that they would honor our seal and await our test results. Nebraska Beef always believed we still had control of the product as the truck driver had also indicated that he would wait for a proper release from us. However, our customer apparently did not perceive that waiting for the COA was a necessity to grind the product. This started the chain of events that lead to positive product being ground, then loaded back on a trailer, and shipped to a "cooker" in Wisconsin, all without our knowledge or approval. As the agency is aware, the product ended up at
where it is presently under HSIS Retention. We have a letter from the company that states it will notify
our customer) once lethality has been achieved. In turn,
will notify us so we can close out our corrective action record. As stated in #6 above, we have immediately written and implemented a
procedure which instructs all products tested to be held until the results have been received, regardless of the customer (Attachment 9).

(8) In light of 19 combos in the month of June 2008, that have tested positive by an outside lab, you have not re-assessed your hazard analysis or HACCP plan and at this point cannot support the decisions made in your hazard analysis that CCP 3B is reducing or preventing *E. coli* O157:H7 from occurring (Noncompliance w/9 CFR 417.4 (a) (3), 417.4 (b), 417.5 (a) (2).

(9) Because you have not been able to support the decisions you made about the testing methodology used in your in-house lab, the results produced from this testing do not adequately verify and in fact do not give you or us any assurance that your system is working as designed, in light of the test results

Next, on June 25, 2008, we were notified by [redacted] of the 19 combos in question. Again, because we were in the process of reassessing both HACCP programs with no finalized decisions, no documentation was made to the "HACCP Changes Page."

In conclusion, we are taking the agency's findings very seriously and perceive them as a way to further strengthen our food safety program. Therefore, effectively immediately, Nebraska Beef has instituted a reassessment procedure whereby all decisions causing us to review any part of our HACCP program are documented on our "HACCP Changes Page," including notations of reassessments in progress. As an example, because we started reassessing all of the aforementioned issues on June 18, 2008, and have completed partial segments of the reassessment, we have provided a copy of our most recent "HACCP Changes Page" which indicates our present reassessment is in progress (See Attachment 13).

Nebraska Beef believes the information and enclosures demonstrate the commitment of our company to food safety and continuing improvement.

If you have any questions please contact my office at 402-733-0456.

Bill Hughes
President
Nebraska Beef

Attachment 1

Attachment 2

Attachment 4

s.(b)(6)
s.(b)(7)(C)

FSIS FORM 5000-8 (10/13/2003) REPLACES FSIS FORM 5000-8 (08/27/2002), WHICH IS OBSOLETE.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
OFFICE OF FIELD OPERATIONS

COMPREHENSIVE ASSESSMENT OF THE EXECUTION AND DESIGN OF AN ESTABLISHMENT'S FOOD SAFETY SYSTEMS

DISTRIBUTION INSTRUCTIONS:
Submit this report to your District Manager and the Front-Line Field Supervisor via email.

EST. NO.	DATES CSO VISITED EST.
19336 M	FROM: 11/26/2007 TO: 12/14/2007

NAME AND ADDRESS OF ESTABLISHMENT
Nebraska Beef
4501 South 36th Street
Omaha, NE 68107 (Large HACCP plant)

NAME OF CSO:
and

DISTRICT	CIRCUIT VISITED
Des Moines (25)	Omaha (21)

REASON FOR VISIT *(Check all that apply)*:

- [X] A. District Office Direction
- [ ] B. Consumer Complaints
- [ ] C. Foodborne Illness
- [ ] D. Foreign Particle Contamin.
- [ ] E. Repetitive Lm Findings
- [ ] F. STEPS triggered Sample Form # _____
  - [ ] A set
  - [ ] B set
  - [ ] C set
- [ ] G. Salmonella Performance Standard Failure
- [X] H. Other *(Specify)*:

As directed by FSIS Notice 66-07, Implicated as a source of a ground beef component in five (5) positive *E. coli* O157:H7 samples. In two cases Nebraska Beef was the sole supplier.

SUMMARY OF DATA ASSESSMENT PRIOR TO VISIT:

System Tracking *E.coli* Positive Sample (STEPS): Five dates were reported with Nebraska Beef as a supplier of product that was positive in FSIS test results. Data and analysis in the following section under ST 9 and ST 9A.

Consumer Complaint Monitoring System (CCMS): No complaints found.

Performance Based Inspection System (PBIS): From 04/01/2007 through 11/15/2007 there were 79 non-compliance reports (NRs) issued. 01B02-17 NRs
01C01- 4 NRs
01C02- 32 NRs
03J01 - 16 NRs
06D01- 8 NRs
These NRs will be analyzed in a later section of the FSA.

RECOMMENDATIONS *(Check only one)*:

- [X] A. No further action
- [ ] B. 30 day letter
- [ ] C. NOIE
- [ ] D. NOIE & 30 day letter
- [ ] E. Suspension/Withdrawal

F. Summary of reason(s) for recommendation:

The establishment has developed and implemented a comprehensive food safety system through their SSOP, Generic *E. coli*, HACCP, and prerequisite programs. Three non-compliances associated with prerequisite programs to adequately support decisions made were identified during the assessment and were addressed with a non-compliance record.

FINDINGS:

Summary of data assessment prior to visit continued

Laboratory Electronic Application Results Notification (LEARN) – All results on LEARN show acceptable results. Tests results include:

- HC01-PR/HACCP *Salmonella* Verification Testing, reporting dates 12/05/2007, 12/04/2007, 12/03/2007, 11/30/2007, 11/28/2007, 11/27/2007, 11/26/2007, all acceptable.
- Monitoring Residue Domestic National, reporting date 11/29/2007, two tests (liver tested for Sulfas and liver tested for Avermetins, both residue not detected.

Best Copy Available

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- MT52 *E.coli* O157:H7 Followup Sampling- Beef Trim Suppliers, reporting dates 11/15/2007 and 11/12/2007 (six samples), all negative.

Prior Assessments and Actions

-Issued Notice of Intended Enforcement (NOIE) 09/06/2002 -Suspension 09/14/2002 -Abeyance on 09/17/2002. This NOIE and suspension was based on a failure to implement SSOPs.

-Reinstatement of Suspension 12/19/2002 -Abeyance 12/20/2002 -Reinstatement 01/16/2003, a Temporary Restraining Order was issued by the Federal Court (01/16/2003). Consent order signed 01/27/2003

-*E. coli* reassessment 08/11/2003 to 08/14/2003 resulted in a 30 day reassessment letter.

-Withholding use of labels for based on product testing positive for spinal cord tissue, 04/05/2004.
-Release of labels 04/09/2004.

-Food Safety Assessment (FSA) from 06/22/2004 to 06/29/2004 resulted in no further action.

-FSA completed on 10/19/2004 to 10/29/2004 as part of on-going verification. Result of this FSA was the recommendation that no further action be taken.

equipment rejected on 11/26/2004 based on product sample dated 11/23/04 testing positive for CNS tissue. Equipment released on 11/29/2004.

-FSA from 01/04/2005 to 01/13/2005, as part of on-going verification and because it was listed as a supplier of beef used at another establishment to produce ground beef that tested positive for *E. coli* O157:H7 on a FSIS lab sample from 01/02/2005. This FSA recommended a 30-Day Letter for failure to provide supporting documentation to ensure control of variety meats associated with grinding is going for further processing (cooking) and not used for raw ground product.

-Label withholding on AMR product 05/19/2005.

-Humane handling NOIE issued on 06/24/2005, which was deferred on 06/30/2005. Issued letter of concern on 09/01/05 for humane handling issues. Humane handling NOIE closed out on 12/21/2005 with a letter of warning.

-FSA from 7/10/2006 to 08/03/2006 resulting in a NOIE issued on 08/03/2006 based on the establishment's failure to implement and maintain SSOPs which contributed to an inadequate HACCP system which allowed adulterated beef product to be produced. This was placed in Deferral 08/04/2006 and closed with a Letter of Warning.

Predication

On 11/26/2007, Enforcement Investigations & Analysis Officer (EIAO) and EIAO/Public Health Veterinarian (PHV) for the Des Moines District of the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS), visited Establishment 19336, Nebraska Beef, Inc., 4501 South 36th Street, Omaha, Nebraska 68107. The visit was initiated to conduct a comprehensive assessment of the design and implementation of the food safety systems in place at the facility.

Scope

Responsibilities included working with assigned FSIS personnel in the examination of Nebraska Beefs' HACCP programs including the evaluation of Critical Control Points (CCP's) and supportable data for Est. 19336 decision making process. Additionally, the Sanitation Standard Operating Procedure (SSOP) and *E. coli* control programs were examined to determine if they were properly designed and implemented. New methodology was assigned to be used in the form of checklists for use for General Sanitation SSOP/SPS, HACCP 03J Slaughter, and HACCP 03C Raw Not Ground.

Profile

Establishment 19336 is a large (in HACCP terms) beef slaughtering and processing facility. The Grant of Inspection is dated 02/20/2003. The plant is approximately quare feet in size and has approximately mployees. The plant produces approximately ounds of caroasses per and pounds of primals and trim per

The FSIS Frontline Supervisor (FLS) is Assigned inspection staff consists of ten on line inspectors, two off line CSI's and one SPHV/EIAO.

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s.(b)(7)(C)

Contact information for Establishment 19336 is: Food Safety Director, Telephone: (402)-733-0822. Fax: (402) 733-1302. E-mail: @nbeef.com

Entrance Meeting

An entrance meeting was conducted in a conference room at Nebraska Beef in Omaha, NE, at approximately 1130 on 11/26/2007. The review process used for this assessment was discussed along with the possible outcomes of the assessment according to the Rules of Practice (9 CFR 500). Those present at the meeting representi Beef were Food Safety Director HACCP Administrator nior Vice President, Plant Fabrication Superintendent. Those present representing USDA were: SPHV/EIAO, HC) (EIAO/PHV) (EIAO) and Emile Randazzo, Deputy District Manager (DDM). The plant representatives were given the chance to ask questions, none were asked so arrangements were made for contacts during the assessment and the FSA was started.

GENERAL SANITATION: SPS and SSOP

GS1. Is the building maintained in a sound condition as described in 9 CFR 416 (e.g., no leaks, wall integrity good, no standing water)? Yes

GS1a. Describe your observations.

On 11/27/07, 0730, the slaughter floor, yards, offal product area, and outside premise were viewed. All areas showed adequate maintenance. The yard pens were relatively clean and free of manure. The cattle were calmly moving through the area and water was available in all pens. The slaughter floor walls and area barriers were either tile or stainless steel. The hand rails were recently painted. The floor is extremely worn condition with rough surface and deeply corroded crevices made apparent the age of the facility. There was plastic hung in several places but no uncontrolled condensation was noted. One sink behind the head inspection area was seen with a company QA tag on it. The offal collection, tunnel, production room, and cooler were acceptable. Several other tours were taken with no non-compliances found with SPS issues.

GS2. When was the main structure of the premises built?

1970-1980- Built in 1975

1990-2000- Major remodeling in 1995

GS3. Is the equipment free of cracks, pitting, rust or other defects that could affect cleaning and sanitizing procedures? Yes

GS4. Are there any findings during the course of the FSA that raise a concern as to whether the sanitation system is adequate to meet the sanitation performance standard requirements (e.g. ventilation, condensation, structural integrity)? No

GS4a. Free Text Box. Briefly describe your observations and any non-compliances with the SPS regulations. Multiple tours showed no non-compliances.

GS5. Are the SSOPs designed to include all procedures necessary to prevent direct contamination or adulteration of product? Yes

GS5a. Analysis. Describe how you came to the conclusion to GS5.

Preoperational SSOPs include general equipment and facility cleaning with the cleaning procedures designated, a sanitation step with sanitizer used included, designated proper use of chemicals, and the use of a AT Pabioluminescence test used once a week to evaluate the product contact surfaces (PCS).

Operational sanitation include procedures

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GS6. Does the plant have an extended cleanup (less than daily) written in the SSOP? No

GS6a. If yes, does the design of the procedure support extended clean up? NA

GS7. Are the pre-operational sanitation procedures identified as such? Yes

GS8. Do the SSOPs at a minimum address the cleaning of food contact surfaces of facilities, equipment and utensils? Yes

GS9. Are all sanitation procedures conducted incorporated into the SSOP? No, non-product contact areas are included in SPS and GMPs

GS10. Does the plant monitor the implementation of SSOP procedures no less than daily? Yes

GS10a. Analysis: Explain your answer. The preoperational monitoring is prior to operations and the operational SSOPs as designated in GS 5A is documented

GS11. Has the establishment maintained daily SSOP records as required? Yes

GS12. Has the establishment taken corrective actions in response to non-compliances/deviations as required by 9 CFR 416.15 (a)? Yes

GS12a. If yes, were all three parts of 9 CFR 416.15 (b) met? Yes

GS12b. Briefly describe the corrective actions taken and discuss any non-compliances. The corrective actions for preoperations always included recleaning, sanitizing, and release. Operational findings had corrective actions preventive measures that met regulatory requirements.

GS13. Does the establishment conduct microbiological testing as part of the SSOP? Yes

GS13a. If yes, what organism(s)? check all that apply

Records show is taken in the kill department and in the fabrication department each week. Records from 04/09/2007 to 11/26/2007 show no failed tests. The testing frequency is based on the plant's history which showed consistent results in the passing parameters.

GS13b. Is the procedure designed to find the organisms of concern? No, s performed to verify the adequacy of the sanitation procedures with the tests used to indicate proteins associated with organic matter.

GS13c. Does the plant use the data in decision making? Yes

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GS14. Are employee hygiene procedures available in a written document? Yes

GS15. Are employees trained in hygiene procedures? Yes, employees are trained at hiring and then yearly or more after that.

GS15a. Describe the training procedures and discuss whether they are adequate to prevent direct product contamination. Are they available in multiple languages? I

GS16. Are outer garments removed when leaving work area? Yes

GS17. Are gloves used properly? Yes

GS17a. Describe how you came to the conclusion in GS17. Employees were observed on multiple trips through the production areas. At no time was any contamination issues associated with glove usage noted.

GS18. Do the employees use a 20 second hand wash (or comparable method of sanitizing) before starting and returning to work? Yes, employees are required to wash their hands and use a hand operated sanitizer applicator prior to entering the production floors. On 12/05/2007, following our observation of the plant's preoperational procedures, employees were observed entering the fabrication floor. Although all used the equipment sanitizer many had to be stopped by either a QA or supervisor and be reminded to use the hand sanitizer. This observation was discussed with plant management and the CSI, with the CSI to perform follow up observations at later time.

GS19. Are food and operator hand tools (knives/food contact utensils) stored in a sanitary manner? Employees are required to clean and store their hand tools in their lockers between uses. In the morning prior to entering the production floor, the tools (knifes and scabbards) are required to be dipped in a barrel of sanitizer ( ). This sanitizing of equipment and cleanliness of the personal equipment is monitored as part of the preoperational inspection.

GS20. Does the establishment rotate sanitizers? Yes

GS20a. Describe the rotation procedure? The rotation is not written as a rotation but in discussion verified that the plant has the practice of rotating between and a on a basis.

GS21. Describe any findings during review of the SSOP records? Under the Implementation, Monitoring, and Recordkeeping section of the plant's preoperational SSOP (page 5 of 9) it reads

Preoperational records reviewed from 09/24/2007 to 11/23/2007 showed the following: Slaughter preop is split in four areas with units in each that cover all the equipment and the facility. The units include both PCS and non contact surfaces such as walls and floors. When a unit is found unacceptable a SSOP Preoperational Log is completed by the plant. This describes the finding, states the immediate action and measures to prevent recurrence of incident.
On the majority of records phrases containing generalities such as "Sanitation employee will be more thorough ...", "Sanitation employee will be more observant when cleaning", etc were used. This was explained by to be supported with a checklist form that is completed and given to the sanitation leadman which documents the areas and what was found deficient. This way the sanitation leadman can assure the cleaning is effectively completed on those areas as a follow up. The preventive measure were supported with these additional SOP documents that show the sanitation employees do receive notification of the findings and document those as being "done".

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The records for operational sanitation from the same 60 day time frame show the frequency of monitoring for the slaughter floor is daily and for the fabrication floor every. Records show the monitoring done with all incidents found documented with the immediate action (correctives) taken, disposition of involved product, and measures to prevent recurrence. If employees are retrained the training documentation is attached. If the incident involves work by maintenance a work order is attached that has date of completion.

GS22: Free Text Box: Briefly describe any SSOP program design concerns and non-compliances found. Also describe any findings not addressed in any of the previous questions.
Employee training is documented and proper sanitary dressing procedures were observed for the following: hide removal, carcass dressing, carcass evisceration, and knife and equipment sanitation. The SSOPs are designed, implemented, and maintained as required under §416.11 through 416.16. No non-compliances were found.

HACCP 03J Slaughter Meat

Which of the following products does the plant produce under HACCP 03J?

___ Pork (answer general, interventions and validation, animal drug and biological residues, and miscellaneous questions only)
X Beef (answer all questions)

GENERAL

G1: Free Text Box in a table format. List all HACCP 03J plans, products produced using those plans, CCPs, critical limits, and verification procedures associated with those plans.

Beef Slaughter HACCP Plan
Products: Beef carcass sides, offal products/by-products

CCPs	Critical Limits	Verification Procedures
	Zero visible fecal, milk, or ingesta contamination.	

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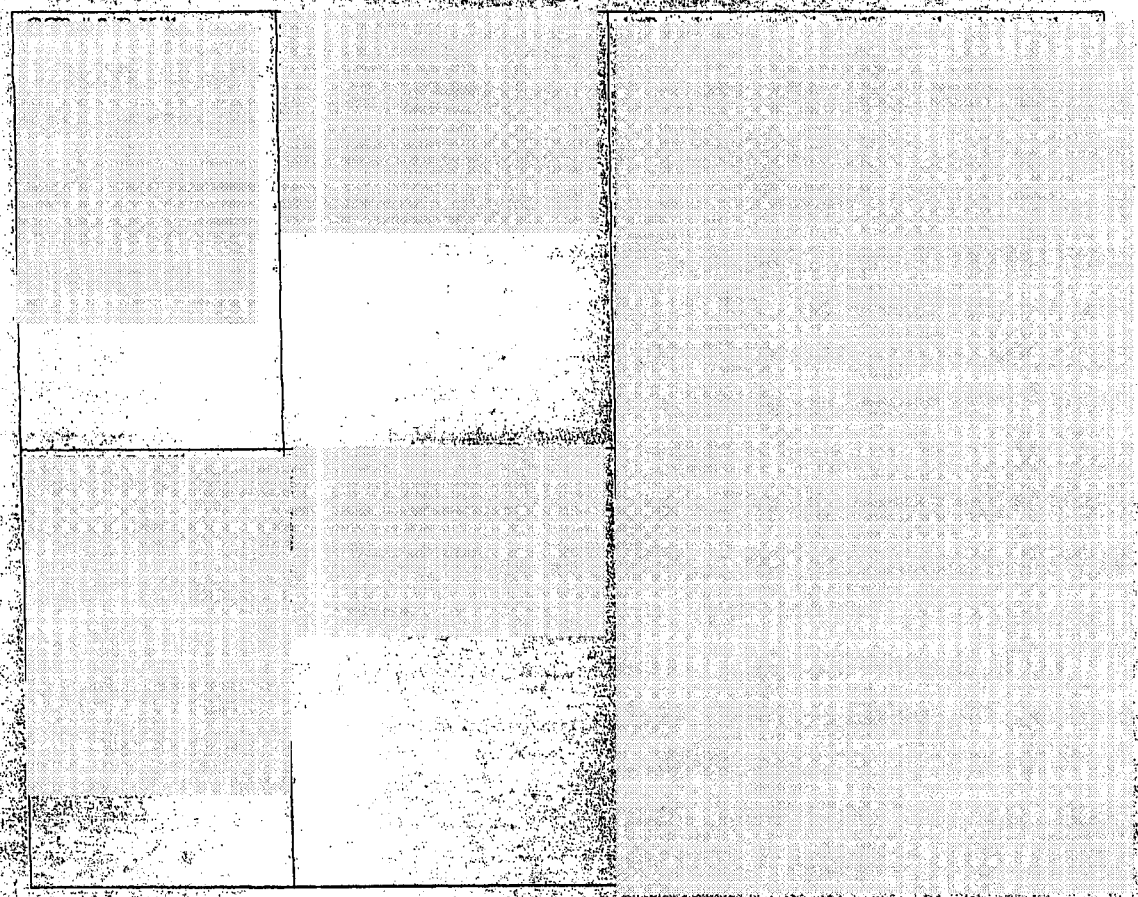

CCP 1B, 3B, and 4B

Monitoring:

and

Corrective Actions: Corrective actions mirror the requirements of §417.3.

CCP 2B

Monitoring:

Corrective Actions: Corrective actions mirror the requirements of §417.3.

HAZARD ANALYSIS, FLOW DIAGRAM and HACCP

H1. Are all hazards reasonably likely to occur identified as appropriate (including allergens, *E. coli* O157:H7, LM, SRM, metal, *Salmonella*, etc.)? Yes. The hazards identified as reasonably likely to occur in the hazard analysis include: *E. coli* O157:H7, *Salmonella*, and visible feces/milk/ingesta.

H2. Are all decisions made in the Hazard Analysis supported with documentation on file? No. Supporting documentation noncompliances related to two prerequisite programs are discussed under question H4.c below.

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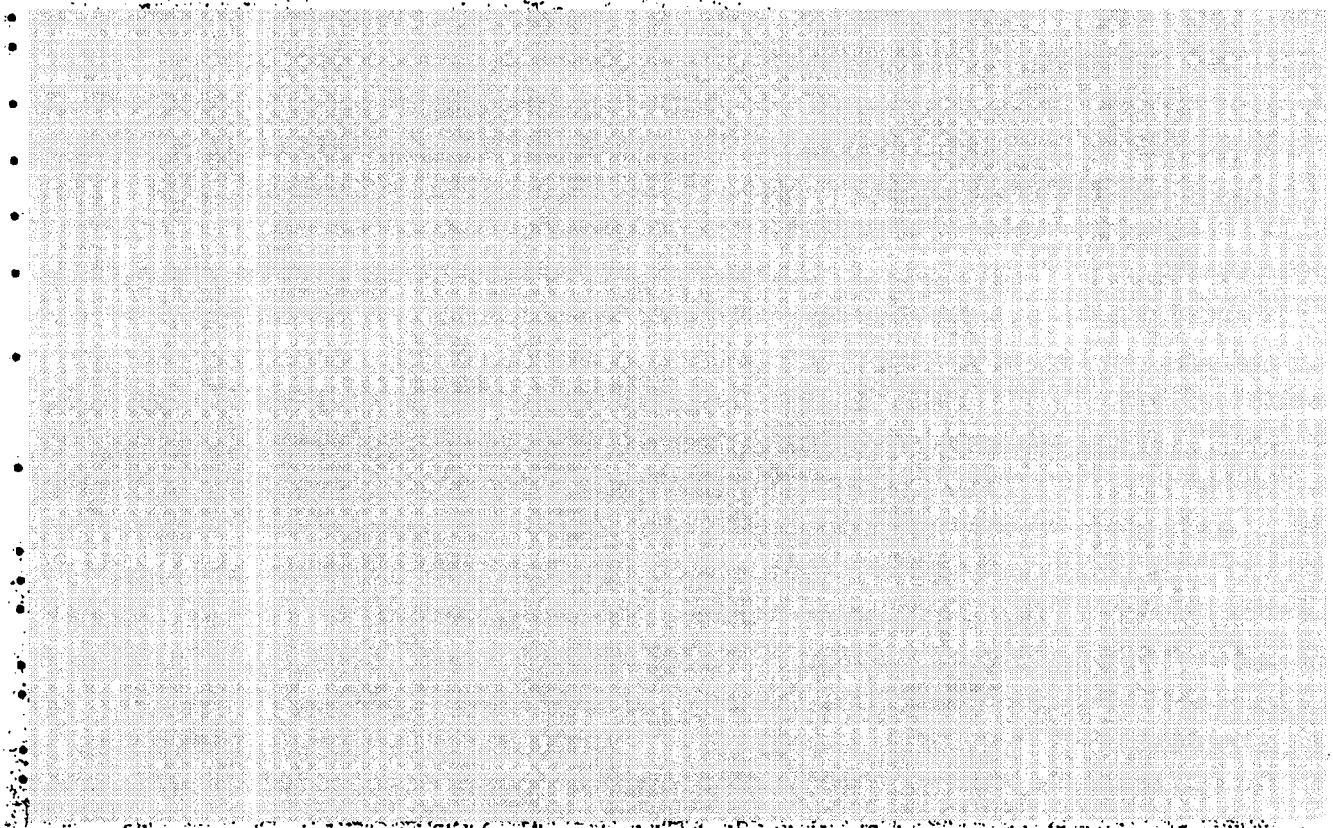
H3. Briefly explain how the answers in H1 and H2 were determined including the names of documents used. The current supporting documentation on file includes:



Upon review of the current documentation on file it was determined that the hazards identified as reasonably likely to occur are being controlled with CCPs that are sufficiently supported and validated. All other decisions made in the hazard analysis are adequately supported with the exception of the noncompliances discussed below in the prerequisite program section (H4c).

H4. Does the plant use a prerequisite program(s)? Yes

H4a. If yes to H4, list the names of all the prerequisite programs used as part of 03 and briefly describe the hazards each prerequisite program is preventing, monitoring procedures, and records generated.

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H4b. Are there any prerequisite programs lacking adequate supporting documentation that the hazard is not likely to occur? Yes

H4c. Free Text Box: Briefly describe the reasoning why these prerequisite program(s) lack adequate support and how this may effect the production of safe product.

The SOP states However, the supporting documentation states that The establishment is not monitoring the time component stated in the supporting documentation. From a review of the records from September 24, 2007, through November 23, 2007, it was noted that the temperature of the water in the cabinet is actually maintained at or higher. The establishment has documentation to support this temperature achieves a log reduction with no time parameters. This is a noncompliance with 417.5(a)(1) and was documented on NR #121-2007-8903.

The SOP for the states that

Upon review of records from September 24, 2007, through December 3, 2007, there were 29 instances of the temperature dropping below F with no documentation of the corrective actions taken as prescribed by the SOP. The establishment is not implementing the prerequisite plan as written. This is a noncompliance with 417.5(a)(1) and was documented on NR #121-2007-8903. The establishment has validated their slaughter process to control identified hazards without this step and the temperature deficiencies documented did not drop below F. Therefore, no food safety hazard was created based upon analysis of the data presented.

H4d. If yes to H4, has the plant ever had a deviation in the prerequisite program? No

H4e. If yes to H4d, did the plant reassess? N/A

H4e. Is the establishment monitoring and keeping adequate records for each of the prerequisite programs? Yes, with one exception. There was one monitoring check for spinal cord in the spinal canal described in the Specified Risk Material Prerequisite Program that was performed but not actually recorded on the appropriate record on 10/19/2007. This is a noncompliance with 417.5(a)(1) and was documented on NR #121-2007-8903.

H4f. Describe any additional findings regarding prerequisite programs and briefly describe your analysis of how the prerequisite programs impact the food safety system.

With the exception of the noncompliances discussed above, the prerequisite programs are supported by documentation on file. Records reviewed from September 24, 2007, through November 23, 2007, as well as observations made during plant tours indicate that the procedures are being implemented as written.

H5. Are all steps in the process(s) included in the flow diagram? Yes

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s.(b)(7)(C)

H6. Free Text Box: Briefly discuss any regulatory noncompliance associated with a hazard analysis or flow diagram. N/A

H7. Does the HACCP plan(s) adequately address each of the hazards that appear reasonably likely to occur based on the hazard analysis(s)? Yes

H7a. Free Text Box: Briefly discuss any hazards that are not adequately addressed and the thought process behind the conclusion. N/A

H8. Based on the questions in FSIS Directive 5100.1, does the design of the HACCP plan meet all requirements of 9 CFR 417 (monitoring, verification, record keeping, corrective action, and reassessment)? Yes

H8a. Free Text Box: Describe the analysis conclusions that led to your answer in H7. Describe all non-compliance findings. The establishment maintains a record keeping system that effectively documents the implementation of the HACCP plan and includes all pertinent supporting documentation. Documentation on file supports the monitoring procedures identified in the HACCP plan as well as the frequencies of those procedures. Corrective actions mirror the requirements of §417.3. Verification procedures include calibration of process monitoring instruments, direct observations of monitoring activities, review of records, and microbial sampling. Reassessment requirements are met and documented on a reassessment log. The design of the HACCP plan meets requirements of §417.

H9. Based on the questions in Directive 5100.1, does the execution of the HACCP plan meet all requirements of 9 CFR 417 (monitoring, verification, record keeping, corrective action, and reassessment)? Yes

H9a. Free Text Box: Describe the analysis conclusions that led to your answer in H7. Describe all non-compliance finding. With exception of the noncompliances discussed above, review of the pertinent records from September 24, 2007, through November 23, 2007, as well as observations made during plant tours including observations of establishment monitoring of all CCPs indicate the HACCP plan is being implemented as written.

G2. What PR/HACCP *Salmonella* category is the establishment currently in? N/A
- Category 1
- Category 2
- Category 3

G2a. Free Text Box: If answer Cat. 2 or 3, what if anything has the plant done or proposed to do in order to move to Category 1? N/A

G3. Does the establishment conduct its own testing for *Salmonella* spp.? No

G3a. Does the plant have documented sampling and testing procedures for *Salmonella* spp.? N/A

G3b. Free Text Box: Briefly describe any sampling and testing procedure for *Salmonella* spp. used by the establishment. N/A

G4. Does the establishment test product, equipment, or processing area for microbial indicator organisms (e.g. generic *E. coli*, coliforms, APC, Enterobacteriaceae)? If yes, check all that apply
- No
- X Carcass before intervention
- X Carcass after intervention
- Slaughter Equipment
- Slaughter area
- Others, please specify (free text box)
- Information not available

G4a. Analysis, does the establishment use testing data for decision making and how does the establishment use the data? Yes. The establishment uses the data as an indicator of process control and for ongoing validation/verification of their interventions. Under their validation actions, Nebraska Beef has an outside processing authority, evaluate samples taken in mapping studies from April through October. Sampling occurs on the foreshank, hindshank, round, and midline prior to interventions, after interventions, and in the cooler. samples are taken each (i.e. from the foreshank, from the hindshank, etc.). All samples were negative for *E. coli* O157 and *E. coli* O157:H7 (out of samples taken).

G5. Does the establishment have written generic *E. coli* procedures? Yes

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G5a. Which of the following sampling methods does the establishment use? Check all that apply.

Cattle, Excision, m/M
Cattle, Sponging, Statistical process control
Swine, Excision, m/M
Swine, Sponging, Statistical process control
Hide On Cattle, Excision, m/M
Other Hide on Carcasses, Sponging, Statistical process control
Chickens, Whole bird rinse, m/M
Other Poultry, Whole bird rinse, Statistical process control
Turkeys & Geese, Sponging, Statistical process control
Ratites, Sponging, Statistical Process Control
Equines, Sponging, Statistical Process Control
Sheep & Goats, Sponging, Statistical Process Control
Other, Please specify non-compliance (free text box)

G6. What sampling frequency is the plant using?

X Regulatory frequency
Alternative sampling frequency

G6a. Does the establishment have adequate justification for an alternative sampling frequency per the regulation? N/A

G7. Does the establishment have support for the sampling procedure and testing method? Yes

G8. Describe the generic *E. coli* sampling and testing procedures. As per 9 CFR 310.25 (2)(ii)(A) Samples are collected by

G9. Is the establishment implementing generic *E. coli* procedures as written? Yes. The sample collection procedures for generic *E. coli* were observed during the assessment and were being executed as per the written program.

G10. Over the past 60 days, has the establishment routinely met their limits as determined by either m/M or statistical process control? Yes

G10a. If No, are there any correlations with fecal failure NRs, deviations from the zero tolerance critical limit, or positive FSIS sampling results for the same time period? N/A

G10b. Free Text Box: Briefly describe any correlations, corrective actions taken by the establishment, and possible regulatory non-compliance N/A

G11. Does the plant actively use generic *E. coli* test results for decision making purposes? Yes.

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G12. Free Text Box. Briefly describe any non-compliances found while reviewing the establishment's generic *E. coli* testing program. N/A

BEEF (Only answer if chosen Beef)

B1. Is *E. coli* O157:H7 addressed in the establishment's food safety system? Yes

B2. What program is used to control *E. coli* O157:H7 on incoming beef products? Check all that apply.

HACCP
SSOP
Pre-requisite
Don't Know

Does the establishment apply any of the following decontamination procedures prior to hide removal?

X No
Pre-slaughter animal wash
Pre-slaughter head wash
Post-slaughter dehairing
Pre-dehiding carcass wash
Others, please specify (free text box)
Don't Know

Does the establishment have documentation of employee training in any of the following areas? If yes, check all that apply.

No
X Proper hide removal
X Proper evisceration procedures
X Adequate sanitation of knives and sharpening steels
X Importance of minimizing cross contamination
Don't Know

INTERVENTIONS and VALIDATION

IV1. Does the establishment apply any intervention on carcasses? check all that apply

No Intervention
Chlorine
Hot Water Wash
Organic Acid
Lactoferrin
Steam vacuum
Steam pasteurization
Peroxyacid (Inspexx)
Acidified sodium chlorite
Acidified calcium sulfate
Irradiation
Verify fecal contamination equipment
Carcass Chilling
Metal detection
Others, please specify Lactic Acid Spray
Don't Know

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The next 11 questions should be answered for each answer chosen in the above question other than No intervention or Don't know

IV1a. Is the intervention included in any of the following? Check all that apply.
HACCP Plan Is the intervention a CCP? Yes/No
Sanitation SOP
X Prerequisite Program
GMP
Other, specify (free text box)

IV1b. Is the intervention validated and documented? Yes

IV1c. Has the establishment identified the critical variables (e.g., time, temperature, pressure, concentration, pH, etc) used in the validation? Yes

IV1d. If the critical values have been identified for the intervention, are they being applied in the HACCP plan in a similar manner? No.

This was discussed above and documented on NR # #121-2007-8903.

IV1e. Is the establishment using the intervention as described in the validation with regards to equipment and procedures? Yes

IV1f. If the critical variables, procedure or equipment used by the establishment are not the same as or similar to those used in the validation, did the establishment conduct additional validation that demonstrated the changes are effective? Yes. The establishment has supporting documentation to demonstrate that

this was discussed above under prerequisite programs above.

IV1g. If the establishment did not conduct additional validation, did it provide any rationale to explain why the intervention is effective and has the same impact even though the critical variables, procedure or equipment are different? N/A

IV1h. Did the establishment initially test for the adequacy of the intervention to reduce pathogenic organisms and fecal contamination? Yes

IV1i. Does the establishment have a rational basis or data to show that the reduction of pathogenic microorganisms and/or fecal contamination by the intervention is sufficient to control the level of contamination of contamination that may occur on carcasses? Yes

Organic Acid

IV1a. Is the intervention included in any of the following? Check all that apply.
HACCP Plan Is the intervention a CCP? Yes/No
Sanitation SOP
X Prerequisite Program
GMP
Other, specify (free text box)

IV1b. Is the intervention validated and documented? Yes

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IV1c. Has the establishment identified the critical variables (e.g., time, temperature, pressure, concentration, pH, etc.) used in the validation? Yes

IV1d. If the critical values have been identified for the intervention, are they being applied in the HACCP plan in a similar manner? Yes

IV1e. Is the establishment using the intervention as described in the validation with regards to equipment and procedures? Yes

IV1f. If the critical variables, procedure or equipment used by the establishment are not the same as or similar to those used in the validation, did the establishment conduct additional validation that demonstrated the changes are effective? N/A

IV1g. If the establishment did not conduct additional validation, did it provide any rationale to explain why the intervention is effective and has the same impact even though the critical variables, procedure or equipment are different? N/A

IV1h. Did the establishment initially test for the adequacy of the intervention to reduce pathogenic organisms and fecal contamination? Yes

IV1i. Does the establishment have a rational basis or data to show that the reduction of pathogenic microorganisms and/or fecal contamination by the intervention is sufficient to control the level of contamination of contamination that may occur on carcasses? Yes

[redacted]

IV1a. Is the intervention included in any of the following? Check all that apply.

- HACCP Plan Is the intervention a CCP? Yes/No
- Sanitation SOP
- X Prerequisite Program
- GMP
- Other, specify (free text box)

IV1b. Is the intervention validated and documented? Yes

IV1c. Has the establishment identified the critical variables (e.g., time, temperature, pressure, concentration, pH, etc.) used in the validation? Yes

IV1d. If the critical values have been identified for the intervention, are they being applied in the HACCP plan in a similar manner? Yes

IV1e. Is the establishment using the intervention as described in the validation with regards to equipment and procedures? Yes

IV1f. If the critical variables, procedure or equipment used by the establishment are not the same as or similar to those used in the validation, did the establishment conduct additional validation that demonstrated the changes are effective? N/A

IV1g. If the establishment did not conduct additional validation, did it provide any rationale to explain why the intervention is effective and has the same impact even though the critical variables, procedure or equipment are different? N/A

IV1h. Did the establishment initially test for the adequacy of the intervention to reduce pathogenic organisms and fecal contamination? Yes

IV1i. Does the establishment have a rational basis or data to show that the reduction of pathogenic microorganisms and/or fecal contamination by the intervention is sufficient to control the level of contamination of contamination that may occur on carcasses? Yes

[redacted]

IV1a. Is the intervention included in any of the following? Check all that apply.

HACCP Plan Is the intervention a CCP? Yes
Sanitation SOP
Prerequisite Program
GMP
Other, specify (free text box)

IV1b. Is the intervention validated and documented? Yes

IV1c. Has the establishment identified the critical variables (e.g., time, temperature, pressure, concentration, pH, etc.) used in the validation? Yes

IV1d. If the critical values have been identified for the intervention, are they being applied in the HACCP plan in a similar manner? Yes

IV1e. Is the establishment using the intervention as described in the validation with regards to equipment and procedures? Yes

IV1f. If the critical variables, procedure or equipment used by the establishment are not the same as or similar to those used in the validation, did the establishment conduct additional validation that demonstrated the changes are effective? N/A

IV1g. If the establishment did not conduct additional validation, did it provide any rationale to explain why the intervention is effective and has the same impact even though the critical variables, procedure or equipment are different? N/A

IV1h. Did the establishment initially test for the adequacy of the intervention to reduce pathogenic organisms and fecal contamination? Yes

IV1i. Does the establishment have a rational basis or data to show that the reduction of pathogenic microorganisms and/or fecal contamination by the intervention is sufficient to control the level of contamination of contamination that may occur on carcasses? Yes

IV2. Free Text Box: Further describe interventions the establishment has in place addressing pathogenic organisms, milk, ingesta and fecal contamination that were touched on by the questions in this section. N/A

SAMPLING and TESTING (Beef Only)

ST1. Does the establishment sample carcasses for *E. coli* O157:H7? No

ST1a. Does the establishment have support documented and filed for the sampling procedure? N/A

ST1b. Free Text Box: Briefly describe the sampling method and support associated with the carcass sampling procedure. Are they being followed as written? N/A

ST1c. What microbiological method does the establishment use to test carcasses for *E. coli* O157:H7? (free text box) N/A

ST1d. Does the establishment have support documented and filed for the testing procedure? N/A

ST1e. Free Text Box: Briefly describe the microbiological method and support associated with the carcass testing procedure. N/A

ST1f. Based on the supporting documentation, is the sampling and testing procedure adequate to detect low levels of *E. coli* O157:H7 on carcasses? N/A

ST1g. Does the establishment hold the sampled lot of product pending test results? N/A

ST2. Has the establishment ever been identified in the STEPS database as a supplier of E. coli O157:H7 positive product? Yes. The establishment was identified in STEPS in the past eight months on five separate dates: 4/19/2007, 6/23/2007, 9/25/2007, 10/3/2007, 10/28/2007.

ST3. Does the plant have corrective action procedures in place when a carcass is positive for *E. coli* O157:H7? N/A

ST3a. Free text box: Describe the corrective action procedures. N/A

Specified Risk Material (SRM) 9 CFR 310.22 (Beef Only)

SRM1. Does the establishment have a written plan for the removal of identify SRM materials? Yes

SRM2. Does the establishment receive cattle 30 months of age or older? Yes

SRM3. Where is the SRM control system located? Check all that apply
- HACCP Plan
- Sanitation SOP
- Prerequisite Program
- GMP
- Other, specify (free text box)

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Ante-mortem:

SRM 4. Does the establishment handle all animals as if they were from cattle 30 months or older? No

SRM5. Has the establishment developed procedures to identify through appropriate documentation or dentition examination whether cattle to be slaughtered are 30 months of age or older? Yes

SRM5a. Are the records acceptable for determining age? Yes

SRM6. Does the establishment segregate animals determined to be 30 months of age and older from younger animals? No

SRM7. What controls has the establishment developed and implemented to identify *non-ambulatory* animals and handle them appropriately? All non-ambulatory cattle found at time of unloading will be sent back with the carrier. FSIS will be notified of any

SRM8. Is the establishment complying with the prohibition on injecting compressed air into the cranium of cattle during stunning (9 CFR 310.13 and 310.15)? Yes

Free Text Box. Describe the ante-mortem SRM control program. Describe any non-compliance. The establishment's written ante-mortem SRM control program primarily deals with procedures to identify non-ambulatory animals, which is described above under SRM7.

Post Mortem

SRM9. How are the carcasses over 30 months of age identified? Dentition

SRM10. Can carcasses over 30 months be identified in coolers, at shipping, and at boning? Yes for the coolers and boning. N/A for shipping. the establishment doesn't ship carcasses.

SRM Removal and Segregation from cattle 30 months and older:

SRM 11. Does the establishment

Remove the entire small intestines to ensure effective removal of the distal ileum? Yes
Remove the distal ileum and use the remainder of the small intestines for human food? Yes. The establishment has a written procedure for harvesting small intestines, however at the present time it is not implemented on a daily basis.

SRM13.a.If the establishment removes the distal ileum and uses the rest of the small intestine for human food, is the distal ileum removed in accordance with 9 CFR 310.22 (a) (3)? Yes

SRM12. What procedures are in place to remove vertebral column? As part of the SRM prerequisite program, the vertebral column, excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum, will be removed with normal boning procedures and transported to inedible rendering.

SRM13. Are tongues trimmed correctly and saved? Yes

SRM14. Is the establishment disposing of all carcasses, carcass parts, and other products contaminated with SRMs in accordance with 9CFR 314.1 and 3.14.3)? Yes

Cross Contamination:

SRM15. Is the establishment segregating product by whether the cattle was 30 months and older at the time of slaughter in accordance with 9 CFR 310.22? Yes

SRM15a. If yes, segregation occurs, is dedicated equipment used to cut through SRMs? Yes

SRM15b. If dedicated equipment is not used, does the establishment clean and sanitize equipment, including the splitting saw prior to use on cattle younger that 30 months? N/A

SRM16. What controls has the establishment implemented to ensure that SRMs do not contaminate edible product? The

SRM17. Is the establishment properly reconditioning the carcasses or head by knife trimming when on-line inspection personnel observe visible and identifiable SRMs on edible portions of the product? Yes

Control Plan:

SRM18. Does the establishment have written procedures for when either the establishment or FSIS determines that the

SRM19. Is the establishment maintaining daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of the SRMs, and any corrective actions taken? Yes

SRM20. Is the establishment retaining records for at least one year and making the records accessible to FSIS? Are these records maintained at the establishment for at least 48 hours following completion, and made available to FSIS within 24 hours of request? Yes

Shipping:

SRM21. When shipping carcasses or parts that contain SRM vertebral columns, does the establishment maintain control of the carcasses or parts while they are in transit (e.g., through company seals) or ensures that the carcasses or parts move under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1)) as provided in FSIS Notice 68-05? N/A

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SRM22. Are carcasses or parts containing SRMs identified by a method that will transfer with the carcass during shipping? N/A

SRM22a. Free text box: Describe shipping method. N/A

SRM23. Free Text Box: Describe any further SRM controls employed by the establishment and any non-compliance.

ANIMAL DRUG and BIOLOGICAL RESIDUES

AR1. Does the establishment have a residue control program? N/A

AR1a. If yes, describe the program. Free text. N/A

AR2. Has the establishment identified animal drug or biological residues as a hazard reasonably likely to occur? N/A

AR2a. If no, has the establishment performed a reassessment in accordance with 69 FR 76884, and 9 CFR 417.4? N/A

AR2b. What control(s), including documentation is available to support the premise that animal drugs or biological residues are not a hazard reasonably likely to occur?

AR2c. If yes, how is the hazard controlled in their HACCP System (HACCP plan, Sanitation SOP, or prerequisite program)? N/A

AR3. Are animal health records available that provide documentation on what animal drugs were administered, when and for what purpose? N/A

AR4. What type of animal identification system is the establishment using? The establishment initially identifies the animals in lots

- Is the system followed through slaughter and inspection in accordance with 9CFR 310.2? Yes
- Is the system designed in a way that would provide for trace back to the producer? Yes

AR5. Has the establishment ever received a "Notification" from USDA for violative levels of animal drug residues? No

- If yes
  - What steps has the establishment taken to prevent this from reoccurring?
  - Is there a system in place to notify the supplier in writing of the animal(s) that had violative residue findings?
  - Does the written notice to the supplier include discussions on the seriousness of selling and purchasing animals that contain both high and violative levels of animal drugs?
  - Has the establishment supplied FSIS the name and address of the supplier?

AR6. Is the establishment aware of the "Repeat Violators Alert List" (RVAL) posted on the USDA website at: www.fsis.usda.gov? Yes

AR7. Is the establishment involved with any voluntary residue avoidance program offered by a professional or state-certified organization? No

AR8. Does the establishment slaughter non-ruminating veal calves? No

AR9. Is there documentation that verifies the age of the veal calf at time of slaughter? N/A

AR10. Free text box: Analysis: Describe how the establishment's residue control program impacts the food safety system. N/A

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MISCELLANEOUS

M1. Does the establishment have documented monitoring that product is maintained at 45°F or below after 24 hours of chilling? Yes

M2. Has the plant had a third party audit of its food safety system? Yes.

M2a. If yes, did the establishment implement any of the recommendations? N/A, no recommendations were made

M2b. Free Text Box: Briefly discuss the 3rd party audit recommendations and indicate which were implemented by the plant.

method as performing the review, having a meeting with Nebraska Beef's food safety personnel where he gives a summary of his findings and recommendations, and the issuance of a summary letter at a later date. The plant does not maintain a record of what is discussed during the meeting with the processing specialist. Following this visit a letter is received by the

M3. Free text box: Analysis and Summary: Please discuss findings and any regulatory non-compliances associated with HACCP 03J plans at this establishment. Also include any additional findings which were not addressed by any of the proceeding questions.

implemented as written.

HACCP 03C Raw, Not Ground Meat

Which of the following products does the establishment produce under HACCP 03C?

Beef (gets general and beef questions only)

GENERAL

G1. Free Text Box in a table format: List all HACCP 03C plans, products produced using those plans, CCPs, critical limits, and verification procedures associated with those plans.

Products	CCP	Critical Limits	Verification Procedures

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GENERAL HAZARD ANALYSIS, FLOW DIAGRAM and HACCP

H1. Are all hazards reasonably likely to occur, identified as appropriate (Including allergens, *E. coli* O157:H7, LM, SRM, metal, *Salmonella*, etc.)? Yes

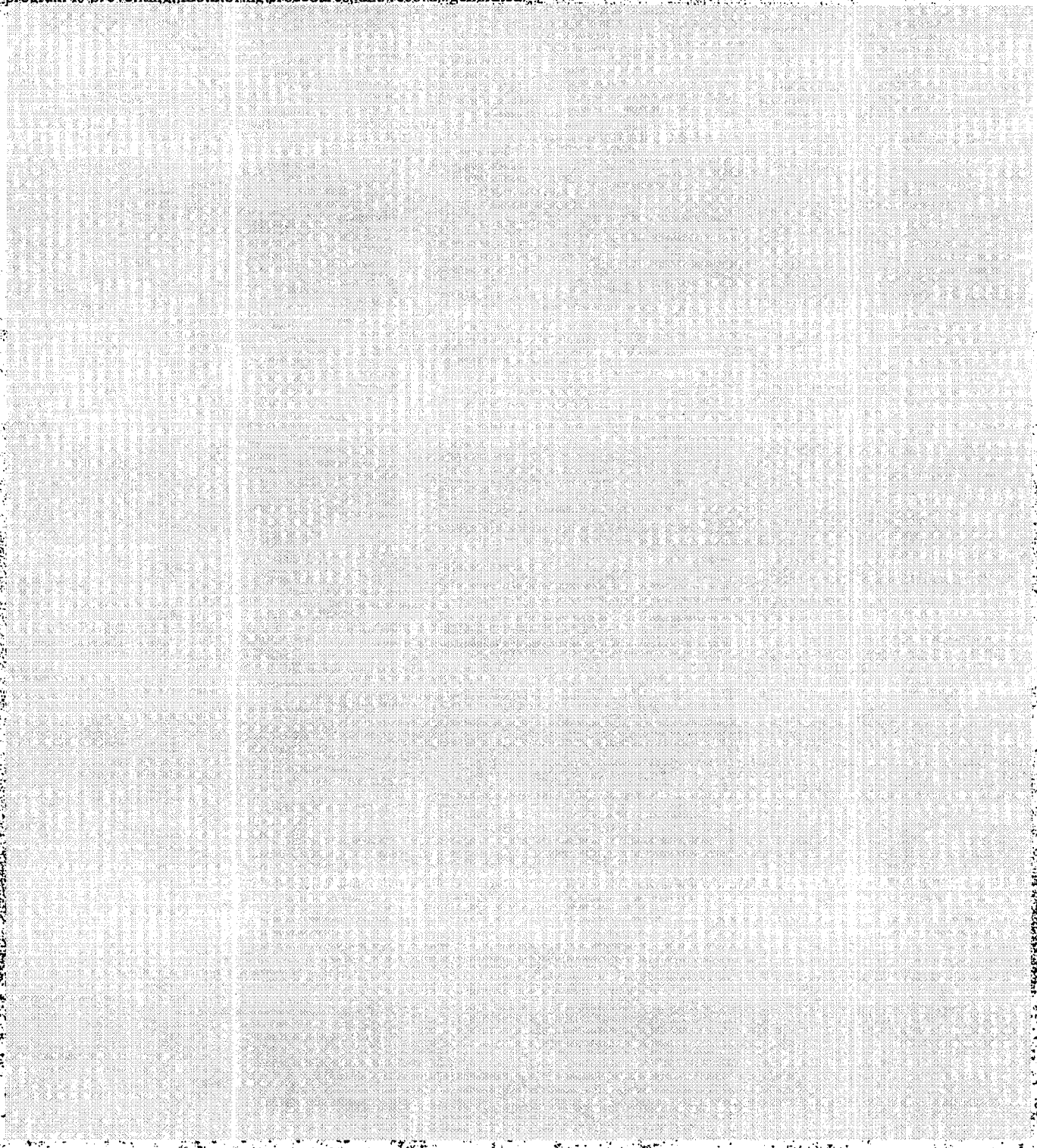
H2. Are all decisions made in the Hazard Analysis supported with documentation on file? Yes

H3. Briefly explain how the answers in H1 and H2 were determined including the names of documents used. Support for the decisions made was available based on various scientific data available in a folder for review. For the decision made at

Fo

H4. Does the plant use a prerequisite program(s)? Yes

H4a. If yes to H4, list the names of all the prerequisite programs used as part of 03J and briefly describe the hazards each prerequisite program is preventing, monitoring procedures, and records generated.



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H4b. Are there any prerequisite programs lacking adequate supporting documentation that the hazard is not likely to occur? No

H4c. Free Text Box: Briefly describe the reasoning why these prerequisite program(s) lack adequate support and how this may effect the production of safe product. NA

H4d. If yes to H4, has the plant ever had a deviation in the prerequisite program? NA

H4e. If yes to H4d, did the plant reassess? NA

H4e. Is the establishment monitoring and keeping adequate records for each of the prerequisite programs? Yes

H4f. Describe any additional findings regarding prerequisite programs and briefly describe your analysis of how the prerequisite programs impact the food safety system.
Review of the perquisite programs showed they support the decisions in the hazard analysis. All had associated records that confirmed the programs were implemented and consistent control of the parameters identified within the program was maintained.

H5. Are all steps in the process(s) included in the flow diagram? Yes

H6. Free Text Box: Briefly discuss any regulatory noncompliance associated with a hazard analysis or flow diagram. None found.

H7. Does the HACCP plan(s) adequately address each of the hazards that appear reasonably likely to occur based on the hazard analysis(s)? Yes. CCPs are in place for all hazards found reasonably likely to occur.

H7a. If yes: Text Box: Briefly discuss any hazards that are not adequately addressed and the thought process behind the conclusion. None found.

H8. Based on the questions in FSIS Directive 5100.1, does the design of the HACCP plan meet all requirements of 9 CFR 417.

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G2. What PR HACCP *Salmonella* category is the establishment currently in? NA, beef only.

G3. Does the establishment conduct its own product testing for *Salmonella* spp.? No

G3a. Does the establishment have supporting documentation filed for the sampling procedure? NA

G3b. Briefly describe the sampling method and supporting documentation associated with the sampling procedure. What area (in cm^2) or volume (if rinsate) is typically tested? Is the procedure being followed as written? (free text box) NA

G3c. Does the establishment have supporting documentation filed for the microbiological testing method? NA

G3d. Briefly describe the microbiological method and supporting documentation associated with the microbiological testing method. Is the method being followed as written? (free text box) NA

G3e. Does the establishment serotype in-house positive *Salmonella* samples? NA

G3f. Do any of the serotypes match the current CDC list of top 20 serotypes associated with common human illness? NA

G4. Does the establishment sample and test product, equipment, or processing areas for microbial indicator organisms (e.g. generic *E.coli*, coliforms, ARC, Enterobacteriaceae)? Check all that apply.

Finished product
Fabrication equipment (knives, steels, belts, etc.)
Processing area
Others, please specify (free text box)

Under their validation actions, Nebraska Beef has an outside processing authority, evaluate samples taken in mapping studies monthly from April through October. These include samples taken during the slaughter process and follows through to samples taken on foreshank, hindshank, inside round, and midline in the cooler and samples taken of the fabrication environment.

G4a. Does the establishment have supporting documentation filed for the sampling procedure, i.e. locations chosen for sampling, etc.? No
had provided plant personnel training and instruction for the sampling used but this was not available during the FSA review.

G4b. Briefly describe the sampling method and supporting documentation associated with the sampling procedure. What area (in cm^2) is typically tested? Is the procedure being followed as written? (free text box)
No written procedure was available.

G4c. Does the establishment have supporting documentation filed for the microbiological testing method? No

G4d. Briefly describe the microbiological method and supporting documentation associated with the microbiological testing method. Is it being followed as written? (free text box) Not available.

G5. Does the establishment use the microbiological data generated for decision making? Yes

G5a. Briefly describe (free text box)
Results of the testing is used by Nebraska Beef as validation of their HAGCP plan.

BEEF (Only answer if chosen Beef)

B1. Is *E. coli* O157:H7 addressed in the establishment's food safety system? Yes

B2. What program is used to control *E. coli* O157:H7 on incoming beef products? Check all that apply.
HACCP

B3. Does the establishment produce raw ground beef components? Check all that apply.
Trim and subprimals

B4. Does the establishment use tenderizing methods (e.g. blades, pins, injectors etc.) on fabricated products? No.

B5. Does the establishment produce "Specially handled beef manufacturing trimmings"? No

INTERVENTIONS and VALIDATION for *E. coli* O157:H7

IV1. Does the establishment have purchase specifications for product intended for grinding requiring that suppliers conduct any of the following? (Purchase specifications a set of requirements for incoming product established by buyer and agreed to be met by the supplier b[illegible] the product is purchased) If yes, check all that apply

Other, please specify (free text box)

OR

IV1a. How are purchase specifications verified? NA

Third Party audit
Test results from supplier
In-house testing
Other, please specify (free text box)
Don't Know

IV2. Does the establishment use one or more of the following cross-contamination controls? Check all that apply.

Sanitation of knives and steels. If yes, briefly describe how this is done (free text box). The sanitation of equipment and [illegible]ct surfaces is under a SSOP. This is monitored with associated records showing implementation.
Maintain separation of lots from different suppliers
None of the above
Other, please specify (free text box) There are SSOPs in place that cover cross contamination due to abscess or contamination. This is monitored twice daily with associated records showing implementation. Monitoring for physical contamination is done once an hour with associated records showing implementation.
Don't Know

IV3. Does the establishment have documented monitoring that the carcass surface temperature was maintained at or below 45°F within 24 hrs of slaughter?

Yes

IV4. If the establishment applies any intervention on the fabricated product, check all that apply

The next 10 questions should be answered for each answer chosen in the above question, other than "No intervention" or "Don't know"

IV2a. Is the intervention included in any of the following? Check all that apply.

HACCP plan, used only on beef trimmings destined for raw ground use

IV2b. Is the intervention adequately validated and documented? Yes, Nebraska Beef uses:

IV2c. Has the establishment identified the critical variables (e.g., time, temperature, pressure, concentration, pH, etc.) used in the validation? Yes, the concentration, temperature, and application documented under the study are in use in the plant environment.

IV2d. If the critical values have been identified for the intervention, are they being applied in the HACCP plan in a similar manner? Yes.

IV2e. Is the product or product formulation referred to in the documented validation the same as or similar to the product or product formulation for which the establishment is using the intervention? Yes, beef trim

IV2f. Is the establishment using the intervention as described in the validation with regards to equipment and procedures? Yes, spray application is used with a mixing of the trim pieces to expose the surfaces to the treatment.

IV2g. If the critical variables, product formulation, procedure or equipment used by the establishment are *not* the same as or similar to those used in the validation, did the establishment conduct additional validation that demonstrated the changes are effective? NA

IV2h. If the establishment did not conduct additional validation, did it provide any rationale to explain why the intervention is effective and has the same impact even though the critical variables, product formulation, procedure or equipment are different? NA

IV2i. Did the establishment test for the adequacy of the intervention to reduce *E. coli* O157:H7? Yes, the plant maintains ongoing test results which validate the intervention used.

IV2j. Does the establishment have a rational basis or data to show that the reduction of *E. coli* O157:H7 by the intervention is sufficient to control the level of contamination of *E. coli* O157:H7 that may be present on incoming products? Yes, provided as support and validation for the decisions made in the slaughter plan and the fabrication plan.

IV4. What is the *Salmonella* category of the establishment supplying the carcasses? NA

SAMPLING and TESTING

ST1. Does the establishment sample incoming carcasses for *E. coli* O157:H7? No, although testing is done on carcasses under a validation mapping study.

ST1a. Does the establishment have supporting documentation filed for the sampling procedure? NA

ST1b. Briefly describe the sampling method and supporting documentation associated with the carcass sampling procedure. What area (units cm²) is typically tested? Is the procedure being followed as written? (free text box) NA

ST1c. Does the establishment have supporting documentation filed for the microbiological testing method? NA

ST1d. Briefly describe the microbiological method and supporting documentation associated with the microbiological testing method. Is the method being followed as written? (free text box) NA

ST1e. Using the FSIS method for comparison, is the sampling and testing procedure used by the establishment adequate to detect low levels of *E. coli* O157:H7 contamination present on the carcass, i.e. is this procedure as sensitive as the FSIS method? NA

ST1f. Describe how you came to your conclusion in ST1e. NA

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ST2. Has the establishment ever had a carcass sample test positive for *E. coli* O157:H7? No, for the year 2007, testing under the validation studies provide data that shows all negative test results.

ST3. Does the establishment have corrective action procedures in place when a carcass is positive for *E. coli* O157:H7? NA

ST3a. Describe the corrective action procedures. (free text box) NA

ST4. Does the establishment sample fabricated product (can include both raw ground beef components and non-raw ground beef components) for *E. coli* O157:H7? Check all that apply.

Yes – if destined for raw ground beef production.
Yes – testing is required by one of their customers.
No – if beef trimmings are not intended for grinding. Beef trimmings are labeled "Not tested for E coli O157:H7, Not intended for raw ground beef", and shipped to official establishments for further lethality.

ST4a. Is sampling for *E. coli* O157:H7 included in any of the following. Check all that apply. Prerequisite Program, *E coli* O157:H7 Testing Procedure dated 07/23/2006.

ST4b. If fabricated product testing for *E. coli* O157:H7 included in the HACCP plan, is it a CCP? NA, not tested under the HACCP plan.

ST4c. Does the establishment have supporting documentation filed for the sampling procedure? Yes.

ST4d. Briefly describe the sampling method and supporting documentation. Is the procedure being followed as written? (free text box) A

ST4e. Does the establishment have supporting documentation filed for the microbiological testing procedure? Yes, supplied from

ST4f. Briefly describe the microbiological method and supporting documentation filed associated with the testing procedure. Is the method being followed as written? (free text box) The testing

ST4g. Using the FSIS method for comparison, is the sampling and testing procedure used by the establishment adequate to detect low levels of *E. coli* O157:H7 contamination in every lot, i.e. is this procedure as sensitive as the FSIS method? Yes

ST4h. Describe how you came to your conclusion in ST4g. Following discussion with [redacted] changes made to their testing protocol the pl[redacted]

ST5. Does the establishment hold the sampled lot of fabricated product pending test results? Yes

ST6. Has the establishment ever had a sample test positive for *E. coli* O157:H7 from its own testing of fabricated product? Yes

ST7. Has the establishment ever had a sample test positive for *E. coli* O157:H7 from FSIS testing of fabricated product? Yes

ST8. Does the establishment have corrective action procedures in place when a fabricated product is positive for *E. coli* O157:H7? Yes

ST8a. Briefly describe the corrective action procedures, adequacy, and history of implementation (free text bo[redacted]

ST9. Has the establishment ever been implicated by FSIS as supplier to a lot of raw ground beef that tested positive for *E. coli* O157 and/or was associated with a recall? Yes, in 2007, Nebraska Beef had five notifications of being a supplier in product that was tested as a FSIS ground beef sample with the result of positive. The specific dates and product involved follows:

- 04/19/2007, ILN X070419, shortloin, boneless strip, and sirloin top butt- not sole supplier
- 06/23/2007, ILN MF70037, beef chuck (clods)- sole supplier
- 09/25/2007, ILN X070925, chuck clod in box and chuck clod in bin- not sole supplier
- 10/13/2007, ILN MF42649, chuckroll, teres major, flats, peeled knux, and outside skirt- not sole supplier
- 10/28/2007, ILN MF55512, beef rounds (peeled knux)- sole supplier

ST9a. Briefly describe the outcome of these findings. Was any regulatory action taken at this establishment? (free text box) The outcome of the 03C02 procedures performed in response to the STEPS data was all acceptable with no non-compliance found and no regulatory action taken. Nebraska Beef, when notified reviewed all production records although they did not have written documentation of the review. [redacted] tated he had reviewed all CCPs and shared a document showing informal monitoring done by the QA. This document records the carcass number and defect information related to the carcass. The record is used to help the plant maintain a history of the day's events related to production. For each incident, Nebraska Beef's review resulted in nothing of significance found. [redacted] tated all products in the STEPS reports were not produced and sold as intended for grinding so had not been processed through the lactic acid step of CCP 3-B Fab. Since no issues were noted in their investigations, Nebraska Beef did not make any modifications to their HACCP plans. He indicated they are currently investigating the use of a [redacted] rovide an additional hurdle but currently have not implemented this intervention step.

MISCELLANEOUS

M1. He[redacted]es the establishment define a lot?
Based on 5 combo bins.

M2. How many outside suppliers of carcasses has the establishment used in the last 30 days? Check all that apply.
Only from its own slaughter plant.

M3. How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas?
[redacted] equipment and processing areas are cleaned. Sanitation of equipment, such as employee's hook and knife [redacted] is completed after each combo is sampled.

M4. Has the establishment had a third party audit of its food safety system? Yes, there is a yearly audit done by John H. Miller, a processing authority. The written programs are reviewed as well as the plant's monitoring of their programs and record keeping aspects. He also reviews the plant's operational performance.

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M4a. If yes, were any of the recommendations implemented? The plant has no documentation to show wha

M4b. Briefly discuss the third-party audit recommendations and indicate which were implemented by the establishment. (free text box) NA, as stated under M4a.

M5. Discuss findings and any regulatory non-compliances associated with HACCP, SSOP, plans, at this establishment. (free text box) No non-compliances were found. The changes made following the NOIE issued on 08/03/2006 are all effectively implemented. Under 03C this includes the determination that *E. coli* O157:H7 is reasonably likely to occur for beef trim intended for grinding. The CCP [redacted] s in use and records document all parameters under the critical limit are met. With the scientific supporting document and the entire year's test results as negative the Nebraska Beef shows their HACCP plan is effective.

NR Analysis

From 04/01/2007 through 11/15/2007 there were 79 NRs issued. Except for two preoperational non-compliances the NRs are not linked. The plant does not provide written answers to NRs so the description written by the IIC/CSI includes the verbal response, actions taken by the plant under corrective actions, and preventive actions.

- 01B02 - 17 NRs - Nine NRs are for preoperational findings on the fabrication floor, seven for preoperational findings on the slaughter floor, and one for preoperational findings in the cooler.
- 01C01 - 4 NRs - These four NRs document a failure of the plant to document sanitation incidents observed by FSIS personnel. Three of the findings had been documented on NRs but the plant failed to include the information required in their records.
- 01C02 - 32 NRs - The majority of the NRs document failures of the plant's operation sanitation system. The NRs document a variety of findings, including the majority cross contamination issues, build up on the viscera table, fecal findings on the carcass prior to final rail inspection, damaged product in boxed storage, condensation dripping in the cooler, and meat reconditioning non-compliances.
- 03J01 - 16 NRs - Ten of the NRs were for fecal findings, two involved non-compliances associated with the BSE/SRM program, one was for a failure to switch knives during the process, one was documenting ingesta on head meat, one for corn in the bung, and one for a failure to update the HACCP plan when a product (edible kidneys) was added.
- 06D01 - 8 NRs - These NRs were for a variety of issues including condensation, flaking paint, gas from a floor drain, lack of sanitary conditions in dry storage, and lack of sanitary conditions in a trailer prior to use. All documented non-product contact issues.

The IIC and CSIs have provided information that shows the plant is being well monitored for compliance. They document issues as found. The information included in the documentation demonstrates the ability of Nebraska Beef to provide adequate corrective and preventive measures.

Analysis and Recommendation

The establishment has developed and implemented a comprehensive food safety system through their SSOP, Generic *E. coli*, HACCP, and prerequisite programs. Three non-compliances were identified during the assessment and were addressed with a non-compliance record.

[redacted]

In response to the most recent FSA on 08/03/2006 which resulted in a NOIE the plant implemented several significant changes. These changes included several major facility changes, primarily designed to address cross contamination concerns, including a new

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hide puller and banners built to separate the processing areas as they proceed through the slaughter process. The plant's generic *E coli* data shows the effectiveness of those changes.

Based on the information contained in this report we recommend that no further action is necessary at this time.

Exit Meeting:

On 12/14/2007, at approximately 1130 an exit meeting was held in the conference room at Nebraska Beef Inc. Those present at the meeting representing Nebraska Beef were, [redacted] ood Safety Director, [redacted] HACCP Administrator, and [redacted] Senior Vice President. Those present representing USDA were, [redacted] JIC [redacted] CSI, [redacted] AO/PHV, [redacted] BIAO/I [redacted] nd FLS, [redacted]. [redacted] there was a follow up discussion to clarify the plant's actions taken in response to being named as a supplier in FSIS *E. coli* O157:H7 tests. The outcome of the HSA was given along with a description of the non-compliances found. The plant was given an opportunity to ask questions, since they had none they were thanked for their cooperation and the meeting ended.

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FSIS FORM 5000-8 (10/13/2003) REPLACES FSIS FORM 5000-8 (08/27/2002) WHICH IS OBSOLETE.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
OFFICE OF FIELD OPERATIONS

COMPREHENSIVE ASSESSMENT OF THE EXECUTION AND DESIGN OF AN ESTABLISHMENT'S FOOD SAFETY SYSTEMS

ESTABLISHMENT NO.	DATES CSO VISITED EST.
19336 M	FROM 04/30/2008 TO 05/19/2008

NAME AND ADDRESS OF ESTABLISHMENT
Nebraska Beef
4501 South 36th Street
Omaha, NE 68107 (Large HACCP plant)

DISTRIBUTION INSTRUCTIONS
Submit this report to your District Manager and the Front-Line Field Supervisor via email.

DISTRICT	CIRCUIT VISITED
Des Moines (25)	Omaha (21)

REASON FOR VISIT (Check all that apply)

- [X] A. District Office Direction
- [ ] B. Consumer Complaints
- [ ] C. Foodborne Illness
- [ ] D. Foreign Part de Contamin.
- [ ] E. Repetitive Im Findings
- [ ] F. STEPS Triggered Sample Form #: _____
- [ ] G. Salmonella Performance Standard Failure
  - [ ] A set
  - [ ] B set
  - [ ] C set
- [X] H. Other (Specify)
  Elevated number of sanitation related Non-Compliance Reports

SUMMARY OF DATA ASSESSMENT PRIOR TO VISIT

Performance Based Inspection System (PBIS): From 01/01/2008 through 04/27/2008 there were 55 non-compliance reports (NRs) issued.

- 01B02 - 6 NRs
- 01C02 - 29 NRs
- 03J01 - 7 NRs
- 03J02 - 2 NRs
- 06D01 - 9 NRs
- 04A03 - 2 NRs

Analysis of the NRs is included in a later section of the Food Safety Assessment (FSA).

Consumer Complaint Monitoring System (CCMS): No complaints found.

RECOMMENDATIONS (Check only one)

- [X] A. No further action
- [ ] B. 30-day letter
- [ ] C. NOIE
- [ ] D. NOIE & 30-day letter
- [ ] E. Suspension/Withdrawal
- [ ] F. Summary of reason(s) for recommendation

Based on a review of the establishment's records documenting the implementation of their programs and procedures including SSOP records, HACCP records and pre-requisite program records, as well as a review of their scientific supporting documentation, microbiological sampling data, and observations made during plant tours, it was determined that at the present time, Nebraska Beef is operating within the regulatory requirements of §§416 and 417 and any food safety concerns are being documented and appropriately handled by the in-plant FSIS inspection team.

FINDINGS:

Summary of data assessment prior to visit continued:

Laboratory Electronic Application Results Notification (LEARN) - Tests results include:

- HC01 - PR/HACCP *Salmonella* Verification Testing: 47 samples were taken between 1/29/2008 and 4/21/2008 with all results on LEARN showing acceptable results.
- results posted on 2/2/2008 and 3/6/2008 reported diagnoses of skeletal muscle and associated tissues; sample result posted on 2/23/2008 reported diagnosis of spinal cord tissue;
- [illegible] 2/2008, 3/20/2008, 3/20/2008, and

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spinal cord tissue/dorsal root ganglia-sensory ganglia resulted in the withholding of the use of labels bearing the marks of inspection for [redacted] roduct on 3/26/2008. The withholding action was released on 4/23/2008.

- MT50 *E.coli* O157:H7 routine testing of Domestic Trim Sampling: sample results posted on 4/4/2008 and 3/7/2008 were both listed as negative.

Prior Assessments and Actions

- FSA from 7/10/2005 to 8/03/2006 resulting in a Notice of Intended Enforcement (NOIE) issued on 8/03/2006 based on the establishment's failure to implement and maintain SSOPs which contributed to an inadequate HACCP system which allowed adulterated beef product to be produced. A Deferral was issued on 8/04/2006 and closed with a Letter of Warning on 4/05/07.

- FSA from 1/26/2007 to 12/14/2007 resulting in a recommendation of no further action. Three non-compliances associated with prerequisite programs utilized to support decisions made in the hazard analysis were identified and addressed with a non-compliance record.

Predication

On 04/30/2008 [redacted] Enforcement Investigations & Analysis Officer (EIAO)/Public Health Veterinarian (PHV) [redacted] EIAO/PHV, and [redacted] EIAO, for the Des Moines District of the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS), visited Establishment 19336, Nebraska Beef, Inc., 4501 South 36th Street, Omaha, Nebraska 68107. The visit was initiated to conduct a comprehensive assessment of the design and implementation of the food safety systems in place at the facility.

Scope

Responsibilities included working with assigned FSIS personnel in the examination of Nebraska Beefs' Pathogen Reduction/Hazard Analysis and Critical Control Points (HACCP) programs, including the evaluation of Critical Control Points (CCPs) and supportable data for Est. 19336 decision making process. Additionally, the Sanitation Standard Operating Procedure (SSOP) and *E.coli* control programs were examined to determine if they were properly designed and implemented.

Profile

Establishment 19336 is a large (in HACCP terms) beef slaughtering and processing facility. The Grant of Inspection is dated 2/20/2003. The plant is approximate [redacted] square feet in size and has approximate [redacted] employees. The plant produces approximate [redacted] pounds of carcasses per week and [redacted] pounds of primals and trim per week.

The FSIS Frontline Supervisor (FLS) is [redacted] Assigned inspection staff consists of [redacted] line inspectors [redacted] ff line [redacted] CSI's, and one SPHV. Contact information for the establishment is: [redacted] ood Safety Director, Telephone: (402) 733-0415, Fax: (402) 733-1302, E-mail: [redacted] @nbeef.com.

Entrance Meeting

An entrance meeting was conducted in a conference room at Nebraska Beef Inc in Omaha, NE, at approximately 1000 on 4/30/2008. The review process used for this assessment was discussed along with the possible outcomes of the assessment according to the Rules of Practice (9 CFR 500). Those present at the meeting representing Nebraska Beef were: [redacted] ,ood Safety Director, [redacted] HACCP Administrator, and [redacted] enior Vice President. Those present representing USDA were: [redacted] ((SPHV/EIAO, ITC) [redacted] EIAO/PHV), [redacted] IAO), and [redacted] EIAO/PHV). The plant representatives were given the chance to ask questions. None were asked at that time.

GENERAL SANITATION SPS and SSOP

GS1. Is the building maintained in a sound condition as described in 9 CFR 416 (e.g., no leaks, wall integrity good, no standing water)? Yes

GS1a. Describe your observations. Walls, floors, and ceilings are of sound construction and are built of durable materials impervious to moisture. All areas showed adequate maintenance and are kept in good repair. Concrete floors showed considerable wear but were deemed acceptable considering the age of the facility. No evidence of water leaks or areas of standing water were observed during plant tours.

GS2. When was the main structure of the premises built?

Before 1960
1960-1970
1970-1980: Built in 1975
1980-1990
1990-2000: Major remodeling in 1995
2000-Present

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GS3. Is the equipment free of cracks, pitting, rust or other defects that could affect cleaning and sanitizing procedures? Yes
Equipment is of such material and construction to facilitate thorough cleaning and is maintained in sanitary conditions.

GS4. Are there any findings during the course of the FSA that raise a concern as to whether the sanitation system is adequate to meet the sanitation performance standard requirements (e.g. ventilation, condensation, structural integrity)? No

GS4a. Free Text Box. Briefly describe your observations and any non-compliances with the SPS regulations. (Sanitation performance

GS5. Are the SSOPs designed to include all procedures necessary to prevent direct contamination or adulteration of product? Yes

GS5a. Analysis: Describe how you came to the conclusion to GS5.
The SSOPs describes the program procedures Nebraska Beef conducts daily, before, and during operations to prevent direct contamination of product. Preoperational SSOPs include general equipment and facility cleaning with the cleaning procedures designated, a sanitation step included, designated proper use of chemicals, and the use of [redacted] sting once a week to evaluate the effectiveness of the cleaning procedures.

Operational SSOPs include procedures describing product handling practices, hand washing, proper clothing/attire as well as cleaning of gloves, knives, other hand tools, and other product contact surfaces as necessary to maintain sanitary conditions throughout production. Procedures listed in the operational SSOPs include the following:

1.
2.
3.
4.
5.
6.
7.
8.
9.
10.
11.
12.
13.

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[redacted]

GS6. Does the plant have an extended cleanup (less than daily) written in the SSOP? No

GS6a. If yes, does the design of the procedure support extended cleanup? N/A

GS7. Are the pre-operational sanitation procedures identified as such? Yes

GS8. Do the SSOPs at a minimum address the cleaning of food contact surfaces of facilities, equipment and utensils? Yes

GS9. Are all sanitation procedures conducted incorporated into the SSOP? No. Sanitation procedures not addressed through the establishment SSOPs are covered through establishment GMPs/SPSs.

GS10. Does the plant monitor the implementation of SSOP procedures no less than daily? Yes

GS10a. Analysis. Explain your answer. Preoperational monitoring is daily prior to operations. Operational SSOPs are monitored four times daily.

GS11. Has the establishment maintained daily SSOP records as required? Yes

GS12. Has the establishment taken corrective actions in response to non-compliances/deviations as required by 9 CFR 416.15 (a)? Yes

GS12a. If yes, were all three parts of 9 CFR 416.15 (b) met? Yes

GS12b. Briefly describe the corrective actions taken and discuss any non-compliances. Preoperational and operational SSOP records from 1/2/2008 through 4/26/2008 were reviewed. The corrective actions for identified deficiencies during pre-operational inspection included restoring sanitary conditions through re-cleaning, sanitizing, re-inspection and release. Preventative measures typically focused on retraining of employees. Review of the company operational monitoring records revealed the establishment is meeting all parts of corrective actions. Preventative measures included employee training, instruction, counseling, discipline, and work orders submitted for repair. Monitoring frequencies are being completed as listed in plan. No regulatory non-compliances were identified.

GS13. Does the establishment conduct microbiological testing as part of the SSOP? Yes

GS13a. If yes, what organism(s)? check all that apply

- [redacted] Generic E. coli
- [redacted] Coliform
- [redacted] Enterobacteriaceae
- [redacted] APC
- [redacted] ATP luminescence
- Other, please specify. (free text box)
- Don't Know

GS13b. Is the procedure designed to find the organisms of concern? No

GS13c. Does the plant use the data in decision making? Yes. The plant utilizes the sampling data for verification of their preoperative cleaning procedures. Records from 1/02/2008 to 4/26/2008 show all negative test results.

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GS14. Are employee hygiene procedures available in a written document? Yes

GS15. Are employees trained in hygiene procedures? Yes, employees are initially trained at hiring, annually, and as necessary.

GS15a. Describe the training procedures and discuss whether they are adequate to prevent direct product contamination. Are they [illegible] multiple languages? Training procedures include

GS16. Are outer garments removed when leaving work area? Yes

GS17. Are gloves used properly? Yes

GS17a. Describe how you came to the conclusion in GS17. Employee product handling practices were observed during operational tours. Employees were observed wearing and changing gloves as per written procedures.

GS18. Do the employees use a 20 second hand wash (or comparable method of sanitizing) before starting and returning to work? Yes. A 20 second hand washing procedure is not required, however all employees must wash and sanitize hands/gloves upon returning to production area/work station. Hand washing policies and procedures are included the plant SSOPs and GMPs.

GS19. Are food and operator hand tools (knives, food contact utensils) stored in a sanitary manner? Employees are required to clean hand tools and store them in their lockers when they enter the [illegible] in the morning prior to entering the production floor. Tools (i.e. knives and

GS20. Does the establishment rotate sanitizers? Yes

GS20a. Describe the rotation procedure? The establishment r

GS21. Describe any findings during review of the SSOP records? Review of the pre-operational and operational sanitation records from 1/2/2008 through 4/26/2008 show the frequency of SSOP monitoring is being conducted as per the written plan. Records show that when deficiencies are identified, they are documented with the immediate action (correctives) taken, disposition of involved product, and measures to prevent recurrence. Preventative measures included employee training, instruction, counseling, discipline, and work orders submitted for repair. If employees are retrained the training documentation is attached. If the incident involves work by maintenance a work order is attached that has date of completion.

GS22. Free Text Box. Briefly describe any SSOP program design concerns and non-compliances found. Also describe any findings not addressed in any of the previous questions. The SSOPs describe all the procedures the establishment will conduct daily, before and during operations, that are sufficient to prevent direct contamination or adulteration of product. Monitoring activities, and the frequency of those monitoring activities are also identified as are the records that will be maintained. Corrective actions listed in the operational SSOPs mirror 417.3. No regulatory non-compliances were identified.

HACCP 030 Slaughter Meat

Which of the following products does the plant produce under HACCP 03J?

Pork (answer general interventions and validation, animal drug and biological residues, and miscellaneous questions only)

Beef (answer all questions)

GENERAL

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G1. Free Text Box in a table format. List all HACCP 03J plans, products produced using those plans, CCPs, critical limits, and verification procedures associated with those plans.

Beef Slaughter HACCP Plan

Products produced in the Beef Slaughter HACCP plan include [redacted] products. The following CCP's control hazards identified as likely to occur in the Beef Slaught[redacted]

CCP #1B [redacted]

CCP #[redacted]

CCP #3B [redacted]

CCP #4 [redacted]

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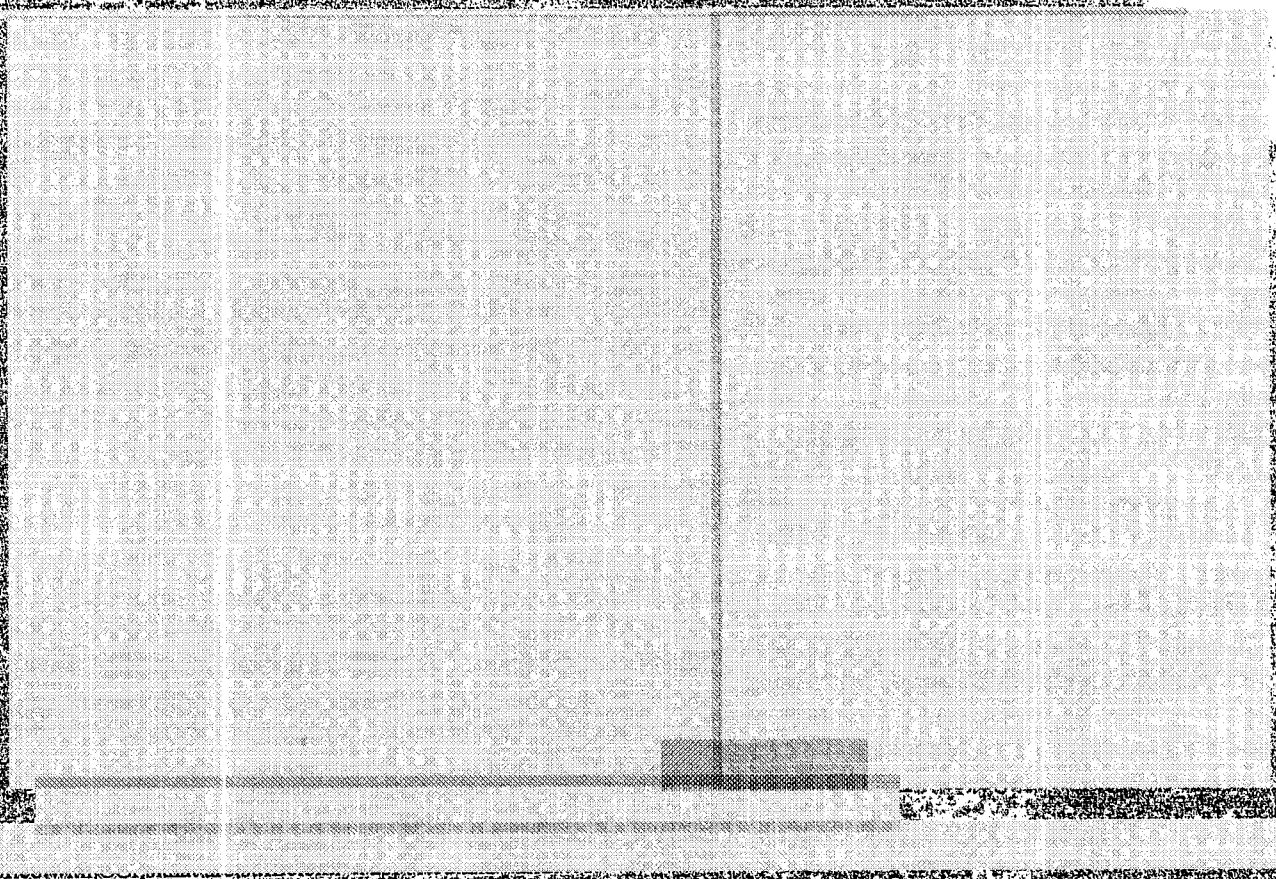
HAZARD ANALYSIS, FLOW DIAGRAM and HACCP

H1. Are all hazards reasonably likely to occur identified as appropriate (including allergens, *E. coli* O157:H7, LM, SRM, metal, *Salmonella* etc.)? Yes. The hazards identified as reasonably likely to occur in the hazard analysis include *E. coli* O157:H7, *Salmonella* and visible feces, milk, ingesta.

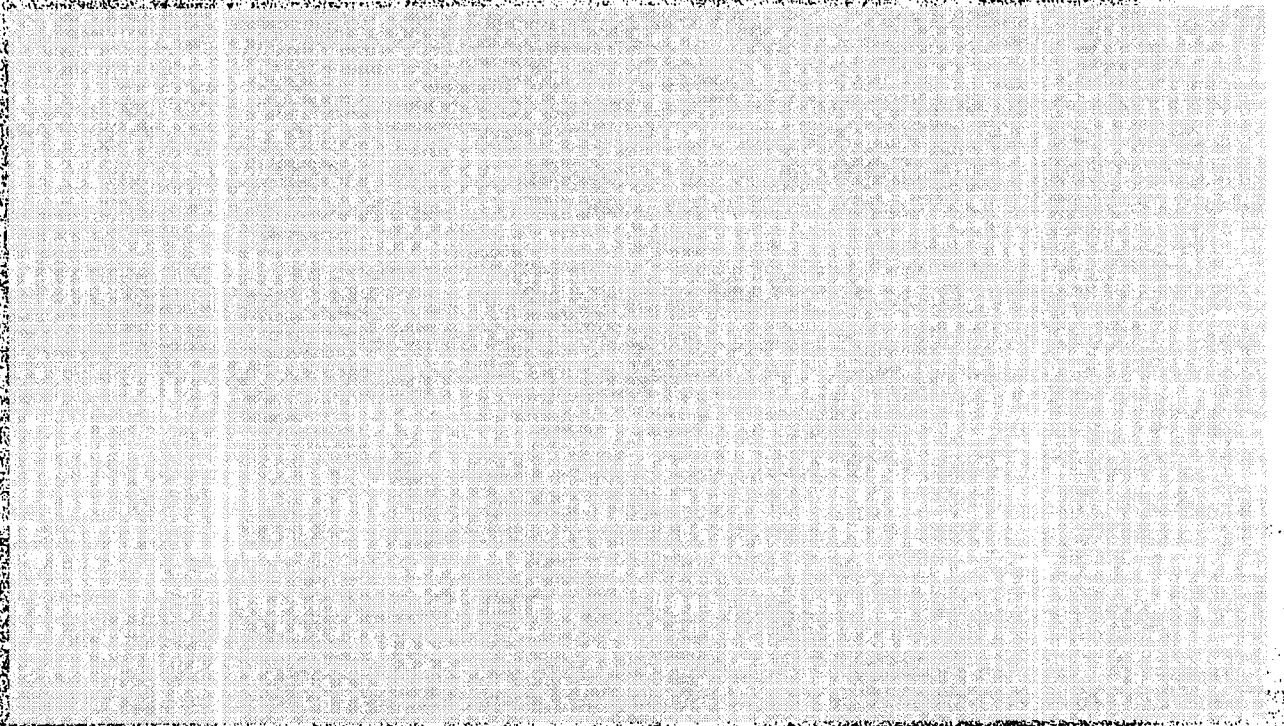
H2. Are all decisions made in the Hazard Analysis supported with documentation on file? Yes

H3. Briefly explain how the answers in H1 and H2 were determined including the names of documents used. The current supporting documentation on file includes:



H4. Does the plant use a prerequisite program(s)? Yes

H4a. If yes to H4, list the names of all the prerequisite programs used as part of 9 CFR 430 and briefly describe the hazards each prerequisite program is preventing, monitoring procedures, and records generated.



H4b. Are there any prerequisite programs lacking adequate supporting documentation that the hazard is not likely to occur? No

H4c. Free Text Box: Briefly describe the reasoning why these prerequisite program(s) lack adequate support and how this may effect the production of safe product. N/A

H4d. If yes to H4, has the plant ever had a deviation in the prerequisite program? No

H4e. If yes to H4d, did the plant reassess? N/A

H4e. Is the establishment monitoring and keeping adequate records for each of the prerequisite programs? Yes

H4f. Describe any additional findings regarding prerequisite programs and briefly describe your analysis of how the prerequisite programs impact the food safety system. The pre-requisite programs in place fully support that the potential hazards identified are not reasonably likely to occur and have sufficient documentation on file to support decisions made.

H5. Are all steps in the process(s) included in the flow diagram? Yes

H6. Free Text Box: Briefly discuss any regulatory noncompliance associated with a hazard analysis or flow diagram. N/A

H7. Does the HACCP plan(s) adequately address each of the hazards that appear reasonably likely to occur based on the hazard analysis(s)? Yes

H7a. Free Text Box: Briefly discuss any hazards that are not adequately addressed and the thought process behind the conclusion. N/A

H8. Based on the questions in FSIS Directive 5100.1, does the design of the HACCP plan meet all requirements of 9 CFR 417 (monitoring, verification, record keeping, corrective action, and reassessment)? Yes

H8a. Free Text Box: Describe the analysis conclusions that led to your answer in H7. Describe all non-compliance findings. The establishment maintains a record keeping system that effectively documents the implementation of the HACCP plan and includes all pertinent supporting documentation. Documentation on file supports the monitoring procedures identified in the HACCP plan for [redacted] sampling. Reassessment requirements are met and documented on the reassessment log. The design of the HACCP plan meets requirements of §417.

H9. Based on the questions in Directive 5100.1 does the execution of the HACCP plan meet all requirements of 9 CFR 417 (monitoring, verification, record keeping, corrective action and reassessment)? Yes

H9a. Free Text Box: Describe the analysis conclusions that led to your answer in H7. Describe all non-compliance finding. Review of the pertinent record from 1/02/08 through 4/26/08, as well as observations made during plant tours including observations of establishment monitoring of all CCPs indicate the HACCP plan is being implemented as written.

G2. What PR/HACCP *Salmonella* category is the establishment currently in? N/A

- Category 1
- Category 2
- Category 3

G2a. Free Text Box: If answer Cat. 2 or 3, what if anything has the plant done or proposed to do in order to move to Category 1? N/A

G3. Does the establishment conduct its own testing for *Salmonella* spp.? No

G3a. Does the plant have documented sampling and testing procedures for *Salmonella* spp.? N/A

G3b. Free Text Box: Briefly describe any sampling and testing procedure for *Salmonella* spp. used by the establishment. N/A

G4. Does the establishment test product, equipment, or processing area for microbial indicator organisms (e.g. generic *E. coli*, coliforms, APC, Enterobacteriaceae)? If yes, check all that apply.

- No
- Carcass before intervention
- Carcass after intervention
- Slaughter Equipment
- Slaughter area
- (Others, please specify (free text box))
- Information not available

G4a. Analysis: does the establishment use testing data for decision making and how does the establishment use the data? N/A

G5. Does the establishment have written generic *E. coli* procedures? Yes

G5a. Which of the following sampling methods does the establishment use? Check all that apply.

- Cattle, Excision, m/M
- Cattle, Sponging, Statistical process control
- Swine, Excision, m/M
- Swine, Sponging, Statistical process control
- Hide-On Cattle, Excision, m/M
- Other Hide-on Cattasses, Sponging, Statistical process control
- Chickens, Whole bird rinse, m/M
- Other Poultry, Whole bird rinse, Statistical process control
- Turkeys & Geese, Sponging, Statistical process control
- Ratites, Sponging, Statistical Process Control
- Equines, Sponging, Statistical Process Control
- Sheep & Goats, Sponging, Statistical Process Control
- Other, Please specify non-compliance (free text box)

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G6. What sampling frequency is the plant using?
Regulatory frequency
Alternative sampling frequency

G6a. Does the establishment have adequate justification for an alternative sampling frequency per the regulation? N/A

G7. Does the establishment have support for the sampling procedure and testing method? Yes

G9. Is the establishment implementing generic *E. coli* procedures as written? Yes. The sample collection and testing procedures for generic *E. coli* were observed during the assessment and were being executed as per the written program.

G10. Over the past 60 days, has the establishment routinely met their limits as determined by either m/M or statistical process control? Yes

G10a. If No, are there any correlations with fecal failure NRs, deviations from the zero tolerance critical limit, or positive FSIS sampling results for the same time period? N/A

G10b. Free Text Box. Briefly describe any correlations, corrective actions taken by the establishment, and possible regulatory non-compliance. N/A

G11. Does the plant actively use generic *E. coli* test results for decision making purposes? Yes. If one sample exceeds the upper

G12. Free Text Box. Briefly describe any non-compliances found while reviewing the establishment's generic *E. coli* testing program. N/A

BEEF (Only answer if chosen Beef)

B1. Is *E. coli* O157:H7 addressed in the establishment's food safety system? Yes

B2. What program is used to control *E. coli* O157:H7 on incoming beef products? Check all that apply.
HACCP
SSOP
Pre-requisite
Don't Know

IV.1f. If the critical variables, procedure or equipment used by the establishment are not the same as or similar to those used in the validation, did the establishment conduct additional validation that demonstrated the changes are effective? N/A

IV.1g. If the establishment did not conduct additional validation, did it provide any rationale to explain why the intervention is effective and has the same impact even though the critical variables, procedure or equipment are different? N/A

IV.1h. Did the establishment initially test for the adequacy of the intervention to reduce pathogenic organisms and fecal contamination? Yes

IV.1i. Does the establishment have a rational basis or data to show that the reduction of pathogenic microorganisms and/or fecal contamination by the intervention is sufficient to control the level of contamination of contamination that may occur on carcasses? Yes

IV.2. Free Text Box: Further describe interventions the establishment has in place addressing pathogenic organisms, milk, ingesta and fecal contamination that were touched on by the questions in this section. N/A

SAMPLING and TESTING (Beef Only)

ST.1. Does the establishment sample carcasses for *E. coli* O157:H7? No

ST.1.a. Does the establishment have support documented and filed for the sampling procedure? N/A

ST.1.b. Free Text Box: Briefly describe the sampling method and support associated with the carcass sampling procedure. Are they being followed as written? N/A

ST.1.c. What microbiological method does the establishment use to test carcasses for *E. coli* O157:H7? (free text box) N/A

ST.1.d. Does the establishment have support documented and filed for the testing procedure? N/A

ST.1.e. Free text Box: Briefly describe the microbiological method and support associated with the carcass testing procedure. N/A

ST.1.f. Based on the supporting documentation, is the sampling and testing procedure adequate to detect low levels of *E. coli* O157:H7 on carcasses? N/A

ST.1.g. Does the establishment hold the sampled lot of product pending test results? N/A

ST.2. Has the establishment ever been identified in the STEPS database as a supplier of E. coli O157:H7 positive product? Yes. The establishment was identified in STEPs in the past year on five separate dates 4/19/2007, 6/23/2007, 9/25/2007, 10/13/2007, 10/28/2007. The outcome of the 03C02 procedures performed in response to the STEPS data was all acceptable with no non-compliance found and no regulatory action taken. Nebraska Beef when notified also reviewed all production records although they did not have written documentation of the review.

ST.3. Does the plant have corrective action procedures in place when a carcass is positive for *E. coli* O157:H7? N/A

ST.3.a. Free text box: Describe the corrective action procedures. N/A

Specified Risk Material (SRM) 9 CFR 310.22 (Beef Only)

SRM.1. Does the establishment have a written plan for the removal of identify SRM materials? Yes

SRM.2. Does the establishment receive cattle 30 months of age or older? Yes

SRM.3. Where is the SRM control system located? (Check all that apply
- [redacted] HACCP Plan

- Sanitation SOP
- X Prerequisite Program
- GMP
- Other, specify (free text box)

Ante-mortem:

SRM 4: Does the establishment handle all animals as if they were from cattle 30 months or older? No

SRM5: Has the establishment developed procedures to identify through appropriate documentation or dentition examination whether cattle to be slaughtered are 30 months of age or older? Yes

SRM5a. Are the records acceptable for determining age? Yes

SRM6: Does the establishment segregate animals determined to be 30 months of age and older from younger animals? No

SRM7: What controls has the establishment developed and implemented to identify *non-ambulatory* animals and handle them appropriately? [redacted]

Free Text Box: Describe the ante-mortem SRM control program. Describe any non-compliance. The establishment's written ante-mortem SRM control program primarily deals with procedures to identify non-ambulatory animals, which is described above under SRM7.

Post Mortem:

SRM9: How are the carcasses over 30 months of age identified? Dentition

SRM10: Can carcasses over 30 months be identified in coolers, at shipping, and at boning? Yes for the coolers and boning. N/A for shipping, the establishment doesn't ship carcasses.

SRM Removal and Segregation from cattle 30 months and older:

SRM 11: Does the establishment:

i) Remove the entire small intestines to ensure effective removal of the distal ileum? Yes

Remove the distal ileum and use the remainder of the small intestines for human food? Yes. The establishment has a written procedure for harvesting small intestines, however at the present time it is not being implemented.

SRM 11a: If the establishment removes the distal ileum and uses the rest of the small intestine for human food, is the distal ileum removed in accordance with 9 CFR 310.22(a)(3). Yes

SRM 12: What procedures are in place to remove vertebral column? [redacted]

SRM 13: Are tongues trimmed correctly and saved? Yes

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SRM 14. Is the establishment disposing of all carcasses, carcass parts, and other products contaminated with SRMs in accordance with 9CFR 314.1 and 314.3)? Yes

Cross Contamination:

SRM 15. Is the establishment segregating product by whether the cattle was 30 months and older at the time of slaughter in accordance with 9 CFR 310.22? Yes

SRM15a. If yes, segregation occurs, is dedicated equipment used to cut through SRMs? Yes

SRM15b. If dedicated equipment is not used, does the establishment clean and sanitize equipment, including the splitting saw prior to use on cattle younger than 30 months? N/A

SRM16. What controls has the establishment implemented to ensure that SRMs do not contaminate edible product? The establishment

SRM 17. Is the establishment properly reconditioning the carcasses or head by knife trimming when on-line inspection personnel observe visible and identifiable SRMs on edible portions of the product? Yes

Control Plan:

SRM18. Does the establishment have written procedures for when either the establishment or FSIS determines that the establishments procedures for the removal, segregation, and disposition of SRMs, or the implementation or maintenance of such procedures, have failed to ensure that such materials are adequately and effectively removed from the carcass of cattle, segregated from edible materials, and properly disposed of? Yes

SRM19. Is the establishment maintaining daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of the SRMs, and any corrective actions taken? Yes

SRM20. Is the establishment retaining records for at least one year and making the records accessible to FSIS? Are these records maintained at the establishment for at least 48 hours following completion, and made available to FSIS within 24 hours of request? Yes

Shipping:

SRM21. When shipping carcasses or parts that contain SRM vertebral columns, does the establishment maintain control of the carcasses or parts while they are in transit (e.g., through company seals) or ensures that the carcasses or parts move under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1) as provided in FSIS Notice 68-05? N/A. The establishment does not ship carcasses or parts that contain SRM vertebral columns

SRM22. Are carcasses or parts containing SRMs identified by a method that will transfer with the carcass during shipping? N/A

SRM22a. Free text box. Describe shipping method. N/A

SRM23. Free Text Box. Describe any further SRM controls employed by the establishment and any non-compliance. Carcasses identified as 30 months or older are isolated in the hot box/coolers on separate rails.

ANIMAL DRUG and BIOLOGICAL RESIDUES

AR1. Does the establishment have a residue control program? No

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AR1a. If yes, describe the program. Free text. N/A

AR2. Has the establishment identified animal drug or biological residues as a hazard reasonably likely to occur? No

AR2a. If no, has the establishment performed a reassessment in accordance with 69 FR 76884, and 9 CFR 417.4? N/A

AR2b. What control(s) including documentation is available to support the premise that animal drugs or biological residues are not a hazard reasonably likely to occur? Plant history indicates that this hazard is not reasonably likely to occur. The establishment also

AR2c. If yes, how is the hazard controlled in their HACCP System (HACCP plan, Sanitation SOP, or prerequisite program)? N/A

AR3. Are animal health records available that provide documentation on what animal drugs were administered, when and for what purpose? N/A

AR4. What type of animal identification system is the establishment using? The establishment initially identifies the animals in lots as they come into receiving. Each carcass is then given an individual number that allows the establishment to identify it and associated parts throughout the process.

- Is the system followed through slaughter and inspection in accordance with 9CFR 310.2? Yes
- Is the system designed in a way that would provide for trace back to the producer? Yes

AR5. Has the establishment ever received a "Notification" from USDA for violative levels of animal drug residues? No

- If yes
  - What steps has the establishment taken to prevent this from reoccurring?
  - Is there a system in place to notify the supplier in writing of the animal(s) that had violative residue findings?
  - Does the written notice to the supplier include discussions on the seriousness of selling and purchasing animals that contain both high and violative levels of animal drugs?
  - Has the establishment supplied FSIS the name and address of the supplier?

AR6. Is the establishment aware of the "Repeat Violators Alert List" (RVAL) posted on the USDA website at: www.fsis.usda.gov? Yes

AR7. Is the establishment involved with any voluntary residue avoidance program offered by a professional or state-certified organization? No

AR8. Does the establishment slaughter non-ruminating veal calves? No

AR9. Is there documentation that verifies the age of the veal calf at time of slaughter? N/A

AR10. Free text box: Analysis. Describe how the establishment's residue control program impacts the food safety system. N/A

MISCELLANEOUS

M1. Does the establishment have documented monitoring that product is maintained at 45°F or below after 24 hours of chilling? Yes

M2. Has the plant had a third party audit of its food safety system? Yes. A third party audit was conducted and 4/2008.

M2a. If yes, did the establishment implement any of the recommendations? Yes

M2b. Free Text Box: Briefly discuss the 3rd party audit recommendations and indicate which were implemented by the plant. The audit summary stated that

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The auditors recommended

The next audit will be conducted in the second quarter of 2008.

M3, Free text box 'Analysis and Summary' Please discuss findings and any regulatory non-compliances associated with HACCP 03C plans at this establishment. Also include any additional findings which were not addressed by any of the proceeding questions.

HACCP 03C Raw Not Ground Meat

Which of the following products does the establishment produce under HACCP 03C?

Pork (gets general questions only)

Beef (gets general and beef questions only)

GENERAL

Q1, Free Text Box) In a table format, List all HACCP 03C plans, products produced using those plans, CCPs, critical limits, and verification procedures associated with those plans.

Products produced under this plan include Beef primals, sub-primals and trim.

CCP 1

CCP 2

CCP 3-1

GENERAL HAZARD ANALYSIS FLOW DIAGRAM and HACCP

H1. Are all hazards reasonably likely to occur identified as appropriate (Including allergens, *E. coli* O157:H7, TM, SRM, metal, *Salmonella*, etc.)? Yes/No

H2. Are all decisions made in the Hazard Analysis supported with documentation on file? Yes/No

H3. Briefly explain how the answers in H1 and H2 were determined including the names of documents used:

Support for the decisions made was available based on various scientific data available in a folder for review.

For the decision made at CCP

For the

For the decision made at CCP

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- Nebraska Beef *E.coli* O157:H7 Combo Testing Results, Records from 01/02/2008 through 05/02/2008 show all combo results are negative for *E.coli* O157:H7.

H4. Does the plant use a prerequisite program(s)? Yes/No

H4a. If yes to H4, list the names of all the prerequisite programs used as part of 03J and briefly describe the hazards each prerequisite program is preventing, monitoring procedures, and records generated.

Prerequisite Program name	Hazards prevented	Monitoring & Records

H4b. Are there any prerequisite programs lacking adequate supporting documentation that the hazard is not likely to occur? Yes/No

H4c. Free Text Box. Briefly describe the reasoning why these prerequisite program(s) lack adequate support and how this may effect the production of safe product. NA

H4d. If yes to H4, has the plant ever had a deviation in the prerequisite program? Yes/No

H4e. If yes to H4d, did the plant reassess? Yes/No/NA

H4e. Is the establishment monitoring and keeping adequate records for each of the prerequisite programs? Yes/No

H4f. Describe any additional findings regarding prerequisite programs and briefly describe your analysis of how the prerequisite programs impact the food safety system.
Review of the perquisite programs showed that they support the decisions in the hazard analysis. All associated records confirmed the programs were implemented and consistent, controls of the parameters identified within the program were maintained.

H5. Are all steps in the process(s) included in the flow diagram? Yes/No

H6. Free Text Box. Briefly discuss any regulatory noncompliance associated with a hazard analysis or flow diagram. NA

H7. Does the HACCP plan(s) adequately address each of the hazards that appear reasonably likely to occur based on the hazard analysis(s)? Yes/No

H7a. Free Text Box. Briefly discuss any hazards that are not adequately addressed and the thought process behind the conclusion. NA

H8. Based on the questions in FSIS Directive 5100.1, does the design of the HACCP plan meet all requirements of 9 CFR 417 (monitoring, verification, record keeping, corrective action, and reassessment)? Yes/No

H8a. Free Text Box. Describe the analysis conclusions that led to your answer in H8. Describe all non-compliance findings.
Review of records and the written plan did not reveal any non-compliances.

H9. Based on the questions in Directive 5100.1, does the execution of the HACCP plan meet all requirements of 9 CFR 417 (monitoring, verification, record keeping, corrective action, and reassessment)? Yes/No

H9a. Free Text Box. Describe the analysis conclusions that led to your answer in H9. Describe all non-compliance finding.
Review of records and the written plan did not reveal any non-compliances.

G2. What PR HACCP *Salmonella* category is the establishment currently in?
- Category 1
- Category 2
- Category 3

G2a. If in Category 2, were either of the sets at < 50% of the performance standard or guideline?
- No
- Most recent set
- Previous set

G2b. If answer Cat. 2 or 3, what, if anything, has the establishment done or proposed to do in order to move to Category 1? (free text box)

G3. Does the establishment conduct its own product testing for *Salmonella* spp.? Yes/No

G3a. Does the establishment have supporting documentation filed for the sampling procedure? Yes/No/NA

G3b. Briefly describe the sampling method and supporting documentation associated with the sampling procedure. What area (in cm^2) or volume (if ansate) is typically tested? Is the procedure being followed as written? (free text box) NA

G3c. Does the establishment have supporting documentation filed for the microbiological testing method? Yes/No/NA

G3d. Briefly describe the microbiological method and supporting documentation associated with the microbiological testing method. Is the method being followed as written? (free text box) NA

G3e. Does the establishment serotype in-house positive *Salmonella* samples? NA

G3f. Do any of the serotypes match the current CDC list of top 20 serotypes associated with common human illness? NA

G4. Does the establishment sample and test product, equipment or processing areas for microbial indicator organisms (e.g. generic *E. coli*, coliforms, APC, Enterobacteriaceae)? Check all that apply
- Finished product
- Fabrication equipment (knives, steels, belts, etc.)
- Processing area
- Others, please specify (free text box)
- No
- Don't Know

G4a. Does the establishment have supporting documentation filed for the sampling procedure, i.e. locations chosen for sampling, etc.? Yes/No/NA

G4b. Briefly describe the sampling method and supporting documentation associated with the sampling procedure. What area (in cm^2) is typically tested? Is the procedure being followed as written? (free text box) NA

G4c. Does the establishment have supporting documentation filed for the microbiological testing method? Yes/No/NA

G4d. Briefly describe the microbiological method and supporting documentation associated with the microbiological testing method. Is it being followed as written? (free text box) NA

G5. Does the establishment use the microbiological data generated for decision making? Yes/No/NA
- G5a. Briefly describe (free text box)

BEEF (Only answer if chosen Beef)

B1. Is *E. coli* O157:H7 addressed in the establishment's food safety system? Yes/No

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B2. What program is used to control *E. coli* O157:H7 on incoming beef products? Check all that apply.

- HACCP
- Sanitation SOP
- Pre-requisite Programs
- Other, specify
- Don't Know

B3. Does the establishment produce raw ground beef components? Check all that apply.

- No
- Trim and subprimals
- Head meat
- Cheek meat
- Weasand meat
- Advanced Meat Recovery (AMR) product
- Other low-temperature rendered products
- Other, please specify (free text box)

B4. Does the establishment use tenderizing methods (e.g. blades, pins, injectors etc.) on fabricated products? Yes/No

If yes, what does the establishment use for tenderizing? Check all that apply

- Blades
- Pins
- Needles
- Injection of tenderizers
- Others, please specify

B3a. Briefly describe (free text box)

B5. Does the establishment produce Specially handled beef manufacturing trimmings? Yes/No Has

INTERVENTIONS and VALIDATION for *E. coli* O157:H7

IV1. Does the establishment have purchase specifications for product intended for grinding requiring that suppliers conduct any of the following? (Purchase specifications: a set of requirements for incoming product established by buyer and agreed to be met by the supplier before the product is purchased) If yes, check all that apply

- No
- Validated intervention methods during slaughter
- Testing of carcasses for *E. coli* O157:H7
- Temperature
- Other, please specify (free text box)
- Don't Know

IV1a. How are purchase specifications verified?

- Third Party audit
- Test results from supplier
- In-house testing
- Other, please specify (free text box)
- Don't Know

IV2. Does the establishment use one or more of the following cross-contamination controls? Check all that apply

- Sanitation of knives and steels If yes, briefly describe how this is done (free text box)
- Maintain separation of lots from different suppliers
- None of the above
- Other, please specify (free text box)
- Don't Know

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IV3. Does the establishment have documented monitoring that the carcass surface temperature was maintained at or below 45°F within 24h of slaughter?

- Yes
- No
- Don't Know

IV4. If the establishment applies any intervention on the fabricated product, check all that apply

- No intervention
- Organic acid
- Acidified sodium chlorite
- Acidified calcium sulfate
- Irradiation
- Other, please specify (free text box)
- Don't Know

The next 10 questions should be answered for each answer chosen in the above question, other than 'No intervention' or 'Don't know'

IV2a. Is the intervention included in any of the following? Check all that apply

- HACCP plan
- Sanitation SOP
- Prerequisite Program
- GMPs
- Other, specify (free text box)

IV2b. Is the intervention adequately validated and documented? Yes/No

IV2c. Has the establishment identified the critical variables (e.g., time, temperature, pressure, concentration, pH, etc.) used in the validation? Yes/No

IV2d. If the critical values have been identified for the intervention, are they being applied in the HACCP plan in a similar manner? Yes/No

IV2e. Is the product or product formulation referred to in the documented validation the same as or similar to the product or product formulation for which the establishment is using the intervention? Yes/No

IV2f. Is the establishment using the intervention as described in the validation with regards to equipment and procedures? Yes/No

IV2g. If the critical variables, product formulation, procedure or equipment used by the establishment are *not* the same as or similar to those used in the validation, did the establishment conduct additional validation that demonstrated the changes are effective? Yes/No/NA

IV2h. If the establishment did not conduct additional validation, did it provide any rationale to explain why the intervention is effective and has the same impact even though the critical variables, product formulation, procedure or equipment are different? Yes/No/NA

IV2i. Did the establishment test for the adequacy of the intervention to reduce *E. coli* O157:H7? Yes/No

IV2j. Does the establishment have a rational basis or data to show that the reduction of *E. coli* O157:H7 by the intervention is sufficient to control the level of contamination of *E. coli* O157:H7 that may be present on incoming products? Yes/No

IV3. Further describe intervention(s) the establishment has in place addressing *E. coli* O157:H7. (free text box). Trim goes through a lactic acid bath and then is dumped into combos with holes in the bottom to allow excess lactic acid to drain off.

IV4. What is the *Salmonella* category of the establishment supplying the carcasses? NA

SAMPLING and TESTING

ST1. Does the establishment sample incoming carcasses for *E. coli* O157:H7? Yes/No

ST1a. Does the establishment have supporting documentation filed for the sampling procedure? Yes/No NA

ST1b. Briefly describe the sampling method and supporting documentation associated with the carcass sampling procedure. What area (in cm^2) is typically tested? Is the procedure being followed as written? (free text box) NA

ST1c. Does the establishment have supporting documentation filed for the microbiological testing method? Yes/No NA

ST1d. Briefly describe the microbiological method and supporting documentation associated with the microbiological testing method. Is the method being followed as written? (free text box) NA

ST1e. Using the FSIS method for comparison, is the sampling and testing procedure used by the establishment adequate to detect low levels of *E. coli* O157:H7 contamination present on the carcass, i.e. is this procedure as sensitive as the FSIS method? Yes/No NA

ST1f. Describe how you came to your conclusion in ST1e. NA

ST2. Has the establishment ever had a carcass sample test positive for *E. coli* O157:H7? Yes/No From third party audit testing.

ST3. Does the establishment have corrective action procedures in place when a carcass is positive for *E. coli* O157:H7? Yes/No

ST3a. Describe the corrective action procedures. (free text box)

ST4. Does the establishment sample fabricated product (can include both raw ground beef components and non-raw ground beef components) for *E. coli* O157:H7? Check all that apply.

- Yes – all product
- Yes – if destined for raw ground beef production
- Yes – if required to by customers
- No
- Other (free text box)

ST4a. Is sampling for *E. coli* O157:H7 included in any of the following? Check all that apply.

- HACCP plan
- Sanitation SOP
- Prerequisite Program
- GMPs
- Other, specify (free text box)

ST4b. If fabricated product testing for *E. coli* O157:H7 included in the HACCP plan, is it a CCP? Yes/No

ST4c. Does the establishment have supporting documentation filed for the sampling procedure? Yes/No

ST4d. Briefly describe the sampling method and supporting documentation. Is the procedure being followed as written? (free text box) Twelve samples are taken from each domestic combo lot. The samples are placed in a sterile whirlpak bag. After all five combos are sampled, the samples are taken to the lab and tested.

ST4e. Does the establishment have supporting documentation filed for the microbiological testing procedure? Yes/No

ST4f. Briefly describe the microbiological method and supporting documentation filed associated with the testing procedure. Is the method being followed as written? (free text box) The establishment lab uses SDI Rapidchek to test for O157.

s.(b)(4)

ST4g. Using the FSIS method for comparison, is the sampling and testing procedure used by the establishment adequate to detect low levels of *E. coli* O157:H7 contamination in every lot, i.e. as this procedure as sensitive as the FSIS method? Yes/No

ST4h. Describe how you came to your conclusion in ST4g. The SDI Rapidchek test is an approved test to detect O157.

ST5. Does the establishment hold the sampled lot of fabricated product pending test results? Yes/No

ST6. Has the establishment ever had a sample test positive for *E. coli* O157:H7 from its own testing of fabricated product? Yes/No

ST7. Has the establishment ever had a sample test positive for *E. coli* O157:H7 from FSIS testing of fabricated product? Yes/No

ST8. Does the establishment have corrective action procedures in place when a fabricated product is positive for *E. coli* O157:H7? Yes/No

ST8a. Briefly describe the corrective action procedures, adequacy, and history of implementation. (free text box)

ST9. Has the establishment ever been implicated by FSIS as supplier to a lot of raw ground beef that tested positive for *E. coli* O157 and/or was associated with a recall? Yes/No

- 04/19/2007 TLN X070419 sirloin boneless strip and sirloin top butt, not sole supplier
- 06/23/2007 TLN MI 70037 beef chuck (clods), sole supplier
- 09/25/2007 TLN X070925 chuck clod in box and chuck clod in bin, not sole supplier
- 10/13/2007 TLN MF42649 chuck roll, tejes, major flats, peeled knux, and outside skirt, not sole supplier
- 10/28/2007 TLN MF55512 beef rounds (peeled knux), sole supplier

ST9a. Briefly describe the outcome of these findings. Was any regulatory action taken at this establishment? (free text box)

The outcome of the 03C02 procedures performed in response to the STEPS data was all acceptable with no non-compliance found and no regulatory action taken. Nebraska Beef, when notified also reviewed all production records although they did not have written documentation of the review.

MISCELLANEOUS

M1. How does the establishment define a lot?

- 1 Based on 5 combo bins
- 2 Based on combo bins from one supplier
- 3 Based on combo bins from suppliers that use validated intervention methods
- 4 All combo bins received in one day
- 5 Clean up to clean up
- 6 Period of time
- 01 Other, please specify (free text box)

M2. How many outside suppliers of carcasses has the establishment used in the last 30 days? (Check all that apply)

- Only from its own slaughter plant
- 1 (other slaughter plant)
- 2-3
- 4-6
- >6

M3. How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas?

- After processing carcasses from a supplier
- After processing carcasses from a group of suppliers
- After each shift
- Daily, after production
- Less than daily (extended clean up)
- Other, please specify (free text box)

Best Copy Available

Don't Know

M4. Has the establishment had a third-party audit of its food safety system? Yes/no

M4a. If yes, were any of the recommendations implemented? Yes/No

M4b Briefly discuss the third-party audit recommendations and indicate which were implemented by the establishment. (free text box) See page 15 question M2b

M5. Discuss findings and any regulatory non-compliances associated with HACCP 03C plans at this establishment. (free text box) During a review of records associated with this plan no non-compliances were observed.

NR Analysis

There have been 35 Non-compliance Records (NRs) issued since 1/1/2008 through 4/27/2008. The NRs represent both the Slaughter and Processing departments and were issued under the following procedure codes:

- 01C02 (Slaughter)-26;
- 01C02 (Processing)-3;
- 06D01-9;
- 03J01-7;
- 03J02-2;
- 01B02 (Slaughter)-4;
- 01B02 (Processing)-2;
- 04A03-2;

The following table breaks down the combined number of scheduled and unscheduled tasks performed in the same time period and the rate of non-compliance for each task.

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s.(b)(7)(A)

[redacted]

weekly meetings with the establishment and is currently verifying that the establishment's corrective actions are adequate.

Analysis and Recommendation

Nebraska Beef has developed and implemented a food safety system through their SSOP, HACCP, prerequisite, and microbiological sampling/testing programs. The primary hazards identified in the establishment's hazard analyses as reasonably likely to occur without appropriate control measures in place include *E. coli* O157:H7, *Salmonella*, and visible fecal/milk ingesta. At the present time, the establishment can demonstrate that appropriate controls are in place to prevent these hazards and that all critical limits related to those controls are being met. Further, establishment microbiological data (generic *E. coli*, *E. coli* O157:H7) as well as FSIS microbiological data (*Salmonella*, *E. coli*) support that plant procedures are currently effective in preventing the creation of unsanitary conditions related to product contamination or adulteration. A recurrent trend of non-compliance related to the implementation/monitoring of a pre-evisceration cabinet procedure was identified, however the in-plant FSIS inspection team has documented this trend and is currently verifying that the establishment's corrective actions are adequate. Based on a review of the establishment's records documenting the implementation of their programs and procedures including SSOP records, HACCP records and prerequisite program records, as well as a review of their scientific supporting documentation, microbiological sampling data, and observations made during plant tours, it was determined that at the present time, Nebraska Beef is operating their food safety system within the regulatory requirements of 9 CFR 416 and 417, and any food safety concerns are being documented and appropriately handled by the in-plant FSIS inspection team. We recommend no further action be taken at this time.

Exit Meeting

On 5/19/2008, at approximately 0900, an exit meeting was held in the conference room at Nebraska Beef Inc. Those present at the meeting representing Nebraska Beef were [redacted], Food Safety Director, [redacted], HACCP Administrator, and [redacted], Senior Vice President. Those present representing USDA were [redacted], EIAO/PHV, [redacted], EIAO, and [redacted], EIAO/PHV. The establishment representatives were informed of the findings and recommendation of the assessment. The representatives were also given an opportunity to ask questions and were thanked for their cooperation throughout the assessment.

Best Copy Available

Attachment 5

Attachment 6

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

Subject: Notification of Ecoli O157:H7-positive Result
From: @fsis.usda.gov
Date: Mon, 09 Jun 2008 09:47:42 -0400
To: @nebraska-beef.com
CC: fsis.recallnotification@fsis.usda.gov; @fsis.usda.gov;;

Bill Hughes
Nebraska Beef, Ltd.
Omaha, NE

This message is issued as a follow-up to your telephone conversation with the FSIS Des Moines District Office on 06/09/2008.

Your establishment, Nebraska Beef, Ltd., establishment 19336-M, has been listed as a supplier of beef used to produce ground beef products at establishme M. The product produced at that establishment was sampled by FSIS and returned a positive result for *Escherichia coli* O157:H7 in a FSIS laboratory on 06/04/2008.

Material from your establishment was not the only raw material used in the sampled product.

The material from your establishment was identified as:
Source MaterialBeef Chuck - Nebraska Beef Inc. Est. 19336 production date 5/19/08

If you have any questions you may contact Jeff Enlow in the Des Moines District Office.

Des Moines District Office
Office of Field Operations
Food Safety & Inspection Service

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

Subject: Notification of Ecoli O157:H7 positive Result
From: @fsis.usda.gov
Date: Tue, 17 Jun 2008 16:07:58 -0400
To: @nebraskabeef.com
CC: "FSIS Recall Notification" @fsis.usda.gov, @fsis.usda.gov;;

Food Safety Director
Nebraska Beef, Ltd.
Omaha, NE

This message is issued as a follow-up to your telephone conversation with the FSIS Des Moines District Office on 06/17/2008.

Your establishment, Nebraska Beef, Ltd., establishment 19836M, has been listed as a supplier of beef used to produce ground beef products at establishment . The product produced at that establishment was sampled by FSIS and returned a positive result for *Escherichia coli* O157:H7 in a FSIS laboratory on 06/15/2008.

Material from your establishment was not the only raw material used in the sampled product.

The material from your establishment was identified as:
Product code 67200, Front Shank Meat with production date 6/9/2008.

If you have any questions you may contact Thomas Beck in the Des Moines District Office.

Des Moines District Office
Office of Field Operations
Food Safety & Inspection Service

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

Subject: Notification of Ecoli O157:H7-positive Result
From @fsis.usda.gov
Date: Wed, 18 Jun 2008 16:56:33 -0400
To @nebraska-beef.com
CC: fsis.recallnotification@fsis.usda.gov; @fsis.usda.gov;;

Food Safety Director
Nebraska Beef, Ltd.
Omaha, NE

This message is issued as a follow up to your telephone conversation with the FSIS Des Moines District Office on 06/18/2008.

Your establishment, Nebraska Beef, Ltd., establishment 19336 M, has been listed as a supplier of beef used to produce ground beef products at establishment . The product produced at that establishment was sampled by FSIS and returned a positive result for *Escherichia coli* O157:H7 in a FSIS laboratory on 06/11/2008.

Material from your establishment was not the only raw material used in the sampled product.

The material from your establishment was identified as:
Nebraska Beef Ltd. Est 19336 M, supplied the following: Special Trim ; Front Shank ; and 67200 Hind Shank All, with a production date of 05/16/2008.

If you have any questions, you may contact Thomas Beck in the Des Moines District Office.

Des Moines District Office
Office of Field Operations
Food Safety & Inspection Service

Best Copy Available

Subject: Notification of Ecoli O157:H7-positive Result
From: [redacted]@fsis.usda.gov
Date: Thu, 19 Jun 2008 15:35:10 -0400
To: [redacted]@nebraska-beef.com;
CC: fsis.recallnotification@fsis.usda.gov; [redacted]@fsis.usda.gov;; [redacted]

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

[redacted] Quality Assurance Manager
Nebraska Beef Ltd.
Omaha NE

This message is issued as a follow-up to your telephone conversation with the FSIS Des Moines District Office on 06/19/2008.

Your establishment, Nebraska Beef, Ltd., establishment 19336 M has been listed as a supplier of beef used to produce ground beef products at establishment [redacted]. The product produced at that establishment was sampled by FSIS and returned a positive result for *Escherichia coli* O157:H7 in a FSIS laboratory on 06/19/2008.

Material from your establishment was not the only raw material used in the sampled product.

The material from your establishment was identified as:
Product Name: Nebraska Clods & Nebraska Knuckles Supplied these products to: [redacted] thru [redacted] This material was received by [redacted] on 6/9/2008 No lot # or Production date is available

If you have any questions you may contact Thomas Beck in the Des Moines District Office.

Des Moines District Office
Office of Field Operations
Food Safety & Inspection Service

Attachment 7

Best Copy Available

Attachment 8

Best Copy Available

Attachment 9

Attachment 10

Attachment 11

Attachment 12

Attachment 13

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 13

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-13

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

☑ COPY ☐ ORIGINAL	1. DESCRIPTION OF EVIDENCE Copy of a submission from Nebraska Beef containing an analysis from consultant microbiologist [redacted] n audit rating analysis from [redacted] and a memorandum addressing sanitation issues at Nebraska Beef.

2. EVIDENCE OBTAINED FROM (Name, address, etc.) Nebraska Beef, Est 19336 M 4501 S. 36th Street Omaha, Ne 68107	3. NAME OF PERSON OBTAINING EVIDENCE [redacted] DVM
	4. TITLE Enforcement Investigations Analysis Officer
	5. BADGE NO.
	6. DATE EVIDENCE OBTAINED 07/03/2008

7. LOCATION OF ORIGINAL(S) (If not attached)
USDA ,FSIS OFO
Des Moines District Office
210 Walnut Street, Suite 985
Des Moines, IA 50309

8. EXHIBIT NO. 13

NEBRASKA BEEF, LTD
4501 S. 36th Street
Omaha, Nebraska 68107
(402) 733-7000
Fax: (402) 733-1624

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

To: Dr. Kenneth Petersen
Mr. Alfred Almanza

cc. Dr. Richard Raymond

In advance of our call at 8:00 AM EDT, we would ask that the Recall Committee reconsider its decision to request a voluntary expansion by Nebraska Beef of the current recall. In support of this request we have attached the comments by our consultant microbiologis s well as our memorandum addressing the sanitation issues addressed in the June 2 letter.

ANALYSIS BY

after reviewing the July 2, 2008, communication states that the scientific basis to support the conclusion that Nebraska Beef is the source of the outbreak is lacking. We have attached her memorandum to this letter.

FSIS FOOD SAFETY ASSESSMENTS

As additional support for the validity of our microbiological programs, during the past 7 months, our company has been subjected to two Comprehensive Food Safety Reviews by FSIS, one in December, 2007, and another in May, 2008. Those audit reports contained information relating to thorough direct observations and records review of our micro sampling and testing programs. The analysis and recommendation section in the December, 2007, report states:

"The step is used for all trim destined for use as ground beef. The establishment performs studies throughout the slaughter and fabrication processes prior to and following interventions to evaluate process control and to validate their food safety system. All microbiological data demonstrates the system is adequate and effective to reduce, eliminate, and control E.coli. Two outside sources are used to provide validation of their food safety plan. Both of these processing authorities documented an adequate system in place."

The analysis and recommendation section of the May, 2008, report states:

"Based on the review of the establishments records documenting the implementation of their programs and procedures including SSOP records, HACCP records, and prerequisite program records, as well as a review of their scientific supporting documentation, microbiological sampling data, and observations made during plant tours, it was determined that at the present time, Nebraska Beef is operating their food safety system within the regulatory requirements of 416 and 417 and any food safety concerns are being documented and appropriately handled by the in plant FSIS inspection team."

s.(b)(4)

INDEPENDENT THIRD PARTY AUDIT

A further audit was performed by n May 13 and 14. A copy of their report setting forth the audit rating analysis is attached. Please note that our overall score was vith Plant Sanitation scoring and Food Safety

MICROBIOLOGICAL TESTING

As further evidence of the sanitary condition of our facility, approximately 178 plant samples were tested by or USDA from January 1 to date all of which were negative. Testing for the time period from May 16, 2008, to June 26, 2008, 51 tests were performed all of which were negative.

CONCLUSION

On behalf of Nebraska Beef we respectfully request that the Recall Committee reconsider its decision based upon the material provided by Nebraska Beef and the analysis of microbiologist

Response to Sanitation Issues

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The FSIS has submitted statements regarding the sanitation of Nebraska Beef's facility; specifically the suggestion that the facility is insanitary. We take exception to statements of this nature and, in fact, are particularly troubled by such a claim given that we have had two comprehensive assessments performed by FSIS within the last nine months which resulted in absolutely no negative comments about the condition of our plant or the viability and effectiveness of our processes. Furthermore, the statement that Nebraska Beef took no action in response to the four email notifications we received in June is inaccurate.

Following the email notification we received on June 9, 2008, our Food Safety Director, nd our HACCP Coordinator, ointly addressed the notification. anc engaged in a HACCP reassessment by reviewing all HACCP and SSOP records from three days before the identified production date of May 19, 2008, and three days after the identified production date. They further reviewed the relevant lab results in an effort to identify any abnormalities such as a deviation from the critical limit, an increase in plate count or an increase in generic *e. coli* occurrence. They also notified the plant's slaughter manager of the situation. While neither ıor ocumented these actions as a formal HACCP reassessment their actions were known to in plant FSIS personnel.

Similarly, following the email notification received on June 17, 2008, nd again conducted the above described assessment. Additionally, they reviewed notation at the viscera table regarding dressing procedures looking for any abnormalities in the process or repetitive incidents such as too many cut weasands or guts. additionally confirmed that Nebraska Beef personnel were operating the front shank area appropriately.

Following the email notification received on June 18, 2008, ınd again conducted the above described actions in an effort to reassess the HACCP plan. Further, following this notification the plant began the process of implementing the cabinet. It also verified that the slaughter processes were being performed appropriately by plant personnel.

Finally, following the email notification received June 19, 2008, the plant continued to prepare th step for use and take steps as described above.

You also reference four NRs received by Nebraska Beef since the beginning of May, 2008. Those NRs are in the process of being appealed and bear no relation to any of the four email notifications received in June, 2008. Indeed, they represent isolated incidents capable of

occurring in this industry and demonstrate no pattern which would raise a concern about Nebraska Beef's processes or ability to control its production.

For example, the referenced NR for a carcass neck "dragging on the floor" was addressed by Nebraska Beef. The NR was written at a time when the line was stopped and there is no indication as to when the neck descended such that it would cause it to drag on the floor. Regardless, Nebraska Beef utilized this isolated incident as an opportunity to retrain its personnel on identifying and re-trimming product when necessary to prevent occurrences such as this.

The single incidence of condensation dripping on a carcass was caused by steam being produced by another of Nebraska Beef's interventions. When FSIS personnel stopped the line Nebraska Beef wiped down the underside of the cat-walk from where the condensation was falling and installed a fan to control the steam accumulation in that location. Again this is an isolated incident not unique to Nebraska Beef.

The NR for a failure of a for the heads was simply not warranted and, like the other NRs referenced, is being appealed. In this case, Nebraska Beef's control processes performed exactly as designed. Nebraska Beef utilizes a in the subject wash cabinet. So, while the outside sprayers visible to inspection personnel may not have operated adequately the back-up sprayers function as a protection which satisfies the critical limit. Further, Nebraska Beef has a CCI and checks by Nebraska Beef personnel would have identified any problem and the effect product would have been retained.

Finally, the NR for a fecal finding on a carcass was another isolated incident that does not create a pattern of failure of the process. In fact, Nebraska Beef has not experienced another instance of a zero tolerance failure since April 17, 2008. Nonetheless, in this instance the carcass was trimmed and all carcasses were retained from the last acceptable to the next acceptable zero tolerance check as stated in our HACCP plan. Further, also in accordance with Nebraska Beef's HAGCP plan, the line speeds were slowed so that the process could be traced to determine the cause of the deviation. Corrective measures were taken on all carcasses which included re-inspection and trimming as necessary. Preventative measures were also given and no further incidents have occurred since the reference incident. Again, FSIS was present and aware of the corrective actions.

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 14

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-14

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

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☑ COPY ☐ ORIGINAL	1. DESCRIPTION OF EVIDENCE Copy of Nebraska Beef's second response to the NOIE, dated 7/3/2008, which contains the second response, a protocol for an in-plant validation study of [redacted] on beef trim for non-intact use, revised [redacted] procedure, and a protocol for comprehensive assessment of sanitary conditions in the slaughter process.

2. EVIDENCE OBTAINED FROM (Name, address, etc.) Nebraska Beef, Est 19336 M 4501 S. 36th Street Omaha, Ne 68107	3. NAME OF PERSON OBTAINING EVIDENCE [redacted] DVM
	4. TITLE Enforcement Investigations Analysis Officer
	5. BADGE NO.
	6. DATE EVIDENCE OBTAINED 07/03/2008

7. LOCATION OF ORIGINAL(S) (If not attached)
USDA FSIS OEO
Des Moines District Office
210 Walnut Street, Suite 985
Des Moines, IA 50309

8. EXHIBIT NO. 14

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

From: [redacted]
Sent: Thursday, July 03, 2008 11:06 PM
To: Sprouls, Dawn; [redacted]
Cc:
Subject: Fw: NOIE Response Concerns

Attachments: Trim Validation Study.doc; [redacted]-1.doc; Slaughter Assessement of Sanitary Conditions.doc

I haven't reviewed yet but youcan email me your comments when you get a chance to review it. Thanks and have a fun filled fourth.

Sent from my BlackBerry Wireless Handheld

-----Original Message-----
From: [redacted]ebraska-beef.com>
To: [redacted]@cox.net [redacted]@cox.net>; [redacted]cox.net [redacted]@cox.net>
Sent: Thu Jul 03 22:39:02 2008
Subject: NOIE Response Concerns

Slaughter [redacted]ssessement of Sanit

Dear [redacted]

[redacted] wanted me to thank you for meeting with him this afternoon to discuss the agency's concerns regarding our response to the NOIE. This e-mail is to inform you that based on that discussion; Nebraska Beef will take the following actions;

1. Nebraska Beef will continue to utilize outside laboratory and [redacted] for 120 days or until the process is under control.
2. The[redacted] [redacted]tilizes a [redacted] sample.
3. Developed a protocol for our in-plant validation study of [redacted] application of [redacted] (See Attachment).
4. A protocol for our in-plant validation study of [redacted] of beef carcasses prior to entering fabrication will be developed and submitted to FSIS by COB Monday July 7, 2008. Planned implementation will be Tuesday July 8, 2008 (next day). Pertinent information relative to the sampling and testing methodology of cold beef carcasses will need to be discussed with our scientific advisor for accuracy before proceeding.
5. We have revised our [redacted] procedures to include a provision which states [redacted]

Please call if you have any questions.

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 15

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-15

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

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☑ COPY
☐ ORIGINAL

1. DESCRIPTION OF EVIDENCE

Copy of additions to Nebraska Beef's second response, dated 7/7/2008, which includes [redacted] trim samples, revised [redacted] revised comprehensive slaughter re-assessment protocol, and a copy of the form to be used for continuous monitoring of the slaughter area.

2. EVIDENCE OBTAINED FROM (Name, address, etc.)

Nebraska Beef, Est 19336 M
4501 S. 36th Street
Omaha, Ne 68107

3. NAME OF PERSON OBTAINING EVIDENCE

[redacted] DVM

4. TITLE

Enforcement Investigations Analysis Officer

5. BADGE NO.

6. DATE EVIDENCE OBTAINED

07/07/2008

7. LOCATION OF ORIGINAL(S) (If not attached)

USDA FSIS OFO
Des Moines District Office
210 Walnut Street, Suite 985
Des Moines, IA 50309

8. EXHIBIT NO. 5

A0002222_74-000000

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

From:
Sent: Monday, July 07, 2008 7:27 AM
To: y; Sprouls, Dawn
Cc:
Subject: FW: addedums - Nebraska Beef

Attachments: 1.doc; Process monitoring.xls; Slaughter Assessement of Sanitary Conditions.doc



1 Process Slaughter
R nitoring.xls (18 KB) ssessement of Sanit.

FYI - updated revisions for NB.

DVM
EIAO/PHV
Des Moines District
402 437-
402 437-5635 (FAX)
(Blackberry)

-----Original Message-----
From: mailto @nebraska-beef.com]
Sent: Monday, July 07, 2008 7:22 AM
To:
Subject: addedums - Nebraska Beef

Good Morning
Over the weekend, we made some decisions that caused us to revise what was already submitted to you in response to the NOIE. First of all, we will be utilizing for all trim samples. Attached you will find revised copies of the and comprehensive slaughter re-assessment protocol. Also, we are adding a copy of the form our designated QC person will be using for the continuous monitoring of the slaughter area. Just so you know we are presently evaluating these areas and will keep you informed of any changes as they occur.

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 16

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-16

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

s.(b)(6)
s.(b)(7)(C)

☑ COPY ☐ ORIGINAL	1. DESCRIPTION OF EVIDENCE Copy of a Memorandum of Information from EIAO [redacted] dated 7/3/2008, detailing a meeting held with a Nebraska Beef representative regarding clarifications with the company's response to the NOIE issued on 6/27/2008.

2. EVIDENCE OBTAINED FROM (Name, address, etc.)	3. NAME OF PERSON OBTAINING EVIDENCE	
USDA FSIS OFO Des Moines District Office 210 Walnut Street, Suite 985 Des Moines, IA 50309	[redacted] DVM 4. TITLE Enforcement Investigations Analysis Officer	
	5. BADGE NO.	6. DATE EVIDENCE OBTAINED 07/03/2008

7. LOCATION OF ORIGINAL(S) (If not attached)

USDA FSIS OFO
Des Moines District Office
210 Walnut Street, Suite 985
Des Moines, IA 50309

8. EXHIBIT NO. 16

United States Department of Agriculture
Food Safety and Inspection Service
Des Moines District Office
210 Walnut Street. Suite 985
Des Moines, IA 50309
Phone: 515-727-8960

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

7/03/2008

Memorandum of Information

RE: Meeting with Bill Hughes regarding clarifications with response to NOIE issued on 6/27/2008

I, EIAO with the Des Moines District) met with Bill Hughes on Thursday, July 3, 2008, at approximately 1410. (EIAO with the Des Moines District) was also present. Mr. Hughes asked if he could get one Of Nebraska Beefs' HACCP consultants, on the phone to be part of the discussion. We stated that it would be OK to do that.

Once was on the phone we went ahead to discuss clarifications that should be addressed in their response to the NOIE.

The agency wanted clarification that a gram sample would be tested using the method, Which Mr. Hughes said would be occurring.

Nebraska Beef (NB) was also asked to provide clarification on how they know whether or not the cabinet that is being used in the Pre-Fab area on carcasses, before they enter the Fab area is effective? Since it is not a CCP, but a processing aid, how do they (NB) know whether it is working or not?

Discussed whether NB has any plans to go back to using the in-house lab and if so how are they going to assure that it is functioning so that we and they can have confidence in the results obtained.

Asked NB to clarify if they have any current validation or verification data on CCP 3 in since the support that they provided is different than what they are doing.

Since O157 comes from the slaughter side, what is going to be done on the slaughter side to prevent it from getting into the fab side and to improve sanitary conditions on the slaughter.

That being the concerns needing to be clarified for the district the meeting was adjourned at approximately 1450.

Respectfully submitted by,

[redacted] EIAO/PHV
Des Moines District

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 17

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-17

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

☑ COPY ☐ ORIGINAL	1. DESCRIPTION OF EVIDENCE A copy of an Addendum to the NOIE responses from Nebraska Beef, received on 7/7/2008. Addendum includes the following; CCP #3-B(a scientific article regarding the use of on cold beef carcasses to reduce bacterial pathogens, Employee and Slaughter Process Monitoring form, and a daily documentation of discussions form.

2. EVIDENCE OBTAINED FROM (Name, address, etc.) Nebraska Beef, Est 19336 4501 S. 36th Street Omaha, Ne 68107	3. NAME OF PERSON OBTAINING EVIDENCE JVM 4. TITLE Enforcement Investigations Analysis Officer 5. BADGE NO. 6. DATE EVIDENCE OBTAINED 07/07/2008

7. LOCATION OF ORIGINAL(S) (If not attached)
USDA FSIS OFO
Des Moines District Office
210 Walnut Street, Suite 985
Des Moines, IA 50309

8. EXHIBIT NO. 17

From:
Sent: Monday, July 07, 2008 4:54 PM
To: Sprouls, Dawn;
Cc:
Subject: Fw: Addendom to NOIE Response

s.(b)(6)
s.(b)(7)(C)

Attachments: Addendum to NOIE Repsonses.pdf

Sent from my BlackBerry Wireless Handheld

-----Original Message-----
From: nebraska-beef.com>
To:
Sent: Mon Jul 07 17:37:30 2008
Subject: Addendom to NOIE Response

Addendum to NOIE Repsonses.pdf...

:

Here is the answers to you questions at today's meeting. Let me know if there are any other further questions so we can get this issue resolved.

s.(b)(4)
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Addendum to NOIE Response

1. The (is located in th oom just as it leaves the sales cooler but prior to the fabrication area. The as been operating within parameters as designed by the cabinet manufacturer as well as the chemical manufacturer in relation to cold carcasses. has formulated a study protocol to support effectiveness. During the study, will be providing ongoing feedback and recommendations so we can react accordingly. (See Attachments)

2. Nebraska Beef is submitting a revised protocol prepared by for validating our . During the study, will be providing ongoing feedback and recommendations so we can react accordingly. (See Attachment)

3. Nebraska Beef has increased its testing of trim t This higher sampling plan is intended to increase the probability of finding the organism if it is present.

4. In clarification to FSIS concerns, all validity and/or verification testing will have the actual testing completed at 3rd party laboratories.

5. During the comprehensive re-assessment that is taking place, HACCP team members have been instructed to keep notes on conversations and any meetings that would pertain to how to improve the efficiencies of pathogen removal. Notes will be kept and shared so that all may see the ongoing thought process that is prevalent with the different people involved. Documentation will be available for review.

6. The line speed has been reduced to a maximum of ead per hour (based on the for a minimum of 30 days and until such a time as Nebraska Beef microbiological testing indicates all operations are under control.

7. Nebraska Beef has chosen as our initial starting point for our "don't grind" cutoff number. As we create new data and develop a standard deviation on combo lots that pass/fail, this initial number will move in a normal mathematical pattern. We will begin the analysis of the data beginning after 30 days of collection.

8. We have amended the Employee and Slaughter Process Monitoring form to include the and Also, we have created a form for the Plant manager to complete upon correlation with the QC representative responsible for monitoring. (See Attachments)

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 18

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-18

s.(b)(6)
s.(b)(7)(C)

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

☑ COPY
☐ ORIGINAL

1. DESCRIPTION OF EVIDENCE

Copy of a Memorandum of Information from EIAO [redacted] dated 7/7/2008, detailing a meeting held with Nebraska Beef representatives regarding further clarification of responses proffered by Nebraska Beef to the NOIE issued on 6/27/2008.

2. EVIDENCE OBTAINED FROM (Name, address, etc.)

Nebraska Beef, Est 19336
4501 S. 36th Street
Omaha, Ne 68107

3. NAME OF PERSON OBTAINING EVIDENCE

[redacted] DVM

4. TITLE

Enforcement Investigations Analysis Officer

5. BADGE NO.

6. DATE EVIDENCE OBTAINED

07/07/2008

7. LOCATION OF ORIGINAL(S) (If not attached)

USDA FSIS OFO
Des Moines District Office
210 Walnut Street, Suite 985
Des Moines, IA 50309

8. EXHIBIT NO. 18

United States Department of Agriculture | Food Safety and Inspection Service | Field Operations | Mack Bolyard EIAO 1040 F Plaza Omaha, NE 68127-1000

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s.(b)(7)(C)

Memorandum of Information

Date: 7-7-08

To: Dr. Dawn Sprouls,
District Manager, Des Moines

From:
EIAO Des Moines District

Subject: Further clarification of response by Nebraska Beef, Est. 19336 for the Notice of Intended Enforcement (NOIE) issued on 6-27-08.

On 7-7-08, and EIAOs) met with Nebraska Beef officials at 1125 in the conference room of Nebraska Beef to discuss the responses proffered by Nebraska Beef to the NOIE. Those present for the company were Bill Hughes, This discussion was to present concerns of the agency and clarification to the response made by Nebraska Beef. These were:

1. The company proffered the installation (The company needs to validate this process to ensure the intended effectiveness is being attained to control *E. coli* O157:H7 as intended.
2. We discussed the We discussed the need to test the liquid at some frequency to test for cross contamination of the liquid.
3. We requested clarification to the and the associated SOP describing method and intended use. The company stated it was increased to improve confidence level of testing.
4. We requested the method of validating sampling and testing CCP 3. We requested the lab be listed in the explanation and the testing methodology.
5. We explained that records would be required as part of the response identified as "Comprehensive Assessment of Sanitary Conditions in Nebraska Beef Slaughter Process". Each item was discussed to assure the company understood the importance of the agency being able to verify their procedures. We discussed that minutes be kept of any meetings addressing these issues.
6. We discussed the importance of the company to react to the information gathered from observations and use this information to address possible flaws in their operational sanitation procedures.

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7. We requested clarification on how the company determined that would determine that all trim produced during would go to cooking.
8. The company asked about how they could eventually go back to in house testing following the methodology. One item discussed was the company have a verification method in place with an outside lab to support the accuracy of their procedures.

discussed the methodology of NOIE and what would occur once the agency gets the final response to the NOIE. We discussed the importance of records being maintained on the propose changes to allow the agency the ability to verify his corrective actions. We also requested the clarification be finished by the end of business today so the agency can make a decision on whether to place the NOIE into Deferral.

At approximately 1315 after answering all questions the company personnel had, we adjourned.

EIAO, Des Moines District

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 19

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-19

s.(b)(6)
s.(b)(7)(C)

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

☑ COPY
☐ ORIGINAL

1. DESCRIPTION OF EVIDENCE

A signed copy of the Notice of Deferral hand delivered to Nebraska Beef on 7/8/2008, and Verification Plan hand delivered on 7/9/2008.

2. EVIDENCE OBTAINED FROM (Name, address, etc.)

USDA, FSIS
Des Moines District Office
210 Walnut Street, Suite 985
Des Moines, IA 50309

3. NAME OF PERSON OBTAINING EVIDENCE

[redacted]

4. TITLE

Enforcement Investigations Analysis Officer

5. BADGE NO.

6. DATE EVIDENCE OBTAINED

07/09/2008

7. LOCATION OF ORIGINAL(S) (If not attached)

Nebraska Beef, Est 19336
4501 S. 36th Street
Omaha, Ne 68107

8. EXHIBIT NO. 19

United States Department of Agriculture
Food Safety and Inspection Service
Field Operations
Des Moines District Office
Federal Building
210 Walnut, Room 985
Des Moines, IA 50309-2123

Hand delivered

July 8, 2008

Bill Hughes, President
Nebraska Beef, Ltd.
PO Box 510
Omaha, NE 68352

NOTICE OF DEFERRAL

Dear Mr. Hughes,

This letter confirms oral notification provided to you by the Food Safety and Inspection Service (FSIS) on July 8, 2008, of our decision to defer the implementation of the Notice of Intended Enforcement (NOIE) dated 06/27/2008.

On June 27, 2008, the Food Safety Inspection Service (FSIS) issued to your Establishment 19336, a "Notice of Intended Enforcement." This was based on your establishment's failure to comply with the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) regulations. Specifically, your establishment's failure to do the following:

(1) The establishment has an inadequate HACCP system as defined in 9 CFR 417.6(a), as it has not met the requirements of 9 CFR 417.2(a)(c), 9 CFR 417.3, 9 CFR 417.4(a)(3) & (B) and 9 CFR 417.5(a).
(2) The HACCP system in place at Est. 19336 is deemed to be inadequate according to 9 CFR 417.6(b) as establishment personnel are not performing an adequate pre-shipment review prior to shipping product as they are not reviewing all records (COAs) associated with the production of trim product prior to product being shipped.
(3) The HACCP system in place at Est. 19336 is deemed to be inadequate according to 9 CFR 417.6(c) as the establishment is not taking all parts of corrective action by not doing a proper disposition on presumptive positive product and not maintaining control of the product.
(4) The establishment has an inadequate HACCP system, as it has allowed adulterated product to be produced and shipped as defined in 9 CFR 417.6(e).

On July 2, 2008, July 3, 2008 and again on July 7, 2008 your firm provided written documentation in response to the issues that were contained in the June 27, 2008 NOIE.

After careful review of your response, FSIS has decided to defer a decision regarding enforcement action pending verification by FSIS inspection personnel. Assigned inspection personnel will continue to monitor your operations and provide your establishment an opportunity to demonstrate that regulatory compliance has been achieved.

This deferral hinges on the actions that you stated you would take in your response to the August 3, 2006 NOIE. Specifically,

1. Instituted a reassessment procedure where by all decisions causing review of any part of your HACCP program are documented on a "HACCP changes Page".
2. Starting on 6/27/08 sing the at the level for 120 days or until the process is under control.
3. Implemented a that includes a provision are positive for *E. coli* O157:H7, the
4. Have developed a validation study to determine the effectiveness of your CCP
5. Have developed a validation study to determine the effectiveness for the on carcasses before they enter fab.
6. Are using the or the sampling of trim.
7. Have developed a protocol for comprehensive assessment of sanitary conditions in your slaughter process with the appropriate documentation records.
8. Line speed on the slaughter side has been reduced to ıead/hour for 30 days with a re-evaluation of the observations made at that time. If line speed is increased at that time a new set of observations will be correlated with the increased line speed.

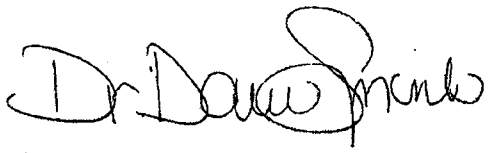
A copy of FSIS' Verification Plan is enclosed to assist you in understanding the nature and importance of the Agency's verification activities. The FSIS Verification Plan is designed to assure ongoing regulatory compliance.

If you need to make any further changes relevant to the corrective actions you made in your July 8, 2008 final submission letter to FSIS, please notify the district office prior to making those changes. As the decision to defer is based on the responses you have given thus far.

Please be advised that, as a federally inspected Establishment, you are expected to comply with 9 CFR § 416 and 417 *et. seq.* of the regulations and all other requirements concerning the preparation, sale, and transportation of meat and poultry products. Failure to comply with these requirements could lead to the withholding or suspension of inspection or other appropriate action.

If you have questions, please contact the Des Moines District Office at (515) 727-8960 or EIAO/PHV at 402 437- or it 402 829-

Sincerely,



Dr. Dawn Sprouls
District Manager

Verification Plan – 19336 M

July 9, 2008

9 CFR 416.17 identifies FSIS responsibilities for verifying the adequacy and effectiveness of Sanitation SOPs and procedures. 9 CFR 417.8 identifies FSIS responsibilities for verifying the adequacy of Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) plans. This must be accomplished by determining that the Nebraska Beef, Ltd. SSOP and HACCP plans meet the requirements of this part and all other applicable regulations. Verification activities need to focus on how is controlling the hazards and whether such controls have a scientific or technical basis. . This verification includes review of the SSOP and HACCP plans and the daily records, and/or direct observation of its implementation of these plans.

Basic compliance checks for SSOP and HACCP should be performed as scheduled tasks during the deferral period. These procedures are to be used to verify the Nebraska Beef, Ltd. . compliance with regulatory requirements. Any noncompliance found while performing a HACCP 01 task should lead to inspection personnel performing the appropriate 02 procedure.

During the time of deferral, any proposed changes to the Nebraska Beef, Ltd. HACCP plan must be reviewed by the Des Moines District Office prior to implementation.

REMEMBER TO DOCUMENT ALL PERTINENT DATES AND TIME OF VERIFICATION ACTIVITIES PERFORMED IN THE INSPECTION REMARKS SECTION.

Issue/Action	Regulation	ISP Code	Inspection Remarks	NR#
Basic SSOP Compliance Checks should be done upon start of this verification plan.		01A01		
Nebraska Beef has instituted a reassessment procedure where by all decisions causing review of any part of the HACCP plan will be documented on a "HACCP Changes Page"	§417.4(a)(3)	03C01		

s.(b)(4)

Issue/Action	Regulation	ISP Code	Inspection Remarks	NR#
Nebraska Beef has [redacted] method for collection into [redacted] composite sample	§417.5(a)(1)	03C01 & 03C02		
Nebraska Beef, as of 06/26/08 has chosen to have [redacted] samples be tested by the [redacted] using the [redacted] at the [redacted] evel for 120 days or until process is under control.	§417.5(a)(1)	03C01 & 03C02		
Nebraska Beef has implemented a [redacted] procedure including a provision that if [redacted] lots or more on [redacted] re positive for *E. coli* O157:H7, the [redacted]	§417.5(a)(1)	03C01 & 03C02		
Nebraska Beef has implemented a [redacted] rocedure where results are received prior to signing the Pre-shipment Review for a lot of product.	§417.5(c) & §417.3(b)	03C01 & 03C02		
Nebraska Beef has written procedures to control adulterated product while being shipped to another facility and these procedures are being followed as written. 9 CFR 325.10.	§325.10	03C01 & 03C02		

s.(b)(4)

Issue/Action	Regulation	ISP Code	Inspection Remarks	NR#
Nebraska Beef has developed and initiated a validation study	§417.(a)(2)	03C01 & 03C02		
Nebraska Beef has developed and initiated a validation study	§417.(a)(2)	03C01 & 03C02		
Nebraska Beef has developed a protocol for comprehensive assessment of sanitary conditions in the slaughter process with appropriate documentation records. This would follow Attachment 10 proffered by the Nebraska Beef.	§416.13(c) & §416.14	01C01 & 01C02		
Nebraska Beef has reduced the line speed of the chain on the Kill floor to head/hour for the next 30 days to evaluate process. If line speed is increased at the end of 30 days based on process control, additional evaluations will be conducted for process control.	§416.13(c) & §416.14	01C01 & 01C02		

These procedures are to be used to verify compliance with regulatory requirements. Any noncompliance found while performing a HACCP 01 task should lead to inspection personnel performing the appropriate 02 procedure.

Using this VP will allow FSIS to evaluate that the establishment is implementing their proposed plan until it can be determined whether the plan is effective. The District Manager (DM) will make a decision on the adequacy of the preventive action as soon as sufficient information becomes available. If, at any time, during the period of deferral, the establishment fails to adhere to the proposed action plan and the DM determines that an enforcement action is warranted, the DM will instruct the IIC to either impose a withholding action or effect the suspension in accordance with 9 CFR 500. The DM will immediately notify the establishment management of this decision and the basis for it in accordance with § 500.5.

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 20

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-20

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

s.(b)(6)
s.(b)(7)(C)

☑ COPY ☐ ORIGINAL	1. DESCRIPTION OF EVIDENCE Copy of the final submission NOIE response from Nebraska Beef received and accepted on 7/8/2008. Submission includes the company response and eleven attachments including clarifications proffered in previous addendums.

2. EVIDENCE OBTAINED FROM (Name, address, etc.) Nebraska Beef, Est 19336 4501 S. 36th Street Omaha, Ne 68107	3. NAME OF PERSON OBTAINING EVIDENCE [redacted]
	4. TITLE Enforcement Investigations Analysis Officer
	5. BADGE NO.
	6. DATE EVIDENCE OBTAINED 07/08/2008

7. LOCATION OF ORIGINAL(S) (If not attached)

USDA FSIS
Des Moines District Office
210 Walnut Street, Suite 985
Des Moines, IA 50309

8. EXHIBIT NO. 20

Latest Response

NEBRASKA BEEF AT ITS BEST

NEBRASKA BEEF, LTD
4501 S. 36th Street
Omaha, Nebraska 68107
(402) 733-7000
Fax: (402) 733-1624

s.(b)(4)

July 8, 2008

Dr. Dawn Sprouls
Des Moines District Manager
210 Walnut Street, Room 985
Des Moines, IA 50309-2123

Dear Dr. Sprouls:

On June 27, 2008, Nebraska Beef was issued a Notice of Intended Enforcement (NOIE) in accordance with the Rules of Practice, 9 CFR 500.4. An Action Plan was submitted on July 2, 2008. In response to further clarification points raised by the agency, we are submitting this revised Action plan which only includes attachments specific to corrective actions taken. All other attachments previously submitted are on file with FSIS.

(1) **There is reason to believe that Nebraska Beef continues to produce beef trim positive for *E. coli* O157:H7, and that the microbiological testing procedure in place at this establishment is not detecting positive sample lots, i.e, is not functioning appropriately (No regulation cited). The package insert states that the intended use is to analyze 25g samples only, however, the method has been validated to work using a 375g sample, though this use has not been AOAC approved.**

The was being used according to the manufacturer's instructions. According to the manufacturer; the test is sample. The is identified by and has been approved since July 17, 2002.

*further planned actions located in last paragraph in response #5 below.

(2) **It is reasonable to suggest the testing methodology is not being performed correctly as supported by the following facts: In the two years that Nebraska Beef has been doing in-house testing of trim for *E. coli* O157:H7, they have never had a positive. The nationwide prevalence of *E. coli* O157:H7 in trim is below ≤ 1%, so positives, while rare, should be found occasionally.**

(3) **It is reasonable to suggest the testing methodology is not being performed correctly as supported by the following facts: Samples from trim produced from animals custom slaughtered and processed at Nebraska Beef were sent to an outside lab for *E. coli* testing in June 2008, where 19/326 combos were found positive, a percent positive rate of 5.8%. In the same**

period (June 2008), all trim produced from animals slaughtered and processed at Nebraska beef but tested in house (approx. 1493 combos) tested negative.

Nebraska Beef understands the agency's concern about the absence of an in-plant positive since 2006. However, prior to that year, we received several positives as a result of FSIS' testing of beef trim for the nationwide baseline and due to those findings, we made the decision to install a

We believe that the installation and implementation of this intervention has performed the function it was intended to do by reducing *E. coli* O157:H7 to below detectable levels in trim, thus resulting in a low incidence rate (0%). Also, FSIS has sampled our trim routinely over the same time period and those tests have resulted in the same incidence rate (0%). During the same timeframe, our company submitted to with beef trim samples for validation testing.

As a result, a total of 1849 samples were tested with 10 presumptive positives resulting in an incidence rate of (0.54%). After consultation with our technical consultan she reviewed the data. Her review revealed that our statistical validation of the microbiological tests comparing our lab tests to the tests conducted at was highly significant. For 8000 samples for an alpha level of 0.05 (95% confidence) we would need to collect 367 samples (1970). At our facility, we collected 7800 samples and verified a minimum of 1219 samples at which is more than 3 times the needed number for 95% validation of the microbiological method we used. Our test results were validated compared to It is important to note that is also on record as recognizing that we were one of the first to apply on beef trim, and that we took a leadership role within the industry to improve the safety of our beef products.

In 2006, the began testing in our slaughter facility to determine the sources of pathogens in the final product. This testing involved multiple sampling sites in both the slaughter and fabrication areas. In the slaughter area, they tested the fore shank, hind shank, neck, midline and inside round individually for the presence of *E. coli* O157:H7. Samples were collected on the hides and on the carcass after interventions. Carcass samples were analyzed using the system AOAC approved). Hides were analyzed using methods combined with

As a result of these data, they received o continue to follow the pathogen loads in Nebraska Beef as well as in two other facilities in the US through 2007 and 2008. In each facility a total of 960 carcass samples and 160 hide samples were collected with detection methods being combined with two separate methods of enumeration. One method of enumeration involved the combined with an determine the total numbers of *E. coli* O157:H7 on the carcass while the other

combined the combined with and/or

Throughout 2007 and the winter of 2008 not a single sample collected from a carcass in the cooler was positive for *E. coli* O157:H7 using all three methods. Additionally, testing at the other two facilities revealed that up to 20% of the samples collected from the carcasses in the other plants were positive for this pathogen.

The implementation of the targeted interventions was effective controlling *E. coli* O157:H7 in our facility which was indicated by their testing using three separate methods and by additionally testing done by the facility itself with negative results on the final product using AOAC approved methods internally and by an external laboratory all using AOAC approved methods.

As additional support for the validity of our microbiological programs, during the past 7 months, our company has been subjected to two Comprehensive Food Safety Reviews by FSIS, one in December 07 and another in May 08. Those audit reports contained information relating to thorough direct observations and records review of our micro sampling and testing programs, and in each case the decision was that we were in compliance with all regulatory requirements.

*further planned actions located in last paragraph in response #5 below.

(4) It is reasonable to suggest the testing methodology is not being performed correctly as supported by the following facts: Nebraska Beef does not use a positive control and so has no verification that the test method, as performed by the in-house technician, can in fact detect positives if present at low levels.

The test method is so designed that the positive control is on describing usage of the product. This test was developed in such a way that there would readily be an identifier to indicate if the test was completed correctly.

*further planned actions located in last paragraph in response #5 below.

(5) It is reasonable to suggest the testing methodology is not being performed correctly as supported by the following facts: Nebraska Beef has been identified as a supplier to grinders where raw ground beef tested positive for *E. coli* O157:H7 four times in 2008.

The notifications from FSIS revealed that our establishment was not the only raw material used in the sampled product. While our company takes very seriously anytime

our products are implicated as a raw material supplier of non-intact products that test positive for *E. coli* O157:H7, the fact that we were not the only supplier does call into question whether our raw materials were a definitive source of the adulteration.

In all of the aforementioned incidents, the establishments of record received boxed beef sub-primals that they converted for non-intact use. Our HACCP program clearly identifies that beef primals and sub-primals are not intended for non-intact use and our understanding of existing agency policy is as follows;

1. When a company makes a conscious decision to use any raw materials for conversion to non-intact use, they must analyze for potential biological hazards and specify appropriate controls within their own HACCP program.
2. Nebraska Beef has over ', and it should neither be reasonable or practical for the agency to expect our company to oversee how each customer utilizes whole muscle, beef products.
3. *E. coli* O157:H7 is not considered an adulterant in whole muscle cuts of beef

Once notified, our quality control department reviewed all records associated with the production dates supplied by FSIS and no deficiencies were found. Because we considered this record review outside the scope of the regulatory mandate relating to Reassessment (417.4), no record of these reviews were documented. However, effectively immediately, Nebraska Beef has instituted a reassessment procedure whereby all decisions causing us to review any part of our HACCP program are documented on our "HACCP Changes Page," including notations of reassessments in progress (See our response to #8 below).

* In conclusion to items 2 through 5, on Friday June 27, 2008 and continuing for 120 days, all microbiological samples collected by Nebraska Beef will be submitted for pathogen testing to our outside contractor Our contract laboratory has immediately implemented the of testing utilizing samples. This test is considered by the industry to be a more sensitive test than the method, which was previously used. We feel that the utilization of outside laboratories and a more sensitive testing method will provide the agency with sufficient confidence in the testing methodology performance of Nebraska Beef's food products (See Attachment 1).

(6) Prior to getting the Certificate of Analysis (COA) results, Nebraska Beef produced and on 6/19/08 shipped adulterated product into commerce which was ground by establishment 4215 (Non-compliance w/ 9 CFR 417.5 (c)).

As stated in the text of the NOIE, Nebraska Beef shipped 7 combos of beef trimmings to rior to them receiving a copy of the COA.

Nebraska Beef normally ships all beef trimmings intended for non-intact use to customer, Since is located in an operating we always tested and held

the product within our facility. As standard in our process, we sign a pre-shipment review once all critical control points have been completed for a specific lot of production. We had previously never considered the product "shipped", only that the critical control points had been met. However, in this isolated incident the particular product was purchased by a new customer in which we custom slaughter, process, pack, and ship. Since the incident, our company has written and implemented a procedure regardless of the customer (See Attachment 2).

(7) By not properly implementing the pre-shipment review, you lost control of the product and were not able to take corrective actions including the proper disposition of product (Non-compliance w/ 9 CFR 417.3).

As mentioned previously above, our normal policy of holding product until test results were received were waived on this one occasion when the customer assured us that they just wanted the product at their facility so they could start the process as quickly as possible, once the results were received. Our company was assured more than once that the seal would not be broken nor would the product be removed from the trailer until they had received word from us stating the product was confirmed negative for *E.coli* 0157:H7. We denied their request several times during the day until it was finally determined that they would honor our seal and await our test results. Nebraska Beef always believed we still had control of the product as the truck driver had also indicated that he would wait for a proper release from us. However, our customer apparently did not perceive that waiting for the COA was a necessity to grind the product. This started the chain of events that lead to positive product being ground, then loaded back on a trailer, and shipped to a "cooker" in all without our knowledge or approval. As the agency is aware, the product ended up at where it is presently under FSIS Retention. We have a letter from the company that states it will notify (our customer) once lethality has been achieved. In turn, will notify us so we can close out our corrective action record. As stated in #6 above, we have immediately written and implemented a regardless of the customer (Attachment 3)

(8) In light of 19 combos in the month of June 2008, that have tested positive by an outside lab, you have not re-assessed your hazard analysis or HACCP plan and at this point cannot support the decisions made in your hazard analysis that CCP 3B is reducing or preventing *E. coli* O157:H7 from occurring (Noncompliance w/ 9 CFR 417.4 (a) (3), 417.4 (b), 417.5 (a) (2).

(9) Because you have not been able to support the decisions you made about the testing methodology used in your in-house lab, the results produced from this testing do not adequately verify and in fact do not give you or us any assurance that your system is working as designed, in light of the test results obtained by the outside lab (Non-compliance w/ 9 CFR 417.2 (a)(c) & 417.5(a).

s.(b)(4)

To help clarify our reassessment process regarding this particular issue, we would like to chronologically explain our thought process and subsequent actions;

On June 9, 12, and 17 of 2008, our company was notified by FSIS that our beef products had been implicated as a supplier in ground beef product that tested positive for *E. coli* O157:H7. Material from our establishment was not the only raw material used in the production of these products. After each notification, our quality control department reviewed all records associated with the production dates supplied by FSIS and no deficiencies were found. Because we considered this record review outside the scope of the regulatory mandate relating to Reassessment (417.4), no record of these reviews were documented.

On June 18, 2008, our company was again notified by FSIS that our beef products had been implicated as a supplier in ground beef product that tested positive for *E. coli* O157:H7. Material from our establishment was not the only raw material used in the production of these products. At this time, our company made a decision to reassess both our HACCP programs, but because this reassessment was in progress, no entry was made in our "HACCP Changes Page," which identifies reassessments completed. It was our understanding that the record should reflect the reassessment results when decisions are finalized, not while they are in progress.

While our reassessment is still in progress, significant changes have been made to our process. In an effort to provide support for those actions, and known future actions, we are providing the following information;

1. On June 21, 2008, we began t
   records available upon request (See Attachment 4).
2. On June 25, 2008
   -work completed on 6/25/08 (See Attachment 5).
3. On June 26, 2008, work orders were submitted
   work completed on 6/25/08 (See Attachment 5).
4. Sometime in July, vill visit our establishment to conduct an audit of our rogram (specific date to be determined).
5. Effective July 5, 2008, the line speed has been reduced to a maximum of head per hour (based on the for a minimum of 30 days but not until such time as Nebraska beef microbiological testing indicates all operations are under control. When the decision to increase line speed above is made, a repeat of

our comprehensive assessment of sanitary conditions in our slaughter process to determine effectiveness at the higher line speed.

6. On Sunday July 6, 2008, our sanitation crew will conduct an intensified sanitation clean-up of our fabrication department using different sanitizers than we presently use (See Attachment 6).
7. [redacted] providing ongoing feedback and recommendations so we can react appropriately (See Attachment 7).
8. [redacted] begin on July 8, 2008. During the study, I [redacted] ill be providing ongoing feedback and recommendations so we can react accordingly (See Attachment 8).
9. Nebraska beef has increased its testing of trim t[redacted] This higher sampling plan is intended to increase the probability of finding the organism if it is present (See Attachment 9).
10. We have revised our [redacted] rocedures to include a provision which states [redacted] We will begin the analysis of the data beginning after 30 days of collection (See Attachment 3).
11. Our HACCP team has developed a protocol for a comprehensive assessment of sanitary conditions in our slaughter process which began on Saturday July 5, 2008 (See Attachment 10).

Next, on June 25, 2008, we were notified by I [redacted] of the 19 combos in question. Again, because we were in the process of reassessing both HACCP programs with no finalized decisions, no documentation was made to the "HACCP Changes Page."

In conclusion, we are taking the agency's findings very seriously and perceive them as a way to further strengthen our food safety program. Therefore, effectively immediately, Nebraska Beef has instituted a reassessment procedure whereby all decisions causing us to review any part of our HACCP program are documented on our "HACCP Changes Page," including notations of reassessments in progress. As an example, because we started reassessing all of the aforementioned issues on June 18, 2008, and have completed partial segments of the reassessment, we have provided a copy of our most recent "HACCP Changes Page" which indicates our present reassessment is in progress (See Attachment 11).

Nebraska Beef believes the information and enclosures demonstrate the commitment of our company to food safety and continuing improvement.

If you have any questions please contact my office at 402-733-0456.

Bill Hughes
President
Nebraska Beef

Attachment 1

Attachment 2

Attachment 3

Attachment 4

Attachment 5

Attachment 6

Attachment 7

Attachment 8

Attachment 9

Attachment 10

Attachment 11

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 21

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-21

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

☑ COPY
☐ ORIGINAL

1. DESCRIPTION OF EVIDENCE

E-mail request from [redacted] of Nebraska Beef requesting that the statement in the [redacted] procedure submitted on 7/10/2008, be recognized as the one that will be implemented during the verification period. Revised [redacted] Procedure also included.

2. EVIDENCE OBTAINED FROM (Name, address, etc.)

Nebraska Beef, Est 19336
4501 S. 36th Street
Omaha, Ne 68107

3. NAME OF PERSON OBTAINING EVIDENCE

[redacted]

4. TITLE

Enforcement Investigations Analysis Officer

5. BADGE NO.

6. DATE EVIDENCE OBTAINED

07/10/2008

7. LOCATION OF ORIGINAL(S) (If not attached)

USDA FSIS
Des Moines District Office
210 Walnut Street, Suite 985
Des Moines, IA 50309

8. EXHIBIT NO. 21

From: Sprouls, Dawn
Sent: Thursday, July 10, 2008 7:44 AM
To:
Cc:
Subject: FW: NOIE Deferral

Attachments: PROCEDURE.doc

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

Request from NB on the program.

-----Original Message-----
From: [mailto: @nebraska-beef.com]
Sent: Thursday, July 10, 2008 8:41 AM
To: Sprouls, Dawn
Subject: Re: NOIE Deferral

Good Morning Dr. Sprouls

On July 8, 2008, we submitted a revised response to our Action Plan which clarified several further actions we plan to implement in light of the NOIE.
One clarification we submitted had to do with our procedure
In that attached procedure, we stated that, the lots tested have a positive (for E.coli 0157:H7) result, in the paragrapn above."

In looking at both our cover letter and the Deferral, it states, are positive for E. coli O15:H7, the

With your permission, we would like to formally request that the statement in the attached procedure be the one recognized by the agency as the one we will implement.
For example, if result in a positive, we would take action on those lots but not the others.
If tested positive, we would take action on

We apologize for any confusion but would greatly appreciate your consideration on this matter.

Respectfully,

Food Safety Director
Nebraska Beef Ltd
4501 S. 36th Street
Omaha, NE 68107
402-733-0415
402-733-1302 (fax)

EXHIBIT SHEET FOR SCANNING

OCIO (05/03/2005)

EXHIBIT NUMBER: 22

EXHIBIT ALPHA:

REPORT NUMBER: 25-08-N008

25-08-N008-22

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

s.(b)(4)
s.(b)(6)
s.(b)(7)(C)

☑ COPY ☐ ORIGINAL	1. DESCRIPTION OF EVIDENCE Letter from District Manager Dr. Dawn Sprouls to [redacted] Nebraska Beef Food Safety Director, accepting the revised [redacted] as the procedures to be implemented during the verification and revised Verification Plan, dated 7/10/2008.

2. EVIDENCE OBTAINED FROM (Name, address, etc.) USDA FSIS Des Moines District Office 210 Walnut Street, Suite 985 Des Moines, IA 50309	3. NAME OF PERSON OBTAINING EVIDENCE [redacted] 4. TITLE Enforcement Investigations Analysis Officer 5. BADGE NO. 6. DATE EVIDENCE OBTAINED 07/10/2008

7. LOCATION OF ORIGINAL(S) (If not attached)

Nebraska Beef, Est 19336
4501 S. 36th Street
Omaha, Ne 68107

8. EXHIBIT NO. 22

United States Department of Agriculture
Food Safety and Inspection Service
Field Operations
Des Moines District Office
Federal Building
210 Walnut, Room 985
Des Moines, IA 50309-2123

7/10/2008

s.(b)(4)
s.(b)(6)
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HAND DELIVERED

Food Safety Director
Nebraska Beef, Ltd. Est. 19336
4501 S. 36th Street
Omaha, NE 68144

The Des Moines District office has reviewed your request to change the action level where Nebraska Beef

You are proposing when more than are found positive for *E. coli* O157:H7 instead of as originally submitted, the You gave the example that of the lots were found positive. you would take action on those lots but not the others found negative. You go on to say that if

We have found this to be acceptable. We will revise the Verification Plan dated 7/9/08 to reflect the change and a copy will be made available to you by

If there are any other questions, you may contact at 402-829-

Sincerely,

Dr. Dawn Sprouls
District Manager
Des Moines District

A0002222_169-000000

Verification Plan – 19336 M

Revised July 10, 2008

9 CFR 416.17 identifies FSIS responsibilities for verifying the adequacy and effectiveness of Sanitation SOPs and procedures. 9 CFR 417.8 identifies FSIS responsibilities for verifying the adequacy of Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) plans. This must be accomplished by determining that the Nebraska Beef, Ltd. SSOP and HACCP plans meet the requirements of this part and all other applicable regulations. Verification activities need to focus on how is controlling the hazards and whether such controls have a scientific or technical basis. This verification includes review of the SSOP and HACCP plans and the daily records, and/or direct observation of its implementation of these plans.

Basic compliance checks for SSOP and HACCP should be performed as scheduled tasks during the deferral period. These procedures are to be used to verify the Nebraska Beef, Ltd. compliance with regulatory requirements. Any noncompliance found while performing a HACCP 01 task should lead to inspection personnel performing the appropriate 02 procedure.

During the time of deferral, any proposed changes to the Nebraska Beef, Ltd. HACCP plan must be reviewed by the Des Moines District Office prior to implementation.

REMEMBER TO DOCUMENT ALL PERTINENT DATES AND TIME OF VERIFICATION ACTIVITIES PERFORMED IN THE INSPECTION REMARKS SECTION.

Issue/Action	Regulation	ISP Code	Inspection Remarks	NR#
Basic SSOP Compliance Checks should be done upon start of this verification plan.		01A01		
Nebraska Beef has instituted a reassessment procedure where by all decisions causing review of any part of the HACCP plan will be documented on a "HACCP Changes Page"	§417.4(a)(3)	03C01		

s.(b)(4)

Issue/Action	Regulation	ISP Code	Inspection Remarks	NR#
Nebraska Beef has chosen to	§417.5(a)(1)	03C01 & 03C02		
Nebraska Beef, as of 06/26/08 has chosen to have	§417.5(a)(1)	03C01 & 03C02		
Nebraska Beef has implemented a	§417.5(a)(1)	03C01 & 03C02		
Nebraska Beef has implemented a	§417.5(c) & §417.3(b)	03C01 & 03C02		
Nebraska Beef has	§325.10	03C01 & 03C02		

When more than of the lots are found positive, you will	§417.4(a)(3)	03C01 & 03C02		
Nebraska Beef has developed and initiated a	§417.(a)(2)	03C01 & 03C02		
Nebraska Beef has developed and initiated a	§417.(a)(2)	03C01 & 03C02		
Nebraska Beef has developed a This would follow Attachment 10 proffered by the Nebraska Beef.	§416.13(c) & §416.14	01C01 & 01C02		
Nebraska Beef has based on process control, additional evaluations will be conducted for process control.	§416.13(c) & §416.14	01C01 & 01C02		

These procedures are to be used to verify compliance with regulatory requirements. Any noncompliance found while performing a HACCP 01 task should lead to inspection personnel performing the appropriate 02 procedure.

Using this VP will allow FSIS to evaluate that the establishment is implementing their proposed plan until it can be determined whether the plan is effective. The District Manager (DM) will make a decision on the adequacy of the preventive action as soon as sufficient information becomes available. If, at any time, during the period of deferral, the establishment fails to adhere to the proposed action plan, and the DM determines that an enforcement action is warranted, the DM will instruct the IIC to either impose a withholding action or effect the suspension in accordance with 9 CFR 500. The DM will immediately notify the establishment management of this decision and the basis for it in accordance with § 500.5.