



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

DEC 20 2002

Mr. Robert M. Houston
Chief Veterinary Officer
Department of Agriculture and Rural Development
Veterinary Service
Dundonald House, Upper Newtownards Road
Belfast BT4 3SB
Northern Ireland

Dear Mr. Houston:

Enclosed is a copy of the final report of the Food Safety and Inspection Service (FSIS) August 2-7, 2002, audit of Northern Ireland's meat inspection system. We received your letter dated December 3, 2002, providing detailed comments to our draft final report of the same audit. This letter has been incorporated into the enclosed report as Attachment "G."

We have thoroughly reviewed your comments and, where appropriate, made minor revisions to the audit report to clarify the findings of the FSIS auditor. We appreciate your feedback, as we believe it is this type of dialogue that enhances the equivalence of our food regulatory systems. In reviewing your comments, I recognize there is a difference of opinion between the FSIS auditor and the Government of Northern Ireland regarding the validity of some of the FSIS audit findings. In that regard, we fully support our auditor's findings and appreciate the Government of Northern Ireland concurring with the auditor's conclusion regarding the non-relisting of Northern Ireland's Establishment 9014 to export meat to the United States.

In regard to FSIS' decision not to accept further establishment certifications by the Government of Northern Ireland until we conduct a full on-site system audit of your meat inspection system, we accept your request, as stated in your December 3 letter, to further discuss this issue. We will arrange through our embassy in London a teleconference with you in early January 2003. Notwithstanding our acceptance, we restate our concerns about the Government of Northern Ireland to adequately certify establishments as meeting U.S. import requirements; based on the results of this audit.

As you know, in a June 18, 2002, letter, the Government of Northern Ireland requested FSIS to conduct an on-site audit of Establishment 9014. In that letter, Mr. R. M. McCracken, Chief Veterinary Officer, Department of Agriculture and Rural Development, inquired whether the FSIS auditor, who would be conducting a system audit of the Republic of Ireland's meat inspection system in mid-July, would have the opportunity to travel to Northern Ireland and audit Establishment 9014. As I indicated to you in my letter of October 11, 2002, FSIS does not usually audit a foreign inspection system consisting only of establishment reviews. Nonetheless, we agreed to review this one establishment to accommodate the Government of Northern Ireland considering the circumstances under which it was facing.

FSIS audits of a foreign country's food regulatory system are taken very seriously by our Agency, the U.S. Department of Agriculture, and U.S. Congress as FSIS has the responsibility to ensure that meat, poultry, and egg products imported into the United States are safe and wholesome as domestic products. Again, as I advised you in my October 11 letter, FSIS system audits focus on two essential components of safe food production that must be present in a foreign food regulatory system; *process controls* of a foreign establishment, and *oversight* by the foreign government to verify the effectiveness of industry process controls, detect noncompliance, and provide the necessary enforcement. Countries eligible to export meat, poultry, or egg products to the United States must meet this fundamental level of protection to maintain equivalence. If equivalence is not maintained, FSIS can immediately suspend a country from importing its products into the United States.

Although FSIS agreed to audit Establishment 9014, it did not lessen the oversight responsibility by the Government of Northern Ireland to make certain that this establishment is executing adequate process controls of safe food production. Once the Government of Northern Ireland requested FSIS to audit Establishment 9014, it is our supposition that this establishment's process controls had been verified by the Government of Northern Ireland as meeting all U.S. import requirements.

However, the FSIS audit indicated otherwise, and both FSIS and the Government of Northern Ireland agreed that Establishment 9014 should not be relisted to export meat to the United States. Unfortunately, the audit finding of inadequate process controls in Establishment 9014 also highlighted the possibility of a fundamental weakness in the Government of Northern Ireland's oversight responsibility. FSIS could have suspended Northern Ireland from importing its meat products into the United States, but decided to take the lesser action of accepting no further establishment certifications by the Government of Northern Ireland until FSIS conducts a full system audit of Northern Ireland's meat inspection system.

We appreciate your understanding of FSIS' decision and will continue to work collaboratively with the Government of Northern Ireland to ensure that Northern Ireland maintains eligibility to export meat products to the United States and regains its authorization to certify additional establishments for export to the United States. I look forward to our January 2003 teleconference.

Sincerely,



Sally Stratmoen
Acting Director
Equivalence Staff
Office of International Affairs

Enclosure

- cc. Peter Kurz, Minister Counselor, American Embassy, London
James Hughes, Agricultural Attaché, British Embassy, Washington, DC
Joerg Niederberger, Agric./Consumer Affairs, EU Mission to the U.S.
Norval Francis, Minister-Counselor, U.S. Mission to the EU in Brussels
John Wilson, FAS Area Officer
Dave Young, FAS
Amy Winton, State Department
Linda Swacina, Associate Administrator, FSIS
Donald Smart, Director, Review Staff, FSIS
Karen Stuck, Acting Assistant Deputy Administrator, OIA, FSIS
Sally Stratmoen, Acting Director, ES, OIA, FSIS
Clark Danford, Acting Director, IES, OIA, FSIS
Steve McDermott, ES, OIA, FSIS
Country File (FY 2002 Audit)



AUDIT REPORT FOR NORTHERN IRELAND

AUGUST 2 THROUGH AUGUST 7, 2002

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Northern Ireland's meat inspection system from August 2 through August 7, 2002. This audit consisted solely of reviewing Est. 9014, which was not certified to export to the United States. This establishment requested delistment just prior to the last FSIS audit of Northern Ireland's meat inspection system. FSIS advised the Northern Ireland government that the establishment would have to pass an acceptable review by FSIS before it could be relisted to export meat to the United States. Est. 9014 was conducting processing operations.

The last audit of the Northern Ireland meat inspection system was conducted in November 2001. At that time, no establishments were certified by the Northern Ireland government to export to the United States. During the previous audit, which occurred in April/May 2000, the FSIS auditor reviewed Est. 9014 and designated it as marginal/re-review. The major deficiencies reported during the April/May 2000 audit were as follows:

1. Several instances of inadequate cleaning of product-contact equipment prior to pre-operational sanitation inspection were observed.
2. Numerous examples of deteriorated product-contact equipment, in need of repair or replacement, were found to be in use.
3. No formal pre-shipment reviews were being conducted, as required.
4. The system in effect did not ensure timely re-sampling of water for portability in the event of noncompliant water samples.
5. Documentation of operational sanitation activities in the establishment was in need of improvement.

Importation of beef or beef products was not allowed at the time of this recent audit due to the presence of Bovine Spongiform Encephalopathy (BSE) in the United Kingdom.

From January 1 through June 2, 2002, Northern Ireland establishments did not export any product to the United States.

PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with Northern Ireland national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the inspection office of the meat product establishment during the on-site visit. The third was conducted by an on-site visit to the establishment. There were no visits to laboratories, performing analytical testing of field samples for the national residue testing program, and culturing field samples for the presence of microbiological contamination with *Salmonella*.

Northern Ireland's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems, and (5) enforcement controls.

During the on-site establishment visit, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials. This establishment was voluntarily delisted prior to the last FSIS audit.

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were not found to be in place in the one establishment audited (Est. 9014) and this establishment was found to be unacceptable. Details of audit findings, including compliance with HACCP, and SSOPs are discussed later in this report.

Entrance Meeting

On August 2, an entrance meeting was held in the Belfast offices of the Department of Agriculture and Rural Development for Northern Ireland (DARDNI), and was attended by Mr. Bert Houston, Chief Veterinary Officer; Dr. George McIlroy, Deputy Chief Veterinary Officer; Mr. Colin Hart, Supervisory Veterinary Officer; Mr. Jean Wales, Divisional Veterinary Officer; Mr. Tom Coulter, Divisional Veterinary Officer, Meat and Meat Hygiene, Mr. Robert Huey, Divisional Veterinary Officer, APHIS; and Dr. Oto Urban, International Audit Staff Officer, FSIS. Topics of discussion included the following:

1. The audit itinerary and lodging accommodations.

2. Discussion on the data-collection instruments that would be used during the establishment audit for SSOPs and the HACCP program.
3. Updating of the country profile information for Northern Ireland.
4. Information on the country disease status.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of the Northern Ireland's inspection system in November 2001, except Mr. Bert Houston became the Chief Veterinary Officer.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audit of the establishment be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted a review of inspection system documents pertaining to the establishment listed for the on-site review. This record review was conducted at the inspection service office in the establishment. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Food safety initiatives such as SSOPs, and HACCP programs.
- Sanitation, slaughter and processing inspection procedures and standards.
- Enforcement records.

The following concerns arose as a result the examination of these documents:

1. The SSOP documents did not accurately reflect the conditions observed in the establishment.
2. The SSOP records were not descriptive enough of some deficiencies observed on the pre-operational sanitation and preventive action was not included. Only general statements were included, such as "dirty floor."
3. The HACCP plan did not contain some of the requirements for verification, corrective action, or pre-shipment review.

Government Oversight

All inspection veterinarians and inspectors in the establishment assigned to this establishment were full-time DARDNI employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

This audit consisted solely of reviewing Est. 9014, which was not certified at this time to export to the United States. This establishment requested delisting just prior to the last FSIS audit of Northern Ireland's meat inspection system. FSIS advised the Northern Ireland government that the establishment would have to pass an acceptable review by FSIS before it could be relisted to export meat to the United States. Est. 9014 was conducting processing operations for Northern Ireland domestic only.

Laboratory Audits

No laboratory audits were conducted during this visit.

Establishment Operations by Establishment Number

The following operations were being conducted in this one establishment:

Pork boning and processing establishment (Est. 9014)

SANITATION CONTROLS

Based on the on-site audit of Establishment 9014, Northern Ireland's inspection system had controls in place for adequate light, ventilation, plumbing/sewage, and water supply.

Sanitation Standard Operating Procedures (SSOPs)

Establishment 9014 was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs did not meet the FSIS on-going requirements. The following deficiencies were observed:

1. Repeated deficiencies of cleaning the equipment (meat scraps and fat) were observed during the pre-operational sanitation.

2. The SSOP documents did not accurately reflect the conditions observed in the establishment.
3. The SSOP records were not descriptive enough of some deficiencies observed on the pre-operational sanitation and preventive action was not included.
4. Pieces or particles, possibly rust from the overhead ventilation unit, were observed on the boning table. Although the contamination of the belt was corrected immediately, the source of the contamination was not positively identified and corrected at the time of this audit.

Establishment Grounds and Pest Control

1. The offal area requires upgrading. This issue was going to be resolved by the inspection service officials.
2. Moths and flies were observed inside the establishment. There was a commitment from the inspection service to correct this deficiency.

Establishment Construction/Maintenance

1. Two doors were not completely closed to the outside elements because of structural damages. This deficiency was scheduled for correction by the establishment and the inspection service.
2. A rusty air fan was observed over the boning table. This was scheduled for correction by the establishment.

Dressing Rooms/Lavatories

A waste receptacle was missing next to a lavatory in the shipping area. This deficiency was corrected immediately by the establishment management.

Equipment and Utensils

1. Dirty trays were observed in the boning room during the pre-operational sanitation. The establishment officials corrected this deficiency.
2. A conveyor belt with deep knife cuts and holes was being used with exposed product. This belt was placed in service after the inspection service official requested replacement of a conveyor belt with more extreme holes and cuts. It is unknown whether the inspection service official had observed the replacement belt in use prior to the time of this audit.

Employee Hygiene

Working clothes were observed in the street clothes dressing room. Working and street clothes should be separated from each other to prevent contamination. This deficiency was corrected immediately by the establishment officials.

ANIMAL DISEASE CONTROLS

Northern Ireland's meat inspection system had controls in place to ensure adequate disposition, condemned and restricted product control, and procedures for the sanitary handling of returned and rework product.

Tuberculosis and Brucellosis are present in this country, but Northern Ireland has been declared free of Foot-and-Mouth Disease since January 10, 2002.

There were no reports of outbreaks of animal diseases with public-health significance since the previous U.S. audit. There was a system of full identification and tracking of movement of all bovines from birth to death called Animal and Public health Information System. Information was also being provided to DARDNI by veterinarians at all barns and when doing tuberculin testing.

RESIDUE CONTROLS

Northern Ireland's National Residue Testing Plan for 2002 was being followed and on schedule. The Northern Ireland inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

SLAUGHTER/PROCESSING CONTROLS

The meat inspection system of Northern Ireland had controls in place to ensure adequate pre-processing trim, processed product reinspection, identification of ingredients, packaging materials, laboratory confirmation, label approvals, inspector monitoring, processing equipment, and post-processing handling.

HACCP Implementation

Establishments approved to export meat products to the United States are required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. The HACCP system was evaluated according to the criteria employed in the U.S. domestic

inspection program. The data collection instrument used to evaluate the HACCP program accompanies this report (Attachment B).

The FSIS auditor determined that the HACCP program in Establishment 9014 did not meet the FSIS regulatory implementation requirements. The findings were:

1. The HACCP plan did not include the verification requirements for calibration of process monitoring instruments, direct observation of monitoring activities and corrective actions, and reviews of records.
2. Corrective action requirements for identifying and eliminating the cause of the deviation were not fully addressed in the establishment's HACCP plan to ensure that the CCP is under control.
3. Pre-shipment review was conducted but did not clearly indicate whether all critical limits were met, corrective action was taken, and proper disposition of product was performed if deviation occurred.

Testing for Generic *E. coli*

Establishment 9014 was not required to meet the basic FSIS regulatory requirements for generic *E. coli* testing because it does not slaughter animals for export to the United States. This establishment did have adequate controls in place to prevent meat products intended for domestic consumption from being commingled with products eligible for export to the United States.

ENFORCEMENT CONTROLS

Inspection System Controls

The DARDNI inspection system controls [control of inspection samples, boneless meat reinspection, shipment security including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls, and the importation of only eligible meat products from other counties for further processing] were not found to be in place based on deficiencies regarding the establishment's process controls and the following deficiencies:

1. Inedible product was not denatured and stored under lock.
2. There was no timely response to some of the sanitary and enforcement problems indicated by the inspection officials from establishment representatives (i.e., rusty fan on the refrigeration unit, cuts on the conveyor belt).

Testing for *Salmonella* Species

Establishment 9014 was not required to meet the basic FSIS regulatory requirements for *Salmonella* testing since this establishment did not slaughter animals or produced ground meat for export to the United States.

Species Verification Testing

At the time of this audit, Northern Ireland was not exempt from the species verification-testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

There were two internal reviewers designated as Regional Veterinary Managers assigned to Northern Ireland's meat inspection system. Both were veterinarians with at least five years of experience.

In general, establishments certified to export to the United States are being reviewed once per month by one of the internal reviewers. DARDNI does not announce these reviews to the establishment management, but do announce them to its inspection personnel.

Copies of each report generated by the internal reviewers are maintained at the establishment and at DARDNI headquarters. The internal reviewer also keeps a copy.

Enforcement Activities

Northern Ireland had developed a full system of enforcement capability, which was documented in an information packet entitled "Veterinary Services Prosecutions Policy", which was available to the general public. This report contained summaries of official DADRNI enforcement activities and actions.

Exit Meetings.

An exit meeting was conducted in on August 7. The participants included Mr. Colin Hart, Supervisory Veterinary Officer; Mr. Tom Coulter, Divisional Veterinary Officer; Mr. Henry Flynn, Veterinary Officer, Mr.; Robert Huey, Divisional Veterinary Officer, APHIS; and Dr. Oto Urban, International Audit Staff Officer, FSIS.

The following was discussed:

Deficiencies observed during the establishment visit including inadequate SSOP implementation and documentation, pest control, HACCP implementation and documentation, and denaturing of inedible product.

CONCLUSION

FSIS conducted a special audit at the request of the Government of Northern Ireland. The audit consisted of reviewing only Establishment 9014, which was not certified at the time of this audit to export meat to the United States. FSIS has determined that this establishment was not in total compliance with U.S. import requirements. Based on this audit, the inspection system of Northern Ireland was found to have effective controls in some areas to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. However, the inspection system was found to have ineffective controls regarding other inspection areas including deficiencies in SSOP and HACCP implementation

Dr. Oto Urban
International Audit Staff Officer

(Signed) Dr. Oto Urban

ATTACHMENTS

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing (*not applicable*)
- D. Data collection instrument for *Salmonella* testing (*not applicable*)
- E. Laboratory audit form (*not applicable*)
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1. Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. identified	7. Documentation done daily	8. Dated and signed
9014	√	√	√	√	√	√	no	√

Data Collection Instrument for HACCP Programs

One establishment approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. procedures	10. Adequate documentation	11. Dated and signed	12. Pre-shipment doc. review
9014	√	√	√	√	√	√	no	no	√	√	√	no

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Eurostock Foods Newry Ltd. Greenbank Industry Establishment	2. AUDIT DATE 8-5-02	3. ESTABLISHMENT NO. 9014	4. NAME OF COUNTRY Northern Ireland
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X	37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X	38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	X
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	X
20. Corrective action written in HACCP plan.	X	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

NORTHERN IRELAND – Est. 9014

- 10. Deficiencies of cleaning of product areas were observed in the boning room. Repeated deficiencies of cleaning the equipment (meat scraps and fat) were observed during the pre-operational sanitation.
- 10/11. Pieces of particles possibly rust from the overhead rusty refrigeration unit, which was not properly maintained, was observed on the boning table. This deficiency (cleaning of the boning table) was corrected immediately by the establishment management.
- 12/13. The SSOP documents did not accurately reflect the conditions observed in the establishment (some deficiencies observed on the pre-op were not addressed in the SSOP documentation). The establishment management the inspection service promised corrective action in future cases.
- 13. The SSOP records were not descriptive enough of some deficiencies observed on the pre-operational sanitation and preventive action was not included. Only general statements were included, such as “dirty floor”. The establishment management promised corrective action in future cases.
- 14. The HACCP plan did not respond to the verification requirements for calibration of process monitoring instruments, direct observation of monitoring activities and corrective actions and reviews of records.
- 15. Corrective action requirement were not fully responded for identifying and eliminating cause of the deviation, ensuring that CCP is under control, establishing preventive measures, and make appropriate disposition of the product.
- 22. The HACCP plan did not contain some of the requirements for verification, corrective action and pre-shipment review.
- 38. The offal area requires upgrading. Chapter III. 3.
- 38. Moth and fly observed inside of the establishment areas. The inspection service gave assurances that this deficiency will be corrected promptly. Chapter III. 3
- 39. Two doors had structural damage including holes, which were open to the outside premises. These deficiencies were scheduled for correction by the establishment. Chapter I and II.
- 39. The rusty air fan was observed over the boning table. This was scheduled for correction by the establishment. Chapter I and II.
- 44. A waste receptacle was missing next to a lavatory in the shipping area. This deficiency was corrected immediately by the establishment management. Chapter III. 3.
- 45. Dirty trays were observed in the boning room during the pre-operational sanitation. The establishment officials corrected this deficiency. Chapter II and III. .
- 45. Conveyor belt was observed with big cuts and wholes in the packaging room. This conveyor belt was asked to be repaired by the inspection service official but that has not been done at the time of the audit. Chapter II and III
- 47. Working clothes were observed in the street clothes dressing room. Working clothes and street clothes should be separated to prevent contamination. This deficiency was corrected immediately by the establishment officials. Chapter III.3.
- 51. Inedible product was not denatured and under lock, while condemned product was properly denatured and kept under lock.
- 51. There was no timely response to some of the sanitary and enforcement problems indicated by the inspection officials from establishment representatives (rusty fan on the refrigeration unit, cuts on the conveyor belt).
- 56. European Community Directives, Chapter II. 2 and Chapter III. 3.

61. NAME OF AUDITOR Dr. Oto Urban	62. AUDITOR SIGNATURE AND DATE
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Department of Agriculture and Rural Development

VETERINARY SERVICE

3 December 2002

Dear Ms Stratmoen

Thank you for your letter of 11 October, and Dr Urban's report of his audit of Eurostock Ltd (Establishment Number 9014) carried out by him during his visit to Northern Ireland from 2-7 August 2002.

I have attached a detailed reply to the points made by Dr Urban in relation to Establishment 9014, though we accept your conclusions in relation to re-listing. While the Department did formally request this audit it was not entirely of its own volition. Political representations were made through diplomatic channels in London and Dublin to support this case; and in many ways what the Department did was to facilitate an audit, bearing in mind that the USA team had already planned to be in Ireland. In any other circumstances the Department would not have facilitated such a request.

The Department's track record in this area is excellent and it had taken all reasonable steps to ensure that this plant complied with the standards expected and addressed previously identified deficiencies. While the result of this exceptional case is accepted we find it hard to accept the consequential decision to withdraw approval for pre-listing establishments. This conclusion and action comes as a considerable surprise and shock for a number of reasons. First it is at variance with previous full system audits of our Meat Hygiene systems carried out by Dr Singh during February 1999 and by Dr Bolstad during June 2000 and December 2001. Secondly as you state in your letter this was a "special audit" of an individual establishment and not a full Meat Hygiene system audit and the extrapolation of the findings to our system in general is unfair and unreasonable.

We fully believe that the authority for the Department of Agriculture and Northern Ireland and Rural Development to pre-list establishments should be maintained until the system inspection proposed for June 2003 and we request an urgent discussion about this matter before a decision is confirmed.

Yours sincerely


R M HOUSTON
Chief Veterinary Officer

ENC

Ms Sally Stratmoen
Acting Director
Equivalence Division, Office of International Affairs
USDA, Food Safety & Inspection Service
Washington DC 20250
United States of America



INVESTOR IN PEOPLE

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Telephone (028) 90 Fax (028) 90
Website: www.dardni.gov.uk

Annex A

The Government of Northern Ireland wishes to make the following comments on the report received from FSIS of Dr Urban's audit carried out in Northern Ireland during early July 2002.

Establishment audit (page 4, last line)

Establishment 9014 was conducting processing operations, but these were entirely unrelated to the SSOP and HACCP plans for the product that the establishment intended to export to the US. No product had been produced for US export since January 2001, some 18 months prior to this inspection.

Establishment Operations by Establishment number (page 4)

No fresh/frozen sausage for either home/export market was being produced in this establishment at the time of this audit.

SANITATION CONTROLS (page 4)

We note that Dr Urban reported that the deficiencies relating to water supply reported by Dr Bolstad in his audit of December 2001 had been corrected to his satisfaction.

Sanitation Standard Operating Procedures (page 4)

1. This comment relates to a piece of processing equipment that was being held in a store and that had not been in use for some time. While accepting that the equipment was not cleaned properly as it should have been if the detail of the SSOP had been followed, the SSOP stated that the equipment should be washed and sanitised again before being used. This deficiency did not therefore present any imminent risk to the hygiene of the process.
2. This relates to point 1. We fully accept that the equipment should have been washed and sanitised properly before being put into storage.
3. We disagree that the SSOP records were not descriptive enough. The statement that the floor is dirty should be adequate for an operational record. The required result is that the non-compliance is corrected, namely a floor which is clean. Further descriptive terms should not have a bearing on that outcome.
4. This comment relates to small specks of dirt observed on the cutting tables at the time of pre-sanitation checks. Our staff who were carrying out the check at the time of the audit identified the problem, uncovered the cause and as Dr Urban's report states had the non-compliance corrected immediately by the establishment management. This new hazard having now been identified a corrective action can be put in place. We believe this is how the system is supposed to work in order to prevent the risk of any contamination. We are concerned that you do not consider this to be the case especially as in attachment A, you confirm that the 'data collection instrument' addresses pre-operational sanitation adequately. In fact the only non-compliance you record

with regard to the SSOP data collection instrument is that the documentation is not completed daily. This is not an unsurprising finding given that no product for US export has been produced in the plant for 18 months.

Establishment Grounds and Pest Control (page 5)

1. As stated, our officials are aware that the offal area required upgrading and were working with the establishment prior to the audit to correct this deficiency.
2. The moth was found on the surface of the incorrectly sanitised piece of stored equipment mentioned above. It is possible that the equipment may have been removed from the store in order to access other equipment and that the moth had found its way under the machine cover before the machine was returned.

Establishment Construction/Maintenance (page 5)

The non-compliances listed relate to routine on-going maintenance which as the audit report states were scheduled for correction.

Dressing rooms/Lavatories

The waste receptacle had been moved from beside the wash-hand basin to outside the door.

Equipment and Utensils

1. The dirty trays were observed by the establishment employee during her pre-operation check. She corrected the non-compliance immediately, before action by the establishment official was necessary, demonstrating that the pre-operational check was effective.
2. The conveyor belt in question had been removed from production earlier that week by the establishment officials. It was not in use at the time of the audit and was awaiting removal from the work area for the required maintenance to be carried out. It is our view that the presence of this belt is irrelevant to this audit.

Employee Hygiene

Working clothes were observed in the street clothes dressing rooms by the establishment employee during her pre-operational check. Again she corrected this non-compliance without reference to the establishment official demonstrating that the system pre-operational checks were effective.

SLAUGHTER/PROCESSING CONTROLS (page 6)

We note that Dr Urban found that the meat inspection system of Northern Ireland had controls in place to ensure adequate pre-processing trim, processed product reinspection, identification of ingredients, packaging materials, laboratory

confirmation, label approvals, inspector monitoring, processing equipment and post-processing handling.

HACCP Implementation (page 6)

1. While accepting that the HACCP plan did not include verification requirements for calibration of process monitoring instruments and a review of records, it did include direct observation of monitoring activities and corrective actions. These requirements had been introduced by FSIS since the last review and validation had been carried out of this HACCP plan during the year 2000.
2. We accept that the corrective action requirements for identifying and eliminating the cause of the deviation were not fully addressed.
3. Dr Urban accepted during the audit that an acceptable pre-shipment review was in place but that it was not laid out as he would have liked it. We would strongly question whether this can thus be considered to be a non-compliance.

ENFORCEMENT CONTROLS (page 7)

Inspection System Controls

We note that Dr Urban found DARDNI inspection system controls were adequate to ensure that products produced by the establishment were wholesome, unadulterated and properly labelled.

The failure to denature the inedible product resulted from a DARD interpretation of the legal position that it was inappropriate to rigorously enforce a matter which is currently the subject of court proceedings at a European and national level.

2. The establishment representatives had been informed earlier in the week of the audit by officials of the corrective actions required and had undertaken to carry out the work.

These comments relate only to establishment 9014. No HQ audit of Northern Ireland's Meat Inspection System was carried out and no laboratories or other establishments were visited as would be normal practice when carrying out a system audit. I must therefore express my view that the decision made by FSIS that they will accept no further establishment certifications by the government of Northern Ireland is unwarranted.