United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

MAY 16 2002

Dr. R.M. McCracken
Chief Veterinary Officer
Department of Agriculture for Northern Ireland
Dundonald House
Upper Newtownards Road
Belfast
BT4 3SB
Northern Ireland

Dear Dr. McCracken:

Enclosed is a copy of the Final report of the Food Safety and Inspection Service (FSIS) November 28 through December 7, 2001, audit of Northern Ireland's meat inspection system. We received your March 25, 2002 letter providing comments to the draft final report. Accordingly, this letter was incorporated into the Final report as Attachment "G."

We appreciate the corrective actions taken by the Department of Agriculture and Rural Development to address the laboratory deficiencies noted during the audit. If I can provide further information regarding this audit, please contact me by telephone (202-720-3781), facsimile (202-690-4040), or email (sally.stratmoen@fsis.usda.gov). You may also contact Richard Brown by telephone (202-690-2679), facsimile (202-720-7990) or email (richard.brown@fsis.usda.gov).

Sincerely,

Richard F. Brown

/s/Sally Stratmoen, Chief
Equivalence Section
International Policy Staff
Office of Policy, Program Development
And Evaluation

Enclosure

cc: James Hughes, Agriculture Attaché, British Embassy, Washington, DC
Peter Kurz, Minister Counselor, FAS, U.S. Embassy, London
John Wilson, Area Officer, FAS
Bob Macke, FAS
Mary Revelt, Minister Counselor (Agriculture), USEU/Brussels
Gerry Keily, Counselor (Agriculture), EU Mission to the U.S., Washington, DC
Amy Winton, State Department
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Donald Smart, Dir. Review Staff, TSC, FSIS
Sally Stratmoen, Chief, ES, IPS, FSIS
Karen Stuck, Acting Director, IPS
Steve McDermott, ES, IPS, FSIS
Country File-Northern Ireland (Audit – FY 2002)

FSIS:OPPDE:IPS:ES:S.MCDERMOTT:bw:5/14/02:690-0297:05/6/02:No. Ireland Audit FY2002

United States Department of Agriculture
Food Safety And Inspection Service
Technical Service Center
Suite 300, Landmark Center
1299 Farnam Street
Omaha, NE 68102

AUDIT REPORT FOR NORTHERN IRELAND
NOVEMBER 28 THROUGH DECEMBER 7, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Northern Ireland's meat inspection system from November 28 through December 7, 2001. The management of the only establishment (9014) certified to export meat to the United States at the time this audit was planned voluntarily withdrew its eligibility for U.S. export prior to the date when it was scheduled for an on-site audit by the FSIS Auditor. The auditor was informed by the Department of Agriculture and Rural Development in Northern Ireland (DARDNI) officials that there were no plans by the establishment management to reinstate Est. 9014's certified status within the foreseeable future. The audit, therefore, was limited to visits to the laboratories conducting residue analysis and to one microbiology laboratory and discussions with Northern Ireland's meat inspection officials.

The last audit of the meat inspection system of Northern Ireland was conducted in May 2000. One establishment (9014) was certified for U.S. export at that time; it was audited on-site and was evaluated as acceptable/ re-review. The following major concerns had been identified at that time:

- The maintenance and cleaning program for product contact equipment had been found to be deficient.
- No formal pre-shipment reviews had been performed as required.
- The system in effect had not ensured timely re-sampling of water for potablilty in the event of non-compliant water samples.

Importation of beef or beef products was not allowed at the time of this audit due to the presence of Bovine Spongiform Encephalopathy (BSE) in the United Kingdom. The pork that had been used by the establishment for U.S.-eligible product had been imported from the Republic of Ireland; however, due to the confirmation of Foot-and-Mouth Disease in Ireland, Irish pork had also been under restriction since early in 2001. This restriction had been lifted within two weeks of this audit, but the establishment had exported no product to the United States since the onset of the Foot-and-Mouth Disease restrictions. There had been one further restriction: pork products were required to be processed in a dedicated establishment that received no animals from countries where Swine Vesicular Disease exists (these conditions had been fulfilled in Northern Ireland).

Beginning January 1, 2001, three establishments (9014, 9034, and 9043) were certified to export meat to the United States. Establishments 9034 and 9043 were decertified by the Northern Ireland government during September 2001. From January 1 through September 30, 2001, two establishments (9014 and 9043) exported 80,643 lbs. of cured pork and pork sausage to the United States. The only rejections at U.S. ports of entry during this period were 160 lbs. of sausage, for labeling defects.

PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with national meat inspection officials of Northern Ireland to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits. The third involved visits to the two laboratories performing analytical testing of field samples for the national residue testing program.

Program effectiveness determinations for FSIS requirements normally focus on 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 the generic *Escherichia coli (E. coli)* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species. Since no slaughter or processing establishments were certified as eligible to export to the United States at the time of this audit, Northern Ireland's inspection system was assessed by evaluating the residue controls through the visits to the laboratories and the remaining risk areas through evaluation of documents available in the central government offices and discussions with meat inspection officials.

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place. Details of the audit findings are discussed later in this report. As stated above, three major concerns had been identified during the 2000 FSIS audit:

- *The maintenance and cleaning program for product contact equipment had been found to be deficient.* Although the establishment was not visited during this new audit, since it had been delisted for U.S. export eligibility, the DARDNI meat inspection officials provided documentation that this had been corrected in a timely manner.

- *No formal pre-shipment reviews had been performed as required.* The Northern Irish meat inspection officials assured the Auditor that a formal document for pre-shipment reviews had been developed in the single establishment that had been certified for export

to the U.S. during the previous FSIS audit in May 2000 and had been implemented while product from this establishment had been eligible for the U.S. market.

- *The system in effect had not ensured timely re-sampling of water for potablilty in the event of non-compliant water samples.* An improved, more reliable system had been developed and implemented within several days of the establishment audit.

The following deficiencies were identified during this new audit (details of the findings will be discussed later in the body of this report):

Entrance Meeting

On November 28, an entrance meeting was held at the Belfast offices of the Department of Agriculture and Rural Development for Northern Ireland (DARDNI), and was attended by Dr. S. George McIlroy, MVB, MSc, PhD, MRCVS, Deputy Chief Veterinary Officer; Mr. Robert Huey, Divisional Veterinary Officer; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS, hereinafter called the Auditor. Topics of discussion included the following:

1. Considering the unusual circumstances that there were no establishment eligible to export to the United States at the time of the audit, the Auditor ensured that the meat inspection officials were aware of the standard FSIS policy that, when an establishment was delisted, for any reason, after the country had been notified by FSIS of an intention to audit the meat inspection of the country, that establishment will not be eligible for re-listing until FSIS is given the opportunity to visit the establishment on-site for an in-depth evaluation. Considering the unusual circumstances, that establishment will not be eligible for relisting until the DARDNI notifies FSIS in writing that corrective actions have taken place and FSIS is given the opportunity to visit the establishments on-site for an in-depth evaluation.

2. The Auditor provided the DARDNI officials with information regarding how to access the FSIS Quarterly Enforcement Report via the FSIS homepage, and inquired whether Northern Ireland makes similar data available to the public; the officials replied that there was, as yet, no publication of enforcement actions by DARDNI on the internet, although there were plans to offer it in the foreseeable future. Two monthly periodical publications for the U.K., one for BSE and one for a Hygiene Assessment System (HAS), were available to the general public.

3. The Auditor provided copies of the data-collection instruments that are normally used during the FSIS audits for SSOPs, HACCP program, and testing programs for *Salmonella* species and generic *E. coli*.

4. The Auditor gathered data to update the country profile for Northern Ireland.

5. The Auditor informed the DARDNI inspection officials that the draft audit report would be transmitted to them within 60 days of the country exit conference, that they would have a further 60 days from that time to evaluate the draft report and submit comments, that the comments would be incorporated into the final report, and that the final report, once a consensus had been reached on the contents, would be published on the FSIS Website.

6. The Auditor reminded the DARDNI inspection officials that the deadline for official notification of establishments eligible to export to the United States for calendar year 2002 would be on January 1, 2002.

7. The results of the previous FSIS audit of Northern Ireland's meat inspection system were reviewed.

8. Auditor informed the DARDNI inspection officials that there would be a special emphasis on compliance controls in all countries certified to export meat and/or poultry products to the United States in calendar year 2002.

Headquarters Audit

An overview of the organizational structure of Northern Ireland's inspection system was presented. The structure had been modified since the previous FSIS audit. The Northern Irish Veterinary Service was now responsible to the Department of Agriculture and Rural Development regarding health and welfare matters and to the Food Standards Agency regarding public health issues. Northern Ireland's own regional executive and advisory committee of the U.K. Food Standards Agency went into effect as of April 3, 2000, but went into full operation several months thereafter. Dr. George McIlroy had replaced Dr. Liam McNeill as one of the two Deputy Chief Veterinary Officers; the other was Dr. Bert Houston.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audit of the establishment be led by the inspection official who normally conducts the periodic reviews for compliance with U.S. specifications. The FSIS Auditor observed and evaluated the process.

The auditor conducted a review of inspection system documents at the headquarters of the inspection service. This records review focused primarily on food safety hazards and included the following:

- New directives and guidelines,
- Copies of official communications with field personnel, both in-plant and supervisory, in which U.S. requirements (including instructions to inspection personnel on how to monitor and document the plants' compliance with the requirements of SSOPs and HACCP) are conveyed,
- Supervisory visits to the previously U.S.-certified establishment,
- Animal disease status,

- Statistics on food-borne illnesses,
- Enforcement records, including examples of non-compliance records and the related forms used in case of further noncompliance (see the section on Inspection Supervision), and
- Export product inspection and control, including export certificates.

No concerns arose as a result the examination of these documents.

Government Oversight

All inspection veterinarians and inspectors in the establishment certified by Northern Ireland as eligible to export meat products to the United States were full-time Veterinary Service employees, receiving no remuneration from either industry or establishment personnel.

The DARDNI equivalent of a Noncompliance Record was a Corrective Action Request (CAR), which could cover any deficiency, from welfare through food hygiene to pet food. If a corrective action was not taken according to requirements, then legislative action would be taken through Statutory Notices according to either Deregulation (Improvement of Enforcement Procedures) (Food Safety) Order (Northern Ireland) 1996 or the Fresh Meat (Hygiene and Inspection) Regulations (Northern Ireland) 1997.

For problems not posing an immediate food-safety risk, e.g., relatively minor structural deficiencies, the first legislative step was a "Minded To" Notice, which was legally binding: this gave the management notice that an Improvement Notice would be served if the deficiency was not corrected within the specified time frame (usually 14 days). The Improvement Notice would specify an absolute time frame for correction. Failure to comply with the Improvement Notice would lead to formal court action.

In situations in which food safety issues could come into play, a Regulation Nine Notice, under the Fresh Meat (Hygiene and Inspection) Regulations (Northern Ireland) 1997, was used. This had the effect of immediately impacting on the conditions of the license to operate. Possible actions included slowing of production speed, prohibition or alteration of certain operations, and halting production. Failure to comply with a Regulation Nine Notice would result in formal court action.

There was also a provision for an Emergency Prohibition Notice, which could be employed in case of a serious imminent risk to public health. Its use had not been necessary to date.

The Veterinary Service in Northern Ireland employed, at the time of this audit, 140 Veterinary Officers, 166 Animal Health & Welfare Inspectors, 148 Meat Inspectors, 260 Administrative Staff, and (following the FMD outbreak), also 60 Import Inspectors.

Establishment Audit

One establishment (Est. 9014) had been certified to export meat and/or poultry products to the United States at the time this audit was planned; however, the management of this establishment relinquished its U.S. certification several days before it was due to be audited. Government inspection system officials stated that they clearly understood, and that the establishment management also clearly understood that, when an establishment is delisted, for any reason, after the country has been notified of an impending FSIS audit, that establishment may not be re-listed until FSIS is given the opportunity to conduct an on-site audit. Considering the unusual circumstances, that establishment will not be eligible for relisting until the DARDNI notifies FSIS in writing that corrective actions have taken place and FSIS is given the opportunity to visit the establishments on-site for an in-depth evaluation.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about intra-laboratory quality assurance procedures, including sample handling, and methodology.

The Veterinary Sciences Division Laboratory in Stormont, Belfast was audited on November 29, 2001. Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency). No deficiencies had been reported as a result of the previous FSIS audit of this laboratory on May 22, 2000.

- One deficiency was found: no intra-laboratory check samples were being performed in the hormone section of the Veterinary Sciences Division laboratory in Stormont. The intra-laboratory check sample program for hormones was, however, under development and nearing completion, and was expected to be implemented within the next several months. Positive and negative controls were run with each sample set, and the written corrective action program, employed in the event that an analyst did not get the expected results, was demonstrated. For all other classes of compounds, unknown intra-laboratory check samples were performed together with all routine field sample analyses, which were being run at least once per month.

The DARDNI Food Chemistry Analytical Unit in Belfast was audited on November 26. Effective controls were in place for sample handling and frequency, data reporting, tissue matrices for analysis, equipment operation and printouts, and recovery frequency. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency). The following concerns were identified:

- Turnaround times (the period of time between sample receipt in the laboratory and the completion of analysis) for chlorinated hydrocarbons and organophosphates ranged up to

two months. FSIS expects turnaround times of one month. Dr. Mitchell indicated he would make an effort to reduce the turnaround times.

- Standards that had expired (several expiration dates of 1999, 1998, and one of 1994 were observed) were still being used for new standard solutions. (Dr. Mitchell stated that all new standard solutions were checked, however, by mass-spectrometry for purity and stability and compared with old standard solutions before being used.) Expiration dates of the parent standards were not noted on the log sheets for the preparation of the stock solutions. This policy satisfied the written requirements of the laboratory's quality assurance program. The issue of using expired standards was also discussed at the country exit meeting; the officials at that meeting agreed that there were grounds for concern, and gave assurances that the matter would be discussed at a forthcoming general policy meeting.

- The standards books were loose-leaf, and pages were not numbered. Information on the sheets was complete, except that (1) the stock solution sheets for heavy metals lacked the countersignature of the supervisor and (2) the instrument printouts for chlorinated hydrocarbons and organophosphates lacked the signature of the operator. Dr. Mitchell agreed to correct this promptly.

NOTE: As was stated earlier, no slaughter establishment was certified as eligible to export to the United States at the time of this audit. Furthermore, no meat produced at any slaughter establishment in Northern Ireland had been exported to the U.S. since the last FSIS audit.

Establishment Operations

As stated previously, only Establishment 9014 had been certified at the time Northern Ireland was informed of the scheduled audit of its meat inspection system. The operations at this establishment were beef, pork, and lamb boning and fresh/ frozen sausage production and (not for U.S. export) pressed and sliced pork liver. No beef was exported to the U.S. due to the presence of BSE. The management of this establishment voluntarily withdrew its eligibility for U.S. export prior to the date when it was scheduled for an on-site audit by the FSIS Auditor; the establishment was therefore not visited.

SANITATION CONTROLS

No establishments were certified as eligible to export to the United States at the time of this audit. See Establishment Operations, above.

ANIMAL DISEASE CONTROLS

Since there were no establishments certified as eligible to export to the United States at the time of this audit, no products from Northern Ireland were eligible to enter the U.S. market. All pork that had been used in Est. 9014, while its products were eligible for U.S. export, had

originated at Est. 332, in the Republic of Ireland. This establishment was certified to produce product for export to the United States.

The following diseases with public-health importance had been confirmed in Northern Ireland since the previous audit in May 2000: Bovine Spongiform Encephalopathy, Foot-and-Mouth Disease (the last confirmed case was April 20, 2001), *Brucella abortus* in cattle, and *Mycobacterium bovis* in cattle.

There was a system of full identification and tracking of movement of all bovines from birth to death, called the Animal and Public Health Information System (APHIS), which replaced the Animal Health Computer in 1998. This was demonstrated for the auditor. Information was also being provided to DAFRD by veterinarians at all sale barns and when doing tuberculin testing.

RESIDUE CONTROLS

Northern Ireland's National Residue Testing Plan for 2001 was being followed, and was on schedule. The inspection system of Northern Ireland had adequate controls in place to ensure compliance with sampling and reporting procedures.

PROCESSING CONTROLS

No establishments were certified as eligible to export to the United States at the time of this audit. See Establishment Operations, above.

The inspection system of Northern Ireland had controls in place to ensure adequate laboratory confirmation, label approvals, and inspector monitoring,

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Northern Ireland's meat inspection officials assured the Auditor that a formal document for pre-shipment reviews had been developed in the single establishment that had been certified for export to the U.S. during the previous FSIS audit in May 2000 and had been implemented while product from this establishment had been eligible for the U.S. market. This had been the only HACCP deficiency identified during the previous FSIS audit.

Testing for Generic *E. coli*

Northern Ireland had adopted the FSIS regulatory requirements for *E. coli* testing, but since there were no slaughter establishments eligible to export to the U.S. at the time of this audit, testing for generic *E. coli* was not required.

ENFORCEMENT CONTROLS

Inspection System Controls

The DARDNI inspection system controls were in place and effectively capable of ensuring that products produced by establishments eligible to export to the U.S. were wholesome, unadulterated, and properly labeled. These included control of restricted product and inspection samples, processed 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 (including the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, the importation of only eligible livestock from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat or poultry products from other counties for further processing.

Testing for *Salmonella* Species

No establishments were certified as eligible to export to the United States at the time of this audit; therefore, testing for *Salmonella* species was not required. See Establishment Operations, above.

Northern Ireland had implemented the same *Salmonella* testing program, as described in the PR/HACCP final rule, and was prepared to implement the requirements in any slaughter facility which might request eligibility to export to the U.S.

Species Verification

At the time of this audit, Northern Ireland was not exempt from the species verification testing requirement. The country had the capability and had conducted the testing when an establishment was certified for US export up until the time of the Foot-and-Mouth Disease outbreak; none had been done, however, since January 2001, because of the FMD activities and the ineligibility of any product from Northern Ireland for export to the U.S. No slaughter establishments had been certified to export to the U.S. since the previous FSIS audit in May 2000.

Monthly Reviews

There were two internal reviewers; their titles were Regional Veterinary Managers. Both were veter-inarians with at least 5 years' experience in establishments, and similar time in headquarters policy positions. Both had had special instruction and ongoing training in foreign require-ments, and were being provided promptly with copies of new information by Dr. Robert Huey, Divisional Veterinary Officer, Policy Division.

The establishment that had been listed for U.S.-eligibility prior to this audit had been reviewed, by either one or the other of the two reviewers, once per month. Other meat establishments in Northern Ireland were also reviewed, but not monthly. None of the reviews of the U.S.-eligible establishments were announced to the establishment management, but some were announced to the inspection personnel (one day in advance).

One copy of each report generated by the internal reviewers was maintained on file in the establishment; one was retained by the internal reviewer, and one copy at headquarters. These records were being maintained on file for at least two years.

The internal reviewers reported their findings to Dr. Robert Huey, Divisional Veterinary Officer, Policy Division, who would, in case of serious noncompliance, pay a personal visit to the establishment the same or the next day. All U.S.-eligible product produced on the day of the unacceptable evaluation would be retained pending Dr. Huey's visit and evaluation. Dr. Huey had full authority up to an including withdrawal of U.S. certification.

Enforcement Activities

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

Exit Meeting

An exit meeting was conducted in Belfast on December 7, 2001. The participants included: Dr. S. George McIlroy, MVB, MSc, PhD, MRCVS and Mr. Robert Houston, MRCVS, Deputy Chief Veterinary Officers; Mr. Robert Huey, Divisional Veterinary Officer; and Dr. Glenn Kennedy, Head of the Chemical Surveillance Department; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS. The audit findings were discussed:

- No intra-laboratory check samples were being performed in the hormone section of the Veterinary Sciences Division Laboratory in Stormont. The intra-laboratory check sample program for hormones was, however, under development and nearing completion, and was expected to be implemented within the next several months.

- Turnaround times for chlorinated hydrocarbons and organophosphates ranged up to two months. FSIS expects turnaround times of one month. Dr. Mitchell indicated he would make an effort to reduce the turnaround times.

- Standards that had expired (several expiration dates of 1999, 1998, and one of 1994 were observed) were still being used for new standard solutions. (Dr. Mitchell stated that all new standard solutions were checked, however, by mass-spectrometry for purity and stability and compared with old standard solutions before being used.) Expiration dates of the parent standards were not noted on the log sheets for the preparation of the stock

solutions. This policy satisfied the written requirements of the laboratory's quality assurance program. The DARDNI officials agreed that there were grounds for concern, and gave assurances that the matter would be discussed at a forthcoming general policy meeting.

- The standards books were loose-leaf, and pages were not numbered. Information on the sheets was complete, except that (1) the stock solution sheets for heavy metals lacked the countersignature of the supervisor and (2) the instrument printouts for chlorinated hydrocarbons and organophosphates lacked the signature of the operator. Dr. Mitchell agreed to correct this promptly.

CONCLUSION

The inspection system of Northern Ireland was found to have effective controls to ensure that, when there are again establishments certified as eligible for export to the United States, the products would be again produced under conditions equivalent to those which FSIS requires in domestic establishments.

Dr. Gary D. Bolstad — (signed)Dr. Gary D. Bolstad
International Audit Staff Officer

ATTACHMENTS

A. Reserved for the data collection instrument for SSOPs *(not applicable for this audit)*
B. Reserved for the data collection instrument for HACCP programs *(not applicable for this audit)*
C. Reserved for the data collection instrument for *E. coli* testing *(not applicable for this audit)*
D. Reserved for the data collection instrument for *Salmonella* testing *(not applicable for this audit)*
E. Laboratory audit forms
F. Reserved for the Foreign Establishment Audit Form *(not applicable for this audit)*
G. Written Foreign Country’s Response to the Draft Final Audit Report (when it becomes available)

Attachment E

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
11/29/2001	Veterinary Services Division

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Dept. of Agriculture & Rural Development	Belfast, Northern Ireland	Stony Road, Stormont

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Gary D. Bolstad	Dr. Glenn Kennedy, Dr. Robert Huey

	REVIEW ITEMS	ITEM #	EVALUATION CODE	abc	cap	hor	des	cbd	ivm	bmz	ß-ag
	Residue Code/Name ▶										
SAMPLING PROCEDURES	Sample Handling	01		A	A	A	A	A	A	A	A
	Sampling Frequency	02		A	A	A	A	A	A	A	A
	Timely Analyses	03		A	A	A	A	A	A	A	A
	Compositing Procedure	04		O	O	O	O	O	O	O	O
	Interpret Comp Data	05		O	O	O	O	O	O	O	O
	Data Reporting	06		A	A	A	A	A	A	A	A
ANALYTICAL PROCEDURES	Acceptable Method	07		A	A	A	A	A	A	A	A
	Correct Tissue(s)	08		A	kid	urine	bile	liver	liver	liver	retina liver
	Equipment Operation	09		A	A	A	A	A	A	A	A
	Instrument Printouts	10		A	A	A	A	A	A	A	A
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11		A	A	A	A	3 ppb	A	A	A
	Recovery Frequency	12		A	A	A	A	A	A	A	A
	Percent Recovery	13		A	A	A	A	>60	80	86	60-90
	Check Sample Frequency	14		A	A	C	A	A	A	A	A
	All analyst w/Check Samples	15		A	A	C	A	A	A	A	A
	Corrective Actions	16		A	A	A	A	A	A	A	A
	International Check Samples	17		A	A	A	A	A	A	A	A
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	A	A	A	A	A	A	A	A
OTHER REVIEW		19	EVAL. CODE								
		20	EVAL. CODE								

SIGNATURE OF REVIEWER

DATE

FSIS FORM 9500-1 (9/96)

Designed on FormFlow Software

FOREIGN COUNTRY LABORATORY REVIEW *(Comment Sheet)*	REVIEW DATE	NAME OF FOREIGN LABORATORY
	11/29/2001	Veterinary Services Division

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Dept. of Agriculture & Rural Development	Belfast, Northern Ireland	Stony Road, Stormont

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Gary D. Bolstad	Dr. Glenn Kennedy, Dr. Robert Huey

RESIDUE CODES	ITEM NO.	COMMENTS
des	14-15	The intra-laboratory check sample for hormones was under development and nearing completion, and was expected to be implemented within the next several months. Positive and negative controls were run with each sample set, and the written corrective action program, employed in the event that an analyst did not get the expected results, was demonstrated.

Attachment E

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
12/6/01	DARDNI Food Chemistry Analytical Unit

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Dept. of Ag. and Rural Development (Northern Ireland)	Belfast, Northern Ireland	Newforge Lane, Belfast BT9 5PX

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Gary D. Bolstad	Dr. Robert Huey, Dr. Sam Mitchell

	REVIEW ITEMS	ITEM #	EVALUATION CODE	chc	op	hm
SAMPLING PROCEDURES	Sample Handling	01		A	A	A
	Sampling Frequency	02		A	A	A
	Timely Analyses	03		C	A	A
	Compositing Procedure	04		O	O	O
	Interpret Comp Data	05		O	O	O
	Data Reporting	06		A	A	A
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A
	Correct Tissue(s)	08		A	A	A
	Equipment Operation	09		A	A	A
	Instrument Printouts	10		A	A	A
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A	A	C
	Recovery Frequency	12		A	A	A
	Percent Recovery	13		C	A	A
	Check Sample Frequency	14		A	A	A
	All analyst w/Check Samples	15		A	A	A
	Corrective Actions	16		C	C	C
	International Check Samples	17		A	A	A
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O
OTHER REVIEW		19	EVAL. CODE	C	C	C
		20				

SIGNATURE OF REVIEWER

DATE

FOREIGN COUNTRY LABORATORY REVIEW *(Comment Sheet)*	REVIEW DATE	NAME OF FOREIGN LABORATORY
	12/6/01	DARDNI Food Chemistry Analytical Unit

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Dept. of Ag. and Rural Development (Northern Ireland)	Belfast, Northern Ireland	Newforge Lane, Belfast BT9 5PX

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Gary D. Bolstad	Dr. Robert Huey, Dr. Sam Mitchell

RESIDUE CODES	ITEM NO.	COMMENTS
CHC,OP	03	Turnaround times for chcs and ops ranged up to two months. Dr. Mitchell indicated he would make an effort to reduce the turnaround times.
HM	11	lead: 70 ppb, cadmium 10 ppb. No testing for arsenic or mercury. chc 10 ppb, op 50 ppb
CHC	13	recoveries: chc - 60-80% (FSIS expects 80%)
All	16	Documentation of corrective actions was provided, but there was very little formal written description of actions to be taken in the event that an analyst's performance did not meet expected standards.
CHC,OP	19	Standards that had expired (several expiration dates of 1999, 1998, and one of 1994 were observed) were still being used for new standard solutions. All new standard solutions were checked, however, by mass-spectrometry for purity and stability and compared with old standard solutions before being used. Expiration dates of the parent standards were not noted on the log sheets for the preparation of the stock solutions. This policy satisfied the written requirements of the laboratory's quality assurance program.
All	19	The standards books were loose-leaf, and pages were not numbered. Information on the sheets was complete, except that the stock solution sheets for heavy metals lacked the countersignature of the supervisor and the instrument printouts for chcs and ops lacked the signature of the operator. NOTE: No slaughter establishment was certified as eligible to export to the United States at the time of this audit. Furthermore, no meat produced at slaughter establishments in Northern Ireland had been exported to the U.S.

Attachment G

Department of Agriculture and Rural Development

VETERINARY SERVICE

25 March 2002

Dear Dr Stratmoen

FSIS ON-SITE AUDIT OF NORTHERN IRELAND 2001

Thank you for your letter dated 7 February 2002, with which you included a copy of the final draft report. I would wish to make the following comments on the points which you raise with regard to laboratory procedures.

No intra-laboratory check samples being performed for residue testing (hormones) at the Veterinary Sciences Division Laboratory, Stormont
I can confirm that the Chemical Surveillance Department, Veterinary Sciences Division Laboratory, Stormont, took immediate remedial action on this point and introduced a check sample programme into the hormone screening test.

Inadequate turnaround times for laboratory results for some residue compounds at the Food Chemistry Analytical Unit, Newforge Lane
The Food Chemistry Analytical Unit, Newforge Lane continues to endeavour to meet the turnaround times required by the USDA. The small numbers of samples analysed by the laboratory causes of scale and disproportionate costs associated with the quality assurance of the data. Further efforts will be made to address the issue.

Inadequate percentage of recoveries for chlorinated hydocarbons at the Food Chemistry Analytical Unit, Newforge Lane.
The percentage recoveries achieved at the Food Chemistry Analytical Unit, Newforge Lane satisfies the requirements set out in document 7826/VI/97, "Quality Control Procedures for Pesticide Residues Analysis" (Guidelines for Residues Monitoring in the European Union). The methods and procedures at the laboratory are under constant internal review.

Inadequate procedures regarding corrective actions to be taken when analyst's performance does not meet expected standards at the Food Chemistry Analytical Unit, Newforge Lane.
The Quality Manual for the Food Chemistry Analytical Unit, Newforge Lane, section 4.6 covers the corrective action to be taken in the event of non-conforming work being identified. Dr Mitchell, Head of Unit, states that this section is necessarily general in wording since all eventualities can not be predicted. The quality document has satisfied the laboratory's two accreditation bodies.

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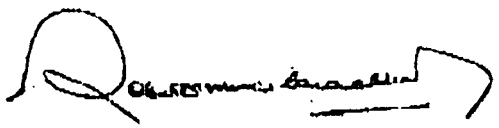
The standards books were inadequate and some standards had expired at the Food Chemistry Analytical Unit, Newforge Lane.
The Food Chemistry Analytical Unit, Newforge Lane intends to introduce a bound standards book for new standards as they are obtained. Dr Mitchell, Head of Unit, has pointed out that some of the standards held would be difficult to replace as many are no longer commercially available. The laboratory's approach is to analyse standards chromatographically both qualitatively and quantitatively prior to use has been accepted by the laboratory's external accreditation bodies.

I trust that these comments help to clarify the points which your letter raised. Should you require further information please do not hesitate to contact either me directly or my staff.

Kind regards.

Yours sincerely



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