



INCIDENT REPORT

Smithfield Beef Group – Souderton, INC., Establishment 1311
Export of Ineligible Beef to Japan Report

August 13, 2008

EXECUTIVE SUMMARY

Shipments from Smithfield Beef Group (Souderton), Establishment 1311, Souderton, PA to Japan included non-conforming products from carcasses less than 22 months age. This incident was identified at the facility by an Agricultural Marketing Service (AMS) auditor conducting a routine QSA/EV program audit on January 8, 2008. During the audit the AMS auditor found that there was a formula error in one of the computer terminals used to calculate the age of the carcasses. This error allowed a small number of carcasses less than 22 months of age to enter into the program.

Corrective actions and preventive actions have been taken to prevent the non-conforming products for export to Japan, in summary as follows:

This incident was immediately notified to their Japanese customers and representatives of the Japanese governments. The product recovery was initiated on January 11, 2008 and working with their Japanese customers and representatives of the Japanese government Smithfield Beef Group was able to recover or destroy all products that were still available.

The computer terminal used to flag age verified cattle has been reprogrammed to only flag carcasses that are less than 21 months of age on the day of slaughter. The age calculation accuracy will be tested by the IT department and verified by the Quality Assurance of the establishment.

The plant has also implemented additional verification activities as follows:

- 1) Before the kill date someone other than the person originally entering the data will verify all birth data and ear tag data entered.
- 2) Prior to fabricating any flagged carcass sides Smithfield Beef Group will verify that the ear tag and birth date data match the data shown on the associated Birth Date Certificate.
- 3) A report will be generated and reviewed by the QA manager or designee after each Japanese Export Production run and prior to shipment of product from the run.

The United States Department of Agriculture (USDA) has verified the corrective and preventive actions taken by Smithfield Beef Group Souderton.

PURPOSE

USDA has conducted a follow-up audit at operations of Smithfield Beef Group – Souderton, PA, in order to assess corrective actions initiated surrounding its inclusion in shipments to Japan of ineligible products due to the fact that some of the animals harvested did not meet the age requirement for the EV program for Japan which was discovered during a routine AMS QSA/EV audit.

BACKGROUND

The export of U.S. meat products to other countries is facilitated by the activities of three separate but interdependent entities:

- 1) the U.S. meat and poultry industry,
- 2) USDA's Food Safety and Inspection Service (FSIS), and
- 3) USDA's Agricultural Marketing Service (AMS).

The U.S. meat industry is responsible for the slaughter of healthy animals and preparation of food products that are wholesome, properly labeled, and not adulterated. In addition to meeting U.S. food safety standards, the industry must meet all requirements imposed by importing countries. Both U.S. food safety requirements and the trade requirements of importing countries must be met before a product can be certified by USDA for export from the United States.

FSIS is responsible for the inspection of meat and poultry products and the certification of products for export to other countries. FSIS Directive 9000.1, Revision 1, "Export Certification," published March 1, 2006, provides an in-depth description of these responsibilities. The primary regulatory role of FSIS is to make critical determinations that meat and poultry products are not adulterated and meet all U.S. food safety standards for sale in domestic or international commerce. This regulatory activity is complete when FSIS applies the USDA mark of inspection. However, additional verifications are necessary after inspection is complete in order for FSIS officials to execute certifications of product for export.

AMS is responsible for developing EV Program standards to ensure that establishments certified for export can meet the additional requirements of importing countries. These programs are approved and monitored by AMS for a fee, which is paid by participating establishments.

The combination of a USDA mark of inspection and an AMS EV Program provide assurance that U.S. meat and poultry products offered for export may be certified as meeting all U.S. food safety standards and importing country trade requirements.

RESULTS OF ORIGINAL AUDIT

This incident of non-conforming product was identified at the facility by an AMS auditor conducting a routine QSA/EV program audit. During the onsite audit on

January 8, 2008 the AMS auditor performed a manual computation of the documented birth date compared to the harvest date to verify the age of the animal. This indicated that some of the animals were over 20 months of age. Further review of the process revealed that Smithfield Beef Group - Souderton used a computer terminal equipped with software to calculate the age of the animals once the birth date has been entered. By entering the declared birth date the computer would compute the age and identify the animal as conforming or nonconforming in the system.

There were two computer terminals being used where the date of birth compared to the harvest date is calculated and determines if the carcass is conforming or nonconforming for the age requirement. It was found that there was a formula error in the first computer terminal. It is not known why one computer had the correct formula and the second computer did not. The formula was set to accept animals that were "less than or equal to 21 months of age" but in order to meet the age requirement for the EV for Japan program the formula should have just been set at "less than 21 months of age". This error allowed a small number of carcasses less than 22 months of age into the program. Since this was based on individual birth dates computed with harvest dates none the animals were over 22 months of age.

The formula error of the computer was during the initial programming. The verification of this process was conducted by the programmer who was operating under the knowledge that the formula was correct. The actual computer command which was in error was as follows with the "=" sign being mistakenly included in the formula:

When DateDiff (mm,@Bdate, GetDate()) <= 21 then 'Y' Else 'N'

The new corrected computer command which was immediately installed is as follows:

When DateDiff (mm, @Bdate, GetDate ()) <21 then 'Y' Else 'N'

It was determined during the original audit that documented procedures for verifying the output of the computer program were not in place. The verification process was conducted by the IT person programming the computer and was not included in the plant Quality Control verification activities.

Smithfield Beef Group – Souderton has always included Standard Operating Procedures in their QSA/EV program manual for receiving and identifying age verified cattle as well as Canadian cattle for direct slaughter. In the case of Smithfield Beef Group – Souderton this was not an alteration of the plants procedure, it was the initial use of a previously approved process and no specific onsite audit was required. During the last onsite audit prior to this incident conducted by AMS the AMS auditor indicated that they had not received any age-verified cattle at that time but the procedures were in place in the event age-verified cattle were processed.

Age-verified cattle arrive at the plant and are identified and segregated in the receiving pens. Once the age-verified cattle arrive in the bleeding the RFID tags are read and the birth date associated with the animal is entered into the computer along with the ear tag number and carcass ID. The computer identifies the carcasses that are 20 months or younger and identifies them in the system. Once the carcasses arrive at the hot scale prior to leaving the kill floor a printed hot scale ticket for conforming carcasses identifies carcasses that are age and source verified on the weight ticket. Also, a plant employee applies an "XX" to the brisket also identifying the carcass as age-verified.

Determining the cattle involved in the nonconforming product included information from two departments within the plant. The harvest floor and offal department provided information on carcasses used for processing offal products, in this case tongues, and fabrication floor provided the actual numbers of carcasses entering the cut floor that were processed for Japan.

The harvest/offal department identified 1831 cattle as being available to produce offal products, tongues. Not all tongues from these age verified carcasses were processed for Japan. It must be noted that there were only 66 boxes of tongues that contained product from nonconforming animals.

The fabrication floor processed 1569 carcasses beginning on November 24, 2007, which was the date the first nonconforming carcasses entered the fabrication floor. Of the 1831 cattle harvested only 1569 carcasses were fabricated for product destined for Japan during this time period.

On April 4, 2008 a final report from Smithfield Beef Group was submitted to AMS describing the recovery of non-conforming product shipped to Japan between November 23, 2007 and December 28, 2007. During that time frame, a total of 62,730 lbs. were shipped to Japan. Of that total amount, 46,506 lbs. were determined to be non-conforming. It was noted that any product produced during a Japanese production run that contained one or more non-conforming carcass sides was considered non-conforming.

As a result of this non-compliance, the Government of Japan requested all products (both conforming and nonconforming) from shipments between November 23, 2007 and December 28, 2007, be withdrawn from the Japanese markets by the importers.

Letters from the two importers were also provided to AMS declaring that all product available for recover and not already consumed had been recovered.

Since this incident resulted in the shipping of nonconforming product it was considered a Major nonconformance and AMS immediately suspended Smithfield-Beef Group Souderton EST 1311. Further, AMS requested corrective and preventive actions and notified Smithfield Beef Group that they would also require an onsite audit by AMS prior to lifting of the suspension of the facility as eligible to export to Japan.

CORRECTIVE ACTIONS

- To address the non-conforming product SBG - Souderton immediately notified their customers in Japan of the issue and informed them to recover all products listed on the report titled "Orders Shipped To Japan That Contain Non Conforming Product" this report was provided to both AMS and their Japan customers.
- Product that was not shipped to Japan was identified and placed on hold, not to be shipped.
- The product recovery was initiated on January 11, 2008 and working with their Japanese customers and representatives of the Japanese government SBG was able to recovery or destroy all products that were still available for recovery or destruction.
- All product recovered in the US has been declared ineligible for export to Japan and where possible diverted to domestic customers.

PREVENTIVE ACTIONS

- The computer terminal used to flag age verified cattle as less than 21 months of age based on individual animal age verification has been reprogrammed to only flag carcasses that are less than 21 months of age on the day of slaughter.
- The age calculation accuracy will be tested by their IT department and verified by QA on a continuous basis.
- Before the kill date someone other than the person originally entering the data will verify all birth data and ear tag data entered. This verification will be documented.
- After each day's kill a report will be generated that lists the carcass identification, ear tag identification, birth date entered, slaughter date, source age verification indicator and carcass age on the day of slaughter. Prior to fabricating any flagged carcass sides SBG will verify that the ear tag and birth date data on the report match the data shown on the associated Birth Date Certificate. If the birth date or ear tag identification on the report are not an exact match with the data on the Birth Date Certificate the carcass ID will be flagged as non-conforming for Japanese export production. This flag will cause the side to be rejected and railed out when it is scanned at the grading terminal. The cooler personnel will remove the "XX" marking and the source and age verified tag from the carcass and notify QA that they have removed the marking and tag.
- A report will be generated and reviewed by the QA Manager or designee after each Japanese Export Production run and prior to shipment of product from the run. The report will indicate each carcass side that as run, the age of the carcass on the day it was slaughtered, the source age verification indicator status and the mode that the fabrication scale was during the run. If the report indicates that the age of any carcasses is not less than 21 months, or the source age verified indicator isn't "Y" or the fabrication scale wasn't in the Japanese Export Production mode the entire run will be evaluated to determine if any or if the entire run was non-conforming.

- Any product found to be non-conforming will immediately be placed in quarantine, which will remove it from sales inventory. Only the QA Manager or designee is allowed to remove product from quarantine.

CONCLUSIONS

Since this non-conformance was identified by an AMS auditor during a routine QSA/EV program audit the actual cause of the non-conformance was identified in the original audit report and included in the **Results of the Original Audit Section** of this Report. AMS has conducted a thorough review of all documents involved in this non-conformance including, corrective actions submitted by Smithfield Beef Group - Souderton, recovered product summary documents, declaration from Smithfield's Japanese customers verifying that all product that could be recovered has been recovered, and results of the recent onsite AMS QSA/EV program audit as such, USDA conclusions from this incident report are as follows:

- A review of the export documents indicated that there were no specific issues with the issuance of the FSIS export certificates.
- There were no incidents similar to what was found at this Smithfield plant found in any other facilities during AMS audits.
- The finding of this non-conformance by AMS has raised the awareness of AMS and AMS auditors conducting audits at other locations. AMS will ensure that care will be taken to verify specific procedures even when the activity is not being conducted during that audit. This would include computer programs for age verification and scanning systems used for inventory control when included in the QSA/EV Program. AMS auditors will request a demonstration of all verification activities used to ensure compliance to the EV Program for Japan, even when that activity is not currently being conducted. This will be done by checking system operation capabilities even when the system is not in use. Such as, if a computer program is used to verify the age of the cattle being harvested, the AMS auditor will physically compute the age to verify the accuracy of the program, even if age verified cattle are not be harvested during that audit.
- A review of all other Smithfield Beef Group plants indicated that this incident was specific to the Smithfield Beef Group- Souderton plant and was not a companywide issue.
- AMS has determined that Smithfield Beef Group – Souderton EST 1311 has made changes in their formula used in the computer to calculate the age of the animals which will prevent the some non-conforming from reoccurring.
- New IT and Quality Control verification activities are in place that will ensure that this type of non-conformance will not be repeated.
- AMS considers Smithfield Beef Group- Souderton in compliance with all requirements of the Export Verification Program for Beef to Japan.
- It is AMS' intention to relist Smithfield Beef Group – Souderton EST 1311 as an eligible supplier to the EV program for Japan and remove the suspension.

- Upon acknowledgement of this report by the Government of Japan AMS will lift the current suspension and list Smithfield Beef Group – Souderton with an appropriate harvest date from which product produced will be eligible.
- All product produced prior to the appropriate harvest date will be considered nonconforming product and will not be eligible to be exported to Japan.