

平成20年8月15日
厚生労働省
農林水産省

対日輸出認定施設等の現地査察の実施等について

厚生労働省及び農林水産省においては、米国における対日輸出認定施設について、対日輸出条件の遵守状況等を確認するため、以下のとおり、担当者を派遣することとしましたので、お知らせします。

なお、今回の現地査察は、米国産牛肉の混載事案についての米国農務省の調査報告書が別添[※]のとおり提出されましたので、これらの施設を含めて実施することとしており、これらの施設の混載事案については、その結果を踏まえて適切に対応します。

- 注) ① スミスフィールド社サウダートン工場を出荷施設とする21か月齢の牛由来の牛肉等の混載（平成20年1月12日事案公表）
② ナショナルビーフ社カリフォルニア工場を出荷施設とする骨付きショートロインの混載（平成20年4月23日事案公表）

また、今般ひき肉の混載事例が確認されたカーギル社ドッジシティ工場についても、現地において米側の原因究明の状況等について情報収集することとしています。

1 日程

平成20年8月17日（日）～8月31日（日）（15日間）

2 出張者

厚生労働省及び農林水産省の担当者

3 査察場所

対日輸出認定施設等10か所（アリゾナ州、カリフォルニア州、カンザス州、コロラド州、ネブラスカ州及びペンシルバニア州）

現地査察の日程

月 日	チーム①	チーム②
17日(日)	成田発 デンバー(コロラド州)着	成田発 フィラデルフィア(ペンシルバニア州)着
18日(月)	スイフト社 グリーリー工場(コロラド州)	マーチョファームズプレミアムヴィール社(ペンシルバニア州) (注1)
19日(火)	同上	スミスフィールド社 サウダートン工場(ペンシルバニア州)
20日(水)	ナショナルビーフ社 カリフォルニア工場(カリフォルニア州)	同上
21日(木)	同上	【カーギル社ドッジシティ工場(カンザス州)】(注2)
22日(金)	ハリスランチ社 (カリフォルニア州)	クリークストーン社(カンザス州)
23日(土)	(移動日)	(移動日)
24日(日)	(移動日)	(移動日)
25日(月)	スミスフィールド社 トレソン工場(アリゾナ州)	カーギル社 スカイラー工場(ネブラスカ州)
26日(火)	同上	同上
27日(水)	(移動日)	タイソン社 ダコタシティ工場(ネブラスカ州)
28日(木)	スカイラークミート社 (ネブラスカ州)	同上
29日(金)	出口会合(ネブラスカ州)	出口会合(ネブラスカ州)
30日(土)	オマハ発	オマハ発
31日(日)	成田着	成田着
	5施設	5施設

(注1) 米側が新規認定を予定している施設

(注2) カーギル社ドッジシティ工場については、今回現地査察の実施はなく、現地において、今般のひき肉混載事例に関する米側の原因究明の状況等について情報収集を行うもの。

米国産牛肉（月齢条件違反）の混載事例に関する
米国農務省の調査報告書について

- 1 8月14日、米国産牛肉の混載事例（スミスフィールド社サウダートン工場（旧モイヤーパッキング工場））について、米国農務省から別紙1（英文・仮訳）の原因と改善措置に関する調査報告書が提出されました。
- 2 当該調査報告書の概要は以下のとおりです。
 - ① 今回の混載事例の原因は、
 - ア 月齢計算用のコンピュータ^(※)のうち、1台のプログラムにおいて「21か月齢未満」（「<21」）とするところが「21か月齢以下」（「≤21」）となっていたため、21か月齢の牛由来の牛肉が混入したという、プログラム作成時の人的エラーによる。
 - ※ 生年月日を入力すると自動的に月齢を計算し、日本向けに適合するものか否かを判別するコンピュータ
 - イ なお、当該プログラム利用開始前に行われた検証は、当該プログラムが正しいという認識の元で作業する施設のIT部門の担当者により行われていた。
 - ② 当該施設については改善措置として、以下を実施。
 - ア 月齢計算プログラムについて「21か月齢未満」の枝肉のみが適格である旨識別されるよう（「<21」に）再プログラムした。
 - イ 本プログラムについては、継続的に、施設のIT部門による検査及び品質保証部門による検証を実施する。
 - ウ と殺前に、データ入力者以外の担当者が生年月日を検証し、文書化する
 - エ 部分肉加工前に枝肉に由来する牛の生年月日等のデータが対日輸出適格なものであるか確認するとともに、対日処理後出荷前にも再確認する。
- 3 当該報告書を受けて、厚生労働省と農林水産省は、当該施設に対して査察を行い、その結果を踏まえ適切に対応することとします。

米国産牛肉（骨付きショートロイン）の混載事例に関する
米国農務省の調査報告書について

- 1 8月14日、米国産牛肉の混載事例（ナショナルビーフ社カリフォルニア工場）について、米国農務省から別紙2の原因と改善措置に関する調査報告書が提出されました。
- 2 当該調査報告書の概要は以下のとおりです。
 - ① ばら肉とショートロインは、それぞれ異なるラインで部分肉加工、袋詰め、箱詰めされているが、今回の事案の原因は、箱が損傷したショートロイン（20か月齢以下だが日本向けではないもの）を新しい箱に再箱詰めした際に、あらかじめ、「日本向け」ラベルが貼り付けられた箱を誤って使用したという人的エラーによる。
 - ② 当該施設については改善措置として、以下を実施。
 - ア 日本向けばら肉には、他国向けと異なる白い箱を使用。
 - イ 箱にあらかじめ「日本向け」ラベルを貼り付けることを禁止し、日本向け製品の箱詰めを行う全てのエリアに対し、品質保証部門の担当者が、ラベルの貼り付け禁止の遵守状況を1時間ごとに監査。
 - ウ 日本向けの製品は、箱詰め後封印前（箱が損傷した場合には再箱詰め後も）に全ての箱の内容と表示の同一性を確認し、箱詰めミスがチェックされるようマニュアルを改善。
 - エ 従業員のトレーニングを実施。
 - ③ 米国農務省は、全ての対日輸出施設に対し、輸出適格品のみが確実に輸出されるよう、日本向け輸出証明書発給条件に改めて注意喚起を記述。
- 3 当該報告書を受けて、厚生労働省と農林水産省は、当該施設に対して査察を行い、その結果を踏まえ適切に対応することとします。



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.

報告書

スミスフィールドビーフグループ社サウダートン工場
(旧モイヤーパッキング工場) Est. 1311
日本向け不適格牛肉輸出に関する報告書

2008年8月13日

要約

スミスフィールドビーフグループ社（ペンシルバニア州サウダートン所在）Est.1311より日本向けに輸出された製品には22ヶ月齢未満の枝肉由来の不適格製品が含まれていた。本事案は2008年1月8日に実施されたQSA/EV定期査察において、農業販売促進局（AMS）査察官により発見された。この査察において、AMS査察官は枝肉の月齢計算に使用されていたコンピューター端末の1台に計算式のエラーを発見した。このエラーによりプログラムは少数の22ヶ月齢未満の枝肉を受け入れていた。

不適格製品が日本向けに輸出されることを防止するためにとられた是正措置及び予防措置の概要は以下のとおり：

本事案はスミスフィールド社の日本の顧客及び日本政府担当者に対して迅速に通報された。製品の回収は2008年1月11日に開始され、日本側顧客と日本政府担当者との協力により、スミスフィールドビーフグループ社は回収もしくは廃棄可能であった製品はすべて回収もしくは廃棄することができた。

月齢証明牛の判別に利用されていたコンピューター端末はとさつ日に21ヶ月齢未満である枝肉を判別するよう再プログラミングされた。月齢計算の精度は施設のIT部門により検査され、QAにより検証されることとなる。

サウダートン工場は以下の追加的な確認作業についても実施する：

- 1) とさつ日前に、元のデータ入力を行った担当者とは異なるスタッフが、入力された全ての生年月日と耳標データを検証することとする。
- 2) 部分肉加工の前に、識別された枝肉のいずれについても、レポート上の耳標と生年月日のデータが当該牛の生年月日証明書に記載されている情報と合致しているか検証することとする。
- 3) 全ての日本向け処理後、その製品が出荷される前にレポートが作成され、QA マネージャーもしくはその代理人による、確認を受けることとする。

米国農務省（USDA）はスミスフィールドビーフグループ社サウダートン工場にお

いてとられた是正措置及び予防措置を検証した。

目的

USDA は AMS の QSA/EV 定期査察において確認された、とさつされた動物の一部が日本向け EV プログラムの月齢条件に合致していなかったことによる日本向け貨物への不適合製品の混入事案に対して執られた是正措置を評価するため、スミスフィールドビーフグループ社サウダートン工場（ペンシルバニア州サウダートン所在）の追加査察を行った。

背景

他国向け米国産牛肉製品の輸出品は、独立しているが相互に依存した 3 つの組織の活動により促進されている：

- 1) 米国の食肉および家畜業界
- 2) USDA 食品安全検査局 (FSIS)、及び
- 3) USDA 農業販売促進局 (AMS)

米国食肉業界は健康な動物のと畜と、健全で、適切に表示され、適正な食品の提供に関する責任を負っている。米国食品安全基準への適合に加え、業界は輸入国によって課される全ての条件を満たさなければならない。米国からの製品の輸出が米国農務省により認可されることが可能となる以前に、米国食品安全条件及び輸入国の貿易条件の双方に適合しなければならない。

FSIS は食肉及び食鳥製品の検査と他国への製品の輸出証明についての責務を負っている。2006 年 3 月 1 日に公表された FSIS 指令 9000.1 改訂 1「輸出証明」は、これらの責務について詳細な記述を提供している。FSIS の規制に関する主要な役割は、食肉及び食鳥製品が適正で、国内及び国際取引における販売に関する全ての米国食品安全基準に適合しているという重要な決定を行うことである。この規制に関する活動は、FSIS が USDA の検査印を貼付する時点で完了する。しかし、FSIS の職員が製品の輸出証明書に署名するためには、検査完了後に追加的な確認が必要である。

AMS は、輸出認定された施設が輸入国の条件に適合できることを保証するための EV プログラムの基準を設定する責任を負っている。これらのプログラムは AMS によって有料で認定・監視され、手数料は参加する施設が支払う。

USDA 検査印と AMS の EV プログラムの組み合わせにより、輸出向けの米国産食肉及び食鳥製品が、全ての米国食品安全基準および輸入国の貿易条件に適合しているものとして認証されるに足るとの保証が得られる。

当初の査察結果

今回の不適合製品の確認事例は、施設における AMS 査察官の定期的な QSA/EV 査

察により発見された。2008年1月8日に行われた現地査察において、AMS査察官は動物の月齢を検証するため、書類上の生年月日ととさつ日を手作業により計算し比較した。この作業の結果、何頭かの動物がとさつ時に20ヶ月齢を超えていたことが明らかとなった。さらに手順を検証したところ、スミスフィールドビーフグループ社サウダートン工場が、入力された生年月日から動物の月齢を計算するためのソフトウェアを備えたコンピューター端末を利用していることが明らかとなった。申告された生年月日を入力することにより、コンピューターは月齢を計算し、その動物が規定に適合しているものか、そうでないものかを判別する。

生年月日とと畜日を比較計算し、その枝肉が月齢条件に適格か不適格かを判定する場所では2台のコンピューター端末が用いられていた。この1台目のコンピューター端末に、計算式のエラーが存在することが発見された。何故1台目のコンピューターに間違いがあり、2台目のコンピューターに正しい計算式が入力されていたかは不明である。問題となる計算式は「21ヶ月齢以下」の動物を受け入れるよう設定されていたが、日本向けのEVプログラムの月齢条件を満たすためにはその計算式を「21ヶ月齢未満」と設定すべきであった。このエラーにより、プログラムは少数の22ヶ月齢未満の枝肉を受け入れていた。これは、個々の生年月日をと畜日と比較するものであるため、22ヶ月齢を超える動物は全く含まれていなかった。

コンピューターの計算式の間違ひは、当初のプログラミングの時点で起こっていた。この手順の検証は、この数式が正しいという認識の元で作業するプログラマーによって行われた。実際の間違ったコンピューターのコマンドは、下記のように計算式に誤った“=”が含まれているものだった（訳注：___部分）：

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

ただちに訂正された新たなコマンドは以下の通り：

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

当初の査察により、コンピュータープログラムの結果を検証するための手順文書が整備されていなかったことが確認された。検証はプログラミングを担当したIT担当者により行われていたが、施設の品質管理検証作業には含まれていなかった。

スミスフィールドビーフグループ社サウダートン工場のQSE/EVプログラムマニュアルには、カナダ産と場直行牛と同様に月齢証明牛を受け入れ、個体識別するための標準作業手順書が含まれていた。スミスフィールドビーフグループ社サウダートン工場の場合、施設の手順の変更ではなく、すでに承認されていたプロセスの最初の使用であったため、現地査察は要求されなかった。今回の事案以前の直近のAMSによる現地査察の時点では、月齢証明牛は受け入れてはいなかったが、月齢証明牛の処理にあたっての手順は整備されていたことをAMS査察官は述べていた。

施設に到着した月齢証明牛は個体識別され、受入ペンに隔離される。月齢証明牛が

放血されると直ちに RFID タグが読み取られ、生年月日が耳標番号及び枝肉 ID と共にコンピューターに入力される。コンピューターは 20 ヶ月齢以下の枝肉を特定し、システム上で認識する。枝肉がとさつフロアから離れる前、温と体計量場に持ち込まれると直ちに、印刷された温と体票により重量票上で月齢と由来が証明された枝肉が特定される。また、施設従業員より、枝肉を月齢証明牛として特定するための“XX”印が、ブリスケット（胸部）に記される。

不適格製品中に含まれる牛の特定は、施設の 2 つの部門からの情報により行われた。とさつフロアと内臓部門は内臓製品、本事案ではタンの加工に用いられた日本向け枝肉の情報を提供し、部分肉加工フロアはカットフロアに持ち込まれた日本向け枝肉の数量の情報を提供した。

とさつ／内臓部門は 1831 頭の牛が内臓製品、つまりタンの生産に利用されたことを確認した。これらの月齢証明牛から生産されたタンのすべてが日本向けとされたわけではない。66 箱のタンのみが不適格な動物からの製品を含んでいたことに留意しなければならない。

部分肉加工フロアは 2007 年 11 月 24 日以降 1569 頭の枝肉を処理し、これが、不適格な枝肉が部分肉加工フロアに入った最初の日である。と畜された 1831 頭の牛のうち、1569 頭の枝肉のみがこの期間中に日本向けに部分肉加工された。

2008 年 4 月 4 日、スミスフィールドビーフグループ社による 2007 年 11 月 23 日から 12 月 28 日の間に日本向けに出荷された不適格製品の回収に関する最終報告書が AMS に提出された。この期間中、合計 62,730 ポンドが日本向けに輸出されていた。輸出総量中、46,506 ポンドが不適格であると決定された。報告書では、一つでも不適格な枝肉を含む対日処理工程で生産された製品は全て、不適格製品と見なされていた。

この不適合の結果、日本政府は 2007 年 11 月 23 日から 2007 年 12 月 28 日の間に出荷された全ての製品（適格品、不適格品共に）を市場から回収することを輸入業者に要求した。

輸入者 2 者からの書簡も AMS へ提出され、回収可能で消費されていない製品の全てが回収されたことが報告された。

不適切な製品の輸出をもたらしたことから、本事案は重大な不適合（Major nonconformance）と見なされ、AMS はスミスフィールドビーフグループ Est. 1311 の対日輸出認可施設の資格を直ちに停止した。さらに、AMS はスミスフィールドビーフグループ社に対して是正措置及び予防措置を指示し、対日輸出施設の認定停止措置を解除する前に AMS による現地査察が必要であることを通知した。

是正措置

- 不適格製品に対応するため、スミスフィールドビーフグループ社サウダートン工場は直ちに日本側顧客に対して本件を通知し、「不適格製品を含む日本向け製品の出荷について」と題したレポートに記された全ての製品の回収のために、本レポートを AMS 及び日本側顧客の双方に送付した。

- 日本向け製品のうち船積みされていなかったものを確認し、発送を中止するため留め置いた。
- 製品の回収は 2008 年 1 月 11 日に開始され、日本側顧客と日本政府担当者との協力により、スミスフィールドビーフグループ社は回収もしくは廃棄可能であった全ての製品を回収もしくは廃棄することができた。
- 米国で回収された全ての製品は日本向け輸出に適合しないものとされ、可能な場合には、国内消費者向けに転用された。

予防措置

- 個別の牛の月齢証明に基づいて月齢が 21 ヶ月齢未満である月齢証明牛を識別するために利用されるコンピューター端末は、とさつ日において 21 ヶ月齢未満の枝肉のみが識別されるよう再プログラムされた。
- 月齢計算の精度は継続的に施設の IT 部門により検査され、QA により検証されることとなる。
- とさつ日前に、元のデータ入力を行った担当者とは異なるスタッフが、入力された全ての生年月日と耳標データを検証することとする。この検証は文書化される。
- とさつ日毎に、とさつ後、枝肉識別番号、耳標番号、入力された生年月日、とさつ日、由来及び月齢証明の表記、およびとさつ時点の枝肉月齢をリストしたレポートが作成されることとなる。スミスフィールドビーフグループ社は、部分肉加工の前に、識別された枝肉のいずれについても、レポート上の耳標と生年月日のデータが当該牛の生年月日証明書に記載されている情報と合致しているか検証することとしている。もしレポート上の生年月日もしくは耳標番号が生年月日証明書上の情報と正確に合致していなければ、その枝肉 ID は日本向け輸出製品として不適格な製品として識別される。この識別により、格付け段階でスキャンされた際に、その枝肉は拒絶され、日本向け製品からはずされることとなる。枝肉冷蔵庫担当者は“XX”のマーク及び由来と月齢を証明するタグを枝肉から取り除き、QA までマーキングとタグを取り除いたことを報告することとなる。
- 全ての日本向け処理後、その製品の出荷前にレポートが作成され、QA マネージャーもしくはその代理人による再確認を受ける。レポートには、処理された全ての枝肉、とさつ日の枝肉月齢、由来及び月齢証明の表記、及び処理中の部分肉加工計量の状態が記されることとなる。もしレポートでいずれかの枝肉が 21 ヶ月齢未満のものではない、由来及び月齢証明の表記が“Y”でない、もしくは部分肉計量の状態が日本向け輸出製品となっていないことを示している場合、その処理工程中の一部が不適格製品なのか、それとも全体が不適格製品なのか、評価されることとなる。
- 不適格製品であるとされたいかなる製品もただちに隔離され、それらの製品は販売目録から排除されることとなる。QA マネージャーもしくは被指名者のみが当該製品をの隔離措置を解除することができる。

結 論

本不適合が QSA/EV プログラムの定期査察において、AMS 査察官によって確認されたことから、当該不適合事案の実際の原因は、当初の査察報告において特定されており、それは本報告の「当初の査察報告」の章に含まれている。AMS は、スミスフィールドビーフグループ社サウダートン工場により提示された改善措置、回収製品についての概要報告書、回収可能な全製品が回収されたことを確認するスミスフィールドの日本の顧客からの書面、および直近の AMS の QSA/EV プログラム査察の結果自体を含む、本不適格製品の混入事案に関する全ての文書の徹底的な検証を実施し、USDA はこの調査報告書から以下のように結論づけた：

- 輸出書類の検証は、FSIS 輸出証明書の発行には特段の問題がないことを示した。
- AMS の査察では、スミスフィールド社の当該施設で明らかとなった本事案と同様の事案は他のいかなる施設においてもみられなかった。
- AMS により確認された今回の不適格事案は、AMS 及び他の場所で査察を実施している AMS 査察官の認識を高めた。AMS は、査察時には作業が行われていなくても、特定の手順を確認するための注意を払うことを確保する。月齢証明のためのコンピュータープログラム及び在庫管理用のスキャナが QSA/EV プログラムに含まれる場合、これらは確認の対象に含まれる。このような作業が査察時に実行されてない場合であっても、AMS 査察官は日本向け EV プログラムの遵守を確保するため、全ての検証作業のデモンストレーションを要求する。対象となるシステムが実行されていない場合でも、この確認作業はシステム作業能力を検証することにより行われる。例えば、もしコンピュータープログラムがとさつされる牛の月齢を証明するために使われるのであれば、監査の際に月齢証明牛のとさつが行われない場合であっても、AMS 査察官はプログラムの精度を検証するために手作業による計算を行うことになる。
- 他の全てのスミスフィールドビーフグループ社の施設の調査は、この事案がスミスフィールドビーフグループ社サウダートン工場に固有のもので、全社的な問題でないことを示した。
- AMS は、スミスフィールドビーフグループ社サウダートン工場 (Est. 1311) が月齢計算を行うためのコンピューターで利用されている計算式の変更を行なったことが、このような不適格事案の再発を防ぐであろう事を断定した。
- 新たな IT 及び品質管理の検証作業が、この種の不適格が繰り返されないことを確実とするよう、実施されている。
- AMS は、現在はスミスフィールドビーフグループ社サウダートン工場が日本向け牛肉の輸出証明プログラムのすべての要件に従っていると考える。
- AMS としては、スミスフィールドビーフグループ社サウダートン工場を日本向け EV プログラム適格施設に再リストアップし、停止措置を解除したいと

考えている。

- 日本政府により本報告書が受領され次第、AMS は、生産される製品が適格であるとされる適切などさつ日をもって現在の停止措置を解除し、スミスフィールドビーフグループ社サウダートン工場を再リストアップする予定である。
- 適切など畜日以前に生産されるすべての製品は、不適格な製品と考えられ、対日輸出適格とはならない。



INQUIRY

National Beef (California), Establishment 21488
Export of Ineligible Beef to Japan

August 13, 2008

EXECUTIVE SUMMARY

A shipment from National Beef (California), Establishment 21488, 57 East Shank Road, Brawley California to Japan included one box of bone-in short loins with an end panel label for product code 9781 (Beef Plates Yoshinoya). An inquiry by National Beef concluded the error was caused by a practice that permitted the pre-labeling of boxes prior to packing.

Corrective actions have been taken to prevent the pre-labeling of boxes for export to Japan, in summary as follows:

National Beef (California) has always had an internal procedure that boxes of product destined for export to Japan are checked for miss-packs prior to the box being sealed. As part of this procedure every box that is QA-checked receives a unique stamp on the inside lid of the box. The plant QSA program has been revised to address the root cause of the mispack (pre-labeling of boxes). The QA group will audit each area where packaging is taking place for products destined for Japan. The audit will be conducted once per hour during all production to verify that there are no pre-labeled boxes in any production areas including re-boxing areas. Employee training has been conducted verbally in a class setting with documented sign offs. Verification of training effectiveness is conducted by supervisors physically watching job task performance. Audits of the process will also verify that the training was adequate. Product for export to Japan will be checked in the following ways after boxing: 1) Final verification prior to case sealer, 2) weight range for product code at the final scale, 3) case damage and condition inspection during order staging, and 4) all cases will be double scanned to ensure that only approved codes are included.

USDA has verified the corrective actions taken by National Beef (California).

PURPOSE

The United States Department of Agriculture (USDA) has conducted an inquiry into the operations of National Beef (California), Establishment 21488, in order to assess events surrounding inclusion in a shipment to Japan of one box beef bone-in short loins incorrectly identified as Frozen Beef Plate Yoshinoya.

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 Export Verification (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.

EXPORT CERTIFICATION PROCESS

The export certification process for Japan is documented in FSIS Directives 9000.1 rev.1 and 9040.1 rev.3 (see Annex) as follows: An FSIS inspection program official receives an application for export (FSIS Form 9060-6) to Japan and verifies that it is complete and accurate and is signed by the applicant. The "Product as Labeled" block must show all products to be exported by their product code and description as they appear in the AMS list of approved products for the plant indicated on the application as the producing plant.

The FSIS inspection program official then compares the listed products on the unsigned application to the list of approved exportable products by the approved plant to determine product eligibility for export to Japan. If all products are found and determined to be produced after AMS approval of the plant, the inspection program official proceeds with export re-inspection as per FSIS Directive 9000.1 examining additional documentation presented with the application and a representative number of containers for condition.

If the documentation and condition of the product are acceptable, the FSIS inspection program official signs the export application, allows product to be stamped and signs the export certificates (FSIS Forms 9060-5, 9290-1 and the letterhead certificate for beef).

RESULTS OF USDA INQUIRY

USDA conducted an inquiry to determine whether the procedures and actions of National Beef (California) complied with U.S. export certification requirements and the import requirements of Japan.

Results are as follows:

1. Inclusion of ineligible beef products

- National Beef (California) management controls failed to prevent the inclusion of nonconforming product in a shipment of products otherwise eligible for export to Japan.
- National Beef (California) employees were responsible for packing boxes of beef for export to Japan in a manner that ensured packed product was consistent with box labeling.
- The mispack occurred because of a production practice that permitted pre-labeling of boxes, thus presenting an opportunity for packing error.

2. Product traceability

- USDA trace-back analysis confirmed all shipment documentation was verified during the export approval process.
- All FSIS and AMS export certifications of approved products were correctly performed.
- The one mispacked box has been verified as originating from an A40 cattle slaughter run.

3. Chronology of Events As Reported by National Beef (California)

To the best of National Beef's knowledge, following is the chronological chain of events:

- June 26, 2007 - The product was produced/ boxed at National Beef (California), Est. # 21488.
- July 27, 2007 - Product shipped to Icrest from Inland Cold Storage in Vernon CA. under MPG Certificate # 550910.
- August 4, 2007 – Product Arrived in Japan
- August 10, 2007 – MHLW/MAFF border inspections conducted
- August 28, 2007 – Shipment cleared customs
- April 19, 2008 – Product transferred to end-user processing plant
- April 22, 2008 – Non-conformance box found
- April 23, 2008 - Letter of Investigation and corrective action sent to USDA (District level as per instruction by FSIS in DC and FAS).
- April 24 - 25, 2008 USDA sent OPEER Investigator to National Beef (California) – Verbally stated that they found no issues
- May 2 , 2008 - USDA FSIS District had additional questions from OPEER Audit

RESULTS OF NATIONAL BEEF (California) INQUIRY

National Beef (California) conducted an internal review of the circumstances that resulted in the export of ineligible product to Japan. Following is a summary of that inquiry:

The root cause of a mislabeled box being exported to Japan was a National Beef (California) Fabrication Department practice of pre-labeling boxes before they were packed. That practice has ceased.

The Beef Plates were fabricated, bagged and boxed on a separate line from the short loins. National Beef (California) was not producing short loins for export to Japan. As per our QSA program the plant segregated product by grade and age coming into the fabrication floor. From there the plates and short loins go down separate boning tables. Products rejoin in a common case sealing area. Segregation is maintained in this area by a

product code label on the end panel of the box. When we produce Japan designated product for verified aged cattle, they are fabricated as a separate run on the fabrication floor. We verify that only approved labels are used product destined for Japan. As with all U.S. plants anything that is not destined for Japan is packaged and boxed in non-approved Japan codes.

This scenario happened when the employee correcting a damaged box of short loins grabbed a box and did not personally apply the product code label. This box had been pre-labeled for plates. Due to the location where this re-boxing occurred, the product did not go through the normal plant inspection process.

A trace back was conducted and all products exported with this load were verified as being eligible to export to Japan.

Since this incident, the QSA manual has been revised and an added hourly check for pre-labeled boxes is conducted in all packaging areas.

CORRECTIVE ACTIONS

National Beef (California), Establishment 21488, has taken actions to correct conditions that caused or contributed to the export of ineligible product to Japan. The corrective actions reported to USDA by National Beef (California) are as follows:

- National Beef (California) continues to use their internal procedure that boxes of product destined for export to Japan are checked for miss-packs prior to the box being sealed. Every box that is QA-checked receives a unique stamp on the inside lid of the box
- This stamp when used is applied at the end of the process. For plates, the stamp is applied in the separated room at the end of processing before the boxes go to the case sealing room. For all other export products the stamp when used is applied directly prior to the case sealer. The stamp identifies who checked the box. (Although the AMS QSA program does not require 100% box stamping as a specified product requirement, stamping of all QA inspected boxes is an internal tool used to ensure that plant QA personnel are inspecting boxes as per company expectations.)
- Although National Beef (California) does not require that every box contain a unique QA stamp every box of product that is destined for Japan is monitored/inspected by plant personnel/QA. As stated above the stamping of boxes by the QA is done as a way to help the plant ensure that the process is working.
- To further improve their process and QSA program to ensure that pre-labeling boxes for the EV Japan program does not re-occur, National Beef has revised the National Beef (California) plant QSA Program. The Plant QA group will audit each area where packaging is taking place for

products destined for Japan. The audit will be conducted once per hour during all production.

- This audit was added to the QSA Program to verify that there are no pre-labeled boxes in any production areas including re-boxing areas. Any "re-boxing" that may take place with Japan destined product is only done on the production floor. That process is monitored by plant management and QA. That product is then subject to plant/QA inspection like all Japan destined product.
- National Beef (California) added the written requirement that pre-labeling boxes is not acceptable in their program and added audit criteria to verify that they are in compliance with the revised program.
- Although National Beef (California) does not plan to use certain color boxes for all Japan destined products, the Beef Plates Yoshinoya will for the immediate future be packed in white boxes as a means to differentiate them from bone in short loins, which are packed in brown boxes. As stated earlier, the root cause for this failure was the practice of pre-labeling boxes which no longer occurs during the production of product destined for Japan. This change is reflected in the revised QSA program for the National Beef (California) plant.
- Employee training has been conducted verbally in a class setting with documented sign offs. Verification of training effectiveness is conducted by supervisors physically watching job task performance. Audits of the process will also verify that the training was adequate. (See Annex)
- With the elimination of pre-labeling boxes, employees now know what code they are physically packaging and will apply the label at the time of packaging. Export labels are not in close proximity to non-export labels.
- Product for export to Japan will be checked in the following ways after boxing: 1) Final verification prior to case sealer, 2) weight range for product code at the final scale, 3) case damage and condition inspection during order staging, and 4) all cases will be double scanned to ensure that only approved codes are included.

CONCLUSIONS

USDA conclusions from this inquiry are as follows:

- The one box of ineligible beef was not intended for export to Japan as it was produced for the domestic market.
- The ineligible product was inspected and passed by USDA for human consumption and was at the time of export a safe and wholesome product fit for consumption in the United States.
- Documentation for the shipment complies with the Specified Product Requirements under the EV Program for beef to Japan, including being from age-verified animals.
- USDA agrees with National Beef (California) that the root cause for inclusion of ineligible product in an export shipment to Japan was a plant-

specific mispacking error that occurred because the establishment was pre-labeling boxes for export.

- USDA has reviewed the corrective actions taken by National Beef (California) and finds them sufficient to address and resolve the root cause of this shipping mistake.
- In order for ensuring only eligible products be shipped to Japan, FSIS cautioned export facilities by posting a reminder in the FSIS Export Library on July 02, 2008. (See Annex)
- USDA is prepared to resume the certification of National Beef (California) Establishment 21488 products for export to Japan immediately upon acknowledgement this report is accepted by the GOJ.

ANNEX

Annex 1 FSIS Directive 9000.1 Rev. 1

Annex 2 FSIS Directive 9040.1 Rev. 3

Annex 3 Employee training

- Annex 4 Export Requirements for Japan JA-144 (Jul 2, 2008)

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

9000.1,
Revision 1

3/1/06

EXPORT CERTIFICATION

I. PURPOSE

The export certification process serves to instill confidence in United States (U.S.) meat and poultry products throughout the world. Therefore, the Food Safety and Inspection Service (FSIS) must continue to ensure a high level of integrity, security, and accuracy within the process. This directive provides a clear set of standards for District Offices (DO) and inspection program personnel to follow. This directive clarifies the process if an FSIS certifying official feels that he or she is unable to sign an export certificate; makes clear that a facsimile of FSIS Form 9060-6, Application for Export Certificate, may be used to provide the information requested in that form; clarifies the purpose of the Export Library; and clarifies other aspects of the directive.

II. CANCELLATION

FSIS Directive 9000.1, dated 9/9/99

III. REASON FOR REISSUANCE

FSIS is reissuing this directive in its entirety to clarify Agency policy regarding the export certification process.

IV. REFERENCES

21 U.S.C. 616
9 CFR 156, 307.4(c), 312.8, 316.5, 317.1, 317.7, 318.2, 322.1, 322.2, 322.4, 325.8, 325.13, 350, 351, 354, 355, 362, 381.37(c), 381.66, 381.104, 381.105-107, 381.128, 381.193
FSIS Directives 5110.1, Revision 1 and 9040.1, Revision 3

V. BACKGROUND

A. As specified in FSIS regulations, upon application by an exporter (applicant), an FSIS inspection program employee is authorized to issue official export certificates for the shipment of inspected and passed products to any foreign country. The applicant provides a completed FSIS Form 9060-6 to an inspection program employee. An inspection program employee may sign the application and

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issue (but not sign) an export certificate (FSIS Form 9060-5, Meat and Poultry Export Certificate of Wholesomeness) and export stamp, only after he or she has:

1. verified that the information on the application is correct, and the applicant has signed the application attesting to the accuracy of the information;
2. verified that the country requirements as specified in the Export Library have been met; and
3. re-inspected the product as set out in Part VII of this directive and has no reason to conclude that the product has become adulterated or unwholesome, or that the product is mislabeled or ineligible for export to the country listed on the application.

The inspection program employee should request from the exporter any documentation needed. (See paragraph VII. of this directive for more specific direction.)

B. After receiving a completed export certificate from an exporter, an FSIS certifying official (inspection program employee that signs the certificate) verifies the information by comparing the information on the certificate to the information on the certified (signed) application. The statement on the export certificate is a certification that may be based on information provided to the certifying official, and he or she need not have been directly associated with the inspection of the product. If further clarification is needed, the certifying official will request additional information or documentation from the inspection program employee who signed the application or from the exporter. Once the certifying official is assured that all information is accurate, he or she is to sign the export certificate. If a certifying official refuses to sign a certificate, he or she should have good and sufficient reasons (e.g., the documents are incomplete, or he or she cannot verify, based on the information provided, that the product meets the export requirements). The certifying official should document the reasons for his or her refusal to sign and notify the exporter. The exporter may correct the reasons identified by the certifying official, or forward a copy of the export documentation to the next-line supervisor (See paragraph VII. of this directive for more specific direction.)

C. If a certifying official refuses to sign a certificate, his or her refusal and the reasons for doing so will be reviewed by the next-line supervisor. Based on the review, the next-line supervisor will take one of the following actions:

1. uphold the refusal of the certifying official to sign the export certificate on the grounds that the information presented by the exporter is not adequate to justify signing the certificate; or
2. decide, based on his or her review of the record, that the signature is justified and sign the certificate. If a Public Health Veterinarian (PHV) signature is required, the next-line supervisor would forward, if necessary, to the appropriate DO personnel the findings with a recommendation that the certificate and other export documents be signed.

D. If the Front-line Supervisor signs the export certificate and determines that the certifying official's refusal to sign the export certificate was not based on good and sufficient reasons as outlined in Section B above (e.g., the documents are incomplete, or he or she cannot verify requirements), the Front-line Supervisor documents the incident and forwards a report to the DO. The DO will review the information from the Front-line Supervisor and make a decision whether or not to forward the information to the Labor and Employee Relations Division, Employee Relations Branch, for determination of appropriate administrative action, including disciplinary or adverse action.

E. When export certification services are performed in an official establishments, the issuance of export certificates that are required by 9 CFR Part 322 and 381.104 through 381.111 are not reimbursable services. Only the execution of certifications that are in addition to FSIS regulatory requirements, e.g., additional certifications that are required by the importing country, and the transferring of products for export as described in 9 CFR 322.3, are considered reimbursable services. When export certifications services are performed at non-official establishments, the services are reimbursable and charged as set out in FSIS Directive 5110.1.

VI. EXPORT LIBRARY

A. The Export Library contains the requirements that have been officially communicated to FSIS by the country to which the product is to be exported. It should be used to determine the eligibility of shipments for export and includes information such as:

1. certificate requirements
2. eligible and ineligible products
3. facility requirements
4. labeling requirements
5. edible and inedible products
6. plant requirements to become eligible to export
7. PHV signature requirements, if any
8. animal health requirements
9. list of plants eligible to export

10. export notices

11. Frequently Asked Questions

B. Ways to access information from the Export Library:

1. on the internet at:

www.fsis.usda.gov/Regulations&Policies/Export_Information/index.asp

2. Outlook: Public Folders/All Public Folders/Export Library

3. The FSIS Technical Service Center (TSC) at 1-800-233-3935 or 402-221-7400

C. For information regarding animal health status and certification:

1. consult the Export Library;

2. consult the TSC at the above numbers; and

3. after consulting the Export Library and the TSC, if specific questions remain regarding the status of a particular disease within a state, consult the Animal and Plant Health Inspection Service (APHIS) Area Veterinarian in Charge (AVIC) for that state. A list of AVIC's is available on the APHIS website at:

<http://www.aphis.usda.gov/vs/areaoffices.htm>

VII. APPLICATION FOR EXPORT CERTIFICATE

A. Upon receiving an application for export, an inspection program employee reviews the application to verify that it is complete and that all pertinent information is included.

B. An inspection program employee reviews the application to verify that the requirements of the receiving country have been met. The inspection program employee verifies statements on the application, when necessary, by requesting appropriate documentation from the applicant. The inspection program employee should inform the applicant that the process may be expedited if he or she provides the necessary documents (e.g., Export Verification record eligibility information), along with the application.

1. If the inspection program employee has concerns as to whether each product listed on the application is eligible for export to the country listed on the application, he or she is to:

- a. raise such concerns with exporter;
- b. document a memorandum of interview addressing what was discussed, and whether the concerns were adequately addressed; and
- c. provide a copy of the memorandum to the applicant and maintain a copy in the inspection files.

C. An inspection program employee performs a sensory evaluation of the product to determine its eligibility for export. The inspection program employee should be particularly alert for signs that product is or may become adulterated or unwholesome (e.g., off-condition odor, torn, damp cartons, or other evidence of insanitary handling or storage).

1. If the inspection program employee finds signs of poor product handling and storage, he or she may examine the product as set out in FSIS Directive 9040.1, Revision 3, Re-inspection of Product Intended for Export, and take any necessary actions when the product may be adulterated as provided in FSIS Directive 5000.1 (at official establishments (e.g., regulatory control actions or issuance of Non-Compliance Records (NRs)) or FSIS Directive 8410.1 (at non-official establishments (e.g., detaining products)).

2. Also, if an inspection program employee has reason to question whether the products are properly identified and labeled to meet FSIS regulatory requirements and the requirements of the importing country, he or she may examine the product as set out in FSIS Directive 9040.1, Revision 3, and:

a. when the product is not properly labeled or misbranded, take the appropriate action as provided in 9 CFR part 500 and FSIS Directive 5400.5, (at official establishments issuing NRs, taking regulatory control action) or FSIS Directive 8410.1 (at non-official establishments); or

b. when the product in the container or the labeling of the product does not meet the requirements of the importing country, raise the concern with the applicant and prepare a memorandum of interview as described in paragraph VII. B. 1. b. and c. above.

D. An inspection program employee verifies that the foreign language sticker, if required, shows no wording other than that shown on the approved label.

NOTE: The inspection program employee also verifies that any required letter of guarantee from the exporter supplying the foreign language sticker, which certifies that the sticker is an accurate translation of the wording on the approved label, is included.

E. After the inspection program employee completes A. through D. above, and everything is acceptable, he or she:

1. signs the application;
2. retains a copy of the application and any accompanying documents for filing;
3. returns the originals to the applicant;
4. provides the export certificate for completion by the exporter and issues the export stamp;
5. permits the establishment to stamp product; and
6. secures the stamp after the establishment finishes stamping the product.

F. An inspection program employee may permit an establishment to stamp boxes and complete the export certificate when he or she is not present (pre-stamp). However, the inspection program employee should verify that the establishment can ensure the stamp will be applied in a clear and legible manner only to boxes that are in sound condition before presenting the stamp to be used. An inspection program employee performs re-inspection as specified in paragraph VII. C. anytime he or she determines that it is necessary.

NOTE: An inspection program employee may allow an establishment to use a computer generated export stamp (sticker) as long as the establishment identifies the number of stickers produced before applying them to product and provides the inspection program employee with any unused stickers.

G. On the day inspection program personnel perform the procedures above at official establishments, they are to record Inspection System Procedure code 06A01 as performed. Inspection program personnel only record the procedure as performed once in a day and not for each application received. At a non-official establishment, inspection program personnel charge for the service as set out in FSIS Directive 5110.1.

VIII. EXPORT CERTIFICATES

A. The certifying official receives the appropriate completed export certificate (FSIS Form 9060-5), other certificates as required by the importing country (see paragraph X.), letterhead certificates (see paragraph VIII. C.), and a copy of the signed application (FSIS Form 9060-6) from the exporter. The certifying official verifies that the information on the certificates is consistent with the information on the application by reviewing any attached documentation or checking in the Export Library and no additional statements or documents not provided for in the Export Library are added.

B. If needed, a continuation sheet is prepared by the exporter when multiple items in the shipment exceed the space available on the face of the certificate. The continuation sheet is to be prepared in quadruplicate and includes:

1. date issued;
2. title (e.g., Continuation Sheet for Export Certificate # _____);
3. product description – name, boxes, weight, as indicated on the face of the certificate; and
4. the certifying official's name and signature, followed by the district number. The name and code number must be the same as that on the face of the certificate.

C. In some cases, a USDA/FSIS letterhead certification is necessary and is issued for certain products when specified in the individual country requirements found in the Export Library. If the exporter submits a letterhead certificate along with the certificate, the FSIS certifying official is to verify that:

1. the most current version of the letterhead certificate found in the Export Library was submitted;
2. no statements on the letterhead certificate have been changed from what appears in the Export Library and no additional statements have been added;
3. the certificate is dated by the exporter; and
4. any certification required by another USDA Agency (e.g., AMS) is provided along with the completed letterhead.

The letterhead certifications are prepared in quadruplicate and must include:

1. corresponding export certificate number;

2. certification statement (e.g., I (name of inspector/veterinarian) certify...);
3. inspector/veterinarian name typed/printed, followed by professional degree, if applicable, and the District number;
4. signature of inspector/veterinarian exactly as typed/printed; and
5. date signed.

D. If the certifying official has questions about the information on the application (FSIS Form 9060-6), the certificate (FSIS Form 9060-5), any other certificates, including letterhead certificates, he or she does not sign the certificate until he or she has contacted the inspection program employee who signed the application or the exporter. Any communication that the certifying official has with the exporter should be documented in a memorandum of interview as described in paragraph VII. B. 1. b. and c. above.

E. Before signing the certificate, the certifying official:

1. checks the certificate for accuracy and corrections;
2. checks the boxes indicating that the animal received ante- and post-mortem inspection;
3. checks for attachments and ensures that the exporting firm has lined-out any unused space; and
4. initials minor erasures or alterations, unless this is not acceptable to a foreign country (see Export Library to verify if receiving country permits erasures or alterations).

F. The certifying official signs the original certificate in the signature block in **other than** black ink, all continuation sheets, and other certifications, including letterhead certifications. Also, if the importing country requires a PHV's signature, the certifying official is to include his or her professional degree. The certifying official should not stamp the certificate with the export stamp unless required by a receiving country as specified in the Export Library.

IX. REPLACEMENT CERTIFICATES

A. A certificate replacing an original certificate is a re-certification of the product's condition **at the time of the initial export certification**. A replacement certificate for a lot **does not** represent that lot's current condition. A replacement certificate may be issued in situations such as, but not limited to:

1. the original certificate did not carry required information;
2. the original certificate carried incorrect information;
3. the name of the consignee or exporter has changed; and
4. the certificate has been lost.

B. The replacement certificate must be dated with the same date as that shown on the original certificate.

C. A request to increase the box count or the total net weight shall not be honored unless the product is re-inspected in accordance with paragraph VII. C. of this directive.

D. An application (FSIS Form 9060-6) is submitted to request a new certificate and must be accompanied by (if possible) the original and all copies of the original certificate. Exception: In the case of lost certificates, the exporter should provide a letter of assurance to the certifying official stating the certificate will be returned if found.

E. Multiple export certificates may be issued to replace an original if the exported product has been subdivided for shipping to more than one consignee, and an export certificate is required for each part, provided that:

1. the lot was originally manifested in sufficient detail to enable the direct correlation of containers, identification, and corresponding weights on the new certificate; and

2. the original certificate is returned for cancellation.

F. Before signing a replacement certificate, an inspection program employee:

1. verifies that the following statement is in the top left margin or in the "Remarks" block of the new certificate: "Issued in lieu of certificate no. _____. The export mark on the product covered by this certificate shows certificate no. _____."

2. obtains the superseded certificate (if possible), and:

- a. verifies that it is marked in the left margin or in the "Remarks" block with the number of the certificate which supersedes it (e.g., "Superseded by No. _____"); and

- b. attaches it to the "inspector's" copy of the replacement certificate and files it in the government office.

X. INVENTORY

A. Official export stamps must be controlled at all times. Export certificates, stamps, and pertinent inventory records must be maintained under official lock or seal when not in use.

B. The inspection program employee at each establishment must maintain an accurate inventory record of export certificates issued and voided certificates.



Assistant Administrator
Office of Policy, Program, and Employee Development

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

9040.1,
Revision 3

3/1/06

RE-INSPECTION OF PRODUCT INTENDED FOR EXPORT

I. PURPOSE

This directive provides inspection program personnel with the procedures for reinspecting product that has been presented for export. These responsibilities and procedures apply whether the product is located at the establishment, or off-site at a non-official establishment, such as at an Identification (ID) warehouse (as provided for at 9 CFR 350.3(a)) or at a cold storage facility.

II. CANCELLATION

FSIS Directive 9040.1, Revision 2, dated 8/12/93

III. REASON FOR REISSUANCE

This directive has been revised to provide for the examination of boxes or containers in situations where inspection program personnel have a reason to question whether the product as labeled meets the importing country's requirements.

IV. REFERENCES

9 CFR 322.2, 381.105, and 350.3(a)
FSIS Directives 7520.2 and 9000.1 and 12,600.1

V. POLICY

A. The regulations at 9 CFR 322.2 and 381.105, provide for the re-inspection and certification of products for export. The purpose of a re-inspection of product that is to be exported is to verify the product's safety, wholesomeness, identity, and eligibility for export. Inspection program personnel conduct a re-inspection of product for export after they receive and review FSIS Form 9060-6, Application for Export.

B. As set out in FSIS Directive 9000.1, Export Certification, inspection program personnel are to verify that each product listed on the application complies with the meat and poultry product regulations and the importing country's requirements (e.g., that each product listed on the application is eligible for export to the country listed on the application).

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt., T/A Plant Mgt., TRA; ABB; TSC; Import Offices

OPI: OPPED

C. If the application is complete and accurate, inspection program personnel perform an organoleptic examination of the shipping cartons for signs of poor product handling or storage (e.g., torn, damp, damaged, or off-condition cartons). If the cartons are sound, inspection program personnel proceed by following the instructions in FSIS Directive 9000.1 regarding signing the application, FSIS Form 9060-6, Application for Export Certificate, and issuing the FSIS Form 9060-5, Export Certificate.

VI. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES WHEN PRODUCT HAS BEEN FOUND NOT TO BE SOUND

A. If inspection program personnel find signs of poor product handling and storage while conducting the organoleptic examination of the shipping cartons at either official or non-official establishments, they are to (under Inspection System Procedure codes 06 using the inspection methodology outlined in FSIS Directives 5400.5 and 5000.1, Revision 1):

1. In official establishments and non-official establishments, randomly select up to 5 percent of the boxes or containers. In considering the percentage of boxes to select, inspection program personnel should consider the basis for their concern and the need to expose the contents of boxed product to the environment:

a. In an official establishment, request that the applicant open the selected sample of boxes or containers in a manner that will not create insanitary conditions or lead to product adulteration; and,

b. In a non-official establishment, request that the applicant open the selected sample of the boxes or containers in a sanitary environment (e.g., identification services area of the facility), or have the shipment or selected sample of the boxes or containers moved to a facility where boxes can be opened in a sanitary environment (e.g., from a cold storage facility without an ID services area).

2. Reinspect the contents for soundness and wholesomeness.

NOTE: If product is frozen, inspection program personnel are to have the official establishment or identification facility temper or thaw all individual packages in the randomly selected boxes or cartons under sanitary conditions at the official establishment or in the ID services area of a non-official establishment to conduct the reinspection. If product is canned, inspection program personnel are to follow the instructions in FSIS Directive 7520.2, Procedures for Condition of Canned Product Container Examination.

a. If the product is found to be sound and wholesome, inspection program personnel may permit the product to be re-packaged (at the packers option), sign the export application, and proceed by following the instructions in FSIS Directive 9000.1.

b. If the product is found to be not sound or not wholesome, or the establishment or facility does not open the boxes, or if the establishment elects to not move the sample or cancels the shipment, and inspection personnel have reason to believe the product may be adulterated, inspection program personnel:

i. are not to sign the application,

ii. at official establishments when any of the product is determined to be unsound or unwholesome, are to issue a Non-Compliance Record under the appropriate 06 code and are to take the appropriate enforcement action FSIS Directive 5000.1, Revision 1,

iii. at non-official establishments when any of the product is determined to be unsound or unwholesome, are to detain product as set out in FSIS Directive 8410.1 and complete FSIS Form 8080-1 Notice of Detention (at non-official establishments).

VII. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES WHEN INFORMATION ON THE APPLICATION DOES NOT MEET THE REQUIREMENTS

A. If inspection program personnel have questions regarding the information on the application, they are to present them to the applicant as set out in FSIS Directive 9000.1 e.g., request applicant to provide supporting information that verifies that the requirements of the country importing the product have been met).

B. If inspection program personnel have reason to question whether the product is properly identified and labeled to meet the importing country's requirements, they are to (under Inspection System Procedure codes 04 using the inspection methodology outlined in FSIS Directives 5400.5 and 5000.1, Revision 1) follow the above methodology for:

1. Opening boxes to reinspect the product to ensure that it is properly labeled, not misbranded, and eligible for export to the country listed on the application; and
2. Taking and documenting enforcement or detention actions.

C. In official or non-official establishment if the product in the container or the labeling of the product does not meet the importing country's requirement.

1. Raise the concern with the applicant;
2. Document a memorandum of interview addressing what was discussed, and whether the concerns were adequately addressed; and
3. Provide a copy of the memorandum to the applicant and maintain a copy in the inspection files.

Direct questions to the Technical Service Center at 1-800-233-3935.



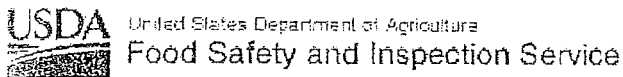
Assistant Administrator
Office of Policy, Program, and Employee Development

Annex 3

Employee Training

National Beef (California) Reports: Once the change to the QSA program was made concerning the stopping of pre-labeling boxes the following occurred:

- Changes were made and submitted to USDA AMS to approval
- USDA AMS approved the changes
- QSA Manual was updated with the revision
- All plant management and hourly work force that is involved in the production of Japan product in the packaging area were retrained on the revised QSA program
- Documentation of the retraining was placed on file
- USDA AMS and USDA OPEER reviewed the training and program and found it acceptable



Export Requirements for Japan

JA-144 (Jul 2, 2008)

Asterisks (*) indicate the most recent revision to these requirements. To search, click on your browser's "Edit" menu, then click on "Find (on this page)". Enter "*" in the "Find What" field, then click "Find" or "Find Next" until all asterisks have been identified.

Go to Poultry Export Requirements

Red Meat Export Requirements for Japan

Eligible/Ineligible Product

A. Eligible Products - The following products are eligible to be exported to Japan as edible product:

1. Beef and beef offal and veal and veal offal intended for export to Japan must be produced from animals slaughtered after 5:00 AM Eastern Daylight Time on July 27, 2006.

Fresh/frozen beef and beef offal and veal and veal offal derived from animals 20 months of age or younger. Spinal cord and spinal column (excluding the transverse process of the thoracic and lumbar vertebrae, the wings of the sacrum, and the vertebrae of the tail) must be removed. Eligible beef and beef offal and veal and veal offal must be produced under an approved AMS Export Verification (EV) program for beef to Japan. Information about the EV program for Japan and a list of BEV approved establishments can be obtained from AMS' Web site.

If FSIS inspection personnel become aware of concerns that an AMS approved EV establishment is not properly executing its EV program, export certification should not be issued for the product in question and AMS should be notified at ARCBbranch@usda.gov. Inspection personnel should include their immediate supervisor on messages to AMS. The following information should be included in the message:

- Establishment name, address, and establishment number
- Product type, product code, and quantity of product
- Date of production, lot number, and shift
- Date and nature of observation
- Name of country product is intended for export
- Export certificate number (if applicable)
- Any other information to verify claim
- Name of inspection official

Exporting establishments are cautioned that great care should be taken when assembling shipments of beef products for export to Japan. In particular, exporting establishments should establish and enforce sufficient management controls to prevent the inclusion of ineligible beef products in any box or other container that is exported to Japan.*

2. Pork and pork products.
3. Non-ruminant origin meat products produced using natural ruminant casings (See Processing Section and Documentation Section A.4.a. and b. Plant Eligibility

Section.)

4. Non-ruminant origin meat products produced using natural pork casings (See Documentation Section A.4.c.)
5. Non-ruminant origin meat products produced using artificial casings derived from cattle hides and pork skins. (See Documentation Section A.4.d. and e.)
6. Natural pork casings and imported natural ruminant casings. (See Processing, Documentation, and Plant Eligibility Sections.)

B. Ineligible Meat Products

1. Beef heads (hygienically removed tongues and cheek meat are eligible), processed beef products and veal products, ground beef and ground veal, and advanced meat recovery products containing beef or veal.
2. Meat and meat products derived from sheep and goats.
3. Coloring agents are not permitted in raw meat products.
4. Deer and elk meat

C. Eligibility of Meat Imported into the U.S.

1. Pork imported from Canada is eligible for export to Japan. See the documentation requirements in A.3.b. of the Documentation section. Pork imported from other countries is not eligible for export to Japan at this time.

Processing Requirements

Note: Exporters are advised to work closely with their importer regarding Japanese standards of meat products intended for export to Japan. The information presented below is not inclusive of all the details of the standards of composition and manufacture. Please contact the Technical Service Center at (402) 344-5000 if additional assistance is needed.

A. Processed Meat Product.

1. Unheated Meat Products (e.g., parma, prosciutto, coppa or country ham or unpasteurized ham requiring refrigeration)
 - a. May contain up to 70 ppm nitrite in the finished product (NOTE: USDA requires a minimum of 120 ppm nitrite going into non-heated, cured products. Non-heated, cured product containing a maximum of 70 ppm nitrite may be exported to Japan provided that the outside container is marked "For Export to Japan.").
 - b. Exporters should be aware of the raw material requirements for producing unheated meat products for Japan since they may have to document this information to their Japanese importer. The meat must be maintained chilled at 4° C (39.2° F) and the pH of the meat is to be 6.0 or below.
 - c. Smoked or dried product intended to be stored at room temperature must either have a pH below 4.6 or the water activity less than .93, if the pH is between 4.6 and 5.1.
2. Specifically heated meat products. (e.g., bacon, etc.)
 - a. may contain up to 70 ppm nitrite in the finished product,
 - b. must be heated to an internal temperature of 60° C (140° F) maintained for 12 minutes maximum or the equivalent. **Note:** Current Japanese regulations recognize the cooking standards for roast beef (9 CFR 318.17) as equivalent to the above requirements or the time/temperature chart listed below:

C°	(F°)	Time (min)
55	(131.0)	97
56	(132.8)	64
57	(134.6)	43

58	(136.4)	28
59	(138.2)	19
60	(140.0)	12
61	(141.8)	9
62	(143.6)	6
63	(145.4)	0

- c. Exporters should be aware of the raw material requirements for producing specifically heated meat products for Japan since they may have to document this information to their Japanese importer. The meat must be maintained chilled at 4° C (39.2° F) and the pH of the meat is to be 6.0 or below:
3. Heat treated products. (e.g., Ham, bacon, corned beef, sausage products)
 - a. May contain up to 70 ppm nitrite in the finished product,
 - b. Must be heated to an internal temperature of 63° C (145° F) maintained for 30 minutes minimum or equivalent. Current Japanese regulations recognize the following time/ temperature relationships as equivalent:

C°	(F°)	Time (min)
60	(140.0)	129
61	(141.8)	80
62	(143.6)	49
63	(145.4)	30
64	(147.2)	19
65	(149.0)	12
66	(150.8)	7
67	(152.6)	5
68	(154.4)	3
69	(156.2)	2
70	(158.0)	1
71	(159.8)	38 sec.
72	(161.6)	23 sec.
73	(163.4)	14 sec.
74	(165.2)	9 sec.
75	(167.0)	5 sec.

4. Dried meat products. (e.g., beef jerky, dried beef, salami)
 - a. May contain up to 70 ppm nitrite in the finished product,
 - b. Water activity must be under 0.87.
5. Sodium tripolyphosphate and sodium phosphate are permitted to be used in processed meats. Product descriptions entered on FSIS Form 9060-5 and FSIS form 9290-1 should coincide exactly with product name approved by the Label Review Branch (LRB).
6. Intestines
 - a. Pork intestines must be cleaned, then scalded at 80° C (176° F) for 3

minutes. When the export request is for chitterlings or bungs, scalding is not required.

7. Nongravid Uteri--Immediately after passing inspection, uteri must be chilled, preferably in crushed ice. Uteri are then drained, packed, and frozen. Hot freezing is not permitted.
8. Non-ruminant origin meat products produced using natural ruminant casings.
 - a. The natural casings must be derived from animals which were born and raised in countries other than the United Kingdom (Great Britain and Northern Ireland), Ireland, Switzerland, France, Portugal, Belgium, Luxembourg, Denmark, the Netherlands, Liechtenstein, Germany, Spain, Greece, Italy, Czech Republic, Slovakia, Austria, Finland, Slovenia, Poland, Sweden, Israel, Canada, or the USA.
 - b. U.S. establishments that process or repackage the imported natural casings and establishments that produce the meat product must only handle ruminant casings that comply with the source requirement in 1. for all production. Segregation programs are not permitted.
9. Imported natural ruminant casings
 - a. The natural casings must be derived from animals which were born and raised in countries other than the United Kingdom (Great Britain and Northern Ireland), Ireland, Switzerland, France, Portugal, Belgium, Luxembourg, Denmark, the Netherlands, Liechtenstein, Germany, Spain, Greece, Italy, Czech Republic, Slovakia, Austria, Finland, Slovenia, Poland, Sweden, Israel, Canada, or the USA.
 - b. U.S. establishments that process or repackage the imported natural ruminant casings must only handle ruminant casings that comply with the source requirement in 1. for all production. Segregation programs are not permitted.
10. Natural Pork casings
 - a. If U.S. establishments that process or repackage natural pork casings also process or repackage natural ruminant casings, the ruminant casings must comply with the source requirement in 9.a. above for all production. Segregation programs are not permitted.

Labeling Requirements

A. Meat Products

1. Cartons containing non-heated, cured only products with a maximum of 70 ppm nitrite must be labeled "For Export to Japan."
2. Water activity, pH, cooking temperatures and heated before packing/heated after packing, must be identified on the labels when printed in Japanese.
3. If there are no specification standards for processed meat products in Japan, then the product name can be used in the Japanese Label (example: Salisbury Steak.)

B. Net Weight

1. If not preprinted by the label manufacturer, the net weight (in kilograms) should be stenciled, stamped or handwritten on the carton. Pounds may be shown on the label as well.
2. Product arriving in Japan without net weight labeling on the retail packages must be weighed and labeled in compliance with the Japanese Measurement Law.

C. Food Additives. Japanese food additives requirements are very complex. Importers can provide samples of new products to the Ministry of Health and Welfare inspectors to verify that all additives are approved by Japan. Exporters are advised to work with their importers to confirm eligibility of additives in the products being exported to Japan.

D. Meat or meat products that deteriorate within days must bear a "use by" date, and products whose quality can be maintained longer than five days are required to show a "best before" date. This information must be present on imported products when the product enters Japanese commerce. The date information can be applied in the United States prior to export or it can be applied in Japan prior to release from a bonded

warehouse. This requirement applies to bulk packed products as well as consumer ready packages.

Documentation Requirements

A. Certification requirements for red meat products.

1. Obtain FSIS Form 9060-5 Meat and Poultry Certificate for Wholesomeness and FSIS Form 9290-1 (12/06/2000) Certificate for Export to Japan.
2. Fresh/frozen beef and beef offal and veal and veal offal
 - a. The export applicant must provide information about the consignment that includes specific product identification information, production date, number of boxes, manufacturer, and the statement "Product meets EV Program requirements for Japan" in Block 14 of FSIS Form 9060-6.
 - b. Obtain FSIS Form 9060-5, Meat and Poultry Export Certificate of Wholesomeness
 - c. Obtain FSIS Form 9290-1, Certificate for Export to Japan. See e. Clarification of Export Procedures for Certifying Product below for information about completing this certificate.
 - d. Obtain an FSIS Letterhead Certificate with the following statements:
 1. Cattle slaughtered for the production of the exported beef to Japan (hereinafter referred to as "the slaughtered cattle") have been born and raised only in the USA, or legally imported from Canada, or legally imported from the third free countries listed here and raised in the USA. Third free countries are: Norway, Hungary, Iceland, Mexico, Belize, Guatemala, Honduras, El Salvador, Nicaragua, Costa Rica, Panama, Dominican Republic, Chile, Commonwealth of the Northern Mariana Islands, New Zealand, Vanuatu, New Caledonia, Australia
 2. The slaughtered cattle were not suspect or confirmed BSE cases, or confirmed or suspected progenies, or cohorts of BSE cases, as defined in the Terrestrial Animal Health Code adopted by the World Organization for Animal Health (OIE).
 3. The slaughtered cattle were found to be sound and healthy as a result of ante- and post-mortem inspections conducted by USDA veterinary inspectors in the designated facilities at the time of slaughter.
 4. The exported beef to Japan fulfilled all of the required conditions described in the EV Program. In case the slaughtered cattle have been legally imported from Canada, criteria 5.2.1.1 or 5.2.1.2 of the EV program is applied in order to verify 20 months of age or younger. In case the slaughter cattle have been legally imported from the third free countries listed above other than Mexico and raised in the USA, only criteria 5.2.1.1 of the EV Program is applied in order to verify 20 months of age or younger.
 5. The exported beef to Japan has been handled at the designated facilities in such a way as to prevent contamination with any causative agents of animal infectious diseases until shipment to Japan.
 - e. Review Clarification of Export Procedures for Certifying Product prior to product certification.
3. Pork and pork products - The following statements and information must be included in the "Remarks" section of FSIS Form 9060-5:
 - a. For pork and pork products of U.S. origin:

"The USA is free of hog cholera; vaccination against hog cholera is prohibited; and importation of pigs vaccinated against hog cholera is prohibited."
 - b. For pork and pork products imported into the U.S. from Canada, and now being exported to Japan:

"for the product described above, the processing including slaughtering,

dressings, eviscerating, dividing and chopping or the manufacturing, has been done in accordance with Canadian livestock meat inspection requirements which are deemed equivalent to the Japanese Food Sanitation Law, and the Japanese Abattoir Law."

"Canada is free from hog cholera and that vaccination against hog cholera and the importation into Canada of pigs vaccinated against hog cholera is prohibited."

Also include the name, address, official establishment number of the Canadian facility and the slaughter or processing dates in Canada in the Remarks section.

It is the exporter's responsibility to provide a copy of an official Canadian Food Inspection Agency (CFIA) certificate that includes this information for the consignment in order for these statements to be included on the FSIS certificate. A copy of the CFIA certificate must also be presented at the Japan port of entry.

- c. Label claims such as "Berkshire" or "Kurobuta" should not be part of the product name identified on the export certificate. Further, additional certification statements referring to such label claims should not be included on FSIS export certificates.
4. Non-ruminant origin meat products produced using natural or artificial casings. In addition to the certification indicated above, the following specific certification is required for these products.
 - a. For meat products using natural sheep casings the following statements must be included in the Remarks section of FSIS 9060-5:
 - (1) *"The casings are derived from animals which were born and raised in countries other than the United Kingdom (Great Britain and Northern Ireland), Ireland, Switzerland, France, Portugal, Belgium, Luxembourg, Denmark, the Netherlands, Liechtenstein, Germany, Spain, Greece, Italy, Czech Republic, Slovakia, Austria, Finland, Slovenia, Poland, Sweden, Israel, Canada, or the USA. At the time of import to the United States it has been confirmed that the casings do not have risk of infection with contagious animal disease by health certificates issued by the originating government."*
 - (2) *"Natural casings from (country of origin) of ovine origin."*
 - b. For meat products using natural bovine casings the following statements must be included in the Remarks section of FSIS 9060-5 or on an FSIS letterhead certificate:
 - (1) *"The casings are derived from animals which were born and raised in countries other than the United Kingdom (Great Britain and Northern Ireland), Ireland, Switzerland, France, Portugal, Belgium, Luxembourg, Denmark, the Netherlands, Liechtenstein, Germany, Spain, Greece, Italy, Czech Republic, Slovakia, Austria, Finland, Slovenia, Poland, Sweden, Israel, Canada, or the USA. At the time of import to the United States it has been confirmed that the casings do not have risk of infection with contagious animal disease by health certificates issued by the originating government."*
 - (2) *"Natural casings from (country of origin) of bovine origin."*
 - (3) *"The cattle origin raw material from which the certified casing were derived originate from raw materials from cattle slaughtered in countries other than those listed above, and these materials and final products were kept separate from any bovine materials from animals slaughtered in countries listed above."*
 - (4) *"The casings production facility is under official U.S. Department of Agriculture (USDA) supervision and maintains a system for tracing the animal*

- origin materials, which guarantees the origin (collagen production facility for artificial casings and country of origin for intestinal casings) can be identified."*
- c. For meat products using natural pork casings the following statements must be included in the Remarks section of FSIS 9060-5:
- (1) *"The casings are free from animal infectious disease as a consequence of ante- and postmortem inspection conducted by official USDA inspectors. If the casings are imported from third countries, at the time of import into the United States, it has been confirmed that the casings do not have risk of infection with contagious animal disease by health certificates issued by the originating government."*
- (2) *"Natural casings from (country of origin) of porcine origin."*
- d. For meat products using artificial casing derived from pork skins the following statements must be included in the Remarks section of FSIS 9060-5:
- (1) *"Artificial casings prepared exclusively from hides and skins."*
- e. For meat products using artificial casing derived from cattle hides the following statements must be included in the Remarks section of FSIS 9060-5 or on an FSIS letterhead certificate:
- (1) *"Artificial casings prepared exclusively from hides and skins."*
- (2) *"The cattle origin raw material from which the certified casing were derived originate from raw materials from cattle slaughtered in countries other than those listed in the annex, and these materials and final products were kept separate from any bovine materials from animals slaughtered in countries listed in the annex."*
- (3) *"The casings production facility is under official US Department of Agriculture (USDA) supervision and maintains a system for tracing the animal origin materials, which guarantees the origin (collagen production facility for artificial casings and country of origin for intestinal casings) can be identified."*
- "Annex: United Kingdom (Great Britain and Northern Ireland), Ireland, Switzerland, France, Portugal, Belgium, Luxembourg, Denmark, the Netherlands, Liechtenstein, Germany, Spain, Greece, Italy, Czech Republic, Slovakia, Austria, Finland, Slovenia, Poland, Sweden, Israel, Canada, or the USA."*
- f. For meat products using artificial casings derived from cellulose, a statement indicating the composition of the casing must be included in the Remarks section of FSIS 9060-5. For example, "Artificial casings prepared from cellulose, fibrous paper, glycerin, and moisture".
5. Imported natural ruminant casings
- a. Obtain FSIS Form 9060-18. The following statements must be included the Remarks section or on an FSIS letterhead certificate:
1. *"The casings are derived from animals which were born and raised in countries other than the United Kingdom (Great Britain and Northern Ireland), Ireland, Switzerland, France, Portugal, Belgium, Luxembourg, Denmark, the Netherlands, Liechtenstein, Germany, Spain, Greece, Italy, Czech Republic, Slovakia, Austria, Finland, Slovenia, Poland, Sweden, Israel, Canada, or the USA."*
2. *"At the time of import to the United States it has been confirmed by official inspection, or confirmed by health certificates issued by the originating government that the casings do not have risk of infection with contagious animal disease. The casings were transported to the approved facilities in a manner to prevent contamination with infectious animal diseases."*
3. *"The casings were stored in clean and sanitary containers and handled*

in a way to prevent contamination with infectious animal disease."

4. *"Natural casings from (country of origin) of (ruminant species) origin."*

5. *Name, address, and establishment number of approved casings facility.*

6. Natural pork casings`

a. Obtain FSIS 9060-7 for casings derived from swine slaughtered in the U.S. and processed in the U.S. The following statements must be in the Remarks section or on an FSIS letterhead certificate:

1. *"The casings were derived from pigs born and raised in the U.S. or legally imported from Canada and subjected to ante-mortem and post-mortem veterinary inspection conducted by official inspectors at the time of slaughter. The casings were transported to the approved facilities in a manner to prevent contamination with infectious animal disease."*

2. *"The casings were stored in clean and sanitary containers and handled in a way to prevent contamination with infectious animal disease."*

3. *"Natural casings from the United States or Canada of porcine origin."*

4. *Name, address, and establishment number of approved casings facility.*

b. Obtain FSIS 9060-18 for imported pork casings. The following statements must be in the Remarks section or on an FSIS letterhead certificate:

1. *"At the time of import to the United States it has been confirmed by official inspection, or confirmed by health certificates issued by the originating government that the casings do not have risk of infection with contagious animal disease. The casings were transported to the approved facilities in a manner to prevent contamination with infectious animal disease."*

2. *"The casings were stored in clean and sanitary containers and handled in a way to prevent contamination with infectious animal disease."*

3. *"Natural casings from (country of origin) of porcine origin."*

4. *Name, address, and establishment number of approved casings facility.*

Note: APHIS regulation (9 CFR 96.3) requires imported natural casings to be certified by the originating country as coming from healthy animals which received antemortem and postmortem inspection and are clean and sound and were prepared in a sanitary manner. Producers must be able to demonstrate that the casings comply with the country of origin requirements indicated above.

B. Pharmaceutical requirements. Export certification of inedible products, other than technical animal fat (9 CFR 351) and certified pet food (9 CFR 355), is no longer provided by FSIS. Exporters should contact APHIS field offices to obtain information about certification of inedible products. A list of APHIS offices is available at <http://www.aphis.usda.gov/vs/ncie/iregs/products/vsavic.pdf>. See FSIS Notice 17-05 for additional information.

C. All export certificates to Japan may be signed by an FSIS veterinarian or inspector.

D. If the meat product transits through a third country, the official USDA seal number applied to the container must be indicated in the "Remarks" section of FSIS Form 9060-5.

E. Military requirements for red meat purchases. Delivery/Purchase Order Number must be placed on the face of FSIS Form 9060-5 for all Defense Personnel Support Center (DPSC) purchases of meat. Military shipments must also be accompanied by a completed FSIS Form 9290.1.

F. When multiple establishments must be entered into blocks 5, 6, and/or 8 of FSIS form 9290-1 it is acceptable to use a continuation sheet that includes the MP(D) number of the 9060-5 and is signed by the same individual signing the 9060-5 and 9290-1.

G. Include the word "chilled" or "frozen" as applicable, on FSIS Form 9060-5 under product description and on FSIS Form 9290-1 in Block 2.

- H. On FSIS Form 9290-1, indicate species for each item in Block 1; for example, franks made of pork and chicken must be shown as "pork and chicken". "FSIS" should be placed in Block 10 for fresh/frozen product.
- I. When multiple establishments must be entered into blocks 5, 6, and/or 8 of FSIS form 9290-1 it is acceptable to use a continuation sheet that includes the MP(D) number of the 9060-5 and is signed by the same individual signing the 9060-5 and 9290-1.

Other Requirements

A. Products for Personal Consumption.

- 1. Products intended for personal consumption in Japan must either be certified with FSIS forms 9060-5 and 9290-1 or labeled as outlined below. Products exported to Japan through mail order will be considered as product for personal consumption, provided the quantity is small enough to reasonably believe that it is intended for personal use and the addressee is an individual (not a company or organization.)
- 2. Personal consumption entries of inspected and passed meat and meat products and poultry products are permitted under simplified certification as provided in section 322.4 of the MPI Regulations. Such product need not be accompanied by FSIS Form 9060-5 and FSIS Form 9290-1 and must enter Japan as it was packaged at time of preparation in a federally inspected plant.

- a. The package must be labeled to include:

- (1) Name of product.
- (2) Name and address of packer or distributor.
- (3) Statement of net quantity of contents.
- (4) Official inspection legend including the official establishment number.
- (5) For other than shelf-stable canned product, the label must bear the following statement immediately below the product name.

"The meat contained herein is for personal use only and not for sale. It is derived from animals that received ante-mortem and post-mortem inspection and were found sound and healthy and have been inspected and passed as provided by law and regulations of USDA."

- b. Meat products which are imported from Australia or New Zealand and are repackaged in USDA approved establishments in the U.S. can be exported to Japan for personal consumption provided the label contains the following statement, in addition to items (1) through (4) in para. a. above:

"The meat contained herein is for personal use only and not for sale. It is legally imported into the United States directly from (Australia or New Zealand) and was packed in a U.S.D.A. approved plant under supervision of the U.S.D.A."

- c. Meat products which are imported into the U.S. from New Zealand and are sold in the original package at U.S. airports are eligible for entry into Japan for personal consumption, provided the following information is provided on the label:

- (1) Name of the product
- (2) Name and address of distributor
- (3) Net Weight
- (4) New Zealand inspection legend
- (5) The following statement:

"The meat contained herein is for personal use and not for sale. It is legally imported into the United States directly from New Zealand and passed import inspection by the U.S.D.A."

- 3. Applying label to package - The required labeling must be applied to the carton by a printed adhesive label that will self destruct if the package is opened between time of packaging at the producing establishment and inspection at the Japanese port of entry. (NOTE: Labels should be applied on cartons at the junction of closed lid flaps

or at the junction of the top and bottom of telescope cartons.)

- B. Microbiological standards. Japanese standards for imported ready-to-eat meat/poultry products (dried or heat treated processed products) require coliform and salmonella to be negative and clostridia or staphylococci to be <1000 organisms per gram. Japanese standards for unheated or specifically heated processed products require coliform to be <100 organisms per gram, clostridia or staphylococci to be <1000 organisms per gram and salmonella to be negative. The Japanese Ministry of Health and Welfare reserves the right to test shipments upon arrival and exporters should be aware of such testing and possible rejection as a result of such test.
- C. Japan has established provisional maximum residue limits (MRLs) for agricultural chemicals (veterinary drugs and pesticides) on foods. These MRLs can be found at <http://www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/index.html>.
- D. Classification as a sausage. Japanese standards require products classified as sausage to be made from meat that is ground or minced, mixed with spices, and formed into a "sausage-like" shape. In addition, the product name must contain the word "sausage".
- E. Any container of meat product exported to Japan, including Okinawa, regardless of the product's source, that transits through a third country, must be sealed with an official USDA seal at a USDA inspected facility.

Plants Eligible for Export

Effective July 27, 2006, federally inspected establishments producing fresh/frozen beef and beef offal intended for export to Japan must participate in an AMS, BEV program and be present on the "Official Listing of Eligible Suppliers for USDA Bovine EV Program". The list can be accessed at <http://www.ams.usda.gov/lsg/arc/b ev.htm>.

A list of cold storage facilities eligible to export fresh/frozen beef and beef offal to Japan is available on FSIS' website, and can be accessed at the following location: http://www.fsis.usda.gov/regulations_&_policies/Eligible_US_Establishments_by_Country/index.asp. Cold storage establishments that want to be added to the list should complete and submit FSIS 9080-3, Establishment Application for Export, to the Office of International Affairs, Import-Export Programs Staff, Washington, DC, Phone (202) 720-0082, Fax (202) 720-7990 through FSIS supervisory channels.

Cold storage facilities are cautioned to be constantly vigilant when assembling shipments of product for export to Japan. Export orders must be carefully carried out to ensure that all products loaded are Japan-eligible. Assembly and loading errors have in the past resulted in the suspension of cold storage and slaughter/cutting facility eligibility for export to Japan and must be avoided in the future.

Beef and beef products intended for U.S. military, airline meals, or shipstores can originate from any federally inspected establishment. Beef and beef products for these uses do not have to be produced under the BEV Program.

Casings establishments that process or repackage natural ruminant casings for direct export to Japan or for use in the production of meat products for export to Japan and the meat processing establishments that produce meat products with natural ruminant casings must comply with the specific establishment requirements indicated in the Processing Section, and must be notified to Japan prior to export. Establishments that comply with these requirements should submit FSIS Form 9080-3 as directed on the Form. FSIS will notify Japan of eligible establishments and maintain the list of eligible establishments in the Export Library.

All other red meat and red meat products eligible for export to Japan can originate from any federally inspected establishment.

Exporters should be aware that establishments not listed in the Meat, Poultry and Egg Products Inspection Directory may experience delayed entry into Japan. Contact the Office of International Affairs, Import-Export Programs Staff, (202) 720-0082, for assistance.

Plants Not Eligible for Export

http://www.fsis.usda.gov/regulations_&_policies/Japan_Requirements/index.asp

Export Requirements for Japan

Beef and beef offal and veal and veal offal from the following establishment are not eligible for export to Japan until further notice:

Est. 1311, Smithfield Beef Group - Souderton, Inc. (formerly Moyer Packing Company) Souderton, PA is ineligible for export effective on and after January 11, 2008.

Est. 21488, National Beef, Brawley, CA is ineligible for export effective on and after April 23, 2008.

Plants Relisted for Export

Est. 86K, Cargill Meat Solutions, Dodge City, KS is relisted for export of product with a certification date on or after January 11, 2008.

Est. 267, Smithfield Beef Group, Tolleson, AZ is relisted for the export of eligible product certified before February 28, 2008, or on or after April 3, 2008. Product produced during the period of suspension is eligible for certification on or after April 3, 2008.

Poultry Export Requirements for Japan

Eligible/Ineligible Poultry Products

A. Eligible Products

1. Poultry and poultry products (except as restricted in the INELIGIBLE section below).

Note: Japan accepts chicken, turkey, guinea fowls, ducks, pigeons, and ostrich.

B. Ineligible Products

1. Specific state restrictions:

Connecticut - Poultry slaughtered on or after November 10, 2006 are eligible. Poultry slaughtered prior to that date are ineligible.

Pennsylvania - Poultry slaughtered on or after November 10, 2006 are eligible. Poultry slaughtered prior to that date are ineligible.

New York - Poultry slaughtered on or after February 22, 2008 and on or before April 10, 2008 are eligible. Poultry slaughtered prior to February 22, 2008 and after April 10, 2008 are ineligible.

West Virginia - Poultry slaughtered prior to March 9, 2007 or slaughtered on or after August 2, 2007 is eligible. Poultry slaughtered on or after March 9 and before August 2, 2007 is ineligible.

Minnesota - Poultry slaughtered prior to March 28, 2007 or on or after September 14, 2007 is eligible. Poultry slaughtered on or after March 28, 2007 and before September 14, 2007 is ineligible.

South Dakota - Poultry slaughtered prior to May 24, 2007 or slaughtered on October 12, 2007 to October 17, 2007 and on or after March 21, 2008 is eligible. Poultry slaughtered on May 24, 2007 to October 11, 2007, or slaughtered after October 18, 2007 and prior to March 21, 2008 is ineligible.

Nebraska - Poultry slaughtered prior to May 23, 2007 or on or after November 30, 2007 is eligible. Poultry slaughtered on or after May 23, 2007 and before November 30, 2007 is ineligible.

Virginia - Poultry slaughtered prior to June 15, 2007 is eligible. Poultry slaughtered on or after June 15, 2007 and before November 2, 2007 is ineligible. Poultry slaughtered on or after November 2, 2007 is eligible.

New Jersey - Poultry slaughtered on or prior to January 15, 2008 is eligible. Poultry slaughtered after January 15, 2008 is ineligible.

Arkansas - Poultry slaughtered prior to May 9, 2008 is eligible. Poultry slaughtered on or after May 9, 2008 is ineligible.

See new certification statements.

The following FSIS Letterhead Certificates are available:

- FSIS Letterhead Certificate for Poultry Slaughtered Prior to November 10, 2006.
- FSIS Letterhead Certificate for Poultry Slaughtered on or after November 10, 2006, but prior to March 9, 2007.
- FSIS Letterhead Certificate for Poultry Slaughtered on or after March 9, 2007, but prior to March 29, 2007.
- FSIS Letterhead Certificate for Poultry Slaughtered on or after March 29, 2007, but prior to May 23, 2007.
- FSIS Letterhead Certificate for Poultry Slaughtered on or after May 23, 2007, but prior to May 24, 2007.
- FSIS Letterhead Certificate for Poultry Slaughtered on or after May 24, 2007, but prior to June 15, 2007.
- FSIS Letterhead Certificate for Poultry Slaughtered on or after June 15, 2007, but prior to August 2, 2007.
- FSIS Letterhead Certificate for Poultry Slaughtered on or after August 2, 2007, but prior to September 14, 2007.
- FSIS Letterhead Certificate for Poultry Slaughtered on or after September 14, 2007, but prior to October 12, 2007.
- FSIS Letterhead Certificate for Poultry Slaughtered on or after October 12, 2007, but prior to October 18, 2007.
- FSIS Letterhead Certificate for Poultry Slaughtered on or after October 18, 2007, but prior to November 2, 2007.
- FSIS Letterhead Certificate for Poultry Slaughtered on or after November 2, 2007 and before November 30, 2007.
- FSIS Letterhead Certificate for Poultry Slaughtered on or after November 30, 2007 and before January 15, 2008.
- FSIS Letterhead Certificate for Poultry Slaughtered on or after January 15, 2008 and before February 22, 2008.
- FSIS Letterhead Certificate for Poultry Slaughtered on or after February 22, 2008 and before March 21, 2008.
- FSIS Letterhead Certificate for Poultry Slaughtered on or after March 21, 2008 and before April 10.
- FSIS Letterhead Certificate for Poultry Slaughtered on or after April 10, 2008 and before May 9, 2008.
- FSIS Letterhead Certificate for Poultry Slaughtered on or after May 9, 2008.

Notes:

1. Eligibility will be determined by the slaughter or production date entered on FSIS Form 9290-1 which must be in month/day/year format (use this format in lieu of the "Month & Year" indicated on Form 9290-1).
2. These restrictions and poultry certification statements do not apply to product in hermetically sealed containers cooked to 100° C. It is the importer's responsibility to complete an application at the port of entry to confirm that it is canned product that is cooked to 100° C.
2. Duckling Giblet Imports. Though Japanese regulations permit the import of liver in the giblet pack of whole frozen ducklings, the Ministry of Agriculture, Forestry and Fisheries (MAFF) prefer the liver not to be included in the package. Import inspectors have been notified of this preference and exporters should be aware that consignments may be detained/rejected.
3. Coloring agents are not permitted in raw products in Japan.

Processing Requirements

Note: Exporters are advised to work closely with their importer regarding Japanese standards of meat products intended for export to Japan. The information presented below is not inclusive of all the details of the standards of composition and manufacture. Please contact the Technical Service Center (402) 344-5000 if additional assistance is needed.

- A. Processed Poultry Product.

1. Unheated Poultry Products

- a. May contain up to 70 ppm nitrite in the finished product (NOTE: USDA requires a minimum of 120 ppm nitrite going into non-heated, cured products. Non-heated, cured product containing a maximum of 70 ppm nitrite may be exported to Japan provided that the outside container is marked "For Export to Japan.").
- b. Exporters should be aware of the raw material requirements for producing unheated meat products for Japan since they may have to document this information to their Japanese importer. The meat must be maintained chilled at 4° C (39.2° F) and the pH of the meat is to be 6.0 or below.

2. Specifically heated meat products.

- a. May contain up to 70 ppm nitrite in the finished product
- b. Must be heated to an internal temperature of 60° C (140° F) maintained for 12 minutes maximum or the equivalent. **Note:** Current Japanese regulations recognize the cooking standards for roast beef (9 CFR 318.17) as equivalent to the above requirements or the time/temperature chart listed below:

C°	(F°)	Time (min)
55	(131.0)	97
56	(132.8)	64
57	(134.6)	43
58	(136.4)	28
59	(138.2)	19
60	(140.0)	12
61	(141.8)	9
62	(143.6)	6
63	(145.4)	0

- c. Exporters should be aware of the raw material requirements for producing specifically heated meat products for Japan since they may have to document this information to their Japanese importer. The meat must be maintained chilled at 4° C (39.2° F) and the pH of the meat is to be 6.0 or below.

3. Heat treated products. (e.g., Turkey Ham, bacon, sausage products):

- a. May contain up to 70 ppm nitrite in the finished product.
- b. Must be heated to an internal temperature of 63° C (145° F) maintained for 30 minutes minimum or equivalent. Current Japanese regulations recognize the following time/temperature relationships as equivalent:

C°	(F°)	Time (min)
60	(140.0)	129
61	(141.8)	80
62	(143.6)	49
63	(145.4)	30
64	(147.2)	19
65	(149.0)	12
66	(150.8)	7

67	(152.6)	5
68	(154.4)	3
69	(156.2)	2
70	(158.0)	1
71	(159.8)	38 sec.
72	161.6)	23 sec.
73	(163.4)	14 sec.
74	(165.2)	9 sec.
75	(167.0)	5 sec.

4. Dried meat products.
 - a. May contain up to 70 ppm nitrite in the finished product.
 - b. Water activity must be under 0.87.

Labeling Requirements

- A. Net Weight
 1. If not preprinted by the label manufacturer, the net weight (in kilograms) should be stenciled, stamped or handwritten on the carton. Pounds may be shown on the label as well.
 2. Product arriving in Japan without net weight labeling on the retail packages must be weighed and labeled in compliance with the Japanese Measurement Law.
- B. Food Additives. Japanese food additives requirements are very complex. Importers can provide samples of new products to the Ministry of Health and Welfare inspectors to verify that all additives are approved by Japan. Exporters are advised to work with their importers to confirm eligibility of additives in the products being exported to Japan.
- C. Packages, which contain products that deteriorate within five days must bear a "use by" date, and products whose quality can be maintained longer than five days are required to show a "best before" date. The date information can be applied in the United States prior to export or it can be applied in Japan prior to release from a bonded warehouse. This requirement applies to bulk packed products as well as consumer ready packages.

Documentation Requirements for Poultry Products

- A. Certification requirements for poultry products.
 1. Obtain FSIS Form 9060-5.
 - a. In the "remarks" section of FSIS 9060-5, include the word "chilled" or "frozen", as applicable. FSIS Form 9060-5 must bear the following statement under "Remarks":

"There have been no outbreaks of fowl pest (fowl plague) for at least 90 days in the United States. Further, in the area where birds for export meat were produced (such an area being within a minimum radius of 50 kilometers from the production farm), Newcastle disease, fowl cholera and other serious infectious fowl diseases as recognized by the government of the United States, have not occurred for at least 90 days."
 - b. If the poultry product transits through a third country, the official USDA seal number applied to the container must be indicated in the "Remarks" section of FSIS Form 9060-5.
- B. Poultry may be restricted from originating or passing through certain states in which low path avian influenza has been reported. Applicants for export certification must determine which certification statement or statements apply to the product to be exported based on the date of slaughter. The statement(s) must be typed in the "Remarks" section of FSIS

Form 9060-5 or supplied on FSIS Letterhead Certificate(s):

1. Slaughtered prior to November 10, 2006 FSIS Letterhead Certificate:
"The live poultry used for the production of the exported poultry meat did not originate from Connecticut, Pennsylvania, or New York and did not pass through Connecticut, Pennsylvania, or New York before being carried into poultry processing plants."
2. Slaughtered on or after November 10, 2006, but prior to March 9, 2007 FSIS Letterhead Certificate:
"The live poultry used for the production of the exported poultry meat did not originate from New York and did not pass through New York before being carried into poultry processing plants."
3. Slaughtered on or after March 9, 2007, but prior to March 29, 2007 FSIS Letterhead Certificate:
"The live poultry used for the production of the exported poultry meat did not originate from New York or West Virginia and did not pass through New York or West Virginia before being carried into poultry processing plants."
4. Slaughtered on or after March 29, 2007, but prior to May 23, 2007 FSIS Letterhead Certificate:
"The live poultry used for the production of the exported poultry meat did not originate from New York, West Virginia, or Minnesota and did not pass through New York, West Virginia, or Minnesota before being carried into poultry processing plants."
5. Slaughtered on or after May 23, 2007, but prior to May 24, 2007 FSIS Letterhead Certificate:
"The live poultry used for the production of the exported poultry meat did not originate from New York, West Virginia, Minnesota, or Nebraska and did not pass through New York, West Virginia, Minnesota, or Nebraska before being carried into poultry processing plants."
6. Slaughtered on or after May 24, 2007, but prior to June 15, 2007 FSIS Letterhead Certificate:
"The live poultry used for the production of the exported poultry meat did not originate from New York, West Virginia, Minnesota, Nebraska, or South Dakota and did not pass through New York, West Virginia, Minnesota, Nebraska, or South Dakota before being carried into poultry processing plants."
7. Slaughtered on or after June 15, 2007, but prior to August 2, 2007 FSIS Letterhead Certificate:
"The live poultry used for the production of the exported poultry meat did not originate from New York, West Virginia, Minnesota, Nebraska, South Dakota, or Virginia and did not pass through New York, West Virginia, Minnesota, Nebraska, South Dakota, or Virginia before being carried into poultry processing plants."
8. Slaughtered on or after August 2, 2007, but prior to September 14, 2007 FSIS Letterhead Certificate:
"The live poultry used for the production of the exported poultry meat did not originate from New York, Minnesota, Nebraska, South Dakota, or Virginia and did not pass through New York, Minnesota, Nebraska, South Dakota, or Virginia before being carried into poultry processing plants."
9. Slaughtered on or after September 14, 2007, but prior to October 12, 2007 FSIS Letterhead Certificate:
"The live poultry used for the production of the exported poultry meat did not originate from New York, Nebraska, South Dakota, or Virginia and did not pass

through New York, Nebraska, South Dakota, or Virginia before being carried into poultry processing plants."

10. Slaughtered on or after October 12, 2007, but prior to October 18, 2007 FSIS Letterhead Certificate:

"The live poultry used for the production of the exported poultry meat did not originate from New York, Nebraska, or Virginia and did not pass through New York, Nebraska, or Virginia before being carried into poultry processing plants."

11. Slaughtered on or after October 18, 2007, but prior to November 2, 2007 FSIS Letterhead Certificate:

"The live poultry used for the production of the exported poultry meat did not originate from New York, Nebraska, South Dakota, or Virginia and did not pass through New York, Nebraska, South Dakota, or Virginia before being carried into poultry processing plants."

12. Slaughtered on or after November 2, 2007 and before November 30, 2007 FSIS Letterhead Certificate:

"The live poultry used for the production of the exported poultry meat did not originate from New York, Nebraska or South Dakota and did not pass through New York, Nebraska, or South Dakota before being carried into poultry processing plants."

13. Slaughtered on or after November 30, 2007 FSIS and before January 15, 2008 Letterhead Certificate:

"The live poultry used for the production of the exported poultry meat did not originate from New York or South Dakota and did not pass through New York or South Dakota before being carried into poultry processing plants."

14. Slaughtered on or after January 15, 2008 FSIS and before February 22, 2008 Letterhead Certificate:

"The live poultry used for the production of the exported poultry meat did not originate from New York, South Dakota, or New Jersey and did not pass through New York, South Dakota, or New Jersey before being carried into poultry processing plants."

15. Slaughtered on or after February 22, 2008 and before March 21, 2008 FSIS Letterhead Certificate:

"The live poultry used for the production of the exported poultry meat did not originate from South Dakota or New Jersey and did not pass through South Dakota or New Jersey before being carried into poultry processing plants."

16. Slaughtered on or after March 21, 2008 and before April 10, 2008 FSIS Letterhead Certificate:

"The live poultry used for the production of the exported poultry meat did not originate from New Jersey and did not pass through New Jersey before being carried into poultry processing plants."

17. Slaughtered on or after April 10, 2008 and before May 9, 2008 FSIS Letterhead Certificate:

"The live poultry used for the production of the exported poultry meat did not originate from New York or New Jersey and did not pass through New York or New Jersey before being carried into poultry processing plants."

18. Slaughtered on or after May 9, 2008 Letterhead Certificate:

"The live poultry used for the production of the exported poultry meat did not originate from Arkansas, New York, or New Jersey and did not pass through Arkansas, New York, or New Jersey before being carried into poultry processing plants"

- C. Additional certification is required that trucks and railcars either did not transit any restricted states OR were sealed by USDA during transit of any restricted state.
- If the product will not transit restricted states during the period of restriction or transited before or after the period of restriction, statement 1 may be completed and signed at the plant where the export originates.
 - If the product must be sealed for transport through restricted states, the FSIS program employee breaking the seal prior to loading into Japan-bound ocean containers verifies that the seal was intact, then completes statement 2 and signs the certificate.

The statements below are provided on an FSIS Letterhead Certificate:

1. "To the best of FSIS' knowledge, the exported poultry meat did not transit _____ during the period of restriction before leaving the United States" OR
2. "The container was sealed by FSIS prior to transiting _____ with USDA seal number _____. If seal number _____ was removed by FSIS, the exported poultry meat did not transit restricted states after the removal in _____."

See Guideline for completion of this certificate.

Procedure for determining states to include in the statement above:

1. Determine the earliest date of slaughter for birds in the consignment.
2. Determine that the product did not transit unsealed any state that is currently restricted. The restriction periods are listed below:

Connecticut (CT) - Before November 10, 2006
Pennsylvania (PA) - Before November 10, 2006
New York (NY) - Before February 22, 2008 and on or after April 10, 2008.
West Virginia (WV) - March 9, 2007 to August 2, 2007.
Minnesota (MN)- March 29, 2007 to September 13, 2007.
South Dakota (SD) - May 24, 2007 to October 11, 2007, and October 18, 2007 to March 21, 2008.
Nebraska (NE) - May 23, 2007 to November 30, 2007.
Virginia (VA) - June 15, 2007 to November 2, 2007.
New Jersey (NJ) - After January 15, 2008.
Arkansas (AR) - On or after May 9, 2008.

- D. On FSIS Form 9290-1, the species for each item should be indicated in Block 1; for example, all turkey franks must be shown as "turkey" and franks made of beef, pork and chicken as "beef, pork and chicken". Block 2 should contain the same product description as listed on FSIS form 9060-5. Blocks 6 and 7 should be completed for plants preparing cuts or packing byproducts (including legs, thighs, drumsticks, midjoint wings). Blocks 7 and 8 should be completed for all processed products. The slaughter or production date (month/day/year format) should be entered in Block 9 for all poultry and poultry products. "FSIS" should be placed in Block 10 for fresh/frozen product. Blocks 11 and 12 must agree with the consignor and consignee on FSIS form 9060-5. The same USDA official that signed FSIS form 9060-5 must sign FSIS form 9290-1.
- E. Ready-to-cook poultry products. When poultry for export to Japan is processed with shank portion attached, the statement "*portion of shank attached*" shall be entered on FSIS Form 9060-5 under "remarks."
- F. Certification requirements for ground or comminuted turkey or chicken. Such products include those labeled "Ground Turkey", "Ground Chicken", "Ground Turkey Meat," "Ground Chicken Meat," "Mechanically Deboned Turkey," "Mechanically Deboned Turkey Meat," and Mechanically Deboned Chicken Meat." The Japanese Ministry of Health and Welfare reserves the right to test such shipments for Salmonellae upon arrival and exporters should be aware of such testing and possible rejection as a result of such test.
- G. Ostrich Meat. Obtain FSIS Form 9060-5 and FSIS Form 9290-1.

Export Requirements for Japan

- H. Military requirements for Poultry Purchases. Delivery/Purchase Order Number must be placed on the face of FSIS Form 9060-5 for all Defense Personnel Support Center (DPSC) purchases of poultry. Military shipments must also be accompanied by a completed FSIS Form 9290.1.
- I. All export certificates to Japan may be signed by an FSIS veterinarian or inspector.
- J. When multiple establishments must be entered into blocks 5, 6, and/or 8 of FSIS form 9290-1 it is acceptable to use a continuation sheet that includes the MP(D) number of the 9060-5 and is signed by the same individual signing the 9060-5 and 9290-1.

Other Requirements

A. Products for Personal Consumption.

- 1. Products intended for personal consumption in Japan must either be certified with FSIS forms 9060-5 and 9290-1 or labeled as outlined below. Products exported to Japan through mail order will be considered as product for personal consumption, provided the quantity is small enough to reasonably believe that it is intended for personal use and the addressee is an individual (not a company or organization.)
- 2. Personal consumption entries of inspected and passed meat and meat products and poultry products are permitted under simplified certification as provided in section 322.4 of the MPI Regulations. Such product need not be accompanied by FSIS Form 9060-5 and FSIS Form 9290-1 and must enter Japan as it was packaged at time of preparation in a federally inspected plant.

a. The package must be labeled to include:

- Name of product.
- Name and address of packer or distributor.
- Statement of net quantity of contents.
- Official inspection legend including the official establishment number.

b. For other than shelf-stable canned product, the label must bear the following statement immediately below the product name:

"The poultry contained herein is for personal use only and not for sale. It is derived from birds that received ante-mortem and post-mortem inspection and were found sound and healthy and have been inspected and passed as provided by law and regulations of USDA."

c. Applying label to package--The required labeling must be applied to the carton by a printed adhesive label that will self destruct if the package is opened between time of packaging at the producing establishment and inspection at the Japanese port of entry. **NOTE:** Labels should be applied on cartons at the junction of closed lid flaps or at the junction of the top and bottom of telescope cartons.

- B. Microbiological standards. Japanese standards for imported ready-to-eat meat/poultry products (dried or heat treated processed products) require coliform and salmonella to be negative and clostridia or staphylococci to be <1000 organisms per gram. Japanese standards for unheated or specifically heated processed products require coliform to be <100 organisms per gram, clostridia or staphylococci to be <1000 organisms per gram and salmonella to be negative. The Japanese Ministry of Health and Welfare reserves the right to test shipments upon arrival and exporters should be aware of such testing and possible rejection as a result of such test.
- C. Japan has established provisional maximum residue limits (MRLs) for agricultural chemicals (veterinary drugs and pesticides) on foods. These MRLs can be found at <http://www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/index.html>.
- D. Any container of poultry product exported to Japan, including Okinawa, regardless of the product's source, that transits through a third country, must be sealed with an official USDA seal at a USDA inspected facility.

Plants Eligible for Export

http://www.fsis.usda.gov/regulations_&_policies/Japan_Requirements/index.asp

Export Requirements for Japan

All federally inspected establishments are eligible to export to Japan. Exporters should be aware that establishments not listed in the Meat, Poultry and Egg Product Inspection Directory may experience delayed entry into Japan. Contact the Technical Service Center at (402) 344-5000 for assistance.

JA-144 (Jul 2, 2008)

調査報告

ナショナルビーフ社カリフォルニア工場 (Est. 21488)

日本への不適格な牛肉の輸出

2008年8月13日

要約

ナショナルビーフ社カリフォルニア工場 (Est. 21488, 57 East Shank Road, Brawley California 所在) から日本向けに輸出された貨物には 1 箱の製品コード 9781 (Beef plates Yoshinoya) とラベルされた骨付きショートロインが含まれていた。ナショナルビーフ社による調査によってエラーの原因が、箱詰め前にラベリングを行うことが許されていたことによるものと結論付けられた。

日本向け製品用の箱への事前のラベリングを防ぐための改善措置はすでにとられており、概要は下記のとおり：

ナショナルビーフ社カリフォルニア工場は、日本向けに輸出される製品の箱について、封印される前に梱包ミスが確認されるよう、内部手順を措置している。本内部手順の一環として QA (品質保証) チェック後の箱は、ふたの内側に独自のスタンプが押印される。梱包のミスの根本原因(事前のラベリング)に対処するよう施設の QSA (品質システム評価) プログラムは変更されている。施設の QA グループは日本向け製品の箱詰めが行われているそれぞれのエリアを監査することとしている。QA グループによる監査は再箱詰めエリアを含むいかなる生産エリアにも事前にラベルされた箱がないことを証明するため、生産時間の間、1 時間毎に行われることとなる。職員には出席簿をとった上で、口述での研修が行われた。研修の効果の検証は管理職が業務を目視確認することで行われる。手順の監査によっても研修が適切に行われていたことが検証される。日本向け製品は箱詰めされた後、次の手順で確認されることとなる：1) 箱を封印する前の最終確認、2) 最終計量時においてコードごとの重量範囲を確認、3) 出荷準備中の箱の損傷や状態の検査、4) すべての箱は承認されたコードの製品のみが含まれていることを保証するための二重スキャンが行われる。

USDA はナショナルビーフ社カリフォルニア工場によってとられた改善措置を検証した。

目的

米国農務省（USDA）は日本向け貨物の中に Frozen Beef Plate Yoshinoya として不適切に識別された骨付きショートロインが混入した事案の周辺状況を評価するため、ナショナルビーフ社カリフォルニア工場（Est. 21488）における操業状況の調査を行った。

背景

他国向け米国産牛肉製品の輸出品は、独立しているが相互に依存した 3 つの組織の活動により促進されている：

- 1) 米国の食肉および家畜業界
- 2) USDA 食品安全検査局（FSIS）、及び
- 3) USDA 農業販売促進局（AMS）

米国食肉業界は健康な動物のと畜と、健全で、適切に表示され、適正な食品の提供に関する責任を負っている。米国食品安全基準への適合に加え、業界は輸入国によって課される全ての条件を満たさなければならない。米国からの製品の輸出が米国農務省により認可されることが可能となる以前に、米国食品安全条件及び輸入国の貿易条件の双方に適合しなければならない。

FSIS は食肉及び食鳥製品の検査と他国への製品の輸出証明についての責務を負っている。2006 年 3 月 1 日に公表された FSIS 指令 9000.1 改訂 1「輸出証明」は、これらの責務について詳細な記述を提供している。FSIS の規制に関する主要な役割は、食肉及び食鳥製品が適正で、国内及び国際取引における販売に関する全ての米国食品安全基準に適合しているという重要な決定を行うことである。この規制に関する活動は、FSIS が USDA の検査印を貼付する時点で完了する。しかし、FSIS の職員が製品の輸出証明書に署名するためには、検査完了後に追加的検証が必要である。

AMS は、輸出認定された施設が輸入国の条件に適合できることを保証するための EV プログラムの基準を設定する責任を負っている。これらのプログラムは AMS によって有料で認定・監視され、手数料は参加する施設が支払う。

USDA 検査印と AMS の EV プログラムの組み合わせにより、輸出向けの米国産食肉及び食鳥製品が、全ての米国食品安全基準および輸入国の貿易条件に適合しているものとして認証されるに足るとの保証が得られる。

輸出証明プロセス

日本向け輸出証明プロセスは FSIS 指令 9000. 1 改定 1 及び 9040. 1 改定 3(別添参照)

に記載されており、下記のとおり行われる：FSIS 検査官は日本向け輸出申請書 (FSIS Form 9060-6) を接受し、申請書が間違いなく記載され、完備しており、申請者により署名されていることを確認する。「ラベル上の製品名」欄には、すべての輸出される製品が、該当する製品コードと、申請書上の生産施設における AMS 認定製品リスト上に記されているとおりに製品コードと製品概要により記されている必要がある。

FSIS 検査官はまだ署名していない申請書上の製品について、対日輸出適格品生産施設が日本向け適格品として AMS へ送付している製品リストと比較する。すべての製品が AMS による施設承認後に生産されたものと確認されれば、検査官は、FSIS 指令 9000. 1 に定められた輸出検査に進み、申請書とともに提出された追加書類と、抽出された箱の状態の確認を行う。

書類及び製品の状態に問題がなければ、FSIS 検査官は輸出検査申請書にサインし、製品へのスタンプを許可し、輸出検査証明書 (FSIS Forms 9060-5, 9290-1 および牛肉への追加証明書) へサインする。

調査結果

USDA はナショナルビーフ社カリフォルニア工場の手続き及び業務が、米国の輸出認証要件及び日本の輸入条件に合致しているかどうかを判断するために調査を実施した。

結果は以下のとおりである：

1. 不適格な牛肉製品の混入

- ・ ナショナルビーフ社カリフォルニア工場の管理措置は、日本向け輸出適格製品の貨物に不適格な製品が混入することを防ぐことができなかった。
- ・ ナショナルビーフ社カリフォルニア工場の従業員は箱詰めされる製品が箱のラベルと確実に一致するように、日本向け牛肉を箱詰めする責任を負っていた。
- ・ 間違った梱包は、箱への事前のラベリングを許可し、結果として箱詰めの間違いを生む余地を生じさせてしまったことにより起こった。

2. 製品のトレーサビリティ

- ・ USDA によるさかのぼり調査で、すべての輸出書類は輸出認証プロセスを通じて確認されたことが明らかとなった。
- ・ 認定製品に対するすべての FSIS および AMS 輸出認証は正確に実施されていた。
- ・ 間違っ て梱包された製品は、A40 の牛のと畜工程由来であることが確認された。

3. ナショナルビーフ社カリフォルニア工場より報告された本事案の経緯

ナショナルビーフ社が把握しうる限り、本事案の一連の経緯は下記のとおり：

- ・ 2007 年 6 月 26 日 - 問題となった製品がナショナルビーフ社 (カリフォルニア州ブローリー Est.21488) にて生産/箱詰めされた。

- ・ 2007年7月27日 - インランド・コールドストレージ（カリフォルニア州バーノン）より、MPG Certificate #550910 の証明書とともにアイクレスト社へ出荷
- ・ 2007年8月4日 - 日本到着
- ・ 2007年8月10日 - 厚生労働省検疫所および農林水産省動物検疫所による輸入検査の実施
- ・ 2007年8月28日 - 通関
- ・ 2008年4月19日 - エンドユーザーの加工工場へ輸送
- ・ 2008年4月22日 - 不適格製品が発見される。
- ・ 2008年4月23日 - 調査報告書及び是正措置を記した書簡が USDA へ送付される（ワシントンDCのFSISおよびFAS（海外農業局）の指示により地方レベルへ伝達）。
- ・ 2008年4月24 - 25日 - USDAはOPEER（FSISプログラム評価・執行・レビュー室）調査官をナショナルビーフ社カリフォルニア工場へ派遣 - OPEER 調査官は問題は見つからなかったことを口頭にて報告。
- ・ 2008年5月2日 - USDA FSIS 地域事務所はOPEERによる監査結果をもとにした追加質問を受けた。

ナショナルビーフ社カリフォルニア工場の調査結果

ナショナルビーフ社カリフォルニア工場は日本向けに不適格製品を輸出することとなった背景について内部調査を行った。以下は調査の概要である。

ラベルを貼り間違えられた箱が日本に輸出された根本原因は、ナショナルビーフ社カリフォルニア工場の部分肉加工部門が箱詰め前にあらかじめ箱にラベルを貼り付けていたことである。この作業は中止された。

バラ肉は、ショートロインとは異なるラインで部分肉加工、袋詰め、箱詰めされていた。ナショナルビーフ社カリフォルニア工場は対日輸出用のショートロインの製造は行っていなかった。施設のQSAプログラムどおりに、工場はフロアに入る製品をグレードと月齢によって区分していた。ここからバラ肉とショートロインは別々の加工台に送られる。製品は再び封印エリアで一緒になる。このエリアでは、箱の後面の製品コードラベルにより区分管理が保たれている。月齢が証明された牛として日本向けに指定された製品を生産する際には、これらの製品は部分肉加工フロアにおいて区分された処理により部分肉加工される。我々は、日本向け製品には許可されたラベルのみが使用されることを確認している。全てのアメリカ国内の施設と同様、日本向けでない製品は日本向けに許可されていないコードで梱包・箱詰めされている。

今回のシナリオは、ショートロインの外装検品担当者が損傷した箱をその場にあった箱と取替えた際に、詰め替えた製品の製品コードラベルを、自ら、直接貼り付けなかったことに起因していた。この箱にはすでにバラ肉のラベルが貼られていた。再箱詰めが行われていた場所の関係から、この箱は通常行われている施設の検査プロセスを経てい

なかった。

追跡調査が行われ、この箱と一緒に輸出された製品はすべて、日本向け適格品であることが証明された。

今回の事案を受け、QSA マニュアルは改善され、すべての箱詰めエリアにおいて、箱への事前ラベル貼り付けを1時間ごとに確認することが盛り込まれた。

改善措置

ナショナルビーフ社カリフォルニア工場 (Est. 21488) は、日本への不適格製品の輸出を引き起こした、または助長した状況を改善するための対策をとった。

ナショナルビーフ社カリフォルニア工場から USDA へ報告された改善措置は以下のとおり：

- ・ ナショナルビーフ社カリフォルニア工場は、日本向け製品の箱は箱が封印される前に、箱詰めミスがチェックされる内部手順を引き続き措置する。QA チェックを受けたすべての箱は、ふたの内側に独自のスタンプを押される。
- ・ このスタンプは処理の最終段階で行われる。バラ肉については、このスタンプは封印室へ箱が送られる前の処理の最終段階に、別の部屋で行われる。その他のすべての輸出製品では、封印機の直前で直接スタンプされる。スタンプは箱を確認したスタッフを特定するものである。(AMS QSA プログラムは 100%の箱へのスタンプを特定の製品要件として要求していないが、QA 検査を受けた全箱へのスタンプは、施設の QA 担当者が企業側の要望により箱を検査していることを保証するための内部ツールとして利用される。
- ・ ナショナルビーフ社カリフォルニア工場は、全ての箱の内部に独自の QA スタンプが押されていることを要求していないが、全ての日本向け製品の箱は施設従業員/QA 担当者により監視/検査される。上で述べたとおり、QA 担当者による箱へのスタンプは、施設が手順の実行を保証する上での補助的な手段である。
- ・ 対日 EV プログラム用の箱への事前のラベル貼り付けが再発しないことを確実にする目的で、作業手順と QSA プログラムをさらに改良するために、ナショナルビーフ社はカリフォルニア工場の QSA プログラムを変更した。工場の QA グループは日本向けの製品の箱詰めが行われるそれぞれのエリアの監査を行うこととしている。この監査はすべての生産プロセスの間、1時間に1回行われることになる。
- ・ この監査は再箱詰めエリアを含むすべての生産エリアにおいてあらかじめラベルされた箱がないことを保証するため、QSA プログラムに加えられた。日本向け製品に対して行われるいかなる再箱詰めも、生産フロアのみで行われる。この手順は施設管理者と QA 担当者により監視される。そしてその再箱詰めされた製品には、全ての日本向け製品と同様に施設/QA 検査を受ける。
- ・ ナショナルビーフ社カリフォルニア工場は、事前のラベル貼り付けが許可されないこ

とを明文化した条件を QSA プログラムに追加したほか、変更したプログラムの遵守を保証するための監査基準を追加した。

- ・ ナショナルビーフ社カリフォルニア工場は、全ての対日輸出製品に特定の色の箱を使うことを計画してはいないが、近々、Beef Plate Yoshinoya については、茶色い箱に梱包される骨付きショートロインと分別するために白い箱に梱包することとする。上述のとおり、事前のラベル貼り付けが今回のミスの根本原因であり、対日輸出製品については、それはもはや実施されていない。この変更は工場の QSA プログラムに反映されている。
- ・ 従業員のトレーニングは、出席簿をとり、口述で行われた。トレーニングの効果の検証は、管理者が業務を目視確認することで行われる。このプロセスに対する監査によっても、トレーニングが適切であったことが証明されるだろう。(別紙参照)
- ・ 事前にラベルを貼り付けられた箱の排除により、従業員は現在どのコードの製品を箱詰めしているか把握しており、箱詰め時にラベルを貼り付けることとする。輸出用ラベルは非輸出用ラベルと近接した場所に置かれない。
- ・ 日本へ輸出される製品は箱詰めされた後、次の方法で確認されることとなる：1) 箱を封印する前の最終確認、2) 最終計量時においてコードごとの重量範囲を確認、3) 出荷準備中の箱の損傷や状態の検査、4) すべての箱は承認されたコードの製品のみが含まれていることを保証するための二重スキャンが行われる。

結論

USDA はこの調査に対して以下のように結論付けた：

- ・ 1 箱の不適格な牛肉は日本向けのものではなく、国内市場用に生産されたものであった。
- ・ 不適格な製品は USDA により食品として検査・合格し、輸出された時点においてアメリカ国内にて消費するのに適した安全で健全な食品であった。
- ・ 当該貨物に発行された証明書は月齢証明された動物由来であることを含み、日本向け牛肉の EV プログラムに基づく特定製品要件を満たしたものである。
- ・ USDA はナショナルビーフ社カリフォルニア工場において日本向けの輸出に不適格な製品が混入した根本原因、当該施設が輸出用梱包の箱に事前にラベルを貼り付けたことから起こった当該施設に固有の梱包ミスであることに同意する。
- ・ USDA はナショナルビーフ社カリフォルニア工場がとった改善対策を確認し、この誤出荷の元となった根本原因を改善し、対処するに十分であることを確認した。
- ・ 適格品のみが日本向けに輸出されることを確実にするため、FSIS は 2008 年 7 月 2 日に FSIS 輸出ライブラリに注意喚起の文書を掲載することで輸出施設に対して注意を促した。(別紙参照)
- ・ USDA はナショナルビーフ社カリフォルニア工場 (Est. 21488) からの日本向け輸出

製品に対して、この報告を日本政府が受け入れ次第、証明書の発行を再開する準備がある。

別添

別添 1 FSIS 指令 9000.1. 改訂 1

別添 2 FSIS 指令 9040.1 改訂 3

別添 3 従業員のトレーニング

別添 4 日本向け輸出条件 JA-144 (2008 年 7 月 2 日付)

米国農務省 (USDA)
食品安全検査局 (FSIS)
ワシントン・D. C.

FSIS 指令 9000.1 改定1版 2006年3月1日

輸出証明

I. 目的

米国産食肉及び食鳥肉製品の世界的な信頼を確立するために、輸出証明プロセスは重要な役割を果たしている。したがって、FSISは、このプロセスにおける統一性・安全性・正確性を今後も高いレベルで確保していかなければならない。本指令は、地域事務所 (DO) 及び検査プログラム担当職員を対象に、遵守すべき明確な基準を定めるものである。本指令は、FSISの証明担当職員が輸出証明書に署名できないと感じた場合のプロセスを明示し、FSIS書式9060-6のファックスを使ってその書式で求められている情報を提供できることを明示し、輸出条件ライブラリーの目的を明示し、本指令の他の側面も明示するものである。

II. 取消し

FSIS 指令9000.1 1999年9月9日付け

III. 再発令の理由

FSISは、輸出証明プロセスに関するFSISの方針を明らかにするため、本指令を全体として再発令するものである。

IV. 根拠となる法令

21 U. S. C 616

9CFR 156, 307.4(c), 312.8, 316.5, 317.1, 317.7, 318.2, 322.1, 322.2, 322.4, 325.8, 325.13, 350, 351, 354, 355, 362, 381.37(c), 381.66, 381.104, 381.105-107, 381.128, 381.193

FSIS 指令5110.1 改定1版、9040.1 改定3版

V. 背景

- A. FSIS規則に定めるとおり、輸出者 (申請者) による申請が提出されると、FSIS検査プログラム担当職員は、その職権にもとづき、検査合格済み製品を海外に出荷できる公的な輸出証明書を発行する。まず、申請者が、検査プログラム担当職員に対して、記入済みのFSIS書式9060-6を提出する。検査プログラム担当職員は、以下の手続きが終了した場合に限り、その申請書に署名をし、輸出証明書 (FSIS様式9060-5,

健全な食肉及び食鳥輸出証明)及び輸出印を発行することができる(証明書への署名はしない)。

1. 申請書に記載された情報が正確であること、及び申請者が情報の正確さを証明する申請書に署名していることを確認する。
2. 輸出条件ライブラリーで特定されている当該国の条件が満たされていることを確認する。
3. 本指令パートVIIの規定にしたがって製品を再検査し、当該製品に不純物がある、不良である、表示に誤りがある、申請書に記載された国への輸出に不適格であると判断する理由がないことを確認する。

検査プログラム担当職員は、必要な資料があれば、輸出者に請求すべきである。(より特別な指示に関しては本指令のパートVIIを参照)

- B. 記入済みの輸出証明書を輸出者から受け取ったら、FSIS証明担当職員(当該証明書に署名をする検査プログラム担当職員)は、証明された(署名済みの)申請書の情報と、証明書の情報が一致していることを確認する。証明書の声明は、証明担当職員に提示された情報に基づく証明であり、この証明担当職員が直接当該製品の検査に関わる必要はない。より明確にする必要がある場合には、証明担当職員は、申請書に署名した検査プログラム担当職員もしくは輸出者に対して、追加の情報もしくは文書を請求することができる。すべての情報が正確であることを確認して、証明担当職員は輸出証明書に署名する。証明担当職員が署名を拒否する場合、相応の根拠(例:文書に不備がある、提出された情報だけでは製品が輸出先の条件を満たしているかどうかを確認できない)がなければならない。証明担当職員は、署名拒否の理由を記録しなければならない。輸出業者は、証明担当職員に同定された理由を正してよく、あるいは、監督官(next-line supervisor)に輸出文書の写しを回してよい。(より特別な指示に関しては本指令のパートVIIを参照)
- C. 証明担当職員が証明書への署名を拒否した場合、その拒否の事実と理由は、監督官(next-line supervisor)による審査を受ける。この審査にもとづき、監督官は、以下の措置のうちいずれかを選択する。
1. 輸出者が提示した情報が証明書への署名を正当化するのに不十分であるという理由に基づいて、証明担当者の当該輸出証明書への署名拒否を支持する。
 2. 自身が行う記録の検証に基づいて署名が正当であるという判断を下し、当該証明書に署名する。公衆衛生獣医師(PHV)の署名が必要な場合には、監督官は、勧告とともに、証明書及び他の輸出文書に署名をした審査結果を適切な地域事務所の担当者に送付する。
- D. 監督官(Front-line Supervisor)が輸出証明書に署名し、証明担当職員の署名拒否に上記Bにいう相当の根拠(例:文書に不備がある、条件を満たしているかどうかを確認できない)がないと判断する場合、監督官はこの事例を文書化し、当該地

域事務所に報告書を送付する。地域事務所は、監督官からの情報を検証し、懲罰もしくは対抗措置を含む適切な行政行為の決定のために労働人事課人事室に情報を送付するかどうかを判断する。

- E. 輸出証明業務が公認施設で実施される場合、9CFR part322及び381.104～381.111で要求される輸出証明の発行は弁済的業務ではない。FSISの規制的要求に加えられ証明の実施（例：輸入国で要求される追加的証明）及び9CFR 322.3に規定された輸出のための製品輸送は、弁済的業務と考えられる。輸出証明業務が非公認施設で実施される場合、その業務は、弁済的であり、FSIS指令5110.1で規定されたように課される。

VI. 輸出条件ライブラリー

- A. 「輸出条件ライブラリー」には、製品が輸出される相手国からFSISに公式に通達された諸条件が集積されている。輸出の適格性を判断する際には、これを利用しなければならない。輸出条件ライブラリーには以下のような情報が含まれている。
1. 証明書の要件
 2. 適格及び不適格製品
 3. 施設の要件
 4. 表示の要件
 5. 食用及び非食用製品
 6. 輸出適格となるための施設の要件
 7. PHVの署名の要件（あれば）
 8. 家畜衛生の要件
 9. 輸出適格施設の一覧
 10. 輸出に関する通知
 11. よく尋ねられる質問
- B. 輸出条件ライブラリーの情報へのアクセス方法
1. インタネットで検索する
[www.fsis.usda.gov/Regulations & policies/Export Information/index.asp](http://www.fsis.usda.gov/Regulations%20&%20policies/Export%20Information/index.asp)
 2. 閲覧する： Public Folders/All Public Folders/Export Library
 3. FSIS技術サービスセンター（TSC）に電話する
(1-800-233-3935または、402-221-7400)
- C. 家畜衛生の状態および証明に関する情報は、
1. 輸出条件ライブラリーに問い合わせる
 2. TSCの上記の電話番号に問い合わせる

3. ライブラリーおよびTSCに問い合わせた後、州内の特定の疾病の状況に関して具体的な疑問が残る場合は、その州の動植物検疫局（APHIS）地域担当獣医（AVIC）に問い合わせる。AVICの一覧は、APHISのウェブサイトに掲載。

<http://www.aphis.usda.gov/vs/areaoffices.htm>

VII. 輸出証明書の申請

- A. 輸出証明申請書を受領したら、検査プログラム担当職員は、記入が完全であることと、すべての関連情報が含まれていることを確認する。
- B. 検査プログラム担当職員は、申請書を審査し、輸出先の国の条件に適合していることを確認する。検査プログラム担当職員は、必要なときには、申請者に適切な文書の提出を要請して、申請書の記述内容を確認する。検査プログラム担当職員は、申請書に加えて必要な文書（例：輸出証明記録適格性情報）を提出すれば処理が迅速化されることを、申請者に伝える。
 1. 検査プログラム担当職員が、申請書に記載された各製品が申請された輸出先に適格かどうか懸念を持つ場合には、以下の措置をとる。
 - a. 申請者に懸念を提示する。
 - b. 議論された内容と懸念が十分に解決されたか否かについて、面談の記録を残す。
 - c. 申請者にこの記録の写しを渡し、検査ファイルにも写しを保管する。
- C. 検査プログラム担当職員は、製品の官能試験を実施し、輸出に適格かどうかを判断する。検査プログラム担当職員は、製品が粗悪あるいは不良の疑いがあることの兆候（例；異常なおおい、破れ、箱の湿り気、不衛生な取り扱い・保管のその他の証拠）に特に注意を払うこと。
 1. 検査プログラム担当職員は、不適切な取り扱い・保管の証拠の疑いを持つ場合、当該製品をFSIS指令 9040.1改定3版「輸出目的の製品の再検査」に定めるとおり検査し、製品が不純である場合には、必要な措置をFSIS指令5000.1（公認施設に（例；規制管理措置または違反通知書（NR）の発行）またはFSIS指令8410.1（非公認施設に（例；製品の留置））に従って講じることができる。
 2. また、検査プログラム担当職員は、製品がFSIS規則の要件及び輸入国の要件に従って適切に識別・表示されていないと疑う理由がある場合、FSIS指令9040改定3版に定めるとおり検査することができ、
 - a. 適切に表示されていない、または誤った表示がされている場合には、製品が、9 CFR part 500及びFSIS指令5400.5（NRが発行され、規制管理措置がとられている公認施設）または、FSIS指令8410.1（非公認施設）に定めるとおり、必要な措置を講じるか、
 - b. コンテナ内の製品または製品の表示が輸入国の条件に適合していない場合

には、製品申請者に懸念を示し、上記VII. B 1 b及びcに規定する面談記録を作成する。

D. 検査プログラム担当職員は、必要に応じて、承認された表示内容以外の内容が外国語表記ステッカーにないことを確認する。

注：検査プログラム担当職員は、また、外国語表記ステッカーを提供する輸出者からの保証書（当該ステッカーが承認された表示内容の正確な翻訳である旨を証明するもの）が含まれていることを確認する。

E. 検査プログラム担当職員は、上記AからDが完了し、すべてが容認できるとなった後、以下を行う。

1. 申請書に署名する。
2. 申請書および付属文書の写しを保管する。
3. 申請書の原本を申請者に返還する。
4. 輸出者が記入する輸出証明書を提供し、輸出印を発行する。
5. 当該施設が製品に押印することを許可する。
6. 当該施設が製品に押印した後、当該印を回収する。

F. 検査プログラム担当職員は、当該職員が立ち会っていないとき、当該施設が箱に押印し、輸出証明書に記入することを許してよい（Pre-stamp）。しかし、検査プログラム担当職員は、用いるスタンプを提示する前にスタンプが優良な状態にある箱だけに明確に読みやすく押印されることを施設が確認できることを検証しなくてはならない。検査プログラム担当職員は、必要と判断するときにはいつでも、VII. Cに定める再検査を実施する。

注：検査プログラム担当職員は、施設がコンピュータで作成した輸出証（ステッカー）を使用することを許してよい。ただし、当該施設が製品に施す前にステッカーの枚数を特定し、検査プログラム担当職員に未使用のステッカーを提出する場合に限られる。

G. 検査プログラム担当職員が公認施設で上記の手続きを実施したその日のうちに、検査プログラム担当職員は、実施した内容を検査制度手続きコード06A01に記録する。検査プログラム担当職員は、1日1回実施した手続きを記録するのであり、申請書受領のたびに記録するのではない。非公認施設において、検査プログラム担当職員はFSIS指令5110.1に規定された業務を行う。

VIII. 輸出証明書

- A. 証明担当職員は、正しく記入された輸出証明書（FSIS様式9060-5）、輸入国で要求された他の証明書（X参照）、レターヘッド証明書（VIII. C. 参照）と署名済み申請書の写し（FSIS様式9060-6）を輸出者から受領する。証明担当職員は、付属文書の審査もしくは輸出条件ライブラリーのチェックにより証明書に記載された情報と申請書に記載された情報に矛盾がないことを確認し、また、輸出条件ライブラリーで提供されない声明や文書が付加されないことを確認する。
- B. 複数の品目が同時に出荷され、証明書の表面の欄が足りない場合には、必要に応じて、別紙をつけること。この別紙は四枚複写とし、以下の内容を含むこと。
1. 発行日
 2. タイトル（例；輸出証明書第〇〇号の別紙）
 3. 製品概要－製品名、箱数、重量（証明書表面に記載のとおりとする）
 4. 証明担当職員の氏名と署名。その次に地域番号。氏名とコード番号は、証明書表面に記載されたものと同じでなければならない。
- C. ある場合には、USDA／FSISレターヘッドによる証明が必要であり、また、輸出条件ライブラリーにおいて個々の国の要件で特定されるような製品に対して発行される。輸出業者が証明書とともにレターヘッドによる証明を申請する場合、FSISの証明担当職員は以下の内容を確認する。
1. 輸出条件ライブラリーにあるレターヘッドによる証明の直近版が提出されたこと
 2. レターヘッドによる証明上の声明が輸出条件ライブラリーに示された事項から変更されていないこと及び追加的な声明が付加されていないこと
 3. 証明書が輸出業者により日付されていること
 4. 他のUSDAの機関（例：AMS）により要求されるあらゆる証明書が記入されたレターヘッドとともに提供されていること
- レターヘッドによる証明は、四枚複写とし、以下の内容を含まなくてはならない
1. 対応する証明書の番号
 2. 証明内容（例：私（検査官／獣医師の氏名）は、以下を証明する…）
 3. タイプ／印字された検査官／獣医師の氏名。引き続いて、必要があれば専門学位、及び地域番号
 4. タイプ／印字されたものと同じ検査官／獣医師の署名
 5. 署名した日
- D. 証明担当職員は、申請書（FSIS様式9060-6）、証明書（FSIS様式9060-5）、レターヘッドによる証明を含むその他の証明書上の情報について疑問がある場合、申請書または輸出業者に署名した検査プログラム担当職員に連絡するまで、証明書に署

名をしない。証明担当職員が輸出業者と共有するいかなる伝達情報も上記VII. B 1 b及びcに規定する面談記録を作成する

- E. 証明書に署名する前に、証明担当職員は、以下のことを行う。
1. 証明書の内容の正しさと、訂正箇所を確認する。
 2. 生体検査及びとさつ後検査を受けたことを示す欄を確認する
 3. 付属文書を審査して、輸出業者が未使用の欄を線で消していることを確認することを確認する。
 4. 海外で許容されない場合を除き、削除あるいは修正箇所にイニシャルを記入する（輸出先の国が削除あるいは修正を認めるかどうかを確認するため、輸出条件ライブラリーを参照すること）。
- F. 証明担当職員は、証明書原本、すべての連続した用紙、及びレターヘッド証明を含むその他の証明書の署名欄に黒インク以外で署名する。また、輸入国がPHVの署名を要求する場合は、証明担当職員は、その専門学位を含めて記入する。証明担当職員は、輸出条件ライブラリーで特定されるように、受入国で要求されない場合には、輸出印を輸出証明書に押しはならない。

IX. 代替証明書

- A. 元の証明書に代わる証明書は、最初の輸出証明の時点における製品の状態の再証明である。あるロットに関する代替証明書は、そのロットの現在の状態を反映するものではない。代替証明書は以下のような場合に発行されるが、これらの場合に限られるわけではない。
1. 元の証明書に必要な情報が記載されていない場合
 2. 元の証明書に間違った情報が記載されている場合
 3. 荷受人もしくは輸出者の氏名が代わった場合
 4. 証明書を紛失した場合
- B. 代替証明書は、元の証明書に記載されたのと同じ日付になっていなければならない。
- C. 箱数もしくは総正味重量を増やす申請は、製品が本指令のVII. Cに基づいて再検査されないならば、受け入れられない。
- D. 新規の証明書を申請する場合は、申請書（FSIS書式9060-6）に（可能な場合）元の証明書の原本およびすべての写しを添えて、提出しなければならない。例外：証明書を紛失した場合、輸出者は、証明書が発見されたときには返還する旨の確約書

を証明担当職員に提出する。

- E. 輸出される製品が複数の荷受人に対して出荷するためにすでに分割されていて、輸出証明書がそれぞれに必要な場合は、一通の証明書に代わる複数の証明書を発行することができる。ただし、以下の条件を満たしていなければならない。
1. 元の証明書に当該ロットについて十分詳細に明示されていて、新しい証明書に記載された容器・識別・対応する重量との直接の相互関係がわかること。
 2. 元の証明書が返還・取り消しされること。
- F. 代替証明書に署名する前に、検査プログラム担当職員は以下を行う。
1. 新しい証明書の左上部の余白もしくは備考欄に、以下の記述があることを確認する。
「証明書番号〇〇に代えて発行。本証明書の対象となる製品の輸出マークには、証明書番号〇〇を記載」
 2. 取消される証明書を入手し（可能な場合）、以下を行う。
 - a. 左上部の余白もしくは備考欄に、代替となる証明書の番号が明記されていることを確認する（例：番号〇〇により代替）。
 - b. 代替証明書の「検査官用」写しを貼り付け、政府事務所に保管する。

X. 目録

- A. 公式の輸出印は、常時管理下に置かれなければならない。輸入証明書、印、関連の目録は、使用时以外は公的な鍵もしくは封印で管理しなければならない。
- B. 施設に配置された検査プログラム担当職員は、発行された輸出証明書及び取消された証明書の正確な目録を管理しなければならない。

政策プログラム人材育成事務局

次長

—

米国農務省
食品安全検査局
ワシントン D.C

FSIS 指令 9040.1 改訂 3 版 2006 年 3 月 1 日

輸出を目的とした製品の再検査

I. 目的

本指令は、検査プログラム担当職員に対して、輸出を目的とした製品を再検査するための諸手続きを規定するものである。製品が該当施設にあるか、認定済み (ID) 倉庫 (連邦規則 9 CFR 350.3 (a) の規定による) または冷凍保管設備など、非公認施設の遠隔地保管場所にあるかに関係なく、この責務および手続きを適用することとする。

II. 取消し

1993 年 8 月 12 日付 FSIS 指令第 9040.1 号改訂第 2 版

III. 再発令の理由

本指令は、製品が表示どおりに輸出先国の要件を満たしているかどうかに関して、検査プログラム担当職員が疑念を抱くに足る理由がある場合に実施する製品の箱または容器の検査を規定するために改定された。

IV. 根拠となる法令

連邦規則 9 CFR 322.2、381.105、350.3 (a)

FSIS 指令第 7520.2 号、第 9000.1 号、第 12,600.1 号

V. 方針

A. 連邦規則 9 CFR 322.2 および 381.105 は、輸出用製品の再検査および認証を規定している。輸出向け製品の再検査の目的は、製品の安全性、健全性、均一性および輸出への適格性を検証するためである。検査プログラム担当職員は、FSIS 書式 9060-6「輸出申請書」を受領後、これを審査したうえで輸出用製品の再検査を実施する。

B. FSIS 指令第 9000.1 号「輸出証明」に規定されているとおり、検査プログラム担当職員は、申請書に記載されている各製品が食肉および食鳥肉製品に関する規則および輸出先国の要件を遵守しているかどうか (たとえば、申請書に記載された各製品は、同申請書に記載された国向けの輸出に適格であるかどうか) を検証す

るものとする。

- C. 申請書に不備がなく正確であれば、検査プログラム担当職員は、製品の取扱いまたは保管に不良な徴候（たとえば、破損、湿り、損傷または状態の悪い段ボール箱）がないかどうか、出荷用段ボール箱の官能検査を実施する。段ボール箱に問題がなければ、検査プログラム担当職員は、FSIS 書式 9060-6「輸出証明申請書」の署名に関する FSIS 指令 9000.1 に示された指示に従って手続を進め、FSIS 書式 9060-5「輸出証明書」を発行する。

VI. 製品に異常が認められた場合の検査プログラム担当職員の責務

- A. 公認施設または非公認施設において出荷段ボール箱の官能検査を実施中、製品の取扱いおよび保管に不良な徴候を認めた場合には、検査プログラム担当職員は次の措置を実行するものとする（FSIS 指令第 5400.5 号および第 5000.1 号改訂第 1 版に概括された検査方法を用いる検査制度手続コード 06 に基づく）。

1. 公認施設および非公認施設では、総数の 5%を上限に箱または容器を無作為に抽出する。抽出する箱の割合を考えるにあたっては、検査プログラム担当職員は、懸念の根拠のほか、梱包された製品の内容物を周囲環境にさらす必要性を考慮する必要がある。

- a. 公認施設では、申請者に対して、不衛生な状況を招いたり製品に不純物が混和したりすることのないように考慮して、抽出した箱または容器のサンプルを開けるように求める。
- b. 非公認施設では、申請者に対して、衛生的な環境（たとえば、施設内の認定済み検査室など）のもとで抽出した箱または容器を開けるように求めるかまたは、出荷貨物あるいは抽出した箱または容器のサンプルを衛生的な環境のもとで開くことのできる場所へ運ぶように求める（たとえば、認定済み（ID）検査室のない冷凍保管設備の場合）。

2. 内容物の無傷性および健全性を再検査する。

注：製品が凍っている場合には、検査プログラム担当職員は、公認施設または認定済み設備に対して、公認施設では衛生的環境のもとで、非公認施設では認定済み（ID）検査室で、無作為に抽出した箱または段ボール箱の中の個々のパッケージを緩めたり解凍したりさせて再検査を実施する。製品が缶詰にされている場合には、検査プログラム担当職員は、FSIS 指令 7520.2「缶詰製品の容器検査の条件にかかる手続き」の指示に従うものとする。

- a. 製品が無傷かつ健全であれば、検査プログラム担当職員は、製品の再梱包(梱包者の選択に委ねる)を許可し、輸出申請書に署名して、FSIS 指令第 9000.1 号の指示に従って手続きを進める。
 - b. 製品に問題があるかまたは健全でないことが判明した場合、施設または設備が箱を開けない場合、あるいは施設がサンプルを移動させることを選択せず出荷を取りやめる場合には、製品が粗悪品であると確信するに足る理由があれば、検査プログラム担当職員は以下の措置をとるものとする。
 - i. 申請書に署名をしない。
 - ii. 公認施設において製品のいずれかが不良または不健全であると判明した場合には、該当する 06 コードに基づいて「不適格記録」を発行し、FSIS 指令 5000.1 改訂 1 版に示された適切な強制措置をとる。
 - iii. 非公認施設において製品のいずれかが不良または不健全であると判明した場合には、FSIS 指令第 8410.1 号の規定に従って製品の差し止めを行い、FSIS 書式 8080-1「差し止め通知」(非公認施設に適用)に記入する。
- VII. 申請書に記載された情報が要件を満たしていない場合の検査プログラム担当職員の責務
- A. 申請書に記載された情報に関して疑問がある場合には、検査プログラム担当職員は、FSIS 指令第 9000.1 号の規定に従って、申請者に対してその疑問を提示するものとする(たとえば、申請者に対して、当該製品が輸出先国の要件を満たしていることを実証する補足情報の提供を求めるなど)。
 - B. 製品が輸出先国の要件を満たすように適切に識別・表示されていないのではないかと疑われる場合には、検査プログラム担当職員は、上に示した方法に従って以下の措置をとるものとする(この場合、FSIS 指令第 5400.5 号および第 5000.1 号改訂第 1 版に概括された検査方法を用いる検査制度手続きコード 04 に基づく)。
 - 1. 箱を開けて、表示が適切であるか、不正な商標表示がないか、申請書に記載された国向けの輸出に適格であるかを確認するために製品を再検査する。
 - 2. 強制措置または差し止め措置をとり、これを記録する。

C. 公認施設または非公認施設において、容器内の製品または製品の表示が輸出先国の要件を満たしていない場合には、以下の措置をとるものとする。

1. 申請者に対して懸念を提示する。
2. 何を話し合ったのか、懸念は十分に解消されたのか、面談の内容を記録に残す。
3. 申請者にこの記録の写しを渡すとともに、検査ファイルにも写しを保管する。

直接の質問は、技術サービスセンター、電話番号 1-800-233-3935 まで問い合わせることとする。

政策プログラム人材育成事務局
次長 Philip S. Derfler

別添 3

従業員のトレーニング

ナショナルビーフ社カリフォルニア工場の報告：事前のラベル貼り付けの取りやめに関する QSA プログラムの変更後、以下が実施された。：

- ・ 変更が行われ、USDA AMS へ承認のために提出された。
- ・ USDA AMS は変更を承認した。
- ・ QSA マニュアルが改訂された。
- ・ 箱詰めエリアにおいて日本向け製品の生産に関係している全ての施設管理者と時間給従業員は、変更された QSA プログラムについて再トレーニングされた。
- ・ 再トレーニングに関する文書はファイルされた。
- ・ USDA AMS および USDA OPFER はトレーニングとプログラムを検証し、受け入れ可能であるとした。

日本向け輸出条件（抜粋）

JA-144（2008年7月2日付）

日本向け赤肉の輸出条件

適格な／不適格な製品

A. 適格な製品 - 以下の製品は食品として日本向けに輸出する資格がある：

1. 日本向けに輸出する牛肉と牛内臓及び子牛と子牛内臓は 2006 年 7 月 27 日の東部夏時間午前 5 時以降にと殺されたものでなければならない。

生鮮／冷凍の牛肉及び牛内臓と子牛肉および子牛内臓は 20 ヶ月齢以下の個体に由来する。脊髄及び脊柱（胸椎横突起、腰椎横突起、仙骨翼及び尾椎を除く）は除去されなければならない。適格な牛肉及び牛内臓と子牛肉及び子牛内臓は日本向け牛肉に対して承認された AMS 輸出証明（EV）プログラムの下で生産されなければならない。日本向け EV プログラム及び牛肉 EV 認可施設に関する情報は、AMS のウェブサイトから得ることができる。

FSIS 検査官が特定の AMS 認可 EV 施設において EV プログラムが適切に遂行されていないという懸念を持った場合には、問題となる製品には輸出証明書は発行されず、AMS へは ARCBbranch@usda.gov まで通報されなければならない。検査官は AMS への通報の際に直属の上司を含める必要がある。通報の際には以下の情報が含まれている必要がある。

- ・ 施設名称、住所及び施設番号
- ・ 製品の種類、製品コード及び製品の数量
- ・ 生産年月日、ロット番号及びシフト
- ・ 観察年月日及び観察内容
- ・ 製品の輸出予定国名
- ・ 輸出証明書番号（可能であれば）
- ・ 申し立てを証明するためのその他情報
- ・ 検査官氏名

輸出施設は、日本向けに牛肉製品を輸出する際の出荷準備においては、多大な注意を払わなければならないことを警告されている。特に、輸出施設は日本向けに輸出される箱や他の容器に不適格な牛肉製品が混入することを防ぐための十分な管理措置を定め、実施する必要がある。

- 2.～6. 〔略〕
- B. 不適格な肉製品〔略〕
- C. 米国に輸入された食肉の適格性〔略〕

加工条件

(以下略)

注：下線部が報告書本文の参照関係部分