資料２－１

厚生労働省発食安第０５２４００１号
１７消安第１３８０号
平成１７年５月２４日

食品安全委員会
委員長　寺田　雅昭　殿

厚生労働大臣　尾辻　秀久

農林水産大臣　島村　宜伸

食品健康影響評価について

食品安全基本法（平成１５年法律第４８号）第２４条第３項の規定に基づき、下記事項に係る同法第１１条第１項に規定する食品健康影響評価について、貴委員会の意見を求めます。

記

現在の米国の国内規制及び日本向け輸出プログラム（別添）により管理された米国から輸入される牛肉及び牛の内臓を食品として摂取する場合と、我が国でとさつ解体して流通している牛肉及び牛の内臓を食品として摂取する場合の牛海綿状脳症（ＢＳＥ）に関するリスクの同等性

USDA Export Verification (EV) Program
Specified Product Requirements for Beef - Japan

1 Purpose

This document provides the specified product requirements for marketing U.S. beef to Japan under the USDA Export Verification (EV) Program. It also provides the additional requirements for the USDA Quality System Assessment (QSA) Program for marketing U.S. beef to Japan.

2 Scope

This document applies to U.S. companies, producers, feedlots, slaughterers, fabricators (fabricators perform the initial separation, or cutting of carcasses into wholesale cuts) that supply beef and beef offal that are eligible for export to Japan as listed on the Food Safety and Inspection Service (FSIS) website. Companies must meet the specified product requirements for Japan under the EV Program through an approved USDA QSA Program. The requirements for the USDA QSA Program are defined in *ARC 1002 Procedure, Quality System Assessment (QSA) Program*. The QSA Program ensures that the specified product requirements are supported by a documented quality management system.

Only companies with an approved USDA QSA Program for the EV Program for Japan may label and sell product as meeting the specified product requirements for Japan under the EV Program.

3 Reference Documents

ARC 1000 Procedure, Quality Systems Verification Program General Policies and Procedures
ARC 1002 Procedure, Quality System Assessment (QSA) Program
MGC Instruction 709 Physiological Maturity Evaluation of Beef Carcasses for Japan Export Program
Physiological Maturity Determination Guidelines - Appendix F
U.S. Standards for Grades of Carcass Beef http://www.ams.usda.gov/lsg/stand/standards/beef-car.pdf
http://www.fsis.usda.gov/regulations/FSIS_policies/Index_of_Import_Requirements_by_Country/index.asp
http://www.ams.usda.gov/lsg/arc/evjapan.htm

4 Additions to the USDA Quality System Assessment (QSA) Program Requirements

The specified product requirements listed in Section 5 of this Procedure must be met through an approved USDA QSA Program. The QSA Program ensures that the specified product requirements are supported by a documented quality management system. In addition to the requirements listed in *ARC 1002 Procedure, Section 7, Program Requirements*, companies must also incorporate the following requirements into their USDA QSA Program:

4.1 *Internal Audit*

The company must conduct internal audits at planned intervals.

The internal audits must determine whether the QMS

a) *Conforms to the planned arrangements,* to the requirements of this Procedure, and to the QMS requirements established by the company; and
b) Is effectively implemented and maintained.

The company must have a documented procedure which defines

（参考資料１－３－４）

a) The planning of an audit program, which must consider the status and importance of the processes and areas to be audited, as well as the results of the previous audit;
b) The audit criteria, scope, frequency, and methods;
c) The selection criteria of the auditors and conduct of auditors which must ensure objectivity and impartiality of the audit process (Auditors must not audit their own work.);
d) The responsibilities for planning and conducting audits;
e) The reporting of results;
f) The follow-up activities (Follow-up activities must include the verification of the actions taken and the reporting of the verification results.); and
g) The maintenance of records.

Within the area being audited, management must ensure that actions are taken without undue delay to eliminate detected non-conformances and their causes.

The company must maintain records of the internal audits.

4.2 *Company's Suppliers Listing*

The company must maintain an approved suppliers listing which must
a) Identify the supplier's name, address, and approval date; and
b) Be available to the USDA for review.

The company must also maintain the date that suppliers were removed from the suppliers listing.

5 Specified Product Requirements

5.1 *Beef and beef offal* that are eligible for export to Japan as listed on the Food Safety and Inspection Service (FSIS) website must be processed using the procedures as incorporated into the facility's HACCP or Sanitation SOP's, and must be produced in a manner that ensures the hygienic removal of the following materials and prevents the contamination of these tissues with meat products being produced for export to Japan:

5.1.1 Bovine heads (except for hygienically removed tongues and cheek meat, but including tonsils); spinal cords; distal ileum (two meters from connection to caecum); and vertebral column (excluding the transverse processes of the thoracic and lumbar vertebrae, the wings of the sacrum, and the vertebrae of the tail).

5.2 Eligible products must be derived from cattle that are 20 months of age or younger at the time of slaughter using either one of the following methods (5.2.1 or 5.2.2):

5.2.1 Cattle must be traceable to live animal production records. Verification activities for age requirements must be conducted at the slaughter, feedlot, and producer levels as required by the submitted QSA Program. Records used to verify this requirement must meet any one of the following criteria (5.2.1.1. to 5.2.1.3):

5.2.1.1 Individual Animal Age Verification

5.2.1.1.1 Animals must have a unique individual identification.

5.2.1.1.2 Records must be sufficient to trace the individual animal back to ranch records.

5.2.1.1.3 *Records must indicate the actual date of birth of the animal* and must accompany each animal through the process.

5.2.1.2 Group Age Verification

5.2.1.2.1 All animals within a group and born during the same birthing season must be individually identified.

5.2.1.2.2 Records must indicate the actual date of birth of the first calf of the birthing season.

5.2.1.2.3 The age of all calves within a group must be *derived from* the actual date of birth of the first calf born within the group.

5.2.1.2.4 Records indicating the date the bulls are given access to the cows may be used as a supplementary measure verifying the oldest age of animals in the group which is determined in 5.2.1.2.2.

5.2.1.3 USDA Process Verified and/or USDA Quality System Assessment Programs.

5.2.1.3.1 The USDA Process Verified Program must include age verification as a process verified point as defined in 5.2.1.1 and 5.2.1.2.

5.2.1.3.2 The USDA Quality System Assessment Program for feedlots and producers must include age verification as a specified product requirement as defined in 5.2.1.1 and 5.2.1.2.

5.2.1.3.3 All animals must be individually identified.

5.2.2 Age Verification through Carcass Evaluation.
Official USDA evaluation at the slaughter facility must be conducted as required by the submitted QSA program and meet each of the following criteria (5.2.2.1, 5.2.2.2, and 5.2.2.3):

5.2.2.1 Cattle must be determined to be A^{40} physiological maturity or younger by an official USDA evaluation. Official USDA evaluations must determine carcasses to be A^{40} physiological maturity or younger using the U.S. Standards for Carcass Beef http://www.ams.usda.gov/lsg/stand/standards/beef-car.pdf and the description of maturity characteristics within A maturity (Physiological Maturity Determination Guidelines Appendix F).

5.2.2.2 USDA Evaluators must meet or exceed accreditation performance standards for determining physiological maturity as outlined in Meat Grading and Certification Branch Instruction 709 in order to ensure the accuracy of the evaluation.

5.2.2.3 USDA Evaluators must keep records for each of the determining factors (skeletal, lean, and overall maturity) for each carcass which is determined to be A^{40} or younger for exportation to Japan.

5.3 Identification Requirements –

5.3.1 All carcasses complying with 5.2.1 and 5.2.2 must be uniquely identified. Carcasses complying with the "Age Verification through Carcass Evaluation" must be marked once evaluated and approved by proficiency-tested USDA Evaluators. These identification marks must remain with the product through processing, packaging, storage, and shipping to insure the integrity of the process and the product.

5.3.2 Shipping documentation (bills of lading, shipping manifests, or letters of guarantee) must have the statement "Product Meets EV Program Requirements for Japan" and must clearly identify the product and product quantity.

5.3.3 Eligible products produced by eligible companies and identified as meeting the requirements of the EV Program for Japan shall receive a FSIS export certificate with the statement "Product Meets EV Program Requirements for Japan".

6 Listing of Approved Programs

Only U.S. companies that have an approved USDA QSA Program which meets the specified product requirements for Japan will be listed on the *Official Listing of Eligible Companies for the Export Verification (EV) Program for Japan.*

7 Responsibilities

U.S. companies must meet all policies and procedures outlined in this Procedure, *ARC 1000 Procedure, Quality Systems Verification Program General Policies and Procedures,* and *ARC 1002 Procedure, Quality System Assessment (QSA) Program.*

［仮訳］

ＵＳＤＡ輸出証明（ＥＶ）プログラム（案）：牛肉に関する特定された製品の条件

１．目的

本文書は、ＵＳＤＡの輸出証明（ＥＶ）プログラムの下で、日本向けの米国産牛肉のマーケティングのための特定された製品の条件を規定するものである。さらに、米国産牛肉の日本向けのマーケティングのための USDA 品質システム評価（QSA）プログラムの追加的条件も併せて規定する。

２．範囲

本文書は、日本向けに輸出可能な牛肉及び牛の内臓を供給する米国の企業、生産者、フィードロット、と畜業者、解体業者（解体業者は、枝肉の半丸や部位の市場向けのカットへの加工を実施）に適用され、これらは、食品安全検査局(FSIS)のウェブサイトに掲載される。企業は、認証されたＵＳＤＡのＱＳＡプログラムを通じ、EVプログラムの下で日本向けに特定された製品の条件を満たさなければならない。ＵＳＤＡのＱＳＡプログラムのための条件は、ARC1002手順書（*手続き及び品質システム評価（QSA）プログラム*）で定義される。このＱＳＡプログラムは、特定された製品の条件が文書化された品質管理システムによって裏打ちされていることを確保するものである。

日本向けＥＶプログラムのためにＵＳＤＡのＱＳＡプログラムの認証を受けた企業だけが、ＥＶプログラムの下で日本向けに特定された製品の条件を満たしているとして製品を表示、販売することができる。

３．参照文書

ARC1000 手順書：手続及び品質システム証明プログラムの一般的な方針及び手続き
ARC1002 手順書：手続及び品質システム評価（QSA）プログラム
MGC 通知 709：日本に輸出される牛枝肉の生理学的成熟度の評価
別添Ｆ：生理学的成熟度の判別に係るガイドライン
米国の牛枝肉格付基準 http://www.ams.usda.gov/lsg/stand/standards/beef-car.pdf
FSIS Export Library：日本向け red meat（牛肉、豚肉等）の輸出条件
http://www.ams.usda.gov/lsg/arc/evjapan.htm

４．ＵＳＤＡの品質システム評価（ＱＳＡ）プログラムの条件に追加される事項

セクション５の手順に記載されている特定された製品の条件は、ＵＳＤＡのＱＳＡプログラムの認証を通じて満たされなくてはならない。このＱＳＡプログラムは、特定された製品の条件が文書化された品質管理システム（ＱＭＳ）によって裏打ちされていることを確保するものである。ARC1002 のセクション７（プログラムの条件）に記載された条件に加え、企業は、以下の条件を自身の USDA のＱＳＡプログラム内で満たす必要がある。

４．１　内部監査

企業は、計画された期間毎に内部監査を実施しなければならない。

内部監査は、ＱＭＳが、
ａ）計画された手順、本手順書の条件及び企業によって設けられたＱＭＳの条件のそれぞれに適合しているかどうか、
ｂ）効果的に実行され、維持されているかどうか
について決定しなければならない。

企業は、以下の事項を規定する文書化された手順書を整備しなければならない。
a）監査プログラムの計画については、それまでの監査結果だけでなく、手順と監査の範囲の状態と重要性が考慮されなければならない。
b）監査の基準、範囲、頻度及び手法
c）監査手順の客観性と公平性を確保するような監査官の選定と監査官の行動（監査官は自身が所属する部署を監査してはならない。）
d）監査の計画及び実行の責任
e）結果の報告
f）フォローアップ活動（フォローアップ活動は、実施された行為の証明と証明結果の報告を含まねばならない。）
g）記録の保存

監査対象の範囲内において、経営者は検出された不適合とそれらの原因を撲滅するための措置が遅滞なく実施されていることを確保しなければならない。

企業は、内部監査の記録を保存しなければならない。

4．2　企業に対する供給者のリスト作成
企業は、以下の事項に係る承認された（企業に対する）供給者のリストを維持しなければならない。
a）供給者の名称、住所、承認月日を特定すること
b）ＵＳＤＡが閲覧できるようにすること

5．特定された製品の条件
5．1　食品安全検査局（FSIS）のウェブサイトに記載されている日本に輸出可能な牛肉及び牛の内臓は、施設のＨＡＣＣＰ又は衛生ＳＯＰｓ（標準作業手順）中で規定されている手順で加工されなければならず、以下の部位を衛生的に除去し、これらの組織が日本向けに輸出される食肉製品に混入することを防止なければならない。
5．1．1　牛の頭部（舌、ほほ肉を除くが、扁桃を含む）脊髄、回腸遠位部（盲腸との接続部分から２メートルまでの部分）、脊柱（胸椎横突起、腰椎横突起、仙骨翼及び尾椎を除く）

5．2　輸出可能な製品は、以下のいずれかの方法（5.2.1 又は 5.2.2）を用いて、と畜時において２０か月齢以下の牛由来でなければならない。
5．2．1　牛は、生体生産記録まで遡ることが可能でなくてはならない。月齢要件の証明活動は、と畜場、フィードロット及び生産農場の段階において、提出されたＱＳＡプログラムで要求されているとおり実施されなくてはならない。この条件を証明するために利用される記録は、以下の基準のいずれかを満たさなければならない。（5.2.1.1 から 5.2.1.3）
5．2．1．1　個体月齢証明
5．2．1．1．1　家畜は個体特有の識別を施されていなければならない。
5．2．1．1．2　記録は、個々の家畜について生産農場の記録まで遡るのに十分でなくてはならない。
5．2．1．1．3　記録は、当該家畜の実際の出生日を示すものであって、プログラムを通じ個々の家畜に携行されなくてはならない。

5．2．1．2　集団月齢証明
5．2．1．2．1　単一の群に属し、同じ繁殖季節内に出生した全ての家畜は、個体ごとに標識が施されていなければならない。
5．2．1．2．2　記録は、繁殖季節において最初の子牛が実際に出生した日を示すものでなくてはならない。
5．2．1．2．3　群に属する全ての子牛の月齢は、当該群の最初に生まれた子牛の実際の出生日に由来しなければならない。
5．2．1．2．4　種雄牛が雌牛群との接触を許された日を示す記録は、5.2.1.2.2 で規定される集団に属する家畜の中で最も高い月齢を証明する補足的手段として用いることができる。

5．2．1．3　USDA の工程証明プログラム及び USDA の品質管理評価プログラム
5．2．1．3．1　ＵＳＤＡの工程証明（ＰＶ）プログラムは、月齢証明を工程証明ポイントとして 5.2.1.1 及び 5.2.1.2 に規定されたとおりに含まねばならない。
5．2．1．3．2　フィードロット及び生産農場向けのＵＳＤＡの品質システム評価（ＱＳＡ）プログラムは、特定された製品の条件として月齢証明を 5.2.1.1 及び 5.2.1.2 に規定されたとおりに含まねばならない。
5．2．1．3．3　全ての家畜は個体毎に標識が施されていなければならない。

5．2．2　枝肉の格付を通じた月齢証明
と畜場における公式なＵＳＤＡの格付は提出されたＱＳＡプログラムの条件通りに行われ、かつ、以下のそれぞれの基準（5.2.2.1、5.2.2.2 及び 5.2.2.3）に適合しなければならない。
5．2．2．1　牛は、公式なＵＳＤＡの格付により生理学的成熟度Ａ４０かそれより若いと決定されなければならない。公式なＵＳＤＡの格付は、米国の牛枝肉格付基準（http://www.ams.usda.gov/lsg/stand/standards/beef-car.pdf）及び成熟度Ａにおける成熟度の特徴（別添Ｆ：生理学的成熟度の判別に係るガイドライン）を用いて決定されなければならない。
5．2．2．2　ＵＳＤＡの格付員は、評価の適正さを確保するため、食肉格付証明（ＭＧＣ）課通知７０９に概説されているとおり、生理学的成熟度の決定に用いられる適正パフォーマンス基準に適合するか又は上回らければならない。
5．2．2．3　ＵＳＤＡの格付け員は、日本に輸出されるＡ４０又はそれより若いと決定された各々の枝肉の決定要素（骨、肉色及び総合的な成熟度）それぞれについて記録を保存しなければならない。

5．3　識別要件
5．3．1　5.2.1 及び 5.2.2 に適合するすべての枝肉は個別に識別されなければならない。「枝肉の格付を通じた月齢証明」に適合する枝肉は、熟練度がテストされたＵＳＤＡの格付員によって格付され、認証された段階で標識されなければならない。これらの識別の標識は、プロセスと製品の一貫性を確保するため、加工、包装、保管及び出荷を通じ、維持されなければならない。

５．３．２　出荷時の書類（船荷証券、積荷目録又は保証書）は、「製品は日本向けＥＶプログラムの要件に適合している。」という記述を含み、製品と製品の量を明確に特定するものでなければならない。

５．３．２　要件を満たすサプライヤーによって生産され、日本向けＥＶプログラムに適合すると認められた要件を満たす製品は、「製品は日本向けのＥＶプログラムの要件に適合している。」という記述を含むＦＳＩＳの輸出証明を受けることができる。

６　認証プログラムのリストの作成

日本向けに特定された製品の条件を満たすＵＳＤＡのＱＳＡプログラムの認証を受けた米国企業のみが、日本向け輸出証明（ＥＶ）プログラムにおいて資格のある企業の公式リストに記載される。

７　責任

米国企業は、本手順書、ARC1000 手順書（手続及び品質システム証明プログラムの一般的な方針及び手続き）及び ARC1002 手順書（手続及び品質システム評価（QSA）プログラム）に記載された全ての方針及び手続に適合する必要がある。

Quality Systems Verification Programs
General Policies and Procedures

1 Purpose

This Procedure outlines the policies and procedures for services under the Quality Systems Verification Programs (QSVP). The QSVP are designed to provide independent verification that special processes or marketing claims are clearly defined and verified by an independent third party. The QSVP are voluntary, user-fee programs that are available to suppliers of agricultural products or services.

QSVP are provided by the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Livestock and Seed (LS) Program, Audit, Review and Compliance (ARC) Branch, under the authority of the Agricultural Marketing Act of 1946, *as amended; the Code of Federal Regulations (CFR) 7, Part 54; and* as detailed in individual program procedures.

2 Scope

The provisions of this Procedure apply to all QSVP. Specific program requirements are set forth in individual program procedures. Individual program procedures are available on the ARC Branch website at http://www.ams.usda.gov/lsg/arc/audit.htm.

Note: All provisions of this Procedure do not apply to the Commodity Purchase Programs or the National Organic Program, as outlined in the individual program procedures.

3 References

ISO 19011:2002 Guidelines for quality and/or environmental management systems auditing

4 Responsibilities

Suppliers must meet all applicable policies and procedures outlined in this Procedure.

The ARC Branch must meet all applicable policies and procedures outlined in this Procedure. All audit activities are conducted in accordance to *ISO 19011:2002 Section 6 Audit Activities.* The ARC Branch must not consult with suppliers regarding the development, implementation, and maintenance of programs.

Any suggested changes to this Procedure should be submitted via email to the ARC Branch Program Manager.

5 Contact Information

Program Manager
USDA, AMS, LS Program, ARC Branch
STOP 0294, Room 2627-S,
1400 Independence Avenue, S.W.
Washington, D.C. 20250.

Date Issued 04/16/04 Approved by_____JLR
Date Revised N/A

6 Requirements (Clauses 1 to 17)

The following clauses apply when applying, receiving, or providing service for the QSVP.

1 Application for Service

Suppliers must submit an application for service for the QSVP. To submit an application, supplier must complete and submit to the ARC Branch Washington, DC office the following documents:

1.1 *LS Form 313, Application for Service.* The original form must be mailed to the ARC Branch Washington, DC office. However, for faster service, suppliers may also fax the form to the ARC Branch Washington, DC office.

1.2 Cover letter requesting QSVP services for each program in which the supplier wishes to participate.

1.3 *A complete copy of the supplier's program documentation as described in the applicable* program procedure.

The supplier may withdraw from the application process at any time. Suppliers are responsible for fees accrued prior to withdrawing their application.

2 Receiving Applications for Service

The Program Manager or designee notifies the supplier upon receiving the application for service. If the submitted application is inadequate, the Program Manager or designee contacts the supplier to request the additional documentation. The Program Manager withholds the application from further processing until the necessary documentation is received.

Once the Program Manager has determined that the application is complete, it is forwarded to the assigned auditor. The Program Manager or designee notifies the supplier of the assigned auditor.

3 Initial Desk Audit

The assigned auditor conducts a desk audit of the supplier's program documentation to ensure that all program requirements as outlined in the individual program procedure are fully addressed. The auditor uses the appropriate program checklist to conduct the desk audit.

3.1 If the program documentation is adequate and the majority of the program requirements are met, then the auditor arranges an on-site audit with the supplier.

3.2 If the program documentation requires clarification or additional information that can be easily obtained by working directly with the supplier, then the auditor obtains the clarification or additional information. Once the program documentation is adequate, then the auditor arranges an on-site audit with the supplier.

3.3 If the supplier's program documentation does not meet the majority of the program requirements or identifies that the supplier would not pass an on-site audit, then the auditor prepares and submits a desk audit report itemizing the deficiencies. This report is submitted to the Program Manager. The Program Manager sends the report, along with a cover letter, to the supplier discussing the action that the supplier must take before continuing the audit process.

4 Pre On-site Audit Activities

The size and composition of the audit team is determined in accordance to *ISO 19011:2002 Section 6 Audit Activities.* An audit plan and cost estimate must be prepared by the team leader and submitted to the supplier prior to the scheduled on-site audit.

5 On-site Audits

On-site audits are conducted in accordance to ISO 19011:2002 Section 6 Audit Activities. The frequency of on-site audits is outlined in the individual program procedures.

The objective of on-site audits is to verify the supplier's conformance (compliance) to the audit criteria.

5.1 *Conformance*: The condition or fact of a supplier being in agreement with the requirements of a quality or environmental standard.

5.2 *Compliance*: The condition or fact of a supplier being in agreement with regulatory requirements

6 Post On-site Audit Activities

Corrective action audits and any other post on-site audit activities are conducted in accordance to *ISO 19011:2002 Section 6 Audit Activities.* All audit documentation is retained by the ARC Branch in an electronic format.

7 Audit Findings

All audit findings, including identified non-conformances, continuous improvement points, and recommendations, *are discussed with the supplier at the conclusion of the on-site audit. The audit findings are* outlined in the audit report, which is submitted to the Program Manager for final review and disposition. The Program Manager has the discretion to modify the audit findings.

7.1 *Major non-conformance*: A non-conformance that compromises the integrity of the program or product to the extent that program approval should be denied, revoked, or delayed until corrective action can be completed. Any absence or complete breakdown of a program requirement is considered a major non-conformance.

7.2 *Minor non-conformance*: A non-conformance that does not compromise the integrity of the program or product. Isolated incidences of non-conformance are considered a minor non-conformance. *Minor non-conformances not corrected or addressed in a timely manner may be* upgraded to a major non-conformance.

7.3 *Continuous improvement point (CIP):* Observations or areas identified as opportunities for improvement. Although not identified as non-conformances, CIPs have the potential to become non-conformances if not corrected or addressed.

8 Correcting Identified Non-conformances

Suppliers must address all non-conformances and respond to all requests for corrective actions and corrections, as applicable, within the time frame specified by the Program Manager.

Requests are based on non-conformances identified during the audit. Suppliers must identify the cause(s) of the non-conformance, determine the necessary corrective action, and implement the corrective actions. Additionally, if the non-conformance resulted in the use or delivery of non-conforming product, the company must make correction appropriate to the non-conformance.

8.1 *Corrective Action*: Action to eliminate the cause of a detected non-conformance. Corrective action is taken to prevent recurrence.

8.2 *Correction*: Action to eliminate a detected non-conformance. Correction does not address the cause of the non-conformance but rather the specific non-conforming product.

8.3 *Preventative Action*: Action to eliminate the cause of a potential non-conformance. Preventative action is taken to prevent occurrence.

9 Approval Status

Program approval is based upon the audit findings and the recommendation of the auditor. The approval will be issued for the appropriate time period in accordance to the individual program procedure. The Program Manager makes the final decision regarding approval status. When appropriate, a Program Review Committee makes the final decision regarding approval status, in accordance to the individual program procedure.

Program approval status will be one of the following:

9.1 *Approval:* No non-conformances were identified during the audit. No actions are necessary by the supplier.

9.2 *Approval with Conditions*: Only minor non-conformances were identified during the audit. Suppliers must submit corrective actions and corrections as applicable within the time frame specified by the Program Manager. Additional desk audits and/or on-site audits may be conducted at the supplier's expense.

9.3 *Denied Approval*: Denied approval may be issued prior to the initial program approval for any of the reasons outlined below. Suppliers must submit corrective actions and correction as applicable to address any identified non-conformances before approval may be issued. Additional desk audits and/or on-site audits may be conducted at the supplier's expense.

- 9.3.1 Failure to adequately address any program requirement resulting in a major non-conformance.
- 9.3.2 Failure to demonstrate capability to meet any program requirement resulting in a major non-conformance.
- 9.3.3 Finding of objective evidence of a major non-conformance within the scope of the program.
- 9.3.4 An accumulation of minor non-conformances that result in the assignment of a major non-conformance for the program.
- 9.3.5 Presenting false or misleading information to any ARC Branch official.
- 9.3.6 Denying access to supplier's facilities and records within the scope of the program.

Upon reaching a decision, the Program Manager sends the supplier a cover letter, along with the audit report and any additional documentation. The cover letter details the approval status and any terms and conditions as appropriate. When appropriate, the Program Manager or designee will add the supplier's program to the listing on the applicable ARC Branch Program website in accordance with the individual program procedure.

10 Suspending Program Approval

The Program Manager may suspend program approval and remove a supplier's program from the listing on the applicable ARC Branch Program website for any of the following reasons:

10.1 Failure to adequately address any program requirement resulting in a major non-conformance.

10.2 Failure to demonstrate capability to meet any program requirement resulting in a major non-conformance.

10.3 Failure to follow the supplier's approved program.

10.4 Failure to provide corrective actions and correction as applicable in the timeframe specified.

10.4 Failure to maintain the supplier's approved program.

10.6 Implementing significant changes to approved program without prior written notification to and approval by the Program Manager.

10.7 Deliberate misrepresentation of the eligibility of agricultural products or services distributed under an approved program.

10.8 Confirmed finding of any prohibited compounds or substances or other violations as described in the specific program procedure. Upon confirming the violation, AMS suspends all approvals for suppliers in the product's chain of custody pending a complete investigation, in cooperation with appropriate regulatory agencies.

10.9 Denying access to supplier's facilities and records within the scope of the program.

10.10 Failure to pay ARC Branch fees.

Prior to the suspension, the Program Manager notifies the supplier in writing of the suspension, the effective date, and details of actions required to regain approval status. The details of actions do not include specific remedies to barriers of approval.

The continuous suspension of a supplier's approved program may result in the permanent suspension of the approved program.

11 Reinstatement of Suspended Program Approval

Program approvals suspended for implementing significant changes to the supplier's approved program without prior written notification to and approval by the Program Manager are reinstated immediately upon receipt of appropriate corrective actions and corrections as applicable. Additional desk audits and/or on-site audits may be conducted at the supplier's expense.

AMS reinstates program approvals for suppliers whose programs are within the chain of custody of products identified as containing or having been treated with any prohibited substance only upon revalidation of the integrity of their program in cooperation with appropriate regulatory agencies.

Program approvals for suppliers found to be responsible for the introduction of prohibited substances into the affected livestock or products are suspended until such a time as the client provides objective evidence that the *program has been completely purged of all potentially affected products and an on-site audit verifies that* effective corrective action and corrections as applicable have been taken. Final decisions regarding the suitability of corrective action, corrections, and the supplier's eligibility for reinstatement are at the discretion of the Program Manager.

Program approvals for suppliers who fail to follow the approved program are reinstated upon submission of acceptable corrective actions and corrections as applicable that address the failure to follow the approved program.

Program approvals for suppliers who fail to provide corrective actions and/or corrections within the timeframe specified are reinstated upon submission of acceptable corrective actions and corrections as applicable.

Program approvals for suppliers suspended for failure to pay ARC Branch fees are reinstated upon notification *that all outstanding fees and interest have been paid in full.*

Suppliers who are permanently suspended may be reinstated based upon the decision of a Program Review Committee.

12 Maintaining Approved Programs

Suppliers are required to maintain and implement their programs as described in their approved program documentation. Any significant changes to the supplier's approved program must be submitted in writing to the Program Manager and approved prior to implementation. Depending upon the nature and extent of the changes, the Program Manager may require a complete or partial on-site audit of the program prior to approval. In situations where an additional on-site audit is required, a new approval will be issued for an appropriate time period based on the findings of the audit.

13 Surveillance

All approved programs are audited on an on-going basis as listed in the individual program procedures unless a cancellation request is received in writing or a program is suspended. All approved programs are subject to unannounced audits by ARC Branch representatives. The auditor documents the findings of unannounced audits in an audit report and submits the report to the Program Manager. Findings of unannounced audits are considered when determining conformance of the program for continued approval, or may provide the basis for suspending approval.

14 Cancellation

Suppliers with approved programs may cancel service at any time by notifying the Program Manager in writing. Suppliers who cancel service are removed from the listing on the applicable ARC Branch Program website. Suppliers who cancel service must reapply and be approved through an audit before they are returned to the list. Suppliers are responsible for fees accrued prior to cancellation of the approved program.

15 Appeals, Complaints, and Disputes

Suppliers have the right to appeal any adverse audit findings or decisions issued by the Program Manager or Program Review Committee. Appeals, complaints, and disputes must be submitted in writing to the ARC Branch Chief within 30 days of the date of the official report or letter rendering the findings or decisions.

Requests for appeals, complaints, and disputes must include:

15.1 The basis for the appeal, complaint, or dispute, and

15.2 The requested alternative decision or actions.

The ARC Branch Chief, or designee, reviews any request for action and notifies the supplier of the final decision within 30 working days of the receipt of the request. Any suspensions or denied approvals remain in effect pending the outcome of the appeal.

16 Fees for Services

All QSVP are user-fee programs. The fees for QSVP services are the responsibility of the supplier requesting the services. Fees will be charged according to the approved hourly rate published in 7 CFR Part 54.27 (http://www.access.gpo.gov/nara/cfr/waisidx_04/7cfr54_04.html) or as outlined in individual program procedures. The fees for QSVP services include the following:

16.1 *Audit preparation*: Time to review the approved program documentation and records from previous audits, and to prepare checklists.

16.2 *Audit Time*: Time to conduct the audit, report the results of the audit, and conduct post-audit activities.

16.3 *Travel*: Travel time and expenses to and from the assigned auditor's official duty location and between audit sites. When traveling to provide services to multiple suppliers, charges will be prorated between the suppliers.

16.4 Other related expenses

Auditors document all hours of service charged to the suppliers on *LS Form 5-3 (1-93), Agricultural Products Certificate*. The original and pink copies are submitted to the Meat Grading and Certification Branch Office of Field Operations (OFO) for billing. One green copy is submitted to the ARC Branch Washington, DC office. One green copy is retained by the auditor.

17 Confidentiality

All documentation submitted by suppliers and maintained by the ARC Branch is subject to disclosure under the Freedom of Information Act (FOIA). FOIA applies to documents that are in the control of or maintained by a government agency.

Any portion of the program documentation that the supplier considers proprietary must be identified to the ARC Branch at the time the information is submitted. The ARC Branch will make appropriate provisions to protect the information from disclosure to the extent possible under existing Federal laws.

All ARC Branch representatives have signed conflict of interest statements and appropriate disclosure agreements on file with the ARC Branch prior to assignment to provide QSVP service to suppliers.

ARC1000
2004年4月16日

品質システム証明プログラム
全般的執行方針および手順

1. 目的

この手順書は品質システム証明プログラム（QSVP）のサービスに関する執行方針および手順についての概要説明である。特別のプロセスもしくはマーケティング主張が独立した第三者機関によって明確に規定、証明されていることを独自に証明するようにQSVPは計画されている。QSVPは農産物の供給者もしくは農業サービスの供給者が利用できる自主的な受益者負担のプログラムである。

QSVPは1946年の修正農業マーケティング法（連邦規則集（CFR）7、パート54；詳細は個々のプログラム手順に記載。）の権限の下に、米国農務省（USDA）、農業販売促進局（AMS）、畜産・種子（LS）プログラム、監査・検討・遵守（ARC）支局によって提供される。

2. 適用範囲

本手順書の各条項はすべてのQSVPに適用される。プログラムの特別な要求事項は個別のプログラム手順書に解説してある。個別のプログラム手順書は、*http://ams.usda.gov/lsg/arc/audit.htm* のARC支局ウェブサイトで入手できる。

注：個々のプログラム手順書に概説してあるように、本手順書のすべての条項が、農作物購買プログラムもしくは全国有機プログラムに当てはまるわけではない。

3. 参考資料

ISO 19011:2002　品質および/または環境管理システム監査のための指針

4. 責任

供給者は本手順書に述べられている適用可能な方針および手続きのすべてに適合していなければならない。

ARC支局は本手順書に述べられている適用可能な方針および手続きのすべてに適合していなければならない。すべての監査活動はISO 19011:2002 第6節 監査活動に従って実施しなければならない。ARC支局はプログラムの進展、実施および維持管理について供給者と協議してはならない。

本手順書について提案されたいかなる変更についても電子メールにてARC支局プログラム・マネージャーへ提出すべきである。

5. 連絡先

プログラム・マネージャー
USDA、AMS、LSプログラム、ARC支局
STOP 0294、Room 2627-S、
1400 Independence Avenue、S.W.
Washington, D.C. 20250.

6. 要求事項（第1条から第17条）

QSVPに関するサービスの申請、受入および提供に際して、以下の条文を適用する。

1. サービスの申請

供給者はQSVPのサービスの申請書を提出しなければならない。申請書の提出にあたっては、以下の文書について記入の上ARC支局のワシントン市事務所まで提出しなければならない：

1.1　LS様式313　サービスの申請。原本はARC支局のワシントン市事務所まで郵送すること。ただし早期にサービスが必要な場合は、供給者は様式をARC支局のワシントン市事務所までファックス送信することも可能である。

1.2　供給者が参加したいと考えるプログラムに関するQSVPサービスを要請するカバーレター。

1.3　適用されるプログラム手順中に記載されているとおりの供給者によるプログラムの証拠書類の完全な写し。

申請を行った供給者は随時申請を取り消すことができる。供給者は申請の取り消し前に生じた経費については責任を持つ。

2. サービス申請書の受理

プロジェクト・マネージャーもしくは被指名人はサービス申請書の受理時に、供給者に通知する。もし提出された申請書が不十分な場合は、プログラム・マネージャーもしくは被指定人が供給者に連絡をとり、追加文書の要請を行う。プログラム・マネージャーは必要文書を受け取るまでは、それ以降の申請の処理を留保する。

申請書類が不備がないとプログラム・マネージャーが判断したときは、申請書は担当監査官に送られる。プログラム・マネージャーもしくは被指名人は担当監査官について供給者に通知をする。

3. 当初の書面監査

担当監査官は、個々のプログラム手順書に記載してあるプログラム要求事項のすべてが十分に対応がなされていることを確認するために、供給者のプログラム文書について書面監査を実施する。監査官はこの書面監査を実施するために適当なプログラム・チェックリストを使用する。

3.1 もしプログラム文書が適切であり、プログラムの要求事項の大部分が適合しているならば、監査官は供給者を伴う現場監査の準備をする。

3.2 もしプログラム文書において、直接供給者に働きかけることにより容易に解決できる明確化もしくは追加情報が必要となった場合は、監査官は当該明確化もしくは追加情報を入手する。プログラム文書が適切になったならば、監査官は供給者を伴う現場監査の準備をする。

3.3 もしプログラムの文書がプログラムの要求事項の大部分に合致しないか、もしくは供給者が現場監査に合格しないであろうことが確認されれば、監査官は不備な事項について箇条書きにした書面監査報告の作成および提出を行う。この報告書はプログラム・マネージャーに提出される。プログラム・マネージャーは、監査プロセスを継続するために供給者が取らなければならない措置を記したカバーレターを添付して、当該報告を供給者に送付する。

4. 現地監査前の活動

ISO 19011:2002 第 6 節 監査活動に従って監査チームの人数および構成を決定する。チームリーダーは監査計画および費用見積を準備して、予定された現場監査前に供給者へ提出しなければならない。

5. 現地監査

現地監査はISO 19011:2002 第 6 節 監査活動に従って実施される。現地監査の回数は個々のプログラム手順に記してある。

現地監査の目的は監査基準に対する供給者の規格適合性（標準適合性）を検証することにある。

5.1 規格適合性：供給者が品質基準もしくは環境基準の要求事項にどれだけ従っているかという状況もしくは実態。

5.2 標準適合性：供給者が要求事項にどれだけ従っているかという状況もしくは実態。

6. 現地監査後の活動

是正措置のための監査およびその他の現地監査後の活動は ISO 19011:2002 第 6 節 監査活動に従って実施する。すべての監査資料は電子フォーマットの形でARC支局が保管する。

7. 監査所見

確認された不適合事項、継続的改善事項および勧告を含む監査所見についてはすべて現地監査の最後に供給者と協議を行う。監査所見は監査報告に概要をまとめて、最終審査および最終的な処置のためにプロジェクト・マネージャーに提出する。プロジェクト・マネージャーは報告を修正する決定権を有する。

7.1 重大な不適合：是正措置が完全にとられるまではプログラムの承認の否定、取り消しもしくは延期をすべきであるような程度まで、プログラムもしくは製品の完全性を危うくするような不適合。プログラムの要求事項の何らかの不存在もしくは完全な機能停止は重大な不適合と考えられる。

7.2 軽微な不適合：プログラムもしくは製品の完全性を危うくしないような不適合。不適合の単発的な事例は軽微な不適合と考えられる。時宜を得た方法で修正もしくは対応がなされない軽微な不適合が重大な不適合に拡大することもある。

7.3 継続的改善事項（CIP）：改善の機会として認められた観察結果もしくは分野。不適合とは認められないものの、CIP は修正もしくは対応がなされなければ不適合にまで至る可能性がある。

8. 確認された不適合の修正

供給者はすべての不適合に対応し、是正措置および修正の要請のすべてに対して適用可能であるならばプログラム・マネージャーが定めた期限内に応えなければならない。要請は監査中に確認された不適合に基づくものである。供給者は不適合の原因の特定および必要な是正措置の決定を行い、是正措置を実施するものとする。さらに不適合が不適合製品の使用もしくは配達にまで至っている場合には、当該企業は不適合にふさわしい是正措置を行わなければならない。

8.1 是正措置：検出された不適合の原因を除去するための処置。是正措置は再発生を防止するために講じられる。

8.2 修正：検出された不適合を除去するための処置。修正は不適合の原因ではなく、具体的な不適合製品に対応することである。

8.3 予防措置：潜在的不適合の原因を除去するための処置。予防措置は再発生を防止するために講じられる。

9. 承認ステータス

プログラムの承認は監査所見および監査官の勧告に基づいて行われる。承認は個々のプログラムの手順に従って、適当な時期に出されることになる。承認ステータスについてはプログラム・マネージャーが最終決定を行う。必要に応じて、プログラム審査委員会が個々のプログラムの手順に従って承認ステータスの最終決定を行うこともある。

プログラムの承認ステータスは以下のいずれかである：

9.1 承認：監査期間中には不適合は認められなかった。供給者による措置は必要がない。
9.2 条件付承認：監査期間中には軽微な不適合が認められただけであった。供給者はプロジェクト・マネージャーによって指定された期限内に適用可能な是正措置および修正を提出しなければならない。追加的な書面監査および/または現地監査は供給者の費用負担で行われることになる。
9.3 承認拒否：承認拒否は最初のプログラム承認に先立って、以下のいずれかの理由によって出されることになる。供給者が不適合に対応するために適用可能な是正措置および修正を提出して初めて承認が出されることになる。追加的な書面監査および/または現地監査は供給者の費用負担で行われることになる。
9.3.1 重大な不適合を引き起こす何らかのプログラムの要求事項への適正な対応の不履行。
9.3.2 重大な不適合を引き起こす何らかのプログラムの要求事項を満たすだけの実現能力の提示の不履行。
9.3.3 プログラムの範囲内における重大な不適合の客観的証拠の知見。
9.3.4 プログラムにとって重大な不適合の指定をもたらす軽微な不適合の積み重ね。
9.3.5 いずれかのARC支局の職員に対する虚偽もしくは誤解を招くような情報の提供。
9.3.6 プログラムの範囲内での供給者の施設への立ち入りおよび記録の閲覧の拒否。

結論に到達するにあたって、プロジェクト・マネージャーは供給者に対して、監査報告および何らかの追加文書を添付してカバーレターを送付する。カバーレターには承認ステータスおよび必要に応じて何らかの条件等の詳細を記す。適切な場合にはプログラム・マネージャーもしくは被指名人が、個々のプログラムの手順に従って、適用できるARC支局のプログラムのウェブサイトのリストに供給者のプログラムを追加することになる。

10. プログラム承認の停止
プログラム・マネージャーはプログラムの承認を停止することができる。また以下のいずれかの理由によって、適用できるARC支局のプログラムのウェブサイトのリストから供給者のプログラムを削除することができる。
10.1 重大な不適合を引き起こす何らかのプログラムの要求事項に対する適正な対応の不履行。
10.2 重大な不適合を引き起こす何らかのプログラムの要求事項を満たすだけの実現能力の提示の不履行。
10.3 承認を受けた提供者のプログラム遵守の不履行。
10.4 指定された期限内に適用可能な是正措置および修正の不履行。
10.5 承認を受けた供給者のプログラム維持の不履行。
10.6 事前のプログラム・マネージャーへの書面による通知および承認なしの、承認を受けたプログラムの大幅変更。

10.7 承認されたプログラムにおいて配布される農産物もしくはサービスの適格性についての意図的な虚偽の提示。
10.8 禁止成分もしくは禁止物質、またはそれ以外の具体的なプログラム手順の規定違反とされているものが確認された場合。違反が確認されたならば、AMSはしかるべき規制当局と協力しながら、調査結果が終了するまでは製品の加工・流通過程の管理における供給者のすべての承認を停止する。
10.9 プログラムの範囲内での供給者の施設への立ち入りおよび記録の閲覧の拒否。
10.10 ARC支局への費用支払い不履行。

停止に先立って、プログラム・マネージャーは書面により供給者に停止、発効日、そして承認ステータスの再取得のために必要な措置の詳細について通知する。措置の詳細には承認の障害に対する具体的改善策は含まれない。
供給者に承認されたプログラムに対する停止が継続するということは、承認プログラムの永久停止を意味する。

11. プログラムの承認停止の回復
プログラム・マネージャーへの事前の書面による通知および承認なしに供給者の承認済みプログラムについて顕著な変更を行ったことで、プログラムの承認停止が行われた場合には、適用可能で適切な是正措置および修正が受理されれば速やかに回復がなされる。追加的な書面監査および/または現地監査は供給者の費用負担で行われることになる。禁止されている成分を含有していたり、当該成分によって処理されたことが確認された製品の加工・流通過程の管理内にあるプログラムを有する供給者に対しては、しかるべき規制当局との協力によりそれらのプログラムの完全性が再確認されると同時にAMSはその承認を回復させる。
禁止されている成分の影響を受けた家畜もしくは製品に導入した責任があると認められた供給者のプログラムの承認は、影響を受けた可能性のある製品のすべてがプログラムから完全に一掃されているという客観的証拠が示され、有効で適用可能な是正措置および修正が行われていることが依頼者によって立証されるまでは停止される。回復に向けての是正措置、修正の適合性および供給者の適格性に関する最終判断はプロジェクト・マネージャーの裁量による。
承認されたプログラムに従わなかった供給者へのプログラムの承認は、承認されたプログラムに従えなかった原因に対応するための受入可能な是正措置および修正が適用できるものとして提出されれば回復される。
指定された期限内に是正措置および/または修正を実施できなかった供給者のプログラム承認については、受入可能な是正措置および修正が適用できるものとして提出されれば回復される。

ARC 支局への費用の未払いでプログラム承認が停止されている供給者については、すべての未払い費用および利子が完済されていれば回復される。

永久停止になっている供給者については、プログラム審査委員会の決定に基づいて回復することができる。

12. 承認プログラムの維持

承認されたプログラム文書の規定に従って供給者はそれぞれのプログラムを維持し、実施することが求められる。承認された供給者のプログラムに関する重大な変更については、書面によりプロジェクト・マネージャーに提出して、実施前に承認を得なければならない。変更の性質および程度によっては、プロジェクト・マネージャーは承認に先立って、プログラムについての詳細もしくは部分的な現地監査を求めることもある。追加的な現地監査が求められる状況では、監査の知見に基づいて適当な時期に新規の承認が出されることになる。

13. サーベイランス

承認されたプログラムはすべて、取り消しの要請を書面で受理するかプログラムの停止がない限りは、個々のプログラム手順に規定してあるように継続中の状態で監査を受ける。承認されたプログラムはすべて ARC 支局代表によって無通告監査を受ける。監査官は監査報告中に無通告監査の知見を記録し、当該報告書をプロジェクト・マネージャーに提出する。無通告監査の知見は、継続承認のためのプログラムの適合性の判断の際に考慮されるか、もしくは承認停止の基礎資料となる。

14. 取り消し

プログラムが承認されている供給者はプロジェクト・マネージャーに書面で通知することにより随時、サービスを取り消すことができる。サービスを取り消した供給者は、適用可能な ARC 支局プログラムウェブサイトのリストから削除される。サービスを取り消した供給者がリストに再掲載されようとするときは、再申請および監査を通じての再承認が必要となる。供給者は承認されたプログラムの取り消し前に生じた費用については責任を持つものとする。

15. 訴え、不服および争議

供給者はプログラム・マネージャーもしくはプログラム審査委員会から出される意に沿わない審査の知見もしくは決定に対して訴えを起こす権利を有する。訴え、不服および争議は知見もしく決定を伝える公的報告もしくは書簡の期日から 30 日以内に ARC 支局長へ書面で提出しなければならない。

訴え、不服および争議の要請には以下のようなものが含まれる：

15.1 訴え、不服および争議の根拠となるもの、そして

15.2 要請される決定もしくは措置

ARC 支局長もしくは被指定人は措置の要請を審査し、要請の受理後 30 営業日以内に最終決定を供給者に通知する。訴えの結果が出るまでは、いかなる停止もしくは承認の取り消しも有効のままである。

16. サービス費用

QSVP はすべて受益者負担のプログラムである。QSVP サービスの費用はサービスを要請する供給者の責任となる。費用は 7CFR パート 54.27 (http://www.access.gpo.gov/nara/cfr/waisidx_04/7cfr54_04.html) で公開してある 1 時間当たりの費用もしくは個々のプログラム手順の規定により課金される。QSVP サービスの費用は以下のものが含まれる：

16.1 監査準備：承認されたプログラム文書および前回の監査記録の審査、そしてチェックリストの準備に費やす時間。

16.2 監査時間：監査の実施、監査結果の報告、そして監査後の措置の実施のための時間。

16.3 出張：出張時間と指示された監査官の公的職務地の往復および監査地間の移動費用。複数の供給者へサービスを提供するための出張の際には、諸費用は供給者間で案分する。

16.4 その他関連諸費用

監査官は供給者に課金されることになるサービスの全時間について、LS form5-8(I-93) 農産物証明書に記録する。原本およびピンクの写しを請求書作成のために肉質格付けおよび証明部門の現地事務所運営室 (OFO) に提出する。グリーンの写しは ARC 支局のワシントン市事務所へ提出する。残りのグリーンの写し 1 部は監査官自身が保管する。

17. 守秘義務

供給者によって提出され、ARC 支局によって保管されているすべての文書は、情報公開法 (FOIA) に従って公開に供される。FOIA は政府機関によって管理・維持される文書にも適用される。

プログラム文書の一部にでも供給者が特許権を持つと見なす内容があれば、当該情報が提出される際に ARC 支局によって確認されなければならない。ARC 支局は現行連邦法で可能な範囲において当該情報の開示からの保護のために適当な措置を講じる。

すべての ARC 支局の代表者は、供給者に QSVP サービスを提供する職務の実施に先立って、局内資料について利害関係の衝突に関する陳述書および適正な開示に関する同意書に署名をしている。

USDA Quality System Assessment (QSA) Program

1 Purpose

This Procedure provides the requirements of a USDA Quality System Assessment (QSA) Program. It also provides the criteria used in the objective evaluation of USDA QSA Programs that are submitted for approval. Evaluations are conducted by the Agricultural Marketing Service (AMS), Livestock and Seed (LS) Program, Audit, Review, and Compliance (ARC) Branch

2 Scope

This Procedure applies to marketing programs for agricultural products, including services, that are submitted to the ARC Branch for verification and monitoring. It is limited to programs or portions of programs where specified product requirements are supported by a documented quality management system. The extent of controls included in these programs may include all phases of production and marketing from genetic development through retail distribution, or any portion as described in the scope of the submitted program.

If any program requirements can not be applied due to the nature of a company and its product, then these requirements may be considered for exclusion. Exclusions are limited to program requirements within *Clause 4 Product Realization* and must not affect the company's ability to provide a conforming product. Additionally, exclusions do not affect the company's responsibility to provide a conforming product.

3 References

ARC 1000 Procedure, Quality Systems Verification Programs General Policies and Procedures
Applicable ARC Branch Program Procedure

4 Responsibilities

Companies must meet all applicable policies and procedures outlined in this Procedure, the applicable Program Procedure, and *ARC 1000 Procedure, Quality Systems Verification Program General Policies and Procedure.*

The ARC Branch must meet all applicable policies and procedures outlined in this Procedure, the applicable Program Procedure, and *ARC 1000 Procedure, Quality Systems Verification Program General Policies and Procedure.*

5 Audit Frequency

All approved programs will be audited at least twice per fiscal year (October 1 to September 30). However, more frequent audits may be conducted (1) if either numerous major or minor non-conformances are identified during an audit; (2) if customer complaints indicate an ongoing problem; (3) to satisfy specific requests as declared by customers, trading partners or other financial interested parties; or (4) as directed by the ARC Branch Chief.

USDA Agricultural Marketing Service | Audit, Review, and Compliance Branch | STOP 0294 - Room 2627-S 1400 Independence Avenue SW Washington, DC 20250 | ARC 1002 Procedure March 4, 2004

6 Listing of Approved Programs

Approved programs will be listed on the applicable Program website or on the USDA QSA Program website at http://www.ams.usda.gov/lsg/arc/qsap.htm. Information about the approved program will be in accordance with the applicable Program Procedure. The approved program listing on the USDA QSA Program website will include the following information:

a) Company name;
b) Company contact information;
c) Program requirements;
d) Report reference number (approval number); and
e) Renewal date.

7 Program Requirements (Clauses 1 to 5)

Companies must submit a documented program that addresses the program requirements as outlined in the following clauses (*Clauses 1 to 5*).

1 Quality Management System

1.1 General Requirements

A quality management system (QMS) must be established, documented, implemented, and maintained which ensures that products conform to the requirements of this Procedure, the applicable Program Procedure, and to specified product requirements.

1.2 Documentation Requirements

1.2.1 General

The company must prepare and maintain a QMS that includes:

a) Documented specified product requirements;
b) A quality manual;
c) Documented procedures required by this Procedure;
d) Documents necessary to ensure the effective operation and control of its processes; and.
e) Records required by this Procedure.

1.2.2 Quality Manual

The company must establish and maintain a quality manual that includes at a minimum:

a) An organizational chart or similar document listing all personnel assigned to managerial positions within the program;
b) A description of the scope of the QMS, including details of and justification for exclusions;
c) The specified product requirements;
d) Documented procedures established for the QMS;
e) A master document list that shows the most current issue of all QMS procedures, forms, tags, and labels used to track or demonstrate conformance; and
f) All other documentation as required by this Procedure.

The quality manual must be controlled and available for review at all associated sites where activities are conducted.

1.2.3 Control of Documents

The company must control all documents required by this Procedure.

Control of documents includes at a minimum:

a) All documents must contain the current revision status of the document.
b) The company must ensure that relevant versions of applicable documents are available at all associated sites where activities are conducted.
c) The company must prevent the use of obsolete or unapproved documents.
d) All documents must be retained for a minimum of 1 year.

Substantive changes to QMS documentation must be submitted to the ARC Branch for approval prior to implementation.

1.2.4 Control of Records

The company must establish and maintain records to provide evidence of conformity to program requirements, to specified product requirements, and of the effective operation of the QMS.

Control of records includes at a minimum:

a) The company must control all records required by this Procedure.
b) Records must be stored in a manner so as to prevent loss, damage, or alteration.
c) Records must be legible, easily accessible, and readily available.
d) All records must be retained for a minimum of 1 year.

2 Management Responsibility

Management must ensure that specified product requirements are established at relevant functions and levels within the company.

Management must ensure that QMS responsibilities and authorities are defined and communicated within the company.

The company must have an organizational chart or similar document listing all personnel assigned to managerial positions within the program.

All personnel listed must have their responsibilities and authorities outlined in an auditable method.

A management representative, who has the authority to act on behalf of the company at all locations where program activities are conducted, must be designated.

The management representative must have the responsibility and authority for ensuring that processes needed for the QMS are established, implemented, and maintained.

3 Human Resources - Competence, Awareness, and Training

Personnel performing work affecting product quality must be competent on the basis of appropriate education, training, skills, and/or experience, as applicable.

The company must provide training to all personnel with QMS responsibilities.

The company must have a documented procedure to ensure all personnel performing work affecting product quality are properly trained in relevant aspects of the QMS.

The documented procedure must define the methods for:

a) Determining the necessary competence for personnel performing work affecting product quality;
b) Determining the criteria for training;
c) Evaluating the effectiveness of the training; and
d) Ensuring that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

The company must maintain appropriate records of education, training, skills, and experience, as applicable. These records must include the scope of the training received.

4 Product Realization

4.1 General

Where any program requirements within *Clause 4 Product Realization* can not be applied due to the nature of a company and its product, these requirements may be considered for exclusion. Exclusions must not affect the company's ability to provide a conforming product. Additionally, exclusions do not affect the company's responsibility to provide a conforming product.

4.2 Receiving Process

The company must ensure that product purchased or received from outside establishments and used in the program conform to specified receiving requirements.

The company must ensure the adequacy of specified receiving requirements prior to their communication to the supplier.

The company must evaluate and select suppliers based on their ability to supply product that conforms to the specified receiving requirements.

The company must establish and implement the inspection or other activities necessary for ensuring that product purchased or received from outside establishments and used in the program conform to *specific receiving requirements.*

The company must have a documented procedure addressing products purchased or received from outside establishments.

The documented procedure must describe:

a) All product purchased and/or received from outside establishments regardless of its use within the program;
b) The specified receiving requirements for acceptance of products to be used in the program;
c) The criteria and process for supplier selection, evaluation, and re-evaluation; and
d) The process used to ensure that purchased product and/or product received from outside establishments and used in the program conform to specific receiving requirements.

The company must maintain records of the results of supplier evaluations and any necessary actions arising from the evaluation.

The company must maintain records to provide evidence of conformity to the receiving process and of the effective operation of the receiving process.

4.3 Identification and Traceability

The company must have a documented procedure to identify product (raw materials and/or finished product) by suitable means throughout product realization, where appropriate.

The documented procedure must describe the method for:

a) Identifying the product throughout product realization;
b) Controlling and recording the unique identification of the product; and
c) Identifying the product status with respect to monitoring and measurement requirements.

The method for identifying the product must:

a) Be unique to the program. When applicable, animals must be identified with ear tags or other permanent identification; and
b) Be such that the identification will transfer through all phases of product realization, from receipt into the program through production to delivery.

The company must maintain records of all products as identified and records of all changes of identities.

4.4 Preservation of Product

The company must preserve the conformity of product during internal processing and delivery to the intended destination.

The preservation must include identification, handling, packaging, storage, and protection. It must also apply to the constituent parts of a product.

4.5 Control of Monitoring and Measuring Devices

The company must determine the monitoring and measurement to be undertaken to provide evidence of conformity to specified product requirements.

The company must determine the monitoring and measurement devices needed to provide evidence of conformity to specified product requirements.

The company must establish processes to ensure that monitoring and measurement can be conducted and are conducted in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment must:

a) Be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification must be recorded;
b) Be adjusted or re-adjusted as necessary;
c) Be identified to enable the calibration status to be determined;
d) Be safeguarded from adjustment that would invalidate the measurement result; and
e) Be protected from damage and deterioration during handling, maintenance, and storage.

The company must assess and record the validity of the previous measuring results when the equipment is found not to conform to the requirements. The company must take appropriate action on the equipment and any product affected.

The company must confirm the ability of computer software to satisfy the intended application when used in the monitoring and measurement of specified requirements. This must be performed prior to initial use and reconfirmed as necessary.

The company must maintain records of the results of calibration and verification.

5 Measurement, Analysis, and Improvement

5.1 General

The company must plan and implement the monitoring, measurement, analysis, and improvement processes needed:

a) To demonstrate conformity of the product;
b) To ensure conformity of the QMS; and
c) To continually improve the effectiveness of the QMS.

The plan must include a determination of application methods, including statistical techniques, and the extent of their use.

When statistical methods are used to control product quality or integrity, the basis for those procedures must be clearly defined.

5.2 Monitoring and Measurement

5.2.1 Customer Satisfaction

The company must monitor information relating to customer perception as to whether the company has met customer requirements. This information must be reviewed as a performance measurement of the QMS.

The company must determine the methods for obtaining and using this information.

The company must maintain records relating to customer perception.

5.2.3 Monitoring and Measurement of Processes

The company must apply suitable methods for monitoring and, where applicable, measurement of the QMS processes.

These methods must demonstrate the ability of the processes to meet product requirements.

When product requirements are not achieved, correction and corrective action must be taken, as appropriate, to ensure conformity of the product.

5.2.4 Monitoring and Measurement of Product

The company must monitor and measure the characteristics of the product to verify that product requirements have been met. This must be conducted at appropriate stages of the product realization process.

The company must ensure that product requirements have been meet prior to product release and service delivery, unless otherwise approved by a relevant authority and, where applicable, by the customer.

The company must maintain records to verify evidence of conformity to product requirements. Records must indicate the person(s) authorizing release of product.

5.3 Control of Non-conforming Product within the QMS

The company must ensure that non-conforming product (raw material and/or finished product) is identified and controlled to prevent its unintended use or delivery.

The company must have a documented procedure that defines:

a) The identification of non-conforming product;
b) The controls used to ensure the segregation of non-conforming product; and
c) The related responsibilities and authorities for ensuring the segregation and disposition of non-conforming product.

The company must handle non-conforming product by one or more of the following methods:

a) By taking action to eliminate the detected non-conformity;
b) By authorizing its use, release, or acceptance under concession by a relevant authority and, where applicable, by the customer; or
c) By taking action to preclude its original intended use or application.

When non-conforming product is corrected, it must be subject to re-verification to demonstrate conformity to the product requirements.

The company must take appropriate actions when non-conforming product is detected after delivery or use has started.

The company must maintain records of all non-conforming product and any subsequent actions taken, including concessions obtained.

5.4 Improvement

5.4.1 Continual Improvement

The company must continually improve the effectiveness of the QMS through the use of the quality objectives, customer feedback, audit results, and corrective and preventative actions.

The company must ensure that the integrity of the QMS is maintained when changes to it are planned and implemented.

5.4.2 Corrective Action

The company must take action to eliminate the cause of non-conformance in order to prevent recurrence.

Corrective actions must be appropriate to the effects of the non-conformances encountered.

The company must maintain records of the results of any actions taken.

5.4.3 Preventative Action

The company must determine and implement action to eliminate the causes of potential non-conformances in order to prevent their occurrence.

Preventative actions must be appropriate to the effects of the potential problems.

The company must maintain records of the results of any actions taken.

ARC1002
2004年3月4日

米国農務省品質システム評価（QSA）プログラム

1．目的

この手順書は米国農務省の品質システム評価（QSA）プログラムの要求事項を定めるものである。同手順書はまた、承認を目的として提出された米国農務省のQSAプログラムの客観的評価に使用する基準を定める。評価は、農業販売促進局（AMS）、畜産と種子（LS）プログラムの監査、検討および遵守（ARC）支部により実施される。

2．適用範囲

この手順書は、品質証明および監視を目的としてARC支部に提出される販売後のサービスを含む農産物の販売促進プログラムに適用される。適用範囲は、特定の農産物に関する要求事項が文書化された品質管理システムを土台とするプログラムおよびその一部に限られる。当該プログラムに含まれる管理は、一般的製品開発から小売販売または実施プログラムにおいて認められた範囲における生産および販売のすべての段階に適用される。

いずれかのプログラムの要求事項が企業およびその製品の性質により適用不可能な場合は、それらの要求事項は除外対象にされることもある。除外は、第4条項の製品実現における要求事項に限られ、かつ適合製品を販売する企業の能力に影響を与えるものであってはならない。さらにそれらが、適合製品を販売する企業側の責任に影響するものでもない。

3．参考資料

ARC手順書1000、品質システム保証プログラムの全般的方針および規定事項、適用可能なARC支局プログラム手順書。

4．供給企業の責任

供給企業は、本手順書、適用可能なプログラムの手順書およびARC 1000手順書：品質システム保証プログラムの全般的方針および手続きにおいて定められるすべての適用可能な方針および手続きに適合しなければならない。

ARC支局は、本手順書、適用可能なプログラム手順書およびARC 1000：品質システム保証プログラム、全般的方針および手続きにおいて定められるすべての適用可能な方針および手続きに適合しなければならない。

5．監査頻度

認定されたすべてのプログラムは、会計年度ごと（10月1日から9月30日の間）に最低2回ずつ監査を実施するものとする。ただし、(1) 監査中に数多くの大規模または小規模の不適合が認められる場合、(2) 顧客の不満が問題の発生を示している場合、(3) 顧客、取引相手または経済的利害関係者により訴えられた特定の要求に応えるために、もしくは(4)ARC支局長による指示に従い、それ以上の監査が行われる場合もある。

6．認定プログラムのリストへの掲載

認定されたプログラムは、適用されるプログラムのウェブサイトまたは米国農務省QSAプログラムウェブサイト、http://www.ams.usda.gov/lsv/arc/qsap.htmに掲載されるものとする。認定プログラムに関する情報は、プログラム手順書と一致するものとする。米国農務省QSAプログラムウェブサイトに掲載される認定プログラムには、以下の情報が含まれる。

a) 企業の名称
b) 企業の連絡先
c) プログラムの要求事項
d) 報告書参照番号（認定番号）
e) 更新月日

7．プログラムの要求事項（第1条から第5条）

企業は、以下の条文（第1条～第5条）に概要が示されたプログラムの要求事項を記述した文書化されたプログラムを提出しなければならない。

1．品質管理システム

1.1. 一般的要求事項

品質管理システム（QMS）は、製品が本手順書、適用されるプログラム手順書要求事項ならびに特定製品を対象とする要求事項に対する適合を確保するよう構築、文書化、実施および維持管理されなければならない。

1.2. 文書に関する要求事項

1.2.1. 概要

当該販売企業は、以下を含むQMSを作成および維持管理しなければならない。

a) 文書化された特定製品に関する要求事項
b) 品質マニュアル
c) 当該手順書により義務付けられた文書の手続き

d) 製造工程の効果的運用および管理の確保に必要な文書
e) 本手順書により義務付けられる記録

1.2.2. 品質マニュアル
当該販売企業は、最低限以下の項目を含む品質マニュアルを構築および維持管理しなければならない。
a) 当該プログラムにおいて管理作業を任された全従業員を示す組織図または同等の資料。
b) 除外対象に関する詳細および理由を含む QMS の範囲の説明。
c) 特定製品に関する要求事項。
d) QMS のために確立された文書化された手順書。
e) 適合を追跡または実証する目的で使用される QMS 用のあらゆる手順、様式、タグおよびラベルに関する現状を示す文書リスト。
f) 本手順書により義務付けられるその他すべての文書。

品質マニュアルは、活動が実施されるすべての関連場所で見直しのために管理されてかつ閲覧可能でなければならない。

1.2.3. 文書管理
供給企業は、本手順書により義務付けられるすべての文書を管理しなければならない。

文書管理には最低でも以下が含まれる。
a) すべての文書は、その文書の現行の改正版を掲載しなければならない。
b) 企業は、適用される文書の現行版が販売活動の実施されるすべての関連場所で閲覧可能であることを確保しなければならない。
c) 企業は、使用されなくなったかまたは不適切な文書の使用を防がなければならない。
d) すべての文書は、最低1年間は保存されなくてはならない。

QMS 文書化に対する重要な変更は、実施前に ARC 支局に提示され、承認を得なければならない。

1.2.4. 記録の管理
企業は、各プログラムの要求事項、特定の製品に関する要求事項および QMS の効果的施行に準拠する証拠を提供するために、記録を作成および維持管理する義務がある。

記録の管理には最低でも以下が含まれる。
a) 企業は本手順書により義務付けられるすべての記録を管理しなければならない。

b) 記録は遺失、損傷または変更の発生を防ぐような方法で保管されなければならない。
c) 記録は読みやすく、閲覧が簡単でかついつでも利用可能でなければならない。
d) すべての記録は、最低1年間は保存されなければならない。

2. 経営者の責任
経営者は、製品に関する特定要求事項が企業における適切な機能および水準で確立されることを確保しなければならない。

経営者は、QMS の責任および権限が企業内で規定および浸透することを確保しなければならない。

企業は当該プログラムにおいて運営管理の立場を担う全従業員を列挙する組織図または同等の文書を持たなければならない。

列挙されたすべての従業員は、監査可能な方法で概要を示してある責任及び権限を担う義務を有する。

管理責任者は、プログラム関連の活動が実施されるあらゆる環境で企業に代わって行動する権限を有する者が任じられなければならない。

管理責任者は、QMS が確立、実施および維持管理されるに当たり必要となるプロセスを確保する責任ならびに権限を担わなければならない。

3. 人的資源 - 能力、認識および訓練
製品の品質に影響を与える従業員の作業活動は、使用可能である適切な教育、訓練、技術および/または経験を土台とする力量を備えていなければならない。

企業は QMS の責任に関して、全従業員に訓練を施さなければならない。

企業は、製品の品質に影響を与える従業員の実施作業が QMS の関連項目において適切に訓練されることを確立することを考慮した手順書を持っていなければならない。

手順書は以下に関する方法を規定する必要がある。
a) 製品の品質を左右する従業員の実施作業に必要な能力の判定。
b) 訓練基準の決定。
c) 訓練の効果の評価。

d) 従業員が自ら作業活動の影響力および重要性、ならびにそれが品質達成に与える寄与度を認識する環境の確立。

企業は可能な限り教育、訓練、技術および経験の適切な記録を保管する義務がある。この記録は訓練の範囲を記載しなければならない。

4. 製品実現

4.1. 一般

第4条項の製品実現におけるすべてのプログラムの要求事項が、ある企業およびその製品の性質上適用不可能である場合は、それらの要求事項は除外対象とみなされることもある。除外要求事項は、当該企業の適合製品の供給能力に影響を与えるものであってはならない。また、除外要求事項は、当該企業の適合製品の供給責任に何ら影響を与えるものではない。

4.2. 受け入れプロセス

企業は、外部企業からの購買または受け入れられた製品および当該プログラムにおいて使用された製品が受け入れに関する特定の要求事項に適合していることを確保する義務がある。

企業は、供給者との取引に先立ち、受け入れに関する特定の要求事項の適正を確保しなければならない。

企業は、受け入れに関する特定の要求事項に適合する製品の供給能力に基づき、供給者を評価および選定しなければならない。

企業は、外部から購入または受け入れられ、当該プログラムにおいて使用される製品が、受け入れに関する特定の要求事項に適合することを確保するために、検査またはその他の必要な行動を確立ならびに実施する義務がある。

企業は、外部から購買または受けとった製品を記述した手順書を備えていなければならない。

手順書には以下が記載されている必要がある。

a) 当該プログラムにおいて使用されるか否かにかかわらず、外部から購買および/または受けとったすべての製品。

b) 当該プログラムにおいて使用される製品の受け入れに関する特定の要求事項。

c) 供給者の選定、評価および見直しに関する基準ならびにプロセス

d) 外部から購入された製品および/または受け入れられた製品、ならびに当該プログラムにおいて使用される製品が、受け入れに関する特定の要求事項に適合することを確保するために用いられるプロセス。

企業は、供給企業の評価結果および同評価から発生する必要な行為すべてに関する記録を保管しなければならない。

企業は、受け入れプロセスおよび同プロセスの効果的施行に対する適合性の証拠を示す記録を保管しなければならない。

4.3. 識別およびトレーサビリティ

企業は可能な限り、製品実現全体にわたり、適切な方法により製品（原材料および/または完成品）を識別するための文書化された手順書を備えなくてはならない。

本手順書には以下の方法が記載される必要がある。

a) 製品実現全体にわたる製品の識別方法

b) 製品に関する個有の識別方法の管理および記録

c) 要求事項の監視および測定についての製品の現状を識別する方法。

製品を識別する方法は、

a) プログラム固有のものでなければならない。可能な場合は、家畜は耳標もしくは別の恒久的識別手段で識別されなければならず、

b) その識別は、プログラムへの受け入れから製造、配送に至る製品実現の全段階に伝達されなければならない。

企業は、識別されたすべての製品に関する記録、ならびに識別の変更に関するすべての記録を保管する義務を有する。

4.4. 製品の保存

企業は、製造工程および納品先への配送において、製品の適合性を維持する義務がある。

製品の保存には、識別、受け渡し、梱包、保管および保護が含まれる。製品の保存はまた、製品の成分にも適用されなければならない。

4.5. モニタリングおよび測定機器の管理

企業は、製品に関する特定の要求事項に対する適合の証拠を示す目的で実行するモニタリングおよび測定を決定する義務がある。

企業は、製品に関する特定の要求事項に対する準拠の証拠を示すために必要なモニタリングおよび測定機器を決定する義務がある。

企業は、モニタリングおよび測定の実施ならびに監視および測定に関する要求事項に矛盾しない方法でモニタリングおよび測定が実施可能であることを確保する手順を確立しなければならない。

適正な結果を確保するために必要な場所においては測定装置は、

a) 一定の間隔で、または使用前に、国際あるいは国内測定基準に遡ることが可能な測定基準に照らして校正または検証されなければならない。ただし、そうした基準がない場合は、校正または検証に使用された基準を記録しなければならない。
b) 必要に応じて調整または再調整されなければならない。
c) 校正の状態が明確になるよう識別されなければならない。
d) 測定結果が無効になるような調整が行われないようにしなければならない。
e) 取り扱い、維持管理および保管中の損傷および劣化から保護されなければならない。

企業は、測定装置が要求事項に適合しないことが判明した場合は、それまでの測定結果の有効性を評価の上記録しなければならない。企業は、当該装置および影響を受けた製品に対し、適切な措置を講じなければならない。

企業は、規定要求事項に関わるモニタリングおよび測定にコンピュータソフトを使用する場合は、そのコンピュータソフトが意図した用途を満たす能力を有することを確認しなければならない。これは、初回の使用に先立ち実施され、また必要に応じて再確認される必要がある。

企業は、校正および検証結果の記録を保管する義務を有する。

5. 測定、分析および改善

5.1. 一般

企業は、以下の項目に必要な監視、測定、分析および改善を計画ならびに実施しなければならない。

a) 製品の適合性の実証。

b) QMS の適合性の確保。
c) QMS の有効性の継続的な改善。

当該計画には、統計的手法を含め、適用される方法の決定および適用の範囲が盛り込まれる必要がある。

統計的手法を使用して製品の品質または整合性を管理する場合は、それに必要な手順の基礎を明確に規定する必要がある。

5.2. モニタリングおよび測定

5.2.1. 顧客満足

企業は、同社が顧客の要求事項を満たしているかどうかに関して、顧客の意見についての情報をモニタリングする義務を有する。この情報は、QMS の測定結果として見直される必要がある。

企業は、この情報の取得および使用方法を決定しなければならない。

企業は、顧客の意見に関する記録を保管しなければならない。

5.2.3. プロセスのモニタリングおよび測定

企業は、QMS プロセスに対する適切なモニタリング方法および適用可能な場合には QMS プロセスの測定を適用しなければならない。

これらの方法は、製品に関する要求事項に適合するプロセスの能力を実証するものでなければならない。

製品の要求事項が達成されない場合は、製品の適合性を確保するために適切と思われる是正および是正措置を行わなければならない。

5.2.4. 製品の監視および測定

企業は、製品に関する要求事項が満たされていることを実証するために、製品の特性を監視および測定しなければならない。これは、適切な製品製造段階で実施されなければならない。

企業は、しかるべき権限を有する機関、可能な場合には顧客により承認される場合を除き、

製品を出荷および納品する前に、製品に関する要求事項が満たされてきているかを確認しなければならない。

企業は、製品に関する要求事項への適合性を実証する記録を保管する義務を有する。記録は、製品の出荷を正式に認可した者の氏名を明記しなければならない。

5.3. QMSにおける不適合製品の管理

企業は、不適合製品（原材料および/または製品）が識別され、それらが誤って使用または納品されることを防ぐよう管理されることを確保しなければならない。

企業は、以下を規定する文書化された手順書を備えなくてはならない。

a) 不適合製品の識別方法
b) 不適合製品の確実な分別に使用する管理方法
c) 不適合製品の分別および処理を確保する責任および権限。

企業は、以下の方法のうち1つかそれ以上の方法により不適合製品を処理しなければならない。

a) 発見された不適合製品を除去する措置を講じる。
b) 当該権限を有する者および妥当な場合は顧客による承認の下で、当該製品の使用、出荷または納品を許可する。
c) 本来の用途または適用目的から除外する措置を講じる。

不適合製品が是正される場合は、製品に関する要求事項への適合性を実証するための再検証を実施しなければならない。

納品または使用開始後に不適合製品が発見される場合は、企業は適切な措置を講じなければならない。

企業は、得られた承認を含め、すべての不適合製品およびそれに伴う措置に関する記録を保管する義務がある。

5.4. 改善

5.4.1. 継続的改善

企業は、品質目標、顧客のフィードバック、監査結果の他、是正および保存措置を通じて、QMSの有効性を継続的に改善しなければならない。

QMSへの変更が計画および実施される場合は、企業はQMSの整合性が維持されることを確保しなければならない。

5.4.2. 是正措置

企業は、再発生を防止するために、不適合の原因を取り除く措置を講じなければならない。

是正措置は、発生した不適合の影響に対し適切なものでなければならない。

企業は、講じられたいかなる措置の結果に関する記録も維持する義務を有する。

5.4.3. 予防的措置

企業は、不適合の発生を防止するため、可能性をもたらす恐れのある措置を取り除くための措置を講じなければならない。

予防的措置は、潜在的問題の影響に対応したものでなければならない。

企業は講じられたいかなる措置の結果に関する記録も維持する義務を有する。

Physiological Maturity Evaluation of Beef Carcasses for Export to Japan

1.0 Scope

This instruction provides the requirements and the guidelines to certify beef carcasses for inclusion in a Department of Agriculture (USDA), Agricultural Marketing Service (AMS) approved Export Verification (EV) Program for Japan. Carcass certifications will be conducted by AMS representatives who are accredited with the requirements of this instruction. The carcasses will be certified as A^{40} physiological maturity or younger.

2.0 Reference Documents

1. Official United States Standards for Grades of Carcass Beef
2. USDA Beef Skeletal Maturity Slides
3. USDA beef visual aid photos

3.0 Scope

1. Determine the age of cattle through physiological maturity evaluations of carcasses to assure that beef intended for export to Japan originated from cattle that are 20 months of age or younger at the time of slaughter.
2. An accredited representative of USDA, AMS, LS Program, MGC Branch will determine beef carcass maturity of A^{40} or younger for compliance with part 5.2.2 of the Audit, Review and Compliance Branch 1030 Procedure.
    a) Each plant requesting this service must have an approved EV Program for export to Japan through the ARC Branch of AMS.

4.0 Accreditation Requirements

1. AMS representatives who perform the evaluation duties for beef exported to Japan will be accredited as outlined within this document.
2. USDA Meat Graders must demonstrate a performance level of 98 percent accuracy during the testing process. All supervisors and others responsible for the testing and accreditation of graders must first meet the applicable performance standard administered by a USDA Standardization Branch official responsible for technical issues related to beef carcass evaluation.

3. The accreditation testing will be conducted on carcasses that represent critical physiological maturity end points for accurate classification of carcasses at the A^{40} threshold requirement for export to Japan.
4. Only those USDA graders that have attained the GS-9 (expert) or higher status will be eligible for accreditation.
5. The Standardization Branch and the MGC Branch will maintain a list of accredited graders detailing the date, location, results, and the certifying employee.

5.0 Identification Procedures

1. Beef carcasses meeting the requirements for physiological maturity evaluations of A^{40} or younger shall be identified at the time of certification with a USDA certification stamp.
2. The plants written quality plans for export verification approved by USDA must include *procedures to assure identification and traceability of these carcasses throughout the* grading, fabrication, packaging, and packing process, including handling storage, labeling, and shipment.
3. The MGC Branch will record the physiological maturity factors of each carcass certified on a daily basis.

Larry R. Meadows, Chief
Meat Grading and Certification Branch
Livestock and Seed Program

［仮訳］

MGC通知７０９

日本に輸出される牛枝肉の生理学的成熟度の評価

1.0 範囲

この通知は、ＵＳＤＡ農業販売促進局（ＡＭＳ）の認証された日本向け輸出証明プログラムに乗せるに当たっての、牛枝肉の証明のための条件とガイドラインを提供するものである。枝肉の証明は、この通知の条件を満たしていると認定されたＡＭＳ職員によって行われる。枝肉は、生理学的成熟度がＡ４０かそれより若いと証明されることとなる。

2.0 参照文書

1. 米国の公式な牛枝肉の格付基準
2. 牛肉の骨の成熟度を示したスライド（ＵＳＤＡ）
3. 牛肉の判別の補助となる写真（ＵＳＤＡ）

3.0 範囲

1. 日本に輸出される牛肉が、と畜時において２０か月齢以下の牛からのものであることを確保するため、枝肉の生理学的成熟度の評価を通じ牛の月齢を判別する。
2. ＵＳＤＡの農業販売促進（ＡＭＳ）局畜産種子（ＬＳ）プログラム食肉格付証明（ＭＧＣ）課所属の認定された職員が、ARC1030 手順書（EV プログラム）の 5.2.2 の条項に従って牛枝肉の成熟度がＡ４０かそれより若いと判別する。
   a) このサービスの提供を希望するプラントは全て、AMS の ARC 課によって日本向け輸出のための EV プログラムの認証を受けなければならない。

4.0 認定要件

1. 日本に輸出される牛肉のために格付業務を行う AMS 職員は、本文書で概説されているとおりに認定を受けることとなる。
2. USDA の食肉格付員は、試験において 98 %の正確性で格付を行わなければならない。試験と格付員の認定に責任を有する全ての監視員等は、牛枝肉の評価に関連する技術的課題に公的責任を有する USDA の基準課によって管理される業務遂行基準にまず適合しなければならない。
3. 認定試験は、日本向け輸出条件の境界であるＡ４０において枝肉を正確に分類する上で必要となる重要な生理学的成熟度のエンドポイントを示す枝肉を用いて行われることとなる。
4. ＧＳ－９（熟達者）又はそれ以上のステータスを与えられたＵＳＤＡの格付員のみが認定の資格を有することとなる。
5. 基準課及び食肉格付証明（ＭＧＣ）課により、認定された格付員の認定日、試験地、結果及び試験官を記した名簿が維持される。

5.0 識別手順

1. 生理学的成熟度の評価がＡ４０又はそれより若いという要件を満たす牛枝肉は、評価を受けた段階でＵＳＤＡの証明印によって識別されることとなる。
2. ＵＳＤＡによって認められた工場の輸出証明のための品質計画書は、保管、表示及び出荷を含む格付、解体、包装段階を通じこれらの枝肉の識別及びトレーサビリティを確保する手順を含まねばならない。
3. 食肉格付証明（ＭＧＣ）課は、各々の証明済枝肉について生理学的成熟度の要素の記録を毎日保存することとなる。

畜産種子（ＬＳ）プログラム
食肉格付証明（ＭＧＣ）課長
Larry R. Meadows

APPENDIX F

Physiological Maturity Determination Guidelines

Physiological Maturity Evaluation

For steer and heifer beef, maturity of the carcass is determined by evaluating the size, shape, and ossification of the bones and cartilages -- especially the split chine bones -- and the color and texture of the lean flesh. In the split chine bones, ossification changes occur at an earlier stage of maturity in the posterior portion of the vertebral column (sacral vertebrae) and *at progressively later stages of maturity in the lumbar and thoracic vertebrae.* The ossification changes that occur in the cartilages on the ends of the split thoracic vertebrae are especially useful in evaluating maturity of B^{00} and older carcasses and these vertebrae are referred to frequently in the grading standards. Unless otherwise specified in the standards, whenever reference is made to the ossification of cartilages on the thoracic vertebrae, it is construed to refer to the cartilages attached to the thoracic vertebrae at the posterior end of the forequarter. The size and shape of the rib bones also are important considerations in evaluating differences in maturity. The color and texture of the lean also undergo progressive changes with advancing maturity. In the very youngest of carcasses, the lean flesh will be very fine in texture and light grayish red in color. In progressively more mature carcasses, the texture of the lean becomes more coarse and the color of the lean will become darker red.

Carcasses qualifying for any particular maturity may vary with respect to their relative development of the various factors. There will be carcasses that qualify for a particular maturity, some of whose characteristics may be more nearly typical of another maturity. For example, in comparison with the descriptions of maturity contained in the standards, a particular carcass might have a greater relative degree of ossification of the cartilages on the ends of the lumbar vertebrae in comparison to other evidences of maturity. In *such instances, the skeletal maturity of the carcass is not determined solely by the* ossification of the lumbar vertebrae, but neither is this ignored. Thus, all of the maturity-indicating factors are considered. In making any composite evaluation of two or more factors, it must be remembered that they seldom are developed to the same degree.

In the very youngest carcasses considered as beef (A^0 maturity), the cartilages on the ends of the chine bones show no ossification, cartilage is evident on all of the vertebrae of the spinal column, and the sacral vertebrae show distinct separation. In addition, the split vertebrae usually are soft and porous and very red in color. In such carcasses, the rib bones have only a slight tendency toward flatness. In progressively more mature carcasses, *ossification changes become evident first in the bones and cartilages of the* sacral vertebrae, then in the lumbar vertebrae, and still later in the thoracic vertebrae. The following table provides a reference description of critical characteristics in the evaluation process throughout the A maturity group:

Description of Maturity Characteristics within A Maturity

	A^{00}	A^{40}	A^{50}	A^{100}
Sacral Vertebrae	Show distinct separation	Show distinct separation, caps show considerable evidence of cartilage	Show separation, caps show evidence of cartilage	Completely fused
Lumbar Vertebrae	No ossification	Caps tend to be partially ossified	Caps tend to be nearly moderately ossified	Nearly completely ossified
Lean Color	Light grayish red	Light red	Tends to be moderately light *red*	Moderately light red

Footnote: This information is extrapolated from the United States Standards for Grades of Carcass Beef and is intended to describe the characteristics with the greatest degree of influence for determining physiological maturity at the specified end points. Other characteristics described in the standards are less pronounced at these particular reference points and provide less influence.

〔仮訳〕
別添F
生理学的成熟度の判別に係るガイドライン

生理学的成熟度の評価

去勢牛及び未経産牛においては、枝肉の成熟度は、骨及び軟骨の大きさ、形及び骨化ー特に背骨の断面ー、及び肉の赤身の質感と色によって決定される。背骨の断面においては、骨化は成熟度の初期段階において脊椎の後端（仙堆）において起こり、成熟度が進むにつれ腰椎及び胸椎でも起こる。この胸椎断面の端に位置する軟骨において起こる骨化の変化は、特にB成熟度及びそれより成熟度の進んだ枝肉の評価において有用であり、これらの堆骨は、格付基準で頻繁に言及されている。この基準で指定されていない限り、胸椎の軟骨の骨化に言及されるときはいつも、四分割後の前駆の後端の胸椎の軟骨についてであると解釈される。肋骨の大きさと形も成熟度の違いの評価において重要視される。肉の赤身の質感と色も成熟度が進むにつれ次第に変化する。きわめて若い個体の枝肉においては、肉の赤身は、質感において非常に繊細で明るい灰赤色を示す。成熟度が進むにつれ、赤みの質感はきめが粗くなり、色調も暗赤色となる。

特定の成熟度と判定された枝肉であっても、それぞれの要素の相対的な発達度について様々となるかもしれない。枝肉が特定の成熟度と判定されたとしても、それらの枝肉の特徴が他の成熟度の特徴により近いことがあるかもしれない。例えば、格付基準に収録されている成熟度の記述の比較において、ある枝肉は、成熟度の他の特徴と比較し、腰椎の後端の軟骨における骨化の度合が進んでいることがあるかもしれない。そのような場合、枝肉の骨の成熟度は、腰椎の骨化のみによって決定されることはないが、だからといってそれが無視されるわけでもない。従って、全ての成熟度の指標が考慮される。複数の要素の組み合わせによって評価を行う場合、それらが同程度に発達することはほとんどみられないということに留意する必要がある。

A成熟度中極めて若い個体の枝肉（A0）においては、脊柱の端の軟骨では骨化は見られず、脊柱の全ての堆骨において軟骨が明瞭であり、仙堆の明瞭な分離が見られる。その上、脊柱の断面は通常柔らかく、多孔質で非常に赤い色をしている。このような枝肉における肋骨は、わずかながら平坦になる傾向を持っている。より枝肉の成熟度が進むにつれ、仙堆における骨と軟骨において骨化が最初に明瞭となり、続い腰椎、更に遅れて胸椎で起こる。以下の表は、A成熟度群全体の評価手順における重要な特徴に関する記述をまとめたものである。

A成熟度における成熟度の特徴

	A00	A40	A50	A100
仙椎	明確な分離	明確な分離、上部に相当の軟骨の形跡	分離、上部に軟骨の形跡	完全に融合
腰椎	骨化なし	上部が部分的に骨化	上部がほぼ骨化	ほぼ完全に骨化
赤身の色	明るい灰赤色	明るい赤色	やや明るい赤色	やや明るい赤色

脚注：この情報は、米国の牛枝肉の格付基準をもとに推計されたものであり、特定のエンドポイントにおける生理学的成熟度の決定に最も影響を与える特徴について記述を試みたものである。当該基準で記されている他の特徴は、この特定の参照ポイントにおいてはあまり明瞭ではなく、影響が少ない。

United States Department of Agriculture

Agricultural Marketing Service

Livestock and Seed Division

United States Standards for Grades of Carcass Beef

Effective date January 31, 1997

The following is a reprint of the Official United States Standards for grades of Carcass Beef promulgated by the Secretary of Agriculture under the Agricultural Marketing Act of 1946 (60 Stat. 1087; 7 U.S.C. 1621-1627) as amended and related authority in the annual appropriation acts for the Department of Agriculture. The standards are reprinted with amendments effective January 31, 1997.

Development of the Standards

The tentative U.S. standards for the Grades of dressed beef were formulated in 1916. They provided the basis of uniformly reporting the dressed beef markets according to grades, which work was inaugurated as a national service early in 1917. The grade specifications were improved from time to time as experience gained through their use indicated what changes were necessary. They were published first in mimeograph form in June 1923. After slight changes they were included in the Department Bulletin No. 1246 "Market Classes and Grades of Dressed Beef" which was published in August 1924.

Public hearings were held at Portland, OR, Chicago, IL, and New York, NY, in 1925 to give producers, slaughterers, wholesale and retail meat dealers, agricultural college workers and others interested in the marketing of livestock and meat an opportunity to make suggestions for improving the standards. The sentiment registered at those meetings was overwhelmingly in favor of the grades as presented. The few suggestions and criticisms offered were carefully considered in subsequent revisions of the standards.

The tentative standards, although designed primarily for meat market reporting purposes, were put to further practical test in numerous ways. During World War I they were used in the selection of beef for the Army, Navy, and Allies. Later they were included in the specifications of the Emergency Fleet Corporation for the purchase of its beef supplies. Soon thereafter they were incorporated in the specifications of many commercial concerns, including steamship lines, restaurants, hotels, dining car services, and hospitals.

The revised grade descriptions were promulgated by the Secretary of Agriculture, June 3, 1926, as the Official United States Standards for the Grades of Carcass Beef and published in Service and Regulatory Announcements No. 99 (B.A.E.). These standards provided the basis for grading when the voluntary beef grading and stamping service was begun in May 1927.

The official standards were amended in July 1939 to provide a single standard for the grading and labeling of steer, heifer, and cow beef according to similar inherent quality characteristics. The amendment also changed certain grade terms for steer, heifer, and cow beef from "Medium," "Common," and "Low Cutter" to "Commercial," Utility," and "Canner," respectively. An amendment in November 1941 made similar changes in the grade terms for bull and stag beef and

established the following grade terminology for all beef: Prime[1], Choice, Good, Commercial, Utility, Cutter, and Canner. An amendment in October 1949 eliminated all references to color of fat.

In December 1950, the official standards for grades of steer, heifer, and cow beef were amended by combining the Prime and choice grades and designating them as Prime, renaming the Good grade as Choice, and dividing the Commercial grade into two grades by designating the beef produced from young animals included in the top half of the grade as Good while retaining the Commercial grade designation for the remainder of the beef in that grade. Other revisions in the standards for the Prime, Choice, Good, and Commercial grades were made to clarify them and to facilitate their interpretation. Standards for the Utility, Cutter, and Canner grades were not affected. These changes in the standards were a modification of a proposal by the Department to revise the standards in August 1949, and were adopted after careful consideration of comments received in writing over a period of months and those presented orally at a public hearing at Chicago, on June 28, 1950.

In June 1956, the official standards for grades for steer, heifer, and cow beef were amended by dividing the Commercial grade into two grades strictly on the basis of maturity with beef produced from young animals being designated as Standard while Commercial was retained as the grade name for beef produced from mature animals. This change, which was suggested by the Cattle and Beef Industry Committee, was identical in principle to that proposed by the Department in August 1949.

The official standards for grades of steer, heifer, and cow beef were revised in June 1965 to place less emphasis on changes in maturity in the Prime, Choice, Good, and Standard grades. This change was made to reflect the latest research information available regarding the effect of maturity on beef palatability. The minimum marbling permitted in these grades was not changed for the very youngest beef. However, the rate of increase in required marbling to offset increasing maturity was changed, and the minimum marbling permitted was reduced for more mature carcasses by as much as 1-1/2 degrees in Prime, 1 degree in Choice, and 3/4 of a degree in Good and Standard. In addition, the revision eliminated consideration of the two degrees of marbling in excess of that described as abundant. The manner of evaluating conformation also was clarified by providing that carcasses may meet the conformation requirements for a grade either through a specified development of muscling or a specified development of muscling and fat combined. This revision also included a requirement that all carcasses be ribbed prior to grading and made other minor changes to clarify the intent of the standards and simplify their application. An added provision established standards for cutability grades of carcasses and certain wholesale cuts of all classes of beef. A dual grading system for beef carcasses, involving separate identification of differences in quality and in cutability, had been proposed by the Department in April 1962 and made available for use on a trial basis for a one-year period beginning July 1, 1962. The cutability

[1]The use of the grade specified as "Prime" for beef carcasses and wholesale cuts was suspended for the period September 18, 1942 , to December 3, 1946, pursuant to amendment 5, Maximum Price Regulation 169 of the Office of Price Administration. During that period all carcass beef and wholesale cuts that met the specifications of the "Prime" grade were identified with and graded as "Choice."

standards adopted in 1965 were similar to those included as a part of the dual grading system, but modified on the basis of comments from industry and experience gained during the trial period of the dual grading system.

In July 1973, the official standards were revised to provide separate quality grades for beef from young bulls. Interest in such grades primarily stemmed from earlier research which showed that young bulls were superior to steers in rate and efficiency of feedlot gain and from a belief by many producers that requiring such beef to be identified as "Bull" was a deterrent to its acceptance. Research comparing the palatability of beef from steers and young bulls indicated that young bull beef was slightly less palatable and slightly more variable in palatability than steer beef. These palatability differences were considered sufficient to preclude the grading of young bull beef without a sex identification so this class was designated as "Bullock." The quality grade standards for bullock beef were essentially the same as those for steer, heifer, and cow beef but provided for only five grades--Prime, Choice, Good, Standard, and Utility. "Bull" was retained as the class designation for beef from more mature bulls but the quality grades for such beef were eliminated. As a result, the yield grade standards only applied to the grading of "Bull" beef. The quality grade standards for "Stag" beef also were eliminated and beef formerly included in this class was redesignated as "Bullock" or "Bull" dependent on its evidences of maturity. Related changes also were made in the "Application of Standards" section and, throughout the standards, references to "Cutability groups" were changed to "yield grades."

In April 1975, the official standards were revised to eliminate the consideration of maturity in determining the quality grade (1) of all bullock beef and (2) of all steer, heifer, and cow beef included in the youngest maturity group referenced in those standards. That change resulted from research reported since a related change was made in the standards for grades of steer, heifer, and cow beef in 1965, and which showed that, for beef in this youngest maturity group, increases in maturity did not have a detrimental effect on palatability. In the Prime, Choice, and Standard grades, the minimum marbling requirements for all such beef were revised to be the same as previously required for the very youngest beef in each of these grades. However, for the Good grade, the minimum marbling requirements for the very youngest beef were increased one-half degree. For the more mature beef in each of these grades of steer, heifer, and cow beef, the previous rate of increase in marbling with increased maturity was retained but the minimum marbling requirements were reduced to coordinate them with the changed marbling requirements for beef in the youngest maturity group. In the Prime, Choice, and Standard grades, this reduction was one full degree. In the Good grade, it was one-half a degree. In this same revision, conformation also was eliminated as a quality grade factor and all carcasses graded were required to be identified for both quality grade and yield grade. Variations in conformation had been shown to be unrelated to differences in palatability and their effect on yields of retail cuts was better measured by the yield grades. The combination of these two changes (1) eliminated a factor (conformation) whose use had contributed to variations in the quality of beef in the quality grades, and (2) provided an improved measure of carcass value. Both of these changes were originally proposed by the Department in 1962. An additional change reduced the maximum maturity permitted for steer, heifer, and cow beef in the Good and Standard grades to the same as that permitted in Prime and Choice. The changes that were made in the Good grade were designed to reduce the variability of the beef in that grade and to make it a very restrictive, leaner

grade than Choice which might be more widely used than the previous Good grade. These revised standards were originally scheduled to become effective on April 14, 1975, but because of a series of court actions, they were not implemented until February 23, 1976.

In October 1980, the official standards for grades of steer, heifer, cow, and bullock beef and the related regulations were amended. The conditions necessary for removal of yield grade designations from officially graded beef were clarified by specifying a maximum fat thickness (3/4 inch) to be met prior to removal and by specifying the items to which the requirement applies. Specific language was added to make carcasses which have had the characteristics of the ribeye or the thickness of fat over the ribeye altered ineligible for grading and to specify that the presentation of such carcasses for an official grade determination shall be considered a fraudulent or deceptive practice. Changes were made in the regulations to provide generally for grading only in carcass form and only in the establishment where the animal was slaughtered or initially chilled. In addition, a 10-minute minimum period between ribbing and presentation for grading was established. These changes were designed to increase the accuracy and uniformity of beef grade determinations and to provide more accurate grade information to purchasers of beef by reducing the variation in conditions under which grading could be accomplished.

In November 1987, the official standards were revised to change the name of the U.S. Good grade to U.S. Select for steer, heifer, cow, and bullock carcasses. The revision did not change the requirements for the grade, only the grade name. Although the 1975 changes in the Good grade had made a very restrictive, leaner grade than Choice, the Good grade had not been widely used. This change provided the industry an improved grade term to use in the marketing of this type of beef to consumers who desire an alternative to Choice.

In April 1989, the official standards were revised to allow the official grade to consist of the quality grade only, the yield grade only, or a combination of both. No changes were made in the actual yield grade or quality grade requirements. The change was made to allow the industry greater flexibility in the use of the beef grading system in order to provide consumers with the trimness levels desired.

In January 1997, the official standards were revised to restrict the Select grade to A maturity only and to raise the marbling degree required for Choice to minimum modest throughout B maturity. These changes were made to improve the uniformity and consistency within the Choice and Select grades.

§54.102 Scope.

These standards for grades of beef are written primarily in terms of carcasses. However, they also are applicable to the grading of sides. To simplify phrasing of the standards, the words "carcass" and "carcasses" are used to also mean "side" or "sides."

§54.103 Classes of beef carcasses.

(a) Class determination of beef carcasses is based on evidences of maturity and apparent sex condition at the time of slaughter. The classes of beef carcasses are steers, bullocks, bulls, heifers, and cows. Carcasses from males -- steers, bullocks, and bulls -- are distinguished from carcasses

from females -- heifers and cows -- as follows:

(1) Steer, bullock, and bull carcasses have a "pizzle muscle" (attachment of the penis) and related "pizzle eye" adjacent to the posterior end of the aitchbone.

(2) Steer, bullock, and bull carcasses have, if present, rather rough, irregular fat in the region of the cod. In heifer and cow carcasses, the fat in this region, if present, is much smoother.

(3) In steer, bullock, and bull carcasses, the area of lean exposed immediately ventral to the aitchbone is much smaller than in heifer and cow carcasses.

(b) Steer, bullock, and bull carcasses are distinguished by the following:

(1) In steer carcasses, the "pizzle muscle" is relatively small, light red in color, and fine in texture and the related "pizzle eye" is relatively small.

(2) In bullock and bull carcasses, the "pizzle muscle" is relatively large, dark red in color, and coarse in texture and the related "pizzle eye" is relatively large.

(3) Bullock and bull carcasses usually have a noticeable crest.

(4) Bullock and bull carcasses also usually have a noticeably developed small round muscle adjacent to the hipbone commonly referred to as the "jump muscle." However, in carcasses with a considerable amount of external fat, the development of this muscle may be obscured.

(5) Although the development of the secondary sex characteristics is given primary consideration in distinguishing steer carcasses from bullock or bull carcasses, this differentiation is also facilitated by consideration of the color and texture of the lean. In bullock and bull carcasses, the lean is frequently at least dark red in color with a dull, "muddy" appearance -- and in some cases it may have an iridescent sheen. Also, it frequently has an "open" texture.

(6) The distinction between bullock and bull carcasses is based solely on their evidences of skeletal maturity. Carcasses with the maximum maturity permitted in the bullock class have slightly red and slightly soft chine bones, and the cartilages on the ends of the thoracic vertebrae have some evidence of ossification; the sacral vertebrae are completely fused; the cartilages on the ends of the lumbar vertebrae are nearly completely ossified; and the rib bones are slightly wide and slightly flat. Bull carcasses have evidences of more advanced maturity.

(c)Heifer and cow carcasses are distinguished by the following:

(1) Heifer carcasses have a relatively small pelvic cavity and a slightly curved aitchbone. In cow carcasses, the pelvic cavity is relatively large and the aitchbone is nearly straight.

(2) In heifer carcasses, the udder usually will be present. In cow carcasses, the udder usually will have been removed. However, neither of these are requirements.

§54.104 Application of standards for grades of carcass beef.

(a) The carcass beef grades identify two separate general considerations: The indicated yield of closely trimmed (⅛ inch fat or less), boneless retail cuts expected to be derived from the major wholesale cuts (round, sirloin, short loin, rib, and square-cut chuck) of a carcass, herein referred to as the "yield grade," and characteristics of the meat which predict the palatability of the lean, herein referred to as the "quality grade." When officially graded, the grade of a steer, heifer, cow, or bullock carcass may consist of the quality grade only, the yield grade only, or a combination of the quality grade and the yield grade. The grade of a bull carcass consists of the yield grade only.

(b) The carcass beef grade standards are written so that the quality grade and yield grade standards are contained in separate sections. The quality grade section is divided further into two separate sections applicable to carcasses from: (1) Steers, heifers, and cows, and (2) bullocks. Eight quality grade designations -- Prime, Choice, Select, Standard, Commercial, Utility, Cutter, and Canner -- are applicable to steer and heifer carcasses. Except for Prime, the same designations apply to cow carcasses. The quality grade designations for bullock carcasses are Prime, Choice, Select, Standard, and Utility. There are five yield grades applicable to all classes of beef, denoted by numbers 1 through 5, with Yield Grade 1 representing the highest degree of cutability.

(c) When officially graded, bullock and bull beef will be further identified for its sex condition; steer, heifer, and cow beef will not be so identified. The designated grades of bullock beef are not necessarily comparable in quality or cutability with a similarly designated grade of beef from steers, heifers, or cows. Neither is the cutability of a designated yield grade of bull beef necessarily comparable with a similarly designated yield grade of steer, heifer, cow, or bullock beef.

(d) The Department uses photographs and other objective aids in the correct interpretation and application of the standards.

(e) To determine the grade of a carcass, it must be split down the back into two sides and one or both sides must be partially separated into a hindquarter and forequarter by cutting it with a saw and knife insofar as practicable, as follows: A saw cut perpendicular to both the long axis and split surface of the vertebral column is made across the 12th thoracic vertebra at a point which leaves not more than one-half of this vertebra on the hindquarters. The knife cut across the ribeye muscle starts -- or terminates -- opposite the above-described saw cut. From that point it extends across the ribeye muscle perpendicular to the outside skin surface of the carcass at an angle toward the hindquarter which is slightly greater (more nearly horizontal) than the angle made by the 13th rib with the vertebral column of the hindquarter posterior to that point. As a result of this cut, the outer end of the cut surface of the ribeye muscle is closer to the 12th rib than is the end next to the chine bone. Beyond the ribeye, the knife cut shall continue between the 12th and 13th ribs to a point which will adequately expose the distribution of fat and lean in this area. The knife cut may be made prior to or following the saw cut but must be smooth and even, such as would result from a single stroke of a very sharp knife.

(f) Other methods of ribbing may prevent an accurate evaluation of the grade determining characteristics. Therefore, carcasses ribbed by other methods will be eligible for grading only if an accurate grade determination can be made by the official grader under the standards.

(g) Beveling of the fat over the ribeye, application of pressure, or any other influences which may alter the characteristics of the ribeye or thickness of fat over the ribeye prevent an accurate grade determination. Therefore, carcasses subjected to such influences shall not be eligible for grade determinations, and the presentation of such carcasses for official grade determinations shall be considered a fraudulent or deceptive practice in connection with the services requested for such carcasses. Carcasses that have had more than minor amounts of external fat removed shall not be eligible for a yield grade determination, although carcasses with only minor amounts of external fat removed may be yield graded if the official grader determines that an accurate yield grade determination can be made. Although entire carcasses with more than minor amounts of

lean removed from the major wholesale cuts (round, sirloin, short loin, rib, or square-cut chuck) shall not be eligible for grade determinations, the remaining portions of these carcasses which are unaffected by the removal of lean shall remain eligible for grade determinations, provided that a cross section at the 12th-13th rib is available and accurate grade determinations may be made.

(h) When both sides of a carcass have been ribbed prior to presentation for grading and the characteristics of the two ribeyes (area, marbling, color, texture, and firmness) would justify different quality and/or yield grades, the final grade of the carcass shall reflect the"highest" of each of these grades as determined from either side.

(i) To meet the demand of export trade or changing trade practices, grading of carcasses ribbed other than between the 12th and 13th ribs may be approved by the Director. In such cases, grading shall be based on the requirements specified in these standards and shall be consistent with the normal development of grade characteristics in various parts of a carcass of the quality level involved. When an exception is granted for export trade, such carcasses shall be identified with the word "EXPORT" in such a manner that will clearly distinguish them from other officially graded beef.

(j) Carcasses qualifying for any particular grade may vary with respect to their relative development of the various grade factors. There will be carcasses that qualify for a particular grade, some of whose characteristics may be more nearly typical of another grade. For example, in comparison with the descriptions of maturity contained in the standards, a particular carcass might have a greater relative degree of ossification of the cartilages on the ends of its lumbar vertebrae than its other evidences of maturity. In such instances, the maturity of the carcass is not determined solely by the ossification of the lumbar vertebrae but neither is this ignored. All of the maturity-indicating factors are considered. In making any composite evaluation of two or more factors, it must be remembered that they seldom are developed to the same degree. Because it is impractical to describe the nearly limitless number of recognizable combinations of characteristics, the standards for each quality grade and yield grade describe only beef which has a relatively similar degree of development of the various factors affecting its quality and yield. Also, the quality grade and yield grade standards each describe beef which is representative of the lower limits of each quality grade and yield grade.

(k) For steer, heifer, and cow beef, quality of the lean is evaluated by considering its marbling and firmness as observed in a cut surface in relation to carcass evidences of maturity. The maturity of the carcass is determined by evaluating the size, shape, and ossification of the bones and cartilages -- especially the split chine bones -- and the color and texture of the lean flesh. In the split chine bones, ossification changes occur at an earlier stage of maturity in the posterior portion of the vertebral column (sacral vertebrae) and at progressively later stages of maturity in the lumbar and thoracic vertebrae. The ossification changes that occur in the cartilages on the ends of the split thoracic vertebrae are especially useful in evaluating maturity and these vertebrae are referred to frequently in the standards. Unless otherwise specified in the standards, whenever reference is made to the ossification of cartilages on the thoracic vertebrae, this shall be construed to refer to the cartilages attached to the thoracic vertebrae at the posterior end of the forequarter. The size and shape of the rib bones also are important considerations in evaluating differences in maturity. In the very youngest carcasses considered as"beef," the cartilages on the ends of the chine bones show no ossification, cartilage is evident on all of the vertebrae of the spinal column,

and the sacral vertebrae show distinct separation. In addition, the split vertebrae usually are soft and porous and very red in color. In such carcasses, the rib bones have only a slight tendency toward flatness. In progressively more mature carcasses, ossification changes become evident first in the bones and cartilages of the sacral vertebrae, then in the lumbar vertebrae, and still later in the thoracic vertebrae. In beef which is very advanced in maturity, all the split vertebrae will be devoid of red color, very hard and flinty, and the cartilages on the ends of all the vertebrae will be entirely ossified. Likewise, with advancing maturity, the rib bones will become progressively wider and flatter until in very mature beef the ribs will be very wide and flat.

(l) In steer, heifer, and cow beef, the color and texture of the lean flesh also undergo progressive changes with advancing maturity. In the very youngest carcasses considered as "beef," the lean flesh will be very fine in texture and light grayish red in color. In progressively more mature carcasses, the texture of the lean will become progressively coarser and the color of the lean will become progressively darker red. In very mature beef, the lean flesh will be very coarse in texture and very dark red in color. Since color of lean also is affected by variations in quality, references to color of lean in the standards for a given degree of maturity vary slightly with different levels of quality. In determining the maturity of a carcass in which the skeletal evidences of maturity are different from those indicated by the color and texture of the lean, slightly more emphasis is placed on the characteristics of the bones and cartilages than on the characteristics of the lean. In no case can the overall maturity of the carcass be considered more than one full maturity group different from that indicated by its bones and cartilages.

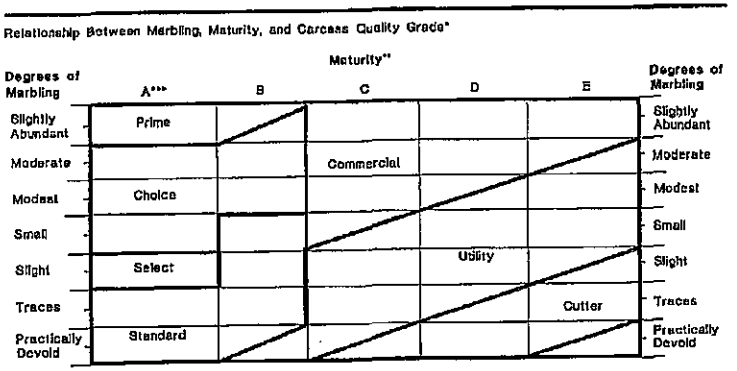
(m) The preceding two paragraphs also are applicable to the determination of quality in bullock beef except for carcasses having darker colors of lean than specified in the standards for the quality level for which they would otherwise qualify. In such carcasses, maturity will be evaluated on the basis of skeletal characteristics only, and the final grade will be determined in accordance with the procedures specified in the standards for grading "dark-cutting beef."

(n) In determining compliance with the maximum maturity limits for the Prime, Choice, and Standard grades for steer, heifer, and cow carcasses, color and texture of the lean are considered only when the maturity-indicating factors other than color and texture of the lean indicate only a slightly more advanced degree of maturity than that specified as maximum for these grades, and provided further that the lean is considerably finer in texture and lighter in color than normal for the grade and maturity involved. The same principle, in reverse, is likewise applicable to determining compliance with the minimum maturity limits of the Commercial grade.

(o) These standards are applicable to the grading of beef throughout the full range of maturity within which cattle are marketed. However, in steer, heifer, and cow carcasses, the range of maturity permitted within each of the grades varies considerably. The Prime, Choice, Select, and Standard grades are restricted to beef from young cattle; the Commercial grade is restricted to beef from cattle too mature for Prime, Choice, and Standard, and the Utility, Cutter, and Canner grades may include beef from animals of all ages. By definition, bullock carcasses are restricted to those whose evidences of maturity do not exceed those specified for the juncture of the two youngest maturity groups referenced in the standards for steer, heifer, and cow carcasses. Except for the youngest maturity group and the Choice grade in the second maturity group, within any specified grade, the requirements for marbling increase progressively with evidences of advancing maturity. In the youngest maturity group, the marbling requirements do not increase

progressively with evidences of advancing maturity. For each grade, the firmness requirements are different for each maturity group, but, within each maturity group, the firmness requirements do not increase progressively with evidences of advancing maturity. Also, regardless of the extent to which marbling may exceed the minimum of a grade, a carcass must meet the minimum firmness requirements for its maturity to qualify for that grade. To facilitate the application of these principles, the standards recognize five different maturity groups and seven different degrees of marbling. The five maturity groups are identified in Figure 1 as A, B, C, D, and E in order of increasing maturity. The limits of these five maturity groups are specified in the grade descriptions for steer, heifer, and cow carcasses. The A maturity portion of the figure is the only portion applicable to bullock carcasses. The degrees of marbling referenced in the specifications, in order of descending quantity are: Slightly abundant, moderate, modest small, slight, traces, and practically devoid. However, for carcass evaluation programs and other purposes, three higher degrees are recognized -- moderately abundant, abundant, and very abundant. Illustrations of the lower limits of nine of these ten degrees of marbling are available from the Department of Agriculture.

(p) The relationship between marbling, maturity and quality grade is shown in Figure 1. This figure assumes that the firmness of lean is comparably developed with the degree of marbling and that the carcass is not a "dark cutter." From this figure it can be seen, for instance, that the minimum marbling requirement for Choice varies from a minimum small amount for carcasses throughout the youngest maturity group to a maximum small amount for carcasses having the maximum maturity permitted in Choice. Likewise, in the Commercial grade the minimum



* Assumes that firmness of lean is comparably developed with the degree of marbling and that the carcass is not a "dark cutter."

** Maturity increases from left to right (A through E).

*** The A maturity portion of the Figure is the only portion applicable to bullock carcasses.

Figure 1

marbling requirement varies from a minimum small amount in beef with the minimum maturity permitted to a maximum moderate amount in beef from very mature animals. The marbling and other lean flesh characteristics specified for the various grades are based on their appearance in the ribeye muscle of properly chilled carcasses that are ribbed between the 12th and 13th ribs. For carcass evaluation programs and other purposes, in the Prime and Commercial grades, each additional degree of marbling (up to three) greater than specified as minimum for each of these grades is equal to one-third of a grade of higher quality.

(q) *References to color of lean in the standards for steer, heifer, and cow beef involve only* colors associated with changes in maturity. They are not intended to apply to colors of lean associated with so-called "dark-cutting beef." "Dark-cutting beef" is believed to be the result of a reduced sugar content of the lean at the time of slaughter. As a result, this condition does not have the same significance in grading as do the darker shades of red associated with advancing maturity. The dark color of the lean associated with "dark-cutting beef" is present in varying degrees from that which is barely evident to so-called "black cutters" in which the lean is actually nearly black in color and usually has a "gummy" texture. Although there is little or no evidence which indicates that the "dark-cutting" condition has any adverse effect on palatability, it is considered in grading because of its effect on acceptability and value. Depending on the degree to *which this characteristic is developed, the final grade of carcasses which otherwise would qualify* for the Prime, Choice, or Select grades may be reduced as much as one full grade. In beef otherwise eligible for the Standard or Commercial grade, the final grade may be reduced as much as one-half of a grade. In the Utility, Cutter, and Canner grades, this condition is not considered.

(r) The yield grade of a beef carcass is determined by considering four characteristics: (1) The amount of external fat, (2) the amount of kidney, pelvic, and heart fat, (3) the area of the ribeye muscle, and (4) the carcass weight.

(s) The amount of external fat on a carcass is evaluated in terms of the thickness of this fat over the ribeye muscle, measured perpendicular to the outside surface at a point three-fourths of the length of the ribeye from its chine bone end. This measurement may be adjusted, as *necessary, to reflect unusual amounts of fat on other parts of the carcass. In determining the* amount of this adjustment, if any, particular attention is given to the amount of fat in such areas as the brisket, plate, flank, cod or udder, inside round, rump, and hips in relation to the actual thickness of fat over the ribeye. Thus, in a carcass which is fatter over other areas than is indicated by the fat measurement over the ribeye, the measurement is adjusted upward. Conversely, in a carcass which has less fat over the other areas than is indicated by the fat measurement over the ribeye, the measurement is adjusted downward. In many carcasses no such adjustment is necessary; however, an adjustment in the thickness of fat measurement of one-tenth or two-tenths of an inch is not uncommon. In some carcasses a greater adjustment may be necessary. As the amount of external fat increases, the percent of retail cuts decreases -- each *one-tenth inch change in adjusted fat thickness over the ribeye changes the yield grade by 25* percent of a yield grade.

(t) The amount of kidney, pelvic, and heart fat considered in determining the yield grade includes the kidney knob (kidney and surrounding fat), the lumbar and pelvic fat in the loin and round, and the heart fat in the chuck and brisket area which are removed in making closely trimmed retail cuts. The amount of these fats is evaluated subjectively and expressed as a percent

of the carcass weight. As the amount of kidney, pelvic, and heart fat increases, the percent of retail cuts decreases -- a change of 1 percent of the carcass weight in these fats changes the yield grade by 20 percent of a yield grade.

(u) The area of the ribeye is determined where this muscle is exposed by ribbing. This area usually is estimated subjectively; however, it may be measured. Area of ribeye measurements may be made by means of a grid calibrated in tenths of a square inch or by other devices designated by *the Agricultural Marketing Service of the U.S. Department of Agriculture.*[2] An increase in the area of ribeye increases the percent of retail cuts -- a change of 1 square inch in area of ribeye changes the yield grade by approximately 30 percent of a yield grade.

(v) Hot carcass weight (or chilled carcass weight x 102 percent) is used in determining the yield grade. As carcass weight increases, the percent of retail cuts decreases -- a change of 100 pounds in hot carcass weight changes the yield grade by approximately 40 percent of a yield grade.

(w) The standards include a mathematical equation for determining yield grade. This grade is expressed as a whole number; any fractional part of a designation is always dropped. For example, if the computation results in a designation of 3.9, the final grade is 3 -- it is not rounded to 4.

(x) The yield grade standards for each of the first four yield grades list characteristics of two carcasses of two different weights together with descriptions of the usual fat deposition pattern on various areas of the carcass. These descriptions are not specific requirements -- they are included only as illustrations of carcasses which are near the borderlines between groups. For example, the characteristics listed for Yield Grade 1 represent carcasses which are near the borderline of Yield Grades 1 and 2. These descriptions facilitate the subjective determination of the yield grade without making detailed measurements and computations. The yield grade for most beef carcasses can be determined accurately on the basis of a visual appraisal.

§54.105 Specifications for official United States standards for grades of carcass beef (yield).

(a) The yield grade of a beef carcass is determined on the basis of the following equation: Yield grade -- 2.50+(2.50 x adjusted fat thickness, inches)+(0.20 x percent kidney, pelvic, and heart fat)+(0.0038 x hot carcass weight, pounds) - (0.32 x area ribeye, square inches).

(b) The following descriptions provide a guide to the characteristics of carcasses in each yield grade to aid in determining yield grades subjectively.

(1) *Yield Grade 1.* (i) A carcass in Yield Grade 1 usually has only a thin layer of external fat over the ribs, loins, rumps, and clods and slight deposits of fat in the flanks and cod or udder. There is usually a very thin layer of fat over the outside of the rounds and over the tops of the shoulders and necks. Muscles are usually visible through the fat in many areas of the carcass.

(ii) A 500-pound carcass of this yield grade which is near the borderline of Yield Grades 1 and 2 might have three-tenths inch of fat over the ribeye, 11.5 square inches of ribeye, and 2.5 percent of its weight in kidney, pelvic, and heart fat.

(iii) An 800-pound carcass of this yield grade which is near the borderline of Yield Grades 1

[2] Information concerning such devices may be obtained from the Agricultural Marketing Service, Livestock and Seed Division.

and 2 might have four-tenths inch of fat over the ribeye, 16.0 square inches of ribeye, and 2.5 percent of its weight in kidney, pelvic, and heart fat.

(2) *Yield Grade 2.* (i) A carcass in Yield Grade 2 usually is nearly completely covered with fat but the lean is plainly visible through the fat over the outside of the rounds, the tops of the shoulders, and the necks. There usually is a slightly thin layer of fat over the loins, ribs, and inside rounds and the fat over the rumps, hips, and clods usually is slightly thick. There are usually small deposits of fat in the flanks and cod or udder.

(ii) A 500-pound carcass of this yield grade which is near the borderline of Yield Grades 2 and 3 might have five-tenths inch of fat over the ribeye, 10.5 square inches of ribeye, and 3.5 percent of its weight in kidney, pelvic, and heart fat.

(iii) An 800-pound carcass of this yield grade which is near the borderline of Yield Grades 2 and 3 might have six-tenths inch of fat over the ribeye, 15.0 square inches of ribeye, and 3.5 percent of its weight in kidney, pelvic, and heart fat.

(3) *Yield Grade 3.* (i) A carcass in Yield Grade 3 usually is completely covered with fat and the lean usually is visible through the fat only on the necks and the lower part of the outside of the rounds. There usually is a slightly thick layer of fat over the loins, ribs, and inside rounds and the fat over the rumps, hips, and clods usually is moderately thick. There usually are slightly large deposits of fat in the flanks and cod or udder.

(ii) A 500-pound carcass of this yield grade which is near the borderline of Yield Grades 3 and 4 might have seven-tenths inch of fat over the ribeye, 9.5 square inches of ribeye, and 4.0 percent of its weight in kidney, pelvic, and heart fat.

(iii) An 800-pound carcass of this yield grade which is near the borderline of Yield Grades 3 and 4 might have eight-tenths inch of fat over the ribeye, 14.0 square inches of ribeye, 4.5 percent of its weight in kidney, pelvic, and heart fat.

(4) *Yield Grade 4.* (i) A carcass in Yield Grade 4 usually is completely covered with fat. The only muscles usually visible are those on the shanks and over the outside of the plates and flanks. There usually is a moderately thick layer of fat over the loins, ribs, and inside rounds and the fat over the rumps, hips, and clods usually is thick. There usually are large deposits of fat in the flanks and cod or udder.

(ii) A 500-pound carcass of this yield grade which is near the borderline of Yield Grades 4 and 5 might have one inch of fat over the ribeye, 9.0 square inches of ribeye, and 4.5 percent of its carcass weight in kidney, pelvic, and heart fat.

(iii) A 800-pound carcass of this yield grade which is near the borderline of Yield Grades 4 and 5 might have one and one-tenth inch of fat over the ribeye, 13.5 square inches of ribeye, and 5.0 percent of its weight in kidney, pelvic and heart fat.

(5) *Yield Grade 5.* A carcass in Yield Grade 5 usually has more fat on all of the various parts, a smaller area of ribeye, and more kidney, pelvic, and heart fat than a carcass in Yield Grade 4.

§54.106 Specifications for official United States standards for grades of carcass beef (quality-steer, heifer, cow).

(a) *Prime.* (1) Depending on their degree of maturity, beef carcasses possessing the minimum requirements for the Prime grade vary in their other indications of quality as evidenced in the

ribeye muscle. Minimum quality characteristics are described for two maturity groups, which cover the entire range of maturity permitted in the Prime grade.

(2) Carcasses in the younger group range from the youngest that are eligible for the beef class to those at the juncture of the two maturity groups, which have slightly red and slightly soft chine bones and cartilages on the ends of the thoracic vertebrae that have some evidence of ossification. In addition, the sacral vertebrae are completely fused and the cartilages on the ends of the lumbar vertebrae are nearly completely ossified. The rib bones are slightly wide and slightly flat and the ribeye muscle is light red in color and is fine in texture. In carcasses throughout the range of maturity included in this group, a minimum slightly abundant amount of marbling is required (see Figure 1) and the ribeye muscle is moderately firm.

(3) Carcasses in the older group range from those described above as representative of the juncture of the two groups to those at the maximum maturity permitted in the Prime grade, which have chine bones tinged with red and cartilages on the ends of the thoracic vertebrae that are partially ossified. In addition, the sacral vertebrae are completely fused, the cartilages on the ends of the lumbar vertebrae are completely ossified, and the cut surface of the lean tends to be fine in texture. The minimum degree of marbling required increases with advancing maturity throughout this group from minimum slightly abundant to maximum slightly abundant (see Figure 1) and the ribeye muscle is firm.

(4) Beef produced from cows is not eligible for the Prime grade.

(b) *Choice.* (1) Depending on their degree of maturity, beef carcasses possessing the minimum requirements for the Choice grade vary in their other indications of quality as evidenced in the ribeye muscle. Minimum quality characteristics are described for two maturity groups, which cover the entire range of maturity permitted in the Choice grade.

(2) Carcasses in the younger group range from the youngest that are eligible for the beef class to those at the juncture of the two maturity groups, which have slightly red and slightly soft chine bones and cartilages on the ends of the thoracic vertebrae that have some evidence of ossification. In addition, the sacral vertebrae are completely fused and the cartilages on the ends of the lumbar vertebrae are nearly completely ossified. The rib bones are slightly wide and slightly flat and the ribeye muscle is moderately light red in color and is fine in texture. In carcasses throughout the range of maturity included in this group, a minimum small amount of marbling is required (see Figure 1) and the ribeye muscle may be slightly soft.

(3) Carcasses in the older group range from those described above as representative of the juncture of the two groups to those at the maximum maturity permitted in the Choice grade, which have chine bones tinged with red and cartilages on the ends of the thoracic vertebrae are partially ossified. In addition, the sacral vertebrae are completely fused, the cartilages on the ends of the lumbar vertebrae are completely ossified, and the cut surface of the lean tends to be fine in texture. In carcasses throughout the range of maturity included in this group, a minimum modest amount of marbling is required (see Figure 1) and the ribeye muscle is slightly firm.

(c)Select. (1) In carcasses throughout the range of maturity permitted in the Select grade, the minimum marbling required is a minimum slight amount (see Figure 1) and the ribeye may be moderately soft.

(2) Carcasses in the maturity group permitted range from the youngest that are eligible for the beef class to those at the juncture of the two maturity groups, which have slightly red and slightly

soft chine bones and cartilages on the ends of the thoracic vertebrae that have some evidence of ossification. In addition, the sacral vertebrae are completely fused and the cartilages on the ends of the lumbar vertebrae are nearly completely ossified. The rib bones are slightly wide and slightly flat and the ribeye muscle is slightly light red in color and is fine in texture. In carcasses throughout the range of maturity included in this group, a minimum slight amount of marbling is required (see Figure 1) and the ribeye may be moderately soft.

(d) *Standard.* (1) Depending on their degree of maturity, beef carcasses possessing the minimum requirements for the standard grade vary in their other indications of quality as evidenced in the ribeye muscle. Minimum quality characteristics are described for two maturity groups which cover the entire range of maturity permitted in the Standard grade.

(2) Carcasses in the younger group range from the youngest that are eligible for the beef class to those at the juncture of the two maturity groups, which have slightly red and slightly soft chine bones and cartilages on the ends of the thoracic vertebrae that have some evidence of ossification. In addition, the sacral vertebrae are completely fused and the cartilages on the ends of the lumbar vertebrae are nearly completely ossified. The rib bones are slightly wide and slightly flat and the ribeye muscle is slightly dark red in color and is fine in texture. In carcasses throughout the range of maturity included in this group, a minimum practically devoid amount of marbling is required (see Figure 1) and the ribeye muscle may be soft.

(3) Carcasses in the older group range from those described above as representative of the juncture of the two groups to those at the maximum maturity permitted in the Standard grade, which have chine bones tinged with red and cartilages on the ends of the thoracic vertebrae that are partially ossified. In addition, the sacral vertebrae are completely fused, the cartilages on the ends of the lumbar vertebrae are completely ossified, and the cut surface of the lean is moderately fine in texture. The minimum degree of marbling required increases with advancing maturity throughout this group from minimum practically devoid to maximum practically devoid (see Figure 1) and the ribeye muscle may be moderately soft.

(e) *Commercial.* (1) Commercial grade beef carcasses are restricted to those with evidences of more advanced maturity than permitted in the Standard grade. Depending on their degree of maturity, beef carcasses possessing the minimum requirements for the Commercial grade vary in their other indications of quality as evidenced in the ribeye muscle. Minimum quality characteristics are described for the youngest and the most mature of these groups. The requirements for the intermediate group are determined by interpolation between the requirements indicated for the two groups described.

(2) Carcasses in the youngest group permitted in the Commercial grade range from those with indications of maturity barely more advanced than described as maximum for the Standard grade to those with moderately hard, rather white chine bones and with cartilages on the ends of the thoracic vertebrae that show considerable ossification but the outlines of the cartilages are still plainly visible. In addition, the rib bones are moderately wide and flat and the ribeye muscle is moderately dark red and slightly coarse in texture. The minimum degree of marbling required increases with advancing maturity throughout this group from a minimum small amount to a maximum small amount (see Figure 1) and the ribeye muscle is slightly firm.

(3) The youngest carcasses in the most mature group included in the Commercial grade have hard, white chine bones and the outlines of the cartilages on the ends of the thoracic vertebrae are

barely visible, the rib bones are wide and flat, and the ribeye muscle is dark red and coarse in texture. The range in maturity in this group extends to include carcasses from the oldest animals marketed. The minimum degree of marbling required increases with advancing maturity throughout this group from a minimum moderate amount to a maximum moderate amount (see Figure 1) and the ribeye muscle is firm.

(f) *Utility.* (1) Depending on their degree of maturity, beef carcasses possessing the minimum requirements for the Utility grade vary in their other indications of quality as evidenced in the ribeye muscle. Carcasses within the full range of maturity classified as beef are included in the Utility grade. Thus, five maturity groups are recognized. Minimum quality requirements are described for three of these groups -- the first or youngest, the third or intermediate, and the fifth or the most mature. The requirements for the second and fourth maturity groups are determined by interpolation between the requirements described for their adjoining groups.

(2) Carcasses in the first or youngest maturity group range from the youngest that are eligible for the beef class to those at the juncture of the first two maturity groups, which have slightly red and slightly soft chine bones and cartilages on the ends of the thoracic vertebrae that have some evidence of ossification. In addition, the sacral vertebrae are completely fused and the cartilages on the ends of the lumbar vertebrae are nearly completely ossified. The rib bones are slightly flat and the ribeye muscle is slightly dark red in color and fine in texture. In carcasses throughout the range of maturity included in this group, the ribeye muscle is devoid of marbling and may be soft and slightly watery.

(3) Carcasses in the third or intermediate maturity group range from those with indications of maturity barely more advanced than described as maximum for the Standard grade to those with moderately hard, rather white chine bones and with cartilages on the ends of the thoracic vertebrae that show considerable ossification but the outlines of the cartilages are still plainly visible. In addition, the rib bones are moderately wide and flat and the ribeye muscle is dark red in color and slightly coarse in texture. The minimum degree of marbling required increases with advancing maturity throughout this group from minimum practically devoid to maximum practically devoid (see Figure 1) and the ribeye muscle may be moderately soft.

(4) The youngest carcasses in the fifth or oldest maturity group have hard, white chine bones and the outlines of the cartilages on the ends of the thoracic vertebrae are barely visible, the rib bones are wide and flat, and the ribeye muscle is very dark red in color and coarse in texture. The range in maturity in this group extends to include carcasses from the oldest animals produced. The minimum degree of marbling required increases with advancing maturity throughout this group from a minimum slight amount to a maximum slight amount (see Figure 1) and the ribeye muscle is slightly firm.

(g) *Cutter.* (1) Depending on their degree of maturity, beef carcasses possessing the minimum requirements for the Cutter grade vary in their other indications of quality as evidenced in the ribeye muscle. Carcasses within the full range of maturity classified as beef are included in the Cutter grade. Thus, five maturity groups are recognized. Minimum quality requirements are described for three of these groups -- the first or youngest, the third or intermediate, and the fifth or the most mature. The requirements for the second and fourth maturity groups are determined by interpolation between the requirements described for their adjoining groups.

(2) Carcasses in the first or youngest maturity group range from the youngest that are eligible

for the beef class to those at the juncture of the first two maturity groups, which have slightly red and slightly soft chine bones and cartilages on the ends of the thoracic vertebrae that have some evidence of ossification. In addition, the sacral vertebrae are completely fused and the cartilages on the ends of the lumbar vertebrae are nearly completely ossified. The rib bones are slightly wide and slightly flat and the ribeye muscle is slightly dark red in color and fine in texture. In carcasses throughout the range of maturity included in this group, the ribeye muscle is devoid of marbling and may be very soft and watery.

(3) Carcasses in the third or intermediate maturity group range from those with indications of maturity barely more advanced than described as maximum for the Standard grade to those with moderately hard, rather white chine bones and with cartilages on the ends of the thoracic vertebrae that show considerable ossification but the outlines of the cartilages are still plainly visible. In addition, the rib bones are moderately wide and flat and the ribeye muscle is dark red in color and slightly coarse in texture. In carcasses throughout the range of maturity included in this group, the ribeye muscle is devoid of marbling and may be soft and watery.

(4) Carcasses in the fifth or oldest maturity group have hard white chine bones and the outlines of the cartilages on the ends of the thoracic vertebrae are barely visible, the rib bones are wide and flat, and the ribeye muscle is very dark red in color and coarse in texture. The range in maturity in this group extends to include carcasses from the oldest animals produced. The minimum degree of marbling required increases with advancing maturity throughout this group from minimum practically devoid to maximum practically devoid (see Figure 1) and the ribeye muscle is soft and slightly watery.

(h) *Canner.* The Canner grade includes only those carcasses that are inferior to the minimum requirements specified for the Cutter grade.

§54.107 Specifications for official United States standards for grades of carcass beef (quality -- bullock).

(a) *Prime.* For the Prime grade, the minimum degree of marbling required is a minimum slightly abundant amount for carcasses throughout the range of maturity permitted in the bullock class. The ribeye muscle is moderately firm and, in carcasses having the maximum maturity for this class, the ribeye is light red in color.

(b) *Choice.* For the Choice grade, the minimum degree of marbling required is a minimum small amount for carcasses throughout the range of maturity permitted in the bullock class. The ribeye muscle may be slightly soft and, in carcasses having the maximum maturity for this class, the ribeye is moderately light red in color.

(c) *Select.* For the Select grade, the minimum degree of marbling required is a minimum slight amount for carcasses throughout the range of maturity permitted in the bullock class. The ribeye muscle may be moderately soft and, in carcasses having the maximum maturity for this class, the ribeye is slightly light red in color.

(d) *Standard.* For the Standard grade, the minimum degree of marbling required is a minimum practically devoid amount for carcasses throughout the range of maturity permitted in the bullock class. The ribeye muscle may be soft and, in carcasses having the maximum maturity for this class, the ribeye is slightly dark red in color.

(e) *Utility.* The Utility grade includes only those carcasses that do not meet the minimum requirements specified for the Standard grade.

【説明資料】

1　米国産牛肉の貿易再開問題の経緯

（1）米国産牛肉の輸入停止

ＢＳＥ発生国で生産された牛肉等については、食品の安全性確保に万全を期すとともに、病原体の侵入を防止するため、食品衛生法及び家畜伝染病予防法に基づき、国産牛肉と同等の安全性が確保されることが確認されるまでの間、その輸入を認めないこととしている。

２００３年１２月２４日、米国国内でＢＳＥ感染牛が確認されたことを受け[6]、厚生労働省及び農林水産省は、米国産牛肉及び牛肉製品等の輸入を暫定的に停止した。

（2）米国産牛肉再開に向けた協議

米国でのＢＳＥ感染牛の確認後、日本は直ちに専門家を現地に派遣し、ＢＳＥ感染牛の由来、同居牛の取扱い等のＢＳＥに係る事実関係や、サーベイランス体制、飼料給与禁止措置等のＢＳＥ対策の調査を行い、２００４年１月、その結果を公表した[8]。その後日米事務レベル協議、日米の科学者・学識者による専門的・科学的な協議を実施した。

２００４年４月２４日に開催されたＢＳＥに関する第３回日米局長級協議における合意に従い、専門家及び実務担当者からなる日米ＢＳＥワーキンググループが設置され、日米間の牛肉貿易再開に向けて、ＢＳＥの検査方法や特定危険部位（ＳＲＭ）の除去方法など７つの項目について、技術的・専門的視点から３回に渡り議論を行った[11]。

２００４年１０月２３日、第４回日米局長級協議において、日米両国政府は、米国産牛肉の日本向け貿易再開に関し、食品安全委員会による審議を含むそれぞれの国内の承認手続きを条件に、米国側が、①ＳＲＭはあらゆる月齢の牛から除去すること、②牛肉は、個体月齢証明等の生産記録を通じて２０ヶ月齢以下と証明される牛由来とすること等を内容とする牛肉輸出証明プログラムを設けることについて認識を共有した。

その後、日米の実務担当者間で、牛肉輸出証明プログラムに関する協議が行われてきた[12、36]。

2　牛肉貿易に関する国際基準とＢＳＥリスク評価

（1）ＳＰＳ協定について[1]

衛生植物検疫措置の適用に関する協定（ＳＰＳ協定）によれば、牛肉の国際貿易については、動物の健康（animal health）及び人

獣共通感染症（zoonosis）に関し、国際獣疫事務局（ＯＩＥ）が作成した国際的な基準、指針及び勧告に基づき、加盟国間で調和のとれた衛生検疫措置をとることを推奨している。

同協定では、科学的に正当な理由がある場合又は適切なリスク評価を行った場合には、国際基準よりも高い水準の検疫措置を導入することができるとしている。また、関連する科学的根拠が不十分な場合には暫定的に検疫措置を採用することができるとしているが、この場合は、客観的なリスク評価のために必要な情報を得るよう努め、また、適当な期間内に当該検疫措置を再検討すること（第３条、第５条）とされている。

（2）ＯＩＥの定める基準[2、3、4]

ＢＳＥに関する国際基準は陸生動物衛生規約に定められている。

この規約で、ＢＳＥに関するリスク評価の手法が定められており、侵入リスク、曝露リスク、監視体制に関する項目を総合的に評価するとともに、その結果特定されたリスクへの適切な対処状況や、サーベイランス、フィードバン等の実施状況により、ＢＳＥの浸潤状況を５段階に分類している。また、輸出国のＢＳＥの浸潤状況の段階に応じて牛肉等の衛生上の輸入条件が定められている。

これまで欧州食品安全庁は、このＯＩＥの規約に挙げられているリスク評価要因を考慮しつつ、各国のＢＳＥのリスクを定性的に評価している[5、6、7、31]。

なお、ＯＩＥでは現在、骨なし牛肉をいかなる輸入条件も要求すべきでない品目に追加すること等を内容とするＢＳＥに関する国際基準の見直し作業を行っているところであり、本年５月のＯＩＥ定例総会において議論されているところである。

3　米国のＢＳＥ対策の概要

（1）肉牛産業の概要

米国には９千４百万頭、日本の約２０倍の牛が飼養されている。このうち、肉牛が６千４百万頭、乳牛が１千３百万頭、子牛等が１千７百万頭である。[14、16]

肉牛の飼養形態は多様であるが、一般的には発育段階に沿って繁殖、育成、肥育の３段階に分かれる。繁殖農家では一般的に周年放牧で、自然交配により出産した子牛が概ね６ヶ月まで飼養される。子牛は次いで、放牧、特に小麦畑での放牧により育成する経営や穀物・補助飼料を与えて育成する農家で、６～８ヶ月間飼養される。育成牛は次いで３～４ヶ月間フィードロット（穀物肥育農場）で肥育され、と畜場に出荷される。なお、子牛のうち、体重の重いもの

等には育成段階を経ずにフィードロットに送られるものがある[13、18、19]。

年間と畜頭数は約３４百万頭で日本の約３０倍であり、年間約８百万トンの牛肉（部分肉ベース）が生産されている[13、15、17]。

（２）輸入規制

１９８９年、英国等ＢＳＥ発生国からの反すう動物及びその肉骨粉の輸入を禁止、１９９１年、ＢＳＥ発生国からの反すう動物の肉の輸入を禁止した[32]。現在、ＢＳＥ発生国及び輸入規制が米国より緩い等の国からこれらの物品の輸入を禁止している[20]。

１９８０年以降、ＢＳＥリスクのある国から輸入された生体牛は、英国から３百頭程度、他の欧州等からは千頭程度となっている。また、肉骨粉は、英国から５トン輸入されており、他の国からは反すう動物の肉骨粉は輸入されていない[31]。

カナダからは生体牛が年間５０万頭～１７０万頭程度、肉骨粉が年間１万８千トン～４万４千トン程度輸入されている（２００３年まで）[31]。

（３）飼料規制[9、10、11、12、25]

現行の飼料規制は、１９９７年８月に施行された連邦規則21CFR§589.2000に基づき行われている[21]。飼料規制の内容としては、一部のたん白質を除きほ乳動物由来たん白質を反すう動物の飼料原料に使用することの禁止及びその旨の表示の義務付け並びに給餌及び飼料製造の記録の保存を義務付けるものとなっている[21]。

これら飼料規制の遵守状況については、米国食品医薬品局（ＦＤＡ）等の検査官がガイドライン[22]に基づき検査を実施しており、検査結果を公表[23]している。また、米国会計検査院（ＧＡＯ）は飼料規制の実施状況について定期的に調査を行い、改善が必要な点について勧告を行っている[26]。

なお、２００３年１２月に米国内でＢＳＥ感染牛が確認されたことを踏まえ、２００４年１月には、牛由来の血液及び血液製品、残飯等の使用規制等について、同年７月には、全ての動物用飼料原料からのＳＲＭ、歩行困難牛及び死亡牛の排除並びに反すう動物用飼料製造施設の専用化等交差汚染防止対策の強化について、パブリックコメントを実施したが[24]、これらの規制は未だ実施されていない。

飼料・レンダリング産業については、畜種別に施設の専用化等が進んでおり、配合飼料については自家配合農家等による畜種別の生産が多い[25]。

（４）報告義務及びサーベイランス[9、10、11、12]

１９８６年以降ＢＳＥについて届出が義務付けられ、獣医官は連邦政府及び州政府に通報することとされた[32]。

サーベイランスについては、１９９０年に米国政府がサーベイランスプログラムを開始し、以降１３年間、ＢＳＥの陽性事例は見られなかった[29、32、34]が、２００３年１２月、ワシントン州のと畜場でと畜された牛で、感染が確認された。

２００３年の対象頭数は２万頭であったが、[28]、ＢＳＥ感染牛が確認されたこと等から２００４年６月からはサーベイランスを強化し、１２ヶ月から１８ヶ月の間に２０数万頭規模を対象とすることとした[27、28、34]。この強化サーベイランスの下で、これまで３５万頭以上の検査を行っているが、ＢＳＥ陽性牛は確認されていない[29]。

（５）と畜場及び食肉処理施設における対策[12、30]

と畜場及び食肉処理施設におけるＢＳＥ対策（２００３年１２月３０日発表）については、①歩行困難な牛の食用禁止、②すべての月齢の牛について扁桃及び小腸を除去し、３０ヶ月齢以上の牛について頭蓋、脳、三叉神経節、眼、せき柱、せき髄及び背根神経節の除去、③ＡＭＲ（高圧で骨を破壊することなく肉を採取する方法）の規制強化（３０ヶ月齢以上の牛のせき柱の使用禁止等）、④空気噴射スタンニングの禁止、⑤ＢＳＥ検査中の牛肉はＢＳＥ陰性が確認されるまで流通禁止等を内容とする規則が２００４年１月１２日に施行されている。

4　米国のリスク評価等

米国におけるＢＳＥのリスクは、米国内では米国農務省の依頼によりハーバード大学も評価を行っている（２００１年、２００３年）[32、33]ほか、米国外では欧州食品安全庁が評価を行っている（２００４年）[31]。また、米国農務省監査官が、サーベイランスについて評価を行っている（２００４年）[34]。

また、ＢＳＥが発生したことを受け、国際的な専門家グループがＢＳＥ感染牛の疫学的調査と米国政府のＢＳＥ対策について、調査・勧告を行っている（２００４年）[9]ほか、米国農務省は、北米で確認された４頭のＢＳＥ感染牛について疫学的な調査を行い、原因究明及びまん延の可能性について検証している（２００５年）[35]。

（以上）

参考資料（米国関連）

○ 牛肉貿易に関する国際基準とBSEリスク評価

1 【衛生植物検疫措置の適用に関する協定（AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES）】（世界貿易機関（WTO）の下で動植物検疫措置について規定したWTO協定の附属協定）

2 【OIE Terrestrial Animal Health Code(2004) GENERAL PROVISIONS SECTION 1.3. RISK ANALYSIS(1.3.1, 1.3.2)】（国際獣疫事務局（OIE）のリスク評価に関する規約）

3 【OIE Terrestrial Animal Health Code(2004) CHAPTER 2.3.13. Bovine spongiform encephalopathy】（OIEのBSEに関する規約）

4 【OIE Terrestrial Animal Health Code(2004) APPENDIX 3.8.5. Factors to consider in conducting the bovine spongiform encephalopathy risk assessment recommended in chapter 2.3.13.】（OIEのBSEに関する規約に基づくリスク評価を行う場合に考慮すべき要因）

5 【Final Opinion of the SCIENTIFIC STEERING COMMITTEE on the Geographical Risk of Bovine Spongiform Encephalopathy(GBR) (Adopted on 6/July/2000)】（欧州科学運営委員会（SSC）によるBSEリスク評価手法の最終意見）

6 【Update of the Opinion of the SCIENTIFIC STEERING COMMITTEE on the Geographical Risk of Bovine Spongiform Encephalopathy(GBR) (adopted on 11 January 2002)】（参考資料5の改正）

7 【REGULATION (EC) No 999/2001 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2001】（欧州連合のTSE対策全般に関する規則）

○ 米国のBSE対策の概要

8 【米国でのＢＳＥ発生に伴う海外調査について】（農林水産省ホームページ：平成16年1月に我が国が実施した米国のＢＳＥに係る事実関係及びＢＳＥ対策についての調査報告）

9 【International Panel Report on BSE Measures in the US (2004.2.2)】（BSE発生を受けて、国際調査団が行った米国のBSE対策に関する調査報告書）

10 【Response to "Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States(2004.3.4)】（国際調査団が行った勧告に対する米国政府の主張）

11 【BSEに関する専門家及び実務担当者会合（ＷＧ）報告書(2004.7.22)】（日米のBSE専門家及び実務担当者による両国のBSE対策に係る技術的会合の取りまとめ）

12 【牛海綿状脳症（ＢＳＥ）に関する質問と答え】（在日本米国大使館ホームページ：米国のBSE対策についてのＱ＆Ａ）

肉牛産業の概要

13 【OVERVIEW OF THE U.S. BEEF INDUSTRY】（米国からの提出資料：米国の肉牛産業の概要）

14 【United States and Canadian Cattle (Agricultural Statistics Board NASS USDA)】（米国農務省の統計資料）

15 【Livestock Slaughter 2004 Summary(NASS USDA)】（米国農務省の統計資料）

16 【畜産統計調査（平成１６年２月１日現在）農林水産統計】（農林水産省大臣官房統計部の資料）

17 【平成１６年畜産物流通統計】（農林水産省大臣官房統計部の資料）

18 【Determination of Cattle Age】（第１回牛の月齢判別に関する検討会資料）

19 【Question and Requests to FDA】（米国からの提出資料：飼料規制に関する米国への質問に対する回答から抜粋）

輸入規制

20 【Title9, Code of Federal Regulations, Part 94.18、94.19、95.4】（畜産物の輸入規制に関する連邦規則）

飼料規制

21 【Title21, Code of Federal Regulations, Part 589.2000(1997.8.4)】（飼料規制に関する連邦規則）

22 【BSE/Ruminant Feed Ban Inspections(2003.10.21)】（FDA検査官等の検査ｶﾞｲﾄﾞﾗｲﾝ）

23 【CVM UPDATE -Update on Feed Enforcement Activities-(2005.3.17)】（飼料規制の遵守状況）

24 【CVM UPDATE-FDA AND USDA REQUEST COMMENTS AND SCIENTIC INFORMATION ON POSSIBLE NEW BSE SAFEGUARDS (2004.7.9)】（飼料規制の強化についてのﾊﾟﾌﾞﾘｯｸｺﾒﾝﾄ募集）

25 【MAD COW DISEASE -FDA'S Management of the Feed Ban has improved, but oversight weaknesses continue to limit program effectiveness(2005.2.25 GAO-05-101)】（飼料規制に関し米国会計検査院が2002年に行った指摘がどの程度改善されたかについて検証した報告書）

26 【米国及びカナダにおけるBSE対策に関する現地調査について（報告）】（農林水産省ﾎｰﾑﾍﾟｰｼﾞ：米国及びカナダにおけるBSE対策の現地調査概要）

報告義務及びサーベイランス

27 【Bovine Spongiform Encephalopathy (BSE) Surveillance Plan (2004.3.15 APHIS)】（2004年6月から実施している拡大サーベイランス計画）

28 【Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States : Harvard Center for Risk Analysis(2004.3.12)】（ハーバード大学が行った拡大サーベイランス計画の評価）

29 【Additional Question and Requests to USDA】（米国からの提出資料：米国への質問に対する回答：サーベイランス部分抜粋）

と畜場及び食肉処理施設における対策

30 【Federal Register/Vol.69, No.7/Monday, January 12, 2004】（と畜場及び食肉処理施設におけるSRMの除去、ダウナー牛の食用禁止等の規制強化に関する連邦規則）

○ 米国のリスク評価等

31 【EFSA Scientific Report on the Assessment of the Geographical BSE-Risk (GBR) of the United States of America (USA)】（欧州食品安全庁が行った米国のBSEリスク評価）

32 【Evaluation of the Potential for BSE in the US (2001.11.26 Harvard Center for Risk Analysis)】（ハーバード大学が行った米国のBSEリスク評価）

33 【Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the US from Canada (2003.10.31 Harvard Center for Risk Analysis)】（ハーバード大学が行ったカナダからBSEが侵入したと仮定した場合の米国のBSEリスク評価）

34 【Audit Report: APHIS and FSIS BSE Surveillance Program - Phase I (2004.8.18 USDA OFFICE OF INSPECTOR GENERAL)】（米国農務省監査官が行った米国のサーベイランスの評価）

35 【U.S.Department of Agriculture's Summary of the Epidemiological Findings of North American Bovine Spongiform Encephalopathy Positive Cattle】（米国農務省による北米で確認された４例のBSE感染牛に関する疫学調査報告書）

牛の個体識別制度及び月齢確認方法について

36 【牛の月齢判別に関する検討会報告書及び関係資料】

資料２－２

参考資料（米国関連）

○ 牛肉貿易に関する国際基準とBSEリスク評価

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9 【International Panel Report on BSE Measures in the US (2004.2.2)】（BSE発生を受けて、国際調査団が行った米国のBSE対策に関する調査報告書）

10 【Response to "Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States(2004.3.4)】（国際調査団が行った勧告に対する米国政府の主張）

11 【BSEに関する専門家及び実務担当者会合（ＷＧ）報告書(2004.7.22)】（日米のBSE専門家及び実務担当者による両国のBSE対策に係る技術的会合の取りまとめ）

12 【牛海綿状脳症（ＢＳＥ）に関する質問と答え】（在日本米国大使館ホームページ：米国のBSE対策についてのＱ＆Ａ）

肉牛産業の概要

13 【OVERVIEW OF THE U.S. BEEF INDUSTRY】（米国からの提出資料：米国の肉牛産業の概要）

14 【United States and Canadian Cattle (Agricultural Statistics Board NASS USDA)】（米国農務省の統計資料）

15 【Livestock Slaughter 2004 Summary(NASS USDA)】（米国農務省の統計資料）

16 【畜産統計調査（平成１６年２月１日現在）農林水産統計】（農林水産省大臣官房統計部の資料）

17 【平成１６年畜産物流通統計】（農林水産省大臣官房統計部の資料）

18 【Determination of Cattle Age】（第１回牛の月齢判別に関する検討会資料）

19 【Question and Requests to FDA】（米国からの提出資料：飼料規制に関する米国への質問に対する回答から抜粋）

輸入規制

20 【Title9, Code of Federal Regulations, Part 94.18、94.19、95.4】（畜産物の輸入規制に関する連邦規則）

飼料規制

21 【Title21, Code of Federal Regulations, Part 589.2000(1997.8.4)】（飼料規制に関する連邦規則）

22 【BSE/Ruminant Feed Ban Inspections(2003.10.21)】（FDA検査官等の検査ｶﾞｲﾄﾞﾗｲﾝ）

23 【CVM UPDATE -Update on Feed Enforcement Activities-(2005.3.17)】（飼料規制の遵守状況）

24 【CVM UPDATE-FDA AND USDA REQUEST COMMENTS AND SCIENTIC INFORMATION ON POSSIBLE NEW BSE SAFEGUARDS (2004.7.9)】（飼料規制の強化についてのﾊﾟﾌﾞﾘｯｸｺﾒﾝﾄ募集）

25 【MAD COW DISEASE -FDA'S Management of the Feed Ban has improved, but oversight weaknesses continue to limit program effectiveness(2005.2.25 GAO-05-101)】（飼料規制に関し米国会計検査院が2002年に行った指摘がどの程度改善されたかについて検証した報告書）

26 【米国及びカナダにおけるBSE対策に関する現地調査について（報告）】（農林水産省ﾎｰﾑﾍﾟｰｼﾞ：米国及びカナダにおけるBSE対策の現地調査概要）

報告義務及びサーベイランス

27 【Bovine Spongiform Encephalopathy (BSE) Surveillance Plan (2004.3.15 APHIS)】（2004年６月から実施している拡大サーベイランス計画）

28 【Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States : Harvard Center for Risk Analysis(2004.3.12)】（ハーバード大学が行った拡大サーベイランス計画の評価）

29 【Additional Question and Requests to USDA】（米国からの提出資料：米国への質問に対する回答：サーベイランス部分抜粋）

と畜場及び食肉処理施設における対策

30 【Federal Register/Vol.69, No.7/Monday, January 12, 2004】（と畜場及び食肉処理施設におけるSRMの除去、ダウナー牛の食用禁止等の規制強化に関する連邦規則）

○ 米国のリスク評価等

31 【EFSA Scientific Report on the Assessment of the Geographical BSE-Risk (GBR) of the United States of America (USA)】（欧州食品安全庁が行った米国のBSEリスク評価）

32 【Evaluation of the Potential for BSE in the US (2001.11.26 Harvard Center for Risk Analysis)】（ハーバード大学が行った米国のBSEリスク評価）

33 【Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the US from Canada (2003.10.31 Harvard Center for Risk Analysis)】（ハーバード大学が行ったカナダからBSEが侵入したと仮定した場合の米国のBSEリスク評価）

34 【Audit Report: APHIS and FSIS BSE Surveillance Program - Phase I (2004.8.18 USDA OFFICE OF INSPECTOR GENERAL)】（米国農務省監査官が行った米国のサーベイランスの評価）

35 【U.S.Department of Agriculture's Summary of the Epidemiological Findings of North American Bovine Spongiform Encephalopathy Positive Cattle】（米国農務省による北米で確認された４例のBSE感染牛に関する疫学調査報告書）

牛の個体識別制度及び月齢確認方法について

36 【牛の月齢判別に関する検討会報告書及び関係資料】