

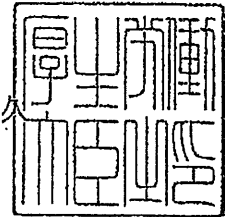
	御意見・情報の概要	専門調査会の回答
151	<p>いったいどれくらいの量のBSE感染牛の肉を食べれば、どのくらいの割合で発病者(死者)が出るのか(高齢のプリオン存在量の多い牛で、年間何頭分を100年間等食べ続ければどのくらいの死者が出るのか。発ガン率等他のものと同等のレベルで)。</p>	<p>今回の報告案は、厚生労働省及び農林水産省からの諮問を受けて、と畜場におけるBSE検査の対象牛を全月齢から21ヶ月齢以上の牛に変更した場合等の食品健康影響(リスク)について評価を行ったものであり、いただいたご意見とは内容が異なります。なお、どれくらいの量のBSE感染牛の肉を食べれば発症するかについては現在の知見では明らかになっていません。</p>
152	<p>食衛法第四条との整合性も検討願います。 本論：食衛法第四条第三項には「病原微生物により汚染され、又はその疑があり、人の健康を害する虞があるもの。」は「販売し、又は販売の用に供するために、採取し、製造し、輸入し、加工し、使用し、調理し、貯蔵し、若しくは陳列してはならない。」と定められております。 しかるに、本審議結果案の結論として、「(人の健康に悪影響を与えるプリオンの)汚染度は無視できる～非常に低い」とされております。これは法で言う「疑いがある」ものに相当するものと考えます。また同条の第二項には「但し、人の健康を害する虞がない場合として厚生労働大臣が定める場合においては、この限りでない。」との例外規定が定められておりますが、第三項には、その例外規定も記されておられません。科学的に「ほぼ安全」と結論づけられても、法的には販売等出来ないものと考えられますが、如何なものでしょうか？</p>	<p>今回の報告案は、厚生労働省及び農林水産省からの諮問を受けて、と畜場におけるBSE検査の対象牛を全月齢から21ヶ月齢以上の牛に変更した場合等の食品健康影響(リスク)について評価を行ったものです。いただいたご意見については、法的な取り扱いに関することであり、リスク管理官庁にお伝えします。</p>



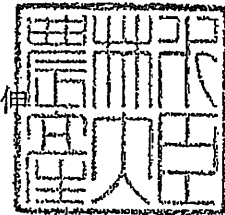
厚生労働省発食安第0524001号
 17消安第1380号
 平成17年5月24日

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_&_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



- 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 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 A⁴⁰ physiological maturity or younger by an official USDA evaluation. Official USDA evaluations must determine carcasses to be A⁴⁰ 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 A⁴⁰ 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*.