参考資料７

食安監発第0708001号
１７消安第３６２３号
平成１７年７月８日

内閣府食品安全委員会事務局評価課長　殿

厚生労働省医薬食品局食品安全部監視安全課長
農林水産省消費・安全局衛生管理課長
（公　印　省　略）

食品健康影響評価に係る資料の提出について

平成１７年６月１０日付け府食第５９２号及び平成１７年６月２４日付け府食第６３４号にて依頼のあった下記の補足資料について別添のとおり提出します。

記

＜平成１７年６月１０日付け府食第５９２号で依頼のあった資料＞
資料番号１３：米国とカナダについて
① と畜場での作業のフローチャート：日本との比較
各段階における検査員の配置状況
Ante mortem inspection 及び Post mortem inspection での検査要領
② 代表的 SSOP と HACCP の見本
ＢＳＥ対策での Critical control point の明示
③ 肉質鑑別にあたる検査員の配置状況と作業量

＜平成１７年６月２４日付け府食第６３４号で依頼のあった資料＞
１．諮問に至った経緯、目的、背景等の説明。
２．米国及びカナダの国内対策と上乗せ条件（輸出管理プログラム）について、具体的な内容、相違点、及び国内対策の問題点を項目別に整理した表。
３．米国及びカナダが実施しているＢＳＥサーベイランスを日本に適用した場合の日本のＢＳＥ検査陽性頭数。
４．ＯＩＥのＢＳＥコード（無条件物品の記載部分）の原文。
５．米国のサーベイランスの詳細（地域別、月齢別等のデータ）。
６．米国政府が６月１０日に発表した疑似陽性牛に関する情報。
７．カナダにおけるＢＳＥ確定検査方法（ウエスタンブロット法の導入の真偽）。
８．米国及びカナダにおけるオランダからの動物性油脂（タロー）の輸入実績（１９９５年～現在）。

（参考資料）
「牛枝肉の生理学的成熟度に関する研究」最終報告書への追加情報について

資料番号13：米国とカナダについて

①と畜場での作業のフローチャート：日本との比較

各段階における検査員の配置状況

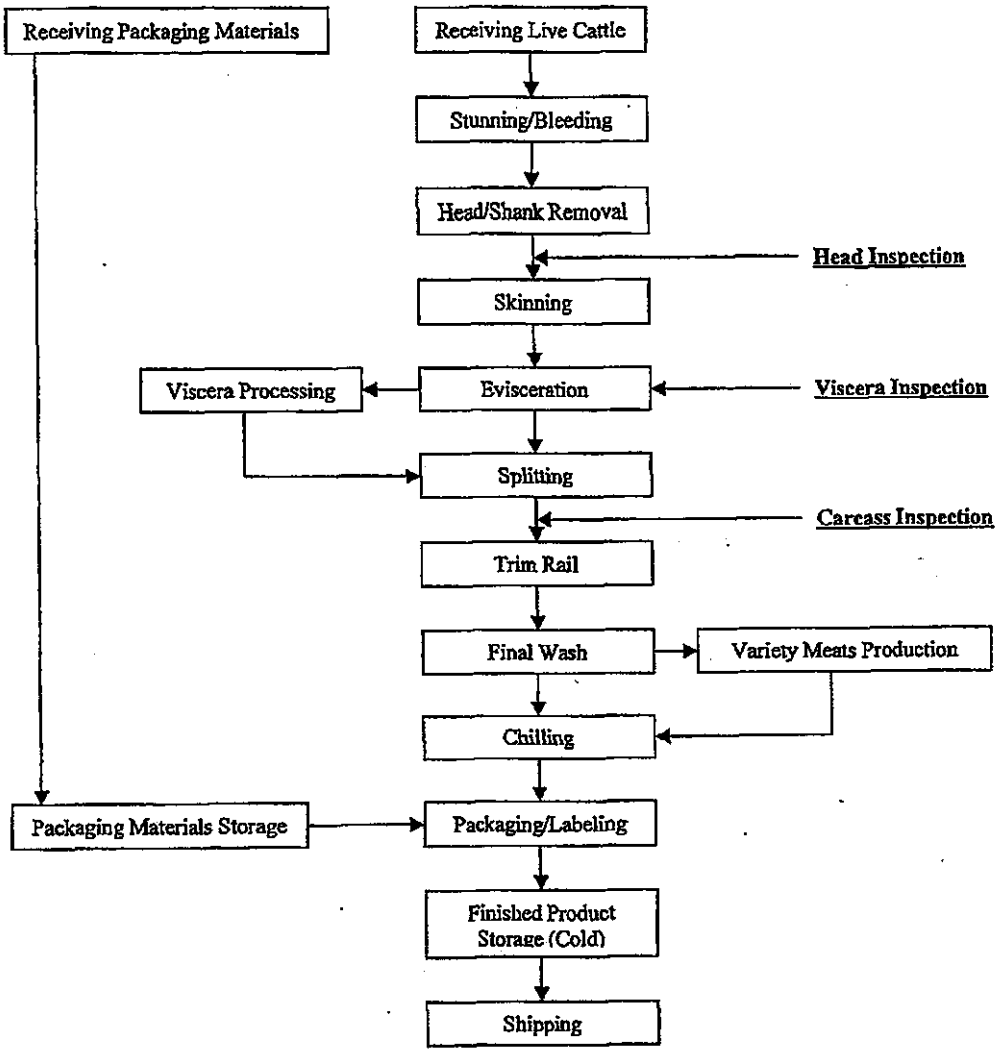
と畜検査員の現場での配置

作業工程		検査員の配置		
		日本	米国	カナダ
繋　留	生体検査	検査員	検査員	検査員
とさつ(スタンニング)	解体前検査			
ピッシング				
シャックリング				
懸垂・放血				
頭部除去		検査員	検査員	検査員
剥　皮				
内臓摘出	解体時及び解体後検査	検査員	検査員	検査員
内臓処理室で除去				
せき髄吸引　せき髄除去				
背割り　せき髄片除去				
枝肉洗浄				
検　印		検査員	検査員	検査員

［米国］

June 24, 2005

FLOW CHART OF TYPICAL BEEF SLAUGHTER FACILITY
INCLUDING LOCATION OF FSIS INSPECTION STATIONS

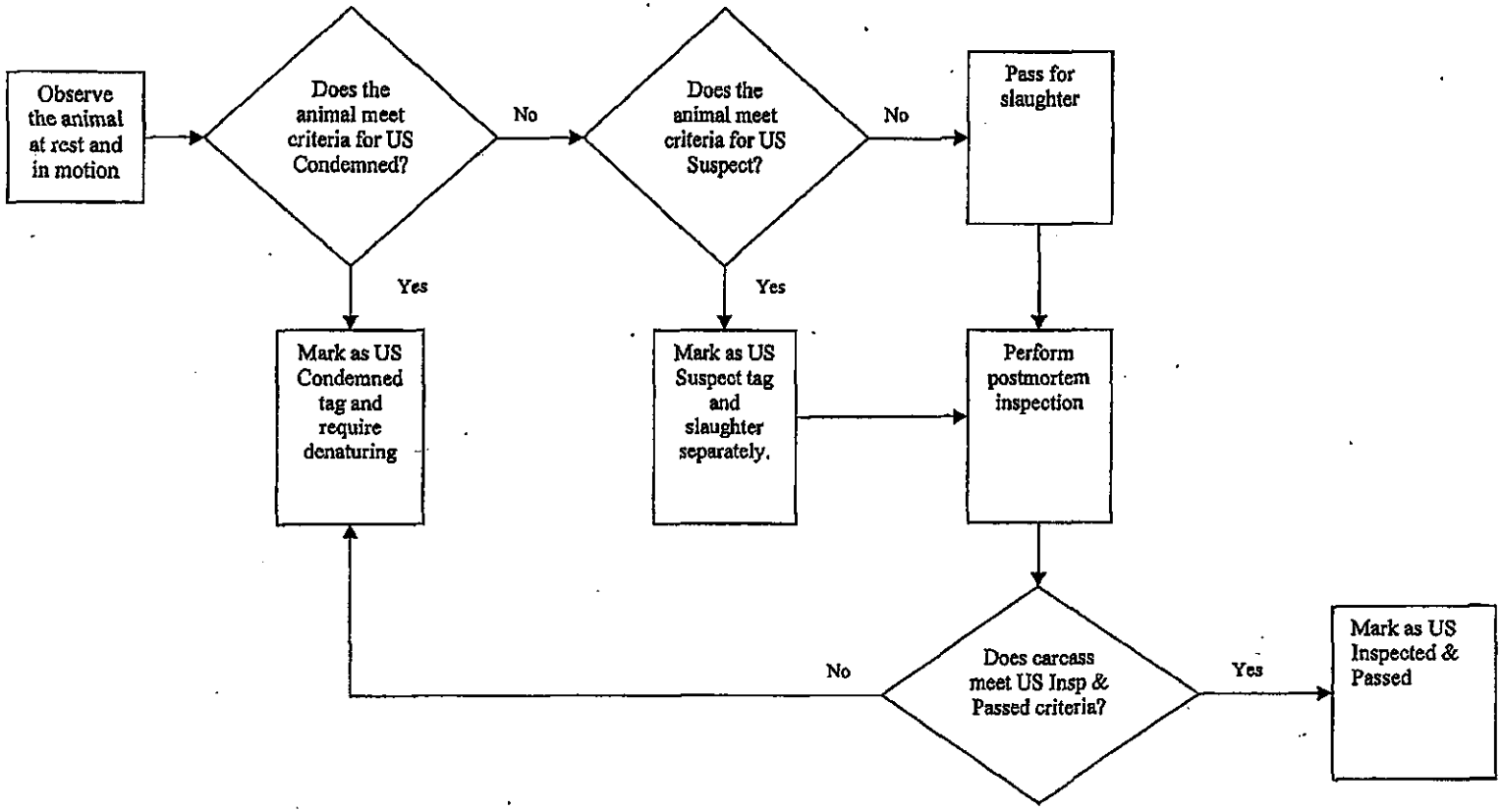


Flow Chart Summarizing Canadian Dressing Procedures for Cattle

[カナダ]

Ante mortem inspection及びPost mortem inspectionでの検査要領

FLOW CHART OF FSIS ANTEMORTEM AND POSTMORTEM INSPECTION PROCESS



DESCRIPTION OF FSIS ANTEMORTEM AND POSTMORTEM INSPECTION

FSIS Antemortem Inspection

The antemortem inspection for cattle involves the following steps:

- Observe animals at rest
- Observe animals in motion (from both sides)

It is important to inspect live cattle at rest and in motion because certain abnormal clinical signs, such as labored breathing, are easier to detect while the cattle are at rest, while other abnormalities, such as lameness, may not be detected until the FSIS Public Health Veterinarian observes the cattle in motion.

The following steps are performed during at-rest antemortem inspection.

- Position yourself at various locations outside the pen.
- Observe all of the cattle and note their general behavior while they're at rest.
- Determine if any of the animals show abnormal behavior patterns such as excessive excitability or severe depression or other central nervous system signs.
- Look at the heads, necks, sides, rumps, and legs of as many animals as you can see and note any abnormalities.

The following steps are performed during in-motion antemortem inspection.

- Position yourself outside of the pen next to the open gate where you can easily view the cattle as they are driven past.
- Direct the establishment employee to move all of the cattle slowly and individually out of the pen and then back into the pen.
- Observe the head, neck, shoulder, flank, legs, and rump on both sides of each animal and note any abnormalities.

FSIS Postmortem Inspection

The postmortem inspection process for cattle involves the following steps:

- Head inspection
- Viscera inspection
- Carcass inspection

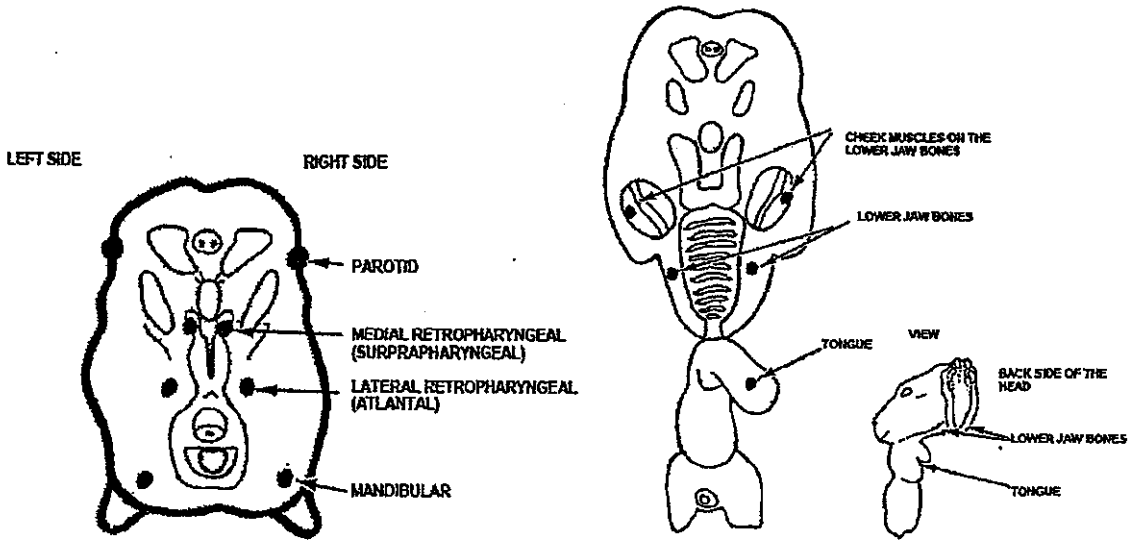
In cattle slaughter establishments, FSIS inspectors perform postmortem inspection procedures at three postmortem inspection stations. The sequence for each postmortem inspection procedure will depend on the method of presentation for postmortem inspection that the establishment uses. But, regardless of the method of presentation, no part to be inspected may be missed, and the presentation must be consistent from carcass to carcass. This permits the FSIS inspector to perform the same postmortem inspection procedure each time, and reduces the chances that a required inspection step will be overlooked

A. Head Inspection

The sequence of inspection of the head is determined by the direction of movement of the head and whether the tongue is in front of the head or behind it. Usually, the leading tissues are examined first, and the trailing tissues are examined last. Presentation methods vary. Some establishments present the head with the tongue in and others present the head with the tongue out. Regardless of the presentation method, certain tissues are always examined, although the sequence, or order, may vary.

The following steps are performed during postmortem head inspection.

- Observe the outer surface of the head and eyes.
- Incise and observe the four pairs of mandibular, parotid, lateral retropharyngeal (atlantal), and medial retropharyngeal (suprapharyngeal) lymph nodes.
- Incise and observe the masticatory or cheek muscles.
- Observe and palpate the tongue.

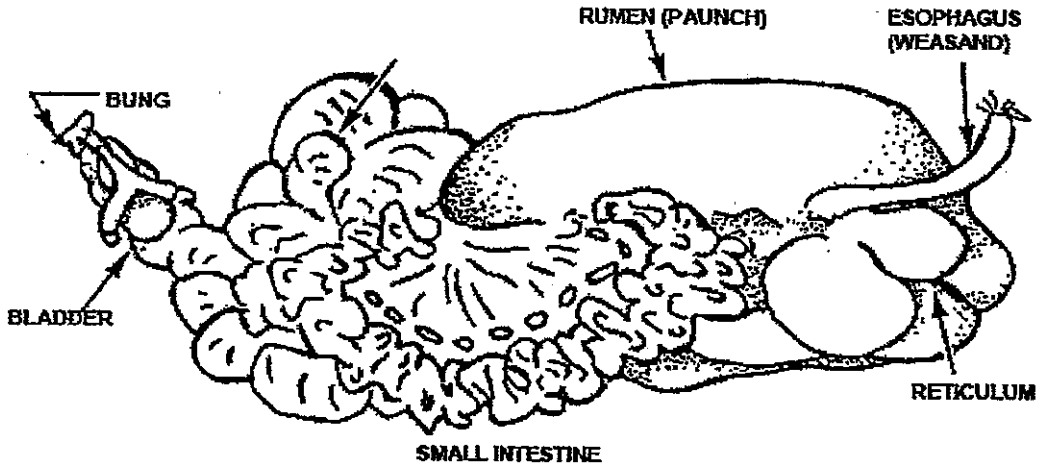


B. Viscera Inspection

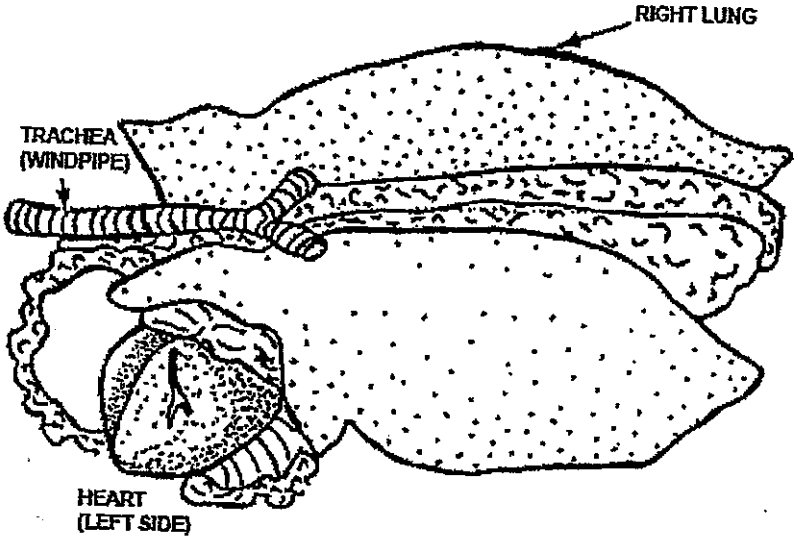
Viscera are typically presented for inspection on a stationary or moving surface. Regardless of the method used by the establishment to present the viscera, certain tissues are always examined.

The following steps are performed during postmortem viscera inspection.

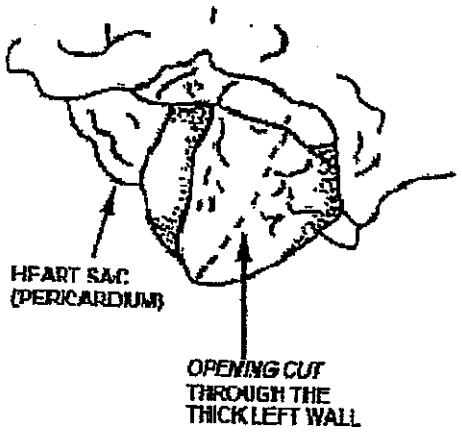
- Observe cranial and caudal mesenteric lymph nodes, and abdominal viscera.
- Observe and palpate rumino-reticular junction.
- Observe esophagus and spleen.

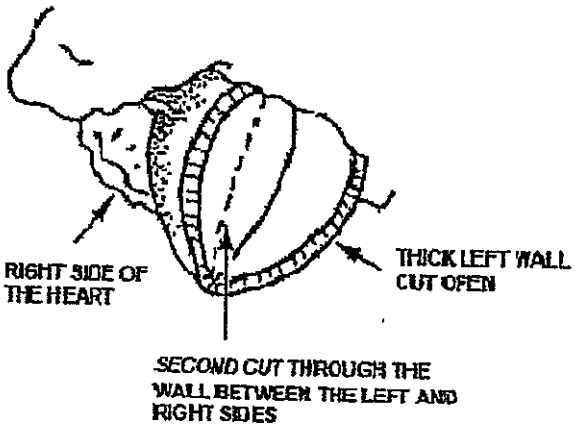


- Incise and observe right and left cranial, middle, and caudal mediastinal lymph nodes and tracheobronchial lymph nodes.
- Observe and palpate costal (curved) surfaces of lungs.



- Incise heart, from base to apex or vice versa, through the interventricular septum, and observe cut and inner surfaces.
- Turn lungs over; observe ventral (flat) surfaces and heart's outer surface.
- Incise and observe hepatic (portal) lymph nodes.
- Observe bile duct in both directions and observe its contents.
- Observe and palpate ventral surface of liver.
- Turn liver over, palpate renal impression, observe and palpate parietal (dorsal) surface.

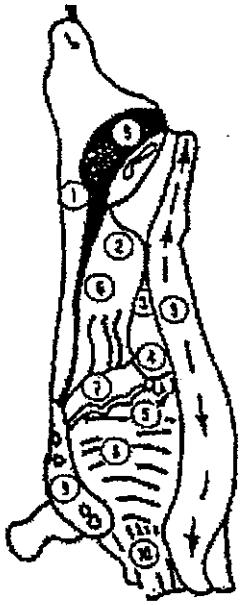




C. Carcass Inspection

The following steps are performed during postmortem carcass inspection.

- Palpate superficial inguinal, (supramammary) and internal iliac lymph nodes.
- Observe lumbar region.
- Observe and palpate kidneys.
- Observe diaphragm's pillars and peritoneum.
- Observe and palpate diaphragm.
- Observe pleura, cut surfaces of muscles and bones, neck, and carcass exterior.



1. PALPATE THE SCROTAL (SUPERFICIAL INGUINAL) OR MAMMARY (SUPRAMAMMARY) LYMPH NODES

2. PALPATE THE MEDIAL (INTERNAL) ILIAC LYMPH NODES

3. OBSERVE THE LUMBAR REGION

4. OBSERVE AND PALPATE THE KIDNEYS

5. OBSERVE THE PILLARS OF THE DIAPHRAGM

6. OBSERVE THE PERITONEUM

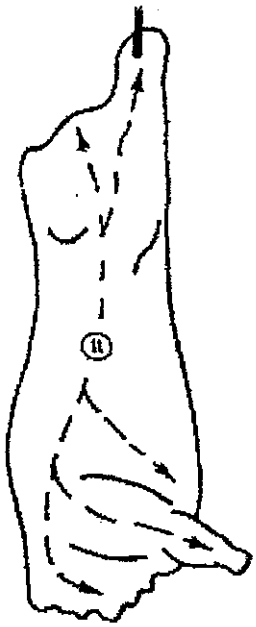
7. OBSERVE AND PALPATE THE DIAPHRAGM

8. OBSERVE THE PLEURA

9. OBSERVE THE CUT SURFACES OF MUSCLES AND BONES.

10. OBSERVE THE NECK MUSCLES

11. OBSERVE THE OUTSIDE OF THE CARCASS.



F:\4-Policy\BSE\FSC Review - June 05\USG responses\Information requested by OIA FSIS - 6-27.doc

[カナダ]

Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Canadian Food Inspection Agency
Animal Products Directorate
Food of Animal Origin

Meat Hygiene Manual of Procedures

Search...

This electronic version of the Meat Hygiene Manual of Procedures was prepared as a reference document for inspectors of the Canadian Food Inspection Agency (CFIA) and all other stakeholders in the Canadian meat hygiene program. The reader should note that, for a complete source of detailed documentation, this manual should be consulted in conjunction with the appropriate legislation, manuals and other reference works.[more...]

- If you would like to purchase a print copy of this Manual, click here for the Order Form (in PDF format)

Meat Hygiene Directives

- If you would like to receive e-mail notification of new directives, click here

- Canadian Microbiological Baseline Survey of Chicken Broiler and Young Turkey Carcasses June 1997 - May 1998

Introduction

This electronic version of the Meat Hygiene Manual of Procedures was prepared as a reference document for inspectors of the Canadian Food Inspection Agency (CFIA) and all other stakeholders in the Canadian meat hygiene program. The reader should note that, for a complete source of detailed documentation, this manual should be consulted in conjunction with the appropriate legislation, manuals and other reference works.

The Manual contains information covering policies on the importation, exportation and interprovincial trade of meat products in addition to policies concerning the preparation of meat products in establishments licensed under the 1990 Meat Inspection Act and Regulations.

The Meat Hygiene Manual of Procedures is amended on a regular basis, and you will find changes to the Manual and the office consolidations of the l990 Meat Inspection Act and Regulations in the MHD section (Meat Hygiene Directives). Each meat hygiene directive is identified by a number composed of the calendar year followed by a figure indicating the order in which it was issued.

Canadian Food Inspection Agency
Meat Hygiene Manual of Procedures

Chapter 4 - Inspection Procedures, Dispositions, and Monitoring and Controls

- 4.4.6 Enforcement actions by inspectors

4.5 Dressing procedures

- 4.5.1 Dressing procedures for cattle
- 4.5.2 Dressing procedures for swine
- 4.5.3 Dressing procedures for poultry - For ratites (ostrich, rhea, emu) see Section 4.5.3(f)
- 4.5.4 Dressing procedures for calves
- 4.5.5 Dressing procedures for sheep, lambs and goats
- 4.5.6 Dressing procedures for horses
- 4.5.7 Dressing procedures for domesticated rabbits
- 4.5.8 Policy on partial dressing of food animals in registered establishments to respond to special requests
    - 4.5.8 (1) Lambs and kids
    - 4.5.8 (2) Head and feet-on poultry carcasses pattes
    - 4.5.8 (3) Head-on rabbit carcasses

4.6 Postmortem inspection

- 4.6.1 Postmortem inspection of cattle carcasses
- 4.6.2 Postmortem inspection of hog carcasses
- 4.6.3 Postmortem inspection of poultry carcasses
- 4.6.4 Postmortem inspection of calf carcasses
- 4.6.5 Postmortem inspection of sheep, lamb and goat carcasses
- 4.6.6 Postmortem inspection of horse carcasses
- 4.6.7 Postmortem inspection of carcasses of domesticated rabbits
- 4.6.8 Postmortem inspection of reindeer, caribou and musk ox carcasses
- 4.6.9 Bacteriological monitoring

4.7 Summary of dispositions

- 4.7.1 Disposition codes
- 4.7.2 Red Meat Species
    - 4.7.2.1 Diseases and conditions diagnosed by organoleptic examination of carcasses and portions thereof and/or reported to the Meat and Poultry Products Division
    - 4.7.2.2 Diseases and conditions generally diagnosed and reported based on laboratory analysis (histopathology, culture, serology, residues testing, etc.)
    - 4.7.2.3 Reportable diseases (Red Meat Species)
- 4.7.3 Poultry species
    - 4.7.3.1 Diseases and conditions diagnosed by organoleptic examination of carcasses and portions thereof and/or reported to the Meat and Poultry Products Division
    - 4.7.3.2 Diseases or conditions generally diagnosed and reported based on laboratory analysis (histopathology, culture, serology, residues testing, etc.)
    - 4.7.3.3 Reportable diseases (Poultry Species)
- 4.7.4 Specific Postmortem/Antemortem Conditions
- 4.7.5 Carcasses rejected by the processing plant operator
- 4.7.6 Determination of the number of carcasses to examine for in-depth inspection of suspect poultry carcasses

4.8 Preparation of offal and other detached portions for edible purposes, for animal food, for pharmaceutical or research use

4.3 Antemortem examination and Antemortem inspection

4.3.4 Procedures

(a) Operator' s Antemortem screening

The operator is responsible for an initial antemortem screening of food animals upon their arrival at the slaughter establishment. Control programs (e.g. HACCP plans) must be established to ensure the proper delivery of this activity.

Plant management is responsible for segregating food animals showing visible abnormalities from normal animals and placing the abnormal animals in designated (suspect) pens upon their arrival at the plant (except for rabbit, chicken, duck, goose, guinea fowl, partridge, pheasant, pigeon, quail or turkey). The lot identity, number screened and number of suspects should be recorded preferably on form CFIA 1438.

Plant employees performing this function must have been trained to do so according to terms of the document entitled "Introduction to Antemortem for Plant Employees" (Annex I).

The operator is also responsible for segregating herds or flocks that are brought to his attention by the seller as having received treatment prior to slaughter when a doubt exists whether or not the observed withdrawal time was sufficient to clear the medication from tissues. All animals with an history of having been treated with a veterinary drug or exposed to a chemical contamination in such a way that their tissues could be unfit for human food, must be held at ante-mortem and considered as suspect animals as defined in the section c) (Suspect animals).

The operator shall :

(i) if the operator has not implemented a HACCP system (FSEP), develop, implement and maintain a control program; or

(ii) if the operator has implemented a HACCP system, reassess the HACCP plans to ensure the hazard associated with veterinary drugs is identified on the list of chemical dangers (FSEP Form 6 or equivalent) and that proper CCPs are clearly identified,

to ensure that animals received and slaughtered, and carcasses and their parts processed in the establishment are in compliance with the applicable requirements respecting the use of veterinary drugs in Canada. Additional specific controls are required respecting the use of hormonal growth promotants in veal calves; consult Chapter 5 of this manual for details.

(b) CFIA Antemortem Inspection

All normal food animals (including ratites) shall be inspected by an inspector while they are at rest and 5 to 10% of such animals from several lots shall be examined on both sides, front and rear while in motion. Records should be kept indicating those lots examined in motions. This information could be indicated on the CFIA 1438. In the case of rabbits and poultry, observation in crates is sufficient for routine examination. The droppings present in the crates should also be observed. During this phase of antemortem inspection, all animals seen to be exhibiting evidence of disease or deviation from normal must be segregated and set aside for detailed veterinary inspection. All identified reactors must be segregated at the time of arrival at the establishment.

N.B.: For establishments exporting to the European Union (E.U.), or to countries demanding inspection to E.U. requirements, a veterinarian must perform antemortem inspection on all animals, both normal and abnormal (subject) animals.

Lots which pass initial antemortem inspection must be identified by means of a lot card, drive card or preferably, form CFIA 1438, all of which should record the following information:

(i) the number of animals in the lot

(ii) the time and date of inspection

(iii) the signature or initials of the inspector who performed the antemortem screening.

All animals screened out by the operator or held by the inspector are to be subjected to a detailed veterinary inspection and, when judged necessary, are to be suitably restrained for this purpose. Based on his findings, the veterinarian will make one of the following dispositions:

(i) the animal is to be permitted to proceed for normal slaughter;

(ii) the animal is to be set aside for rest and/or treatment, or to go through an appropriate withdrawal time if a veterinary medication residue is a cause of concern, prior to slaughter, and further antemortem inspection, as appropriate;

(iii) the animal is to be deemed a suspect and is to be set aside for separate slaughter, along with other suspects, preferably at the end of normal slaughter;

(iv) the animal is to be deemed a suspect but, for humane reasons, is to proceed for immediate slaughter;

(v) the animal is to be condemned.

4.6 Postmortem inspection

(a) Head inspection

The head must be examined before the carcass has passed the final inspection station. The head shall be presented with all lymph nodes in situ and exposed for proper postmortem inspection. The inspection shall not commence until the head is clean, properly prepared, (free of hair, pieces of skin, contamination, horns, tonsils removed, etc.) and presented in a satisfactory manner.

The inspector shall perform a visual examination to detect any dressing defect and abnormality. This visual examination should include the eyes and tongue.

The tongue shall be palpated to detect abscesses, actinobacillosis, and other abnormal conditions. Localized conditions, such as scars, grass awn lesions etc. that have been approved by the VIC shall be trimmed from the tongue by company employee(s).

Incisions shall be made through the centre of the internal pterygoid and external masseter muscles. Such incisions should be made parallel to the mandible and extend through at least 90% of the length of the muscle. This is done to detect parasitic lesions, but other lesions may be revealed as well.

The retropharyngeal medial, atlantal (retropharyngeal lateral), parotid and mandibular lymph nodes are to be exposed, examined visually and carefully incised. In every case, the head shall remain available for disposition until postmortem examination of the corresponding carcass is complete.

The inspector shall frequently check that all heads are properly identified with CFIA 1467's to maintain carcass-head identity.

(b) Thoracic and abdominal viscera inspection

The lungs should be visually inspected and palpated to detect chronic pneumonia, abscesses, tumors, etc. The right and left bronchial, cranial and caudal mediastinal lymph nodes shall be incised and examined.

The liver shall receive a visual inspection and be thoroughly palpated. The hepatic lymph nodes shall be incised and examined. The hepatic ducts shall be opened longitudinally and inspected for the presence of liver flukes.

The exterior of the heart shall be visually inspected. The interior of the heart (i.e. the valvules) and the heart musculature of all cattle and calves over the age of six weeks shall be visually inspected by one of the following methods:

(i) By making one incision in the musculature that passes through the interventricular septum from base to apex in order to open the heart and expose both ventricules.

(ii) By everting the heart and making 3 shallow incisions in the heart musculature.

Any animals suspected of being affected with C. bovis or where the inspector or veterinarian considers that extra incisions of the heart are required to detect defects or reach a diagnosis shall be subject to extra inspection procedures as deemed necessary.

The mesenteric lymph nodes are to be visually examined. The mesenteric lymph nodes should only be incised by the line inspector when an animal is suspected of being affected with M. bovis or when a carcass is held for veterinary examination or when the inspector or veterinarian have found lesions in other lymph nodes during the routine inspection.

The spleen shall be visually examined and palpated; it may be incised if a complete examination is found to be necessary. Kidneys may be examined, either in the carcass or on the viscera table; in either case they shall be fully exposed by the operator prior to inspection and visually examined by the inspector.

A visual examination should be made of the oesophagus and trachea. Whenever lesions suspicious of cysticercus infestation are found elsewhere in the carcass, the oesophagus shall be subjected to a thorough examination. The reticulum, rumen, omasum and abomasum are to be visually inspected. The rumino-reticular junction shall be visually examined to detect any abnormalities that may affect this area of the gastro-intestinal tract such as existing inflammatory conditions, abscesses, presence of protruding foreign bodies as a result of reticular puncture, etc.

An examination shall also be carried out of omental, mesenteric, and any other fatty tissues being saved for edible purposes to ensure freedom from contamination.

There shall be synchronization and identification control between the viscera and the carcass until inspection of both has been completed. Care must be taken to ensure that the viscera of one carcass do not come in contact with those of another until inspection is completed.

Products unsatisfactory for human food which are harvested for animal food must be segregated from products approved for human consumption.

(c) Carcass inspection

After the viscera have been removed and the carcass has been split, but before trimming and washing, every dressed carcass shall be subjected to a careful inspection, externally and internally. A dedicated inspection station shall be provided for the routine on-line carcass inspection as

specified in Chapter 2 Annex E/1.

Although the visual inspection of the joints and outer muscular surfaces will reveal most lesions, the body cavities, the diaphragm and its pillars, the peritoneum, the pleura and the neck shall be observed during the routine on-line carcass inspection. If the kidneys have been left in the carcass, they shall be observed. The spinal cord shall have been completely removed from split carcasses.

When significant deviations from the normal are observed, the dressed carcass and all parts detached previously shall be held and referred to a veterinarian for final inspection and disposition. (Specific guidance can be found in Training Module A-10 "Basic Post Mortem Pathology of Beef/Veal.") It should be noted that it is permissible for an inspector to condemn stomachs and intestines that appear normal instead of holding them, when satisfactory holding facilities are unavailable. Veterinary examination includes assessing the degree of involvement in the case of many diseases and conditions. In order to determine if a disease or condition is localized or generalized, the appropriate lymph nodes shall be examined. These may include prepectoral, prescapular, renal, superficial inguinal, supramammary, internal iliac, prefemoral, popliteal, and sacral.

②代表的ＳＳＯＰとＨＡＣＣＰの見本

[米国]

Beef Food Safety & Quality Assurance

SYSTEMS AND PROGRAMS

Index: Beef Slaughter	Number: 2.2.12	
2.2 Carcass	Issued:	Replaces:
Beef Dentition / Age Segregation	BSE Precautionary Program	
PRE-REQUISITE	X	
SSOP		
HACCP		
PROCEDURE		
ADMINISTRATIVE		
GUIDANCE		

1.0 PURPOSE

This program has been established to define procedures to verify the age of cattle from a visual assessment of bovine teeth [dentition].

2.0 APPLICATION

This policy is applicable for all cattle slaughtered and to be applied by the Plant Manager or designee.

3.0 REFERENCES

3.1 9CFR§310.22(a)(1)
3.2 Specified Risk Material Control Program [2.2.13]
3.3 BSE Precautionary Program

4.0 BACKGROUND

4.1 On January 12, 2004, USDA-FSIS issued new regulatory policy defining SRM's of Beef Cattle

5.0 PROCEDURE

5.1 A trained monitor [Quality Assurance or Designee] will be placed prior to USDA head inspection to visually assess all carcasses for age.
5.2 Age will be determined by dentition assessment.
5.3 Cattle 30 Months of age and older will be identified by the following parameters.
5.3.1 Three permanent incisors are present.
5.3.2 One tooth of the second pair of incisors is erupting.
5.3.3 Two pairs of permanent incisors.
5.4 Cattle identified to be 30 months of age and older will be marked with edible ink.
5.5 If an animal is 'questionable' or 'undeterminable' it is to be identified as 'Mature' and subjected to subsequent skeletal maturity verification as identified in the corrective action section of this document [Section 9.1.2.2].

6.0 VERIFICATION

6.1 Prior to the start of operations Quality Assurance will generate a random timetable to determine the audit time frames.
6.2 Sample Group: 10 heads 1x/hour of production.
6.3 During production, 10 heads will be visually assessed to determine carcass age.
6.4 Cattle with the first pair of permanent incisors present is over 24 months and under 30 months of age. The following will denote cattle over 30 months of age:
6.4.1 Three permanent incisors are present.
6.4.2 One tooth of the second pair of incisors is erupting.
6.4.3 Two pairs of permanent incisors.

Beef Food Safety & Quality Assurance

SYSTEMS AND PROGRAMS

Index: Beef Slaughter	Number: 2.2.13	Page 1 of 3
2.2 Carcass	Issued:	Replaces:
SRM Control Program	BSE Precautionary Program	
PRE-REQUISITE	X	
SSOP		
HACCP		
PROCEDURE		
ADMINISTRATIVE		
GUIDANCE		

1.0 PURPOSE

To address the regulatory requirements for SRM [Specified Risk Material] removal, control, and disposal.

2.0 APPLICATION

This policy is applicable to all Facilities and to be applied by the Quality Assurance Manager or designee.

3.0 REFERENCES

3.1 9CFR§310.22

3.2 Beef Dentition Program 2.2.12

3.3 USDA Specific Risk Material (including skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord and dorsal root ganglia of cattle **30** months of age and older and the small intestine distal ileum and tonsil of all ages).

4.0 BACKGROUND

4.1 On January 12, 2004, USDA-FSIS issued new regulatory policy defining SRM's of Beef Cattle.

5.0 PROCEDURE [SLAUGHTER]

5.1 A trained team member, who is knowledgeable and able to recognize the second set of permanent incisor teeth, examines the teeth prior to head inspection to determine age.

5.1.1 If the age of the animal is determined to be 30 months of age and older, the carcass will be identified as such post hide pulling via identification with a "circle-3" on both hindquarters and both forequarters and a mark on the neck [dorsal from wither to atlas] with edible blue marking ink. The head will be identified with a blue mark on the 'nose' of the head post hide pulling. The carcass will then be further identified prior to the completion of the slaughter process with the use of a ribbon tied onto the front shank [under the tendon and tied on bottom].

5.1.2 The head dropper / de-jointer will be required to sanitize equipment after each animal.

5.1.3 The head hooks will be required to be sanitized in 180°F water between each head.

5.1.4 Heads with seepage of brain tissue [knock-hole from captive bolt or de-horn fracture] or eyes will not be processed through the head wash or allowed on the head table. Heads of this nature will be inspected off-line by USDA and disposed of into inedible rendering, landfill, or incineration.

Beef Food Safety & Quality Assurance

SYSTEMS AND PROGRAMS

Index: Beef Slaughter	Number: 2.2.15	Page 1 of 2
2.2 Carcass	Issued:	Replaces:
Spinal Cord Removal	BSE Precautionary Program	
PRE-REQUISITE	X	
SSOP		
HACCP		
PROCEDURE		
ADMINISTRATIVE		
GUIDANCE		

1.0 PURPOSE

To define spinal cord removal procedures and verification activities.

2.0 BACKGROUND

Requires spinal cord to be completely removed from the beef carcass. Spinal cord is identified is an SRM [Specified Risk Material] for BSE in carcasses 30 months of age and older.

3.0 REFERENCE

3.1 9 CFR 310.22 (a)(1)

3.2 USDA Directive 7160.3

4.0 DEFINITION

4.1 Spinal cord removal applies to the actual "cord-like" material present in the vertebrae column groove after the carcass is split. This is not to be confused with sheath. Sheath is the thin outer covering that spinal cord is contained with-in.

5.0 PROCEDURE

5.1 Slaughter

5.1.1 Spinal cords will be removed in slaughter, before the carcass wash.

5.1.2 Either manual systems or suction equipment are acceptable methods for removal.

5.1.3 Spinal cord material is to be disposed to inedible rendering

5.1.4 Removal processes must address the spinal cord removal from the entire backbone from the neck area back through the loin.

5.1.5 Mis-splits [closed spinal column] are to be corrected with the use of a vertebral saw.

5.1.6 Mis-splits that can not be corrected are identified on the slaughter side must be identified with blue ink on the backbone for subsequent diversion to inedible rendering on cattle that are 30 months of age and older.

5.2 Processing

5.2.1 Neck bones or vertebrae, which contain spinal cords, are not to be processed through any AMR systems.

5.2.2 Plant programs must be in place to ensure that spinal cords are completely removed before bones are processed through the 1st step "pre-sizer".

5.2.3 Mis-splits or bones in which the spinal cord has not been completely removed must be sorted out of the AMR process before the "pre-sizing" or featherbone saw step. Such bones may be whizzard trimmed.

5.2.4 Vertebrae bones with spinal cord remaining CANNOT be diverted into edible product, Edible Rendering, or BPI product unless the spinal cords are removed.

Beef Food Safety & Quality Assurance

SYSTEMS AND PROGRAMS

Index: Beef Slaughter	Number: 2.2.16	Page 1 of 2
2.2 Carcass	Issued:	Replaces:
Live Cattle Receiving / Non-Ambulatory	BSE Precautionary Program	
PRE-REQUISITE	X	
SSOP		
HACCP		
PROCEDURE		
ADMINISTRATIVE		
GUIDANCE		

1.0 PURPOSE

To detail the handling of non-ambulatory, injured, BSE Sampled [Headless], or rejected animals delivered to a facility. A number of actions are available for each situation listed. The action used will depend on individual circumstances and if the animal is obviously suffering.

2.0 SPECIAL INSTRUCTIONS

2.1 If a non-ambulatory animal is either on or off the truck it must be stunned immediately, bled and sent to off-site rendering, incinerator, landfill, or alkaline digestion.

2.2 "NEVER DRAG A SENSIBLE ANIMAL"

3.0 NON-AMBULATORY ANIMALS DELIVERED DURING PRODUCTION HOURS

3.1 Dead on Arrival

3.1.1 The animal must be assessed to assure it is dead. If there is any question or doubt, it must be stunned to assure it is dead, before disposing it to an off-site rendering facility. Dead-on-Arrival animals are not permitted into a Rendering Facility under any circumstances.

3.2 Non-Ambulatory and Still on the Truck

3.2.1 The animal will be stunned and bled then dispatched to an off-site rendering facility.

3.2.2 USDA is to be notified of any rejected Non-Ambulatory animal. The animal **IS TO BE retained** until USDA gives direction as to whether the animal will be subjected to testing for BSE. Reference 9CFR 311.27

3.2.3 Non-Ambulatory on arrival animals are not permitted into a [redacted] Rendering Facility under any circumstances.

3.2.4 Any Non-Ambulatory animals rejected are to be sent to a landfill, incineration, or alkaline digestion.

4.0 NON-AMBULATORY IN THE YARDS

4.1 Injured – Not USDA Ante-Mortem Inspected and Passed.

4.1.1 The animal will be stunned and bled then dispatched to an off-site rendering facility. Non-Ambulatory on arrival animals are not permitted into a Rendering Facility under any circumstances.

4.2 USDA CNS Suspect [SAMPLED FOR BSE or HEADLESS]

4.2.1 Refer to Headless Cattle Procedure [Reference Beef Program 2.2.14 Section 3.1.5]

4.2.2 Plant will stun/bleed/denature animal on-premise [but do not bring into plant proper],

010904 Prohibited Feed SOP v2.doc "Prohibited Feed" Program SOP \
Effective: Replaces

PURPOSE:	Suppliers of slaughter cattle must certify non-use of "prohibited mammalian protein" in their cattle finishing rations (i.e., ruminant meat & bone meal). In 1997, FDA banned the use of such ingredients in feed for ruminant animals. The FDA ban was implemented to prevent the introduction of BSE (Bovine Spongiform Encephalopathy) into the U.S. cattle herd. This initiative is intended to support U.S. efforts to keep the nation's cattle herd BSE-free.
PROCEDURE:	All direct suppliers of cattle are required to certify their compliance to the FDA ruminant feeding ban for "prohibited mammalian protein" (ruminant meat & bone meal). This requirement applies to the owner/agent of cattle that are slaughtered at any beef slaughter facility (USA & Canada).
FDA REQUIRMENTS	Cattle feeders are required to keep invoices and labeling for all feed they receive that contains animal protein products, whether or not the animal protein is prohibited (required by CFR 589.2000). www.access.gpo.gov/nara/cfr/waisidx_00/21cfr589_00.htm

AFFIDAVITS - FREQUENCY:	"Prohibited Feed" Affidavits are required initially for all current suppliers (by 04/01/01). "New" suppliers (after 04/01/01) are required to complete affidavits before cattle are slaughtered. Affidavits must be renewed annually for all cattle suppliers.	<
MONITORING:	Verification of this program will monitored as follows: 1. Affidavit Audit: Will conduct random audits of direct cattle suppliers for *signed and current* "Prohibited Feed Affidavit". This will apply to cattle slaughtered at facilities within 6 months of when the audit is initiated. This audit will be conducted minimally twice per year. 2. Feedlot Audit: Individual cattle suppliers will be randomly selected for an on-site "feeding record" audit. These reviews will consist of an audit of feedlot rations for presence/absence of animal proteins, and associated review of purchase invoices and labels of feeds containing any animal protein products. This will apply to cattle slaughtered at facilities within 6 months of when the audit is initiated. This audit will be conducted minimally twice per year.	
BQA EXEMPTION	Feeders participating in sanctioned Beef Quality Assurance (BQA) programs, and that have a defined CCP for "prohibited mammalian proteins", can be exempted from the "Feedlot Audit". BQA status must be current and an audit of the "prohibited protein" CCP conducted within the past 12 months.	<
NON- COMPLIANCE	If a current, signed affidavit from an owner/agent is not on-record with, cattle will not be slaughtered until the "Prohibited Feed" affidavit is completed.	<

F:\4-Policy\BSE\FSC Review - June 05\USG responses\MEF responses\Prohibited Feed SOP v2.doc

With the implementation on January 12, 2004, of the regulation (9 CFR 310.22) to remove, segregate, and dispose of specified risk materials (SRMs), establishments had to reassess their HACCP programs to determine what steps, if any, were necessary to ensure that their products were free of materials that present the risk of transmitting BSE. Each establishment had to conduct a hazard analysis to assess whether the threat of the BSE agent was reasonably likely to occur. On the basis of these analyses, establishments could elect to incorporate SRM removal in their HACCP plans, Sanitation Standard Operating Procedures (SSOPs), or other prerequisite programs to address SRM removal.

As SRM removal is a regulatory requirement, FSIS Public Health Veterinarians (PHVs) were to verify into which program (i.e., HACCP plan, SSOPs, or prerequisite programs) the establishments incorporated their SRM removal procedures. If an establishment determined that SRMs were a hazard reasonably likely to occur in the process, the PHV was to verify that the establishment had designed controls and incorporated them into its HACCP plan. If an establishment determined that SRMs were not a hazard reasonably likely to occur because of procedures in SSOPs or prerequisite program, the PHV was to verify that the procedures and documentation supporting the establishment's determination were available for review.

Many plants determined that on the basis of the Harvard Risk Assessment that the current risk of transmitting BSE in the United States is very low, so they have chosen to control SRM removal through their SSOPs or prerequisite programs rather than their HACCP plans. However, as SRM removal is a regulatory requirement, the establishments must nonetheless monitor and verify this process on an ongoing basis; keep records of the process; and take corrective actions when needed just as it would do under a HACCP plan.

Inspection program personnel verify that establishments have incorporated appropriate procedures into one of their programs as well as ensure the proper execution of the SRM-removal regulation through verification activities related to SRM removal, including the review of plants' monitoring records; observation of plant employees performing procedures; as well as through inspection of carcasses. If inspection personnel note noncompliance with the regulation, they issue noncompliance reports. And because SRM removal is a regulatory requirement, PHVs can take any number of regulatory actions if corrective actions are not taken by the plants, including retention and condemnation of the carcass at post-mortem inspection or suspension of plant operations in order to ensure that no adulterated products enter commerce.

Therefore, even when SRM removal is conducted under SSOPs or prerequisite programs instead of HACCP plans, the oversight by FSIS is much the same. Inspection personnel still verify establishments' monitoring procedures and corrective actions as well as their record-keeping and documentation procedures. Additionally, PHVs have authority to take action if plants are not in compliance with the regulation.

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

FSIS NOTICE	9-04	1-23-04

VERIFICATION INSTRUCTIONS FOR THE INTERIM FINAL RULE REGARDING SPECIFIED RISK MATERIALS (SRMs) IN CATTLE

I. PURPOSE

This notice provides Veterinary Medical Officers (VMOs) with the methodology to use when verifying that an establishment has properly designed procedures to meet the requirements of 9 CFR 310.22 for the removal, segregation, and disposition of specified risk materials (SRMs). Also, this notice provides inspection program personnel with instructions for verifying that an establishment is executing its programs so that there is proper removal, segregation, and disposal of SRMs.

NOTE: At some establishments that do not slaughter but that process bone-in parts of cattle carcasses, an Enforcement Investigation Analysis Officer may be called upon to perform the verification of the design of the procedures in the absence of an available VMO.

II. REGULATORY REQUIREMENTS

A. What are the regulatory requirements related to SRMs?

9 CFR 310.22(a) defines SRMs as:

(1) the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia (DRG) of cattle 30 months of age and older, and

(2) the tonsils and the distal ileum (for which removal of the distal ileum must be achieved by disposing of the entire small intestine) of all cattle.

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt; T/A Plant Mgt; TRA; ABB; TSC, Import Offices	NOTICE EXPIRES: 2-01-05	OPI: OPPD

9 CFR 310.22(b) and (c) state that SRMs are inedible and shall not be used for human food and shall be disposed of in accordance with 9 CFR 314.1 and 314.3.

B. What are establishments required to do in regard to SRMs?

9 CFR 310.22 states that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall develop, implement, and maintain written procedures that are incorporated into their HACCP plan, or in their Sanitation SOP or other prerequisite program for the removal, segregation, and disposal of SRMs.

III. VERIFICATION FOR THE DESIGN OF PROCEDURES FOR SRMs

A. As described in FSIS Notice 4-04, VMOs are to verify that an establishment has reassessed its hazard analysis to determine what steps, if any, are necessary to ensure that its products are free of materials that present a risk of transmitting BSE.

B. VMOs are to verify into which programs (i.e., HACCP plans, Sanitation SOPs, or prerequisite programs) the establishment incorporated any procedures adopted as a result of its reassessment. All establishments may include their procedures in one or more of these programs.

1. If an establishment determines that SRMs are a hazard reasonably likely to occur in its process, VMOs are to verify that the establishment has designed controls and incorporated them into its HACCP plan in accordance with 9 CFR part 417.

2. If an establishment determines that SRMs are not a hazard reasonably likely to occur because of procedures in its Sanitation SOPs, VMOs are to verify that the procedures and documentation supporting the establishment's determination are available for review under 9 CFR 416.14 and 417.5.

3. If an establishment determines that SRMs are not a hazard reasonably likely to occur because of procedures in a prerequisite program that the establishment has implemented, VMOs are to verify that the procedures and supporting documentation are available for review under 9 CFR 417.5.

C. VMOs should verify that the establishment has designed its monitoring, verification, recordkeeping, and corrective actions, including reassessment as appropriate, to effectuate its HACCP plans, Sanitation SOPs, and other supporting prerequisite programs.

D. Examples of questions that may be asked to verify the design of the establishment's procedures to remove, segregate, and dispose of SRMs include:

1. Has the establishment adopted procedures designed to identify the cattle to be slaughtered that are 30 months of age and older?

NOTE: If the establishment identifies in its hazard analysis that all cattle will be considered 30 months of age and older, it is not necessary for the establishment to have evidence about the proof of the age of the cattle.

2. Has the establishment adopted procedures designed to ensure the complete and proper removal of SRMs?

3. Has the establishment adopted procedures designed to ensure that SRMs are segregated from edible product?

4. Has the establishment adopted procedures designed to ensure that SRMs are disposed of in a manner that will prevent cross-contamination with edible product?

NOTE: The vertebral columns from cattle 30 months of age and older do not have to be removed during the slaughter operation. However, if they are not removed in the slaughter operation, procedures should be put in place to ensure that the vertebral columns are adequately identified as being from cattle 30 months of age and older, and that the means of identification transfers with the vertebral columns until they are appropriately disposed of as inedible.

5. Has the establishment adopted control procedures designed either (1) to not allow bone-in beef from cattle 30 months of age and older into the establishment, or (2) to ensure that such product (e.g., vertebral columns for AMR) is handled in an appropriate manner (e.g., by ensuring that SRMs are removed and disposed of appropriately)? Has the establishment implemented verification measures to ensure that the control procedures are followed?

E. If an establishment has failed to reassess its hazard analysis, the VMOs should document in a decision memorandum to the District Office (DO) the evidence to support the issuance of a Notice of Intended Enforcement Action (NOIE).

IV. VERIFICATION PROCEDURES FOR INSPECTION PROGRAM PERSONNEL

A. Inspection program personnel are to verify the proper execution of the HACCP plans or the prerequisite programs, while conducting HACCP 01 or 02 procedures as set out in FSIS Directive 5000.1, Revision 1, or while verifying the effectiveness of Sanitation SOPs under 01B or 01C procedures. Inspection program personnel are to perform the verification activities related to SRM removal in conjunction with the other food safety concerns by reviewing records (e.g., looking at HACCP monitoring records), observing plant employees performing procedures (e.g., observing plant employee performing a dentition examination), or by conducting hands-on inspection verification procedures (e.g., verify adequacy of Sanitation SOP procedures).

B. Inspection program personnel should verify that the establishment is conducting monitoring, verification, recordkeeping, and corrective actions, including reassessment as appropriate, to effectuate its HACCP plans, Sanitation SOPs, and other supporting prerequisite programs.

C. Post-mortem on-line verification duties

Head and Carcass inspection:

1. When on-line inspection program personnel perform individual carcass or head inspection and observe visible (readily identifiable) SRMs on edible portions of the product, the establishment may recondition the entire carcass or head by knife trimming.

2. On-line inspection program personnel are to notify the VMO or, if unavailable, other off-line inspection program personnel when there is evidence that an establishment's SRM control program is ineffective (for example, when repeated presentation of contaminated heads or carcasses for post-mortem inspection at the rail and head inspection station indicates failure to control SRM contamination).

3. The VMO or other off-line personnel will perform the appropriate HACCP or Sanitation SOP procedures to evaluate the process.

V. ENFORCEMENT

What enforcement actions do inspection program personnel take when finding noncompliance?

If VMOs or off-line personnel determine the process failed to prevent SRMs from adulterating product, they are to issue a NR under the appropriate procedure code and mark the appropriate trend indicator as described in FSIS Directive 5000.1, Revision 1, Chapters I (Sanitation) II (HACCP) and IV (Enforcement) and verify that the establishment takes the corrective actions required by 9 CFR 417.3(a) or (b) or 416.15. If the procedures are under a prerequisite program, inspection program personnel are to verify that the establishment reassesses the HACCP plan to determine whether the decisions made in the hazard analysis continue to support the use of the prerequisite program.

If the establishment does not properly implement procedures (e.g., recordkeeping), inspection program personnel are to issue a NR under the appropriate procedure code and mark the appropriate trend indicator as described in FSIS Directive 5000.1, Revision 1, Chapters I (Sanitation) II (HACCP) and IV (Enforcement) and verify that the establishment takes the immediate and further planned actions to correct the noncompliance.

Refer questions to the Technical Service Center.

/s/ Philip S. Derfler

Assistant Administrator
Office of Policy and Program Development

Types of questions inspection program personnel may seek answers to while verifying that an establishment is properly executing its procedures to remove, segregate, and dispose of SRMs.

1. Is the establishment properly implementing its procedures to segregate animals 30 months of age and older?

NOTE: If the establishment identifies in its hazard analysis that all cattle will be considered 30 months of age and older, it is not necessary for the establishment to have evidence about the proof of the age of the cattle.

2. Is the establishment properly implementing its written procedures to remove, segregate, and dispose of SRMs?

3. Is the establishment cleaning and sanitizing equipment, (e.g., cleaning and sanitizing the splitting saw prior to use on cattle younger than 30 months if used after slaughtering cattle 30 months of age and older)?

4. Is the establishment maintaining daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of SRMs?

5. Is the establishment including documentation with the shipped products identifying them as from cattle 30 months and older? Has it considered this step in its hazard analysis? Does it have procedures to ensure that the SRMs are removed at the receiving establishment?

6. Is the establishment routinely evaluating the effectiveness of their procedures for the removal, segregation, and disposition of SRMs in preventing the use of these materials for human food?

7. If an establishment determines that its process failed to remove SRMs, inspection program personnel are to verify that the establishment implements corrective actions in accordance with 9 CFR 417.3(a) or (b) (under HACCP), 9 CFR 416.15 (under Sanitation SOPs). If the procedures are under a prerequisite program, inspection program personnel are to verify that the establishment reassesses the HACCP plan to determine whether the decisions made in the hazard analysis continue to support the use of the prerequisite program.

8. Is the establishment taking appropriate immediate and further planned action when it identifies that it failed to properly implement its procedures (e.g., recordkeeping).

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

FSIS NOTICE	5-04	1/12/04

INTERIM GUIDANCE FOR NON-AMBULATORY DISABLED CATTLE AND AGE DETERMINATION

I. PURPOSE

This FSIS notice provides Veterinary Medical Officers (VMOs) guidance for implementing new regulatory requirements regarding non-ambulatory disabled cattle and procedures for determining by dentition whether cattle are 30 months of age and older.

II. BACKGROUND

FSIS issued three regulations and a notice in the Federal Register on January 12, 2004, in response to the diagnosis by USDA of a positive case of Bovine Spongiform Encephalopathy (BSE) in an adult Holstein cow in the State of Washington. These regulations and the notice will prevent human exposure to materials that scientific studies have demonstrated as containing the BSE agent in cattle infected with the disease. This FSIS notice provides VMOs guidance in implementing the policy contained in docket #03-025IF ("Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disable Cattle"), that non-ambulatory disabled cattle are unfit for human food. In addition, this FSIS notice provides VMOs guidance on distinguishing cattle 30 months of age and older from younger cattle. Although cattle of any age must have the tonsils and entire small intestine disposed of as inedible, cattle 30 months of age and older have additional specified risk materials (SRMs) that also may contain the BSE agent in cattle infected with the disease. These SRMs must be disposed of as inedible. Consequently, VMOs must verify that the carcasses and parts of cattle 30 months of age and older are properly identified and handled.

Among other requirements, the new regulations at 9 CFR 309.2(b) state that non-ambulatory disabled livestock, including cattle, are livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column or metabolic conditions. The new regulation at 9 CFR 309.3(e) states that non-ambulatory disabled cattle shall be condemned. Consequently, these cattle, which may be on the premise housing the slaughter establishment, cannot enter the slaughter establishment.

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

FSIS NOTICE	28-04	5/20/04

FSIS SAMPLE COLLECTION FROM CATTLE CONDEMNED DURING ANTE-MORTEM INSPECTION FOR THE BOVINE SPONGIFORM ENCEPHALOPHATHY (BSE) SURVEILLANCE PROGRAM

NOTE: FSIS PERSONNEL ARE NOT TO IMPLEMENT THE SAMPLE COLLECTION PROCEDURES IN THIS NOTICE UNTIL JUNE 1, 2004

I. PURPOSE

This notice contains updated information from FSIS Notice 18-03, dated 5/27/03. That notice expires on 6/1/04. In light of recent events, FSIS will be collecting brain samples from cattle at federally-inspected establishments for the purpose of BSE testing. Therefore, FSIS is issuing new sample collection, documentation, and shipping procedures to inspection program personnel, particularly Public Health Veterinarians (PHVs). Specifically trained FSIS PHVs will collect the brain samples. The samples will be shipped to the USDA Animal and Plant Health Inspection Service (APHIS) National Veterinary Services Laboratory (NVSL) in Ames, Iowa, or another APHIS-designated laboratory.

II. BACKGROUND

BSE is a reportable disease in the United States. In cooperation with FSIS, APHIS leads an ongoing, comprehensive, interagency surveillance program for BSE. Using the Federal Meat Inspection Act, 21 U.S.C. 603, part of the FSIS ante-mortem examination and inspection procedure will include the collection of a brain sample from cattle. For the first time, FSIS PHVs will collect brain samples from cattle that are condemned during ante-mortem inspection at federally-inspected establishments. The APHIS Area Veterinary Inspector-in-Charge (AVIC) will focus upon sample collection activities by APHIS at locations other than federally-inspected establishments (e.g., rendering operations and on-farm). FSIS PHVs will take samples from all cattle showing signs of central nervous system (CNS) disorders, as well as the types of cattle that may be at higher risk for being infected with the agent believed to cause BSE, based, in part, on European data. These cattle, while at federally-inspected establishments, are under the control of FSIS and will have the brain sample collected either by the trained FSIS PHV or an available APHIS technician with direct supervision and oversight by the FSIS PHV.

Under FSIS Notice 18-03 FSIS contacted APHIS whenever specific cattle were presented

③肉質鑑別にあたる検査員の配置状況と作業量

肉質鑑別にあたる検査員の配置状況と作業量

米国からの回答によれば、と畜場毎の食肉格付員の配置数は、と畜場のと畜頭数及び格付けされる枝肉の数に応じて決定され、小規模なと畜場では１名、中規模なと畜場ではシフト毎に２名、大規模なと畜場ではシフト毎に３名が配置される。

1. 諮問に至った経緯、目的、背景の説明

諮問に至った経緯、目的、背景の説明

1　経緯

（1）米国産及びカナダ産の牛肉等の輸入停止

米国については平成15年12月24日、カナダについては平成15年5月21日、それぞれの国内でＢＳＥ感染牛が確認されたため、厚生労働省及び農林水産省は食品衛生法及び家畜伝染病予防法に基づき、同日から牛肉及び牛肉製品等の輸入を暫定的に認めない措置をとった。

なお、ＳＰＳ協定においてはこのような暫定的措置を採用した場合、「一層客観的な危険性評価のために必要な追加の情報を得るよう努めるものとし、また、適当な期間内に当該衛生植物検疫措置を再検討する。」と規定している。

（2）米国産及びカナダ産の牛肉輸入再開に向けた協議

米国でのＢＳＥ感染牛の確認後、厚生労働省、農林水産省及び食品安全委員会事務局（オブザーバー）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。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回に渡り議論を行い、その結果をＢＳＥに関する専門家会議及び実務担当者会合(WG)報告書としてとりまとめた。

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、それぞれの国内の承認手続を条件として、科学に基づいて、双方向の牛肉貿易を再開するとの認識を共有した。日本への米国産牛肉の輸出に関しては、食品安全委員会による審議を含むそれぞれの承認手続を条件とし、米国側が、日本向けの特別なプログラムとして、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。20 ヶ月齢以下の牛に由来する牛肉に限定する輸入条件は当時すでに食品安全委員会に諮問した国内対策の見直し内容を踏まえたものであり、すべての月齢の牛からのＳＲＭ除去とあわせて、BSE 検査が食品安全の観点から必要であるという我が国の主張が考慮されたものである。

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を行い、本年5月24日の諮問に至った。

一方、カナダについても、米国と同様、ＢＳＥ感染牛の確認後の現地調査、ＢＳＥ発生状況やＢＳＥ対策等に関する情報収集の結果を踏まえ、カナダ産牛肉の輸入再開に関し、食品安全委員会による審議を含む国内の承認手続を前提として、①ＳＲＭはあらゆる月齢の牛から取り除かれること、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の輸出基準に関する協議が行われ、本年５月 24 日の諮問に至った。

２　趣旨

食品安全規制は、国内対策、輸入対策いずれにおいても従来から科学的合理性を確保することを基本として行ってきており、食品安全基本法において、施策の策定に当たっては、緊急を要する場合等でなければ、その時点において到達されている水準の科学的知見に基づいて食品健康影響評価が行われなければならないとされている。ＢＳＥ国内対策については、平成 13 年 10 月当時、国際基準、ＥＵ基準、専門家の意見などのほか、牛の月齢が必ずしも確認できなかったこと、国民の間に強い不安があったこと等の状況を踏まえて緊急的に策定したことからその評価が課題となっていたものである。そうした中で昨年９月に食品安全委員会において国内対策の評価・検証結果がまとめられたことから、国内対策の見直しについて同年 10 月に諮問し、本年５月の答申を踏まえ、厚生労働省及び農林水産省がリスク管理機関として手続を進めている。

今回諮問した米国産及びカナダ産の牛肉等の輸入再開に関するリスク評価についても、現在の輸入禁止措置が両国におけるＢＳＥ発生に伴う暫定的なものであったため、日米ＢＳＥ協議で設定した一定の条件の下で、輸入される牛肉等を摂取する場合と国産の牛肉等を摂取する場合のＢＳＥに関するリスクの同等性について最新の科学的知見に基づいた食品健康影響評価を求めるものである。

米国産牛肉については、米国の国内措置のみでは国内と同等のＢＳＥリスクに対する安全性が確保されていることを確認することが困難であることから、日米ＢＳＥ協議において、技術的・専門的視点からの議論を経て、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した牛肉輸出証明プログラムを上乗せ措置として設けることとしたものである。

カナダ産牛肉についても同様の考え方によるものである。

なお、輸入を再開した場合には厚生労働省及び農林水産省が現地査察を実施し、日本向け牛肉の管理プログラムが適切に機能しているか確認することとしている。

厚生労働省及び農林水産省では、本諮問に対する食品安全委員会の答申を受けた後、米国産及びカナダ産の牛肉等の輸入再開の可否について判断するとともに、その内容についてリスクコミュニケーション等を通じて丁寧に情報提供を行う予定である。

2. 米国及びカナダの国内対策と上乗せ条件（管理プログラム）について、具体的な内容、相違点、及び国内対策の問題点を項目別に整理した表

2. 米国及びカナダの国内対策と上乗せ条件について、具体的な内容、相違点及び国内対策の問題点を項目別に整理した表

＜米国＞

項目	米国の国内規制	上乗せ基準の具体的な内容	日本向け輸出プログラムの該当項目
SRMの範囲	・30ヶ月齢以上の脳・頭蓋骨・眼・三叉神経節・せき髄・せき柱（尾椎、胸椎及び腰椎横突起、仙椎翼を除く）・背根神経節 ・全月齢の扁桃・回腸遠位部（除去対象は小腸）	日本に輸出される牛肉等は、月齢を問わず、牛の頭部（舌、ほほ肉を除く）、せき髄、せき柱（尾椎、胸椎及び腰椎横突起、仙椎翼を除く）、扁桃及び回腸遠位部について汚染防止を講じて除去	月齢を問わず日本でSRMとされる部位を除去（§5. 1）
			SRMによる交差汚染の防止（§5. 1）
と畜場におけるBSE検査	米国では食用目的で処理される牛のBSE検査を義務づけていない	米国から牛肉等を輸入する場合は、20カ月齢以下と証明される牛からのものに限定	生産記録の確認（§5. 2. 1）
			生理学的成熟度の確認（§5. 2. 2）
定められた措置の確実な実施	USDAの検査官によるとさつ前／とさつ後検査及びと畜場等における衛生管理の検証	上乗せ基準の確実な実施を図るため、パッカーが作成した日本向け輸出プログラムをUSDAが認定・監督	・USDA品質システム評価（QSA）プログラムに基づく認証・監査（パッカーが作成した日本向け輸出プログラムをUSDAが個別に審査するとともに、その遵守状況について定期的に監査を実施（QSAプログラムへの追加事項：認証、内部監査（§4. 1）、リスト作成（§4. 2）））

※ 日本による査察も実施

<カナダ>

項目	カナダの国内規制	上乗せ基準の具体的な内容	日本向け輸出基準の該当項目
SRMの範囲	30ヶ月齢以上の頭蓋骨・脳・三叉神経節・眼・扁桃・せき髄・背根神経節（背根神経節を含むせき柱（尾椎、胸椎及び腰椎横突起、仙椎翼を除く）として除去）、全月齢の回腸遠位部（除去対象は小腸）	日本に輸出される牛肉等は、月齢を問わず、牛の頭部（舌、ほほ肉を除く）、せき髄、せき柱、扁桃及び回腸遠位部について汚染防止を講じて除去	月齢を問わず日本でSRMとされる部位を除去（§2及び§5）
			SRMによる交差汚染の防止（§5）
と畜場におけるBSE検査	カナダではと殺牛のBSE検査を義務づけていない	カナダから牛肉等を輸入する場合は、20カ月齢以下と証明される牛からのものに限定	生産記録の確認（§3）
定められた措置の確実な実施	CFIAの検査官によるとさつ前／とさつ後検査及びと畜場等における衛生管理の検証	上乗せ基準の確実な実施を図るため、日本向け輸出施設をCFIAが認定、検証	日本向け輸出基準への適合性をCFIAが個別に検証するとともに、その遵守状況についてCFIAが監査を実施（生産者が行う生産記録（§3）、基準の審査（§5）、枝肉の識別（§5(3)）、内部監査（§6））

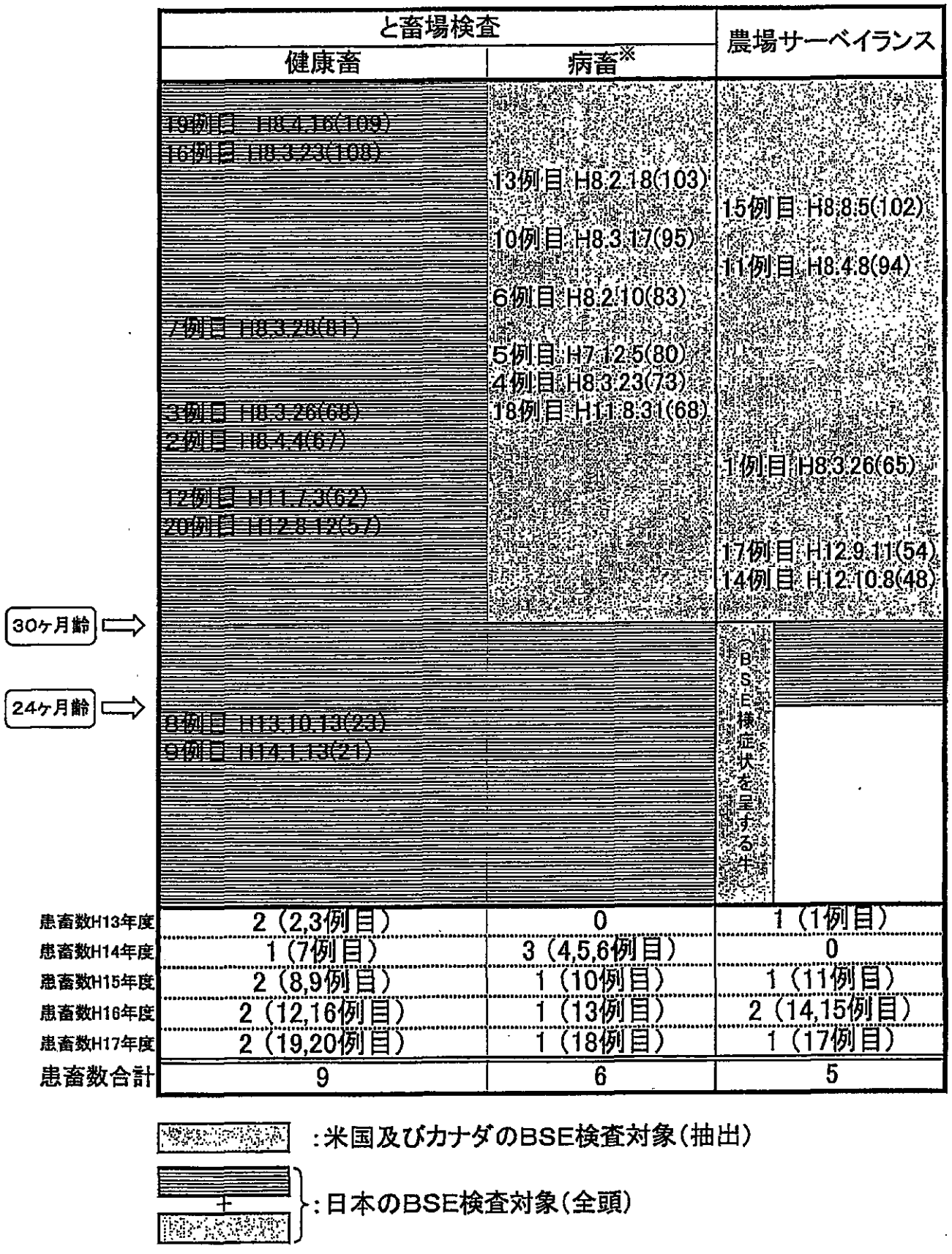
※ 日本による査察も実施

3. 米国及びカナダが実施しているBSEサーベイランスを日本に適用した場合のBSE検査陽性頭数

3. 米国及びカナダが実施しているBSEサーベイランスを日本に適用した場合の日本のBSE検査陽性頭数

		日本	米国	カナダ
検査対象		と畜される牛： 全頭 死亡牛、廃用牛： 24ヶ月齢以上全頭 BSE様症状を呈する牛： 全頭 疑似患畜（コホート）： 全頭	・月齢にかかわらず以下の全ての牛 ①中枢神経症状を呈し、診断機関に検体が送られたもの ②狂犬病陰性となったもの ③と畜場の生前検査で中枢神経症状により廃棄となったもの ④農場における海外疾病調査で中枢神経症状を呈したもの ・30ヶ月齢以上の牛 1 歩行不能牛等 ①起立不能牛、歩行不能牛 ②重篤な衰弱状態の牛 2 BSE以外の症状を呈する牛 ①廃棄又は安楽死とされた牛 ②瀕死状態、強直痙攣、削痩、傷害又は歩行不能となり死亡した牛 3 死亡牛 検査すべき死亡牛の性質を持つものであれば、死亡前の臨床症状、死亡原因がわかっていても検査対象から除くべきではない	・年齢に関わらず、BSEと一致する神経系疾病の症状を示す牛 ・30ヶ月齢以上の牛で、 －BSEと一致しない神経系疾病の症状を示す牛（狂犬病の疑い） －原因不明の死亡牛 －非食用目的のレンダリング処理のため処分された牛 －歩行不能な牛（ダウナー）（重篤な衰弱状態、四肢の骨折、神経麻痺、脊柱もしくは骨盤の骨折を含む。） －と殺前検査で、異常な行動もしくは外貌を示す牛。（緊急と殺、疾病の疑いのある牛を含む。） ・コホート牛
成牛飼養頭数		2百万頭（24ヶ月齢以上）	45百万頭※2	6百万頭（24ヶ月齢以上）
検査対象頭数		と畜される牛： 年間約130万頭 24ヶ月齢以上の死亡牛： 年間約10万頭 （成牛飼養頭数に対する死亡牛割合：5%）	検査対象となる高リスク牛群を446,000頭と推定 （成牛飼養頭数の1%）	検査対象となる高リスク牛群を80,000頭と推定 （成牛飼養頭数の1.3%）
サンプル抽出	前提	－	BSE感染が発見される牛は100%検査対象（高リスク牛）群の中に含まれる。	BSE感染が発見される牛は検査対象（高リスク牛）群の中に80%含まれる。
	信頼度	－	99%	95%
	検出レベル	－	1,000万頭に1頭の感染牛を摘発可能なレベル （国内に5頭の感染牛がいた場合に検出可能）	100万頭に1頭の感染牛を摘発可能 （国内に6頭の感染牛がいた場合に検出可能）
	計画頭数	－	最低268,500頭※3	最低37,140頭
検査方法	1次検査	エライザ法	エライザ法	エライザ法又は簡易ウエスタンブロット法
	確定検査	免疫組織化学的検査及び ウエスタンブロット法 （いずれかが陽性となれば患畜）	免疫組織化学的検査（検査材料が適さない場合、ウエスタンブロット法を実施）※4 （いずれかが陽性となれば患畜）	免疫組織化学的検査又はウエスタンブロット法（サンプルの状態及び一次検査との整合性によって選択） （いずれかが陽性となれば患畜）
検査実績※1		H16年度 98,098頭（死亡牛）、8307頭（病畜と殺）	H16.6～H17.6.21 388,309頭	H16.6～H17.6.21 52,817頭
検査率		100%	388,309/446,000＊100＝87.06%	52,817/80,000*100＝66.02%
陽性率		3/(98,098+8307)*100＝0.002819%	1/388,309＊100＝0.00026%	2/52,817*100＝0.0038%

※1 検査実績については、単年のデータを用いて比較している。
※2 経産牛及び500ポンド以上の雄牛
※3 12-18ヶ月の間にできるだけ多く実施
※4 2005年6月24日以降は免疫組織化学的検査及びウエスタンブロット法を実施



※ 生後24ヶ月齢以上の牛のうち、生体検査において運動障害、知覚障害、反射又は意識障害等の神経症状が疑われたもの及び全身症状を呈する牛

（参考） 日本におけるBSEの農場サーベイランス

	検査頭数（陽性頭数）								
	1996年度	1997年度	1998年度	1999年度	2000年度	2001年度	2002年度	2003年度	2004年度
中枢神経症状等を呈する牛	23	20	36	36	24	132(1)	420	3,411 (暫定値)	958 (暫定値)
疑似患畜	0	0	0	0	0	236	139	266	82
死亡牛 （24ヶ月齢以上）	194	203	210	237	227	801	3,755	44,739(1) (暫定値)	97,616(2) (暫定値)
合計	217	223	246	273	251	1,037	4,314	48,416	98,656

Topic	United States
Animals subject to testing	"BSE surveillance Plan, March 15, 2004" document from APHIS website (*).
Testing Policy	U.S. BSE surveillance programs are intended to assess the status of BSE. (**)
Total Population of Adults	45 million (***)
Targeted Population for Sampling	446,000 (high risk animals) in the targeted sample population
Confidence level of detection in the targeted population	99% detection of one BSE case out of 10,000,000 Adults. Can detect if there are 5 in the national herd.
Feed Ban Implemented	1997
# Animals Planned	A minimum of 268,500. As many as possible in the targeted population in a 12 – 18 period with a reassessment of the levels at the conclusion.
First Screening Test	ELISA
Confirmatory Tests	Initially IHC. Currently, WB utilized as additional confirmatory test.
Animals Tested	1990 – May 31,2004: 74,483 June 1, 2004 (start of enhanced effort)– July 6, 2005: 400,691
Test rate	Collected 150% of the amount initially needed to find one BSE case out of 10,000,000 adults at the 99% confidence level
# Tested Positive	Prior to 6/1/2004: 1 BSE case detected in an imported animal out of 74,483 animals tested. After 6/1/2004: 1 BSE case detected in a native born animal out of 400, 691 animals tested. Epidemiology investigation underway.

2005年7月7日 カナダ側より提出された資料

		Canada
Cattle subpopulations targeted for BSE testing		Cattle with clinical signs consistent with BSE - regardless of age: All Cattle over 30 mths of age; - with clinical signs of neurological disease, not consistent with BSE (i.e. rabies suspects) - that have died of unconfirmed or unknown causes - that have been slaughtered for inedible (non food) rendering - that are non-ambulatory (Downer) including cattle with extreme weakness, fracture of limbs, neuroparalysis, spine or pelvic injury - displaying signs of abnormal behaviour or appearance at time of antemortem inspection - including emergency slaughter cattle, cattle suspected of disease Cohort cattle: All as per OIE
Number of adult fed cattle		6 million (over 24 mths of age)
Test object parameter		Targeted surveillance of high risk cattle: high risk population of adult cattle estimated to be 1.3% of total adult cattle (80,000).
Sampling	Premise	80% of all BSE affected cattle are included in the targeted populations (high risk cattle)
	Reliability	95% confidence level
	Detection level	One infected cow per 1 million adult cattle Detection is possible when 6 infected cattle are present in the cattle population
	Number of cattle planned	Minimum of 37,140 evaluations
Test method	Preliminary test (screening test)	Elisa or Western blot
	Confirmatory test (final test)	IHC or OIE Western blot (depending on condition of sample and agreement with screening test result) Positive by either test indicates infection
Number of Tests		2004/07 - 2005/06 (12 mth): 53,231
Test rate		53,231/80,000*100% = 66.54%
Detection rate		2/53,231*100% = 0.003757%

4. OIEのBSEコード（無条件物品の記載部分）の原文

４．ＯＩＥのＢＳＥコード（無条件物品の記載部分）の原文

ＯＩＥのホームページからの抜粋（Unofficial versions として公表されている。）。

CHAPTER 2.3.13.
BOVINE SPONGIFORM ENCEPHALOPATHY
Article 2.3.13.1.

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

1) When authorising import or transit of the following commodities and any products made from these commodities and containing no other tissues from cattle, Veterinary Administrations should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the exporting country, zone or compartment:
   a) milk and milk products;
   b) semen and in vivo derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;
   c) hides and skins;
   d) gelatin and collagen prepared exclusively from hides and skins;
   e) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;
   f) dicalcium phosphate (with no trace of protein or fat);
   g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle 30 months of age or less, which were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, and which were subject to ante-mortem and post-mortem inspections and were not suspect or confirmed BSE cases; and which has been prepared in a manner to avoid contamination with tissues listed in Article 2.3.13.13.;
   h) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.

2) When authorising import or transit of other commodities listed in this chapter, Veterinary Administrations should require the conditions prescribed in this Chapter relevant to the BSE risk status of the cattle population of the exporting country, zone or compartment.

Standards for diagnostic tests are described in the Terrestrial Manual.

5. 米国のサーベイランスの詳細（地域別、月齢別等のデータ）

５．米国のサーベイランスの詳細（地域別、月齢別等のデータ）
（米国から提供された資料の抜粋仮訳）

米国のＢＳＥ拡大サーベイランス検査
2004年6月1日～2005年7月3日
予備データ*

（１）サーベイランス結果

分類	30ヶ月齢以上	３０ヶ月齢未満	月齢不明**	合計
非常に疑わしい症例及び／又は中枢神経症状	473	273	9	755
歩行困難	32,979	0	10	32,989
死亡	348,506	0	276	348,784
その他の臨床徴候（BSEに関連するもの）	948	1	0	949
合計	382,906	274	297	383,477

** これらは、歯列に関する情報の記録もなく、その年齢が“99才”と登録してあるサンプルで、2004年10月25日以降に採取されたものである。2004年10月25日以前には、年齢が“99才”と登録してある場合、それは当該牛が、“成牛であるが年齢の推定が不可能”であるということを意味していた。我々は、少なくとも、それらの牛が、30ヶ月齢以上であるということを言うことはできる。2004年10月25日以降、“99才”は、もはや用いられないことになっていた。したがって“99才”と登録された牛は、年齢が全く登録されていない可能性があるため（書類中の年齢の欄が空欄のままになっている等）、ここでは、“月齢不明”と表記する。

*この報告書中のデータは、予備的なものであり、変更する可能性があることに注意する必要がある。これらのデータは、提出された資料に基づいている。データは検証中であり、臨床症状に関する追加的データが入手可能となる予定である。当該データが入手可能となれば、分析され、提供されることとなる。

（２）地域別サンプル採取状況
サンプルは全米を６地域に分け、少なくとも各地域から３万サンプルを採取している。

2005年7月6日　米国から提出された資料

BSE Enhanced Surveillance Testing in the United States

June 1, 2004 – July 3, 2005

Preliminary data *

1) Cumulative number of targeted samples tested *by* submission category and cattle age

Submission Type	Age 30 months or greater	Age less than 30 months	Unknown age **	Total
Highly suspicious and/or CNS signs	473	273	9	755
Nonambulatory	32,979	0	10	32,989
Dead	348,506	0	276	348,784
Other clinical signs (that may be associated with BSE)	948	1	0	949
TOTAL	**382,906**	**274**	**297**	**383,477**

** These samples had ages recorded as "99 years" with no recording of dentition information, and the sample was collected after 10/25/2004. Prior to 10/25/2004, ages recorded as "99 years" meant the animal was an "adult but cannot estimate age." We can at least say that these cattle are over 30 months. After 10/25/2004, "99 years" was no longer supposed to be used. Because of the possibility that these cattle may have had no ages recorded (i.e., age was left blank on the paper form), these appear here as "Unknown age."

*** It is important to note that data in this particular report are preliminary and subject to change. These data are based on submission reason only. As data validation continues, additional data regarding clinical signs will become available. This data will be analyzed and provided when available.**

2) Regional collection information

The United States is divided into six regions for data collection purposes. These are the regions:

Region	States Within Region
Northeast (NE)	ME, NH, VT, MA, CT, RI, NY, PA, NJ, DE, MD, WV, OH, DC
Southeast (SE)	VA, NC, SC, KY, TN, MS, AL, GA, FL, PR
North Central (NC)	MN, WI, IL, IN, MI
South Central (SC)	TX, OK, KS, NE, IA, MO, AR, LA
Southwest (SW)	CA, NV, UT, AZ, CO, NM, HI
Northwest (NW)	WA, OR, ID, MT, WY, ND, SD, AK

Data is collected by collection point and region of residence of the animals. At this time, regional data is being validated and therefore validated data broken down by region is not yet available. However, at least 30,000 samples have been collected from each region.

6. 米国政府が6月10日に発表した疑似陽性牛に関する情報

６．米国政府が６月１０日に発表した疑似陽性牛に関する情報

６月２４日（現地時間）、米国農務省が発表した、米国で２頭目のＢＳＥ感染牛についての概要以下のとおり。

１　ＢＳＥ感染牛について

①　約１２歳の肉用雌牛

②　テキサス州の一農場で生産、飼養されたブラーマン種の交雑種

③　昨年１１月、と畜場に出荷されたが、到着時に死亡していたためペットフード工場に搬入

④　当該牛は、食用、飼料(ペットフード)用に供されていない

２　検査結果について

①　一次検査（エライザ検査）で陽性、確認検査（免疫組織化学的検査：ＩＨＣ）でＢＳＥ陰性を確認*(昨年１１月公表)*

②　米国農務省監査室の勧告を受け、別の確認検査方法（ウエスタンブロット法：ＷＢ法）で検査したところ陽性反応*(６月１０日公表)*

③　英国のＯＩＥリファレンス研究所の検査結果として、ＷＢ及びＩＨＣとも陽性*(６月２４日公表)*。

３　飼料、同居牛等の調査について

現在調査中

４　米国の確認検査の方法について

６月２４日､米国農務省は１次検査で陽性となったものについては、今後、確認検査としてＩＨＣ及びＷＢの両方を行い、いずれかが陽性となれば、当該牛はＢＳＥ感染牛と確定される旨公表した。

7. カナダにおけるBSE確定検査方法（ウエスタンブロット法の導入の真偽）

7．カナダにおけるＢＳＥ確定検査方法

（カナダからの回答の要約）

○カナダにおける検査方法

全ての検査材料は、Prionics Check（簡易ウェスタンブロット法）又は BioRad TeSeE（エライザ法）により迅速検査を実施。陽性サンプルは、カナダ国立海外病センター(NCFAD)にある BSE リファレンスラボに送付され、免疫組織化学的検査で確定検査が行われる。国立 BSE リファレンスラボは、カナダにおいて BSE 診断の認可を持つ唯一の施設。

ただし、次の場合には、ウエスタンブロット法が用いられる。

① サンプルの状態により、解剖学的に特徴的な部位が特定できない場合

② 迅速検査と免疫組織化学的検査の結果に相違がある場合

○これまで確認検査の結果陰性となった８例の検査状況

１　３例（２００４年）、２例（２００５年）

ＢＳＥの臨床症状を呈しており、臨床的にＢＳＥを疑う牛とされたことから、検体は直接ＢＳＥリファレンスラボに送られ、確認検査に付された。

確認検査結果は、プリオニクスチェックウエスタンブロット検査陰性、免疫組織化学的検査陰性であった。

２　３例（２００４年）

一次検査施設で実施したプリオニクスチェックウエスタンブロット検査が陽性であったため、ＢＳＥリファレンスラボで確認検査に付された。ＢＳＥリファレンスラボでは、プリオニクスチェックウエスタンブロット検査陰性、免疫組織化学的検査陰性であり、一次検査施設での検査結果が誤りであった。

Canada's BSE Testing Protocol and the Results of Confirmatory Testing – 2004/2005

With regards to Canada's BSE testing procedures, the following is a description of the protocol currently in place, as well as information concerning 8 samples that were submitted for confirmatory testing, and subsequently determined to be negative, during 2004 – 2005.

All BSE sample submissions are initially screened with either the Prionics® Check Western blot (all samples are tested in duplicate) or the BioRad TeSeE elisa (samples are tested singularly), reflecting the individual preference and experience of the network laboratory. Any samples that generate inconclusive results (non- negative results) are referred to the National BSE Reference Laboratory at the National Centre for Foreign Animal Disease (NCFAD) for confirmatory testing. The National BSE Reference Laboratory is the only facility in Canada authorized to diagnose BSE, and uses the immunohistochemistry procedure (IHC), designed to achieve the highest sensitivity possible, as the basis for confirmation of BSE status. The Canadian IHC test procedure employs at least 10 different monoclonal antibodies on approximately 30 to 40 tissue sections. Also, serial sections from 5 to 10 different levels of the obex (brain stem) are examined for histopathology. In recognition of the highest standards of diagnostic proficiency the National BSE Reference Laboratory will soon be recognized by the World Organization for Animal Health (OIE) as a world BSE reference laboratory.

There are two situations in which the OIE SAF Western blot procedure would be routinely incorporated into the testing regime. Firstly, it is important to recognize that the immunohistochemistry procedure requires that anatomical landmarks, within the brain stem, be recognizable in order that the correct part of the brain stem be examined. In rare instances the quality of the sample submission may be such that it can be confirmed to be brain stem tissue, but specific anatomical landmarks cannot be identified, and in such cases confirmatory testing is done with the OIE SAF Western blot procedure. Secondly, Canada's experience to date has reinforced the sensitivity and specificity of the rapid tests currently in use and therefore, should there be a discrepancy between the results of the rapid test evaluation and the immunohistochemistry evaluation, the OIE SAF Western blot procedure is performed to provide further information relative to the true status of the sample. It is important to note that both the immunohistochemistry procedure and the OIE SAF Western blot procedure are recognized internationally as confirmatory tests, and positive results by either test procedure would constitute confirmation of disease.

The Prionics® Check Western test is also used in the confirmatory work up. Although not considered to be a confirmatory test it is used to deliver a rapid test result against which the preliminary result of the screening laboratory is compared and provides an early opportunity to examine the banding pattern of the prion protein for evidence of atypical BSE forms.

During the course of 2004 there were six (6) samples referred to the National BSE Reference Laboratory for confirmatory testing that were subsequently determined to be negative. Three (3)

of these samples were derived from animals that had been designated "clinical suspects". These animals had displayed clinical signs consistent with BSE, were subsequently euthanized, and samples sent directly to the National BSE Reference Laboratory. The fact that these samples were associated with animals that had displayed clinical signs of neurological disease consistent with BSE resulted in them being forwarded directly for confirmatory testing. These samples were initially tested with the Prionics® Check Western test, all with negative results. However, because they were derived from clinical suspect animals the immunohistochemistry procedure was also performed to confirm the result of the initial test procedure (all with negative results).

The remaining three (3) samples were forwarded to the National BSE Reference Laboratory from a BSE screening laboratory, for confirmatory testing, because the Prionics® Check Western test had displayed a banding pattern that was not considered to be routine by the screening laboratory pathologist. The National BSE Reference Laboratory repeated the Prionics® Check Western test procedure, with negative results, and performed the immunohistochemistry procedure and histopathology, all with negative results. The initial test result generated by the screening laboratory could not be duplicated and was therefore attributed to technical error. In this context, although these samples were subjected to the confirmatory test procedures, they are more appropriately classified as quality assurance.

In 2005, to date, there have been two (2) submissions to the National BSE Reference Laboratory for confirmatory testing that were subsequently determined to be negative. Both cases involved submissions from animals that were assessed to have displayed clinical signs consistent with BSE. As a result the samples were sent directly to the National BSE Reference Laboratory for evaluation. As per protocol the samples were tested with the Prionics® Check Western, immunohistochemistry and histopathology, all with negative findings.

It is important to note that at no time has Canada's National BSE Reference Laboratory failed to confirm BSE in samples that have consistently generated a non-negative (positive) result on the initial screening test (Prionics® Check Western or the BioRad TeSeE), using the immunohistochemistry procedure.

8. 米国及びカナダにおけるオランダからの動物性油脂（タロー）の輸入実績（1995年～現在）

８．米国及びカナダにおけるオランダからの動物性油脂（タロー）の輸入実績

米国から提供のあった資料によると、１９９７年以降、オランダから米国及びカナダへの牛脂（タロー）の輸出実績はない。

2005年7月5日　米国より提出された資料

Information on Dutch Tallow Imports
July 5, 2005

Attached are Dutch tallow exports from 1997 to 2004. There were no exports to the United States or Canada during this time period. Dutch trade statistics prior to 1997 are not available. The lack of exports to the United States is not surprising. Since 1989, USDA prohibited imports of live cattle, other ruminants, and certain ruminant products, such as most rendered protein products, from countries where BSE is known to exist. In 1997, USDA prohibited these ruminant and ruminant product imports from all European Union members.

If Japan has data showing U.S. imports of tallow form the Netherlands, we would appreciate information on the source of the data so what we may verify it.

F:\4-Policy\BSE\FSC Review - June 05\USG responses\Information on Dutch Tallow Imports.doc
F:\4-Policy\BSE\FSC Review - June 05\USG responses\ Tallow Data.xls

Netherlands Export Statistics Commodity: 150200, Fats Of Bovine Animals, Sheep Or Goats, Raw Or Rendered, Whether Or Not Annual Series: 1997 - 2004									
		Quantity							
Partner Country	Unit	1997	1998	1999	2000	2001	2002	2003	2004
World	T	24038	29314	24663	20216	19903	25814	25087	22927
Austria	T	0	611	91	228	46	0	0	0
Belgium	T	0	0	9756	7552	7283	9924	3420	3313
Belg-Lux	T	8026	10270	0	0	0	0	0	0
Cape Verde	T	0	199	150	0	0	0	0	0
Ceuta	T	0	0	0	0	17	33	45	33
Ceuta & Melilla	T	0	17	0	0	0	0	0	0
China	T	21	0	0	0	0	0	0	0
Cuba	T	0	0	0	16	0	0	0	0
Cyprus	T	0	0	20	0	0	0	0	0
Denmark	T	0	123	141	121	0	0	0	28
France	T	57	610	745	324	1211	258	76	139
Gambia	T	0	1500	0	0	0	0	0	0
Germany	T	7039	8857	6897	10532	8332	12312	18061	16576
Greece	T	0	1	2	4	0	0	0	0
Hong Kong	T	0	0	0	32	0	0	0	0
Indonesia	T	1	0	0	1	2	4	0	0
Ireland	T	0	0	22	0	0	0	2	0
Italy	T	0	171	1089	52	248	1698	1999	1914
Japan	T	0	0	0	797	295	0	0	0
Jordan	T	981	700	525	0	0	0	0	0
Kazakhstan	T	0	0	1	0	0	0	0	0
Malaysia	T	0	0	1	0	0	0	0	0
Mali	T	77	122	61	91	58	99	84	28
Malta	T	0	0	10	5	5	3	6	0
Nigeria	T	0	0	0	0	0	513	1180	0
Norway	T	1056	1054	19	0	0	0	0	0
Philippines	T	0	1	0	25	0	0	0	0
Poland	T	0	0	0	250	0	0	0	0
Portugal	T	0	0	0	0	0	0	0	5
Romania	T	0	0	0	0	0	21	0	0
Russia	T	15	0	1045	0	0	0	0	0
Saudi Arabia	T	282	528	477	0	0	0	0	0
Senegal	T	0	2	0	0	0	0	0	0
Slovenia	T	0	20	0	0	0	0	0	0
South Africa	T	0	0	0	0	0	0	40	61
Spain	T	138	245	1567	49	497	675	167	819
Sweden	T	29	29	2	3	1	2	2	1
Switzerland	T	0	0	25	49	174	100	0	0
Turkey	T	57	292	175	4	0	0	0	0
UAE	T	93	0	0	0	0	0	0	0
United Kingdom	T	6167	3963	1844	83	1737	173	5	11

（参考資料）

「牛枝肉の生理学的成熟度に関する研究」最終報告書への追加情報について

「牛枝肉の生理学的成熟度に関する研究」最終報告書への
追加情報について

平成１７年７月８日

1　米側からの追加情報

平成 17 年 5 月 24 日、米国農務省から、「牛枝肉の生理学的成熟度に関する研究」の最終報告書への追加情報が日本側に提出された。米側から提出された追加情報は、

① 別添Ｆとして、生理学的成熟度の判別に係るガイドライン、
② 別添Ｇとして、追加データの統計学的分析結果（6 月 13 日再度提出）、
③ 別添Ｈとして、追加データを加えた総合的成熟度別月齢分布表

となっている。

2　枝肉格付の観点からの検証

検討会では、米側から提出された別添 F について、特に枝肉格付の観点から検証を行った。

（１）別添 F の内容は、生理学的成熟度の評価手順における重要な特徴について、米側最終報告書中の表 1 から、特にエンド・ポイント（A40）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載したものとなっている。

（２）この内容については、検討会報告書で留意事項として示した「評価決定ポイントの明確化」に関して、米側最終報告書の表 1 の中から「腰椎、仙椎及び肉の色調」に評価決定のためのポイントを絞り、明確化したものであり、内容的にも妥当なものと考えられる。

3　統計学的観点からの検証

検討会では、米側から提出された別添 G 及び H について、特に統計学的観点から検証を行った。

（１）別添 G の内容については、米側で 21 ヶ月齢以上に焦点を当てたサンプリングを行い、収集した追加データ（439 サンプル）を加えた統計学的分析の結果、21 ヶ月齢以上の牛の枝肉が A40 以下に評価される可能性は、99 %の信頼度で 1.92 %から 0.95 %以下に（18 ～ 20 ヶ月齢までに A40 がなかったという事実を用いた事後解析によれば 0.26 %から 0.23 %以下に）減少したというものである。

別添Ｈは、米側最終報告書の表 11 に追加データ（439 サンプル）を加えた、3,777 サンプルの総合的成熟度別月齢分布表となっている。

（２）追加データを米側最終報告書のデータに加えることにより、21 ヶ月齢以上の牛由来の枝肉が A40 以下に評価される確率が、1.92 %（99 %の信頼度）から 0.95 %に下がるという米側評価結果については、先般の米側研究結果を補完するデータとしては一定の評価ができる。

（３）しかしながら、今回の追加解析はプロスペクティブ（前向き*）な検証ではないことから、0.95 %という米側評価結果については参考値として位置付けることが適当である。

(注) プロスペクティブな検証：事前に研究のプロトコールを定め、それに基づいてデータ収集、分析等の検証作業を行うこと。

（以　上）

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関して、枝肉の成熟度は、骨及び軟骨ー特に背骨の断面ーの大きさ、形状及び骨化、及び肉の赤身の色及び“きめ”によって決定される。背骨の断面において、骨化は成熟度の初期段階に脊柱の後端（仙椎）において起こり、成熟度が後段に進むにつれ腰椎及び胸椎でも起こる。この胸椎断面の末端に位置する軟骨において起こる骨化の変化は、特に成熟度 B00 及びそれより高齢の枝肉の評価において有用であり、これらの椎骨は、格付基準で頻繁に言及されている。基準に明記されない限り、胸椎の軟骨の骨化に言及される場合は必ず、前四分体の後端の胸椎の軟骨についてであると解釈される。肋骨の大きさ及び形状も成熟度の違いの評価において重視される。肉の赤身の色と“きめ”も成熟度が進むに従い次第に変化する。非常に若齢な個体の枝肉では、肉の赤身の“きめ”が非常に繊細で、明るい灰赤色を示す。成熟度が進むに従い、肉の赤身の“きめ”が粗くなり、色調も暗赤色となる。

特定の成熟度とした枝肉は、多様な要素の相対的な発達度を尊重して変更されることもある。特定の成熟度と判定された場合でも、それらの枝肉の特徴が他の成熟度の特徴により近いとされる枝肉がある可能性はある。例えば、格付基準に収録されている成熟度の記述との比較において、ある枝肉が、他の成熟度の特徴と比較し、腰椎の末端の軟骨の骨化の度合が進んでいることがあるかもしれない。そのような場合には、枝肉の骨の成熟度が、腰椎の骨化のみで決定されることはない。しかし、それが無視されることでもない。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おいて、それらが同程度に発達することはほとんどないことに留意する必要がある。

成熟度 A のうち、極めて若い個体の枝肉（A 0）においては、背骨の末端の軟骨では骨化は見られず、軟骨は背骨の全ての椎骨において明瞭であり、仙椎において明瞭な分離が見られる。加えて、背骨の断面は通常柔らかく、多孔質で非常に赤い色となっている。このような枝肉において、肋骨は平らになる傾向がわずかに見られるのみとなっている。より成熟が進んだ枝肉では、先ず初めに仙椎の骨と軟骨において骨化が明瞭となり、続い腰椎、遅れて胸椎で確認される。以下の表は、成熟度 A グループ全体の評価手順における重要な特徴に関する記述となっている。

成熟度A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、棘突起上端に相当の軟骨の形跡	分離、棘突起上端に軟骨の形跡	完全に融合
腰椎	骨化なし	棘突起上端が部分的に骨化	棘突起上端がほぼ骨化	ほぼ完全に骨化
赤身の色	明るい灰赤色	明るい赤色	かなり明るい赤色	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外挿されたものであり、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。

APPENDIX G

Combination of the Discussion of Sampling Protocols and Analysis of Additional Data

PREFACE:

The following are responses to questions raised on April 25, 2005, by the Government of Japan (GOJ), pertaining to the USDA Maturity Study: Determining the Relationship between Chronological and Physiological Age in the U.S. Fed-Beef Population. The following information includes: (1) the impact of the additional data (n= 439) on the statistical probability of a carcass with a physiological maturity score of A^{40} and a chronological age of 21 months or older; and (2) a thorough discussion of the methods used to ensure that sample selection and evaluation were conducted in a completely unbiased method.

Additional data:

As discussed in the Final Report to the GOJ, dated January 19, 2005, entitled USDA Maturity Study: Determining the Relationship between Chronological and Physiological Age in the U.S. Fed-Beef Population, a total of 3,338 (Table 1) cattle and corresponding carcasses were used in the study to substantiate the claims that are documented within the final report. In Appendix E of the previously described final report (pg. 47), the probability of observing at least one carcass from a bovine animal evaluated as A^{40} (or less) that would also be 21 months of age was estimated using two different sub-samples of the total experimental population. The two sub-samples consisted of: (1) n=237; carcasses that were evaluated as A^{50} physiological maturity and higher and were from live animals that were 21 months of age, and (2) n=1,748; carcasses that were evaluated as A^{50} physiological maturity or higher and were from live animals that had a chronological age of 18 to 21 months. The first subset was established to exclude all of the carcasses from cattle that were 22 months of chronological age or older, and the second sub-sample was established to reflect carcasses from cattle of the chronological ages that were described as the "buffer zone" in the January 19, 2005 meetings with the GOJ (substantiating the fact that there were no carcasses older than 17 months of chronological age in the A^{40} physiological maturity classification).

Through these two sub-samples of the original data set, the objective was to discern the probability of detecting a carcass that was over 21 months of chronological age using a sub-sample of the original experimental population that reflected: 1) those that were exactly 21 months of age, and 2) those that were exactly 21 months of age plus those that were between 18 and 20 months of age (inclusively).

We chose to utilize a level of Type I statistical error of $\alpha = 0.01$ in these "vertical" non-parametric analyses for standard significance testing of hypotheses. Probabilities were computed as follows: $P \leq 1 - \alpha^{1/n}\ [(1-P)^n \geq \alpha \leftrightarrow P \leq 1 - \alpha^{1/n}]$. At $\alpha = 0.01$, the probability for sub-sample 1 (n = 237) that an animal would be A^{40} or less in physiological maturity was $P = 0.0192$, while the increased number of observations and the greater statistical power provided by sub-sample 2 (n = 1,748) yielded a probability that an animal would be A^{40} or less in physiological maturity of $P = 0.00263$.

Since the time of initial calculation, additional data has been added to the data set. One of the issues the GOJ had with the original data set was that there were not enough cattle with a chronological age greater than 20 months of age. Because of this, the United States Government agreed to continue to collect data on the older population of cattle. As previously described in the Final Report, the older population of cattle in the fed-beef population is relatively rare in occurrence and therefore collecting information on them is difficult. However, and additional 439 cattle and carcasses were added to the data set to for the total to increase to 3,777 (Appendix H), and of those additional cattle, 263 cattle were 19 months of age or older, and the remaining 176 cattle were 16 months of age or less. When these additional cattle were added to the data set, the number of animals in the sub-sample populations used to calculate probability increased dramatically. The number of cattle increased to 483 and 2,011 for sub-samples 1 and 2 respectively. In addition to the drastic increase in the number of cattle in sub-sample 1 (more than doubled the number of observations), the probability that an animal would be A^{40} or less in physiological maturity was $P = 0.00949$, and for sub-sample 2 (n=2011) the probability decreased to $P = 0.00229$ (Table 1).

Clearly with these additional data, these results ($P = 0.00949$ and $P = 0.00229$) suggest that the probability of a carcass physiologically evaluated as A^{40} with a chronological age of 21 months or older is extremely low. In addition the firewalls put in place to prevent the transmission of BSE in the U.S. beef herd, which either does not have BSE or the prevalence of the disease is extremely low, results in an exceptionally low risk of transmission of the disease and/or food contamination from products produced in the U.S. These additional data clearly show the safety of beef from the U.S. production system.

Table 1. The probability of a carcass with a physiological maturity of A^{40} or less that was 21 months of age or older, using two different sub-sample populations.

Sub-Sample Populations	Probability of a carcass being ≥ 21 MOA	
	Sub-sample 1	Sub-sample 2
N=3,338	0.0192	0.00263
N=3,777	0.00949	0.00229

The selection of cattle and their carcasses for evaluation was done in the same manner as the original study for randomness and blindness. The USDA graders who performed the evaluations were determined by the location of where the known age cattle were slaughtered. Once cattle with known ages were identified and marketing information confirmed (plant name, plant location, and slaughter date/time/tag numbers), the MGC Branch personnel responsible for that specific location collected the information. Depending upon how many graders are stationed at each location of responsibility and which shift the carcasses were graded determined which grader performed the evaluation. Since the graders at large plants have no prior knowledge when the plant intends to present specific carcasses for grading, the grader who is performing the grading function at the time of the presentation performed the evaluations.

【仮訳】

別添G

サンプリング・プロトコールの議論と追加的なデータ分析の組み合わせ

序文：

以下は、2005年4月25日付で日本政府により提起された質問に対する回答であり、米国肥育牛群における暦月齢と生理学的月齢との関連性を確定するUSDA成熟度研究に関するものである。以下の情報には、(1)生理学的成熟度スコアA40と21ヶ月齢以上との枝肉の統計学的可能性の追加的なデータ(n=439)の影響と、(2)サンプル選定と評価が完全に無作為でブラインドされた方法で行われたことを保証する手法の綿密な議論が含まれている。

追加的データ：

2005年1月19日付の、日本政府に対する、米国肥育牛群における暦月齢と生理学的月齢との関連性を確定するUSDA成熟度研究というタイトルの最終報告書で論じられているように、総数3,338頭（表．1）の牛とそれに相当する枝肉は、最終報告書中に文書化されている主張を立証する研究に用いられた。前述の最終報告書の別添Eにおいて（47ページ）、21ヶ月齢以下でかつA40（もしくはそれ以下）と評価された牛枝肉が1つ以上確認される確率を、全検査対象群中の2種類の異なるサブサンプルを用いて算出した。サブサンプルは、(1) n=237；生理学的成熟度A50以上と評価され、21ヶ月齢の牛生体由来だった枝肉、(2) n=1,784；生理学的成熟度A50以上と評価され、暦年齢が18～21ヶ月齢の牛の枝肉の2種類で構成される。第1の集団は暦年齢が22ヶ月齢以上の牛の枝肉を除外するため、第2のサブサンプルは2005年1月19日の日本政府との協議（生理学的成熟度A40に暦年齢17ヶ月齢以上の枝肉が入らないという事実を実証）で、「緩衝帯（buffer zone)」と表現される暦年齢の牛の枝肉の存在を反映するために定められた。

オリジナルのデータセットの2種類のサブサンプルを通じて、下記の存在を反映した本来の検査対象群中のサブサンプルを用いて、暦年齢21ヶ月齢以上の牛の枝肉を検出できる確率を見極めることを目標とした：1) 21ヶ月齢の牛、2) 21ヶ月齢の牛及び18～20ヶ月齢の牛（両方を含む)。

我々は、標準有意検定の仮説のため垂直的なノンパラメトリック分析において、タイプIの統計学的誤差がα=0.01のレベルを使うことを選択した。確率は以下のように算出された：$P \leq 1-\alpha^{1/n}$ [$(1-P)^n \geq \alpha \Leftrightarrow P \leq 1-\alpha^{1/n}$]。$\alpha = 0.01$の場合、サブサンプル1 ($n = 237$) において牛が生理学的マチュリティA40かそれ以下である確率は、$P = 0.0192$となる。一方、より多くの観察件数と高い検定力を備えたサブサンプル2 ($n = 1,478$) においては、生理学的成熟度がA40かそれ以下である確率は$P = 0.00263$となる。

初期の計算以降、追加的なデータがデータセットに追加された。日本政府が考えるオリジナルのデータセットに関する問題点の一つは、暦年齢が20ヶ月齢以上の牛が十分な数を含んでいないということであった。このため、米国政府は、高齢な牛群に関するデータの収集を継続することに同意した。最終報告書中で以前述べたとおり、肥育牛群中に高齢牛は相対的に希であり、これらの牛に関する情報収集は困難である。

しかしながら、データセットに439の牛と枝肉が追加されたことにより、総数は3,777に増加し（別添H）、追加された牛のうち263頭は19ヶ月齢以上で、残りの176頭は16ヶ月齢以下であった。追加の牛をデータセットに加えたことにより、確率を算出するために用いたサブサンプルの牛の数は劇的に増加した。サブサンプル1と2の牛の数はそれぞれ483と2,011に増加した。サブサンプル1の牛の数の劇的な増加に加えて（観察数が2倍以上増加）、生理学的成熟度がA40以下になる確率はP＝0.00949となり、サブサンプル2においては確率がP＝0.00229に減少した。（表1）

追加的なデータで明らかなように、これら結果（P＝0.00949、P＝0.00229）は、暦年齢21ヶ月齢以上であり、生理学的成熟度A40と評価される枝肉が存在する確率は非常に低いことを示している。さらに、BSEが発生していない、あるいは有病率が非常に低い米国の肉用牛群においてBSEの伝播防止のために実施されているシステムにより、ＢＳＥの伝播および／または米国で生産された産物からの食品汚染が格別に低いリスクであるとの結果となっている。これらの追加データは米国の生産システム由来の牛肉の安全性を明確に示している。

表1　21ヶ月齢以上であって生理学的成熟度A40以下の枝肉の確率
２つの異なったサブサンプルを使用

サブサンプル群	21ヶ月齢以上になる確率	
	サブサンプル1	サブサンプル2
N=3,338	0.0192	0.00263
N=3,777	0.00949	0.00229

評価のための牛及びその枝肉の選別は、ランダム性及びブラインド性においてオリジナルの研究と同じ手法によって行われた。評価を行ったUSDA格付検査官は、月齢が判明している牛がと畜された場所によって決定された。月齢が判明している牛が識別され、取引情報が確認（施設の名称、場所、と畜日／時間／耳標番号）されれば、特定の場所を担当するMGC支部の職員はこれら情報を収集した。各担当の場所に駐在している格付検査官の人数および枝肉が格付されるシフトによって、評価を行う格付検査官が決定される。大規模な施設の格付検査官は、何時施設が特定枝肉を格付けのために提出するのか事前に何の情報も得ていないことから、その時点で格付作業を行っていた格付検査官が評価を行った。

APPENDIX H

Contingency table characterizing the distribution of age among overall maturity scores (n=3,777).

Overall Maturity Score	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	Total
A^{20}			1	1	1																3
A^{30}			3	1	47	6															57
A^{40}		2	19	12	93	70	2														198
A^{50}	1	7	31	28	54	162	100	10	19	11	19										442
A^{60}		1	58	177	178	138	164	105	300	46	104										1467
A^{70}		1	30	56	111	43	83	125	442	49	187										1127
A^{80}				2	10	4	11	56	218	56	102	1	1					2	1	1	465
A^{90}			1	3	13		3	1	36	14	27						1	1			100
B^{00}				3	1	1		2	13	4	16					2		1	1		44
B^{10}				4	3			1	9		6										23
B^{20}				4					7		8										19
B^{30}				2	1				1		5							1			10
B^{40}				1							1										2
B^{50}				1	1						3										5
B^{60}									1												1
C^{00}				2	1				2		5										10
Total	1	11	143	297	515	423	363	300	1048	180	483	1	1			2	1	5	2	1	3777