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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 9 月 1 日付け府食第 851 号及び第 857 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

- 1 BSE 確認検査 (WB、IHC) 結果の判定体制。検査担当者が単独で判定するのか、または、専門家会議のような複数の専門家で判定するのか。
- 2 と畜場における検査体制の日米比較
- 3 2004 年 1 月 12 日付け FSIS NOTICE 5-04 の III. A. 2 に関し、FSIS は BSE 検査のためのサンプリングにおいて、20 ヶ月齢以上の牛に関心を示しているとしているが、その理由。
- 4 米国のラボで使用している ELISA、WB 及び IHC の詳細な検査プロトコル又は検査マニュアル
- 5 2005 年 7 月 12 日付け FSIS NOTICE 46-05 において、FSIS の生前検査前に施設側が家畜を区分けすることについて、2005 年 7 月 26 日より牛については停止されているが、本 NOTICE を公布した背景、理由及び施行前後の牛の生前検査の具体的な方法とその違い。
- 6 輸入停止前の米国及びカナダからの牛肉、内臓、舌等の部位別輸入実績
- 7 カナダから米国へ 31 ヶ月齢の生体牛が輸出された事実に関する情報
- 8 米国における、と畜場等の衛生管理に関する規則の遵守状況に関する情報

(参考資料)

米国の 2 頭目の BSE 感染牛の疫学調査結果

- 1 **BSE確認検査（WB、IHC）結果の判定体制。検査担当者が単独で判定するのか、または、専門家会議のような複数の専門家で判定するのか。**
-

(米国からの回答)

For BSE confirmatory testing, a team of pathologists consult. These experts reach and issue a consensus diagnosis.

(仮訳)

BSEの確認検査については、病理学者のチームが協議します。これらの専門家は全員一致の診断に達して発表します。

2 と畜場における検査体制の日米比較

と畜場における生体検査体制の日米比較

	日 本			米 国		
	大規模	中規模	小規模	大規模	中規模	小規模
1日当たりの処理頭数	400頭程度	100頭程度	30～50頭程度	5000頭程度	2000頭程度	500頭程度
生体検査を行う検査員数	3人／3ライン	1人	1人	1人／シフト	1人	1人
生体検査の主な実施場所	係留所及びスタンニングベンへの搬入時等			係留所及びスタンニングベンへの搬入時等		
1頭当たりの生体検査に要する時間 (疾病に罹患している疑いのないもの)	数十秒程度			数十秒程度		
BSEに係る生体検査の内容	奇声、旋回等の行動異常、運動失調等の神経症状の有無を歩様検査の結果もあわせて判断			両体側を確認するとともに、奇声、旋回等の行動異常、運動失調等の神経症状の有無を歩様検査の結果もあわせて判断。体温を測る場合もある。また、当該牛の記録等もあわせて確認。		
BSEに係る生体検査の手順例	<ul style="list-style-type: none"> ・ 係留所に係留されている時点で起立不能牛の有無等について確認し、起立不能牛については、音に対する反応、首筋の刺激に対する反応などを行い、BSEに罹患している疑いがあるか否か判断 ・ スタンニングベンへの追い込み時に一列になったところを通路脇で一頭ずつ歩様の異常の有無を確認し、疑いがあるものについて別の生体検査場所に移動して、さらに音に対する反応、首筋の刺激に対する反応、歩様検査などを行い、BSEに罹患している疑いがあるか否か判断 			<ul style="list-style-type: none"> ・ 係留所に係留されている時点で起立不能牛の有無等について確認し、起立不能牛については、音に対する反応、首筋の刺激に対する反応などを行い、BSEに罹患している疑いがあるか否か判断 ・ スタンニングベンへの追い込み時に一列になったところを通路脇で一頭ずつ歩様の異常の有無を確認し、疑いがあるものについて別の生体検査場所に移動して、さらに音に対する反応、首筋の刺激に対する反応、歩様検査などを行い、BSEに罹患している疑いがあるか否か判断 		

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actinomycosis, or actinobacillosis to such an extent that the lesions would be readily detected on post-mortem inspection, need not be individually tagged on ante-mortem inspection with the U.S. Suspect tag, provided that such cattle are segregated and otherwise handled as U.S. Suspects.

(b) In addition, identification of U.S. Suspect swine must include the use of tattoos specified by the inspector to maintain the identity of the animals through the dehairing equipment when such equipment is used.

(c) All livestock required by this part to be identified as U.S. Condemned shall be tagged with a serially numbered metal ear tag bearing the term "U.S. Condemned."

(d) The devices described in paragraphs (a), (b), and (c) of this section shall be the official devices for identification of livestock required to be identified as U.S. Suspect or U.S. Condemned as provided in this part.

PART 310—POST-MORTEM INSPECTION

Sec.

- 310.1 Extent and time of post-mortem inspection; post-mortem inspection staffing standards.
- 310.2 Identification of carcass with certain severed parts thereof and with animal from which derived.
- 310.3 Carcasses and parts in certain instances to be retained.
- 310.4 Identification of carcasses and parts; tagging.
- 310.5 Condemned carcasses and parts to be so marked; tanking; separation.
- 310.6 Carcasses and parts passed for cooking; marking.
- 310.7 Removal of spermatic cords, pizzles and preputial diverticuli.
- 310.8 Passing and marking of carcasses and parts.
- 310.9 Anthrax; carcasses not to be eviscerated; disposition of affected carcasses; hides, hoofs, horns, hair, viscera and contents, and fat; handling of blood and scalding vat water; general cleanup and disinfection.
- 310.10 Carcasses with skin or hide on; cleaning before evisceration; removal of larvae of Hypodermæ, external parasites and other pathological skin conditions.
- 310.11 Cleaning of hog carcasses before incising.
- 310.12 Sternum to be split; abdominal and thoracic viscera to be removed.

- 310.13 Inflating carcasses or parts thereof; transferring caul or other fat.
- 310.14 Handling of bruised parts.
- 310.15 Disposition of thyroid glands and laryngeal muscle tissue.
- 310.16 Disposition of lungs.
- 310.17 Inspection of mammary glands.
- 310.18 Contamination of carcasses, organs, or other parts.
- 310.19 Inspection of kidneys.
- 310.20 Saving of blood from livestock as an edible product.
- 310.21 Carcasses suspected of containing sulfa and antibiotic residues; sampling frequency; disposition of affected carcasses and parts.
- 310.22 Specified risk materials from cattle and their handling and disposition.
- 310.23 Identification of carcasses and parts of swine.
- 310.24 [Reserved]
- 310.25 Contamination with microorganisms; process control verification criteria and testing; pathogen reduction standards.

AUTHORITY: 21 U.S.C. 601-605; 7 CFR 2.18, 2.53.

SOURCE: 35 FR 15567, Oct. 3, 1970, unless otherwise noted.

§310.1 Extent and time of post-mortem inspection; post-mortem inspection staffing standards.

(a) A careful post-mortem examination and inspection shall be made of the carcasses and parts thereof of all livestock slaughtered at official establishments. Such inspection and examination shall be made at the time of slaughter unless, because of unusual circumstances, prior arrangements acceptable to the Administrator have been made in specific cases by the circuit supervisor for making such inspection and examination at a later time.

(b)(1) The staffing standards on the basis of the number of carcasses to be inspected per hour are outlined in the following tables. Standards for multiple inspector lines are based on inspectors rotating through the different types of inspection stations during each shift to equalize the workload. The inspector in charge shall have the authority to require the establishment to reduce slaughter line speeds where, in his judgment, the inspection procedure cannot be adequately performed at the current line speed because of particular deficiencies in carcass preparation and presentation by the plant at the higher speed, or because the

health condition of the particular animals indicates a need for more extensive inspection.

(2) *Cattle inspection.* For all cattle staffing standards, an "a" in the "Number of Inspectors by Stations" column means that one inspector performs the entire inspection procedure and a "b" means that one inspector performs the head and lower carcass inspection and a second inspector performs the viscera and upper carcass inspection.¹

(i) *Inspection Using the Viscera Truck.*

STEERS AND HEIFERS

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 27	a	a	a
28 to 56	b	b	b
57 to 84	1	1	1
85 to 112	1	2	1
113 to 140	2	2	1

¹The "Maximum Slaughter Rates" figures listed in paragraph (b)(2)(i) of this section for one (a) and two (b) inspector kills are overstated because the time required to walk from one inspection station to another is not included. To determine the proper adjusted maximum slaughter line speed, paragraph (b)(2)(i)(A) of this section for one inspector kills or paragraph (b)(2)(i)(B) of this section for two inspector kills must be used along with their accompanying rules.

COWS AND BULLS

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 27	a	a	a
28 to 56	b	b	b
57 to 77	1	1	1
78 to 81	1	2	1
82 to 134	2	2	1

(A) Rules for determining adjusted maximum slaughter rates for single-inspector kills considering walking distance according to the table in this subdivision: Determine the distances the inspector actually walks between the points shown in columns 2 through 14 of the following table. For each column, determine the deduction figure opposite the appropriate number of feet in column 1. Compute the total of the deduction figures for columns 2 through 14. The adjusted maximum rate is the maximum rate in paragraph (b)(2)(i) of this section minus total of the deduction figures. If the resultant number is not a whole number, it must be rounded off to the next *lowest* whole number.

ONE-INSPECTOR CATTLE KILL—VISCERA TRUCK

[Table of deductions from maximum slaughter rates for each 2 feet between points (in tenths of cattle per hour)]

1 Number of feet between points	2 Head rack and high rail		3 Viscera and low rail		4 Low rail and head rack		5 Head rack and carcasses ²		6 Carcasses ² and washbasin		7 Tags—brands and low rail		8 Viscera and washbasin		9 Viscera and high rail		10 Low rail and high rail		11 Head rack and closest washbasin		12 Washbasin and high rail ¹		13 Head rack and washbasin ¹		14 Viscera and tags—brands		
	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls	
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.1	0
5	0	0	0.1	0	0	0	0	0	0	0	0	0	0	0.1	0.1	0.1	0	0	0	0	0	0	0	0	0	0.2	0.1
7	0	0	0.1	0.1	0.1	0.1	0	0	0	0	0.1	0.1	0.1	0.2	0.2	0.2	0.1	0.1	0	0	0	0	0	0	0	0.3	0.3
9	0	0	0.2	0.1	0.1	0.1	0	0	0	0	0.1	0.1	0.1	0.3	0.3	0.3	0.1	0.1	0	0	0	0.1	0.1	0.1	0.1	0.4	0.4
11	0.1	0.1	0.2	0.2	0.2	0.2	0	0	0	0	0.1	0.2	0.2	0.4	0.4	0.4	0.2	0.2	0	0	0.1	0.1	0.1	0.1	0.5	0.6	0.8
13	0.1	0.1	0.3	0.2	0.2	0.2	0	0	0	0	0.2	0.2	0.2	0.5	0.5	0.5	0.2	0.2	0	0	0.1	0.1	0.1	0.1	0.6	0.7	0.9
15	0.1	0.1	0.4	0.3	0.3	0.3	0	0	0	0	0.2	0.3	0.3	0.5	0.6	0.6	0.3	0.3	0	0	0.2	0.2	0.2	0.2	0.7	0.9	1.0
17	0.1	0.1	0.4	0.3	0.3	0.3	0	0	0	0	0.3	0.3	0.3	0.6	0.7	0.7	0.3	0.3	0	0.1	0.2	0.2	0.2	0.2	0.9	1.0	1.1
19	0.1	0.1	0.5	0.4	0.4	0.4	0	0	0	0	0.3	0.4	0.4	0.7	0.8	0.8	0.4	0.4	0	0.1	0.2	0.2	0.2	0.2	1.0	1.1	1.3
21	0.2	0.2	0.5	0.4	0.4	0.4	0	0	0	0	0.3	0.4	0.4	0.8	0.9	0.9	0.6	0.4	0	0.1	0.3	0.2	0.3	0.2	1.1	1.3	1.4
23	0.2	0.2	0.6	0.5	0.5	0.5	0	0	0	0	0.4	0.5	0.5	0.9	1.0	0.9	0.5	0.5	0	0.1	0.3	0.3	0.3	0.3	1.2	1.4	1.5
25	0.2	0.2	0.7	0.5	0.5	0.5	0	0	0	0	0.4	0.5	0.6	1.0	1.1	1.0	0.6	0.6	0	0.1	0.3	0.3	0.3	0.3	1.3	1.5	1.6
27	0.2	0.2	0.7	0.6	0.6	0.6	0	0	0	0	0.4	0.5	0.6	1.1	1.2	1.1	0.6	0.6	0	0.1	0.3	0.3	0.3	0.3	1.4	1.7	1.8
29	0.2	0.2	0.8	0.6	0.6	0.6	0	0	0	0	0.5	0.6	0.7	1.2	1.3	1.2	0.6	0.6	0	0.1	0.4	0.3	0.4	0.3	1.5	1.8	1.9
31	0.3	0.2	0.8	0.6	0.7	0.7	0	0	0	0	0.5	0.6	0.7	1.3	1.3	1.4	0.7	0.7	0	0.1	0.4	0.4	0.4	0.4	1.6	1.9	2.1
33	0.3	0.3	0.9	0.7	0.7	0.7	0	0	0	0	0.6	0.7	0.8	1.4	1.5	1.5	0.8	0.8	0	0.2	0.5	0.4	0.5	0.4	1.8	2.2	2.3
35	0.3	0.3	1.0	0.7	0.8	0.8	0	0	0	0	0.6	0.8	0.8	1.5	1.6	1.6	0.8	0.8	0	0.2	0.5	0.5	0.5	0.5	1.9	2.3	2.4
37	0.3	0.3	1.1	0.8	0.8	0.8	0	0	0	0	0.7	0.8	0.9	1.6	1.7	1.7	0.9	0.9	0	0.2	0.5	0.5	0.5	0.5	2.0	2.4	2.5
39	0.4	0.3	1.1	0.8	0.9	0.9	0	0.1	0	0.1	0.7	0.8	0.9	1.7	1.7	1.8	0.9	0.9	0	0.2	0.5	0.5	0.5	0.5	2.1	2.6	2.7
41	0.4	0.4	1.2	0.9	1.0	0.9	0	0.1	0	0.1	0.7	0.9	1.0	1.8	1.8	1.9	1.0	1.0	0.1	0.2	0.6	0.5	0.6	0.5	2.2	2.7	2.8
43	0.4	0.4	1.2	0.9	1.0	0.9	0	0.1	0	0.1	0.8	0.9	1.0	1.9	1.9	2.0	1.0	1.0	0.1	0.2	0.6	0.5	0.6	0.6	2.3	2.8	2.9
45	0.4	0.4	1.3	1.0	1.1	1.0	0	0.1	0	0.1	0.8	1.0	1.1	1.9	2.0	2.1	1.1	1.1	0.1	0.2	0.6	0.6	0.6	0.6	2.4	2.9	3.0
47	0.4	0.4	1.4	1.0	1.1	1.0	0	0.1	0	0.1	0.8	1.0	1.1	2.0	2.1	2.2	1.1	1.1	0.1	0.2	0.7	0.6	0.7	0.6	2.5	3.1	3.2
49	0.5	0.5	1.4	1.1	1.2	1.1	0	0.1	0	0.1	0.9	1.1	1.2	2.1	2.2	2.2	1.2	1.2	0.1	0.3	0.7	0.7	0.7	0.7	2.6	3.2	3.3
51	0.5	0.5	1.5	1.1	1.2	1.1	0	0.1	0	0.1	0.9	1.1	1.2	2.2	2.3	2.3	1.2	1.2	0.1	0.3	0.7	0.7	0.7	0.7	2.7	3.3	3.4
53	0.5	0.5	1.5	1.2	1.2	1.2	0	0.1	0	0.1	1.0	1.2	1.2	2.3	2.4	2.4	1.3	1.3	0.1	0.3	0.8	0.7	0.8	0.7	2.8	3.4	3.5
55	0.5	0.5	1.6	1.2	1.3	1.2	0	0.1	0	0.1	1.0	1.2	1.3	2.3	2.4	2.5	1.3	1.3	0.1	0.3	0.8	0.7	0.8	0.7	2.9	3.5	3.6
57	0.5	0.5	1.6	1.3	1.3	1.3	0	0.1	0	0.1	1.0	1.3	1.3	2.4	2.5	2.6	1.4	1.4	0.1	0.3	0.8	0.8	0.8	0.8	3.0	3.6	3.7

¹ The washbasin referred to here is the one the inspector uses while enroute from the head rack to high rail inspection.² This refers to the carcass in the bleeding area.

(B) Rules for determining adjusted maximum slaughter rates for two-inspector kills considering walking distance according to the table in this subdivision: Determine the distances the inspectors actually walk between the points shown in columns 2 through 9 of the following table. Column 9 is used only if the condemned brands and tags the viscera inspector uses are kept at a location other than at the wash-basin-sterilizer. For each column, de-

termine the deduction figure opposite the appropriate number of feet in column 1. Compute the total of the deduction figures for columns 2 through 9. Divide this total by 2. The adjusted maximum rate is the maximum rate in paragraph (b)(2)(i) of this section minus the number calculated above. If the resultant number is not a whole number, it must be rounded off to the next *lowest* whole number.

TWO-INSPECTOR CATTLE KILL—VISCERA TRUCK

[Table of deductions from maximum slaughter rates for each 2 feet between points (in tenths of cattle per hour)]

1 Number of feet between points	Heads and low rail inspection								Viscera and high rail inspection							
	2 Head rack and washbasin		3 Head rack and car- casses*		4 Washbasin and low rail		5 Head rack and low rail		6 Viscera and brands tags (washbasin)		7 Viscera and high rail		8 High rail and wash- basin		9 ¹ Viscera and wash- basin	
	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls	Strs. Hrs.	Cows Bulls
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0.1	0	0.1	0	0.1	0	0	0	0	0	0	0	0	0	0.1	0.2
5	0.1	0.1	0.1	0.1	0.1	0.1	0.8	0.7	0.4	0.5	0.5	0.5	0.1	0.2	0.2	0.3
7	0.1	0.2	0.1	0.1	0.1	0.1	1.5	1.4	0.7	0.9	1.0	0.9	0.3	0.3	0.3	0.4
9	0.2	0.2	0.1	0.2	0.1	0.2	2.2	2.0	1.1	1.3	1.5	1.3	0.4	0.5	0.4	0.5
11	0.2	0.3	0.1	0.2	0.2	0.2	2.8	2.7	1.4	1.7	1.9	1.8	0.5	0.6	0.4	0.6
13	0.2	0.4	0.1	0.3	0.2	0.2	3.5	3.3	1.7	2.1	2.4	2.2	0.6	0.7	0.5	0.8
15	0.3	0.4	0.1	0.3	0.2	0.3	4.1	3.9	2.0	2.5	2.9	2.6	0.7	0.9	0.6	0.9
17	0.3	0.5	0.1	0.4	0.2	0.3	4.8	4.5	2.4	2.9	3.3	3.0	0.8	1.0	0.7	1.0
19	0.3	0.6	0.2	0.4	0.3	0.4	5.4	5.1	2.7	3.3	3.7	3.4	0.9	1.2	0.7	1.2
21	0.3	0.6	0.2	0.4	0.3	0.4	6.0	5.7	3.0	3.7	4.2	3.7	1.0	1.3	0.8	1.3
23	0.4	0.7	0.2	0.5	0.3	0.5	6.6	6.3	3.3	4.0	4.6	4.1	1.2	1.4	0.9	1.4
25	0.4	0.7	0.2	0.5	0.3	0.5	7.2	6.8	3.6	4.4	5.0	4.5	1.3	1.6	1.0	1.6
27	0.4	0.8	0.2	0.6	0.4	0.5	7.8	7.4	3.9	4.7	5.4	4.9	1.4	1.7	1.0	1.7
29	0.5	0.8	0.2	0.6	0.4	0.6	8.3	7.9	4.2	5.1	5.8	5.2	1.5	1.8	1.1	1.8
31	0.5	0.9	0.2	0.7	0.4	0.6	8.9	8.5	4.5	5.4	6.2	5.6	1.6	2.0	1.2	2.0
33	0.5	1.0	0.2	0.7	0.4	0.7	9.4	9.0	4.8	5.8	6.5	5.9	1.7	2.1	1.3	2.1
35	0.6	1.1	0.3	0.8	0.5	0.7	10.0	9.5	5.0	6.1	6.9	6.3	1.8	2.2	1.3	2.3
37	0.6	1.1	0.3	0.8	0.5	0.7	10.5	10.0	5.3	6.4	7.3	6.6	1.9	2.4	1.4	2.4
39	0.6	1.2	0.3	0.9	0.5	0.8	11.0	10.5	5.6	6.8	7.8	6.9	2.0	2.5	1.5	2.5
41	0.7	1.2	0.3	0.9	0.6	0.8	11.5	11.0	5.9	7.1	8.0	7.2	2.1	2.6	1.5	2.6
43	0.7	1.3	0.3	0.9	0.6	0.9	12.0	11.4	6.1	7.4	8.3	7.6	2.2	2.8	1.6	2.8
45	0.7	1.4	0.3	1.0	0.6	0.9	12.5	11.9	6.4	7.7	8.7	7.9	2.4	2.9	1.7	2.9
47	0.8	1.4	0.3	1.0	0.6	1.0	13.0	12.4	6.7	8.0	9.0	8.2	2.5	3.0	1.8	3.0
49	0.8	1.5	0.3	1.1	0.7	1.0	13.4	12.8	6.9	8.3	9.4	8.5	2.6	3.2	1.8	3.1
51	0.8	1.6	0.3	1.1	0.7	1.0	13.9	13.3	7.2	8.6	9.7	8.8	2.7	3.3	1.9	3.3
53	0.9	1.6	0.4	1.2	0.7	1.1	14.4	13.7	7.4	8.9	10.0	9.1	2.8	3.4	2.0	3.4
55	0.9	1.7	0.4	1.2	0.7	1.1	14.8	14.1	7.7	9.2	10.3	9.4	2.9	3.5	2.0	3.5
57	0.9	1.7	0.4	1.3	0.8	1.2	15.2	14.6	7.9	9.5	10.6	9.7	3.0	3.7	2.1	3.6
59	0.9	1.8	0.4	1.3	0.8	1.2	15.7	15.0	8.2	9.7	10.9	9.9	3.1	3.8	2.2	3.8

¹ This column to be used only if brands and tags are not located at the washbasin.² This refers to the carcasses in the bleeding area.

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(ii) Inspection Using Viscera Table,
Tongue-In Presentation of Heads.

STEERS AND HEIFERS

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 32	a	a	a
33 to 56	b	b	b
57 to 84	1	1	1
85 to 88	1	2	1
87 to 143	2	2	1
144 to 171	3	2	1
172 to 198	3	3	1
199 to 226	3	3	2
227 to 253	4	3	2
254 to 280	4	4	2
281 to 306	5	4	2
307 to 333	5	5	2

COWS AND BULLS

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 29	a	a	a
30 to 56	b	b	b
57 to 77	1	1	1
78 to 81	1	2	1
82 to 134	2	2	1
135 to 159	2	3	1
160 to 187	3	3	1
188 to 213	3	4	1
214 to 234	3	4	2
235 to 264	4	4	2
265 to 289	5	4	2
290 to 314	5	5	2

(iii) Inspection Using Viscera Table,
Tongue-Out Presentation of Heads.

STEERS AND HEIFERS

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 32	a	a	a
33 to 56	b	b	b
57 to 86	1	1	1
87 to 103	1	2	1
104 to 156	2	2	1
157 to 186	2	3	1
187 to 218	3	3	1
217 to 246	3	3	2
247 to 275	3	4	2
276 to 304	4	4	2
305 to 333	4	5	2
334 to 362	5	5	2
363 to 390	5	6	2

COWS AND BULLS

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 29	a	a	a
30 to 56	b	b	b
57 to 79	1	1	1
80 to 88	1	2	1
89 to 147	2	2	1
148 to 174	2	3	1
175 to 205	3	3	1
206 to 233	3	4	1
234 to 256	3	4	2
257 to 288	4	4	2
289 to 316	5	4	2
317 to 343	5	5	2

(3) *Swine Inspection.* The following inspection staffing standards are applicable to swine slaughter configurations. The inspection standards for all slaughter lines are based upon the observation rather than palpation, at the viscera inspection station, of the spleen, liver, heart, lungs, and mediastinal lymph nodes. In addition, for one- and two-inspector lines, the standards are based upon the distance walked (in feet) by the inspector between work stations; and for three or more inspector slaughter lines, upon the use of a mirror, as described in §307.2(m)(6), at the carcass inspection station. Although not required in a one- or two-inspector slaughter configuration, except in certain cases as determined by the inspection service, if a mirror is used, it must comply with the requirements of §307.2(m)(6).

TABLE 1—ONE INSPECTOR—STAFFING
STANDARDS FOR SWINE

Distance walked * in feet is—	Maximum inspection rates (head per hour)			
	Market hogs (heads attached or detached)		Sows and boars (heads detached)	
	Without mirror	With mirror	Without mirror	With mirror
0 to 5	140	150	131	143
6 to 10	134	144	126	137
11 to 15	129	137	122	132
16 to 20	124	132	117	127
21 to 25	120	127	113	122
26 to 30	116	122	110	118
31 to 35	112	118	106	114
36 to 40	108	114	103	110
41 to 45	105	110	100	106
46 to 50	101	107	97	103
51 to 55	98	103	94	100
56 to 60	95	100	91	97
61 to 65	93	97	89	94
66 to 70	90	95	87	92

パート 310—死後検査

セクション

- 310.1 死後検査の範囲と時期および死後検査要員の基準
- 310.2 屠体と特定切断部位および由来する動物の同定
- 310.3 保持すべき特定例の屠体と部位
- 310.4 屠体と部位の識別および標識付け
- 310.5 不良品表示屠体と表示が予定される部位：タンク入れと隔離
- 310.6 調理用合格の屠体と部位およびマーク付け
- 310.7 精管・陰茎・包茎憩室の除去
- 310.8 屠体と部位の合格とマーク付け
- 310.9 炭疽、内臓を除去しない屠体、影響を受けた屠体の処分、皮膚・蹄・角・毛・内臓・内容物・脂肪、血液と高熱タンク水の取り扱い、全身洗浄と除染
- 310.10 皮膚のついた屠体、内臓除去前の洗浄、ハイポルデマ幼生・外部寄生虫・その他の病原性皮膚疾患の除去
- 310.11 切除前のブタ屠体の洗浄
- 310.12 胸骨分割、腹部・胸部内臓除去
- 310.13 腸満屠体またはその部位、羊膜またはその他の脂肪の移動
- 310.14 出血部位の取り扱い
- 310.15 甲状腺と喉頭筋組織の処分
- 310.16 肺の処分
- 310.17 乳腺の検査
- 310.18 屠体・臓器・その他の部位の汚染
- 310.19 腎臓の検査
- 310.20 可食製品としての家畜血液の保存
- 310.21 スルファニルアミド・残留抗生物質を含む疑いのある屠体、検体採取頻度、影響を受けた屠体と部位の処分
- 310.22 [変更なし]
- 310.23 ブタ屠体と部位の識別
- 310.24 [変更なし]
- 310.25 微生物汚染、過程管理確認基準と検査、病原体抑制基準

典拠：21U.S.C.601-695 ; 7CFR2.18, 2.53

出典：特に記載がなければ 35FR15567, 1970 年 10 月 3 日

セクション 310.1 死後検査の範囲と時期および死後検査要員の基準

- (a) 公認施設で屠畜するすべての家畜の屠体と部位は、慎重な死後検査を行う。この検査は屠

畜時に行う。ただ、異常事態により、現場監督者が検査の後日実施について、事前に FSIS 局長と交渉し許可を得ている場合を除く。

- (b)(1) 1 時間に検査する屠体数に基づく要員配置基準を以下の表にまとめた。複数の検査官については、作業量を等しくするために検査官がシフト毎に異なる検査を巡回する場合を基準とする。担当検査官は、工場による高速屠体処理における特定の欠陥のため、または特定動物の健康状態がより包括的検査の必要性を示しているという理由で、現行速度では検査過程が適切に実行できないと判断した場合、施設に屠畜速度を落とすよう指示する権限を持つ。
- (2) 牛検査。すべての牛要員基準について、「ステーション毎の検査官数」の a 欄は 1 人の検査官が全検査過程を実施することを意味し、b 欄は 1 人の検査官が屠体頭部と下半身の検査、もう 1 人の検査官が内臓と上半身の検査を担当することを意味する。¹

(i) 内臓用台車を用いる検査

去勢牛と未経産牛

最大屠畜率 (1 時間当たり頭数)	ステーション当たりの検査数		
	頭部	内臓	屠体
1~27	a	a	a
28~56	b	b	b
57~84	1	1	1
85~86	1	2	1
87~143	2	2	1

雌牛と雄牛

最大屠畜率 (1 時間当たり頭数)	ステーション当たりの検査数		
	頭部	内臓	屠体
1~27	a	a	a
28~55	b	b	b
56~77	1	1	1
78~81	1	2	1
82~134	2	2	1

¹ (a)検査官 1 人、(b)検査官 2 人の屠畜数を示す本セクションパラグラフ(b)(2)(i)に示す「最大屠畜率」は、1 つの検査ステーションから別のステーションへの移動時間が含まれていないため、実際より大きくなっている。適切な補正最大屠畜速度を算定するためには、検査官 1 人の屠畜数については本セクションのパラグラフ(b)(2)(i)(A)、検査官 2 人の屠畜数については本セクションのパラグラフ(b)(2)(i)(B)を不随する規則とともに用いなければならない。

- (A) このサブディビジョンの表に従って、移動距離を考慮した検査官 1 人による補正最大屠畜率を算定する規則を以下に示す。検査官が実際に以下の表の欄 2～14 に示す地点間を歩く距離を測定する。各欄について、欄 1 の適切なフィート数に対応するマイナス値を決める。欄 2～14 についてマイナス値の合計を計算する。補正最大率は、本セクションのパラグラフ(b)(2)(i)の最大率からマイナス値合計を引いた値である。結果が整数にならない場合は、四捨五入して次に小さい整数とする。

検査官1人による屠牛—内臓用台車

表 間隔2フィートの地点についての最大屠畜率からのマイナス値 (1時間で牛10頭当たり)

1 地点間の フィート数	2 頭部ラックと ハイ・レール		3 内臓と ロー・レール		4 ロー・レールと 頭部		5 頭部と屠体 ²		6 屠体 ² と洗面台		7 標識・商標と ロー・レール		8 内臓と洗面台		9 内臓と ハイ・レール		10 ロー・レールと ハイ・レール		11 頭部ラックと 最も近い 洗面台		12 洗面台と ハイ・レール ¹		13 頭部ラックと 洗面台 ¹		14 内臓と 標識・商標		
	去勢牛 と未経 産牛	雄牛と 雌牛	去勢牛 と未経 産牛	雄牛と 雌牛	去勢牛 と未経 産牛	雄牛と 雌牛	去勢牛 と未経 産牛	雄牛と 雌牛	去勢牛 と未経 産牛	雄牛と 雌牛	去勢牛 と未経 産牛	雄牛と 雌牛	去勢牛 と未経 産牛	雄牛と 雌牛	去勢牛 と未経 産牛	雄牛と 雌牛	去勢牛 と未経 産牛	雄牛と 雌牛	去勢牛 と未経 産牛	雄牛と 雌牛	去勢牛 と未経 産牛	雄牛と 雌牛	去勢牛 と未経 産牛	雄牛と 雌牛	去勢牛 と未経 産牛	雄牛と 雌牛	
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.1	0	0
5	0	0	0.1	0	0	0	0	0	0	0	0	0	0	0.1	0.1	0.1	0	0	0	0	0	0	0	0	0.2	0.1	0
7	0	0	0.1	0.1	0.1	0.1	0	0	0	0	0.1	0.1	0.1	0.2	0.2	0.2	0.1	0.1	0	0	0	0	0	0	0.3	0.3	0
9	0	0	0.2	0.1	0.1	0.1	0	0	0	0	0.1	0.1	0.1	0.3	0.3	0.3	0.1	0.1	0	0	0.1	0.1	0.1	0.1	0.4	0.4	0
11	0.1	0.1	0.2	0.2	0.2	0.2	0	0	0	0	0.1	0.2	0.2	0.4	0.4	0.4	0.2	0.2	0	0	0.1	0.1	0.1	0.1	0.5	0.6	0
13	0.1	0.1	0.3	0.2	0.2	0.2	0	0	0	0	0.2	0.2	0.2	0.5	0.5	0.5	0.2	0.2	0	0	0.1	0.1	0.1	0.1	0.6	0.7	0
15	0.1	0.1	0.4	0.3	0.3	0.3	0	0	0	0	0.2	0.3	0.3	0.5	0.6	0.6	0.3	0.3	0	0	0.2	0.2	0.2	0.2	0.7	0.9	0
17	0.1	0.1	0.4	0.3	0.3	0.3	0	0	0	0	0.3	0.3	0.3	0.6	0.7	0.7	0.3	0.3	0	0.1	0.2	0.2	0.2	0.2	0.9	1.0	0
19	0.1	0.1	0.5	0.4	0.4	0.4	0	0	0	0	0.3	0.4	0.4	0.7	0.8	0.8	0.4	0.4	0	0.1	0.2	0.2	0.2	0.2	1.0	1.1	0
21	0.2	0.2	0.5	0.4	0.4	0.4	0	0	0	0	0.3	0.4	0.4	0.8	0.9	0.8	0.4	0.4	0	0.1	0.3	0.2	0.3	0.2	1.1	1.3	0
23	0.2	0.2	0.6	0.5	0.5	0.5	0	0	0	0	0.4	0.5	0.5	0.9	1.0	0.9	0.5	0.5	0	0.1	0.3	0.3	0.3	0.3	1.2	1.4	0
25	0.2	0.2	0.7	0.5	0.5	0.5	0	0	0	0	0.4	0.5	0.5	1.0	1.1	1.0	0.5	0.5	0	0.1	0.3	0.3	0.3	0.3	1.3	1.5	0
27	0.2	0.2	0.7	0.5	0.6	0.5	0	0	0	0	0.4	0.5	0.6	1.1	1.2	1.1	0.6	0.6	0	0.1	0.3	0.3	0.3	0.3	1.4	1.7	0
29	0.2	0.2	0.8	0.6	0.6	0.6	0	0	0	0	0.5	0.6	0.6	1.2	1.3	1.2	0.6	0.6	0	0.1	0.4	0.3	0.4	0.3	1.5	1.8	0
31	0.3	0.2	0.8	0.6	0.7	0.6	0	0	0	0	0.5	0.6	0.7	1.3	1.3	1.4	0.7	0.7	0	0.1	0.4	0.4	0.4	0.4	1.6	1.9	0
33	0.3	0.3	0.9	0.7	0.7	0.7	0	0	0	0	0.6	0.7	0.7	1.3	1.4	1.4	0.7	0.7	0	0.1	0.4	0.4	0.4	0.4	1.7	2.1	0
35	0.3	0.3	1.0	0.7	0.8	0.7	0	0	0	0	0.6	0.7	0.8	1.4	1.5	1.5	0.8	0.8	0	0.2	0.5	0.4	0.5	0.4	1.8	2.2	0
37	0.3	0.3	1.0	0.8	0.8	0.8	0	0	0	0	0.6	0.8	0.8	1.5	1.6	1.6	0.8	0.8	0	0.2	0.5	0.5	0.5	0.5	1.9	2.3	0
39	0.3	0.3	1.1	0.8	0.9	0.8	0	0	0	0	0.7	0.8	0.9	1.6	1.7	1.7	0.9	0.9	0	0.2	0.5	0.5	0.5	0.5	2.0	2.4	0
41	0.4	0.3	1.1	0.9	0.9	0.9	0	0.1	0	0.1	0.7	0.9	0.9	1.7	1.7	1.8	0.9	0.9	0	0.2	0.6	0.5	0.6	0.5	2.1	2.6	0
43	0.4	0.4	1.2	0.9	1.0	0.9	0	0.1	0	0.1	0.7	0.9	1.0	1.8	1.8	1.9	1.0	1.0	0.1	0.2	0.6	0.5	0.6	0.5	2.2	2.7	0
45	0.4	0.4	1.2	0.9	1.0	0.9	0	0.1	0	0.1	0.8	0.9	1.0	1.8	1.9	2.0	1.0	1.0	0.1	0.2	0.6	0.6	0.6	0.6	2.3	2.8	0
47	0.4	0.4	1.3	1.0	1.1	1.0	0	0.1	0	0.1	0.8	1.0	1.1	1.9	2.0	2.1	1.1	1.1	0.1	0.2	0.6	0.6	0.6	0.6	2.4	2.9	0
49	0.4	0.4	1.4	1.0	1.1	1.0	0	0.1	0	0.1	0.8	1.0	1.1	2.0	2.1	2.2	1.1	1.1	0.1	0.2	0.7	0.6	0.7	0.6	2.5	3.1	0
51	0.5	0.5	1.4	1.1	1.2	1.1	0	0.1	0	0.1	0.9	1.1	1.2	2.1	2.2	2.2	1.2	1.2	0.1	0.3	0.7	0.7	0.7	0.7	2.6	3.2	0
53	0.5	0.5	1.5	1.1	1.2	1.1	0	0.1	0	0.1	0.9	1.1	1.2	2.2	2.3	2.3	1.2	1.2	0.1	0.3	0.7	0.7	0.7	0.7	2.7	3.3	0
55	0.5	0.5	1.5	1.2	1.2	1.2	0	0.1	0	0.1	1.0	1.2	1.2	2.3	2.3	2.4	1.3	1.3	0.1	0.3	0.8	0.7	0.8	0.7	2.8	3.4	0
57	0.5	0.5	1.6	1.2	1.3	1.2	0	0.1	0	0.1	1.0	1.2	1.3	2.3	2.4	2.5	1.3	1.3	0.1	0.3	0.8	0.7	0.8	0.7	2.9	3.5	0
59	0.5	0.5	1.6	1.3	1.3	1.3	0	0.1	0	0.1	1.0	1.3	1.3	2.4	2.5	2.6	1.4	1.4	0.1	0.3	0.8	0.8	0.8	0.8	3.0	3.6	0

¹ ここでの洗面台は、頭部ラックからハイ・レール検査に移動する際に検査官が用いるものを指す。

² これは出血区域の屠体を指す。

- (B) このサブディビジョン中の表に従って、移動距離を考慮した検査官 2 人による補正最大屠畜率を算出する規則を以下に示す。検査官が実際に以下の表の欄 2~9 に示す地点間を歩く距離を測定する。欄 9 は、内臓検査官が用いる不良品宣言された商標と標識が洗面台・消毒剤以外の場所に保管されている場合にのみ用いる。各欄について、欄 1 の適切なフィート数と対応するマイナス値を決める。欄 2~9 についてマイナス値の合計を計算する。この合計を 2 で割る。補正最大率は、本セクションのパラグラフ(b)(2)(i)の最大率から上記のマイナス値合計を引いた値である。結果が整数にならない場合は、四捨五入して次に小さい整数とする。

検査官2人による屠牛—内臓用台車

表 間隔2フィートの地点についての最大屠畜率からのマイナス値(1時間で牛10頭当たり)

1 地点間の フィート 数	頭部とロー・レール検査								内臓とハイ・レール検査							
	2 頭部ラックと 洗面台		3 頭部ラックと屠体 ²		4 洗面台と ロー・レール		5 頭部ラックと ロー・レール		6 内臓と標識・商標 (洗面台)		7 内臓と ハイ・レール		8 ハイ・レールと 洗面台		9 ¹ 内臓と洗面台	
	去勢牛と 未経産牛	雄牛と 雌牛	去勢牛と 未経産牛	雄牛と 雌牛	去勢牛と 未経産牛	雄牛と 雌牛	去勢牛と 未経産牛	雄牛と 雌牛	去勢牛と 未経産牛	雄牛と 雌牛	去勢牛と 未経産牛	雄牛と 雌牛	去勢牛と 未経産牛	雄牛と 雌牛	去勢牛と 未経産牛	雄牛と 雌牛
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0.1	0	0.1	0	0.1	0	0	0	0	0	0	0	0	0	0.1	0.2
5	0.1	0.1	0.1	0.1	0.1	0.1	0.8	0.7	0.4	0.5	0.5	0.5	0.1	0.2	0.2	0.3
7	0.1	0.2	0.1	0.1	0.1	0.1	1.5	1.4	0.7	0.9	1.0	0.9	0.3	0.3	0.3	0.4
9	0.2	0.2	0.1	0.2	0.1	0.2	2.2	2.0	1.1	1.3	1.5	1.3	0.4	0.5	0.4	0.5
11	0.2	0.3	0.1	0.2	0.2	0.2	2.8	2.7	1.4	1.7	1.9	1.8	0.5	0.6	0.4	0.6
13	0.2	0.4	0.1	0.3	0.2	0.2	3.5	3.3	1.7	2.1	2.4	2.2	0.6	0.7	0.5	0.8
15	0.3	0.4	0.1	0.3	0.2	0.3	4.1	3.9	2.0	2.5	2.9	2.6	0.7	0.9	0.6	0.9
17	0.3	0.5	0.1	0.4	0.2	0.3	4.8	4.5	2.4	2.9	3.3	3.0	0.8	1.0	0.7	1.0
19	0.3	0.6	0.2	0.4	0.3	0.4	5.4	5.1	2.7	3.3	3.7	3.4	0.9	1.2	0.7	1.2
21	0.3	0.6	0.2	0.4	0.3	0.4	6.0	5.7	3.0	3.7	4.2	3.7	1.0	1.3	0.8	1.3
23	0.4	0.7	0.2	0.5	0.3	0.5	6.6	6.3	3.3	4.0	4.6	4.1	1.2	1.4	0.9	1.4
25	0.4	0.7	0.2	0.5	0.3	0.5	7.2	6.8	3.6	4.4	5.0	4.5	1.3	1.6	1.0	1.6
27	0.4	0.8	0.2	0.6	0.4	0.5	7.8	7.4	3.9	4.7	5.4	4.9	1.4	1.7	1.0	1.7
29	0.5	0.9	0.2	0.6	0.4	0.6	8.3	7.9	4.2	5.1	5.8	5.2	1.5	1.8	1.1	1.8
31	0.5	0.9	0.2	0.7	0.4	0.6	8.9	8.5	4.5	5.4	6.2	5.6	1.6	2.0	1.2	2.0
33	0.5	1.0	0.2	0.7	0.4	0.7	9.4	9.0	4.8	5.8	6.5	5.9	1.7	2.1	1.3	2.1
35	0.6	1.1	0.3	0.8	0.5	0.7	10.0	9.5	5.0	6.1	6.9	6.3	1.8	2.2	1.3	2.3
37	0.6	1.1	0.3	0.8	0.5	0.7	10.5	10.0	5.3	6.4	7.3	6.6	1.9	2.4	1.4	2.4
39	0.6	1.2	0.3	0.9	0.5	0.8	11.0	10.5	5.6	6.8	7.6	6.9	2.0	2.5	1.5	2.5
41	0.7	1.2	0.3	0.9	0.6	0.8	11.5	11.0	5.9	7.1	8.0	7.2	2.1	2.6	1.5	2.6
43	0.7	1.3	0.3	0.9	0.6	0.9	12.0	11.4	6.1	7.4	8.3	7.6	2.2	2.8	1.6	2.8
45	0.7	1.4	0.3	1.0	0.6	0.9	12.5	11.9	6.4	7.7	8.7	7.9	2.4	2.9	1.7	2.9
47	0.8	1.4	0.3	1.0	0.6	1.0	13.0	12.4	6.7	8.0	9.0	8.2	2.5	3.0	1.8	3.0
49	0.8	1.5	0.3	1.1	0.7	1.0	13.4	12.8	6.9	8.3	9.4	8.5	2.6	3.2	1.8	3.1
51	0.8	1.6	0.3	1.1	0.7	1.0	13.9	13.3	7.2	8.6	9.7	8.8	2.7	3.3	1.9	3.3
53	0.9	1.6	0.4	1.2	0.7	1.1	14.4	13.7	7.4	8.9	10.0	9.1	2.8	3.4	2.0	3.4
55	0.9	1.7	0.4	1.2	0.7	1.1	14.8	14.1	7.7	9.2	10.3	9.4	2.9	3.5	2.0	3.5
57	0.9	1.7	0.4	1.3	0.8	1.2	15.2	14.6	7.9	9.5	10.6	9.7	3.0	3.7	2.1	3.6
59	0.9	1.8	0.4	1.3	0.8	1.2	15.7	15.0	8.2	9.7	10.9	9.9	3.1	3.8	2.2	3.8

¹ この欄は、商標と標識が洗面所がない場合のみ用いる。

² これは出血区域の屠体を指す。

(ii) 内臓使用検査表、舌付き（内側）頭部提示

去勢牛と未経産牛				雌牛と雄牛			
最大屠畜率 (1時間当たり頭数)	ステーション毎の 検査数			最大屠畜率 (1時間当たり頭数)	ステーション毎の 検査数		
	頭部	内臓	屠体		頭部	内臓	屠体
1 ~ 32.....	a	a	a	1 ~ 29.....	a	a	a
33 ~ 58.....	b	b	b	30 ~ 56.....	b	b	b
59 ~ 84.....	1	1	1	57 ~ 77.....	1	1	1
85 ~ 86.....	1	2	1	78 ~ 81.....	1	2	1
87 ~ 143.....	2	2	1	82 ~ 134.....	2	2	1
144 ~ 171.....	3	2	1	135 ~ 159.....	2	3	1
172 ~ 198.....	3	3	1	160 ~ 187.....	3	3	1
199 ~ 226.....	3	3	2	188 ~ 213.....	3	4	1
227 ~ 253.....	4	3	2	214 ~ 234.....	3	4	2
254 ~ 280.....	4	4	2	235 ~ 264.....	4	4	2
281 ~ 306.....	5	4	2	265 ~ 289.....	5	4	2
307 ~ 333.....	5	5	2	290 ~ 314.....	5	5	2

(iii) 内臓使用検査表、舌付き（外側）頭部提示

去勢牛と未経産牛				雌牛と雄牛			
最大屠畜率 (1時間当たり頭数)	ステーション毎の 検査数			最大屠畜率 (1時間当たり頭数)	ステーション毎の 検査数		
	頭部	内臓	屠体		頭部	内臓	屠体
1 ~ 32.....	a	a	a	1 ~ 29.....	a	A	a
33 ~ 58.....	b	b	b	30 ~ 56.....	b	B	b
59 ~ 86.....	1	1	1	57 ~ 79.....	1	1	1
87 ~ 103.....	1	2	1	80 ~ 98.....	1	2	1
104 ~ 156.....	2	2	1	99 ~ 147.....	2	2	1
157 ~ 186.....	2	3	1	148 ~ 174.....	2	3	1
187 ~ 216.....	3	3	1	175 ~ 205.....	3	3	1
217 ~ 246.....	3	3	2	206 ~ 233.....	3	4	1
247 ~ 275.....	3	4	2	234 ~ 256.....	3	4	2
276 ~ 304.....	4	4	2	257 ~ 288.....	4	4	2
305 ~ 333.....	4	5	2	289 ~ 316.....	5	4	2
334 ~ 362.....	5	5	2	317 ~ 343.....	5	5	2
363 ~ 390.....	5	6	2				

- (3) プタ検査。以下の検査要員配置基準は、ブタ屠畜に適用される。すべての屠畜場についての検査基準は、内臓検査ステーションにおける脾臓・肝臓・心臓・肺・縦隔リンパ節の触診ではなく観察に基づく。さらに、1人・2人の検査官体制では、基準は検査官がステーション間を歩く距離に基づく。3人以上の検査官体制については、セクション 307.2(m)(6)に述べるように、屠体検査ステーションでの鏡の使用に基づく。1人または2人の検査官体制では求められないが、検査局が定める特定の場合を除き、鏡を使用する場合はセクション 307.2(m)(6)の規定に従わなければならない。

3 2004年1月12日付けFSIS NOTICE 5-04の
Ⅲ. A. 2に関し、FSISはBSE検査のためのサンプリングに
おいて、20ヶ月齢以上の牛に関心を示しているとしているが、そ
の理由。

(米国からの回答)

In early November 2003, shortly after reporting the confirmation of BSE in a 23-month-old animal, Japan reported that BSE was confirmed in a 21-month-old animal. The 21-month-old animal was Japan's 9th reported case of BSE. Like the 23-month-old animal, this animal apparently did not have clinical signs of disease. However, the abnormal prion protein detected in this animal does not appear to be the same as the apparently atypical form detected in the 23-month-old animal. Japanese officials reported that they will be conducting testing to determine if the tissues of these relatively young cattle that were recently found positive for BSE contain BSE infectivity. Although rare, confirmed cases of BSE in animals younger than 30 months of age have also been reported in the United Kingdom and in some other European countries. Confirmed cases of BSE in an animal less than 30 months of age generally imply that the animal was exposed to a large dose of the infective agent at a young age. From 1988 to 1996, during the height of the BSE epidemic in the United Kingdom when large amounts of infective agent were being circulated among cattle herds, 19 clinical cases of BSE were confirmed in cattle younger than 30 months of age. The youngest confirmed case of BSE was in the United Kingdom in an animal with clinical disease at 20 months of age in 1992. However, as of September 30, 2003, no cases of BSE in cattle younger than 30 months of age have been detected in the United Kingdom since 1996, and only 3 cases have been found in European animals less than 30 months of age since 2001.

Consequently, FSIS recognizes the remote possibility, under extreme conditions, of finding cattle under 30 months of age that test positive for BSE. FSIS also recognizes that there have been no confirmed cases of BSE for cattle under 20 months of age. Therefore, given a worst-case scenario, testing cattle that are 20 months of age or older would not be out of line with historical evidence; although international guidelines (OIE) do not concur with this level of testing.

However, as you know, FSIS Notice 5-05 dated 1/12/04 states that "The [FSIS] VMO is to contact the Animal and Plant Health Inspection Service (APHIS) Area Veterinarian-in-Charge (AVIC) to allow APHIS the opportunity to collect BSE surveillance samples. APHIS is primarily interested in cattle that are 20 months of age and older and cattle showing signs of CNS disorder. Therefore, if cattle show signs of CNS disorder or are non-ambulatory disabled, and there is reason to believe that they are 20 months of age or older, VMOs are to make this known to the AVIC so the AVIC has an opportunity to collect a surveillance sample from the condemned animals." FSIS has been unable to find written documentation of why APHIS is interested in cattle between 20 and 30 months of age and suggests that APHIS respond directly to this query.

(仮訳)

2003年11月初旬、23ヶ月齢のBSE確認を発表した直後に、日本は別の21ヶ月齢のウシでBSEが確認されたと発表した。この21ヶ月のウシは、日本で9頭目のBSEである。23ヶ月齢の症例と同様、このウシも臨床的兆候は認められなかった。しかし、このウシで検出された非定型プリオンは、先の23ヶ月齢のウシで検出された非定型とは異なるようである。日本政府担当者は、BSE陽性が見つかったこれら比較的若い牛の組織に、BSE感染性があるかどうか今後検査を行ってゆくと報告した。数は少ないが、30ヶ月齢未満のウシのBSE確定例は、英国その他欧州でも報告されている。30ヶ月齢未満でのBSEの確定例は、生後早くに大量の感染因子に曝露したことを示唆する。1988年から1996年にかけて、英国でBSEの発生がピークにあり大量の感染因子が牛群に広がっていた時期には、30ヶ月齢未満のウシでのBSEが19件確認されている。英国で確認された最も若いウシは、1992年の臨床的疾患を伴う20ヶ月の症例である。しかし、2003年9月30日現在で、英国では1996年以降30ヶ月齢未満のウシのBSEは検知されておらず、欧州全体でも2001年以降30ヶ月未満のウシで確認された症例はわずか3件である。

従って、FSISは、極端な条件下で、30か月齢以下のBSE陽性牛を検出するわずかな可能性を認識している。FSISはまた、20ヶ月齢以下でBSE感染が確認された症例がなかったことも認識している。つまり、最悪のシナリオを考慮しても、20か月齢以上の牛を検査することは過去の症例を無視することにはならない；国際的なガイドライン(OIE)はこのレベルの検査に一致していないが。

しかしながら、ご存じのとおり、1/12/04付けFSIS Notice 5-05で次のとおり言及している「(FSISの)VMOは動植物検疫局 (APHIS) のエリア獣医師 (AVIC) と連絡をとり、BSEサーベイランスのサンプルを集めることを許可する。APHISは、主として20か月齢以上でありCNS症状を示す牛に興味を示している。つまり、牛がもしCNS症状を示しているか歩行困難であり、これらの牛が20ヶ月齢以上であるとする理由があるとき、AVICがとさつ禁止の動物からサーベイランスの検体を採取するために、VMOはこのことをAVICに知らせることとなっている。」FSISは、なぜAPHISが20から30か月齢の牛に対して興味を持っているかについて書かれた文書を見つけることができない。APHISがこの質問に直接回答することを勧める。

4 米国のラボで使用しているELISA、WB及びIHCの詳細な検査プロトコール又は検査マニュアル

(米国からの回答)

See attached. With regard to the specific request for description of the antibody used: F97/99 antibody is used for the NVSL IHC procedure and for the NVSL ELISA procedure, the proprietary antibody for BioRad test kit is used.

(仮訳)

別添を参照してください。使用された抗体の具体的な説明要請に関して: NVSLのIHCにはF97/99抗体が使用されます。NVSLのELISAには、BioRadの検査キットに付属の抗体が使用されます。

**United States Department of Agriculture National
Veterinary Services Laboratories**

Standard Operating Procedure

**ELISA Test Procedure
for
Bovine Spongiform Encephalopathy**

Date: August 11, 2004
Supersedes: GPPISOP0030.01
Number: GPPISOP0030.02
Contact Person: Roger E. Brannian

Approvals:

/s./Mark Hall Date: 8/17/04
S. Mark Hall, Head
General Pathology and Pathology Investigations Section

/s./Paul F. Ross, Acting Date: 8/17/04
Arthur J. Davis, Chief
Pathobiology Laboratory

United States Department of Agriculture
Animal and Plant Health Inspection Service
P. O. Box 844
Ames, IA 50010

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ELISA Test Procedure for Bovine Spongiform Encephalopathy

Purpose:

The purpose of this standard operating procedure (SOP) is to document the proper technical procedure for performance of the enzyme-linked immunosorbent supplemental assay (ELISA) test for bovine spongiform encephalopathy (BSE) at the National Veterinary Services Laboratories (NVSL), Pathobiology Laboratory (PL), General Pathology and Pathology

Investigations (GPPI) Section and at designated BSE contract laboratories.

Test Preparation:

Receiving, log-in, sample identification, safety, and sample handling procedures are followed in accordance with the current version of NVSL SOP, "Tracking Protocol for ELISA Test Samples for Bovine Spongiform Encephalopathy" (GPPISOP0031) or, in the case of BSE contract laboratories, in accordance with protocols developed at each individual laboratory.

Cut-in Procedure:

The obex area of the brain stem must be sampled for optimal detection of protease resistant prion protein (PrP^{res}). The NVSL protocol for cutting in the obex differs from the manufacturer's test kit instructions (Bio-Rad TeSeE™ Purification Kit) and is outlined in the following paragraph. This deviation is employed to conserve sample material in the event additional tests are required.

Organize samples in appropriately labeled grinding tubes in numerical order. Make sure the scale is balanced. Place a disposable weigh boat on the balance scale and zero the scale. For each sample, use clean forceps to gently work around the edges of the brain stem and allow the tissue to slide onto another weigh boat. With a sterile scalpel, make a cut to unilaterally remove brain stem tissue that encompasses one of the dorsal vagal nuclei located at the level of the obex. (The sample should incorporate one dorsal vagal nucleus, but NOT both). The sample tissue is placed in the weigh boat on the scale and must weigh 350 +/- 40 mg. Slide the tissue into a grinding tube and use a wood stick or forceps to push the tissue into the buffer. Discard the scalpel and all weigh boats in appropriate biohazard containers. Upon completion of cut-in, the samples are held in a controlled access refrigerator pending testing.

After all the samples from a particular case submission are cut-in, place the samples into a clean bag with the identifying Lab ID number and a copy of the VS 10-4 form, which should include the date and initials of the person cutting in. Any comments on the condition of the samples (autolyzed, mutilated, inappropriate anatomical location, etc.) should also be noted on the VS 10-4 form.

NVSL
Standard Operating Procedure

GPPISOP0030.02
Page 3 of 3

Cut-In Cards:

After cut-in, a cut-in card should be filled out. The form must include the Lab ID number, the initials of the person cutting in, and any determinations on the suitability of the sample for testing as outlined in the following paragraph.

Any samples that are received but are not clearly recognizable as brain stem will not be tested and the results will be reported as Not Tested. For brain stem samples received that have no recognizable obex, test results will be reported but qualified as Not Detected/Not Obex for inappropriate location. (Note that the print-out result from the test equipment will still read ND for not detected, so the inappropriate location information has to be obtained from the cut-in card). Samples suitable for testing will be reported as described in the current version of NVSL SOP, "Protocol for BSE Contract Laboratories to Receive and Test Bovine Brain Samples and Report Results for BSE Surveillance" (GPPISOP0032).

Performance of the ELISA BSE Test:

Aside from the specific above-noted deviation involving the cut-in procedure and the deviation listed below, the NVSL sample purification process follows the manufacturer's instructions for semi-automated processing of the purification protocol (TeSeE™ and TeSeE™ NSP manuals). A deviation from the manufacturer's protocol is that NVSL uses a sample homogenate volume of 350 - 500 microliters (rather than 300 - 750 microliters) to insure there is an adequate amount of sample to perform the test. However, no more than 500 microliters should be used to make sure the sample can be run multiple times if necessary.

In the event of a known splashing or pipetting error, the technician should document the error and report to their supervisor **PRIOR TO READING THE PLATE**. In such cases of a documented error or a run failure that results in NVSL/inconclusive results being generated, the samples should be retested in the primary laboratory before sending samples to NVSL. If, after repeating the sample that had a documented error, the repeated sample results were ND, there would be no need for a contract lab to forward the sample to NVSL.

Center for Veterinary Biologics
and
National Veterinary Services Laboratories
Standard Operating Procedure

Detection of Prion Protein in Formalin-fixed Brain of
Cattle by Immunohistochemistry using the Ventana NexES

Date: May 3, 2004
Supersedes: GPPISOP0026.02, May 28, 2003
Number: GPPISOP0026.03
Contact Person: Sharon A. Lund, Technician
(515) 663-7521

Approvals:

/s/ S. Mark Hall Date: 5/10/04
S. Mark Hall, Head, General Pathology
and Pathology Investigations Section

/s/ Arthur J. Davis Date: 5/10/04
Arthur J. Davis, Chief
Pathobiology Laboratory

National Veterinary Services Laboratories
United States Department of Agriculture
Animal and Plant Health Inspection Service
P. O. Box 844
Ames, IA 50010

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of other products that may be suitable.

TSE IHC PROCEDURES NVSL AMES, IA

Detection of Prion Protein in Formalin-fixed Brain of Cattle by Immunohistochemistry using the Ventana NexES

CAUTION: This protocol uses formalin. This agent is caustic and may cause sensitivity. Handle only in a fume hood and avoid contact with eyes and skin. Avoid breathing fumes.

Brain Tissue is placed in 10% Neutral Buffered Formalin and left for a minimum of 5 days. Appropriate sections are put in cassettes and kept in fresh Formalin until they are processed. (Cassettes containing brain tissue are never left in alcohols for more than 12 hours.)

Automated Tissue Processing utilizes pressure and vacuum to achieve optimum solvent and Paraplast penetration. The routine (overnight) and weekend (48 hour delay) processing schedules consist of 16 - 1 hour-long stations. Solutions in the processor are changed after running approximately 300 samples.

Tissue Processor Solutions

- Station 1 – 70% Ethyl Alcohol
- Station 2 – 70% Ethyl Alcohol
- Station 3 – 80% Ethyl Alcohol
- Station 4 – 95% Ethyl Alcohol
- Station 5 – 95% Ethyl Alcohol
- Station 6 – 100% Ethyl Alcohol
- Station 7 – 100% Ethyl Alcohol
- Station 8 – 100% Ethyl Alcohol
- Station 9 – Xylene
- Station 10 – Xylene
- Station 11 – Paraplast Tissue Embedding Medium
(Oxford Labware of Sherwood Medical)
- Station 12 – Paraplast Tissue Embedding Medium
- Station 13 – Paraplast Tissue Embedding Medium
- Station 14 – Paraplast Tissue Embedding Medium
- Station 15 – Cleaning Xylene
- Station 16 – Cleaning Alcohol (100% Ethyl Alcohol)

1. Cut paraffin embedded tissue sections at 5 microns and mount onto charged glass slides (Fisher Superfrost Plus) using lab quality water (distilled or deionized).
2. Set slides upright; drain and air-dry a minimum of 3 hours.

3. Run positive and negative control tissues with each set of twenty or less slides.
4. Dry slides for 15 minutes at 80 degrees C.
5. Remove from oven and process:
 - Xylene – 5 minutes
 - Xylene – 5 minutes
 - Xylene – 5 minutes
 - 100% Ethyl Alcohol – 1 minute
 - 100% Ethyl Alcohol – 1 minute
 - 95% Ethyl Alcohol – 1 minute
 - Lab quality water (Distilled or Deionized) 10 dips
(Solutions changed after 40 slides)
6. Place 500ml lab grade (distilled or deionized) water in bottom of Biocare Medical Decloaking Chamber.
7. Dilute Dako Concentrated Target Retrieval Solution using 20ml concentrate to 180ml lab grade (distilled or deionized) water. Make 1 container for every 20 slide rack to be run. Place in Biocare Medical Decloaking Chamber.
8. Fill decloaker so there are 4 containers every time, each containing 20 slides (fill to 20 slides with blanks if necessary) and 200ml Target Retrieval solution or lab grade (distilled or deionized) water.
9. Place steam monitor strip across top of dishes. Close and secure lid and lower the weight on the vent nozzle. Set dial for 30 minutes at 120 degrees C.
10. At the end of the timing, cool for 25 minutes. Timing is critical so do not vary times!
11. After 25 minute cool, transfer slides from Target Retrieval solution to Ventana APK Wash. Change APK Wash and soak slides for at least 5 minutes.
12. During the 5 minutes in the second APK Wash, you can apply the appropriately printed bar code label to slide. (DO NOT LET SLIDES DRY WHILE LABELING) Label all slides.
13. Load on the Ventana NexES stainer covering the sample with APK Wash Solution (DO NOT ALLOW SLIDES TO DRY)
14. Place all reagents on carousel and fill APK Wash and Liquid Coverslip bottles.
15. Primary Antibody : Cattle – Primary antibody 97 only (10ug/ml)
 - DILUTE FRESH DAILY using Dako antibody diluent
 - Store concentrate vials in a freezer until ready to use.
 - Once concentrate vial is opened – store in refrigerator.
16. Run slides to completion using Alkaline Phosphatase Red Paraffin Protocols (See attached protocols)
17. Remove slides and place in rack. Dip thirty times in 250ml warm soapy tap water containing 2-3 drops Dawn dishwashing liquid.
18. Rinse in running tap water 2 minutes.
19. Rinse in lab quality water (distilled or deionized) 10 dips.
20. Dehydrate / Clear / Mount
 - Dip 10 times each:
 - 100% Ethyl Alcohol
 - 50/50 – 100% Ethyl Alcohol & Xylene

Xylene

(Change solvents every 40 slides)

21. Coverslip slides or allow slides to dry, rewet with xylene and Coverslip.
22. Clean instrument daily

Demonstration of Results: Prion Protein – pink to red
Background – blue

Protocol # 96 : #96 usda alk phos (11/06/2003)

Procedure: Alk Phos Red Paraffin

NexES IHC Staining Module

NVSL - PL - GPP1 - PrP, Ames, Ia 50010

Step No	Procedure Step
1	***** Warmup Rinse Buffer to 41.0 Deg C *****
2	Rinse Slide
3	Adjust Slide Volume , then Apply Coverslip
4	***** Start Timed Steps *****
5	***** Warmup Slide Chamber to 37.0 Deg C *****
6	***** Start Untimed Steps *****
7	Rinse Slide
8	Adjust Slide Volume , then Apply Coverslip
9	***** Start Timed Steps *****
10	Rinse Slide
11	Adjust Slide Volume , then Apply Coverslip
12	Apply One Drop of [ANTIBODY 87] (Antibody), and Incubate for [32 Minutes]
13	Rinse Slide
14	Adjust Slide Volume , then Apply Coverslip
15	Apply One Drop of Biotinylated Ig, and Incubate for 8 Minutes
16	Rinse Slide
17	Adjust Slide Volume , then Apply Coverslip
18	Apply One Drop of AVIDIN-ALK PHOS, and Incubate for 12 Minutes
19	Rinse Slide
20	Adjust Slide Volume , then Apply Coverslip
21	Apply One Drop of ENHANCER, and Incubate for 4 Minutes
22	Apply One Drop of FAST RED A and One Drop of NAPHTHOL, and Incubate for 8 Minutes
23	Apply One Drop of FAST RED B, and Incubate for 8 Minutes
24	Rinse Slide
25	Adjust Slide Volume , then Apply Coverslip
26	Apply One Drop of [HEMATOXYLIN] (Counterstain), and Incubate for [4 Minutes]
27	Rinse Slide
28	Adjust Slide Volume , then Apply Coverslip
29	Apply One Drop of [BLUING REAGENT] (Post Counterstain), and Incubate for [2 Minutes]
30	Rinse Slide

* one drop is one reagent dispense
NVSL - PL - GPP1 - PrP, Ames, Ia 50010
NexES v0.00

Printed 12/22/2003 3:06:30 PM
Page 1 of 1

5 2005年7月12日付けFSIS NOTICE 46-05において、FSISの生前検査前に施設側が家畜を区分けすることについて、2005年7月26日より牛については停止されているが、本NOTICEを公布した背景、理由及び施行前後の牛の生前検査の具体的な方法とその違い。

FSIS Response is as follows:

Background

FSIS Notice 37-95, effective June 2, 1995, establishments electing to use alternative inspection procedures must receive approval from the Area Supervisor. To obtain approval for alternative ante-mortem inspection procedures, establishments would have to prepare a letter to the Area Supervisor stating that they met the following requirements: (a) have a good history of regulatory compliance; (b) have suitable facilities and volume of operations; (c) have condemnation rates (based on data from the Animal Diseases Reporting System) within the national average for market hogs and fat cattle, respective of species; (d) apply the alternative ante-mortem inspection procedures only to domestic livestock (animals fed-out in the United States); (e) segregate abnormal animals; and (f) hold animals (normal and abnormal) for examination by FSIS personnel.

FSIS would (a) examine ALL animals found normal by the establishment while they were "at rest"; (b) select 5 to 10 percent of such animals from several lots, and observe them in motion on both sides; (c) examine, "at rest" and "in motion," establishment segregated abnormal animals; and (d) ensure animals determined to be USDA suspects are tagged with a U.S. suspect stage.

FSIS Notice 46-05, effective July 12, 2005, due to BSE, replaced existing memorandum and instructions regarding how inspection program personnel verify an establishment's voluntary segregation of animals prior to FSIS ante-mortem inspection (Previously referred to as alternative ante-mortem inspection). **FSIS is announcing that an establishment may no longer employ the practice for cattle, but may continue to do so for swine and sheep.** This notice provides inspection program personnel new instructions regarding their responsibilities at establishments that voluntarily segregate swine or sheep prior to FSIS ante-mortem inspection.

Inspection program personnel, under the Federal Meat Inspection Act, perform an ante-mortem examination and inspection all animals prior to slaughter to determine that an animal is fit for slaughter for human food purposes. If an establishment fails to present animals for ante-mortem inspection in accordance with 21 USC 603 and 9 CFR 309.1, inspection program personnel will be unable to determine that carcasses are not adulterated during postmortem inspection, and therefore cannot permit the carcasses to be marked as "inspected and passed."

Provided the establishment properly presents animals for ante-mortem inspection and properly follows the Humane Slaughter Act, FSIS has permitted an establishment to voluntarily segregate animals, to facilitate the establishment's scheduling of animals for slaughter. As of the implementation date of this notice, FSIS will only permit market classes of swine and sheep (i.e., market hogs and lambs), arriving for regular slaughter (i.e., not arriving for slaughter under any APHIS Veterinary Services permit or certificate) to continue to be voluntarily segregated by the establishment prior to FSIS ante-mortem inspection activities provided that: (a) market classes of animals comprise the predominant class slaughtered at the establishment; (b) the establishment has documented its segregation procedures in a prerequisite program, and (c) all animals are presented to inspection program personnel for examination and inspection prior to slaughter, and (d) the procedures in the prerequisite program and related records are available to inspection personnel upon request (FSIS Directive 5000.2).

Inspection program personnel verification of establishment segregation procedures for market swine and lambs prior to FSIS ante-mortem inspection must (verify) that the segregation procedures are only for market classes of swine and lambs; (b) examine all animals found normal by the establishment while the animals are "at rest," (i.e., by randomly moving around in the pens) (9 CFR 309.1(a)); (c) select 5 to 10 percent of all animals presented for ante-mortem inspection from several lots and observe them on each side in motion; (d) instruct the establishment to move abnormal animals that may be condemned under 9 CFR part 311 to the designated "Suspect" pen under 9 CFR 307.2 for final disposition by the PHV; and (e) randomly observe establishment personnel performing segregation procedures (i.e., segregating those animals showing signs of abnormalities or diseases from healthy animals) at least once per month.

NOTE: For livestock classes other than market swine and lambs (such as cattle), establishments may presort animals prior to inspection and move the animals that may be designated "U.S. Suspect" or "U.S. Condemn" under 9 CFR part 309 and 311 to the designated "Suspect" pen for final disposition by the PHV. The PHV must conduct a careful examination and inspection on all animals in the "Suspect" pen.

The difference in inspection procedures before and after FSIS Notice 46-05 is that now inspection program personnel are to conduct an examination and inspection of ALL remaining animals by observing them at rest and in motion.

SOURCE:

FSIS Notice 46-05, dated July 12, 2005

FSIS Notice 37-95, dated June 2, 1995

(仮 訳)

背景

1995年6月2日発効 FSIS 通知 37-9, 代替検査手順を用いることと決めた施設は地域監督官の承認を受けなくてはならない。代替検査手順の承認を得るためには、施設は以下の要件を満たしていることを記した地域監督官宛ての書簡を準備しなくてはならないことになるであろう。(a) 規制遵守に関する良好な履歴を持つこと；(b) 適切な施設と操業規模をもつこと；(c) 廃棄比率（動物疾病報告システムのデータに基づく）が市場用の豚と牛のうちの相当するほうの種に関する全国平均の範囲内であること；(d) この代替と畜前検査手順が国内産の家畜にのみ適用されること；(e) 異常な動物を隔離し；(f) FSIS 職員による検査のために（正常及び異常な）動物を係留すること。

FSIS は (a) 施設によって正常であるとされたすべての動物を「休息時」の状態で検査し；(b) 数ロットからそのような動物を5から10パーセント選び動作中の状態を両体側から観察し；(c) 施設によって隔離された異常動物の「休息時」および「動作中」の状態を観察し；(d) 「USDA suspect (USDA により疑いのあるとされたもの)」と決定された動物に「USDA suspect」のタグを確実につける。

2005年6月12日発効 FSIS 通知 46-05 は、BSE に鑑み、FSIS によると畜前検査に先立って施設が自主的に行う動物の隔離についての検査プログラム担当官による検証方法に関する、以前の連絡と指示を差し替えるものである。施設は今後この方法を牛について行ってはならないが、豚と羊には引き続き行ってもよいと FSIS は発表している。この通知は検査プログラム担当官に、FSIS によると畜前検査に先立って自主的に豚と羊の隔離を行う施設における責任についての新しい指示を与える。

連邦食肉検査法の下で、検査プログラム担当官はと畜前検査を実施し、人間の食品用に適しているかを決定するためにと畜前にすべての動物を検査する。もし施設が 21 USC 603 と 9 CFR 309.1 に規定されていると畜前検査に動物を供しなかった場合には、と畜後検査の際に検査プログラム担当官は枝肉が不適切なものではないと決定することができないので、「検査済み」とマークすることを許可することができない。

施設がと畜前検査に適切に動物を供し、人道的と畜法（Humane Slaughter Act）を適切に遵守している限りにおいて、動物のと畜スケジュールを円滑に行うために FSIS は施設が自主的に動物を隔離することを許可してきた。当該通知の施行日以降、市場等級の豚と羊（市場用豚とラム）が通常のと畜のために到着した

(APHIS 獣医局のいかなる許可証や保証書に基づくと畜のために到着したのではない) ときにのみ、FSIS は FSIS によると畜前検査行為に先立って施設が自主的に隔離することを以下の条件のもとに許可する。(a) 動物の市場等級が当該施設でと畜される主要な等級であること；(b) 当該施設が隔離手法を必須プログラムのひとつとして書面として持っていること；(c) すべての動物がと畜前の検査のために検査プログラム担当官に供されること；(d) 当該必須プログラム中の手順と関連の記録が、検査官の要求の際に提供されること (FSIS 通知 5002.2)。

FSIS と畜前検査に先立つ施設による市場用豚とラムの隔離手順の検査プログラム担当官による検証においては、隔離手順が市場等級の豚とラムのみに対するものであることを検証し；(b) 当該施設によって「休息時」に正常とされたすべての動物を (たとえば係留場をランダムに移動しながら) 検査し (9 CFR 309.1(a))；(c) と畜前検査に供される動物の数ロットから 5 から 10 パーセント選び動作中の状態を両体側から観察し；(d) 9 CFR part 311 の下で廃棄対象となる可能性のある異常動物を 9 CFR 307.2 の下での「疑い用」係留場へ PHV の最終判断のために移動するように施設に指示し；(e) 隔離手法を実施している (異常や病気の兆候が見られる動物を正常な動物から隔離する) 施設担当者を最低限毎月 1 回ランダムに観察する。

注記：市場用豚とラム以外の家畜 (たとえば牛) については、施設は検査に先立って動物を事前選別し、9 CFR part 309 と 311 の「U.S. Suspect」あるいは「U.S. Condemn」に指定される可能性のある動物を、PHV による最終判断のために「疑い牛」係留場に移動させることができる。PHV は「疑い牛」係留場内のすべての動物について注意深い検査を行わなくてはならない。

FSIS 通知 46-05 以前と以後の検査手法の違いとしては、現在では検査プログラム担当官が残りのすべての動物の検査を休息時と動作中の観察によって行うことになった点である。

SOURCE:

FSIS Notice 46-05, dated July 12, 2005

FSIS Notice 37-95, dated June 2, 1995

**6 輸入停止前の米国及びカナダからの牛肉、内臓、舌等の部位
別輸入実績**

● 米国からの牛肉等の輸入量(平成14年度)

	関税番号	品名	輸入量 14年度実績 (kg)
牛肉	0201	牛の肉(生鮮及び冷蔵)	
	0201, 10-000	骨付き 枝肉及び半丸枝肉	0
	20-010	四分体	2,247
	20-090	その他	5,217
	30-010	骨抜き ロイン	11,198,733
	30-020	かた、うで及びもも	38,654,909
	30-030	ばら	48,009,830
	30-090	その他	150,469
	0202	牛の肉(冷凍)	
	0202, 10-000	骨付き 枝肉及び半丸枝肉	0
	20-000	その他の骨付き	2,136,616
	30-010	骨抜き ロイン	4,588,728
	30-020	かた、うで及びもも	10,349,773
	30-030	ばら	124,702,937
	30-090	その他	332,535
	0206, 10-020	ほほ肉、頭肉(生鮮及び冷蔵)	0
	29-020	ほほ肉、頭肉(冷凍)	12,423
	1602, 50-910	煮沸肉	0
	計		240,144,417
くず肉等	0206, 10	牛のくず肉(生鮮及び冷蔵)	
	0206, 10-010	臓器及び舌	23,111,693
	0206, 10-090	くず肉(ほほ肉及び頭肉、臓器及び舌を除く)	237
		牛のくず肉(冷凍)	
	0206, 21-000	舌	24,613,638
	0206, 22-000	肝臓	2,861,091
	0206, 29-010	臓器	17,873,884
	0206, 29-090	くず肉(ほほ肉及び頭肉、臓器及び舌を除く)	128,711
	0504	動物の腸、ぼうこう又は胃の全形のもの及び断片 (※牛以外のものを含む)	
	0504, 00-019	動物の腸(ソーセージケーシング用のものを除く)	4,985,880
	0504, 00-090	動物のぼうこう又は胃の全形のもの及び断片	3,703,209
	1602, 50	牛の調製品	
	1602, 50-100	腸、ぼうこう又は胃の全形のもの及び断片 (単に水煮したもの)	3,022,717
	1602, 50-291	臓器及び舌(単に水煮したもの)	0
	計		80,301,060

資料:財務省「貿易統計」

● 米国からの輸入牛肉等の頭数換算試算

	米国からの輸入量(トン)① (平成14年度実績)	1頭当たりの重量(kg/頭)②	頭数換算(万頭)①/②
ロイン	15,787	(輸入全てがロインのセットの場合) 26.5	60
バラ	172,713	(輸入全てがバラのセットの場合) 31.5 (輸入全てが牛井用ショートプレートの場合)	548 1,727
タン	36,169	1.5	2,411
肝臓	2,861	5.8	49

注1:ロインの輸入量は、関税番号0201.30-010、0202.30-010の合計数量。

2:バラの輸入量は、関税番号0201.30-030、0202.30-030の合計数量。

3:タンの輸入量は、関税番号0206.10-010(臓器及び舌(冷蔵))の50%【舌の割合:業界聞き取り】と0206.21-000(舌(冷凍))の合計数量。

4:肝臓の輸入量は、関税番号0206.22-000の数量。

5:ロインの1頭当たりの重量は、農畜産業振興機構「牛肉の輸入形態事例集」から推計したリブアイロール、ストリップロイン、フルテンダーロインの合計重量。

6:バラの1頭当たりセット重量は、農畜産業振興機構「牛肉の輸入形態事例集」から推計したブリスケット、ショートプレート、フランクステーキ、ビーフスカートプレート、ショートリブ、チャックリブの合計重量。

7:タン、肝臓の1頭当たり重量は、国産品の重量(事例調査による)。

● カナダからの牛肉等の輸入量(平成14年度)

	関税番号	品 名	輸入量 14年度実績 (kg)
牛肉	0201	牛の肉(生鮮及び冷蔵)	
	0201, 10-000	骨付 枝肉及び半丸枝肉	0
	20-010	四分体	2,482
	20-090	その他	0
	30-010	ロイン	277,274
	30-020	骨抜き かた、うで及びもも	1,303,428
	30-030	ばら	2,656,973
	30-090	その他	30,975
	0202	牛の肉(冷凍)	
	0202, 10-000	骨付 枝肉及び半丸枝肉	0
	20-000	その他の骨付き	59,639
	30-010	ロイン	453,016
	30-020	骨抜き かた、うで及びもも	122,157
	30-030	ばら	14,732,237
	30-090	その他	37,518
	0206, 10-020	ほほ肉、頭肉(生鮮及び冷蔵)	0
	29-020	ほほ肉、頭肉(冷凍)	1,326
	1602, 50-910	煮沸肉	0
	計		19,677,025
くず肉等	0206, 10	牛のくず肉(生鮮及び冷蔵)	
	0206, 10-010	臓器及び舌	573,902
	0206, 10-090	くず肉(ほほ肉及び頭肉、臓器及び舌を除く)	0
		牛のくず肉(冷凍)	
	0206, 21-000	舌	3,148,932
	0206, 22-000	肝臓	0
	0206, 29-010	臓器	488,569
	0206, 29-090	くず肉(ほほ肉及び頭肉、臓器及び舌を除く)	0
	0504	動物の腸、ぼうこう又は胃の全形のもの及び断片 (※牛以外のものを含む)	
	0504, 00-019	動物の腸(ソーセージケーシング用のものを除く)	1,069,389
	0504, 00-090	動物のぼうこう又は胃の全形のもの及び断片	548,949
	1602, 50	牛の調製品	
	1602, 50-100	腸、ぼうこう又は胃の全形のもの及び断片 (単に水煮したもの)	0
	1602, 50-291	臓器及び舌(単に水煮したもの)	0
	計		5,829,741

資料:財務省「貿易統計」

● カナダからの輸入牛肉等の頭数換算試算

	米国からの輸入量(トン)① (平成14年度実績)	1頭当たりの重量(kg/頭)②	頭数換算(万頭)①/②
ロイン	730	(輸入全てがロインのセットの場合) 26.5	3
バラ	17,389	(輸入全てがバラのセットの場合) 31.5 (輸入全てが牛井用ショートプレートの場合)	55
タン	3,436	10.0 1.5	174 229

注1:ロインの輸入量は、関税番号0201.30-010、0202.30-010の合計数量。

2:バラの輸入量は、関税番号0201.30-030、0202.30-030の合計数量。

3:タンの輸入量は、関税番号0206.10-010(臓器及び舌(冷蔵))の50%【舌の割合:業界聞き取り】と0206.21-000(舌(冷凍))の合計数量。

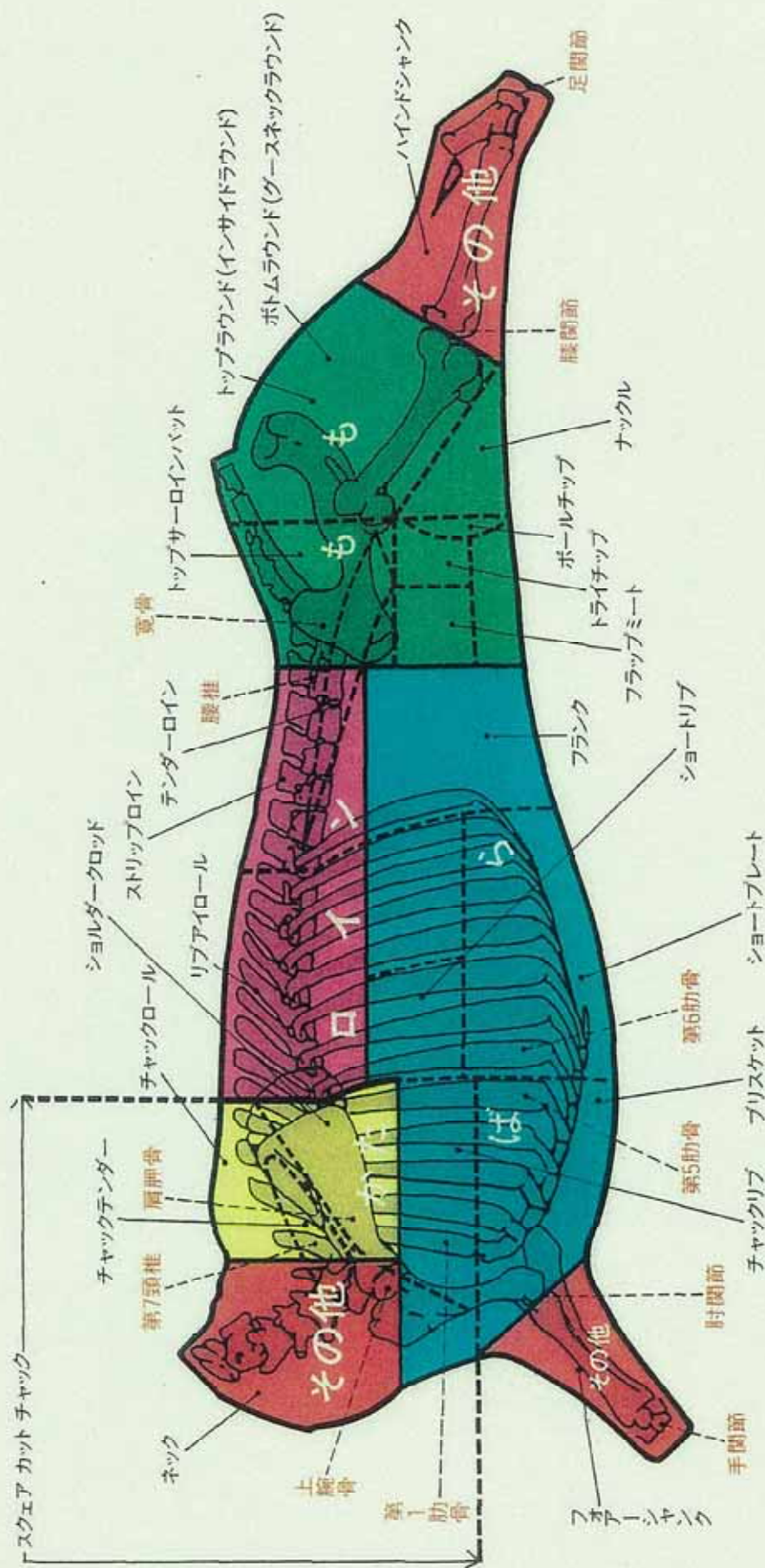
4:肝臓の輸入量は、関税番号0206.22-000の数量。

5:ロインの1頭当たりの重量は、農畜産業振興機構「牛肉の輸入形態事例集」から推計したリブアイロール、ストリップロイン、フルデンダーロインの合計重量。

6:バラの1頭当たりセット重量は、農畜産業振興機構「牛肉の輸入形態事例集」から推計したブリスケット、ショートプレート、フランクステーキ、ビーフスカートプレート、ショートリブ、チャックリブの合計重量。

7:タンの1頭当たり重量は、国産品の重量(事例調査による)。

北米の牛枝肉(カットチャート)



7 カナダから米国へ31ヶ月齢の生体牛が輸出された事実に関する情報

Outline of the incident involving the recent recall case (import of age 31+ animal from Canada).

- 1) What did Canada (CFIA) do? (in terms of investigation, etc.)
- 2) What did the US (abattoir and APHIS) do?

1) CFIA investigated the incident and suspended the accreditation of the veterinarian that certified the shipment for export. CFIA also stopped issuing export health certificates to the exporter. CFIA has made a public statement to accredited veterinarians working on behalf of CFIA and to exporters that there is a zero tolerance for non-compliance with U.S. import requirements. USDA immediately informed Canada and has been monitoring their investigation of this matter

A cow imported directly for slaughter in the US from Canada was approximately one month older than the 30-month age limit. FSIS learned about this as a result of a Canadian audit of their health certificate that accompanied the imported cow. Prior to slaughter, the health certificate accompanying the cow was presented to the establishment, and it appeared complete and accurate. However, a subsequent audit of information related to the health certificate by Canadian officials found that it was not accurate. Action has been taken by Canadian Food Inspection Agency officials in response to findings from the audit. A spokesman for the Canadian Food Inspection Agency said that the veterinarian responsible for issuing the certificate was suspended because of the error.

2) FSIS local field personnel verified the information and documentation that accompanied the animal and followed the guidelines and instructions as outlined in FSIS Notice # 15-05, dated 02/28/2005 (Importation of Canadian Cattle, Sheep, and goats into the United States). The said notice is attached above for reference and details. Both ante-mortem and post-mortem inspection were done on the cow in question. FSIS inspection program personnel determined the cow to be healthy and fit for human food.

See attached Press release for details on recall of meat and FSIS document.

The cause of the incident

- Why did an animal aged 31 months+ and eight pregnant cows get commingled with US cattle (see attached article) ?

As per FSIS Notice 15-05, Canada has provided the US governments (APHIS and FSIS) with documentation and certification that appeared to be complete thus assuring that the conditions of the Minimal Risk Regions Rule were adhered to, as follows:

"Animals shipped directly for slaughter will go to official establishments in sealed trucks, will bear a Canadian ear tag, will be accompanied by VS Form 17-33 and a Canadian Health Certificate, and are to be slaughtered or euthanized within two weeks of entry into the U. S. and are not to leave the official premises. An establishment is to have procedures in place to ensure that animals arriving directly from Canada for immediate slaughter are slaughtered as a group (9 CFR 93. 420(a)(6))".

USDA's Minimal Risk Regions Rule clearly delineates the conditions to which exporting countries (such as Canada) must adhere in order to export animals and products to the United States. Veterinary officials of exporting countries are responsible for meeting those conditions. This includes ensuring that certification and other documentation are error-free. APHIS inspection at the border was conducted according to CFIA/APHIS agreement (based on the Minimal Risk Regions Rule) to ensure compliance. FSIS Notice 15-05 states that "the APHIS veterinarian reviews documents and inspects the shipment to ensure that it is being imported in compliance with the regulations. The APHIS veterinarian also has the authority to offload animals for verification." CFIA has taken swift action in response to the improper exportation cited above and has provided every assurance that they will continue to ensure strict compliance with the conditions of the Minimal Risk Regions Rule. USDA will continue to monitor the situation.

What corrective measures have been (or will be) taken?

Preventing further occurrences: According to the CFIA website they are "Exploring new ways to minimize incidents of noncompliance in the future; including enhancing the tools that they use to monitor the performance of accredited veterinarians in fulfilling their important roles." To date, 5 veterinarians have had their accreditation removed. It is important to note that having one's accreditation removed is a very severe action. Accreditation removal is not taken lightly by any veterinarian. One exporter is no longer able to export. Paperwork is pending on a second exporter.

USDA actions: We are accepting CFIA endorsed export certification regarding the age and pregnancy status and are advising CFIA of any problems. They have been extremely cooperative and have taken swift actions. We are not planning any punitive actions against CFIA.

What happened to the SRMs from the animal (#55 above)? If they entered the food/feed chain, have they also been recalled?

With regard to the food chain, FSIS asked the firm to initiate a voluntary recall of implicated products where the vertebral column may have been involved. FSIS' designation of this recall as Class II is because it is a situation where there is a remote probability of adverse health consequences from the use of the product. Additionally, FSIS verified recall effectiveness checks by the recalling firm. Under the interim final rules FSIS implemented on January 12, 2004, certain specified risk materials must be removed from all cattle depending on the age of the animal. On this animal all specified risk materials for cattle 30 months and over were removed, with the exception of the vertebral column. At the time of slaughter, the animal was certified to be under 30 months of age and removal of the vertebral column was not required. A subsequent audit determined the animal was just over 30 months of age; therefore, the vertebral column is required to be removed. This is the reason for the recall of the selected products.

Since the definition of SRMs is different in the US for 30 MOA under, the prion experts suspect that the SRMs went to rendering facilities, got processed and entered into the food/feed chain.

FDA has not yet completed rulemaking to prohibit SRMs from being rendered for use in feed for non-ruminant species. However, FDA is confident that the current BSE feed regulation provides assurance that rendered offal from this animal was not used in ruminant feed.



Recall Release

CLASS II RECALL
HEALTH RISK: LOW

Congressional and Public Affairs
Steven Cohen (202) 720-9113
RC-FSIS-032-2005

WISCONSIN FIRM RECALLS BEEF PRODUCTS

WASHINGTON, Aug. 19, 2005 – Green Bay Dressed Beef, a Green Bay, Wis., establishment, is voluntarily recalling approximately 1,856 pounds of beef products that may contain portions of the backbone from a cow just over 30 months old, the U.S. Department of Agriculture's Food Safety and Inspection Service announced today. The product was from a cow imported directly for slaughter from Canada.

Based on information provided by Canada, the products subject to this Class II recall are from a cow that is approximately one month older than the 30-month age limit. Both ante-mortem and post-mortem inspection were done on the cow in question. FSIS inspection program personnel determined the cow to be healthy and fit for human food. FSIS' designation of this recall as Class II is because it is a situation where there is a remote probability of adverse health consequences from the use of the product.

FSIS learned about this as a result of a Canadian audit of their health certificate that accompanied the imported cow. Prior to slaughter, the health certificate accompanying the cow was presented to the establishment, and it appeared complete and accurate. However, a subsequent audit of information related to the health certificate by Canadian officials found that it was not accurate. Action has been taken by Canadian Food Inspection Agency officials in response to findings from the audit.

The products subject to recall are:

- Five boxes of 243 lb. vacuum pouched packages of "American Foods Group, NECKBONE UNTRIM'D, USDA CHOICE OR HIGHER" with the case code of 77333;
- One box of 50 lb. vacuum pouched package of "American Foods Group, SHORTLOIN 2X2, USDA SELECT OR HIGHER" with the case code of 75231;
- One box of 60 lb. vacuum pouched package of "American Foods Group, SHORTLOIN 2X2, USDA CHOICE OR HIGHER" with the case code of 75060;
- Five boxes of 258 lb. vacuum pouched packages of "Dakota Supreme Beef, SHORTLOIN 0X1^{1/4}", USDA SELECT OR HIGHER" with the case code of 75442;
- Sixteen boxes of 811 lb. vacuum pouched packages of "American Foods Group, BLADE BI N/O CHUCK, USDA CHOICE OR HIGHER" with the case code of 75955;
- Nine boxes of 435 lb. vacuum pouched packages of "American Foods Group, BLADE BI N/O CHUCK, USDA SELECT OR HIGHER" with the case code of 75952.

Each box bears the establishment number "410" inside the USDA seal of inspection. The products were produced on August 4, and were distributed to wholesale distributors in Pennsylvania, Florida, Illinois, Maryland, Minnesota and Wisconsin.

-MORE-

Under the interim final rules FSIS implemented on January 12, 2004, certain specified risk materials must be removed from all cattle depending on the age of the animal. On this animal all specified risk materials for cattle 30 months and over were removed, with the exception of the vertebral column. At the time of slaughter, the animal was certified to be under 30 months of age and removal of the vertebral column was not required. A subsequent audit determined the animal was just over 30 months of age; therefore, the vertebral column is required to be removed. This is the reason for the recall of the selected products.

Consumers with questions about the recall may contact Sally VandeHei, Executive Assistant at 1-877-894-3927. National media with questions may contact Jim Mulhern at (202) 496-2468. Local media with questions may contact Susan Finco at (920) 965-7750 ext.158.

Consumers with other food safety questions can phone the toll-free USDA Meat and Poultry Hotline at MP Hotline (1-888-674-6854). The hotline is available in English and Spanish and can be reached from 10 a.m. to 4 p.m. (Eastern Time), Monday through Friday. Recorded food safety messages are available 24 hours a day.

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NOTE: Access news releases and other information at the FSIS Web site at <http://www.fsis.usda.gov>

USDA RECALL CLASSIFICATIONS

Class I This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.

Class II This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product.

Class III This is a situation where the use of the product will not cause adverse health consequences.

<仮訳>

(問) 最近のリコールに関連した出来事の概要 (31ヶ月齢の輸入、カナダからの動物)

(APHIS 回答)

- 1) CFIAはこの出来事を調査し、輸出積荷を証明した獣医官の認定を一時停止した。CFIAはまた、輸出者に対し、輸出健康証明書の発給も停止した。CFIAはCFIAに代わって働く認定獣医師と輸出者に対し、アメリカの輸入条件に適合しないことに対して情状酌量の余地はないと公表した。USDAは直ちにカナダに通知し、このことについての調査を監視している。

(FSIS 回答)

カナダからアメリカでと畜するため直接輸入された牛1頭は、30ヶ月齢制限をおよそ1ヶ月超えたものであった。FSISは、カナダによる輸入牛に添付された健康証明書の監査の結果として、このことを知った。と畜の前、牛に添付された健康証明書が施設に提出され、証明書に記入漏れはなく、正しく思われた。しかし、その後のカナダ係官による健康証明書に関連した情報の監査により、それは正しくないことが判明した。監査で明らかとなったことを踏まえ、CFIAは行動をおこした。CFIAのスポークスマンは、証明書の発行に対し責任のある当該獣医師は、この間違いのために一時認定を停止されたと発表した。

(FSIS 回答)

- 2) FSISの地方現地職員は、提供された情報と動物に添付された書類を確認し、2005年2月28日付け、FSIS通知15-05 (カナダ産牛、羊、山羊のアメリカへの輸入について) にあるガイドラインと指示に従った。参考のためノーティスを添付した。質問にある牛について、と殺前、と殺後の検査は行われた。FSIS検査プログラム係官は牛は健康であり、食用に適していると決定した。

添付したプレスリリース (肉のリコールの詳細について) とFSISの書類を参照願う。

(問) 事件の原因

(FSIS 回答)

FSIS 通知 15-05 にあるようにカナダは米国政府 (APHIS および FSIS) に文書と証明を提供した。これらは不備がないようであり、"最小リスク地域ルール(the Minimal Risk Region Rule)"の以下に示す条件を遵守していることを示すものであった。

『と畜場へ直接搬送される動物は封印されたトラックに乗せられ、当局の施設に搬送され、カナダ政府の耳標を取り付けられ、VS 17-33 文書およびカナダ政府による健康証明書を添付することになっており、更に、米国入国後には2週間以内と殺されるか安楽死され、当局の施設の外には移動されないことになっている。施設は、カナダから直接搬送されかつ直ちにと殺されることになっている動物が群でと殺されることを確認できる手続き・手順が実施されていること (米国連邦法 9CFR93.420(a)(6))。』

USDA の最小リスク地域ルールは輸出国 (カナダのような) が家畜および畜産物を米国に輸出する際に遵守しなければならない条件を明確に規定している。輸出国の獣医当局担当官はこれらの条件に満たしていることに関し、責任を負わなければならない。これには証明書およびその他の文書に間違いがないことを保証するということも含まれる。国境における APHIS による検査は法の遵守を確実にする CFIA/APHIS の合意 (最小リスク地域ルールに基づく) に基づいて行われている。FSIS 通知 15-05 には次のようなことが述べられている。「APHIS の獣医官は文書を検閲し、輸入されようとしている積荷が規定に見合うかどうかを検査する。この APHIS 獣医官は査察のため家畜を降ろし検査する職務権限を持っている。」CFIA は、上述されているような不適切な輸出対応のために迅速な措置をとり、また今後もカナダが最小リスク地域ルールの条件を厳密に遵守し続けていくことを確保するためにあらゆる保証を提示してきた。USDA は引き続きこの状況を監視していく。

(問) とられた (今後とられる) 是正措置はなにか。

(APHIS 回答)

今後の発生予防: CFIA の WEB サイトによれば、“今後、非遵守事例の発生を最小化させる新たな方法の検討; 重要な役割を満たす認定獣医師の能力を監視するのに用いられる手段の強化”。これまでに 5 人の獣医師が認定を取り消された。彼らの認定を取り消すという非常に厳しい措置であることに留意すべきである。認定の取り消しはあらゆる獣医師にとって軽い行為ではない。一輸出業者はもはや輸出が不可能である。第 2 の輸出業者について書類事務は保留中である。

USDA の措置: CFIA の発行した年齢と妊娠状態に関する輸出証明書を受け取り、あらゆる問題について CFIA に助言している。彼らは非常に協力的で迅速な対応をとった。我々は CFIA に対して罰することを計画していない。

(問) 当該牛の SRM はどうなったのか。仮にフード/フィードチェーンに入った場合、それらも回収されたのか。

(FSIS 回答)

フードチェーンに関して、FSIS は企業に対して脊柱が含まれる可能性のある関連製品の自主的回収を開始するよう依頼した。FSIS のクラス II としてのこの回収措置は、製品の使用によって健康に有害な結果を起こす可能性とは関連が薄いからである。さらに FSIS は回収を行った企業の回収効果の点検を検証した。2004 年 1 月 12 日に FSIS により施行された最終規則の下で、年齢に従い、全ての牛から SRM が除かれなければならない。当該動物においては、30 ヶ月齢以上で取り除くべき SRM は脊柱以外は全て除去されていた。と殺時に、この動物は 30 ヶ月齢未満とされ、脊柱の除去は要求されなかった。後の監査によりこの動物は 30 ヶ月齢以上であると確定されたため、脊柱の除去が要求される。これが指定製品の回収措置の理由である。

(問) 米国では 30 ヶ月齢以下の牛では SRM の定義が異なるため、SRM がレンダリングされ、加工されたものがフード/フィードチェーンに入ったのではないのか。

(FDA 回答)

FDA は非反すう動物の飼料に SRM の使用を禁止する規則策定をまだ完了していない。しかしながら、FDA は、現在の BSE 飼料規制によりこの動物由来のレンダリングされた臓器が反すう動物に使用されていないことを保証するものと確信している。

Summary of investigation into cattle shipped to U.S. that did not meet the requirements of the U.S. Import Rule

On August 3, 2005, one shipment of cattle from Canada was slaughtered in the United States (U.S.) that included an animal that was subsequently determined to be approximately one month over the 30 month age limit for export eligibility. As a result, this animal was not processed according to SRM removal requirements for animals over 30 months of age.

A shipment of 35 cattle from Ontario, which was certified for export on August 2, included eight animals that were confirmed by the USDA as being pregnant at slaughter. The shipment of pregnant animals is not a food safety issue, but the USDA rule prohibits the import of pregnant animals.

Canada was notified on August 9 that animals in the shipment were pregnant. The CFIA immediately contacted the accredited veterinarian to review the situation and to conduct a follow up investigation on the animals involved. Ear tags were traced to the farm(s) of origin and producers contacted to confirm information. On August 18, during the course of this investigation, it was confirmed that one of the animals was just over the 30-month age limit for export to the U.S. The CFIA immediately informed the USDA, who initiated a product recall because of concerns that product derived from this animal may have been contaminated with tissues designated as specified risk materials which are required to be removed from cattle over 30 months of age.

The U.S. BSE Rule specifies that only animals under 30 months of age are eligible for importation. In their application of the Rule, U.S. regulators have determined that female cows must not be pregnant. Accredited veterinarians certify that females are not pregnant and that all animals in a shipment are under 30 months of age.

In keeping with international practises, the Canadian Food Inspection Agency (CFIA) accredits private veterinary practitioners to act on behalf of the Agency in various animal health programs, including the export certification of cattle to the U.S. There are presently over 2000 accredited private veterinarians in Canada, and of these, approximately 200 are directly involved in the export certification of live cattle. Before a veterinarian is eligible to act on behalf of the agency, he/she must be licensed to practice in the province in which he/she is working, and must have received formal training and appropriate reference materials, including a manual of procedures, from a CFIA veterinary inspector. The Accredited Veterinarian's Manual describes the activities and responsibilities of the accredited veterinarian. Once training has been completed the practitioner is eligible to enter into a formal contractual relationship with the CFIA in the capacity of an accredited veterinarian. The contract is valid for three years and specifies the conditions under which the practitioner agrees to perform various duties on behalf of the Agency, including ramifications of a failure to execute these duties. During the term of the contract the work of the accredited veterinarian is monitored by the CFIA District Veterinarian.

However, even though the accredited veterinarian is responsible for certifying that the export requirements are met, meeting the requirements remains the responsibility of the exporter, including that the animals meet the age limitations and health specifications of the importing country. Once the accredited veterinarian has verified that the animals offered for export meet the requirements of the importing country, formal certification can be obtained from the CFIA.

Accredited veterinarians are kept abreast of changes in the export requirements through regular contact with their supervising CFIA district office.

Accredited veterinarians, and the CFIA, take very seriously their obligation to certify animals in accordance with the importing country's requirements. The accredited veterinarian who certified this shipment has been suspended pending a formal hearing to be held in September. Furthermore, the CFIA has suspended the issuance of export certificates to the Ontario cattle exporter for shipment of ruminant animals to the U.S. pending the outcome of the investigation and the implementation of any remedial actions necessary.

All accredited veterinarians involved in the export certification program were informed about the U.S. import requirements before any certificates were issued. However, a notice will be sent to all accredited veterinarians and exporters to remind them of their responsibilities, including that there will be zero tolerance for any non-compliance with U.S. import requirements. Furthermore, the CFIA will be enhancing monitoring of the certification process with an audit-based verification system.

Over 64,000 Canadian cattle have been exported to the U.S. since the border was reopened in July. To date this is the only instance of an over-aged animal being exported to the U.S. that Canada is aware of. With respect to the shipment of pregnant animals, the CFIA is aware that five shipments made by an Ontario exporter contained pregnant animals. Some of these animals were acquired in Quebec. Canada is also aware of one shipment from Manitoba that contained two pregnant animals and this shipment remains under investigation.

It is worth emphasizing that the export certification of beef and beef products is not a function of the accredited veterinarian. In these cases, the meat exporter assumes responsibility for meeting the requirements of the importing country, and the CFIA assumes responsibility for verification and certification.

September 7, 2005



Canadian Food
Inspection Agency

Agence canadienne
d'inspection des aliments

Notice to Industry

EXPORTING CATTLE, BISON, SHEEP AND GOATS TO THE UNITED STATES ROLES AND RESPONSIBILITIES

The Canadian Food Inspection Agency (CFIA) is reminding cattle producers, exporters, accredited veterinarians and livestock transporters of their obligations when exporting cattle and other live animals to the United States. These groups must ensure that animals presented for export fully meet U.S. import requirements. By doing so, those persons involved in the exportation of Canadian livestock may prevent potential trade disruptions that could arise due to the export of non-compliant animals.

Export Certification

A Government of Canada *Veterinary Health Certificate* must accompany all shipments of live animals. This certificate, which confirms that U.S.'s import requirements have been met, must be completed and signed by a veterinarian accredited by the CFIA. Exporters and producers must provide the accredited veterinarian with all the information necessary for him or her to carry out this function. Producers, exporters and accredited veterinarians are responsible for ensuring the accuracy of the information presented on the certificate.

The export certificate certifies that:

- cattle and bison are less than 30 months of age, and sheep and goats are less than 12 months of age. Where possible, this should be determined using **birth records**. Where records are not available, the accredited veterinarian must determine age based on a dental examination;
- animals are not pregnant;
- animals have been born in the U.S. or Canada, or kept in the U.S. or Canada for at least 60 days prior to importation into the U.S.;
- animals are free from any evidence of communicable diseases and have not been exposed to any such diseases during the 60 days preceding the inspection,;
- animals are subject to Canada's ruminant feed ban;
- sheep and goats have not tested positive for a transmissible spongiform encephalopathy, such as scrapie, or be considered to pose a risk of such diseases; and
- animals are identified with official Canadian ear tags, which can only be removed by U.S. officials at the port of entry or destination slaughter establishment. Cattle, bison, sheep and goats that are exported for feeding in the U.S. must also be permanently identified by branding.

Completed export certificates must be endorsed by an authorized CFIA veterinary officer.

Transporting Animals

Once the export certificate has been endorsed by the CFIA and the animals have been loaded onto a vehicle, the vehicle must be sealed by the accredited veterinarian using official federal seals. The numbers from these seals must be recorded by the accredited veterinarian on the corresponding export certificate. Shipments of animals from Canada will be refused entry into the U.S. if these seals are missing, broken or do not match the numbers on the corresponding export certificate. Sealed vehicles must move directly from the exporting premises to a U.S. port of entry and from the port of entry to a designated slaughter establishment or feedlot.

NOTE: *The Health of Animals Regulations* require that animals be handled and transported in a manner that prevents injury and unnecessary suffering.

Additional Requirements

In addition to an export certificate, a *Declaration of Importation* form must also accompany all shipments. This U.S. government form is generally prepared by a customs broker.

The U.S. Food and Drug Administration (FDA) requires exporters of live animals intended for food use (i.e. slaughter) to provide prior notice before animals enter the U.S. Prior notice must be received and confirmed electronically by the FDA no more than five days before the arrival of the animals and no fewer than two hours for animals arriving by road. In addition, Canadian commercial feedlots exporting live animals to the U.S. must be registered with the FDA.

For additional information:
www.inspection.gc.ca

The word "Canada" in a serif font, with a small Canadian flag to the right of the letters "da".

**8 米国における、と畜場等の衛生管理に関する規則の遵守状況
に関する情報**

米国におけるSRM関係規則遵守状況について

- 1 米国においては、と畜場に常駐する農務省の検査員がSRM管理等のと畜場側の衛生管理について検証を行っており、検査員は連邦規則に適合していない事例を発見した場合には、①と畜場に対し文書（Noncompliance Record）による指摘し、②関係製品の安全性を評価して必要に応じて廃棄等を行い、③違反内容の改善措置の検証を行っており、必要な場合には操業停止措置も講じている。
- 2 SRM関係規則遵守に関する報道について在京米国大使館に確認したところ、昨年1月から本年5月までの間の農務省が検査を行っている対日輸出を行っていた大規模な施設のみでなく小規模施設も含めた6000カ所のと畜場等において、農務省の検査官による1036件のSRM関係規制への不適合を指摘する文書（Noncompliance Record）に対して改善等の措置がとられたものであり、この結果安全性は確保されているとのことであった。
- 3 今回の報道については、Public Citizen という団体の公開請求により農務省が公開可能な829件の情報を提供したものである。米国側は農務省のチェック体制によりSRM規制が機能し、安全性が確保されているとしているが、米国側に対し具体的な不適合事例の内訳、調査方法などさらに詳細な情報の提供を要請したところ、8月18日に不適合事例の概要、昨日（8月23日）にはSRM関係規制への不適合を指摘する個票（Noncompliance Record）の提供があったところである。
- 4 農務省が集計した不適合事例の内訳としては、
 - （1）HACCPプランに関する事例が405件
 - （2）SRMの取扱いに関する事例が467件
 - （3）記録の保存に関する事例が164件であった。

当方で昨日農務省から提供された個票の内容を確認したところ、不適合事例として

は、

(1) HACCPプランについては、と畜場のみでなくカット施設の不適合事例も多く含まれているが、

- ① 出荷者からの30ヶ月齢以下を証明する文書が保存されていないもの
- ② 出荷者からのSRM除去を証明する文書が保存されていないもの
- ③ HACCPプランに関係記録の保存に関する事項が不足しているもの
- ④ HACCPプラン通りに実施されていないものやHACCPプラン中にBSEに関する事項が含まれていないもの

(2) SRMの取扱いについては、

- ① ナイフの洗浄が不十分なもの
- ② 背割り鋸の洗浄が不十分なもの
- ③ せき髓の除去が不十分なもの
- ④ 扁桃の除去が不十分なもの
- ⑤ 従事者の手洗いが不十分なもの

(3) 記録の保存については、

- ① SOPの実施に関する記録の不備
- ② HACCPプランの実施に関する記録の不備
- ③ SRM除去に関する記録の不備
- ④ 研修に関する記録の不備
- ⑤ 月齢確認に関する記録の不備

であった。

また、本規則の施行から1年が経過した2005年1月以降のHACCPプランに関する不適合事例については、BSEやSRMの取扱いに関する修正を求めるものが中心となっている。

なお、これらの不適合事例については、いずれも改善措置がとられ、その確認が行われたほか、6施設については操業停止措置がとられたとのことである。当該6施設については、過去の日本への輸出実績はない。

August 17, 2005 PM

FSIS Monitoring and Enforcement of BSE Safeguards

This document details the successful monitoring and enforcement by FSIS inspection program personnel of BSE safeguards implemented by establishments beginning January 12, 2004. FSIS has exhaustively analyzed all noncompliance record (NR) from all federally inspected establishments subject to BSE regulations. FSIS is confident that BSE regulations are being effectively enforced and that public health is being protected.

FSIS inspection program personnel are assigned to every federally inspected meat, poultry and egg products plant in America. Under the Federal Meat Inspection Act, the Poultry Products Inspection Act and the Egg Products Inspection Act, meat, poultry and egg products cannot enter commerce without federal inspection.

FSIS inspection program personnel use Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) regulations to verify that written procedures for the removal, segregation and disposition of Specified Risk Materials (SRM) are effectively designed and executed. This is consistent with all food safety verification activities completed by FSIS inspection program personnel, such as the cooking and chilling of products.

FSIS conducts ante-mortem and post-mortem inspection on 34 million head of cattle slaughtered annually in federally inspected plants. FSIS inspection program personnel perform thousands of inspection procedures each day to determine whether or not inspected plants are in compliance with regulatory requirements. Each time performance of a procedure results in a finding of noncompliance with regulatory requirements, inspection program personnel document their findings in the form of a NR and immediately take additional enforcement actions when appropriate.

These NRs indicate that FSIS regulations and immediate corrective actions by establishments are effective. They are evidence that actions *are* being taken and the public is and has been protected. We carefully reviewed each plant response to ensure that facilities were following agency procedures and that public health was protected.

The following chart is a distribution of the NR categories FSIS analyzed. The categories of the analyzed NRs include handling and processing, recordkeeping and design flaws. Design flaws were documented when plans at each federally inspected establishment did not meet all regulatory requirements. Handling and processing flaws were documented for failure to fully execute written procedures, such as inadequate sanitation during SRM removal. Recordkeeping flaws were noted when the establishment failed to properly document the execution of the establishment's plan.

The 1036 NRs were written from January 2004 through May 2005. Because all the NRs relate to public health and food safety, all corrective actions were taken immediately. We are confident that no SRMs reached consumers.

August 17, 2005 PM

Design Flaws	Handling and Processing Flaws	Recordkeeping Flaws	Total
405	467	164	1036

These data demonstrate inspection program personnel took immediate action when they determined that regulations were not being strictly followed. The analysis demonstrates public health was protected. The number of enforcement actions associated with these non-compliant findings is a testament to the skill and conscientiousness of 8,000 highly trained inspection program personnel who are assigned to every plant in America and who examine each live animal and each carcass to ensure that the U.S. food supply remains the safest in the world.

On January 12, 2004, the Food Safety and Inspection Service (FSIS) published new rules enhancing its BSE safeguards in order to minimize exposure to BSE infective tissues and better protect public health. These measures included:

- * Banning from the human food supply all tissues that science tells us could be infective in a cow with the disease. These are called specified risk materials (SRMs) and include the skull, brain, trigeminal ganglia, eyes, portions of the vertebral column, spinal cord and dorsal root ganglia of cattle aged 30 months or older, and the tonsils and the distal ileum, (a part of the small intestine) of all cattle.
- * Strict process controls for establishments using advanced meat recovery (AMR) systems for cattle younger than 30 months of age since SRMs are prohibited from use in AMR systems;
- * Banning non-ambulatory cattle from entering the human food supply;
- * Holding the carcass of any animal chosen for testing out of the food supply until the test is confirmed negative and;
- * The prohibition of air-injection stunning of cattle.

Public Health Veterinarians perform or verify ante-mortem and post-mortem inspection on every animal. These highly educated and trained FSIS veterinarians, along with formally trained Consumer Safety Inspectors, are specifically assigned the responsibility for verification of the development, implementation and maintenance of plant control procedures for the removal, segregation, and disposition of SRMs.

Since these BSE regulations were issued, FSIS has implemented a number of programs to train its inspection program personnel and help plants comply with new requirements. FSIS has issued 12 notices to its inspection program personnel detailing specific aspects of the regulations, including BSE surveillance activities in cooperation with the Animal and Plant Health Inspection Service (APHIS).

2005 年 8 月 17 日

(仮訳)

FSIS のモニタリング及び BSE セーフガードの施行

- この文書は、FSIS の検査プログラムの職員によって行われ、成功した監視及び 2004 年 1 月に開始された制度によって施行された BSE セーフガードの施行の詳細を記載している。FSIS は、BSE 規制の対象となり、連邦政府によって検査された全ての施設から得られた全ての違反記録 (noncompliance record、NR) を分析した。FSIS は、BSE 規制が効果的に施行され、公衆衛生が保護されていることを確信している。
- FSIS の検査プログラムの職員は、米国内の連邦政府によって検査されている全ての食肉、家禽及び卵製品の工場に配属されている。連邦食肉検査法令 (Federal Meat Inspection Act)、家禽製品検査法令 (Poultry Products Inspection Act) 及び卵製品検査法令 (Egg Products Inspection Act) に基づき、全ての食肉、家禽及び卵製品は、連邦政府による検査を受けずに流通されることはない。
- FSIS の検査プログラムの職員は、特定危険部位 (SRM) の除去、分別及び処分のための文書化された手順が効果的に設計され、実行されていることを証明するために、病原体削減 (Pathogen reduction) / 危害分析重要管理点方式 (PR/HACCP) の規定を用いている。これは、製品の調理及び冷凍といった、FSIS の検査プログラムの職員による食品安全の証明のための活動との整合性がとれている
- FSIS はと畜前後検査を年間 3400 万頭のと畜牛に対して行う。FSIS の検査プログラムの職員は、連邦政府の検査を受ける工場が、規則の要件を遵守しているかどうかを調べている。違反事例が発見された場合、職員は発見したことを NR の方式で文書化し、必要に応じて補足的な施行措置をとる。
- NR は、FSIS の規則及び施設が行った迅速な是正措置が効果的であることを示している。我々は、各工場の対応の見直しを行い、各施設が当局の手順に従い、公衆衛生が保護されていることを確認した。
- 以下の表は、FSIS が分析した NR の分類の分布を示している。分析された NR の分類には、対応及び処理の不備、記録保持の不備及び設計の不備が含まれる。設計の不備は、連邦政府の検査を受ける各工場における計画が、全ての規則の要件を満たさなかった場合に、記録される。対応及び処理の不備は、SRM の除去作業中の不適切な衛生状態のような、文書化された手順の実行が完璧になされていない場合に記録される。記録保持の不備は、施設の計画の実行が適切に記録されていない場合に指摘される。
- 1036 件の NR が、2004 年 1 月から 2005 年 5 月にかけて記録された。なぜなら、全ての NR が公衆衛生及び食品安全につながり、全ての是正措置が迅速にとられる。我々は、SRM が消費者に達することは全くないということを確認している。

設計の不備	対応及び処理の不備	記録保持の不備	合計
405	467	164	1036

- これらのデータは、規則が厳正に遵守されていないと判断した場合は、検査プログラムの職員が迅速な行動をとったことを示している。分析により、公衆衛生が保護されたことがわかる。これらの違反の発見に伴う執行活動 (enforcement action) の件数は、米国内の全ての工場に配置され、米国の食糧供給が世界で最も安全であり続けることを確保するために、各生体、

各枝肉を検査している 8000 人の高度に訓練された検査プログラム職員の技術と誠実さの証である。

- ・ 2004 年 1 月 12 日、FSIS は、BSE 感染性組織に対する暴露を最小限に抑え、より高水準な公衆衛生の保護を行えるようにその BSE セーフガードを強化した新たな規則を公示した。その措置は以下のようなものである：
- * 人間の食糧供給に、牛において感染性を示すことが科学的に知り得る全ての組織が混入することを禁止する。それらの組織は特定危険部位 (SRM) と呼ばれ、30 ヶ月齢以上の牛の頭蓋、脳、三叉神経節、眼球、脊柱の一部、脊髄及び背根神経節と全ての牛の扁桃及び回腸遠位部が含まれる；
- * 30 ヶ月齢未満の牛に対して先進的食肉回収 (AMR) システムを使用している施設では、SRM は AMR システムにおける使用が禁止されているため、厳格なプロセス管理が行われる；
- * 人間用食糧供給から歩行不能牛を除去する；
- * 検査結果が陰性であると確認されるまで、検査対象となつたいかなる動物の枝肉も、食糧供給に入らないようにしておく、そして；
- * 牛におけるエアインジェクションスタンニングの禁止。
- ・ 公衆衛生に関与する獣医師は、全ての動物におけると畜前後検査を実施もしくは実証する。これらの、高水準の教育及び訓練を受けた FSIS の獣医師は、正式な訓練を受けた消費者安全検査員と共に、SRM の除去、分離及び処分に関する向上の管理手順の作成、実施及び維持の実証に関する責任を特別に与えられている。
- ・ これらの BSE 規則が発行されてから、FSIS は検査プログラムの職員を訓練するための多数のプログラムを実施し、工場が新しい要件を満たす手助けを行ってきた。FSIS は、検査プログラムの職員に、APHIS と共同で行う BSE サーベイランス活動を含む規則の特定の側面の詳細を説明する 12 件の通知を発表した。

(参考資料)

- ・ **米国の2頭目のBSE感染牛の疫学調査結果**

米国の2頭目のBSE感染牛の疫学調査結果

8月30日（現地時間）、米国農務省が発表した、米国で2頭目のBSE感染牛に関する疫学調査結果の概要以下のとおり。

1 BSE感染牛について

- ① テキサス州の一農場で生産、飼養された約12歳のブラーマン種の交雑種
- ② 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
- ③ 当該牛は、当該工場で製品に加工されることなく焼却処分

2 関連牛の調査について

- ① 発生農場で飼養されていた出生同期牛の可能性のある牛67頭についてエライザ検査を実施し、陰性を確認。
- ② 発生農場から移動した出生同期牛の特定のため、出生同期牛の可能性のある1990年以降に発生農場から移動した200頭について追跡調査を実施。その大半はと畜又は死亡。生存を確認した1頭について検査を実施し、陰性を確認。
- ③ 患畜の死亡前2年間生産した産仔は2頭。産仔の可能性のある発生農場から移動した213頭の子牛について追跡調査を実施。その大半はと畜又は死亡と推定

3 給与飼料の調査について

- ① 発生農場においては、1990年以降、21種類の飼料を給与
- ② これらの飼料は、3つの小売店を通じて販売。9つの飼料工場生産。
- ③ 1997年以降、発生農場において禁止原料を含む飼料・飼料添加物が使用されたことは確認されなかった。

Texas BSE Investigation

Final Epidemiology Report

August 2005



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Executive Summary

In June 2005, an inconclusive bovine spongiform encephalopathy (BSE) sample from November 2004, that had originally been classified as negative on the immunohistochemistry test, was confirmed positive on SAF immunoblot (Western blot). The U.S. Department of Agriculture (USDA) identified the herd of origin for the index cow in Texas; that identification was confirmed by DNA analysis. USDA, in close cooperation with the Texas Animal Health Commission (TAHC), established an incident command post (ICP) and began response activities according to USDA's BSE Response Plan of September 2004. Response personnel removed at-risk cattle and cattle of interest (COI) from the index herd, euthanized them, and tested them for BSE; all were negative. USDA and the State extensively traced all at-risk cattle and COI that left the index herd. The majority of these animals entered rendering and/or slaughter channels well before the investigation began. USDA's response to the Texas finding was thorough and effective.

Background of the Investigation

On June 10, 2005, USDA announced that the November 2004 inconclusive BSE sample tested positive on SAF immunoblot. The SAF immunoblot was run at USDA's National Animal Disease Center (NADC) upon the recommendation of USDA's Office of the Inspector General. Samples were sent to a World Organization for Animal Health (OIE) reference laboratory for BSE in Weybridge, England, for confirmatory tests. Farm A, located in Texas, was the suspected farm of origin for the index cow and was placed under hold order on June 20, 2005 pending confirmation of the positive results and DNA analysis of the herd. Weybridge confirmed the BSE positive on June 24, 2005. The carcass of the index cow had been disposed of by incineration in November 2004. Cattle from several units on Farm A were bled for DNA testing (a unit is a part of the business entity of a farm. For example, a pasture on which a group resides may be a unit). Farm A was confirmed as the farm of origin for the index cow on June 29, 2005, and an ICP was established in Texas to coordinate the response. Removal of at-risk cattle from the index herd, and tracing of at-risk cattle and COI that had left the index herd, commenced immediately.

BSE Response Plan

The September 2004 BSE Response Plan outlines the necessary tracing and removal of at-risk cattle and, in some cases, COI, in response to the identification of a BSE-positive animal. Response personnel removed at-risk animals from the index farm and traced at-risk animals and COI in accordance with the response plan.

Definition of At-Risk Cattle

At-risk cattle were cattle that were confirmed to be: part of the birth cohort; part of the feed cohort; or progeny of the positive cow born within 2 years prior to the positive test. Response personnel removed at-risk cattle from the herd, euthanized them, and tested them for BSE; all were negative.

Definition of Cattle of Interest

In many cases, at-risk cattle could not be definitively identified. Response personnel then analyzed herd inventories and herd records to identify a group of cattle that include all potential at-risk cattle and any other cattle that could not be distinguished from at-risk cattle. All of these cattle (at-risk cattle and any additional cattle as necessary) were defined as COI. COI that fell into the appropriate age range and could be part of the birth or feed cohort were removed from the herd, euthanized, and tested for BSE; all were negative.

Definition of Feed Cohort

The feed cohort consisted of all cattle which, during their first year of life, were reared with the positive animal during its first year of life and consumed the same feed during that period. In the index herd, this definition applied to cattle in any unit that were weaned and fed with calves from the other units for a short period of time and then later returned to their respective units of origin from 1991-1995 (the range of years that could have coincided with the first year of life of the index cow).

Definition of Birth Cohort

In most cases, it was impractical or impossible to definitively determine which cattle were exposed to a feed source. Accordingly, response personnel used a birth cohort to determine which cattle to consider at-risk. The birth cohort included all cattle born on the positive animal's birth premises within 1 year before or after the BSE-positive animal's date of birth.

Since the index cow was approximately 12 years of age, but an exact date of birth did not appear in the herd records, response personnel used a potential age range of 12 years with 1 year added to each end of that age (age 11 to 13) to sufficiently cover the most likely age range of the animal. In addition, if the positive animal moved from the birth premises to any other premises during its first year of life, all cattle of less than 1 year of age that were present on such additional premises were also considered to be at-risk. Using the age range of the index animal, all cattle born on the index premises from 1990-1995 were part of the birth cohort of the index animal.

Definition of At-Risk Progeny

Since the index cow was not confirmed to have been exhibiting clinical signs of BSE prior to her positive test results, the at-risk progeny as defined by the OIE were those offspring that were born within the 2 years prior to the positive test result. Those 2 years prior to the positive test result would have included her calves from 2002, 2003, and 2004. According to the owner, the index cow produced her last calf either in Fall 2003 or Spring 2004, and the calf prior to that was born either in Fall 2002 or Spring 2003. Tracing activities focused on these two calves as at-risk progeny.

Epidemiology Investigation of Index Herd: Farm A

Background

The index cow was an approximately 12-year-old yellow or cream-colored Brahma cross that originated from Farm A located in Texas. The cow was sold through a livestock sale on 11/11/04, purchased by an order buyer, and was transported to a packing plant on Monday, 11/15/04. When the truck arrived at the packing plant during the late afternoon of 11/15/04, the index cow and one other were found dead on the truck and were transported to a pet food plant later that day where they were sampled for BSE testing as part of the enhanced BSE surveillance.

DNA analysis of blood samples taken from five of the six units of cattle that comprise Farm A yielded four animals from two different units that were genetically related to the index cow and confirmed Farm A as her herd of origin.

The herd on Farm A consisted of mixed breed beef cattle that are traditionally not used as seedstock replacement animals. Market records and preliminary tracing indicated that most animals that left the index herd either went to slaughter within a few days of sale or, in the case of younger animals, entered into known rendering and slaughter channels immediately following sale. There were only 11 cows identified during the investigation that were traced from Farm A into other herds where they had been used as replacement cows.

The owner of Farm A raised this cow from birth and stated that the cow had never been off the premises prior to its sale. She was marketed because of poor body condition (the animal's condition had not improved despite the early weaning of her 2003/2004 calf). The owner stated that the cow had always been excitable and had fallen while she was being loaded to go to the market, but that this was not unusual behavior for her in his opinion. In addition there was a report of this cow being down in the alley at the livestock market on 11/11/04, but she apparently got up again and was able to be loaded onto the truck to go to the packing plant. When questioned about any previous history of neurological signs in cattle on the farm, the owner reported that no cattle on the farm had ever shown any neurological signs, nor had there been any cases of rabies on the index farm.

Index Herd Census

Farm A consisted of 6 units (Units A through F) containing a total of about 217 adult cattle and approximately 100 to 120 calves. Early in the investigation, response personnel discovered that an additional unit belonging to the owner's son and located adjacent to Unit F could also contain COI. This group, Unit G, contained 16 adult cattle and made a seventh unit that became included in the investigation.

On 6/22/05, the first three of the original six units were sampled for DNA testing to confirm the herd of origin of the index cow. Those first three units consisted of: Unit A contained 62 head with some older cattle (more likely than the other units to provide a DNA match); Unit B with 28 head (3-year-old unit); and Unit C with 25 head (2-year-old unit). Two additional units were sampled for DNA on 6/23/05; Unit D with 31 head and Unit E with 30 head, both of which contained older animals.

The sixth unit, Unit F, containing 41 head, was purchased in 1993 from another source. Because it did not have animals that were genetically related to the other 5 units, this unit was not sampled for DNA testing. Unit F, and adjacent Unit G, contained COI because the weaned heifers from those units were commingled and fed with weaned heifers from the other units for a short period of time before they were returned to their respective units of origin. This practice of weaning and feeding together fit the definition of a feed cohort.

Progeny

The owner did keep some replacement heifers and, although he was relatively sure that he had not kept any offspring from the yellow cow because of her excitable demeanor, DNA analysis of the herd revealed several animals in the herd that may have been older offspring of the index cow. While the owner sold 12 calves at the sale with the index cow on 11/11/04, her last calf was not in that group. According to the owner, the index cow's last calf was born either in Fall 2003 or Spring 2004, weaned early, and sold through the livestock market some time between February and October 2004. The calf prior to that would have been born either in Fall 2002 or Spring 2003 and was sold at the livestock market sometime between January and December 2003.

Birth Cohort

The owner of Farm A kept very few herd records; this made finding documentation on this cow's birth cohort difficult. The birth cohort, by definition, included all cattle born on the positive animal's birth premises within 1 year, before or after, the positive animal's date of birth. The index cow was approximately 12 years of age in November 2004, but there was no exact birth date in the herd records. A potential age range of 11 to 13 years was used to sufficiently cover the animal's most likely age. Using this range, all cattle born on the index premises between 1990 and 1995 were considered part of the birth cohort.

In lieu of the owner's records, herd records from Veterinary Services' Generic Database (GDB) were used to compile a list of brucellosis calfhood vaccination (CV) tag numbers from the index herd that corresponded to animals to be included in the birth cohort. There were 121 animals identified through GDB as having been calfhood vaccinated on the index farm between 1991 and 1994. The owner of Farm A did not calfhood vaccinate after 1994. Moreover, calfhood vaccinates include only heifers. Therefore, the list of 121 animals was not a complete list of all birth cohorts. However the tracing that response personnel conducted on other COI was designed to account for the remainder of the birth cohorts.

Feed Cohort

Animals in Units A, D, and E, that were weaned and fed with the positive cow between 1991-1995, were already considered at-risk as part of the defined birth cohort. Animals in Units B and C were 3-year-olds and 2-year-olds, respectively, and were too young to be either birth or feed cohorts. Although Unit F was purchased separately and did not contain animals genetically related to the other units, calves from Unit F were weaned and fed for a short period of time with weaned calves from other units and all calves were later returned to their respective units of origin. Since Unit F was not purchased until 1993, the feed cohort consisted of those animals in Unit F that could have been weaned and fed with the index cow in 1993 or 1994. Additionally, Unit G contained possible feed cohorts that could have been weaned and fed with the index cow between the years of 1991 and 1995.

Feed

The feeding regimen for the cattle in this herd consisted of natural pasture, hay, mineral supplement, syrup tubs occasionally, and a breeder's supplement (predominantly a name brand manufactured breeder's cube). The Food and Drug Administration (FDA) investigated all sources of feed and supplements used on Farm A. In-depth investigations and site visits were conducted by FDA involving retail feed stores, feed manufacturers, slaughter plants, renderers, and brokers. A more detailed account of the investigation is contained in FDA's final report.

Removal of Cattle from the Index Farm

Any animal still present within the index herd that could have been a possible birth cohort or feed cohort of the index cow was targeted for removal as an at-risk animal. Units A, D, E, F, and G, all of which were known to contain older animals, were inventoried. Identification tags, tattoos, and brands were recorded, and all animals were aged based on their dentition and any man-made identification. Cattle whose estimated age indicated that they could have been part of the index cow's birth or feed cohort were removed from the herd, euthanized, and tested for BSE; all were negative.

Units B and C were exempt from the cohort removal process because they contained only 3-year-old and 2-year-old animals respectively. Although the DNA analysis of animals in Units A through E determined that there were 2 animals present that could have been offspring of the index cow, their estimated age by dentition revealed that they were not of the appropriate age to be at-risk progeny. This verified the owner's claim that he had sold the index cow's last two calves at the livestock market and they were not currently present in the index herd.

After sorting by age, response personnel identified and removed the following numbers of cows from the herd on 7/6/05: Unit A, 11 cows; Unit D, 11 cows; Unit E, 7 cows. The same process was applied to Units F and G and the following numbers of cows were identified and removed from the herd on 7/7/05: Unit F, 28 cows; Unit G, 10 cows.

Of the 67 animals removed from the herd as possible birth cohorts and/or feed cohorts of the index cow, 42 were definitively identified as belonging to the birth cohort due to the presence of a calfhood vaccination tag or tattoo that corresponded to the appropriate birth cohort years. All 67 animals were euthanized on 7/6/05 and 7/7/05 and samples were subsequently sent to USDA's National Veterinary Services Laboratories (NVSL) for BSE testing. All samples were run on the ELISA test and confirmed negative on 7/8/05 and 7/9/05. Upon confirmation of negative results, disposal of carcasses was completed by burial in an approved landfill facility. The index farm was released from hold order on 7/11/05.

Tracing of Progeny

The 2003/2004 progeny of the index cow was known to have left the farm through a specific livestock market sometime between February and October 2004. The 2002/2003 progeny of the index cow left the farm through the same market sometime between January

and December 2003. Response personnel learned early in the investigation that animals from the index farm were sold not only under the index farm owner's name and that of his wife, but also by other members of the owner's immediate family. Additionally, there were no herd records to indicate the gender of the two at-risk progeny. Therefore, market records for February through October 2004 and January through December 2003 were obtained for all calves sold both by Farm A's owner and by members of his immediate family; response personnel traced all such calves to determine their disposition.

With the index herd being composed of mixed breed beef cattle, the calves that left the farm were genetically unsuitable for use as replacement animals or for sale as breeding stock, a fact that was confirmed by the trace work and the documentation of the final disposition of the calves of interest.

Response personnel ultimately identified 213 calves of interest to be traced. Of these, 208 were confirmed to have entered known rendering/slaughter channels, 4 were presumed to have entered rendering/slaughter channels, and 1 was purchased in cash through a livestock market with no buyer name or contact information (this animal was classified as untraceable. See Appendix 1). A calf was categorized as presumed to have entered rendering/slaughter channels if it passed through at least one livestock market subsequent to its original sale and could not be individually traced due to unknown resale date and new backtag, but all calves resold matching that description during an appropriate date range were purchased by known rendering/slaughter order buyers.

It was not possible to DNA test the calves that entered known rendering and slaughter channels – most were of an age in which they were likely to have been slaughtered prior to the time of the investigation. There were no calves traced to farms outside of rendering and slaughter channels.

Tracing of Birth Cohorts

Since there were essentially no records maintained on the index farm, it was necessary to compile the list of known birth cohorts using brucellosis CV tag numbers for this herd from the period 1991 to 1994. The calves vaccinated during that time period were part of the index cow's birth cohort and tracing activities centered on finding those animals.

There were 121 animals whose CV tag number and/or tattoo included them as part of the birth cohort. Of those 121 animals, 67 animals were definitively accounted for (42 were found in the index herd, removed, and tested BSE negative; 25 were identified as having left Farm A through the market system and were traced, 11 of those were reported slaughtered, 13 were classified as presumed dead, and 1 was found alive, euthanized, and tested BSE negative). Of the remaining 54 animals from the birth cohort, there may have been several that died within the index herd, but the majority likely left the herd without identification and would have been either re-tagged at the livestock market or consigned directly to slaughter without identification. To account for these remaining birth cohorts, all adult cattle that left the index farm since 1990 were traced as COI.

Tracing of Cattle of Interest

The investigation revealed that many animals left Farm A, arrived at markets without any identification tags, and were subsequently re-tagged at the market. Due to lack of farm records, it is unknown which of these re-tagged animals may have belonged to the birth cohort. As a result, all animals that may have left Farm A since 1990 were traced as COI. Additionally, animals from the index farm were sold not only under the index farm owner's name and that of his wife, but also by other members of the owner's immediate family; therefore, cattle sold from the index farm by all pertinent family members were traced.

There were some older animals that left the index farm but were able to be excluded from further trace work because they were known not to have been part of the birth cohort or feed cohort of the index cow despite their being of the appropriate age. The index farm owner's late father had maintained a herd of cattle separate from the index farm but which was added to the index farm in 1997. Complete herd test data and CV data from the GDB was obtained for the father's herd and those animals were excluded from the tracing activities.

There were a total of 200 COI traced: 143 were reported to have been slaughtered (131 of those were confirmed as having been slaughtered), 1 is known to have died previously and was buried, 2 were found alive (1 was a known birth cohort that tested negative, 1 was determined not to be one of the cattle of interest due to her young age), 34 were classified as presumed dead, 20 were classified as untraceable. (See Appendix 1). Animals were confirmed at slaughter using GDB slaughter testing data or the hard copies of slaughter testing Form 4-54.

An animal was classified as presumed dead if records that could be used to advance the tracing of the animal were exhausted or did not exist, and the age of the animal at the time of the investigation was estimated to be at least 11 years old or older. Since the index herd was not a purebred or seedstock operation, and animals leaving the herd were unlikely to be purchased as replacement cattle, standard industry practices indicated that most adult animals that had left the herd would have been culled and slaughtered by the time they were in this age group. Additionally, this age cutoff was arrived at through review of market records and the specific years in which Farm A sold cattle through the market. An animal was classified as untraceable if all records to advance the tracing of the animal were exhausted or did not exist, and the age of the animal at the time of the investigation was estimated to be less than 11 years of age (the animal, therefore, could not be presumed dead).

Calculation of Minimum Estimated Ages

Throughout the tracing process, personnel used minimum estimated ages of the 200 COI to evaluate whether those individuals could be old enough to be part of the birth or feed cohort of the index cow. Since Farm A's owner maintained no records on the ages of animals, GDB data assisted in assigning minimum estimated ages. Animals that were wearing brucellosis CV eartags could be aged quite accurately because the exact CV date was recorded in the GDB and those animals would have been vaccinated between 4 to 12 months of age. The GDB also contained lists of individual eartags for all animals on the

index farm that were included in complete herd brucellosis testing in 1991, 1993, and 1994. Cattle included in those herd tests would have been at least 18 months of age at the time of the test and their minimum age today could be extrapolated from that data. Finally, the GDB also contained livestock market testing data that could also be used to assign a minimum age because the animal would have been at least 18 months of age on date the earliest brucellosis market test was conducted. The minimum ages calculated for the cattle of interest were used later in an analysis by USDA's Centers for Epidemiology and Animal Health (CEAH) to determine the probable disposition of untraceable and presumed dead animals based on their age.

Trace Herds

Response personnel made every attempt to trace COI to their final dispositions (which, in most cases, was slaughter). If an animal was traced to a herd owner and the owner could not provide information that indicated that the animal of interest was not currently present within his/her herd, the owner's herds were placed under hold order pending a herd inventory to determine whether or not the animal of interest had been retained. There were eight herds identified as the last traceable location of the animal of interest and were, therefore, subjected to herd inventories in an attempt to locate the animal.

When an animal of interest was located within a herd, the age of the animal was estimated using dentition and any man-made identification. If the animal fell into the appropriate age range to be a possible birth cohort or feed cohort of the index cow, the animal was removed from the herd and tested. If an animal of interest was located within the herd and fell into the appropriate age range to be a possible at-risk progeny of the index cow, the animal was sampled for DNA testing.

Trace Herd 1

The owner of Trace Herd 1 was identified as having received one of the adult COI from the index herd. Trace Herd 1 contained 909 head of cattle in multiple pastures and was placed under hold order on 7/21/05. Upon completion of herd inventory, the animal of interest was not found within the herd. A GDB search of all recorded herd tests conducted on Trace Herd 1 and all market sales by the owner failed to locate the identification tag of the animal of interest and she was subsequently classified as untraceable. The hold order on Trace Herd 1 was released on 8/8/05.

Trace Herd 2

Trace Herd 2 was identified as having received one of the adult COI from the index herd. Trace Herd 2 contained 19 head of cattle on one pasture and was placed under hold order on 7/25/05. The owner of Trace Herd 2 identified the animal of interest by her eartag while he was feeding his cattle out of a bucket and individually penned her for inspection by field personnel. While the cow was identified as one of the animals that had left the index farm, her age by dentition was estimated to be only 5 years old, which was too young to have placed her as part of the birth or feed cohort of the index animal. She was classified as found alive but determined not to be one of the COI; the hold order on Trace Herd 2 was released on 7/26/05.

Trace Herd 3

The owner of Trace Herd 3 was identified as possibly having received an animal of interest. The herd was placed under hold order on 7/27/05. The herd inventory was conducted on 7/28/05. The animal of interest was not present within the herd, and the hold order was released on 7/28/05. The person who thought he sold the animal to the owner of Trace Herd 3 had no records and could not remember who else he might have sold the cow to. Additionally, a search of GDB for all cattle sold through the markets by that individual did not result in a match to the animal of interest. The animal of interest traced to this herd was classified as untraceable because all leads were exhausted.

Trace Herd 4

The owner of Trace Herd 4 was identified as having received one of the COI through an order buyer. Trace Herd 4 was placed under hold order on 7/29/05. A complete herd inventory was conducted on 8/22/05 and 8/23/05. There were 233 head of cattle that were examined individually by both State and Federal personnel for all man-made identification and brands. The animal of interest was not present within the herd. Several animals were reported to have died in the herd sometime after they arrived on the premises in April 2005. A final search of GDB records yielded no further results on the eartag of interest at either subsequent market sale or slaughter. With all leads having been exhausted, this animal of interest has been classified as untraceable. The hold order on Trace Herd 4 was released on 8/23/05.

Trace Herd 5

The owner of Trace Herd 5 was identified as having received two COI and was placed under hold order on 8/1/05. Trace Herd 5 is made up of 67 head of cattle in multiple pastures. During the course of the herd inventory, the owner located records that indicated that one of the COI, a known birth cohort, had been sold to Trace Herd 8 where she was subsequently found alive. Upon completion of the herd inventory, the other animal of interest was not found within the herd. A GDB search of all recorded herd tests conducted on Trace Herd 5 and all market sales by the owner failed to locate the identification tag of the animal of interest and she was subsequently classified as untraceable due to all leads having been exhausted. The hold order on Trace Herd 5 was released on 8/8/05.

Trace Herd 6

The owner of Trace Herd 6 was identified as possibly having received an animal of interest and was placed under hold order on 8/1/05. This herd is made up of 58 head of cattle on two pastures. A herd inventory was conducted and the animal of interest was not present within the herd. The owner of Trace Herd 6 had very limited records and was unable to provide further information on where the cow might have gone after he purchased her from the livestock market. A search of GDB for all cattle sold through the markets by that individual did not result in a match to the animal of interest. Additionally, many of the animals presented for sale by the owner of the herd had been re-tagged at the market effectually losing the traceability of the history of that animal prior to re-tagging. The animal of interest traced to this herd was classified as untraceable due to all leads having been exhausted. The hold order on Trace Herd 6 was released on 8/3/05.

Trace Herd 7

The owner of Trace Herd 7 was identified as having received an animal of interest and was placed under hold order on 8/1/05. Trace Herd 7 contains 487 head of cattle on multiple pastures in multiple parts of the State, including a unit kept on an island. The island location is a particularly rough place to keep cattle and the owner claimed to have lost 22 head on the island in 2004 due to liver flukes. Upon completion of the herd inventory, the animal of interest was not found present within Trace Herd 7. A GDB search of all recorded herd tests conducted on Trace Herd 7 and all market sales by the owner failed to locate the identification tag of the animal of interest. The cow was subsequently classified as untraceable. It is quite possible though that she may have died within the herd, especially if she belonged to the island unit. The hold order on Trace Herd 7 was released on 8/8/05.

Trace Herd 8

Trace Herd 8 received an animal of interest, which happened to be a known birth cohort of the index cow, from Trace Herd 5. Trace Herd 8 consists of 146 head of cattle that were placed under hold order on 8/4/05. A herd inventory was conducted, the birth cohort was found alive in the herd, and she was purchased and euthanized. The hold order on Trace Herd 8 was released on 8/4/05. The cow was sampled on 8/5/05 and BSE tested by ELISA at NVSL. Results were negative (as reported on 8/6/05); carcass disposal was completed by alkaline digestion.

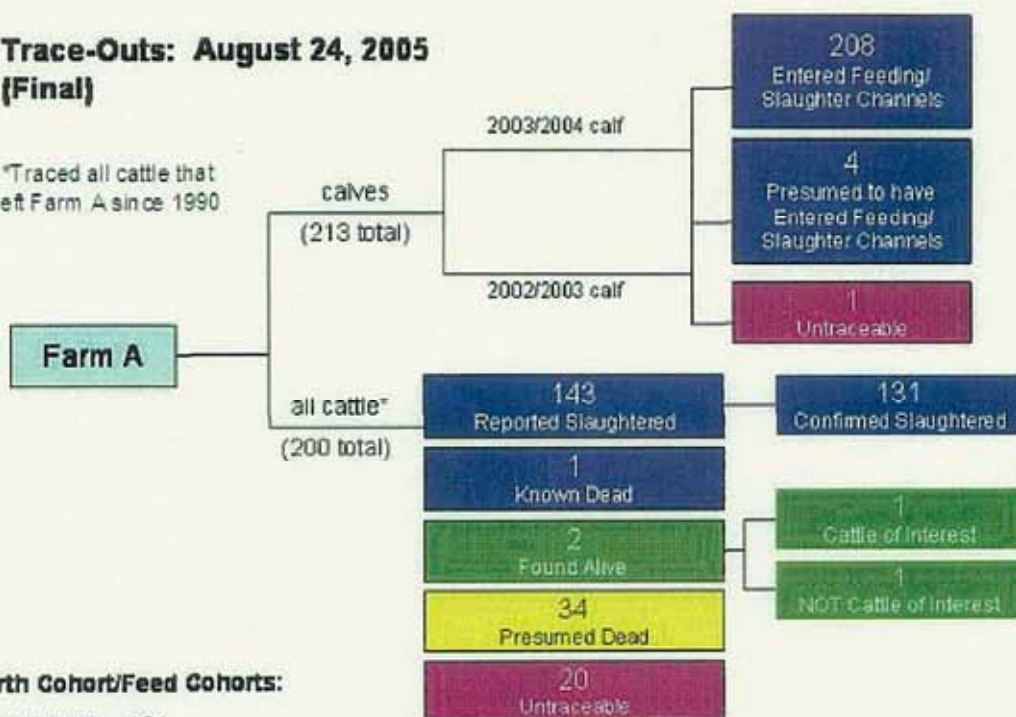
Analysis of Data on Presumed Dead and Untraceable Animals

CEAH performed an analysis of the minimum estimated ages of those COI that were classified as either presumed dead or untraceable to determine the likely disposition of those animals based on their ages. Moreover, CEAH performed an analysis of the likely disposition of the one calf that was classified as untraceable during the investigation.

Appendix 1 – Final Trace-Out Diagram

**Trace-Outs: August 24, 2005
(Final)**

*Traced all cattle that
left Farm A since 1990



Birth Cohort/Feed Cohorts:

Total known = 121

Number found in Index herd = 42

Number known to have left herd = 25

(11 slaughtered, 13 presumed dead,
1 found alive – tested negative)



Report on Food & Drug Administration Dallas District Investigation of Bovine Spongiform Encephalopathy Event in Texas 2005

Executive Summary:

On June 24, 2005, USDA informed FDA that a cow in Texas tested positive for Bovine Spongiform Encephalopathy (BSE). Information provided by APHIS was that the BSE positive cow was born and raised in a herd in Texas and was approximately 12 years old. The animal was sampled for BSE at a pet food plant in Texas on November 15, 2004, as part of USDA's enhanced surveillance program. The animal was disposed of by incineration and did not enter the human food or animal feed chains. Although the positive animal posed no risk to the animal feed supply, FDA, APHIS, the Texas Animal Health Commission (TAHC), and the Texas Feed and Fertilizer Control Service (TFFCS) conducted a feed investigation with two main objectives. The first objective was to identify all protein sources in the animal's feed history that could potentially have been the source of the BSE agent. The second objective was to verify that cattle leaving the herd after 1997 that were identified by USDA/APHIS as animals of concern (e.g. progeny and feed cohorts), were rendered at facilities in compliance with the regulation (21 CFR 589.2000) that prohibits most mammalian protein in feed for ruminants that became effective August 4, 1997 (herein called BSE/Ruminant Feed rule).

The feed history investigation identified 21 feed products that had been used on the farm since 1990. These feed products were purchased from three retail feed stores and had been manufactured at nine different feed mills. The investigators visited these establishments to collect information on formulations, shipping invoices, and use of ruminant meat and bone meal (MBM) on the premises both pre-1997 feed ban and post-1997 feed ban. This investigation found no feed products used on the farm since 1997 that had been formulated to contain prohibited mammalian protein.

The investigation identified one feed which contained an animal protein source that could not be identified. The investigation also found one feed mill that supplied feed to the farm that had used ruminant MBM in feed formulations for non-ruminant species after the BSE/Ruminant Feed rule went into effect, which is permitted under the rule, and that several feed mills had used ruminant MBM in feeds prior to the feed ban. Although the investigation did not identify a specific feed source as the likely cause of this animal's infection, it is probable that the most likely route of exposure for this animal was consumption of an animal feed containing mammalian protein prior to the implementation of the BSE/Ruminant Feed rule in 1997.

The investigation into the disposition of herd mates from this farm involved visits to nine slaughter plants and eight rendering plants. The investigation found that all rendering plants were operating in compliance with the BSE/ruminant feed ban regulation. A review of the inspection history of each of these rendering firms found no violations.

Background of Investigation:

When notified on June 24, 2005, FDA Headquarters and Dallas District management officials immediately began making contacts with their Federal, State and Local counterparts to plan for and initiate follow-up investigational activities to determine the feed history in this herd and to assure the safety of the animal feed supply by evaluating current and historic compliance with the BSE/ruminant feed ban rule.

APHIS established a joint Incident Command Post and FDA Dallas District staffed this post full time with a Supervisory Investigator charged with coordinating activities between FDA, APHIS, TAHC and TFFCS. Coordination conference calls were set up with all Federal and State agencies involved in the investigation to keep everyone apprised of investigational developments.

Animal Tracing Activities and Renderer Follow-up Inspections:

One of APHIS' primary objectives was to identify and trace the animals of interest (animals of interest would include any animals which could have been potential birth cohorts or feed cohorts of the index animal, or potential offspring of the index animal within the two years prior to the positive diagnosis) from the index herd. This objective included the identification of points of sale and ultimately the

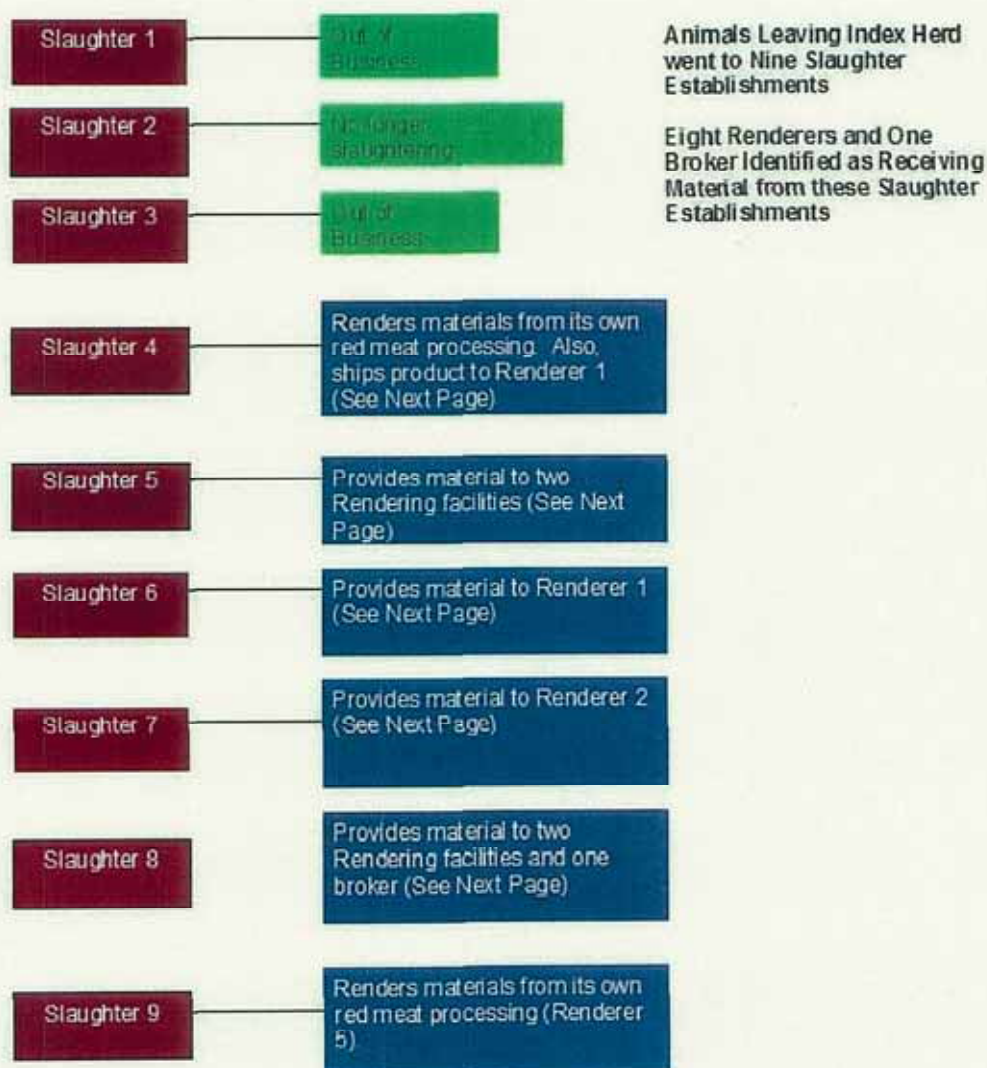
actual slaughter facilities for animals of interest that left the farm. As the trace information was developed, APHIS shared this information with FDA. Further information on animal of interest identification and tracing can be found in the USDA Texas BSE Final Epidemiology report.

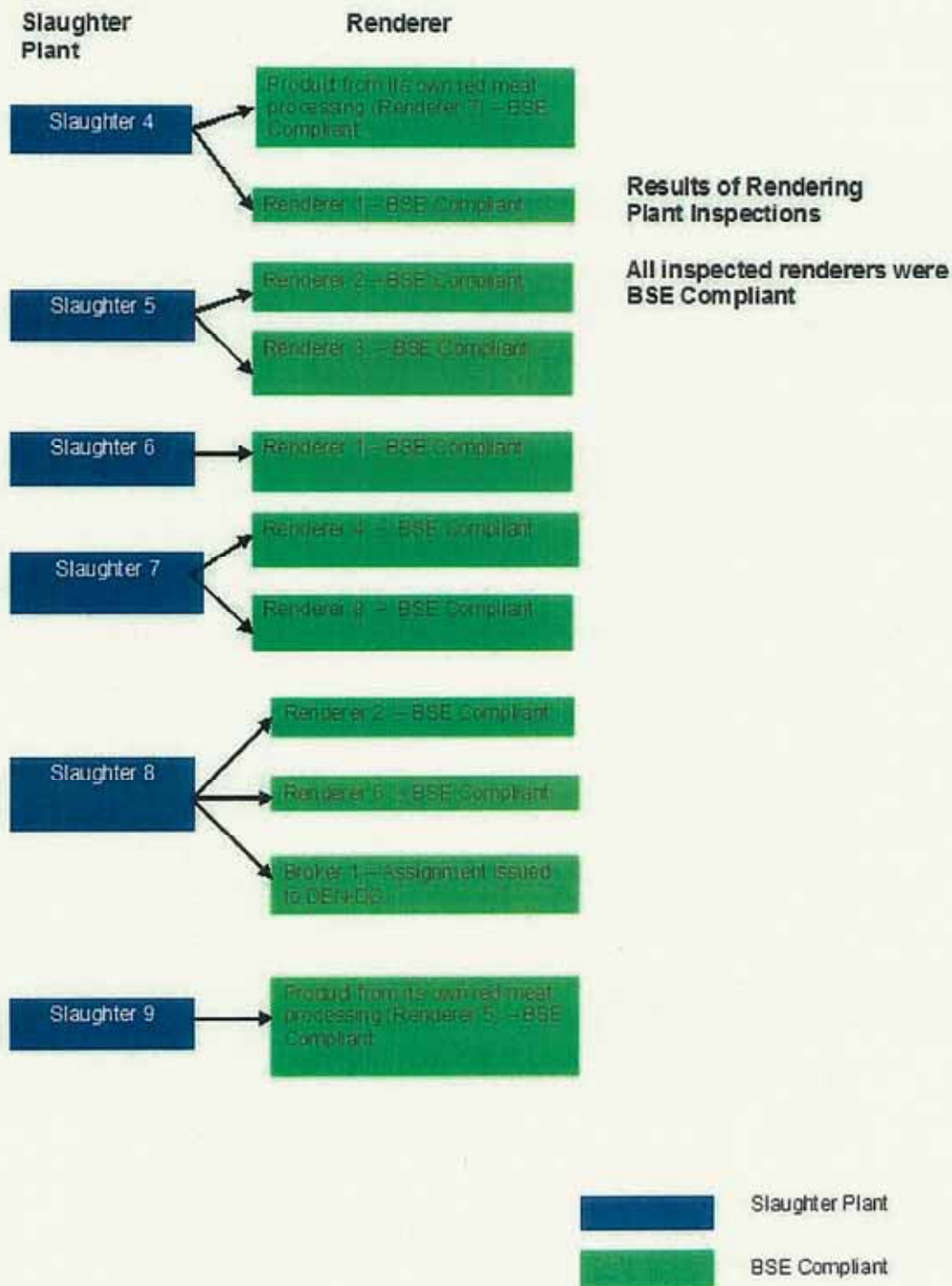
APHIS identified nine slaughter establishments receiving these animals of interest. Eight of the slaughter establishments were located in the State of Texas and one was located in the State of Georgia. Dallas District Investigators notified USDA/FSIS of our plans to visit each slaughter establishment to identify rendering facilities receiving materials from these slaughter establishments during the timeframe they received animals of interest. Dallas District also issued an assignment to Atlanta District to visit and inspect the one slaughter/renderer establishment located in the State of Georgia.

Eight renderers and one protein source broker were identified as receiving materials from these slaughter establishments. Each rendering facility identified was inspected for current compliance with the mammalian protein feed ban rule. Each firm's operations during the period of time of receipt of these animals post 1997 were evaluated from a historical viewpoint and no evidence of noncompliance was detected.

In all, FDA visited nine slaughter facilities, eight rendering facilities and one broker of these materials. All facilities inspected were found to be in compliance with the BSE/ruminant feed ban rule

Following is a graphical representation of the animal product follow-up work performed.





Feed Investigation:

As information was learned about the index herd, FDA Investigators working with TAHC officials conducted multiple interviews with the producer of the animal regarding possible feeds, feed sources, animal husbandry practices, and other events which may have changed normal feeding practices over the course of the index animal's life in the herd and any other information which may have been helpful in identifying the possible sources of feed for this animal and herd. FDA corroborated this information through interviews at the retail feed supply stores where the producer purchased feeds.

Follow-up at these retail feed supply stores identified 21 possible feed products the producer may have used during the history of the herd. Fifteen purchased feed products were identified, along with hay, native grass, rice straw, soybean meal, milk replacer/colostrum and bagged corn. These products were identified as originating from nine different manufacturers. Each of these manufacturers was inspected by FDA Dallas District and TFFCS Investigators.

Feed manufacturers were located throughout the State of Texas. An assignment was also issued to another FDA District to visit a Corporate Headquarters facility in an effort to review archived feed formulations and labels. During each of these inspections, the firm's current compliance with the

BSE/ruminant feed ban rule was evaluated and attempts were made to determine the protein sources used in feeds on the index farm. Many of the feeds investigated were manufactured and used prior to the implementation of the BSE/ruminant feed ban rule in 1997. Feed products of particular interest included any which may have contained a protein source and the primary focus was on identifying any possible mammalian protein source material in those feed products. We found that ruminant feeds that had contained mammalian meat and bone meal (MBM) prior to the BSE/ruminant feed ban rule had been discontinued or reformulated upon the implementation of these rules. There is no regulatory requirement for a feed mill to archive formulations for that length of time, so in those instances where an actual formulation could not be obtained, experienced employees of the firms were interviewed and their recollections recorded.

Of all the feeds in use by the producer since 1997, none were discovered to have contained prohibited material (mammalian protein). Since the age of the index animal was determined to be approximately 12 years, investigating and reconstructing a feed history over such a long period of time is challenging. This ranch is a beef cow-calf operation and minimal feed records were maintained. Due to the nature of this investigation, it is difficult to determine what feeds were in use at specific times and what the formulation of those feeds were at the time they were fed. A feed history was developed through interviews with the producer and other farm personnel since they did not maintain any feed history documentation. Interviews with personnel at retail establishments disclosed incomplete records and cash sales that did not always identify the purchaser. Dallas District investigated any and all feed ingredients that were identified as being fed or potentially fed over the course of the last 15 years of this herd's operation. Feeds discovered during this investigation with potential mammalian protein sources are as below:

- One feed, used prior to 1996, before the implementation of the feed ban, was suspected to contain mammalian meat and bone meal, but this could not be confirmed as no formulation records were available.
- The producer recalled using a particular feed sporadically during the 1980's and 1990's, however, he could not remember the name or manufacturer of the feed and had no records identifying the product. It is not known whether this feed contained an animal protein source. Attempts to identify this feed through interviews with retail sources were unsuccessful.
- The producer identified one feed product that has been used since the year 2000 which contains fish meal as a protein source. Further investigation revealed that this product had contained mammalian meat and bone meal prior to 1997, but that it had been reformulated at that time using fish meal to replace the MBM.

A tabular representation of the feed inspection follow-up activities is presented below:

Feed	Dates of Use	Protein Source	Current BSE Inspection	BSE Compliance History
Feed #1 - Range Meal	1980's - 2000	Unknown - Unable to determine actual manufacturer, no records available from producer	N/A	N/A
Feed #2 - High Protein Starter Feed	2001 to present	Feather meal	BSE Compliant	BSE Compliant
Feed #3 - High Protein Starter Feed	~1995 - 2001	Feather meal	BSE Compliant	BSE Compliant
Feed #4 - Cottonseed cake	Prior to 1990	Cottonseed meal	BSE Compliant	BSE Compliant
Feed #5 - Cottonseed cake	Early 1980's - 1990's	Cottonseed meal	BSE Compliant	BSE Compliant
Feed #6 - Limiter	2001 to present	Feather meal	BSE Compliant	BSE Compliant
Feed #7 - Creep pellets	Prior to 1970	Likely feather meal - no formulation could be obtained	N/A	N/A
Feed #8 - Lick tub	Since 2000	MBM prior to 1997 Fish Meal since	BSE Compliant	BSE Compliant

		1997		
Feed #9 - Cottonseed meal	Continuously	Cottonseed meal	BSE Compliant	BSE Compliant
Feed #10 - Range Cubes	Continuously since 1990	Feather meal	BSE Compliant	BSE Compliant [1]
Feed #11 - Sulfur Salt Block	Continuously	Minerals; calcium - all non-animal derived	BSE Compliant	BSE Compliant
Feed #12 - Lick tub	Continuously since 1995	Feather meal	BSE Compliant	BSE Compliant
Feed #13 - Beef Supplement	Prior to 1996	Prior to 1997, suspect MBM - Not able to confirm, no formulation available	BSE Compliant	Same manufacturer as Feed #10[1]
Feed #14 - Mineralized Salt	Continuously since 1998	Minerals; calcium - all non-animal derived	BSE Compliant	BSE Compliant
Feed #15 - Soybean meal	Since 2000, sparingly	Soybean meal	N/A	N/A
Feed #16 - Corn	Continuously	Corn	N/A	N/A
Feed #17 - Rice straw	1996, during dry year	Rice straw	N/A	N/A
Feed #18 - Hay	Continuously	Hay	N/A	N/A
Feed #19 - Milk Replacer	Since 2000, infrequent use	Dehydrated colostrums, whey	N/A	N/A
Feed #20 - Grass	Continuously	Native grass	N/A	N/A
Feed #21 - Soybean meal	Since 2000, sparingly	Soybean meal	N/A	N/A

Dallas District previously documented one incident of the accidental addition of mammalian protein to a feed that was to be used for cattle at this facility. This incident was isolated to the manufacture of one lot of a custom cattle feed. A cross contamination error resulted in mammalian meat and bone meal being accidentally included in a feed. The error was detected soon after production. The firm acted swiftly in recalling the product and purchasing the animals that had consumed the feed. No products entered the human food or ruminant feed chain.

Dallas District Compliance History with BSE Feed Ban Rules:

Prior to 1997, feed manufacturers were not required to differentiate between protein sources used in ruminant and non-ruminant feeds. For a period of time following the implementation of the BSE/ruminant feed ban rule, some feed manufacturers continued to use both prohibited material and non-prohibited material within the same facility, employing separation and cleanout procedures to minimize cross-contamination. Although the regulations allow this practice, the potential for cross-contamination of ruminant feeds is greater. Most feed mills have found this practice to be difficult and have abandoned this practice.

Since the implementation of the BSE/ruminant feed ban rule in 1997, Dallas District and its State partners have inspected every known or registered feed manufacturer located in the states of Texas, Oklahoma and Arkansas. Further, every rendering operation and feed manufacturer actually processing with prohibited materials has been inspected annually. The compliance rate of the industry has been excellent.

Results:

In total FDA, along with TFFCS, conducted 33 inspections, investigations and interviews of the producer, retail feed establishments, feed manufacturers, corporate headquarters, slaughter facilities, renderers and a protein source broker. The FDA Dallas District follow-up to this incident resulted in the coordination of efforts of multiple Federal and State agencies. This report is the physical output of many hours of research, planning and coordination. All of the inspections conducted confirmed the feed manufacturers and rendering operations to be in compliance with the current BSE/ruminant feed ban rule.

Dallas District conducts annual inspections of all feed mills and rendering facilities who handle, use or

produce PM for feed use. Inspections performed since the initiation of the BSE/ruminant feed ban rules in 1997 have confirmed a high degree of industry wide compliance with these important safeguards. The district also routinely coordinates and shares information regarding feed inspections with the TFFCS who are also responsible for the evaluating feed ban compliance in the state of Texas.

Food and Drug Administration
August 30, 2005

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