２．　米国の検査要領について

材料の取り扱いについて（採材から検査施設への搬入まで）

Revised Testing Protocol for the BSE Surveillance Program
July 1, 2005

All USDA (and contract laboratory) personnel must strictly adhere to the BSE testing protocol for any and all samples. USDA personnel will not deviate from this protocol in any way without the explicit prior approval of the Deputy Administrator of Veterinary Services.

1. A USDA-approved network laboratory or USDA's National Veterinary Services Laboratories (NVSL) receives a bovine brainstem sample submitted as part of the BSE surveillance program. If the sample is not usable (that is, if the brain stem is not recognizable), it is not tested.
2. If the sample is usable (if the brain stem can be recognized), the rapid screening test is completed in accordance with the manufacturers protocol and defined SOP (GPPISOP0030.02).
3. If the sample is negative for BSE on the completed screening test (as defined in manufacturer's instructions and NVSL SOP GPPISOP0032.03), no further action is taken. If the sample is reactive for BSE on the completed screening test (as defined in manufacturer's instructions and NVSL SOP GPPISOP0032.03), it is considered inconclusive and will undergo confirmatory testing at NVSL and USDA's National Animal Disease Center (NADC).*
4. NVSL receives tissue samples from the contract laboratory and immediately transfers at least 2 grams of brain stem tissue to NADC. A chain of custody will be documented and maintained by NVSL and NADC personnel. NVSL and NADC personnel will ensure that the samples are maintained in such a way so as to ensure their integrity.
5. NVSL repeats the screening test on a new piece of brain stem and re-runs the homogenate from the contract laboratory.
6. If the sample is suitable for IHC testing, IHC is run at NVSL. The sample will be considered positive by IHC if criteria in NVSL SOP GPPISOP27 are met as interpreted by the section head or laboratory chief. Concurrent with IHC testing at NVSL, SAF Immunoblot (Western blot) is run at NADC. The sample will be considered positive by SAF Immunoblot if the requirements of the OIE Manual of standards criteria are met as interpreted by the lead scientist or research leader. (If the sample is not suitable for IHC, it will be tested only by SAF Immunoblot).**

7. If the sample is negative on **both** SAF Immunoblot and IHC, it is negative for BSE. No further action is taken.
8. If the sample tests positive on **either** IHC or SAF Immunoblot, it is positive for BSE.
9. If the sample tests positive on either IHC or SAF Immunoblot (or if test results conflict), further testing for the purposes of characterization and/or research may be performed only after consultation with the Secretary of Agriculture. Recommendations for further testing will be conveyed through the Deputy Administrator. If further testing is requested, NVSL will provide the Deputy Administrator with a specific testing protocol together with a written explanation of that protocol.

*Collection personnel that ship samples directly to NVSL for screening and possible confirmatory testing must send fresh tissue to NVSL; fresh tissue must be received at NVSL within 48 hours. If it is not possible for fresh tissue to arrive at NVSL within 48 hours, collection personnel should send the entire sample frozen.
**Although fresh tissue is to be sent to Ames when possible, if frozen tissue must be sent, testing of that frozen tissue will proceed according to this protocol. However, if the frozen tissue cannot be tested using IHC (that is, if the brain stem is not recognizable), it will be tested only by SAF Immunoblot.

（仮訳）

BSE サーベイランスプログラムのための改訂版検査プロトコール
2005 年 7 月 1 日

全ての USDA（及び契約検査機関）の職員は、あらゆるサンプルに関して、BSE 検査プロトコールに忠実に従わなければならない。USDA の職員は、VS の副局長（deputy administrator）による明確な事前認可なしでは、このプロトコールから逸脱することはできない。

1．USDA が認可したネットワークラボラトリーもしくは USDA の国立獣医学研究所（NVSL）に、BSE サーベイランスプログラムの一環として、牛の脳幹サンプルが提出される。サンプルが利用不可能な場合（すなわち、脳幹が認知できない場合）、検査は行われない。

2．サンプルが利用可能な場合（脳幹の認知が可能な場合）、迅速スクリーニング検査は、製造業者のプロトコール及び定義済みの SOP（GPPISOP0030.02）に従って、実施される。

3．（製造業者の使用説明書及び NVSL SOP GPPISOP0032.03 に定義された通りに）スクリーニング検査が完了した時点で、サンプルが BSE 陰性だった場合、それ以上は何も行われない。（製造業者の使用説明書及び NVSL SOP GPPISOP0032.03 に定義された通りに）スクリーニング検査が完了した時点で、サンプルが BSE に対する反応を示していた場合、結果不確定（inconclusive）とみなされ、NVSL 及び USDA の国立動物疾病センター（NADC）で確認検査が実施されることになる。*

4．NVSL は、契約検査機関から組織サンプルを受け取り、最低 2g の脳幹組織を直ちに NADC に送付する。サンプル受け渡し記録は、NVSL と NADC の職員によって文書化、保管される。NVSL 及び NADC の職員は、必ず、サンプルの完全性が確保されるような方法で、保管されるようにする。

5．NVSL は、新たな脳幹の切片でスクリーニング検査を繰り返し行い、契約検査機関から送られてきた懸濁液を再検査する。

6．サンプルが IHC 検査に適している場合、NVSL で IHC が行われる。部長もしくは研究室の主任が、NVSL SOP GPPISOP0032.03 中の基準を満たしたと解釈した場合、そのサンプルは陽性であるとみなされる。NVSL における IHC 検査と併せて、NADC では SAF 免疫ブロット（ウェスタンブロット）が実施される。主席研究員もしくは研究代表者が、OIE の Manual of standards の基準の要件が満たされていると解釈した場合、SAF 免疫ブロットによってサンプルは陽性であると見なされる。（サンプルが IHC に適さない場合は、SAF 免疫ブロットによってのみ検査される）。**

7．サンプルが、SAF 免疫ブロット及び IHC の両方で陰性だった場合、BSE 陰性である。それ以上は何も行われない。

8．サンプルが、IHC もしくは SAF 免疫ブロットのいずれかで陽性を示した場合、BSE 陽性である。

9．サンプルが、IHC もしくは SAF 免疫ブロットのいずれかで陽性を示した場合（もしくは、検査結果が矛盾した場合）、農務長官との協議を経た上でのみ、性質決定を目的としたさらなる検査及び／または調査を実施することができる。さらなる検査を行うという勧告は、副局長を通じて伝えられる。さらなる検査の実施が要請された場合、NVSL は、副局長にプロトコールの説明書とともに具体的な検査プロトコールを提供する。

*スクリーニング検査及び実施される可能性のある確認検査のために、サンプルを直接 NVSL に送付する採材担当職員は、NVSL に新鮮組織を送らなければならない；新鮮組織は、48 時間以内に NVSL にて受け入れされなければならない。
新鮮組織が 48 時間以内に NVSL に到着することが不可能な場合、採材担当職員はサンプル全体を冷凍した状態で送付するべきである。

**可能であれば、新鮮組織は Ames に送付されるが、冷凍状態で送付されなければならない場合、その冷凍サンプルは本プロトコールに沿って処理される。しかしながら、冷凍サンプルを IHC を用いて検査することができない場合（つまり、脳幹の認知が不可能な場合）、SAF 免疫ブロットによってのみ検査される。

３．　米国における強化サーベイランス実施頭数のうち、ELISAを実施せず、IHC（免疫組織化学検査）のみ実施した頭数

To date, 9,245 animals have not been tested by ELISA (and were only subject to IHC). Please note that the number posted on the web for the total of BSE tests under the enhanced surveillance program is only for those animals subjected to the ELISA.
This group of 9,245 animals subjected to the IHC is in addition to the weekly web total.

（仮訳）
9, 245頭がELISA実施せずＩＨＣのみ。
この9, 245頭は公表されている強化サーベイランスの実施頭数には含まれていない。

４．　米国の疑陽性牛のELISA吸光度値

For the first positive, the initial read value at the State laboratory where it was tested was 0.133. It was tested again at the State laboratory with a value of 0.197.

For the second positive, the read value at the State laboratory where it was tested was 0.367.

（仮訳）
1回目の陽性結果については、検査が行われた州研究所における初期の測定値は0.133であった。州研究所において再検査された際の値は0.197であった。

2回目の陽性結果については、検査が行われた州研究所における測定値は0.367であった。

５．　米国における生前検査

獣医師による生前検査の実施状況及びと畜場ラインにおける獣医師の役割

FEDERAL MEAT INSPECTION ACT
TITLE 21 - FOOD AND DRUGS
CHAPTER 12 - MEAT INSPECTION
SUBCHAPTER I – INSPECTION REQUIREMENTS; ADULTERATION AND MISBRANDING

§603. Inspection of meat and meat food products.

- **(a) Examination of animals before slaughtering; diseased animals slaughtered separately and carcasses examined**

For the purpose of preventing the use in commerce of meat and meat food products which are adulterated, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all cattle, sheep, swine, goats, horses, mules, and other equines before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce; and all cattle, sheep, swine, goats, horses, mules, and other equines found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other cattle, sheep, swine, goats, horses, mules, or other equines, and when so slaughtered the carcasses of said cattle, sheep, swine, goats, horses, mules, or other equines shall be subject to a careful examination and inspection, all as provided by the rules and regulations to be prescribed by the Secretary, as provided for in this subchapter.

- **(b) Humane methods of slaughter**

For the purpose of preventing the inhumane slaughtering of livestock, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of the method by which cattle, sheep, swine, goats, horses, mules, and other equines are slaughtered and handled in connection with slaughter in the slaughtering establishments inspected under this chapter. The Secretary may refuse to provide inspection to a new slaughtering establishment or may cause inspection to be temporarily suspended at a slaughtering establishment if the Secretary finds that any cattle, sheep, swine, goats, horses, mules, or other equines have been slaughtered or handled in connection with slaughter at such establishment by any method not in accordance with the Act of August 27, 1958 (72 Stat. 862; 7 U.S.C. 1901-1906) until the establishment furnishes assurances satisfactory to the Secretary that all slaughtering and handling in connection with slaughter of livestock shall be in accordance with such a method.

PART 309—ANTE-MORTEM INSPECTION

Sec.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15563, Oct. 3, 1970, unless otherwise noted.

§309.1 Ante-mortem inspection in pens of official establishments.

(a) All livestock offered for slaughter in an official establishment shall be examined and inspected on the day of and before slaughter unless, because of unusual circumstances, prior arrangements acceptable to the Administrator have been made in specific cases by the circuit supervisor for such examination and inspection to be made on a different day before slaughter.

(b) Such ante-mortem inspection shall be made in pens on the premises of the establishment at which the livestock are offered for slaughter before the livestock shall be allowed to enter into any department of the establishment where they are to be slaughtered or dressed or in which edible products are handled. When the holding pens of an official establishment are located in a public stockyard and are reserved for the exclusive use of the establishment, such pens shall be regarded as part of the premises of that establishment and the operator of the establishment shall be responsible for compliance with all requirements of the regulations in this subchapter with respect to such pens.

§309.2 Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise.

(a) Any livestock which, on ante-mortem inspection, do not clearly show, but are suspected of being affected with any disease or condition that, under part 311 of this subchapter, may cause condemnation of the carcass on post-mortem inspection, and any livestock which show, on ante-mortem inspection, any disease or condition that, under part 311 of this subchapter would cause condemnation of only part of the carcass on post-mortem inspection, shall be so handled as to retain its identity as a suspect until it is given final post-mortem inspection, when the carcass shall be marked and disposed of as provided in parts 310 and 311 of this subchapter, or until it is disposed of as otherwise provided in this part.

(b) All seriously crippled animals and animals commonly termed "downers," shall be identified as U.S. Suspects and disposed of as provided in §311.1 of this subchapter unless they are required to be classed as condemned under §309.3.

(c) Livestock which have reacted to a test for leptospirosis, or anaplasmosis, but which show no symptoms of the disease, shall be identified as U.S. Suspects and disposed of as provided in §311.10 of this subchapter.

(d) Livestock which are known to have reacted to the tuberculin test shall be identified as U.S. Suspects and disposed of as provided in §311.2 of this subchapter, except that livestock bearing an official "USDA Reactor" or similar State reactor tag shall not be tagged as U.S. Suspects.

(e) Any cattle found on ante-mortem inspection to be affected with epithelioma of the eye or of the orbital region to a lesser extent than as described in §309.6 shall be identified as a

U.S. Suspect and disposed of as provided in §311.12 of this subchapter.

(f) Cattle found on ante-mortem inspection to be affected with anasarca to a lesser extent than as described in §309.8 shall be identified as U.S. Suspects and disposed of as provided in §311.8 of this subchapter or paragraph (g) of this section.

(g) Any livestock suspected of being affected with anasarca may be set apart and held for treatment under Program or other responsible official supervision approved by the area supervisor. If at the expiration of the treatment period the livestock upon examination is found to be free from disease, it may be released for any purpose. Otherwise, it shall be identified as U.S. Suspect and disposed of as provided in §311.8 of this subchapter or condemned and disposed of as provided in §309.8, whichever is appropriate.

(h) All hogs suspected on ante-mortem inspection of being affected with swine erysipelas shall be identified as U.S. Suspects and disposed of as provided in §311.5 of this subchapter or paragraph (i) of this section.

(i) A hog suspected of being affected with swine erysipelas may be set apart *and held for treatment under Program* or other responsible official supervision approved by the area supervisor. If at the expiration of the treatment period the animal upon examination is found to be free from disease, it may be released for any purpose. Otherwise, it shall be identified as U.S. Suspect and disposed of as provided in §311.5 of this subchapter, or condemned and disposed of as provided in §309.13, whichever is appropriate.

(j) Any livestock which is affected with vesicular exanthema or vesicular stomatitis, but which has recovered to the extent that the lesions are in process of healing, the temperature is within normal range, and the livestock shows a return to normal appetite and activity, shall be identified as U.S. Suspect and disposed of as provided in §311.32 of this subchapter, except that if desired, such livestock may be set apart and held under supervision of a Program employee or other official designated by the area supervisor for treatment. If the livestock is set aside for treatment, the U.S. Suspect identification device will be removed by a Program employee, following such treatment, if the livestock is found to be free from any such disease. Such livestock found to be free from any such disease may be released for slaughter or for purposes other than slaughter, provided that in the latter instance, the operator of the official establishment or the owner of the animal shall first obtain permission from the local, State, or Federal livestock sanitary official having jurisdiction over the movement of such livestock.

(k) Livestock which are offered for ante-mortem inspection under this part, and which are regarded by the inspector as immature, shall be identified as U.S. Suspects and, if slaughtered, the disposition of their carcasses shall be determined by the post-mortem findings in connection with the ante-mortem conditions. If not slaughtered as suspects, such livestock shall be held under supervision of a Program employee or other official designated by the area supervisor, and after sufficient development may be released for slaughter or may be released for any other purpose, provided they have not been exposed to any infectious or contagious disease. If such exposure occurs, permission should be obtained from the nearest Veterinary Services unit of the Animal and Plant Health Inspection Service prior to release of such livestock.

(l) Livestock previously condemned for listeriosis, if released for slaughter under §309.13(b) shall be identified as a U.S. Suspect in accordance with §309.13(c).

(m) Each animal required by this part to be treated as a U.S. Suspect shall be identified as such by or under the supervision of a Program employee with an official device in accordance with §309.18. No such device shall be removed except by a Program employee.

(n) Each animal identified as a U.S. Suspect on ante-mortem inspection shall be set apart and shall be slaughtered separately from other livestock at that establishment unless disposed of as otherwise provided in this part.

(o) Each animal identified as a U.S. Suspect on ante-mortem inspection, when presented for slaughter shall be accompanied with a form MP 402-2 on

which the inspector at the establishment shall record the U.S. Suspect identification number and any other identifying tag numbers present and a brief description of the animal and of the disease or condition for which the animal was classed as a suspect, including its temperature when the temperature of such animal might have a bearing on the disposition of the carcass on post-mortem inspection.

(p) When any animal identified as a U.S. Suspect is released for any purpose or reason, as provided in this part, the official identification device shall be removed only by a Program employee and he shall report his action to the area supervisor. When a suspect is to be released under the provisions of this part for a purpose other than slaughter, the operator of the official establishment or the owner of the animal shall first obtain permission for the removal of such animal from the local, State or Federal livestock sanitary official having jurisdiction.

[35 FR 15563, Oct. 3, 1970, as amended at 38 FR 29214, Oct. 23, 1973; 39 FR 36000, Oct. 17, 1974]

§309.3 Dead, dying, disabled, or diseased and similar livestock.

(a) *Livestock found to be dead or in a* dying condition on the premises of an official establishment shall be identified as U.S. Condemned and disposed of in accordance with §309.13.

(b) Livestock plainly showing on ante-mortem inspection any disease or condition that, under part 311 of this subchapter, would cause condemnation of their carcasses on post-mortem inspection shall be identified as U.S. Condemned and disposed of in accordance with §309.13.

(c) Any swine having a temperature of 106 °F. or higher and any cattle, sheep, goats, horses, mules, or other equines having a temperature of 105 °F. or higher shall be identified as U.S. Condemned. In case of doubt as to the cause of the high temperature, or when for other reasons a Program employee deems such action warranted, any such livestock may be held for a reasonable time under the supervision of a Program employee for further observation and taking of temperature before final disposition of such livestock is determined. Any livestock so held shall be reinspected on the day it is slaughtered. If, upon such reinspection, or when not held for further observation and taking of temperature, then on the original inspection, the animal has a temperature of 106 °F. or higher in the case of swine, or 105 °F. or higher in the case of other livestock, it shall be condemned and disposed of in accordance with §309.13.

(d) Any livestock found in a comatose or semicomatose condition or affected with any condition not otherwise covered in this part, which would preclude release of the animal for slaughter for human food, shall be identified "U.S. Condemned" and disposed of in accordance with §309.13, except that such animal may be set apart and held for further observation or treatment under supervision of a Program employee or other official designated by the area supervisor and for final disposition in accordance with this part.

§309.4 Livestock showing symptoms of certain metabolic, toxic, nervous, or circulatory disturbances, nutritional imbalances, or infectious or parasitic diseases.

(a) All livestock showing, on ante-mortem inspection, symptoms of anaplasmosis, ketosis, leptospirosis, listeriosis, parturient paresis, pseudorabies, rabies, scrapie, tetanus, grass tetany, transport tetany, strangles, purpura hemorrhagica, azoturia, infectious equine encephalomyelitis, toxic encephalomyelitis (forage poisoning), dourine, acute influenza, generalized osteoporosis, glanders (farcy), acute inflammatory lameness or extensive fistula shall be identified as U.S. Condemned and disposed of in accordance with §309.13.

(b) If any equine is suspected on ante-mortem inspection of being infected with glanders or dourine, the nearest Veterinary Services unit of the Animal and Plant Health Inspection Service shall be so informed by a Program employee. Tests shall be performed by said unit to determine whether the animal is, in fact, infected with such disease. If it is found on such tests to be infected, the animal shall be disposed of in accordance with paragraph (a) of this section. Otherwise, the animal shall be identified as a U.S. Suspect

and disposed of as provided in §311.10 of this subchapter.

[35 FR 15563, Oct. 3, 1970 as amended at 38 FR 29214, Oct. 23, 1973]

§309.5 Swine; disposal because of hog cholera.

(a) All swine found by an inspector to be affected with hog cholera shall be identified as U.S. Condemned and disposed of in accordance with §309.13. Immediate notification shall be given by the inspector to the official in the Veterinary Services unit of the Animal and Plant Health Inspection Service who has responsibility for the control of swine diseases in the State where the swine are located.

(b) All swine, even though not themselves identified as U.S. Suspects, which are of lots in which one or more animals have been condemned or identified as U.S. Suspect for hog cholera, shall, as far as possible, be slaughtered separately and apart from all other livestock passed on ante-mortem inspection.

[40 FR 27225, June 27, 1975]

§309.6 Epithelioma of the eye.

Any animal found on ante-mortem inspection to be affected with epithelioma of the eye and the orbital region in which the eye has been destroyed or obscured by neoplastic tissue and which shows extensive infection, suppuration, and necrosis, usually accompanied with foul odor, or any animal affected with epithelioma of the eye or of the orbital region which, regardless of extent, is accompanied with cachexia shall be identified as U.S. Condemned and disposed of in accordance with §309.13.

§309.7 Livestock affected with anthrax; cleaning and disinfection of infected livestock pens and driveways.

(a) Any livestock found on ante-mortem inspection to be affected with anthrax shall be identified as U.S. Condemned and disposed of in accordance with §309.13.

(b) No other livestock of a lot in which anthrax is found on ante-mortem inspection shall be slaughtered and presented for post-mortem inspection until it has been determined by a careful ante-mortem inspection that no anthrax infected livestock remains in the lot.

(c) Apparently healthy livestock (other than hogs) from a lot in which anthrax is detected, and any apparently healthy livestock which have been treated with anthrax biologicals which do not contain living anthrax organisms, may be slaughtered and presented for post-mortem inspection if they have been held not less than 21 days following the last treatment or the last death of any livestock in the lot. Alternatively, if desired, all apparently healthy livestock of the lot may be segregated and held for treatment by a State licensed veterinarian under supervision of a Program employee or other official designated by the area supervisor. No anthrax vaccine (live organisms) shall be used on the premises of an official establishment.

(d) Livestock which have been injected with anthrax vaccines (live organisms) within 6 weeks, and those bearing evidence of reaction to such treatment, such as inflammation, tumefaction, or edema at the site of the injection, shall be condemned on ante-mortem inspection, or such animals may be held under supervision of a Program employee or other official designated by the area supervisor until the expiration of the 6-week period and the disappearance of any evidence of reaction to the treatment.

(e) When livestock are found on ante-mortem inspection to be affected with anthrax, all exposed livestock pens and driveways of the official establishment shall be cleaned and disinfected by promptly and thoroughly removing and burning all straw, litter, and manure. This shall be followed immediately by a thorough disinfection of the exposed premises by soaking the ground, fences, gates, and all exposed material with a 5 percent solution of sodium hydroxide or commercial lye prepared as outlined in §310.9(e)(1) of this subchapter, or other disinfectant that may be approved in specific cases by the Administrator specifically for this purpose.

§ 309.8 Cattle affected with anasarca and generalized edema.

All cattle found on ante-mortem inspection to be affected with anasarca in advanced stages and characterized by an extensive and generalized edema shall be identified as U.S. Condemned and disposed of in accordance with § 309.13.

§ 309.9 Swine erysipelas.

All hogs plainly showing on ante-mortem inspection that they are affected with acute swine erysipelas shall be identified as U.S. Condemned and disposed of in accordance with § 309.13.

§ 309.10 Onset of parturition.

Any livestock showing signs of the onset of parturition shall be withheld from slaughter until after parturition and passage of the placenta. Slaughter or other disposition may then be permitted if the animal is otherwise acceptable.

§ 309.11 Vaccine livestock.

Vaccine livestock with unhealed lesions of vaccinia, accompanied with fever, which have not been exposed to any other infectious or contagious disease, are not required to be slaughtered and may be released for removal from the premises.

§ 309.12 Emergency slaughter; inspection prior to.

In all cases of emergency slaughter, except as provided in § 311.27 of this subchapter, the animals shall be inspected immediately before slaughter, whether theretofore inspected or not. When the necessity for emergency slaughter exists, the establishment shall notify the inspector in charge so that such inspection may be made.

§ 309.13 Disposition of condemned livestock.

(a) Except as otherwise provided in this part, livestock identified as U.S. Condemned shall be killed by the official establishment, if not already dead. Such animals shall not be taken into the official establishment to be slaughtered or dressed; nor shall they be conveyed into any department of the establishment used for edible products; but they shall be disposed of in the manner provided for condemned carcasses in part 314 of this subchapter. The official U.S. Condemned tag shall not be removed from, but shall remain on the carcass until it goes into the tank, or is otherwise disposed of as prescribed in part 314 of this subchapter, at which time such tag may be removed by a Program employee only. The number of such tag shall be reported to the veterinary medical officer by the inspector who affixed it, and also by the inspector who supervised the tanking of the carcass.

(b) Any livestock condemned on account of ketosis, swine erysipelas, vesicular diseases, grass tetany, transport tetany, parturient paresis, anasarca, anaplasmosis, leptospirosis, listeriosis, or inflammatory condition including pneumonia, enteritis, and peritonitis may be set apart and held for treatment under supervision of a Program employee or official designated by the area supervisor. The U.S. Condemned identification tag will be removed by a Program employee following treatment under such supervision if the animal is found to be free from any such disease.

(c) Livestock previously affected with listeriosis, including those released for slaughter after treatment under paragraph (b) of this section, shall be identified as U.S. Suspect.

(d) When livestock under the provisions of this section is to be released for a purpose other than slaughter, the operator of the official establishment or the owner of the livestock shall first obtain permission for the movement of such livestock from the local, State, or Federal livestock sanitary official having jurisdiction.

§ 309.14 Brucellosis-reactor goats.

Goats which have reacted to a test for brucellosis shall not be slaughtered in an official establishment.

§ 309.15 Vesicular diseases.

(a) Immediate notification shall be given by the inspector to the local, State, and Federal livestock sanitary officials having jurisdiction when any livestock is found to be affected with a vesicular disease.

(b) No livestock under quarantine by State or Federal livestock sanitary officials on account of a vesicular disease will be given ante-mortem inspection. If no quarantine is invoked, or if quarantine is invoked and later removed, upon ante-mortem inspection, any animal found to be affected with vesicular exanthema or vesicular stomatitis in the acute stages, as evidenced by acute and active lesions or an elevated temperature, shall be identified as U.S. *Condemned and disposed of in accordance* with § 309.13.

§ 309.16 Livestock suspected of having biological residues.

(a) Except as provided by paragraph (d) of this section, livestock suspected of having been treated with or exposed to any substance that may impart a biological residue which would make the edible tissues unfit for human food or otherwise adulterated shall be handled in compliance with the provisions of this paragraph. They shall be identified at official establishments as "U.S. Condemned." These livestock may be held under the custody of a Program employee, or other official designated by the Administrator, until metabolic processes have reduced the residue sufficiently to make the tissues fit for human food and otherwise not adulterated. When the required time has elapsed, the livestock, if returned for slaughter, must be re-examined on ante-mortem inspection. To aid in determining the amount of residue present in the tissues, officials of the Program may permit the slaughter of any such livestock for the purpose of collecting tissues for analysis for the residue. Such analysis may include the use of inplant screening procedures designed to detect the presence of antimicrobial residues in any species of livestock.

(b) All carcasses and edible organs and other parts thereof, in which are found any biological residues which render such articles adulterated, shall be marked as "U.S. Condemned" and disposed of in accordance with § 314.1 or § 314.3 of this chapter.

(c) [Reserved]

(d) Calves shall not be presented for ante-mortem inspection in an official establishment except under the provisions of this paragraph.

(1) *Definitions.* For purposes of this paragraph, the following definitions shall apply:

(i) *Calf.* A calf up to 3 weeks of age or up to 150 pounds.

(ii) *Certified calf.* A calf that the producer and all other subsequent custodians of the calf certify in writing has not been treated with any animal drug while in his or her custody or has been treated with one or more drugs in accordance with FDA approved label directions while in his or her custody and has been withheld from slaughter for the period(s) of time specified by those label directions.

(iii) *Healthy calf.* A calf that an inspector determines shows no visual signs of disease or treatment of disease at ante-mortem inspection.

(iv) *Producer.* The owner of the calf at the time of its birth.

(v) *Sick calf.* A calf that an inspector on ante-mortem inspection determines has either signs of treatment or signs of disease.

(vi) *Veterinary medical officer.* An inspector of the Program that has obtained a Doctor of Veterinary Medicine degree which is recognized by the Program.

(2) *General requirements.* (i) The identity of the producer of each calf presented for ante-mortem inspection shall be made available by the official establishment to the inspection prior to the animal being presented for ante-mortem inspection.

(ii) The inspector shall segregate the calves presented for ante-mortem inspection at the establishment and identify each calf as one of the following: (a) Certified, (B) noncertified, or (C) previous residue condemnation.

(3) *Certified group.* (i) For a calf to be considered certified, the producer and all other subsequent custodians of the calf must certify in writing that while the calf was in his or her custody, the calf was not treated with animal drugs or was treated with one or more drugs in accordance with FDA approved label directions and was withheld from slaughter for the period(s) of time specified by those label directions. All prior certifications must be presented with the animal at the time of slaughter.

The certifications shall contain a list of the calves with accompanying identification numbers, as required by paragraph (d)(3)(ii) of this section, followed by the following language:

I hereby certify that, while in my custody, from _____ to _____ (time period of custody), the above-listed calf or calves have not been treated with drugs, or have been treated with one or more drugs in accordance with FDA approved label directions and have been withheld from slaughter for the period(s) of time specified by those label directions. I certify that, to the best of my knowledge and belief, all information contained herein is true, that the information may be relied upon at the official establishment, and that I understand that any willful falsification of this certification is a felony and may result in a fine of up to $250,000 for an individual or up to $500,000 for an organization, or imprisonment for not more than 5 years, or both (21 U.S.C. 677, 18 U.S.C. 1001 and 3571).

Executed on _____
(date of certification)

_____
(signature of certifier)

_____
(typed or printed name and address of certifier)

_____
(business of certifier)

(ii) Each calf must be identified by use of backtag, eartag, or other type of secure identification which displays a number which shall be recorded on all written certifications.

(iii) The inspector shall have segregated for veterinary medical officer examination any certified calf which he or she determines to show any sign of disease or which is not identified individually. Such animal will be tagged as "U.S. Suspect" and its carcass will be retained on post-mortem inspection and handled in accordance with §310.21 (c) and (d).

(iv) The inspector shall handle the remaining carcasses of healthy animals in accordance with §310.21(c) and (d).

(4) *Noncertified group.* On ante-mortem inspection, the inspector shall have segregated for veterinary medical officer examination any calf which he or she determines to show any sign of disease. Such animal will be tagged as "U.S. Suspect" and its carcass will be retained on post-mortem inspection and handled in accordance with §310.21(c). The inspector shall handle the remaining carcasses of healthy animals in accordance with §310.21(c).

(5) *Calves from producers with previous residue condemnation.* On ante-mortem inspection, the inspector shall have segregated for veterinary medical officer examination any calf which he or she determines to show any sign of disease. Such animal will be tagged as "U.S. Suspect" and its carcass will be retained on post-mortem inspection and handled in accordance with §310.21(e). The inspector shall handle the remaining carcasses of healthy animals in accordance with §310.21(e).

(e) The name of each and all person(s) who sold or consigned each swine to the establishment shall be made available by the establishment to any Program employee or other authorized employee of the United States Department of Agriculture upon that employee's request and presentation of his or her official credentials. Swine identification, by means approved by the Animal and Plant Health Inspection Service, USDA, under part 71 of this title, must be maintained throughout post-mortem inspection, in accordance with §310.23(a) of this subchapter.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583-0053)

[36 FR 24928, Dec. 24, 1971, as amended at 44 FR 45606, Aug. 3, 1979; 44 FR 59499, Oct. 16, 1979; 47 FR 746, Jan. 7, 1982; 47 FR 41336, Sept. 20, 1982; 50 FR 32164, Aug. 9, 1985; 50 FR 53127, Dec. 30, 1985; 52 FR 2104, Jan. 20, 1987; 53 FR 40387, Oct. 14, 1988; 55 FR 7474, Mar. 2, 1990]

§309.17 Livestock used for research.

(a) No livestock used in any research investigation involving an experimental biological product, drug, or chemical shall be eligible for slaughter at an official establishment unless:

(1) The operator of such establishment, the sponsor of the investigation, or the investigator has submitted to the Program, or the Veterinary Services unit of the Animal and Plant Health Inspection Service of the Department of Agriculture or to the Environmental Protection Agency or to the Food and Drug Administration of the Department of Health, Education, and Welfare, data or a summary evaluation of the data which demonstrates that

the use of such biological product, drug, or chemical will not result in the products of such livestock being adulterated, and a Program employee has approved such slaughter;

(2) Written approval by the Deputy Administrator, Meat and Poultry Inspection Field Operations is furnished the area supervisor prior to the time of slaughter;

(3) In the case of an animal administered any unlicensed, experimental veterinary biologic product regulated under the Virus-Serum Toxin Act (21 U.S.C. 151 et seq.), the product was prepared and distributed in compliance with Part 103 of the regulations issued under said Act (part 103 of this title), and used in accordance with the labeling approved under said regulations;

(4) In the case of an animal administered any investigational drug regulated under the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.), the drug was prepared and distributed in compliance with the applicable provisions of part 135 of the regulations issued under said Act (21 CFR part 135), and used in accordance with the labeling approved under said regulations;

(5) In the case of an animal subjected to any experimental economic poison under section 2(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 135 et seq.), the product was prepared and distributed in accordance with §362.17 of the regulations issued under said Act (7 CFR 362.17), and used in accordance with the labeling approved under said regulations.

(6) In the case of an animal administered or subjected to any substance that is a food additive or pesticide chemical under the Federal Food, Drug, and Cosmetic Act, supra, there has been compliance with all tolerance limitations established by said Act and the regulations promulgated thereunder (21 CFR 1.1 et seq.), and all other restrictions and requirements imposed by said Act and said regulations will be complied with at the time of slaughter.

(b) The inspector in charge may deny or withdraw the approval for slaughter of any livestock subject to the provision of this section when he deems it necessary to assure that all products prepared at the official establishment are free from adulteration.

§309.18 Official marks and devices for purposes of ante-mortem inspection.

(a) All livestock required by this part to be identified as U.S. Suspects shall be tagged with a serially numbered metal ear tag bearing the term "U.S. Suspect," except as provided in §309.2(d) and except that cattle affected with epithelioma of the eye, antinomycosis, 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.

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

FSIS NOTICE	5-04	1/12/04

INTERIM GUIDANCE FOR NON-AMBULATORY DISABLED CATTLE AND AGE DETERMINATION

I. PURPOSE

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

II. BACKGROUND

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

Among other requirements, the new regulations at 9 CFR 309.2(b) state that non-ambulatory disabled livestock, including cattle, are livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken

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appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column or metabolic conditions. The new regulation at 9 CFR 309.3(e) states that non-ambulatory disabled cattle shall be condemned. Consequently, these cattle, which may be on the premise housing the slaughter establishment, cannot enter the slaughter establishment.

Non-ambulatory disabled cattle are considered unfit for use as human food. This determination is derived from Title 1, Section 1(m)(3) of the Federal Meat Inspection Act. Specifically,

> *The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances: if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food*

Non-ambulatory disabled cattle remain subject to the provisions of the Humane Slaughter Act, its implementing regulations, and FSIS Directive 6900.1, Revision 1.

III. VMOs RESPONSIBILTIES REGARDING NON-AMBULATORY DISABLED CATTLE

A. What actions do VMOs take when non-ambulatory disabled cattle are presented for slaughter?

1. The VMO is responsible for conducting ante-mortem inspection on all non-ambulatory disabled cattle, of any age, presented for slaughter. All non-ambulatory disabled cattle are to be U.S. condemned. VMOs also are to continue to condemn all cattle that are showing central nervous system (CNS) symptoms, even if the animal is ambulatory. Cattle condemned upon ante-mortem inspection cannot enter the slaughter establishment.

2. The 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.

a. If a sample is collected for the APHIS BSE Surveillance program from condemned cattle, VMOs are to ensure that all animal identification is maintained. The VMO should maintain control of the tested animal(s) until the establishment documents how the animal(s) will be properly disposed.

b. If the AVIC determines that it is not possible for APHIS personnel to get to the slaughter establishment, the AVIC will let the VMO know and the VMO is to proceed in verifying that the establishment properly disposes of the animal.

B. What do VMOs verify regarding condemnation?

1. VMOs are to verify that the establishment has properly disposed of animals in accordance with 9 CFR 309.13 and 9 CFR 314, and maintains the records required by 9 CFR 320. In the preamble to the new regulations contained in docket #03-025IF, FSIS recognizes activated charcoal as a proprietary substance approved by the Administrator that can be used for proper disposal in addition to the provisions at 9 CFR 314 for properly disposing of condemned carcasses.

2. At the request of the owner or operator, condemned cattle can be set apart and held for treatment (9 CFR 309.13(b)). Treatment is to be performed under the supervision of an FSIS program employee or designee of the District Manager. In addition, if cattle are to be released for a purpose other than slaughter (9 CFR 309.13(d)), the operator of the official establishment or the owner of the livestock must first obtain permission for the movement of such livestock from the local, State, or Federal livestock sanitary official having jurisdiction.

3. The VMO can inform the establishment that landfills are an acceptable option for disposal.

C. What form do the VMOs use to document condemnation?

VMOs are to complete condemnation certificates for cattle condemned on ante-mortem using FSIS Form 6000-13, Condemnation Certificates.

D. What do VMOs do if cattle are ambulatory at ante-mortem inspection and become non-ambulatory disabled prior to slaughter? What is the disposition of the animal?

If an otherwise normal healthy animal that has passed ante-mortem inspection and is on its way to the knock box and suffers an acute injury (e.g., if the animal falls or if an animal has a leg that gets trapped and broken), the VMO should verify that the animal suffered such an acute injury and allow the animal to proceed to slaughter and post-mortem inspection. FSIS would expect such situations to be extremely rare because cattle, when handled and moved under proper humane handling conditions, should not be injured while being moved in the pens. For cattle that become non-ambulatory disabled after ante-mortem inspection, if the VMO cannot determine that a specific, acute injury occurred that caused the animal to become non-ambulatory disabled, the animal is to be condemned and cannot enter the slaughter establishment.

E. What is the responsibility of the Consumer Safety Inspection/Inspector-in-Charge in an official slaughter establishment where the VMO is not located on premise?

If nonambulatory disabled cattle are presented for ante-mortem inspection, the CSI/IIC is to hold the animal until the VMO can arrive to perform ante-mortem on the animal and condemn it.

IV. VMO RESPONSIBILTIES FOR AGE DETERMINATION

A. VMOs are to examine establishment records that report the age of cattle because cattle 30 months of age and older contain additional SRMs beyond those for cattle of any age. The documentation may be in the form of:

1. a birth certificate,
2. cattle passport, or
3. some other form of identification that is presented with the animal when it arrives for slaughter

B. If VMOs conclude that the records are accurate and reliable, the records will be accepted as verification of the age of the cattle.

C. However, if VMOs examine the records and find significant reasons for questioning their validity, they are to verify the age of the cattle through dental examination.

D. VMOs are to consider cattle to be 30 months and older when the examination of the dentition of the animal shows that at least one of the second set of permanent incisors has erupted (see attachment). FSIS recognizes that the permanent incisors of cattle erupt from 24 through 30 months of age, but the Agency has determined that the described dentition procedure will be most protective of public health.

E. VMOs on patrol assignments are to correlate with inspection program personnel at slaughter establishments.

Direct questions to the Technical Service Center

/s/ Philip S. Derfler

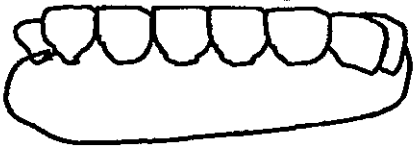
Assistant Administrator
Office of Policy and Program Development

Attachment

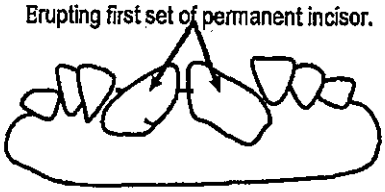
The detention depicted below represents animals less than 30 months of age.

Full set of 8 temporary teeth on young calf.

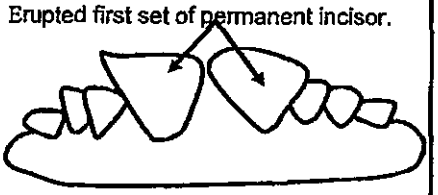
Full set of 8 temporary teeth, at about 15 months of age



Erupting first set of permanent incisor.



Erupted first set of permanent incisor.

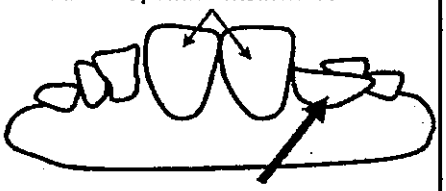


Temporary incisors

Erupting third permanent incisor, top of tooth **NOT** above gum line, animal less than 30 months of age.

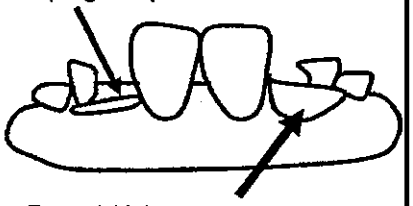
The detention depicted below represents animals 30 months of age or older.

First set permanent incisors

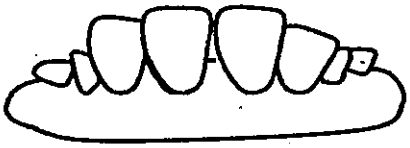


Erupted third permanent incisor, top of tooth above gum line, animal 30 months of age.

Erupting forth permanent incisor.

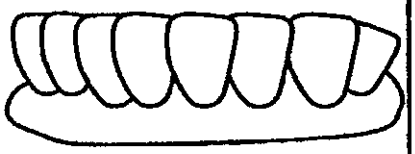


Erupted third permanent incisor (with top corners of the tooth above the gum line), animal 30 months of age or older.



Four permanent incisor, (with top corners of the second set above the gum line), animal 30 months of age or older.

Full set of permanent incisors, animal over 48 months of age.



Age 72 months, medial incisors showing wear and.leveled tops.

Age 120 months or older, permanent incisors showing wear and space between the teeth.