資料１－２

食安監発第0729001号
１７消安第４６３２号
平成１７年７月２９日

内閣府食品安全委員会事務局評価課長　殿

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

食品健康影響評価に係る資料の提出について

平成１７年７月２８日付け府食第７２３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．米国における２頭目のＢＳＥ感染牛
（１）昨年１１月に実施した１次検査のＥＬＩＳＡの値（１回目、２回目）
（２）昨年１１月、１次検査陽性と確認した以降に実施した検査（研究目的で実施し陽性であったものも含む）の内容及びその結果
（３）６月の再検査時にＵＳＤＡで実施した検査について、検査法のプロトコール、使用抗体の種類、各検査法の結果（画像等）
（４）英国で実施した検査法について、検査法のプロトコール、使用抗体の種類、各検査法の結果（画像等）
（５）ＵＳＤＡが通常実施しているＩＨＣ及びＷＢのプロトコール、ＯＩＥの手法と異なる部分、使用抗体の種類等
（６）出生後の代用乳及び配合飼料の使用状況
２．飼料規制
米国で２００４年７月に公表され、パブリックコメントに付された飼料規制の改正案についての検討状況（施行の可能性等）
３．サーベイランス
（１）サーベイランスを実施した牛の年齢分布（カテゴリー別、乳肉別、地域別等）
（２）高リスク牛（446,000頭）の算出根拠について
・死亡牛（251,500頭）について：算出根拠と使用した統計の原典
・と畜場での廃棄牛（194,200頭）について：使用したＦＳＩＳの統計の原典
・中枢神経症状を呈した牛（129頭）について：使用したＦＡＤ調査の原典
４．自国産牛でＢＳＥが確認されたことを受けた、ＢＳＥ清浄性に対する米国の考え方
５．カナダにおける生前検査
カナダのＥＵ輸出用の施設における、生前検査に関する資料とＥＵの生前検査要領

(参考資料)
１．日本と米国のサーベイランスの対比
２．カナダにおけるＢＳＥ感染牛の診断、サーベイランスの年齢分布等

１．米国における２頭目のＢＳＥ感染牛

＜委員限り＞

（１）昨年１１月に実施した１次検査のＥＬＩＳＡの値（１回目、２回目）

（２）昨年１１月、１次検査陽性と確認した以降に実施した検査（研究目的で実施し陽性であったものも含む）の内容及びその結果

（３）６月の再検査時にＵＳＤＡで実施した検査について、検査法のプロトコール、使用抗体の種類、各検査法の結果（画像等）

（４）英国で実施した検査法について、検査法のプロトコール、使用抗体の種類、各検査法の結果（画像等）

（５）ＵＳＤＡが通常実施しているＩＨＣ及びＷＢのプロトコール、ＯＩＥの手法と異なる部分、使用抗体の種類等

（６）出生後の代用乳及び配合飼料の使用状況

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Ministry of Agriculture, Forestry
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JAPAN

Dear Dr. Kugita:

This letter is to inform you of developments concerning an animal diagnosed with bovine spongiform encephalopathy (BSE) in the State of Texas, United States, including progress of the epidemiological investigation and continued efforts by the U.S. Department of Agriculture (USDA) to safeguard animal and human health.

As background information, on November 15, 2004, an approximately 12-year-old nonambulatory cow was sent to a pet food plant for processing in the State of Texas. The animal's health was attributed to a history of a poor body condition. However, because she was presented dead at the pet food plant, samples were taken for routine testing as part of USDA's targeted enhanced BSE surveillance program. This animal was also prevented from entering both the human food supply and animal feed chain through surveillance safeguards already in place. The USDA's Animal and Plant Health Inspection Service and the Texas Animal Health Commission initiated an immediate and comprehensive epidemiological investigation of the case.

When the sample from the Texas animal was initially tested on November 15, 2004, the results from a BSE ELISA rapid test were inconclusive. The sample was then sent to USDA's National Veterinary Services Laboratories (NVSL), the U.S. domestic and foreign animal disease laboratory, for further testing. Two immunohistochemistry (IHC) tests were conducted and on November 23, 2004, both tests were negative for BSE. Upon further testing using the SAF Immunoblot, a reactive result was announced on June 10, 2005. Furthermore, additional testing by the BSE world reference laboratory in the United Kingdom, and by the NVSL, confirmed on June 24, 2005, that the animal was BSE-positive but that the level of infectivity was low.

Unusual and conflicting test results such as these have led to speculation about atypical cases and how they may react to the standard tests used to determine BSE. On June 24, 2005, USDA announced that we are reviewing our BSE testing protocol to help account for future samples that generate unusual test results. USDA is also considering additional BSE testing to learn more about this disease and to explore possible ways to improve the diagnostic process.

The source herd is now under a hold order as we identify animals of interest within the herd. Consistent with OIE (the World Organization for Animal Health) guidelines,

animal, as well as any born the year before and the year after. The United States and several other countries have advocated for guidelines that reflect science, the low risk associated with BSE, and the effectiveness of risk mitigation measures. The OIE has developed guidelines that incorporate all such factors. The international standard for BSE is now based on the same information that has guided the United States current practices and the epidemiologic procedures being implemented now in this case.

Our epidemiological investigation confirms that this infected animal, the second case to be identified in the United States, was indigenous to our country and that the U.S. surveillance system for BSE is sufficient to detect the disease should it occur. Moreover, we have taken additional steps to further safeguard U.S. animals and products moving in international trade. These steps include removing specified risk material; requiring additional process controls for advanced meat recovery; holding meat from cattle that have been tested for BSE until the test has been confirmed negative; and prohibiting the air injection stunning of cattle. We would also like to note that this second positive animal is not connected to the BSE positive animal found in Washington State. This fact supports our position that the mitigation measures currently in place in the United States ensure that the risk of BSE spreading to other ruminants is virtually nonexistent.

USDA is continuing with its intensive BSE surveillance effort. The program is intended to provide data in order to estimate the prevalence of BSE in the domestic cattle population. Since June 1, 2004, more than 400,600 cattle have been tested with no additional BSE-positive results. These efforts are above the requirements specified in the OIE guidelines. These results indicate that the U.S. surveillance program for BSE is effective in detecting the disease and that follow-up epidemiological investigation of suspect cases is also effective.

The United States is closely following the OIE guidelines which reflect the current science and recognize the low risk associated with BSE when effective risk mitigation measures are followed. Guideline updates include the adoption of a streamlined, 3-level country classification system and the acceptance of a revised "non-risk" product list. The OIE has now officially recognized additions to the list of non-risk products, most significantly to include boneless beef that can be traded without regard to a country's BSE status. The OIE has also adopted a new, streamlined system for classifying countries according to relative risk for BSE in a manner that reflects the steps they have implemented to manage and reduce that risk.

The United States is evaluating its status relative to the new BSE requirements presented in the OIE Animal Health Code. This process requires that the United States submit reports to support it being classified in one of the new categories established by the OIE Animal Health Code. The United States is preparing these documents and will submit them according to the requirements spelled out in the Code.

We have enclosed the following for your information: (1) a summary description of the U.S. feed ban and import restrictions; (2) information regarding the surveillance measures in place prior to the new enhanced surveillance; (3) results of the epidemiological investigation, and disposition of the animals of interest within the herd

of origin; (4) information on actions taken by USDA to further reduce risk associated with BSE entering the food and feed supplies; and (5) a copy of our BSE emergency response plan by which the investigation into the recent case is being conducted.

The recent detection and control of this BSE case demonstrates the robust surveillance and other measures in place in the United States to safeguard animal and public health against BSE risk. We hope that you take this into account in future policy decisions regarding trade in ruminants and ruminant products with the United States. USDA will forward you additional information as it becomes available.

Sincerely,

John R. Clifford
Chief Veterinary Officer
Animal and Plant Health Inspection Service
United States Department of Agriculture

5 Enclosures

Enclosure 1

(1) The feed ban and import restrictions

Since the U.S. Department of Agriculture (USDA) has had a feed ban in place since 1997, BSE would be unlikely to spread in the United States. The ban, which prohibits the use of most mammalian protein in feeds for ruminant animals, became effective on August 4, 1997. The rule was implemented by the Food and Drug Administration's (FDA) Center for Veterinary Medicine and appears in Title 21, *Code of Federal Regulations*, part 589.2000.

FDA's enforcement plan for the ruminant feed regulation includes inspections and a targeted educational effort, with FDA taking regulatory action in response to intentional or repeated noncompliance. As part of the enforcement plan, an initial inspection assignment was issued to all FDA District Offices in 1998 to conduct inspections of 100 percent of all renderers and known feed mills to determine compliance. Additional assignments have been issued to FDA District Offices regarding (1) further initial inspections of previously unknown firms potentially handling materials prohibited in ruminant feed and (2) re-inspections of firms found on initial inspection to be out of compliance with this regulation.

Effects of the USDA feed ban were evaluated in a risk assessment conducted by the Harvard University Center for Risk Analysis[1]. This study concluded that the feed ban instituted by the FDA in 1997 was the most effective measure taken by the United States to prevent BSE spread. The study further suggested that the measures taken by the U.S. Government and industry make the United States robust against the spread of BSE among animals, should the disease be introduced into the country. These measures, which include ensuring compliance with the feed ban and reducing the potential for infectious tissues to enter the animal food supply, will ensure that this risk remains low.

USDA has banned imports of live ruminants and most ruminant products from the United Kingdom and other countries having BSE since 1989.

(2) Surveillance measures in place prior to detection of the infected animal that resulted in diagnosis

USDA has had an active surveillance program for BSE in place since May 1990; details are available on the APHIS Web site at www.aphis.usda.gov/lpa/issues/bse/bse-surveillance.html. An updated version is also provided as Enclosure 2.

In summary, since 1993, surveillance samples have included field cases of cattle exhibiting signs of neurologic disease, cattle condemned at slaughter for neurologic reasons, rabies-negative cattle submitted to public health laboratories, neurologic cases submitted to veterinary diagnostic laboratories and teaching hospitals, cattle that are

[1] *Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States,* November 26, 2001, available at http://www.aphis.usda.gov/lpa/issues/bse/bse-riskassmt.html.

nonambulatory, and adult cattle dying on farms. Under this program, the Animal and Plant Health Inspection Service (APHIS) tested more than 20,000 targeted, high-risk adult cattle for BSE in each of the last 2 years. This represents 47 times the number recommended by the Office International des Epizooties in Appendix 3.8.4 of the Terrestrial Animal Health Code. Approximately three-quarters of the samples originated from animals that were nonambulatory at the time of slaughter, whereas 893 samples came from animals that demonstrated neurological signs and the remainder from dead stock. Nonambulatory animals are those that cannot rise from a recumbent position or that cannot walk, including but not limited to those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral columns, or metabolic conditions.

APHIS' preparedness was evident in the fact that a BSE response plan was already in place at the time of the diagnosis and was implemented immediately upon detection of the infected cow. A summary of the response plan is provided as Enclosure 3. In accordance with the principles of this plan, APHIS is working closely with other U.S. Government agencies that regulate various aspects of human and animal health. These agencies include (a) the Center for Veterinary Medicine of the FDA, which is the agency responsible for the 1997 feed ban; (b) the Food Safety and Inspection Service (FSIS) of the USDA, which is the agency responsible for human food safety issues; (c) the Centers for Disease Control and Prevention of the Department of Health and Human Services, which is the agency responsible for human disease investigations; and (d) the Department of Homeland Security, which is the agency responsible for national security against bioterrorism.

APHIS and FSIS continue to work closely with colleagues in State and other Federal agencies as part of the epidemiological investigation. The most up-to-date information can be accessed on the USDA Web site at www.usda.gov or on the APHIS Web site at www.aphis.usda.gov/lpa/issues/bse/bse.html.

APHIS has been actively transparent during the epidemiological investigation, providing up-to-date information to stakeholders on a daily basis. Specifically, APHIS has been in close and regular contact with both Federal and State veterinary officials in the field, and emphasized outreach to the public and the media. Contact was established and has been maintained through frequent nationwide teleconferences and media briefings. The effectiveness of this communication strategy has been demonstrated by the fact that the vast majority of the media reports have contained accurate and factual information regarding the situation.

(3) Chronology of events around detection of the infected animal, results of the epidemiological investigation, and disposition of potentially infected materials

On December 23, 2003, USDA Secretary Ann M. Veneman announced that the United States had a presumptive positive case of BSE in an adult Holstein cow in Washington State. On December 25, 2003, USDA received verification of the findings from the Veterinary Laboratories Agency in Weybridge, England.

The index case was located on a large dairy operation consisting of two premises, one in Mabton, Washington, and one in Grandview, Washington. There are approximately 4,000 adult animals on these two premises.

The index cow was purchased into this herd in October 2001 and was culled in December 2003 due to paralysis resulting from calving complications. It was subsequently confirmed that the cow was born in April 1997 and lived in Alberta, Canada, until she was shipped to the United States on September 4, 2001. The index cow and 80 other animals entered through the port in Oroville, Washington. The animals were identified from a Canadian health certificate dated August 28, 2001. In fact, the certificate listed 82 ear tag numbers from cattle that originated from a single herd that was being sold out. However, it appears that only 81 animals actually entered the United States; one apparently remained in Canada.

Nine of the 81 animals, plus the index cow, remained in the index herd. Three animals have been located at a dairy operation in Mattawa, Washington, which is currently under quarantine. As of January 12, 2004, APHIS is pursuing epidemiological leads on the whereabouts of the remaining 68 animals and is working to confirm this information before making a definitive statement on their disposition.

The infected animal was slaughtered on December 9, 2003, in a facility located in Moses Lake, Washington. Although investigations showed that high-risk materials from the animal did not enter the human food chain, FSIS initiated a recall of approximately 10,410 pounds of raw beef from 20 carcasses that were slaughtered on the same day as the index case. USDA will continue to verify distribution and control of all products related to this recall.

APHIS is working with the Canadian Food Inspection Agency (CFIA) to verify traceback of the index animal. Records obtained from the owner correspond with Canada's records indicating that this animal was approximately 6½ years old at the time of slaughter. The herd of origin in Alberta, Canada, has been confirmed through comparative DNA testing of brain tissue from the infected cow and semen from her sire. Animal health laboratories in the United States and Canada independently confirmed the test results.

Of note is the fact that the infected animal was born prior to the implementation of the ruminant-to-ruminant feed ban in both Canada and the United States. Since she resided only in Canada prior to the bans, it is highly likely that that is where she ingested contaminated feed. The former owner of the Canadian source herd confirms that he was feeding meat and bone meal (MBM) during this period.

The index cow delivered two live calves while she was in the United States. Farm records indicate that one calf, a heifer, remains in the index herd in the State of Washington. DNA testing has confirmed that this heifer was born to the infected cow. The index herd has been quarantined to prevent further complications to traceback and traceforward investigations, and USDA is developing plans for the appropriate disposition of animals in this herd.

The other live calf from the index cow, her most recently born bull calf, was commingled in a herd of 449 young bull calves. Since this bull calf could not be definitively identified, all 449 calves have been depopulated. This action was taken out of an abundance of caution and to preserve public and international confidence in the health of the U.S. cattle herd.

While USDA has not yet decided on the disposition of cattle in the index herd, any animals that die on the farm will be tested for BSE. Federal and State officials are developing a comprehensive written plan for the euthanasia and disposal of potentially BSE-exposed cattle on affected premises.

(4) New initiatives that USDA is taking to enhance the level of animal and human food safety

On December 30, 2003, Secretary Veneman held a press conference to announce several significant steps to enhance public health protection measures and strengthen the U.S. BSE surveillance program. These measures will provide additional safeguards to the rigorous measures already in place for products consumed in the United States as well as those offered in international trade. The following actions were announced:

Nonambulatory cattle. Effective on the day of the announcement (December 30, 2003), USDA banned all nonambulatory cattle from entering the human food chain. USDA will continue its aggressive surveillance program. Since the animals can be rendered, USDA will be working closely with the rendering industry as well as other components of the animal disposal industry to ensure continued surveillance of these animals. USDA will also increase efforts to obtain more samples from this high-risk group on the farm.

Product holding. USDA, FSIS, inspectors will no longer mark cattle tested for BSE as "inspected and passed" until confirmation is received that the animals have, in fact, tested negative for BSE. This new policy was published as an interpretive rule in the *Federal Register,* the official publication of U.S. Government regulations, on January 12, 2004.

Specified risk material (SRM). Effective immediately upon publication in the *Federal Register* on January 12, 2004, USDA strengthened the safeguards in its regulations by declaring as SRM the skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord and dorsal root ganglia of cattle over 30 months of age, as well as the small intestine of cattle of all ages. This regulation prohibits their use in the human food supply. Tonsils from all cattle are already considered inedible and therefore do not enter the food supply. These enhancements are consistent with the actions taken by Canada after the discovery of a single BSE case in Canada in May 2003.

In this interim final rule, FSIS requires federally inspected establishments that slaughter cattle to develop, implement, and maintain procedures to remove, segregate, and dispose of these specified risk materials so that they cannot enter the food chain. Slaughter plants must also make that information readily available for review by FSIS inspection personnel. FSIS has also developed procedures for verifying the approximate age of

cattle that are slaughtered in official establishments. State inspected plants must have equivalent procedures in place.

Advanced Meat Recovery (AMR). FSIS has taken similar actions that will effectively prohibit use of AMR in meat production from cattle that are 30 months of age or older. AMR is an industrial technology that removes muscle tissues from the bone of beef carcasses under high pressure without incorporating bone material when operated properly. AMR enables processors to remove small amounts of meat from carcasses without breaking bones, but concerns have been raised regarding potential contamination of the meat with central nervous system tissue.

FSIS previously had regulations in place that prohibit spinal cord from being included in boneless meat. The new regulation, effective upon publication in the *Federal Register* on January 12, 2004, expands that prohibition to include dorsal root ganglia (clusters of nerve tissue connected to the spinal cord along the vertebral column), which could potentially be incorporated into boneless meat products through AMR. In addition, because the vertebral column and skull in cattle 30 months of age and older will be considered inedible, they cannot be used for AMR.

In March 2003, FSIS began a routine regulatory sampling program for beef produced from AMR systems to ensure that spinal cord tissue is not present in the product. In the new interim rule, establishments will have to ensure process control through verification testing to ensure that neither spinal cord nor dorsal root ganglia is present in the product.

Mechanically separated meat. USDA will prohibit use of mechanically separated meat in human food processing.

Air-injection stunning. Air-injection stunning is a process to humanely stun cattle during the slaughter process. However, with this method, it is possible for brain material to become dislocated and move through the blood stream into the tissues of the carcass. To protect against this happening, FSIS has issued a regulation to ban the practice of air-injection stunning, a practice that had already been implemented voluntarily by industry.

Animal identification. USDA has assigned top priority to implementation of a verifiable, electronic system of national animal identification. Development of this system has been underway for more than a year and a half.

Expert panel. Through the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases, an international panel of scientific experts has been named to provide an objective review of the U.S. BSE response actions and identify areas of potential enhancement. The team will function in the same manner as the panel that lent expertise to Canada after the May 20, 2003, discovery of a BSE infected cow born in Saskatchewan. Members of the panel include Dr. Ulrich Kihm, the former Chief Veterinary Officer of Switzerland; Dr. William Hueston, Director of the Center for Animal Health and Food Safety, University of Minnesota; Dr. Dagmar Heim, Chief of BSE control program in the Swiss Federal Veterinary Office; and Dr. Stuart MacDiarmid, a BSE expert with the Government of New Zealand.

Enclosure 2

1. History of BSE surveillance in the United States

Active surveillance for BSE has been conducted in the United States since 1990. Initially, surveillance was conducted by testing brain samples obtained from animals reported as exhibiting either central nervous system signs or classic clinical signs of BSE. In 1993, the surveillance was expanded to include samples obtained from non-ambulatory animals. This approach, criticized internationally as excessive at that time, was implemented to address concerns that an unrecognized TSE of cattle might exist in the US cattle population. In 2001, in response to the findings in the initial Harvard risk assessment, the surveillance program was again expanded to include additional samples obtained from animals that had died for unexplained reasons.

Total BSE tests conducted, fiscal year basis

Fiscal year	Total tests
FY 1990	40
FY 1991	175
FY 1992	251
FY 1993	736
FY 1994	692
FY 1995	744
FY 1996	1143
FY 1997	2,713
FY 1998	1,080
FY 1999	1,302
FY 2000	2,681
FY 2001	5,272
FY 2002	19,990
FY 2003	20,543
FY 2004 ** Partial year, through May 2004	17,121

In 2001, a goal was established to detect one BSE-infected animal in a population of a million adult cattle. Given that the US has an adult cattle population of approximately 45 million, if BSE were present in this cattle population at the one in a million level, we could assume that we would have 45 infected animals. To achieve a 95 percent confidence level in detecting at least one case from a random sample of adult cattle brains, we would have to randomly sample and test approximately 3 million animals from the population of 45 million.

However, based on the assumption of negligible detectable presence of BSE in the normally appearing adult cattle population, USDA has focused on a subset of the cattle

population more likely to have BSE if it exists in the United States – adult cattle exhibiting some type of clinical sign that could be considered consistent with BSE. This allows us to conduct more efficient, targeted, and effective surveillance. At that time, non-ambulatory cattle were defined as the primary targeted high-risk population. This definition was based on the surveillance experience of European countries that have BSE. Their experience and testing schemes have proven non-ambulatory cattle to be an appropriate and efficient population for active targeted surveillance. For example, in Switzerland, testing of fallen stock (dead cattle) and emergency slaughter cattle (cattle killed for reasons other than routine slaughter) revealed a BSE prevalence of 0.2 percent in 1999 and 0.12 percent in 2000. In comparison, Switzerland's BSE prevalence in routine healthy slaughter populations was 0.004 percent in 1999 and 0 percent in 2000.

BSE surveillance in France during 2001 identified 91 cases (19.4 percent of those tested) from cattle exhibiting central nervous system clinical signs, and 100 BSE cases (0.07 percent of those tested) from the 133,889 nonambulatory cattle tested. French testing of apparently healthy slaughter cattle found 83 BSE cases (0.003 percent of those tested) from the 2,382,225 tested. These data indicate the presence of infected cattle can be determined more efficiently by testing the population most likely to exhibit the disease, thereby supporting the decision to conduct a program of targeted surveillance rather than one of simple random sampling.

The following chart illustrates the categories of animals tested for BSE:

	Highly suspicious and/or CNS	Non-ambulatory	Deadstock	TOTAL
FY 1994	493	199		692
FY 1995	521	223		744
FY 1996	877	266		1,143
FY 1997	2,494	219		2,713
FY 1998	736	344		1,080
FY 1999	651	651		1,302
FY 2000	786	1,895		2,681
FY 2001	808	4,464		5,272
FY 2002	2,280	14,951	2,759	19,990
FY 2003	893	16,560	3,090	20,543
FY 2004 (thru May 2004)	1,398	9,392	6,331	17,121

Sampling at these levels will not prove that BSE does not occur at a lower prevalence level, but it should allow detection of a case if BSE truly exists at a level of one or more cases per million in the adult cattle population given the underlying assumptions including:

1. the majority of cases of detectable BSE would occur in the targeted population
2. the samples collected are broadly representative of the targeted population

3. the testing system, as implemented, has a high sensitivity and specificity.

2. Enhanced BSE surveillance plan in the United States

On June 1, 2004, USDA launched an intensive surveillance program for BSE, with the goal of testing as many cattle as possible in the targeted population for BSE. This program is built on previous surveillance efforts, and is planned to be a one-time effort that will provide a snapshot of the BSE status of the domestic cattle population in the US.

The intent of this intensive surveillance effort is to provide sufficient data and information to assist in a determination of whether risk management policies – for both animal health and public health – are adequate or whether they need to be changed. The data obtained in this effort will be used to help determine parameters around the probable prevalence level of BSE in the U.S. A specific, exact calculation of true prevalence of BSE is not necessary to enable us to make the determination of whether risk management policies need to be changed. These decisions can be made, for example, with information that simply estimates the upper bounds of a prevalence level.

Experience in Europe, as described previously, has demonstrated that targeting surveillance efforts at certain populations is the most effective way to identify BSE if it is present. One way to explain this approach is that we are biasing our sampling towards the population where we are most likely to find the disease, thus helping to ensure that if disease is present at a certain level it will be detected. This approach is not necessarily limited to BSE – similar concepts are used in many disease control programs such as the brucellosis eradication program. In the case of BSE, the population in which we are most likely to find disease are adult animals that demonstrate some clinical abnormality that could be consistent with BSE, and therefore this is the population we continue to target in our surveillance.

Targeting the population where disease is most likely to be diagnosed if it is present is the most efficient and cost-effective way to approach surveillance. This approach requires fewer samples to reach similar conclusions, because it is based on the assumption that if you cannot find disease in the targeted, or most likely, population (i.e., animals with some type of clinical signs), it will be even more unlikely to be found in the non-targeted population (i.e., clinically normal animals). This approach has been evaluated and supported by both the Harvard Risk Analysis and the International Review Team commissioned by USDA to evaluate BSE actions, and is consistent with OIE guidelines.

In order to develop the sample design in the surveillance plan, certain assumptions or estimations were necessary. One of these assumptions is that BSE is more likely to be found in the targeted population. Data from testing within the European Union in 2002 supports this assumption, with a conclusion that it is 29.4 times more likely to diagnose disease in the targeted population than in the clinically normal population.

Our surveillance plan is designed – and this has been confirmed by Harvard University's Center for Risk Analysis – to detect the presence of BSE with 99 percent certainty if as few as five targeted high-risk cattle had BSE.

The following chart illustrates the data for the enhanced BSE surveillance program from June 2004 - March 2005:

Submission category	Number of samples
Highly suspicious and/or CNS	451
Non-ambulatory	25,812
Deadstock	249,857
Other clinical signs	6,093
TOTAL	282,213

The data for the month of April is currently being validated to ensure that submission categories and other information is correct.

Enclosure 3

BSE Epidemiological Process

The main objective of a bovine spongiform encephalopathy (BSE) epidemiological investigation is to identify and locate "at-risk" cattle.

Definition of at-risk cattle:
The World Organization for Animal Health (OIE) gives the following definitions for cattle at-risk for BSE.

- For a female BSE positive animal, all progeny born within 2 years prior to, and after, clinical onset of the disease (or 2 years prior to a positive test, if no clinical signs were recognized).
- In addition, all cattle which, during their first year of life, were reared with the positive animal during the positive animal's first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period.
- Where the results of an investigation are inconclusive as to which animals were exposed to contaminated feed, all cattle born in the same herd as, and within 12 months of the birth of, the positive animal (i.e., the birth cohort).

Definition of Birth cohort:
In most cases, it will not be practical or possible to definitively determine which cattle were exposed to a contaminated feed source. Given that, a birth cohort is used to determine which cattle to consider at-risk. The birth cohort includes all cattle born on the positive animal's birth premises within 1 year, before or after, the date of birth of the BSE-positive animal. (Note: If the precise date of birth [age] of the animal is unclear, a potential age range would need to be used, with 1 year added to each end of that range.) In most cases, some of the birth cohort animals will have moved off the birth premises, and some of those may now be located on other premises; others will have gone to slaughter or died on other premises. 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 would also be considered to be at-risk.

In the current case it is not possible to definitively determine which cattle were potentially exposed to the same feed source as the positive animal. Therefore, a birth cohort is being used to define which cattle we consider to be at-risk. Investigators are using an age range of 11 to 13 years as the age of the index case and as the basis for calculating the cohort birth range of 10 to 14 years of age.

Cattle of interest (sometimes called "animals of interest"):
In many cases at-risk cattle cannot be definitively identified. A herd inventory and analysis of herd records is then used to identify a group of cattle that include all potential at-risk cattle and any other cattle that cannot be distinguished from at-risk cattle. All of

these cattle – at-risk cattle and any additional cattle as necessary – will be defined as cattle of interest (COI).

All COI must be further evaluated using all suitable identification techniques. The goal is to use what is known about the at-risk cattle to include as many of them as possible in the COI group, yet eliminate from the group all cattle that are not at-risk. Depending on the specific circumstances involved, several factors could be useful in determining the COI. These include age, gender, breed, color, man-made identification (eartags, tattoos, brands), and known premises of birth. Obvious factors such as age, gender, and breed, will be used to the extent possible to limit the size of the group being evaluated. More specific information from herd management records and any other available records will then be compared against man-made identification of the remaining potential COI. Ultimately, COI that cannot be eliminated based on any of these kinds of factors will be included in the group of cattle that will be depopulated and tested for BSE.

Epidemiology Report of the Herd of Origin of the Index Cow:

DNA analysis of blood samples from the herd of origin (located in Texas) for #15-4 confirmed that to be the herd of origin for the index cow. Animals still in the herd of origin which fall into the birth cohort age range of the index cow will be identified and sorted out for removal from the herd.

The index cow's herd of origin was placed under Hold Order on June 20, 2005.

Detailed Information on the Epidemiological Investigation

Farm of Origin for Index Cow: Farm A

Background:

This cow was an approximately 12-year-old yellow or cream-colored Brahma cross which 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 along with 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.

DNA analysis of blood samples taken from five of the seven units of cattle which comprise Farm A yielded 5 animals from two different units which were considered to be genetically related to the index cow and confirmed Farm A as the herd of origin.

The owner of Farm A raised this cow from birth and states that she had never been off the premises prior to being sold. She was marketed because of her poor body condition which had not improved despite the owner weaning her large 2003 calf early. The owner stated that the cow had always been an excitable animal 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.

Current Herd Information:

Farm A consists of 7 units containing a total of about 233 head of adult cattle and approximately 100 to 120 calves. On 6/22/05, the first three of the six units were sampled for DNA testing to confirm the herd of origin of the index cow. Those first three units consisted of the following: 62 head in one unit which contained older cattle (more likely than the other units to provide a match), 28 head in the 3-year-old unit, and 25 head in the 2-year-old unit. Two more units were sampled for DNA on 6/23/05 and consisted of 31 cattle in one unit and 30 cattle in the other, both of which contained some older animals. The sixth unit contains 41 head, was purchased in 1993 from another source, and does not contain animals that are genetically related to the other 5 units, so this unit was not sampled for DNA testing. The seventh unit consists of 16 adult cows and is owned by one of the sons of the owner. The sixth and seventh units may, however, contain cattle of interest because the weaned heifers from these units were commingled and fed with weaned heifers from the other units for a short period of time before they were returned to their units of origin. This practice of weaning and feeding together fits the definition of a feed cohort.

Progeny:

Although he does keep some replacement heifers, the owner was relatively sure that he had not kept any offspring from the yellow cow because of her excitable demeanor. While the owner sold 12 calves at the sale with the yellow cow on 11/11/04, he believes that her last calf was not in that group, but rather that he sold that calf in either March or April after early weaning through the livestock sale. This cow's last calf, weaned early and sold in the spring of 2004, would have been born in the fall of 2003. The calf prior to that would have been born in the fall of 2002 and also sold at the livestock sale. Both calves will be traced using records from the sale barn. Preliminary information indicates it is likely that both calves were purchased at the sale for the purpose of being fed for slaughter.

Birth Cohort:

We have a list pulled from the Generic Data Base (GDB) of calf hood brucellosis vaccination tag numbers out of this herd from 1991 to 1994. Those calves vaccinated during that time period would be part of this cow's birth cohort and tracing activities will center on finding those animals. There are 109 calves which were vaccinated from 1991 to 1994 and are being considered part of the birth cohort. In addition, some of those vaccinates in the birth cohort may still be in the herd and will be removed when the cattle currently on the premises are sorted by age.

Regarding trace-outs, we have found that cattle from Farm A were sold through only two sale barns. There are currently 18 of the 109 calf hood vaccination tag numbers which

we know went through those two sale barns and will be traced further using sale barn records and slaughter 4-54's. We also have a list of eartag numbers recorded when Farm A had complete herd tests done for brucellosis in 1991, 1993, and 1994. We can use that data to determine which animals were in the herd during that time period and more tag numbers which could potentially be traced out of the herd and either ruled in or out as cattle of interest.

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) is currently investigating all sources of feed and supplements used on Farm A.

Enclosure 4

USDA NEWS RELEASE

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VENEMAN ANNOUNCES ADDITIONAL PROTECTION MEASURES TO GUARD AGAINST BSE

WASHINGTON, Dec. 30, 2003—Agriculture Secretary Ann M. Veneman today announced additional safeguards to bolster the U.S. protection systems against Bovine Spongiform Encephalopathy, or BSE, and further protect public health.

"For more than a decade, the United States has had in place an aggressive surveillance, detection and response program for BSE," said Veneman. "While we are confident that the United States has safeguards and firewalls needed to protect public health, these additional actions will further strengthen our protection systems."

Veneman said the policies announced today have been under consideration for many months, especially since the finding of a case of BSE in Canada in May 2003. The policies will further strengthen protections against BSE by removing certain animals and specified risk material and tissues from the human food chain; requiring additional process controls for establishments using advanced meat recovery (AMR); holding meat from cattle that have been tested for BSE until the test has confirmed negative; and prohibiting the air-injection stunning of cattle.

While many cattle in the United States can be identified through a variety of systems, the Secretary also announced that USDA will begin immediate implementation of a verifiable system of national animal identification. The development of such a system has been underway for more than a year and a half to achieve uniformity, consistency and efficiency across this national system.

"USDA has worked with partners at the federal and state levels and in industry for the past year and a half on the adoption of standards for a verifiable nationwide animal identification system to help enhance the speed and accuracy of our response to disease outbreaks across many different animal species," Veneman said. "I have asked USDA's Chief Information Officer to expedite the development of the technology architecture to implement this system a top priority.

"These are initial steps that USDA will take to enhance our protection system," Veneman said. "I am appointing an international panel of scientific experts to provide an objective review of our response actions and identify areas for potential additional enhancements."

Specifically, USDA will take the following actions:

Downer Animals. Effectively immediately, USDA will ban all downer cattle from the human food chain. USDA will continue its BSE surveillance program.

Product Holding. USDA Food Safety and Inspection Service inspectors will no longer mark cattle tested for BSE as "inspected and passed" until confirmation is received that the animals have, in fact, tested negative for BSE. This new policy will be in the form of an interpretive rule that will be published in the *Federal Register*.

To prevent the entry into commerce of meat and meat food products that are adulterated, FSIS inspection program personnel perform ante- and post-mortem inspection of cattle that are slaughtered in the United States. As part of the ante-mortem inspection, FSIS personnel look for signs of disease, including signs of central nervous system impairment. Animals showing signs of systemic disease, including those exhibiting signs of neurologic impairment, are condemned. Meat from all condemned animals has never been permitted for use as human food.

Specified Risk Material. Effective immediately upon publication in the *Federal Register*, USDA will enhance its regulations by declaring as specified risk materials skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord and dorsal root ganglia of cattle over 30 months of age and the small intestine of cattle of all ages, thus prohibiting their use in the human food supply. Tonsils from all cattle are already considered inedible and therefore do not enter the food supply. These enhancements are consistent with the actions taken by Canada after the discovery of BSE in May.

In an interim final rule, FSIS will require federally inspected establishments that slaughter cattle to develop, implement, and maintain procedures to remove, segregate, and dispose of these specified risk materials so that they cannot possibly enter the food chain. Plants must also make that information readily available for review by FSIS inspection personnel. FSIS has also developed procedures for verifying the approximate age of cattle that are slaughtered in official establishments. State inspected plants must have equivalent procedures in place.

Advanced Meat Recovery. AMR is an industrial technology that removes muscle tissue from the bone of beef carcasses under high pressure without incorporating bone material when operated properly. AMR product can be labeled as "meat." FSIS has previously had regulations in place that prohibit spinal cord from being included in products labeled as "meat." The regulation, effective upon publication in the *Federal Register*, expands that prohibition to include dorsal root ganglia, clusters of nerve cells connected to the spinal cord along the vertebrae column, in addition to spinal cord tissue. Like spinal cord, the dorsal root ganglia may also contain BSE infectivity if the animal is infected. In addition, because the vertebral column and skull in cattle 30 months and older will be considered inedible, it cannot be used for AMR.

In March 2003, FSIS began a routine regulatory sampling program for beef produced from AMR systems to ensure that spinal cord tissue is not present in this product. In a new interim final rule announced today, establishments have to ensure process control through verification testing to ensure that neither spinal cord nor dorsal root ganglia is present in the product.

Air-Injection Stunning. To ensure that portions of the brain are not dislocated into the tissues of the carcass as a consequence of humanely stunning cattle during the slaughter process, FSIS is issuing a regulation to ban the practice of air-injection stunning.

Mechanically Separated Meat. USDA will prohibit use of mechanically separated meat in human food.

On Dec. 23, Veneman reported that a cow in Washington State has tested positive for BSE. A swift and comprehensive investigation is ongoing to trace the animal to a herd of origin, which is believed to be located in Alberta, Canada, as well as track additional animals that have entered the United States. (For the latest update on the investigation, visit **www.usda.gov**.)

For more than a decade, the United States has had in place an aggressive surveillance, detection and response program for BSE. The United States has tested over 20,000 head of cattle for BSE in each of the past two years, 47 times the recommended international standard.

Since 1989, USDA has banned imports of live ruminants and most ruminant products from the United Kingdom and other countries having BSE.

In 1997, the FDA prohibited the use of most mammalian protein, the main pathway to spread the disease should it be in the United States, in the manufacture of animal feed intended for cattle and other ruminants.

An independent analysis by Harvard in 2001 and again in 2003 shows that the risk of BSE spreading in the United States is low and any possible spread would have been reversed by the controls we have already put in place.

For more information please visit **www.usda.gov**.

Enclosure 5

BSE Response Plan, September 2004

This plan specifies response actions to be taken during the enhanced bovine spongiform encephalopathy (BSE) surveillance effort. As described in this plan, response actions will begin upon receipt of an inconclusive test result from a designated State laboratory. The initial steps taken will be limited. A full response will be initiated only upon receipt of a confirmed positive diagnosis for BSE from the National Veterinary Services Laboratories (NVSL). Potential BSE cases which are reported as foreign animal disease (FAD) investigations during the enhanced BSE surveillance effort will be addressed per current FAD procedures as detailed in Veterinary Services (VS) Memorandum 580.4. Should a positive diagnosis be confirmed as a result of a FAD investigation, response actions detailed in this plan under 1.2 will be initiated. The actual circumstances surrounding a positive BSE case may cause response actions specified in this plan to be modified.

This plan also specifies the organizational structure which will be utilized to respond once a positive BSE case is confirmed. This organizational structure is based on the Incident Command System (ICS). Roles, responsibilities, and reporting lines are detailed under 2.3 of this plan.

IMPORTANT: Notification and communication requirements associated with the enhanced BSE surveillance effort are contained in a separate BSE communication plan. These requirements must be followed.

1.0 Response Actions

Most samples collected during the enhanced BSE surveillance program are initially screened using a rapid test at a designated laboratory. The rapid screening test will be run initially on one well; if this well is reactive, the same homogenate is run again in duplicate wells. If either of the duplicate wells is reactive, the test will be deemed inconclusive and confirmatory testing will be performed at NVSL. Response actions will commence once an inconclusive test result is obtained from a designated laboratory on the initial test and actions will progress to a full scale response if a positive diagnosis is confirmed. Response actions are outlined below.

1.1 Inconclusive Test Result on Rapid Screening Test Performed at a Designated State Laboratory

Field staff should:

- Secure the identification materials and paperwork associated with the animal;
- Determine the site/disposition of the carcass;

- If the carcass is located at a concentration point such as a renderer or salvage (3D/4D) slaughter plant, verify the identity of the carcass. Field staff can also offer to purchase, remove, and dispose of the carcass (following cost recovery guidance provided for the enhanced surveillance effort). If the plant/facility owner does not want to sell or allow removal of the carcass, the owner should be encouraged to hold the carcass until final test results are obtained. Prior to disposing of the carcass, appropriate samples should be taken to allow DNA testing. (Appropriate samples include cerebellum, cerebrum, or spinal cord. Samples should be preserved on ice packs. If brain tissue is not available, collect a sample of muscle. If the head is not attached, take samples from both the head and the carcass). If the carcass is disposed of prior to receiving a negative immunohistochemistry (IHC) test result from NVSL, it should be disposed of by incineration or alkaline digestion.
- Determine last known premises of residence;
- Initiate a FAD investigation using current procedures (VS Memorandum 580.4). Field staff should be prepared to provide headquarters (prior to the confirmatory test results being available) with as much information as available on the signalment of the animal (age, breed, sex, pedigree, and use), clinical signs, birth premises and movement history, reproductive history, feeding history, characteristics of the last known premises of residence, and of any other premises where the animal is known to have resided. Investigation information should also be entered into the Emergency Management Response System (EMRS). A decision on whether to issue a hold order or quarantine to prevent movement of animals off the last known premises of residence will be made by the Area Veterinarian in Charge (AVIC) and State Veterinarian.

Headquarters staff should:

- Begin preparing information to be utilized in technical briefings should a positive result be found on the IHC test at NVSL;
- Utilize the EMRS to obtain some of the information needed for these briefings;
- If necessary, hold conference calls with field staff to obtain the needed information.

Note: NVSL is the designated laboratory for samples submitted from a number of States. If an inconclusive result is obtained at NVSL on the initial rapid screening test for samples submitted from these States, field staff should complete the actions listed above under 1.1.

1.2. Confirmed Positive Diagnosis from NVSL

Upon receipt of a confirmed positive diagnosis of BSE by NVSL, a full BSE response will be initiated. Actions associated with this response are detailed below. The Centers for Epidemiology and Animal Health (CEAH) should be notified to create the appropriate EMRS documents.

1.2.1 Regional Incident Complexity Analysis Team

A Regional Incident Complexity Analysis Team should be deployed immediately to assess the extent and complexity of the incident. Factors such as type of operation involved, State and Federal resources available at the local level, potential duration of the investigation, and regional resources available will be incorporated into the team's report. This report will be used as a basis for obtaining and allocating additional resources required by the incident. The team's report should be provided to the Regional Director and the National Coordinating Group so that the funding requests and other documents can be prepared.

1.2.2 Disposing of the Carcass of the Confirmed Positive Animal

Per the procedures outlined in 1.1., disposal of carcasses that were available at concentration points upon an inconclusive test result may have already occurred. If disposal of the carcass has not already taken place, the carcass should now be disposed of through incineration or alkaline digestion. Samples that will allow DNA testing should be taken prior to disposal (see description in 1.1.).

For carcasses that were not readily available upon receipt of an inconclusive test result, the following steps should be taken:

- If the carcass was rendered, field staff should coordinate with Food and Drug Administration (FDA) personnel on purchasing and destroying the rendered product containing the carcass of the positive animal. (Note: Contracts signed with individual rendering plants must include specifications for how much material will be removed.) The rendered material should be disposed of through incineration, alkaline digestion, or lined landfill (if local conditions allow).
- If the carcass was placed in a lined landfill or buried on farm, coordinate with the Environmental Protection Agency and local officials.

1.2.3 Scope of the Investigation

At-risk cattle

The objective of the BSE investigation will be to trace at-risk cattle defined as those animals that were possibly exposed to the same contaminated feed source as the BSE positive animal or recently born from a BSE positive cow. In most cases, it will not be practical or possible to definitively determine which cattle were exposed to a contaminated feed source. Given that situation, a birth cohort should be used to determine which cattle should be considered at-risk. The birth cohort includes all cattle that were born on the positive animal's birth premises within 1 year before or after the date of birth of the BSE positive animal. In addition, if the positive animal moved from the birth premises to any other premises during it's first year of life, all cattle of less than 1 year of age that were present on such additional premises should also be considered to be at-risk, for example, dairy replacement heifers raised on calf ranches or feedlots.

Specifically, at-risk cattle are defined by OIE as:

> If the BSE positive animal is a female, all progeny born within 2 years prior to, and after, clinical onset of the disease (or prior to positive test, if no clinical signs were recognized);
>
> AND,
>
> All cattle which, during their first year of life, were reared with the positive animal during its first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period;
>
> OR,
>
> Where the results of an investigation are inconclusive as to which animals were exposed to contaminated feed, all cattle born in the same herd as, and within 12 months of the birth of the positive animal (the birth cohort).

Cattle of interest

In many cases at-risk cattle cannot be definitively identified. A herd inventory and analysis of herd records for a given premises will identify a group of cattle that include potential at-risk cattle and other cattle that cannot be distinguished from at-risk cattle. When all at-risk cattle potentially present on the premises cannot be definitively identified, additional cattle will have to be depopulated in order to ensure that all at-risk cattle are removed. All of these cattle – at-risk cattle and any additional cattle as necessary – will be defined as cattle of interest (COI).

Feed

FDA is responsible for feed investigations. As animal health personnel uncover information about the feeding history of the confirmed positive animal, this information should be provided to FDA. Priority should be placed on tracing feeds utilized in the first year of life.

1.2.4 Hold Orders/Quarantines

A hold order or quarantine may have been issued for the last known premises of residence when the FAD investigation is initiated (see 1.1); if not, such a hold order or quarantine should be issued now. The hold order or quarantine will initially apply to all bovines on the premises. As soon as a group of cattle of interest can be determined (i.e., those cattle known to be in the birth cohort, feed cohort, or progeny plus those cattle which cannot be ruled out as being in one of those categories), the hold order or quarantine will be modified to apply only to COI. As additional premises are identified and inventories are initiated on these premises, hold orders or quarantines will be issued. Again, these orders will initially apply to all bovines on the premises but will be reduced

as soon as a group of COI can be determined. Animals not considered of interest can be moved off the premises, as necessary.

1.2.5 Depopulation of Additional Cattle

At-risk cattle found during the investigation will be depopulated and tested. Additional, cattle may need to be depopulated according to the protocol outlined below.

Cattle of interest

All COI will be further evaluated using all suitable identification techniques. The goal is to use what is known about the group of at-risk cattle to eliminate as many cattle as possible from the group of COI, yet still include all possible at-risk cattle. Depending on the specific circumstances involved, several factors may be useful in determining the COI. These include age, gender, breed, color, man-made identification (eartags, tattoos, brands), and known premises of birth. Obvious factors such as age, gender, and breed, should be used to the extent possible to limit the size of the group being evaluated. More specific information from herd management records and any other available records should then be compared against man-made identification of the remaining potential COI. Cattle of interest which cannot be eliminated will be depopulated in order to ensure that all at-risk cattle are removed.

Culls and other cattle

Marketing factors, such as the routine culling of cattle, may require that other cattle be depopulated at the premises under investigation. Cattle scheduled for routine culling, which have not been eliminated as COI, may be purchased, euthanized, and tested during the hold/quarantine period. Every effort should be made to minimize the number of culled animals purchased.

1.2.6 Standard Operating Procedures

Standard operating procedures (SOPs) should be developed and documented for addressing routine procedures required for carrying out the response. These procedures will cover such activities as issuance and removal of hold orders/quarantine and euthanasia/disposal. Setting some of these procedures will require consultation with State animal health officials and others in the local area (such as local environmental protection agencies).

1.2.7 Ending the Investigation

It will be difficult, if not impossible, in most BSE investigations to completely trace all at-risk cattle, therefore, throughout the investigation, traces should be prioritized. Additional effort might be warranted to complete the highest priority traces (see table 1). At some point, without all COI having been traced, a decision may need to be made to end the investigation.

Table 1: Examples of highest priority cattle to be traced

At-risk cattle leaving the positive animal's birth premises for any destination other than slaughter
Unless moving to slaughter, cattle known to have been born on the positive animal's birth premises within 6 months of the date of birth of the BSE positive animal (regardless of where the cattle are now moving from) are a higher priority trace than the entire 12 month birth cohort
Cattle that moved onto a premises where the positive animal is known to have resided within a short time period (e.g., less than 6 months) and from the same source (e.g., a specific dealer) as the positive animal

2.0 Response Structure

The response to a confirmed, positive BSE case will be handled through formation of an Incident Command Post (ICP) following Incident Command System (ICS) procedures. The ICS allows for a flexible, scalable response that can be staffed according to the size and complexity of each investigation.

An initial ICP will be established in the State where the last known premises of residence of the positive animal is located. Depending on the type of facility involved, the ICP may be staffed entirely with local personnel. It is likely, however, that additional personnel will be needed. If the investigation leads to premises in other States, additional ICPs will be established as needed.

2.1 Complexity of the Investigation

The complexity of the investigation will be determined by both the type of facility on which the positive animal is last known to have resided (see table 2) and the timeline imposed on the investigation by outside forces. Response size could range from less than 20 personnel for the least complex to several hundred for highly complex investigations. Staffing at the Yakima, Washington, ICP, for example, reached 100 with 65 personnel in the Plans Section, 25 in the Operations Section, and the remainder in Finance, Logistics, and Incident Commander.

Table 2: Investigation Complexity

Least Complex	Closed Commercial Beef Herd	Raise own replacements, calves sold for feeding purposes, cull adults are slaughtered
	Purebred Beef Operation	Raise own replacements, but many sales of breeding stock, availability and accuracy of sales records and that of subsequent sales is variable.
	Small Dairy	May or may not raise own replacements, culls often go only to slaughter, heifer calves may be sold to other dairies depending on type of bull semen that is utilized
	Large Drylot Dairy	May or may not raise own replacements, heifer calves often raised off-site, ownership may or may not be retained, cull cows usually go directly to slaughter, may have to trace "feed cohorts" vs "birth cohorts"
Most Complex	Feedlot	Identification of individual animals is often lacking, trace leads immediately to a group of animals numbering in the hundreds, birth herds are often impossible to trace due to the large number of trader cattle encountered

2.2 Positions/ Functions at Incident Command Posts

As ICPs are formed to respond to a positive BSE animal, a number of positions and functions can be anticipated. A baseline organizational structure is provided in Figure 1. The number of personnel needed for the response will be dependent on the complexity of the investigation. Both State and Federal personnel will staff the ICP.

A description of some key positions is provided below:

Public Information Officer (LPA and State information officers)
BSE investigations create a substantial amount of media attention and so it is critical to staff this function adequately and to position that staff at the ICP. (**Note**: LPA information officers may not need to be placed at additional ICP opened during the response; a decision on the need for on-site support should be evaluated in light of media and public interest).

Operations
Cleaning and Disinfection (C&D) - Since BSE is not contagious in the normal sense this function is not necessary to control the BSE agent. Instead, C&D is critical for any trailer or container that comes into contact with animals, carcasses or animal products that the incident is transporting to prevent the potential spread of other viral and bacterial diseases.
Euthanasia and Disposal (E&D) - In a BSE incident the euthanasia and sampling of COI poses a disposal problem. Agency policy favors the incineration or alkaline digestion of BSE positive carcasses. The E&D unit will be required to hold sampled COI carcasses until lab testing is completed. Ambient temperature, available storage containers, number of COI to be sampled per day, etc., will affect the E&D options that are available.

Plans
Multiple activities will be required of the planning section:
Situational Epidemiology Group - focus on trace backs, on-farm epidemiology, and identifying at-risk animals (COI). (Short term planning)
Strategic Epidemiology Group - focus on overall direction of the investigation, plot a course for the investigation, define an endpoint and analyze data. Prioritize cattle to be traced. This group will also work closely with the National Coordinating Group. (Long term planning)
Field observers - locate COI in herds that have been identified in the epidemiological investigation.

2.3 Reporting Lines and Roles and Responsibilities

An initial BSE response effort will lead to the formation of an ICP in the State where the last known premises of residence of the positive animal is located. This ICP will report to the Regional Office supervising the affected State. A National Coordinating Group will be established at headquarters. Figure 2a shows this structure. If warranted additional ICS components might be established as the situation increases in size and complexity. These components include one or more Area Commands and a National Incident Command (Figure 2b, 2c). A National Incident Command might be established if the response entails both regions or if the response becomes increasingly complex. It is essential that roles of each of these components be understood and clear channels of communication be established.

2.3.1 Roles and responsibilities:

National Coordination Group located at headquarters
- Coordination with other Federal agencies and APHIS units;
- Coordination with USDA Secretary's office;
- Policy origination;
- Policy clearance (Policies with national implications are approved by the National Coordination Group with appropriate consultation with the regional and local incident levels and the Deputy Administrator's office. A short turnaround time is required.);

- Addressing trade issues (coordinate with NCIE);

- Coordinating arrangements for official visitors and delegations

Note: The Transmissible Spongiform Encephalopathy (TSE) Working Group serves as the subject matter expert for the Coordination Group and assists in the clearance of policies. Depending on the complexity of the incident, one or two members (other than the group leader) of the TSE working group may need to be located in Riverdale during the response.

Note: The National Coordination Group does not provide line supervision for the local/regional incident command

Regional Office
- Coordination with the National Coordination Group;
- Policy origination;
- Setting overall incident-related priorities and objectives;
- Providing delegation of authority to the Incident or Area Commanders;
- Approval of SOPs, if no Area Command;
- Line supervision of the ICPs or Area Command;
- Allocation of critical resources according to priorities;
- Dispatch center

Area Command (if needed)
- Setting overall incident-related priorities and objectives;
- Allocation of critical resources according to priorities;
- Ensuring that incidents are properly managed;
- Ensuring that incident management objectives are met and do not conflict with each other or with agency policy;
- Identifying critical resource needs and reporting them to Region and/or National Coordinating group;
- Coordination with State, local and APHIS Areas offices;
- Policy origination;
- Approval of SOPs

Local Incident Command
- Establishing incident management objectives and strategies;
- Implementation of the incident objectives;
- Managing resources assigned to the incident;
- Policy origination;
- Development of SOPs
- Coordination with local, tribal, and State agencies;
- Coordination with the Regional office

National Incident Command (if needed)

- Coordination with the National Coordination Group;
- Policy origination;
- Setting incident objectives;
- Providing delegation of authority to the Regional Commanders;
- Line supervision of the Regional Command

3.0 Information Flow

The public and media will be interested in any BSE case. This interest will require that information be available to respond to inquiries both at the local site and headquarters on a near real-time basis. Agreement should be reached between the Regional Office and the National Coordinating Group, within the first days of the response, as to what type/format of information should be provided on a daily basis. A sample of daily internal reports from the Yakima, Washington, ICP in January 2004 is provided in Appendix 1. A sample daily report issued internally from the National Coordinating Group is provided in Appendix 2. Information from these internal reports was used to create information for the public. The outline for an external report is provided in Appendix 3.

4.0 Impact of Response Activities on Enhanced BSE Surveillance Effort

BSE response activities should not necessarily interrupt the enhanced BSE surveillance effort. Temporary staff hired for enhanced BSE surveillance activities should continue working on that effort. Response activities, however, could begin to involve significant numbers of VS staff, should tracing efforts become increasingly complicated and widespread. Resources may need to be redirected to continue to accomplish both enhanced surveillance and response activities. Resource needs should be continually monitored and management kept informed when concerns arise in being able to continue both efforts.

Figure 1 – Baseline ICP Organizational Structure

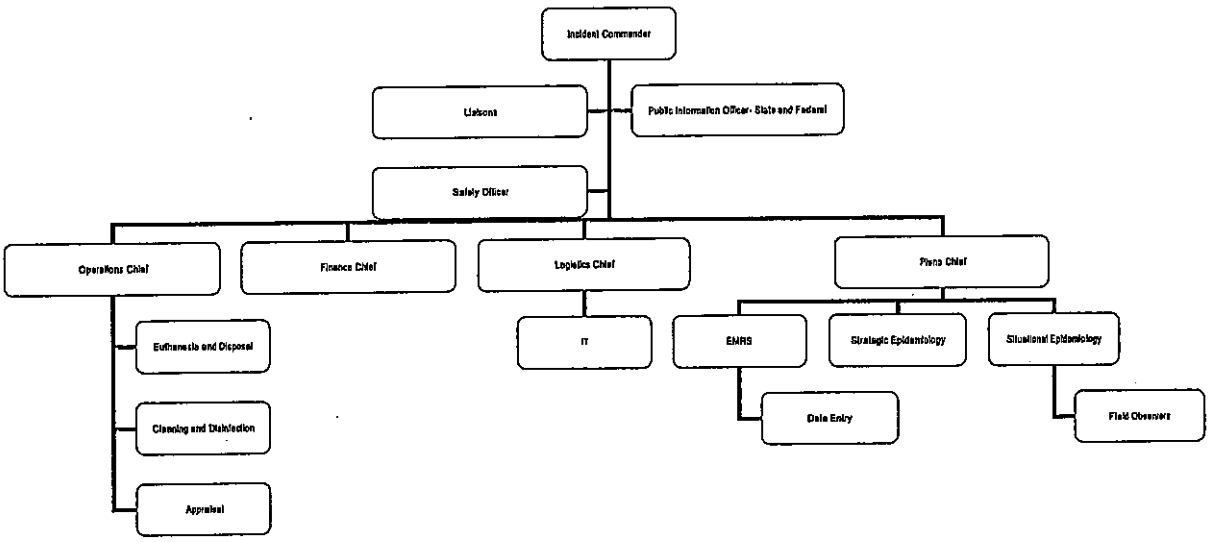
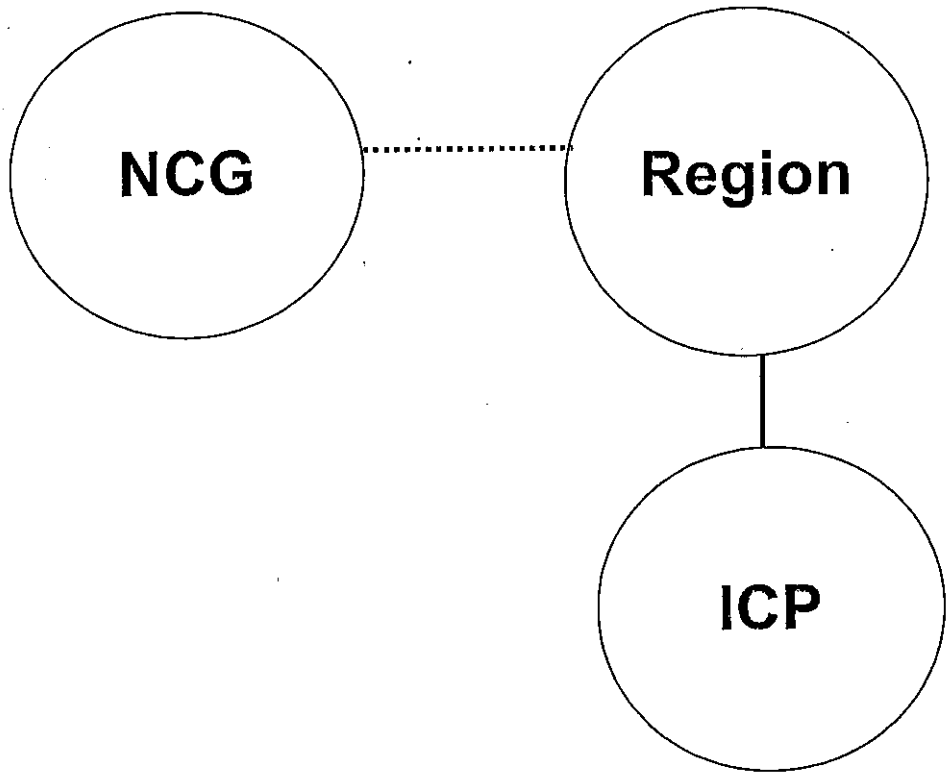
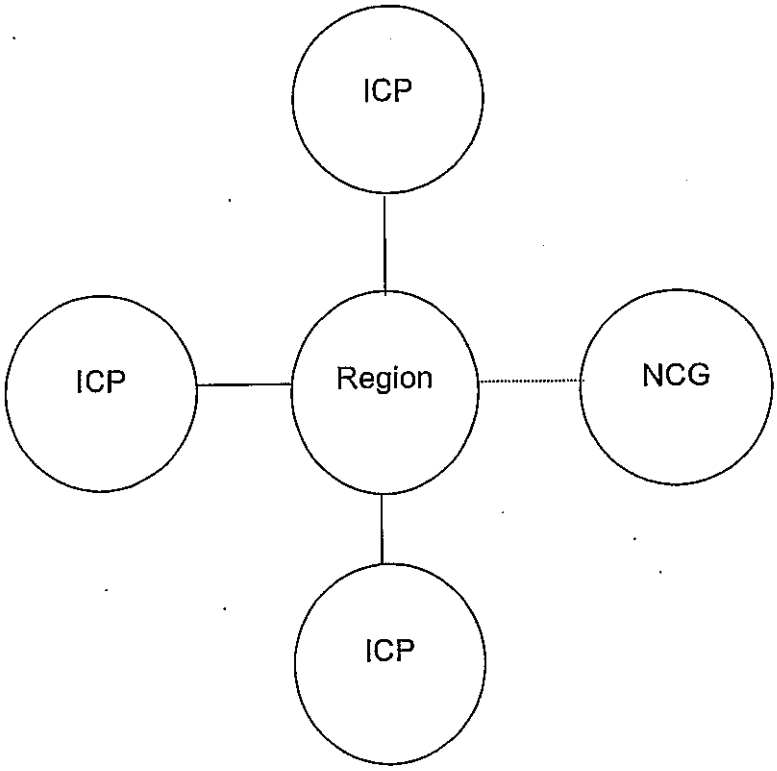


Figure 2a: Reporting Lines for BSE Command

NCG = National Coordinating Group
ICP = Incident Command Post

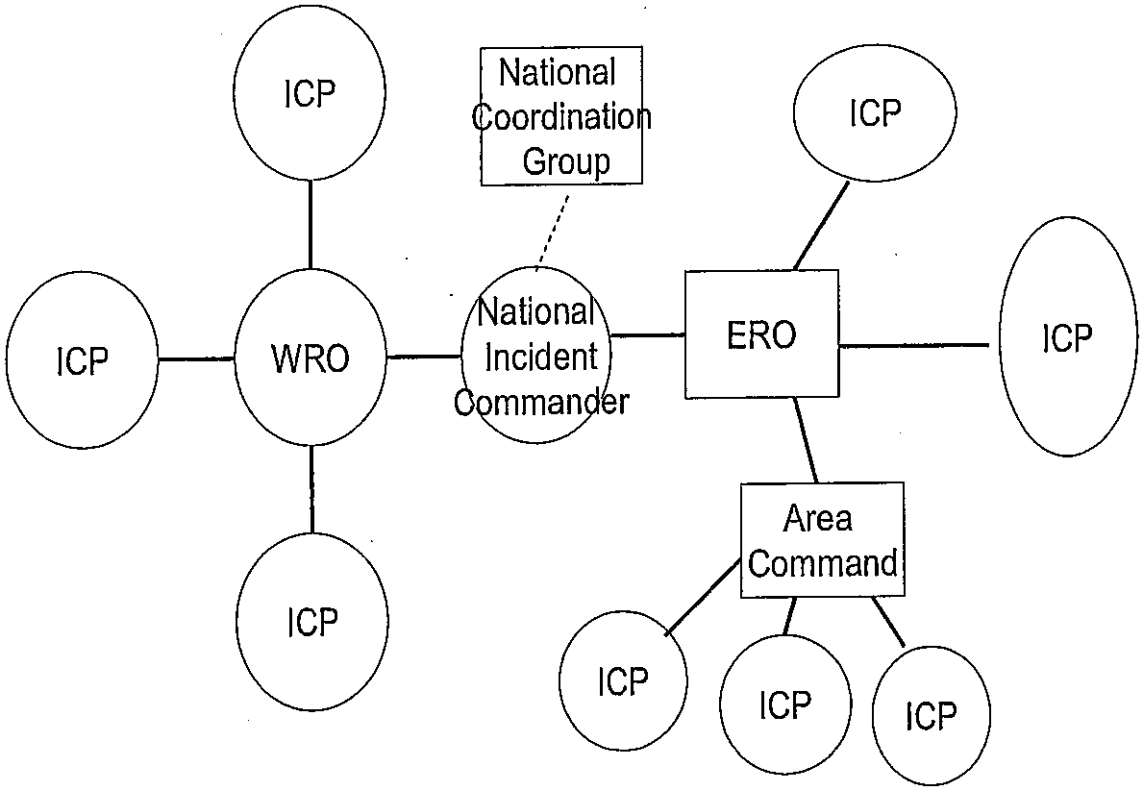


2b. Multiple Sites for Tracing



2c. Multiple Investigations/Both Regions

Multiple Investigations / Both Regions



Appendix 1 – Sample Daily Report from the Yakima ICP, January 2004

Bovine Spongiform Encephalopathy
Area Situation Report – INTERNAL USE ONLY

I. TRACKING THE 81 ANIMALS

The Index animal entered the United States from Canada as part of a group of 81 animals.

29 of those 81 animals have been definitively identified:

- 1 is the BSE-positive cow that was located in the Index herd in Mabton, WA.
- 9 were located in the Index herd in Mabton, WA.
- 3 were located at a facility in Tenino, WA.
- 6 were located at a facility in Connell, WA.
- 1 was located at a facility in Quincy, WA.
- 3 were located at a facility in Mattawa, WA.
- 1 was located at a facility in Moxee, WA.
- 2 were located at a facility in Burley, ID.
- 1 was located at the same facility in Burley, ID, but died.
- 1 was located at a facility in Othello, WA.
- 1 is located at another facility in Mabton, WA.

* Under OIE guidelines, animals born on a premises within 12 months (before or after) of the birth of an affected animal can be considered to be higher risk. Using this definition, 25 of the 81 animals have been identified as "OIE high risk."

14 of the 25 animals that are considered OIE high risk (including the index animal) have been definitively identified.

II. ACTIONS RESULTING FROM FINDING "CATTLE OF INTEREST"

	Washington	Oregon	Idaho
Confirmed Positive	x		
# Cattle on BSE Positive Premises	x,xxx		
# Cattle of Interest Euthanized*	xxx	xx	x

*Euthanasia summary:

- xxx - Bull calf raising premises, Sunnsyside, WA.
- xxx - At-risk animals on index premises, Mabton, WA.
- xx - Dairy cattle finishing location, Mattawa, WA.
- xx - Dairy B, Connell, WA.
- xx - Dairy D, Boardman, OR.
- xx - Dairy A, Quincy, WA.

- x - Dairy C, Tenino, WA.
- xx - Dairy F, Moxee, WA.
- x - Dairy G, Othello, WA.
- x - Dairy E, Burley, ID.

III. INVENTORY AND INVESTIGATION PROGRESS

	Washington	Oregon	Idaho	California	Arizona	Montana
Total Investigations	xxx	xx	xx	xx	x	x
Pending Investigations:						
Pending Interviews	x	x	0	x	0	0
Pending Inventories*	x					
Completed Inventories**	xx	x	x			
Inventoried Cattle on Premises	xx,xxx	xx,xxx	x,xxx			

*Scheduled, not yet complete.
** Includes reinventories.

IV. STATUS OF HOLD ORDERS ON AFFECTED DAIRIES

Dairy	Hold Status
Dairy H (Mabton, WA)	Whole herd hold

Detailed Operational Update

Major Updates

- Three cattle of interest at Dairy H (Mabton, WA) have been identified. The dairy's records will be reviewed on January xx to determine whether additional cattle of interest are present. The 3 cattle of interest that have been identified will be appraised at the same time the review is conducted.
- Inventories on 2 herds are scheduled to be conducted on January xx.
- An updated epidemiology report and diagram appear on pages X and Y.

Public Outreach

- Nothing to report.

Number of Personnel: xx

Personnel

Task Force Members on site in Yakima	
Federal Personnel:	
APHIS-permanent	xx
APHIS-temporary	0
FSIS	0
FDA	0
FSA	0
Other USDA	0
Other Federal	0
Federal-Total	xx
State Personnel:	
WSDA-permanent	x
WSDA-part time	
WSDA Brand Inspectors	x
WSDA-total	xx
Reserves:	0
Contract:	0
Canadian Personnel:	0
TOTAL in Yakima	xx

Task Force Members on site in Olympia:	
Federal Personnel:	
APHIS-permanent	x
APHIS-temporary	0
	x
FSIS	0
FDA	0
Other USDA	x
Other Federal	0
Federal-Total	xx
State Personnel:	x
WSDA-permanent	0
WSDA-part time	0
TOTAL in Olympia	xx
TOTAL Yakima	**xx**
TOTAL Olympia	**xx**
TOTAL WA	**xx**

Epidemiology Report
Washington State BSE Incident Command Post (ICP)
MM/DD/YY

Summary

- xx herds inventoried and analyzed to date
  - x analyses were done on mm/dd/yy and no COI[1] were found.
  - x analyses were done on mm/dd/yy and no COI were found.
  - x analysis was done in the morning of mm/dd/yy and no COI were found.
- x of the analyzed herds were found with COI (includes index herd)
- x herd (Dairy H) is undergoing data validation
- x herds are scheduled for inventory or are currently undergoing inventory

New or significant items

- Dairy H. A trace from the Canadian Dealer has resulted in at least one COI being found during the physical inventory process. The inventory is being data entered and will be analyzed for any more COI. A hold order has been placed.
- All previous quarantine/hold orders in the state of Washington have been released.
- Dairy G. Partial depopulation was completed on mm/dd/yy . The hold order was released with the removal of the selected culls.
- Dairy E. Partial depopulation was completed on mm/dd/yy . The hold order was released with the removal of the selected culls.

[1] Cattle of Interest

Appendix 2 – Sample Daily Report issued from the National Coordinating Group, January 2004

APHIS National Coordination Group
Bovine Spongiform Encephalopathy
Situation Report

I. TRACKING THE 81 ANIMALS

The Index animal entered the United States from Canada as part of a group of 81 animals.

29 of those 81 animals have been definitively identified:

- 1 is the BSE-positive cow that was located in the Index herd in Mabton, WA.
- 9 were located in the Index herd in Mabton, WA.
- 3 were located at a facility in Tenino, WA.
- 6 were located at a facility in Connell, WA.
- 1 was located at a facility in Quincy, WA.
- 3 were located at a facility in Mattawa, WA.
- 1 was located at a facility in Moxee, WA.
- 2 were located at a facility in Burley, ID.
- 1 was located at the same facility in Burley, ID, but died.
- 1 was located at a facility in Othello, WA.
- 1 is located at another facility in Mabton, WA.

* Under OIE guidelines, animals born on a premises within 12 months (before or after) an affected animal can be considered to be higher risk. Using this definition, 25 of the 81 animals have been identified as "OIE high risk." Of the 25 "high risk" animals, **14 of the 25 (including the index animal) have been definitively identified.**

II. ACTIONS RESULTING FROM FINDING "CATTLE OF INTEREST"

Herd (Depopulated)	# of At-Risk Animals	Animals Euthanized
Index Herd – Mabton, WA	XXX	XXX
Mattawa, WA	XX	XX
Bull Calf Facility – Sunnyside, WA	XXX	XXX
Connell, WA	XX	XX
Boardman, OR	XX	XX
Quincy, WA	XX	XX
Tenino, WA	X	X
Moxee, WA	XX	XX
Othello, WA	X	X
Burley, ID	X	X

III. INVENTORY AND INVESTIGATION PROGRESS

	Washington	Oregon	Idaho	California	Arizona	Montana
Total Investigations	xxx	xx	xx	xx	x	x
Pending Investigations:						
Pending Interviews	x	x	x	x	0	0
Pending Inventories*	x					
Completed Inventories**	xx	x	x			
Inventoried Cattle on Premises	xx,xxx	xx,xxx	x,xxx			

*Scheduled, not yet complete.
** Includes reinventories.

- A summary and updated epidemiology diagram appear on pages X-Y.

Detailed Operational Update

Depopulation, Disposal, and Testing

- A cumulative total of xxx samples have been received by NVSL.

Location (City, State)	Premises	No. condem.	No. samp.	Cum. samp/ prem	Date euth.	Date ELISA	ELISA result	Date IHC	IHC result
Mabton, WA	Index Dairy	xxx	x	x	mm/dd/yy	NA	NA	mm/dd/yy	x neg
			x	x	mm/dd/yy	NA	NA	mm/dd/yy	x neg
			x	xx	mm/dd/yy	mm/dd/yy	x neg	mm/dd/yy	x neg
			xx	xx	mm/dd/yy	mm/dd/yy	xx neg	mm/dd/yy	xx neg
			xx	xx	mm/dd/yy	mm/dd/yy	xx neg	mm/dd/yy	xx neg
			xx	xx	mm/dd/yy	mm/dd/yy	xx neg	mm/dd/yy	xx neg
			xx	xxx	mm/dd/yy	mm/dd/yy	xx neg	mm/dd/yy	xx neg
			x	xxx	mm/dd/yy	mm/dd/yy	x neg	mm/dd/yy	x neg
			x	xxx	mm/dd/yy	mm/dd/yy	x neg	mm/dd/yy	x neg
Mattawa, WA	Finishing	xx	xx	xx	mm/dd/yy	mm/dd/yy	xx neg	mm/dd/yy	xx neg
			xx	xx	mm/dd/yy	mm/dd/yy	xx neg	mm/dd/yy	xx neg
Connell, WA	Dairy B	xx	xx	xx	mm/dd/yy	mm/dd/yy	xx neg	mm/dd/yy	xx neg
Boardman, OR	Dairy D	xx	xx	xx	mm/dd/yy	mm/dd/yy	xx neg	mm/dd/yy	xx neg
Tenino, WA	Dairy C	x	x	x	mm/dd/yy	mm/dd/yy	x neg	mm/dd/yy	x neg
Quincy, WA	Dairy A	xx	xx	xx	mm/dd/yy	mm/dd/yy	xx neg	mm/dd/yy	xx neg
								mm/dd/yy	x neg
Moxee, WA	Dairy F	xx	xx	xx	mm/dd/yy	mm/dd/yy	xx neg	mm/dd/yy	xx neg
Othello, WA	Dairy G	x	x	x	mm/dd/yy	mm/dd/yy	x neg		
Burley, ID	Dairy E	x	x	x	mm/dd/yy	mm/dd/yy	x neg		

Major Updates

- Three cattle of interest at Dairy H (Mabton, WA) have been identified. The dairy's records are being reviewed to determine whether additional cattle of interest are present. The 3 cattle of interest that have been identified will be appraised at the same time the review is conducted.
- Inventories on x herds are scheduled to be conducted on January xx, 2004.

Public Outreach

- Nothing new to report.

Trade Issues

- Specific trade ban information is available at:
  http://www.aphis.usda.gov/lpa/issues/bse/bse_trade_ban_status.html
  If you do not see an update for mm/dd/yy, please refresh your browser.

Personnel and Incident Command Operations

- A total of xx personnel are on-site in Yakima, and xx personnel are working in Olympia.

Epidemiology Report
Washington State BSE Incident Command Post (ICP)
MM/DD/YY

Summary

- xx herds inventoried and analyzed to date
  - x analyses were done on mm/dd/yy and no COI[2] were found.
  - x analyses were done on mm/dd/yy and no COI were found.
  - x analysis was done in the morning of mm/dd/yy and no COI were found.
- x of the analyzed herds were found with COI (includes index herd)
- x herd (Dairy H) is undergoing data validation
- x herds are scheduled for inventory or are currently undergoing inventory

New or significant items

- Dairy H. A trace from the Canadian Dealer has resulted in at least one COI being found during the physical inventory process. The inventory is being data entered and will be analyzed for any more COI. A hold order has been placed.
- All previous quarantine/hold orders in the state of Washington have been released.
- Dairy G. Partial depopulation was completed on mm/dd/yy. The hold order was released with the removal of the selected culls.
- Dairy E. Partial depopulation was completed on mm/dd/yy. The hold order was released with the removal of the selected culls.

[2] Cattle of Interest

Appendix 3 - Sample External Daily Report Format

DAILY REPORT FOR EXTERNAL DISTRIBUTION

STATUS OF AFFECTED STATE-COUNTY
Current disease status -- numbers of animals, premises, locations.

PROGRESS OF EPIDEMIOLOGICAL INVESTIGATION(S)
Epi info

EMERGENCY RESPONSE
Overview on key USDA and State actions.

MOVEMENT CONTROLS IMPLEMENTED TO CONTAIN RISKY ANIMALS AND MATERIALS WITHIN THE AFFECTED REGION
Info on movement controls in the affected area.

SURVEILLANCE APPROACHES AND DATA
Update on sampling efforts, latest sampling numbers.

OUTREACH EFFORTS
Info on LPA activities, meetings, press contacts, etc.

TRADE ISSUES
Info on progress with trading partners, trade bans, etc.

クリフォード米国首席獣医官からの書簡（2005年7月11日付け）概要仮訳

テキサス州において確認されたＢＳＥに関する情報をお伝えする。

2004 年 11 月 15 日、約 12 歳の歩行困難牛がテキサスのペットフードプラントに運ばれた。当該牛は衰弱状態であったが、ペットフードプラント到着時に死亡していたため、サンプルはルーチンのサーベイランスプログラムに供された。当該牛は食料及び飼料チェーンに回っていない。APHIS とテキサス州動物衛生委員会は幅広く疫学調査を実施。

当該牛のサンプルは 2004 年 11 月 15 日に検査され、エライザ検査で陽性。サンプルは NVSL に送られ、11 月 23 日、２種類の免疫組織化学的検査（IHC）で陰性となった。SAF イムノブロット（ウェスタンブロット法）による追加検査で反応があった旨を 2005 年 6 月 10 日に公表。英国と USDA による更なる検査を実施し、6 月 24 日、BSE 陽性と確認。

通常見られないこういった結果は、非定型的なものであると推測される。6 月 24 日、USDA は BSE 検査のプロトコールを見直し、更なる研究を行う。

発生農場の牛群は、疫学関連のある牛を特定するため、移動制限を実施中。米国や幾つかの国は科学に基づくガイドラインを提唱。米国は、国際基準と同様な措置を実施。

疫学的な調査により米国内で２例目の BSE が確認され、米国で実施されているサーベイランスシステムはＢＳＥを見つけ出すために十分なものである。さらに我々は米国の動物や製品の安全管理措置を実施している。これらには、ＳＲＭの除去、AMR の管理、検査中の肉の保留、空気注入スタンニングの禁止が含まれる。２頭目のＢＳＥはワシントンで見つかった１例目の牛とは関連がない。米国で現在実施されているリスク低減措置によりＢＳＥの拡大は無い。

USDA は強化サーベイランスを継続している。このデータにより、米国のＢＳＥ浸潤状況が推定できる。2004 年 6 月以降、400,600 頭が検査され、追加的な発生はない。これらの措置は OIE のガイドラインに規定されている。これらの結果により、米国

のサーベイランスプログラムは疾病の摘発に有効であり、疑われるケースにおいての疫学調査にも効果的。

米国は、現在の科学に基づく OIE ガイドラインにしっかりと従い、効果的なリスク低減措置がとられた際、BSE に関して低リスクと認識する。ガイドラインは、国のステータスを３区分する簡素化と、リスク無し製品の見直しが行われた。OIE は、骨なし牛肉について国のステータスにかかわらず貿易可能であることを公式に認定している。OIE は、国の BSE に関する措置に応じて分類する簡素化されたシステムも採択した。

米国は新たな OIE コードに基づく自国のステータスを評価中。米国は関連する文書を準備し、OIE に提出する予定。

以下の関連情報を添付する。①飼料規制と輸入規制の概要、②強化サーベイランスが行われる以前のサーベイランス措置、③疫学調査結果及び発生農場における関連牛の処分、④ USDA による食料、飼料供給に対するリスク低減措置、⑤ BSE 緊急対応計画

最近のＢＳＥの確認事例や防疫措置は、米国の強固なサーベイランスと他の安全措置を実証したもの。反すう動物に関する将来的な貿易方針の決定の際に考慮して頂きたい。USDA は更なる情報提供を行っていく。

＜添付資料＞

別添１：飼料規制と輸入規制の概要（米国における BSE 関連対策の概要を説明した文書。既に同様の文書を接受済み。）

別添２：強化サーベイランスが行われる以前のサーベイランス措置（1990 年から実施されている米国のサーベイランス実績等。既に同様の文書を接受済み。）

別添３：疫学調査結果及び発生農場における関連牛の処分（２例目のＢＳＥに関する疫学調査の状況についての文書。追跡対象となる牛の定義、発生農場の飼養状況、ＢＳＥ感染牛の産仔、コホート牛の追跡状況等について記載あり。）

別添４：USDA による食料、飼料供給に対するリスク低減措置（１例目のＢＳＥが発生した際、ベネマン長官（当時）が発表した新たなＢＳＥ対策に関するニュースリリース。）

別添５：BSE 緊急対応計画（１例目のケースで実施された疫学調査状況）

別添３（Enclosure 3)の抜粋仮訳

○ＢＳＥ疫学調査のプロセス

１．疫学関連牛（at-risk callte）の定義

ＯＩＥの定める以下の３つの基準のを採用。

①感染牛の発症時点から過去２年以内に生まれた産仔

②感染牛が１歳までに摂取した汚染された可能性のある飼料と同じものを１歳までに摂取したことが確認された牛

③どの牛がこの汚染された可能性のある飼料を摂取したか不明の場合は、感染牛と出生月日が１２ヶ月以内の同居牛（出生同期牛：birth cohort）

２．出生同期牛（birth cohort）の定義

今回のケースでは、どの牛が感染牛と同じ飼料を摂取した可能性があるか特定できないため、出生同期牛が疫学関連牛として用いられる。すなわち、調査担当者は、感染牛の年齢の幅を１１～１３歳としていることから、出生同期牛の年齢の幅は１０～１４歳と算出される。

３．追跡対象牛（"animals of interest"とも呼ばれる。）

疫学関連牛は、多くの場合はっきり特定できないため、それらの牛を含む牛群を追跡対象牛とみなす。

４．感染牛の属した牛群に係る疫学レポート

(1) 感染牛の由来農場は2005年6月20日から移動制限の対象。

(2) 疫学調査の詳細情報

a)背景

・当該感染牛は、クリーム色のブラーマ・クロス（インド系の牛の交雑種）でおおよそ 12 歳。

・当該感染牛 2004 年 11 月 15 日にと畜場に搬入されたが、トラックの中で他の１頭とともに死亡していたため、ペットフードプラントに転送され、BSE 検査のため採材された。

・ＤＮＡ検査でＡ農場を特定。
・Ａ農場主は、当該感染牛を生まれてから売却するまで農場内で一貫して飼養。
・当該感染牛については、子牛を早期離乳させたにもかかわらず、ボディコンディションが改善しなかったため農場外に売却された。
・当該感染牛は、興奮しやすく、市場に売却される途中で座り込んだが、農場主によれば、これらは特別な行動ではなかったとのこと。

b)現在の牛群に関する情報
・Ａ農場は７群に２３３頭の成牛と１００～１２０頭の子牛を飼養。
・当該感染牛のオリジンを確認するため、各群についてＤＮＡ検査を実施。

c)当該感染牛の産仔
・Ａ農場主は、更新用に雌牛を自家保留することはあるものの、クリーム色の牛（ブラーマ・クロス）の産仔は気性が荒いため、恐らく売却していると記憶。
・2003 年秋に生まれたであろう最後の産仔は、2004 年春に売却された。
・その前の産仔は、2002 年秋に生まれたと見られており、家畜市場でやはり売却された。
・これらの２頭は、売却記録を用いてトレースしているが、現時点での情報では、肥育目的で２頭とも購入された見込みが高い。
・Ａ農場の牛は、２箇所の家畜市場を通じてのみ売却されていたことが判明。
・家畜市場の売却記録と農場のブルセラ検査の記録を用いて追跡対象牛の特定作業を進めているところ。

d)飼料
・当該牛群が摂取した飼料は、放牧草、採草、ミネラル・サプリメント、時としてシロップ及び種畜用サプリメント（種畜用キューブ）。
・ＦＤＡは現在、Ａ農場の全ての飼料とサプリメントのソースについて調査中。

（以上）

２．飼料規制

米国で２００４年７月に公表され、パブリックコメントに付された飼料規制の改正案についての検討状況（施行の可能性等）

2005年7月28日　米国から提出された資料

Current status of proposed revised feed restriction rules that were made public in July 2004 and gone through the public comment period

"FDA has completed its internal review of the draft proposed rule to prohibit high-risk bovine tissues from use in all animal feed. The proposed rule must now be reviewed by the leadership of the Department of Health and Human Services (HHS) and the Office of Management and Budget. These reviews are the last stage before publication of the proposed rule. Once these reviews are completed, the proposed rule will be published in the Federal Register for public comment. HHS will consider in its development of the final rule all comments that are submitted."

＜仮訳＞

FDA(食品医薬品局)は、高リスクのウシ科動物の組織を全ての動物用飼料に使用することを禁止する規則案の組織内におけるレビューを完了した。現在、当該規則案は、保健福祉省（HHS）及び行政管理予算局（Office of Management and Budget）のリーダーシップの下でレビューされなければならないこととなっている。これらのレビューは、規則案の公表の前段の最終段階にある。これらのレビューが完了すれば、当該規則案は官報に掲載され、パブリックコメントに付される。HHS は提出された全てのコメントを踏まえ、最終規則の策定を検討することとなる。

３．サーベイランス

＜委員限り＞

（１）サーベイランスを実施した牛の年齢分布（カテゴリー別、乳肉別、地域別等）

（２）高リスク牛（446,000頭）の算出根拠について

- 死亡牛（251,500頭）について：算出根拠と使用した統計の原典
- と畜場での廃棄牛（194,200頭）について：使用したＦＳＩＳの統計の原典
- 中枢神経症状を呈した牛（129頭）について：使用したＦＡＤ調査の原典

(2) Source of information used in calculation of the number of high risk cattle (446,000)

i. Dead cattle (251,500): How it was calculated and source of used statistics

This is based on National Animal Health Monitoring System Beef '97 and Dairy 2002 study data which can be accessed at http://www.aphis.usda.gov/vs/ceah/ncahs/nahms/index.htm

In calculating the size of the risk population (number dead on the farm) we multiplied the beef cow population by 1.5% (overall mortality) and 20.3% (the percent of total death loss attributed to unknown causes). [We did not apply these percentages to the beef replacements as indicated in the request].

32860300 * 1.5% * 20.3% = 100060 hd

We multiplied the number of dairy cows by 4.8% (the overall death loss) and by 35.1% (the percentage dead of unknown causes (19.8%) plus the percentage dead with lameness or injury (13.9%) plus the number dead with signs of incoordination (1.4%)). [We did not only use the 19.8% attributed to unknown causes as indicated in the request.]

8990500 * 4.8% * 35.1% = 151472 hd

Together these equal 251,532 hd

ii. Disposed cattle at slaughtering facilities (194,200): source of used statistics by FSIS

This is based on Food Safety Inspection Service condemnation data from fiscal year 2002 which can be accessed at www.fsis.usda.gov/ophs/adrsdata/2002/adrsfy02.htm

iii. Cattle with CNS symptoms (129): source of used statistics by FDA investigation

These are the total number of APHIS investigations conducted by foreign animal disease diagnosticians in 2003 for CNS signs in Cattle.

（仮訳）

（２）高リスク牛（**446,000** 頭）の算出根拠について

ｉ）死亡牛（**251,500** 頭）について：算出根拠と使用した統計の原典

この数字は、全米家畜衛生モニタリングシステムの肉牛編（97 年）及び乳牛編（02 年）に基づいており、これらの情報は以下のウェブサイトで閲覧可能である。

http://www.aphis.usda.gov/vs/ceah/ncahs/nahms/index.htm

リスク牛群の規模（農場での死亡した頭数）の算定に当たっては、我々は、肉用繁殖雌牛の頭数に 1.5%（全体の死亡率）と 20.3%（原因不明で死亡した割合）を掛け合わせた。

32,860,300 頭× 1.5%× 20.3%＝ 10,060 頭

我々は、乳用雌牛の頭数に 4.8%（全体の死亡率）と 35.1%（原因不明で死亡した割合(19.8%）に歩行障害または怪我で死亡した割合(13.9%)と運動失調の症状を呈して死亡した割合（1.4%）を加えたもの）を掛け合わせた。

8,990,500 頭× 4.8%× 35.1%＝ 151,472 頭

10,060 頭＋ 151,472 頭＝ 251,532 頭

ｉｉ）と畜場での廃棄牛 **194,200** 頭について：使用した **FSIS** の統計の原典

この数字は、2002 年度の FSIS(食品安全検査局)の廃棄データに基づいており、これらの情報は、以下のウェブサイトで閲覧可能である。

http://www.fsis.usda.gov/ophs/adrsdata/2002/adrsfy02.htm

ｉｉｉ）中枢神経症状を呈した牛 **129** 頭について：使用したＦＡＤ調査の原典

これらの数字は、海外家畜疾病(FAD)の専門医によって実施された 2003 年における牛の中枢神経症状に関する APHIS（動植物検査局）の調査の総数である。

＜委員限り＞

４．自国産牛でＢＳＥが確認されたことを受けた、ＢＳＥ清浄性に対する米国の考え方

５．カナダにおける生前検査

カナダのＥＵ輸出用の施設における、生前検査に関する資料とＥＵの生前検査要領

カナダのＥＵ輸出用の施設における生前検査に関する資料

Canadian Food Inspection Agency
Meat Hygiene Manual of Procedures

11 EXPORT

11.7.3 European Union

11.7.3.1 General Information

The requirements given in this section apply to the export of fresh meat and meat products to Austria, Belgium, Cyprus, Czech Republic, Denmark (except for the Faeroe Islands and Greenland), Eire (Republic of Ireland), Estonia, Finland, France (including the overseas departments of Guadeloupe, French Guyana, Martinique and Réunion and the Principality of Monaco but excluding the overseas territories), Germany, Greece, Hungary, Italy (excluding the Vatican or the Republic of San Marino), Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal (including Azores and Madeira), Slovakia, Slovenia, Spain (including Canary Islands and the Balearic Isles but excluding Ceuta and Melilla), Sweden and the United Kingdom (including the Channel Islands and Isle of Man).

(a) Definitions

carcass: means the whole body of a slaughtered animal after bleeding, evisceration and removal of the limbs at the carpus and tarsus, removal of the head, tail and the udder, and in addition, in the case of bovine animals, sheep, goats and solipeds, after flaying. However, in the case of pigs, removal of the limbs at the carpus and tarsus and removal of the head may be waived where the meat is intended for treatment in accordance with Directive 77/99/EEC; *(carcasse)*

establishment: means an approved slaughterhouse, an approved cutting plant, an approved cold store or a unit grouping together several such establishments; *(établissement)*

fresh meat: means meat, including meat vacuum-wrapped or wrapped in a controlled atmosphere, which has not undergone any treatment other than cold treatment to ensure preservation; *(viande fraîches)*

meat: means all parts of domestic bovine animals (including the species *Bubalus bubalis* and *Bison bison*), swine, sheep, goats and solipeds which are suitable for human consumption; *(viande)*

meat products: products prepared from or with meat which has undergone treatment such that the cut surface shows that the product no longer has the characteristics of fresh meat; *(produits à base de viande)*

mechanically recovered meat: means meat obtained by mechanical means from flesh-bearing bones apart from the bones of the head, the extremities of the limbs below the carpal and tarsal joints and, in the case of swine, the coccygeal vertebrae, and intended for establishments approved in accordance with Article 6 of Directive 77/99/EEC; *(viande séparées mécaniquement)*

offal: means fresh meat other than that of the carcass as defined above, even if it remains naturally connected to the carcass; *(abats)*

packaging: means the placing of wrapped fresh meat in a second container and the latter container itself; *(emballage)*

pithing: laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into cranial cavity could cause the dissemination of central nervous tissue throughout the body during slaughter; *(jonchage)*

specified risk materials (as defined in Annex XI, section A, to Regulation (EC) No 999/2001):

(i) the skull excluding the mandible and including the brain and eyes, the vertebral column excluding the vertebrae of the tail, the transverse processes of the lumbar and thoracic vertebrae and the wings of the sacrum, but including dorsal root ganglia, and the spinal cord of bovine animals aged over 12 months, and the tonsils, the intestines from the duodenum to the rectum and the mesentery of bovine animals of all ages;

(ii) the skull including the brain and eyes, the tonsils and the spinal cord of ovine and caprine animals aged over 12 months or which have a permanent incisor erupted through the gum, and the spleen and ileum of ovine and caprine animals of all ages; (matériels à risque spécifiés)

treatment: chemical or physical process such as heating, smoking, salting, marinating, curing or drying, intended to lengthen the preservation of meat or animal products whether or not associated with other foodstuffs, or a combination of these various processes; (traitement)

viscera: means offal from the thoracic, abdominal and pelvic cavities, including the trachea and oesophagus; *(viscères)*

wrapping: means the protection of fresh meat by the use of an initial wrapping or initial container in direct contact with the fresh meat concerned and the initial wrapper or initial container itself. *(conditionnement)*

(b) Only establishments listed by the EU (see annex S) may export edible meat and products derived therefrom to the EU. The product must be kept at all times in EU approved establishments in order to maintain its eligibility to be exported to the EU (see section 11.7.3.6.2 for details).

11.7.3.2 Import prohibitions or restrictions

11.7.3.2.1 Prohibitions

- mechanically recovered meat

- meat derived from animals treated with hormonal growth promoters
- specified risk materials (SRM)

11.7.3.2.2 Restrictions

In the area of fresh meat, poultry meat, game meat, farmed game meat and meat products, the following specific additional EU requirements apply:

(1) Wooden pallets

Wooden pallets may be used in areas of the establishments where products are fully packaged (e.g.,freezers or coolers)

The use of wooden pallets in rooms where exposed meat is present must be phased out.

As an interim measure, when wooden pallets are used in rooms where products is exposed, adequate control must be exercised to maintain the pallets free of contamination and damage. Plant management must ensure that pallets are in good repair and clean before use. Wooden pallets must be kept at least 3 metres away from exposed products and covered with a plastic.

(2) Product flow to assure all hygiene requirements

Exposed meat must be stored in a separate room from packaged meat, unless stored at different times.

(3) Packaging operations in the same room are subject to the following conditions

Packaging material must be assembled under hygienic conditions either in a separate room or, if in the cutting room, never within 3 meters of exposed products.

(4) EU ban on the use of anabolic substances in food animals

As a result of the EU ban on the use of anabolic substances in food animals, only pork meat (derived from animals of Canadian origin or if imported, the pigs must be certified by the competent authority as having been raised without hormonal growth promotants), horsemeat, bison meat, beef/veal produced according to the Canadian Program for certifying Freedom from Hormonal Growth Promotants (see Annex R), meat derived from culled dairy cows (e.g. Holstein, Ayrshire, Guernsey, Jersey, etc.), poultry meat, game and farmed game meat are eligible for export to the EU member states.

Controls to be implemented over imported pigs, cows, bison and growth promotants free beef/calves :

- The animals from which the meat is derived must be segregated at the ante-mortem inspection and kept physically separated from the other animals;
- The animals must be presented for slaughter at a predetermined period as a lot;
- The meat must be handled, from the time of evisceration to the time of shipping, in a manner permitting their identification and their continuous segregation from any other non-eligible meat product;
- The boxes containing meat must be properly and conspicuously identified: cow hearts, cow livers, bison tenderloins, beef tenderloins, etc., and to be

sealed with Health Mark at the time of packaging;
- The description of the product on the certificate must reflect the identification of the products printed on the boxes.

Our residue monitoring program for anabolic substances is directed to eligible meats, and veterinarians-in-charge, where applicable, will be requested to submit samples at predetermined date on a random basis.

(5) Microbiological testing for export to Finland and Sweden

All meat (including game and farmed game meat) intended for Finland and Sweden is to be checked for the presence of Salmonella and certified accordingly. For details see Council Decisions 95/409/EC (veal, beef,and pork), 95/410/EC as amended (live poultry for slaughter), 95/411/EC as amended (poultry meat), 2003/644/EC (breeding poultry and day old chicks), 2004/235/EC (laying hens), 95/168/EC as amended (table eggs), and Commission Decision 2003/470/EC (alternative methods for microbiological testing).

Consignments of fresh meat (72/462/EEC) intended for an establishment for the purpose of pasteurisation, sterilisation or for treatment having an equivalent effect are exempted from the above requirement.

(6) Pens for sick and suspect animals

Wood shall not be used for pens for sick and suspect animals.

(7) Dressing of calves

Hides must be removed at the time of slaughter.

(8) Shrouding of carcasses

Shrouding of carcasses is not permitted.

(9) Chilling of poultry meat

Refer to Directive 92/116/EEC, Annex I, Chapter VII.

(10) Compliance with EU rules on decontamination

Steam pasteurization or chemicals cannot be used for such purposes.

(11) Controls to be implemented over imported meat

The present certification provides for export of fresh meat derived from bovine, equine, swine, ovine and caprine animals of Canadian or USA origin.

In the case of meat products imported from the USA for subsequent cutting or boning and export, the following conditions must be met before the Animal Health and the Public Health certification could be issued:

- The meat product must be accompanied by a USDA/FSIS certification stating that the product is fully eligible for export to the E.U.
- The meat product must be marked with the "Health Mark" as required by the EU. The "Health Mark " applied to the boxes must bear identification marks that will permit the correlation between the certificate and the shipment.
- The USDA/FSIS certification must be used in lieu of the Meat Transfer Certificate and the same records as in section 6.2 below must be kept.

The following condition must be met before the "Certificate of Authenticity" for high

quality beef (see section 1.6 of introduction to this chapter for details), if requested, could be issued:

- The meat product must be accompanied by a USDA/FSIS certification stating that "the meat product was derived from carcasses or any cuts from bovine not over 30 months of age which have been fed for 100 days or more on a nutritionally balanced, high energy feed concentration containing no less than 70 per cent grain, and at least 20 pounds total feed per day."

In the case of fresh meat products imported for further processing the same conditions described above must be met. It is understood that the additional declaration need not appear on export certificates issued by E.U. Member States and that the export certificate issued by the appropriate competent authority will be used as a transfer certificate.

(12) Requirements for vehicles used to transport animals

Slaughter establishments must have on their premises facilities for cleaning and disinfecting vehicles used in the transport of animals, or have access to such facilities so that the vehicles can be cleaned and disinfected when required by the CFIA.

Note: in addition to the additional requirements listed above, inspection, marking and other requirements outlined in sections 3, 5 and 6 below must also be complied with, when applicable.

11.7.3.3 Specific or additional inspection procedures

11.7.3.3.1 Ante-mortem inspection

3.1.1 All animals except swine:

Antemortem inspection must be conducted by a veterinarian

3.1.2. Swine

3.1.2.1 Market hogs will be inspected in accordance with CFIA procedures.

3.1.2.2 Swine other than market hogs must be inspected by a veterinarian.

Note: Market hogs means fattening young pigs, as confirmed by antemortem inspection and dressed carcass weight which must not exceed 100 kg.

11.7.3.3.2 Post-mortem inspection

(a) Pigs

(i) heart inspection:

A. For market hogs, the following number of swine hearts from inspected and passed carcasses at each approved slaughter establishment must be incised and their interior surfaces inspected by a CFIA veterinarian:

1. Six (6) hearts per establishment per week (or a rate to yield 300 hearts/establishment/year) must be incised and their interior inspected. The CFIA veterinarian should randomly select one time per week to conduct the inspection. During this time, 6 hearts should be randomly selected. Each of the hearts should be laid open for examination of the endocardium in all chambers and associated valves.

2. Gross pathological lesions, including lesions of endocarditis, should be described and recorded. Negative findings should also be recorded. The records should be maintained on file in the inspection office (see Annex N for more details).

B. For swine other than market hogs, the heart must be incised lengthwise so as to open the ventricles and to cut through the interventricular septum.

(ii) meat: skeletal muscle is to be tested for trichina by the digestion method approved by the CFIA (in an on-site laboratory accredited in accordance with the CFIA requirements) or to be submitted to cold treatment in accordance with the requirements set in section 4.10.2(2) of Chapter 4 in plants specifically approved for that purpose. There are no requirements for freezing of offals such as livers, kidneys or hearts.

(b) Bovine

(i) livers: incision of the gastric surface and at the base of the caudate lobe to examine the bile ducts (see Annex L).

(ii) heads: two incisions must be made in the external masseters parallel to the mandible.

(c) Domestic solipeds

Skeletal muscle is to be tested for trichina by the digestion method approved by the CFIA (in an on-site laboratory accredited in accordance with the CFIA requirements) on a 5g sample from the lingual or the jaw muscle with negative results or to be submitted to cold treatment in accordance with the requirements set in section 4.10.2(2) of Chapter 4 in plants specifically approved for that purpose.

(d) Farmed game - wild boar

Skeletal muscle is to be tested for trichina by the digestion method approved by the CFIA (in an on-site laboratory accredited in accordance with the CFIA requirements) on a 5g sample of muscle with negative results.

11.7.3.3.3 Regular check on general hygiene

In addition to Canadian operational and preoperational sanitation requirements, the products testing requirements for E. coli and Salmonella in the section on USA this chapter (annex T and U) must be implemented.

11.7.3.3.4 CFIA supervision of cutting/boning establishments

CFIA controls of establishments approved to export to the EU must include, in addition to the usual inspection tasks applicable to verify compliance with Canadian requirements, verification of compliance with EU approval conditions specified in this

section, the correct use of the health mark and the eligibility status of the products through the use of transfer certificates.

In order to facilitate the CFIA controls over compliance with EU requirements, the operator is responsible to develop and implement procedures acceptable to the CFIA which will outline how the establishment will meet applicable additional EU requirements. The operator's control program should include monitoring, verification and record keeping activities.

The CFIA inspector must be present at the establishment each day the establishment produces for the EU market in order to verify compliance with applicable additional EU requirements and control the use of the health mark.

11.7.3.3.4.1 Veterinary Supervision

In addition to routine CFIA inspection conducted at the establishment producing for the EU, an official veterinarian must make the final review of the establishment to confirm compliance with all applicable requirements before a recommendation for approval is forwarded to CFIA headquarters.

Following the approval of the establishment, follow-up visits to the establishment by a CFIA official veterinarian must be conducted at least monthly to assess the continued compliance of the establishment, and as deemed necessary when compliance problems are identified (e.g., establishment is rated B or lower, report of non compliance received from the EU/MS country or refused shipment).

11.7.3.3.5 Information from farms supplying farmed game animals for slaughter.

The official veterinarian may issue an export certificate for meat derived from farmed game animals (including ostriches) only if he/she has information from farm of animal origin. The following model document issued from a private or CFIA veterinarian should be used. The official veterinarian signing the export certification shall keep the document from the farm on file.

I, Dr._____ provide regular veterinary inspection to the holding_____ Name and address for the purpose of diagnosing diseases transmissible to humans or animals. The herd is not under any animal health restriction. Done at_____ On_____ Name and signature of veterinarian_____

The certificate shall be renewed on yearly basis or any time when veterinary supervision or animal health of the herd changes.

11.7.3.4 Additional Certification

The certificates must:

- be drawn up in at least one of the official languages* of the country of destination and one of those of the Member State in which the import inspections provided for in articles 23 and 24 of Directive 72/462/EEC are carried out;
- accompany the products in the original;
- be made out for a single consignee;
- * When an importing country requests the additional certification in a language other than the ones currently available, it is the responsibility of the exporter to obtain such documents. A copy should be sent to Headquarters so it can be included in this section.

The following table is a summary of the additional certification required for export of various meat products to the EU Member States based on available information.

Annexes A-1 to A-3, D, E, K are available in foreign languages at the following internet site:

- http://europa.eu.int/eur-lex/en/search/search_lif.html (Decision 04/212/EC)

Annexes H and H-2 are available in foreign languages at the following internet site:

- http://europa.eu.int/eur-lex/en/search/search_lif.html (Decision 04/668/EC)

Annex L is available in foreign languages at the following internet site:

- http://europa.eu.int/eur-lex/en/search/search_lif.html (Decision 04/372/EC)

Product	Destination	Required certification	Remarks
Fresh meat of domestic bovines	All EU countries except France, Finland and Sweden	Annex A	
	France	Annex A + Annex A (France section)	
	Finland and Sweden	Annex A + Salmonella testing certificate (Annex J for Sweden)	For details, see Council Decisions 95/409/EEC, 95/410/EEC, 95/411/EEC and 03/470/EEC

Fresh meat of domestic swine	All countries except Finland and Sweden	Annex A-1	
	Finland and Sweden	Annex A-1 + Salmonella testing certificate (Annex J for Sweden)	For details, see Council Decisions 95/409/EEC, 95/410/EEC, 95/411/EEC and 03/470/EEC
Fresh meat of domestic solipeds	All EU countries	Annex A-2	
Fresh meat of poultry	All countries except Finland and Sweden	Annex C	
	Finland and Sweden	Annex C + Salmonella testing certificate (Annex J for Sweden)	For details, see Council Decisions 95/409/EEC, 95/410/EEC, 95/411/EEC and 03/470/EEC
Farmed game meat	All countries excluding Finland and Sweden	Annex C-1	Fresh meat of ratites
		Annex D	Fresh meat of farmed non-domestic animals other than equidae and suidae
		Annex E	Fresh meat of farmed non-domestic suidae
		Annex K-1	Fresh meat of farmed game birds excluding ratite
	Finland and Sweden	Annex C-1, D, E and K-1 (as applicable) + Salmonella testing certificate (Annex J for Sweden)	For details, see Council Decisions 95/409/EEC, 95/410/EEC, 95/411/EEC and 03/470/EEC
Meat products	All EU countries excluding France	Annex F + G or G-1 +	Annex B is applicable for products containing bovine, ovine, caprine meat

		Annex B	
	France	Annex F + G or G-1 + Annex A (France section)	Annex A (France section) is applicable for products containing bovine, ovine, caprine meat
Game Meat	All countries excluding France, Finland and Sweden	Annex K	Fresh meat of non-domestic animals other that equidae and suidae
	Finland and Sweden	Annex K + Salmonella testing certificate (Annex J for Sweden)	For details, see Council Decisions 95/409/EEC, 95/410/EEC, 95/411/EEC and 03/470/EEC
Casings	All EU countries	Annex I	
Animal by-products for the manufacture of technical products (including pharmaceutical products)	All EU countries Except France	Annex H + Annex B	Annex B is applicable for products containing bovine, ovine, caprine meat
	France	Annexe H + Annex B (France section)	Annex B (France section) is applicable for products containing bovine, ovine, caprine meat
Raw materials destined to the production of gelatine intended for human consumption	All EU countries except France	Annex H-1 + G-1 + Annex B	Annex B is applicable for products containing bovine, ovine, caprine meat
	France	Annexe H + G-1 + Annex B (France section)	Annex B (France section) is applicable for products containing bovine, ovine, caprine meat
Animal by-products for the manufacture of petfood	All EU countries except France	Annex H-2 + Annex B	Annex B is applicable for products containing bovine, ovine, caprine meat

	France	Annexe H-2 + Annex B (France section)	Annex B (France section) is applicable for products containing bovine, ovine, caprine meat

Fresh meat derived from bovine, swine, solipeds, game, farmed game animals,transiting or temporarily stored in EU (1)	Annex T
Casings transiting or temporarily stored in EU (1)	Annex T-1
Poultry meat products transiting or temporarily stored in EU (1)	Annex T-2
Meat preparation transiting or temporarily stored in EU (1)	Annex T-3
Meat products transiting or temporarily stored in EU (1)	Annex T-4

(1) See applicable Annex for the product as indicated in the table above for animal health requirements.

11.7.3.5 Specific marking and packaging requirements

11.7.3.5.1 Label bearing the health mark

The label bearing the health mark (see Annex Q) must be applied on products that fully meet the EU requirements at the time of packaging.

The health mark label must be applied to the packaging in such a way that it is destroyed when the packaging is opened. It must be placed over the lid and bottom junction, or over an encircling strap of the carton to prevent any unauthorized tampering of the product. In cases where the label is applied over an encircling strap, it must be applied in such a way that it will be broken when the strap is removed. If it is possible to remove the strap (and, therefore, open the carton) without damaging or breaking the label, it will be deemed not to comply with EU requirements. The label must also show a serial number.

To order labels bearing the health mark, the procedure described in section 11.3.(7) must be followed. Specifications for the health mark should be reviewed and accepted by the RVO. (Applicable information for the health mark are given in (c) below). When requested by the operator, additional information may appear on the sticker provided it is factual and not misleading. It is understood that unlike export stickers (CFIA 4091), the stickers used to apply the health mark must not bear the department name, logo or form number but the letters EU/UE.

Log books as required for export stickers (CFIA 4091) must also be kept for the health mark label (see 11.3.(6)).

Boxes bearing the health mark label, as described above, need not bear the export stickers (CFIA 4091). Instead, they should be stamped at the time of export with the export stamp.

11.7.3.5.2 Fresh Meat

(a) Health marking must be carried out under the responsibility of the official veterinarian.

The wrapping material bearing the health mark must be under departmental control.

(b) The health mark is oval and must be as follows:

- 6.5 cm wide, 4.5 cm high
- on the upper part: CANADA in capital letters
- in the centre, the registration number of the establishment
- the letters must be 0.8 cm high
- the figures must be 1 cm high

(c) Carcass and offal

The inspection legend must be applied in ink or hot branded as follows:

(i) Carcasses:

- over 65 kg: on each half carcass: external surface of thighs, loins, back, breast and shoulders
- other: at least four places on the shoulders and on the external surface of the thighs

(ii) Offal:

- The livers of bovine animals, swine and solipeds must be hot branded
- All other offal must be stamped in ink or hot branded unless wrapped or packaged and marked in accordance with (g) and (h), below.

(d) Cuts obtained in cutting plants from officially marked carcasses must be stamped in ink or hot branded unless they are wrapped or packaged, and marked in accordance with (g) and (h) below, and ribs must be marked in a way making it possible to identify the slaughterhouse of origin.

(e) Packaging must always be marked in accordance with (g), below.

(f) Packaged cut meat and packaged offal must bear the health mark. The legend must include the veterinary approval number of the cutting plant instead of that of the slaughterhouse. In the case of offal packaged at a slaughterhouse, the number included in the legend must be the veterinary approval number of the slaughterhouse concerned.

(g) In addition to the requirements in (g) above, where fresh meat is wrapped in commercial portions intended for direct sale to the consumer, a reproduction of the legend must also be printed on the wrapping or on a label affixed to the wrapping. The legend must include the veterinary approval number of the cutting plant or of the slaughterhouse concerned in the case of offal wrapped at a slaughterhouse. The

dimension requirements of the legend need not apply to the legend required under this point.

(h) The packaging may contain only meat cut from the same animal species.

(i) Fresh meat, which has undergone a freezing process, must bear an indication of the month and year in which it was frozen.

(j) Fresh meat, which has undergone a freezing process, must bear an indication of the month and year in which it was frozen.

11.7.3.5.3 Fresh Poultry Meat

The health mark must include :

(a) For meat wrapped in individual units or for small packages:

- on the upper part; the ISO code, (CA), reference of the country of origin.
- in the centre, the veterinary approval number of the slaughterhouse or, where appropriate, the cutting premises or rewrapping centre.

The letters and numbers must be 0.2 cm high.

(b) For large packages:

- an oval mark, at least 6.5 cm wide by 4.5 cm high, containing the name of the country;
- its ISO code, (CA), and veterinary approval number of the slaughterhouse or, where appropriate, the cutting premises or rewrapping centre;
- the letter must be at least 0.8 cm high and the figures at least 1.0 cm high;
- in addition, the health mark may include an indication enabling the identification of the veterinarian who carried out the health inspection of the meat.

The material used for marking must meet all hygiene requirements and the information must appear on it in a perfectly legible form.

In the case of (b) alone, please use the model shown in Annex Q and add the letters CA under the establishment number. The serial numbers on the health mark, recorded in inventory, will identify the veterinarian as required.

Details regarding packaging see Directive 92/116/EC, Annex I, Chapter XIV.

11.7.3.5.4 Labelling of beef and beef products

By January 1, 2000, the E.U. will likely have new specific labelling requirements for beef and beef products that would demand the identification of animals for traceability purposes [i.e. traceable to the farm of origin; see regulation - (EC) No. 820/97 of April 21, 1997].

The operator will be responsible for assuring that appropriate measures are taken to meet the labelling requirements of the country to which the product is being exported (including label approval if necessary).

Information on the label must allow traceability to the animals from which meat products are derived. For labelling purposes, records on the slaughtered animals should contain pertinent information such as farm of origin, sex, date of birth, etc. (see Article 16 of Regulation No. 820/97/EC).

Labelling claims:

An identification system must be in place for animals from which beef and beef products (including bison meat) are derived, at a level that will allow for the label claims to be substantiated. As an example, the declaration "Product of Canada" can only appear on products derived from animals born and raised in Canada. Currently, only animals slaughtered under the provisions of the "Canadian Program for Certifying Freedom from Hormonal Growth Promotants" are produced under an identification system that provides the necessary guarantees. Therefore, the words "Product of Canada" should not appear on the label of other products derived from bovine animals.

11.7.3.5.5 Prepared meat products

For details regarding marking and packaging see Directive 77/99/EC, Annex A, Chapter V and VI.

11.7.3.5.6 Mince meat and meat preparation

For details regarding marking and packaging see Directive 94/65/EC, Annex I, Chapter VI and VII.

11.7.3.5.7 Farmed game meat

For details regarding marking and packaging see Directive 91/495/EC, Annex I, Chapter III and 5.2 above for packaging requirements.

11.7.3.5.8 Game meat

For details regarding marking and packaging see Directive 92/45/EC, Annex I, Chapters VII and VIII.

11.7.3.6 Other requirements

11.7.3.6.1 Establishment approval

(i) Approval Protocol

- The operator must make a formal application to the appropriate Director, Program Network through the inspector-in-charge;
- In the application the operator must confirm awareness of applicable requirements and that the establishment is in compliance;
- A regional veterinary officer (RVO) will perform an inspection of the establishment in operation to evaluate its compliance with EU requirements. The RVO will inform the operator of his/her findings. If the RVO is satisfied that the facilities, operations and inspection comply with the requirements, and that the operator will undertake to comply with all applicable requirements, the Director of the Program Network will forward a recommendation for registration of the

establishment by the EU to the Director of the Food of Animal Origin Division (FAOD) ;
- If deemed necessary, a review of the plant by a NVS will be conducted;
- If, in the Canadian Food Inspection Agency's opinion, the plant meets the EU requirements, the Director of the FAOD will then make a formal recommendation for approval to the EU authorities;
- The EU may decide to inspect the establishment if they deem it necessary. The applicant will be informed accordingly;
- The Director, FAOD, will inform all concerned of the approval of the plant, when applicable.

Establishments approved to export to the EU are subject to periodic review by an EU inspector. The operator is responsible to ensure that the requirements are met on an ongoing basis to the satisfaction of the CFIA and EU officials.

(ii) Review Protocol

- Scheduling of reviews will be done as described in Section 1.7.5 of the manual of procedures. At the time of the review the plant should operate as if the product was prepared for export to the E.U. The E.U. reviewer will then be in a position to assess compliance with applicable requirements.
- Prior to the review, the information sheet (Annex M - 11.7.3. EU) should be completed. The inspector in charge and the operator should review the previous inspection reports and assurances given to ensure that appropriate action has been taken.
- With regard to documents review, the E.U. reviewer is mainly interested in the following: water analysis, residue monitoring program, sanitation program, pest control, export controls and inspection controls that will ensure that only eligible product is exported to the E.U. All these files should be pre-verified to make sure that they are complete and in compliance with the E.U. requirements.
- During the review the inspector in charge and the operator are responsible to accompany the E.U. reviewer to give him/her any explanations that may be required on the procedures in place at the establishment. They are also responsible to take appropriate corrective action when required. The NVS will explain the national policies when necessary.
- After the review, the E.U. inspector will give his/her comments as to the establishment and inspectional acceptability and outline deficiencies observed. If necessary, clarifications and reference to the E.E.C. Directives must be requested. Deficiencies will then be listed on form CFIA 1427. The time frame for corrective action plan to be provided by the operator, reviewed and accepted by the regional staff and forwarded to headquarters will also be stated on the CFIA 1427. When assurances are requested by the EU reviewer, part 1 of the Request for Assurances Form will be completed (see Annex P).
- The findings of the visit will then be presented to the operator by the inspector in charge. The RVO, the National Veterinary Supervisor and the E.U. reviewer, if he/she wishes to do so, will also be present to discuss the review findings with the operator. After the meeting, the operator will sign the CFIA 1427 and the Request for Assurances Form, if applicable, and will receive a copy. Additional copies will also be distributed as follows: one to the inspector in charge, one to the RVO and one to the NVS.
- When the E.U. reviewing officer has identified deficiencies in a Canadian establishment and requested assurances the operator must draw up an action plan with completion dates to address the identified deficiencies. Part 2 of the

Request for Assurances Form must be used for that purpose. This action plan is to be reviewed by the inspector in charge who will determine if it is acceptable. If found acceptable, it will be sent to the responsible RVO. The Request for Assurances Form can also be issued to the RVO in the case of deficiencies found in inspection activities. The RVO will then review the action plan. If found acceptable by all concerned at the Regional Office the Request for Assurances Form will be forwarded to headquarters with a covering letter signed by the Regional Director General. This must be done before the date stated on the applicable CFIA 1427. At headquarter's the documents will be reviewed and if found acceptable, the Canadian Food Inspection Agency will send a covering letter and the written assurances to the EU.

- The EU reviewer will determine if the information provided to him/her is satisfactory and will present his final report and recommendations to the EU Standing Veterinary Committee. The EU will update the list of approved establishment based on the Standing Veterinary Committee decision and will inform the Canadian Food Inspection Agency accordingly. Headquarter's will advise regional offices upon receipt of the information from the EU.
- In the case of non compliance to a written assurance without a good reason, it is the responsibility of the IIC (inspector in charge) to suspend certification for export to the EU and to notify the Meat Import/Export Manager at the Regional Office. The Regional Office must then notify headquarter's of this non compliance and headquarter's will in turn notify the EU that this particular establishment is under suspension for certification of export. Suspension of certification of export will continue until the EU is satisfied that the plant is in compliance. This may necessitate a successful review of the plant by an EU officer.
- Six months following an E.U. review a follow-up report signed by the RVO must be sent to the Chief of Export Programs, Meat and Poultry Products Division. This report is to update Plant Management's compliance to written assurances agreed to during the previous E.U. review. Part 3 of the Request for Assurances Form must be used for that purpose. The status of the plant regarding other deficiencies reported but for which no assurances were requested should also be included in the follow-up report.

11.7.3.6.2 Controls to implement to ensure that fresh meats are kept within the EU circuit:

(i) Controls to implement at slaughterhouses:

(A) In the case of packaged products shipped to a storage or directly to EU:

- all shipping containers must be sealed with the health mark at the time of packaging. See 5 (a,c and g) above for detailed information.
- issue a Meat Transfer Certificate (form CFIA 3433 - Annex O) for each meat shipment shipped to a storage awaiting exportation to EU;
- maintain a log book of shipments for export, including the following information:
  - date of health mark application(should also be the date of packaging).
  - health mark numbers
  - type of product
  - total weight
  - date of shipping to the storage, if applicable
- keep on file, a copy of Meat Transfer Certificate.

(B) In the case of products for further processing or packaging (carcasses, primal or subprimal cuts, offal for packaging, etc.) shipped to another establishment:

- issue a Meat Transfer Certificate for each meat shipment destined to EU and shipped to another establishment for further processing-packaging;
- the vehicle carrying these meats must be sealed under supervision of an inspector from the Canadian Food Inspection Agency, using seals supplied by the Agency;
- the seal number will be the identification mark placed on the Meat Transfer Certificate;
- maintain a log book of shipments ultimately destined for export, including the following information:
    - date of vehicle sealing
    - seal number
    - type of product
    - number of carcasses or containers
    - net weight
- keep on file, a copy of Meat Transfer Certificate.

NOTE: This procedure is applicable to all transfer of product for further processing from one approved establishment to another.

(ii) Controls to implement at a cutting/processing establishment:

- all shipping containers must be sealed with the health mark at the time of packaging. See 5 (a,c and g) above for detailed information.
- maintain a log book of shipments for export, including the following information:
    - date of arrival of the meat products
    - establishment number of plant of origin
    - seal number removed from the vehicle
    - type of product received
    - number of carcasses or containers received
    - net weight received
    - date of health mark application(should be also the date of packaging)
    - type of product
    - total weight
    - date of shipment to the storage, if applicable
- issue a Meat Transfer Certificate
- keep on file, a copy of Meat Transfer Certificate.

(iii) Controls to implement at a storage:

- place the products awaiting exportation to EU in a designated area;
- maintain a log book of shipments for export, including the following information:
    - date of arrival of boxes at the storage
    - originating establishment number
    - number of boxes
    - health mark applied on all boxes
    - type of product received
    - total weight of product received
- keep on file, a copy of Meat Transfer Certificate.

NOTES:

If there is no Meat Transfer Certificate issued, the veterinarian shall not sign the export certificate to the EU.

If trichina treatment is performed, all applicable controls must also be registered in a log book. The establishment must be approved by EU for that activity.

(iv) Completion of Form CFIA 3433 "Meat Transfer Certificate for Product Exported to EU", (see Annex O)

The following details shall be adhered to when completing the form CFIA 3433 (Meat Transfer Certificate - for Product Exported to EU):

- Precise and complete product description. (1)
- Identify animal species. (2)
- Must be precise. (3)
- The net weight must be accurate and in kilograms. (4)
- Insert health mark numbers applied on all boxes or the number of the departmental seal placed on a container of product. (5)
- Insert name and address of the consignor, (operator of slaughter or cutting establishment, as the case may be). (6)
- Insert the establishment number of the consignor. (7)
- Insert name and address of the consignee, (operator of slaughter or storage establishment, as the case may be). (8)
- Insert the establishment number of the consignee. (9)
- Insert the date(s) on which the animals were slaughtered. (10)
- Insert the establishment number where the animals were slaughtered. (11)
- Insert the date(s) on which the meat products were processed. (12)
- Insert the establishment number where the meat products were processed. (13)
- Signature of the Official Veterinary Inspector. The name shall be typed below the signature. (14)
- The official title of the signing veterinarian. (15)

11.7.3.6.3 Conditions governing the production, placing on the market and import of cleaned, salted or dried and/or heated stomachs, bladders and intestines

In addition to the conditions in Annex A and Chapter II of Annex B of Council Directive 77/99 EEC, establishments treating stomachs, bladders and intestines must comply with the following conditions:

- raw materials must come from animals which, following ante-mortem and post-mortem inspection have been judged suitable for human consumption;
- products which cannot be kept at ambient temperature must be stored until their dispatch in premises intended for that purpose. In particular, products which are not salted or dried must be kept at a temperature of less than 3 C;
- raw materials must be transported from the slaughterhouse of origin to the establishment under satisfactory hygiene conditions and, where appropriate in the light of the period between slaughter and the collection of the raw materials, refrigerated. Vehicles and containers for transporting such materials must have smooth internal surfaces that are easy to wash, clean and disinfect. Vehicles for refrigerated transport must be designed in such a way that the required temperature can be maintained throughout the period of transport;
- premises must be provided for the storage of wrapping and packaging materials;

- wrapping and packaging must take place under hygienic conditions in a room or in a place intended for that purpose;
- the use of wood is forbidden; however, the use of wooden pallets is authorized for the transport of the containers of the products concerned.

11.7.3.6.4 Conditions governing the production of farmed game meat

In addition to the requirements outlined in this section, requirements in EU Directive 91/495/EEC apply.

11.7.3.6.5 Conditions governing the production of wild game meat

In addition to the requirements outlined in this section, requirements in EU Directive 92/45/EEC and Decisions 97/218/EEC and 97/220/EEC apply.

11.7.3.6.6 Conditions governing the production of meat preparation / minced meat

In addition to the requirements outlined in this section, requirements in EU Directive 94/65/EEC and Decisions 97/29/EEC and 97/534/EEC apply.

PLEASE SEE A CFIA INSPECTOR TO OBTAIN CERTIFICATES/ANNEXES

[11.1] 11.2 | 11.3 | 11.4 | 11.5 | 11.6 | 11.7
Annex A | Annex B | Annex D | Annex E-2 | Annex F | Annex G | Annex I
Annex J | Annex O | Annex P | Annex Q | Annex R | Annex R-1 | Annex R-2]

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Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat /* CONSOLIDATED VERSION SEE 375Y0820(02) */

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COUNCIL DIRECTIVE of 26 June 1964 on health problems affecting intra-Community trade in fresh meat (64/433/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 43 and 100 thereof;

Having regard to the proposal from the Commission;

Having regard to the Opinion of the European Parliament 1;

Having regard to the Opinion of the Economic and Social Committee 2;

Whereas Council Regulation No 20 3 on the progressive establishment of a common organisation of the market in pigmeat is already in force and a similar regulation is to be adopted for beef and veal;

Whereas Council Regulation No 20 substitutes for the numerous traditional means of protection at the frontier a single system designed in particular to facilitate intra-Community trade ; whereas the regulation to be adopted for beef and veal is also designed to eliminate obstacles to such trade;

Whereas, so long as intra-Community trade is hindered by differences between the health requirements of Member States concerning meat, the implementation of the above-mentioned regulations will not have the desired effect;

Whereas, to eliminate such differences, the health provisions of the Member States must be approximated in line with regulations already adopted or in preparation on the progressive establishment of a common organisation of markets;

Whereas the object of this approximation must be in particular to standardise health requirements for meat in slaughterhouses and cutting rooms and during storage and transportation ; whereas the competent authorities of the Member States should be responsible for approving for intra-Community trade, slaughterhouses and cutting plants which meet the health requirements laid down by this Directive and for ensuring that the conditions for such approval are observed ; whereas provision should also be made for approval of cold stores by Member States;

Whereas the issue of a health certificate prepared by an official veterinarian of the exporting country is considered to be the best way of assuring the competent authorities of the country of destination that a consignment of meat complies with the provisions of this Directive ; whereas this certificate must accompany the consignment of meat to the place of destination;

Whereas Member States must have the right to prohibit the introduction of meat into their territory if it is found to be unfit for human consumption or if it does not comply with Community health provisions;

Whereas the consignor should at his own request or upon request of his representative be allowed to return the meat unless on health grounds there are reasons to the contrary;

Whereas, in case of a prohibition or restriction, the reasons therefor should be made known to the consignor or his representative and also, in certain cases, the competent authorities of the exporting country so that they may be aware of the reasons why such measures were imposed;

Whereas, in the event of dispute between himself and the authorities of the Member State of destination as to the justification for a prohibition or restriction, the consignor should be enabled to obtain the opinion of a veterinary expert whom he may select from a panel drawn up by the Commission;

1 OJ No 134, 14.12.1962, p. 2871/62. 2 OJ No 121, 29.7.1964, p. 2028/64. 3 OJ No 30, 20.4.1962, p. 945/62. Whereas, however, a rapid Community procedure should be provided for settling disputes between Member States as to the justification for the approval of a slaughterhouse or cutting room;

Whereas, in certain fields presenting special problems, the provisions in Member States cannot be approximated until a more thorough study has been made;

Whereas animal health provisions governing trade in live animals and meat will be the subject of other Community directives ; whereas it now seems necessary to take the first steps towards approximating national provisions in these fields by laying down certain conditions under which Member States may prohibit or restrict the introduction of meat into their territory for animal health reasons and by providing for a consultation procedure;

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to intra-Community trade in fresh meat of domestic animals of the following species : bovine animals, swine, sheep and goats and solipeds.

2. All parts of these animals which are fit for human consumption shall be considered to be meat.

3. All meat which has not undergone any preserving process shall be considered to be fresh meat ; however, chilled and frozen meat shall for the purposes of this Directive be considered to be fresh meat.

Article 2

For the purposes of this Directive: (a) "carcase" means the whole body of a slaughtered animal after bleeding, evisceration, removal of udders in the case of cows and, except in the case of pigs, skinning and separation of the head and limbs, the latter being cut off at the carpus and tarsus;

(b) "offal" means fresh meat other than that of the carcase as defined in paragraph (a);

(c) "viscera" means offal from the thoracic, abdominal and pelvic cavities, including the trachea and oesophagus;

(d) "official veterinarian" means the veterinarian designated by the competent central authority of the Member State;

(e) "exporting country" means the Member State from which fresh meat is sent to another Member State;

(f) "country of destination" means the Member State to which fresh meat is sent from another Member State.

Article 3

1. Each Member State shall ensure that only fresh meat which, without prejudice to Article 8, meets the following requirements is sent from its territory to that of another Member State: (a) it has been obtained from a slaughterhouse approved and supervised in accordance with Article 4 (1);

(b) it has, in the case of cuts smaller than the quarters listed in Article 6 (1) (A) (a), been cut in a cutting plant approved and supervised in accordance with Article 4 (1);

(c) it comes from a slaughter animal inspected ante mortem by an official veterinarian in accordance with Chapter IV of Annex I and found to be healthy;

(d) it has been treated under satisfactory hygienic conditions in accordance with Chapter V of Annex I;

(e) it has been inspected post mortem by an official veterinarian in accordance with Chapter VI of Annex I, and has shown no change except for traumatic lesions incurred shortly before slaughter or localised malformations or changes, provided that it is established, if necessary by appropriate laboratory tests, that these do not render the carcase and offal unfit for human consumption or dangerous to human health;

(f) it is stamped in accordance with Chapter VII of Annex I;

(g) it is accompanied by a health certificate during transportation to the country of destination in accordance with Chapter VIII of Annex I;

(h) in accordance with Chapter IX of Annex I, it is stored after post mortem inspection under satisfactory hygienic conditions in slaughterhouses and cutting plants approved and supervised in accordance with Article 4 (1) or in approved and supervised cold stores within the meaning of Article 4 (4);

(i) in accordance with Chapter X of Annex I, it is transported to the country of destination under satisfactory hygienic conditions.

2. The official veterinarian may, when carrying out the post mortem inspection referred to in 1 (e), be helped in purely material tasks by assistants specially trained for the purpose.

The Commission may after consulting the Member States lay down detailed rules governing such assistance.

3. The following shall be excluded from intra-Community trade: (a) fresh meat from boars and cryptorchid pigs;

(b) fresh meat treated with natural or artificial colouring matters, with the exception of colouring matters for stamping specified in Chapter VII of Annex I;

(c) fresh meat of animals in which any form of tuberculosis or one or more living or dead cysterci have been found;

(d) parts of carcases or offal showing the traumatic lesions incurred shortly before slaughter, malformations or changes referred to in Article 3 (1) (e);

(e) blood which has been chemically treated to prevent coagulation.

Article 4

1. The competent central authority of the Member State in whose territory the slaughterhouse or cutting plant is situated shall ensure that the approval provided for in Article 3 (1) (a) and (b) is granted only where the provisions of Chapters I, II and III of Annex I are observed.

The competent central authority shall ensure that observance of these provisions is permanently supervised by an official veterinarian ; it shall also ensure that approval is withdrawn when these provisions are no longer observed.

2. All approved slaughterhouses and cutting plants shall be registered on separate lists, each slaughterhouse and cutting plant having a veterinary approval number. Each Member State shall communicate the lists of approved slaughterhouses and cutting plants and their veterinary approval number to the other Member States and the Commission and notify them where necessary of any withdrawal of approval.

3. When a Member State considers that the provisions governing approval are not, or are no longer, observed in a slaughterhouse or cutting plant in another Member State, it shall inform the competent central authority of that State accordingly. The latter shall take all necessary measures and notify the competent central authority of the other Member State of the decisions taken and the reasons for such decisions.

If that other Member State fears that the necessary measures have not been taken or are inadequate, it may inform the Commission accordingly which shall seek the opinion of one or more veterinary experts. If the Commission finds, in the light of that opinion, that the provisions governing approval are not or are no longer observed, it shall authorise Member States to prohibit provisionally the introduction into their territory of fresh meat coming from that slaughterhouse or which has been cut in that cutting plant.

At the request of the Member State responsible for approval, the Commission shall withdraw such authorisation after seeking a further opinion from one or more veterinary experts and ascertaining that approval is once again justified.

Veterinary experts must be nationals of a Member State other than those involved in the dispute.

After consulting the Member States, the Commission shall lay down general rules for applying this paragraph, in particular as regards the appointment of veterinary experts and the procedure to be followed as regards delivery of opinions by them.

4. Cold stores shall, even when situated outside a slaughterhouse, be supervised by an official veterinarian as regards the storage of fresh meat.

The competent central authority of the Member State in whose territory the cold store is situated shall be responsible for approving that store and, for the storage of fresh meat, for withdrawing the approval.

Article 5

1. Without prejudice to the powers arising from the second sentence of the second subparagraph of Article 4 (3) a Member State may prohibit the marketing of fresh meat on its territory if: (a) at the time of the health inspection carried out in the country of destination such meat is found to be unfit for human consumption ; or

(b) the provisions of Article 3 have not been observed.

2. Decisions taken under paragraph 1 must, at the request of the consignor or his representative, authorise the return of the fresh meat provided this is not contrary to considerations of health.

3. These decisions must be communicated to the consignor or his representative together with the reasons for such decisions. These reasoned decisions must, on request, be communicated to him forthwith in writing with an indication of what appeals against them are open under current legislation and of the form and time limits in which they must be commenced.

4. Where such decisions are based on the diagnosis of a contagious or infectious disease, a deterioration dangerous to human health or a serious infringement of the provisions of this Directive, the decisions and the reasons therefor shall also be communicated forthwith to the competent central authority of the exporting country.

Article 6

1. Without prejudice to Article 3 (3) and pending the entry into force of provisions adopted by the European Economic Community, this Directive shall not affect Member States' provisions: A. which prohibit or restrict the introduction into their territory of the following: (a) pieces of carcases other than: 1. in the case of bovine animals, - half carcases and quarters;

2. in the case of swine, - half carcases and quarters;

- whole hams on the bone;

- whole shoulders on the bone;

- the dorso-lumbar region on the bone;

- fat;

- breasts.

The pieces mentioned in the last three indents must weigh at least 3 kilogrammes;

(b) offal separated from the carcase;

(c) fresh meat of solipeds;

B. concerning the conditions for the approval of the cold stores referred to in Article 4 (4) and any withdrawal of this approval;

C. concerning the treatment of slaughter animals with substances such as antibiotics, oestrogens, thyreostatics or tenderisers likely to make the consumption of fresh meat dangerous or harmful to human health;

D. concerning the addition of foreign substances to fresh meat and its treatment by ionising or ultraviolet radiation.

2. This Directive shall not affect Member States' provisions relating to detection of the presence of trichinae in fresh pigmeat.

Article 7

1. Rights of appeal existing under current legislation in the Member States against decisions taken pursuant to this Directive by the competent authorities shall not be affected by this Directive.

2. Each Member State shall grant to consignors whose fresh meat cannot be marketed pursuant to Article 5 (1) the right to obtain the opinion of a veterinary expert. Each Member State shall ensure that, before the competent authorities take any other measures such as destroying the meat, the veterinary experts have an opportunity of determining whether the conditions of Article 5 (1) are fulfilled.

The veterinary expert must be a national of a Member State other than the exporting country or country of destination.

The Commission, acting on a proposal from the Member States, shall draw up a panel of veterinary experts who may be instructed to formulate such opinions. After consulting the Member States, it shall lay down general rules which are to be applied in particular as regards the procedure, for formulation of these opinions.

Article 8

1. Without prejudice to paragraphs 2 to 4, the animal health provisions of Member States concerning trade in live animals and fresh meat shall apply until the entry into force of any measures taken by the European Economic Community in this field.

2. A Member State may, if there is a danger that animal diseases may be spread by the introduction into its territory of fresh meat from another Member State, take the following measures: (a) in the event of an outbreak of an epizootic disease in the other Member State, temporarily prohibit or restrict the introduction of meat from the affected areas of that Member State;

(b) if an epizootic disease becomes widespread or if there is an outbreak of another serious contagious or infectious animal disease, temporarily prohibit or restrict the introduction of meat from the entire territory of that State.

3. Measures taken by a Member State under paragraph 2 must be communicated within ten working days to the other Member States and to the Commission together with the precise reasons for such measures.

4. If the Member State concerned considers that the prohibition or restriction referred to in paragraph 2 is unjustified, it may apply to the Commission for the immediate opening of discussions.

Article 9

If the Community provisions relating to importation of fresh meat from third countries do not apply at the time when this Directive enters into force, or pending their becoming applicable, national provisions relating to imports from those countries shall not be more favourable than those governing intra-Community trade.

Article 10

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive and its Annexes within twelve months following its notification and shall forthwith inform the Commission thereof.

Article 11

This Directive is addressed to the Member States.

Done at Brussels, 26 June 1964.

For the Council

The President

C. HEGER

ANNEX I

CHAPTER I Conditions for the approval of slaughterhouses

1. Slaughterhouses must have: (a) adequate lairage for lodging the animals;

(b) slaughter rooms large enough for work to be carried out satisfactorily and which have a special place for slaughtering pigs;

(c) a room for emptying and cleansing stomachs and intestines;

(d) rooms for dressing guts and tripe;

(e) separate rooms for the storage of fat and for the storage of hides, horns and hooves;

(f) lockable premises reserved respectively for the accommodation of sick or suspect animals, the slaughter of such animals, the storage of detained meat and the storage of seized meat;

(g) sufficiently large chilling or refrigerating rooms;

(h) an adequately equipped lockable room for the exclusive use of the veterinary service ; a room suitably equipped for carrying out a trichinoscopic test when such test is compulsory;

(i) changing rooms, wash basins, showers and flush lavatories ; the latter shall not open directly on to the work rooms ; the wash basins must have hot and cold running water, materials for cleansing and disinfecting the hands and disposable hand towels ; the wash basins must be near the lavatories;

(j) facilities enabling the veterinary inspections provided for in this Directive to be carried out efficiently at any time;

(k) means of controlling access to and exit from the slaughter house;

(l) an adequate separation between the clean and the contaminated parts of the building;

(m) in rooms where work on meat is undertaken: - waterproof flooring which is easy to clean and disinfect, rot proof, slightly sloping and having a suitable drainage system for draining liquids to drains fitted with traps and gratings;

- smooth walls with light, coloured, washable coating or paint up to a height of at least 3 metres, with rounded angles and corners;

(n) adequate ventilation and steam extraction in rooms where work on meat is undertaken;

(o) in the same rooms, adequate natural or artificial lighting which does not distort colours;

(p) an adequate supply, under pressure, of drinking water only;

(q) an adequate supply of hot water;

(r) a waste water disposal system which meets hygiene requirements;

(s) in the work rooms, adequate equipment for cleansing and disinfecting hands and tools;

(t) equipment such that, after stunning, dressing can be carried out as far as possible on the suspended animal ; where flaying is carried out on metal cradles, these must be of non-corrodible materials and high enough for the carcase not to touch the floor;

(u) an overhead system of rails for the later handling of the meat;

(v) equipment for protection against insects and rodents:

(w) instruments and working equipment, in particular paunch tanks, of non-corrodible material and easy to cleanse and disinfect;

(x) a place specially equipped for dung;

(y) a place and adequate equipment for cleansing and disinfecting vehicles.

CHAPTER II Conditions for the approval of cutting plants

2. Cutting plants must have: (a) rooms for cutting meat, separated by walls from the other premises;

(b) sufficiently large chilling and refrigerating rooms;

(c) an adequately equipped lockable room for the exclusive use of the veterinary service;

(d) changing rooms, wash basins, showers and flush lavatories ; the latter shall not open directly on to the work rooms ; the wash basins must have hot and cold running water, materials for cleaning and disinfecting the hands and disposable hand towels ; the wash basins must be near the lavatories;

(e) in the cutting rooms: - waterproof flooring which is easy to cleanse and disinfect, rot proof, slightly sloping and having a suitable drainage system for draining off liquids to drains fitted with traps and gratings;

- smooth walls with light, coloured, washable coating or paint up to a height of at least 2 metres, with rounded angles and corners;

(f) cooling equipment in the cutting rooms to keep meat at a constant internal temperature of not more than + 7 °C;

(g) adequate ventilation in the cutting rooms;

(h) in the same rooms, adequate natural or artificial lighting which does not distort colours;

(i) an adequate supply, under pressure, of drinking water only;

(j) an adequate supply of hot water;

(k) waste water drainage equipment which meets hygiene requirements;

(l) in cutting rooms, adequate equipment for cleansing and disinfecting hands and tools;

(m) equipment for protection against insects and rodents;

(n) instruments and working equipment, such as non-corrodible tables with detachable cutting surfaces, containers, conveyor belts and saws of non-corrodible material and easy to cleanse and disinfect.

CHAPTER III Hygiene of staff, premises and equipment in slaughterhouses and cutting plants

3. Absolute cleanliness shall be required of staff, premises and equipment: (a) Staff must in particular wear clean working clothes and headgear with, where necessary, a neck shield. Persons who have been in contact with sick animals or infected meat must immediately afterwards carefully wash their hands and arms with hot water and then disinfect them. Smoking shall be forbidden in work rooms and store rooms.

(b) Dogs, cats and farmyard animals must not enter slaughterhouses and cutting plants. Rodents, insects and other vermin must be systematically destroyed.

(c) Equipment and instruments used for working on meat shall be kept clean and in a good state of repair. They shall be carefully cleansed and disinfected several times during the working day, at the end of the day's work and before being re-used when they have been contaminated, particularly by diseased germs.

4. Premises, instruments and working equipment must not be used for purposes other than working on meat. Instruments for meat cutting must be used solely for this purpose.

5. Meat must not come into contact with the ground.

6. The use of detergents, disinfectants and pesticides must not affect the health of the meat.

7. Persons likely to contaminate meat shall be prohibited from working on it and handling it, in particular persons: (a) suffering from or suspected of suffering from typhoid fever, paratyphus A and B, infectious enteritis (salmonellosis), dysentery, infectious hepatitis, scarlet fever or carriers of agents of these diseases;

(b) suffering from or suspected of suffering from contagious tuberculosis;

(c) suffering from or suspected of suffering from a contagious skin disease;

(d) exercising at the same time an activity which might cause microbes to be transmitted to meat;

(e) wearing a bandage on the hands, except for a sticking plaster protecting a fresh and non-infected finger wound.

8. A medical certificate shall be required from any person working on meat. It shall attest that there is no impediment to such employment ; it shall be renewed annually and each time the official veterinarian so requests ; it shall be kept at the disposal of the latter.

CHAPTER IV Ante mortem health inspection

9. Animals must undergo ante mortem inspection on the day of their arrival at the slaughterhouse. The inspection must be repeated immediately before slaughter if the animal has been in the lairage for more than twenty-four hours.

10. The official veterinarian must make the ante mortem inspection in accordance with profesional rules and

under suitable lighting.

11. The inspection must determine: (a) whether the animals are suffering from a disease which can be transmitted to humans and animals or whether they show symptoms or are in a general condition such as to indicate that the disease may occur;

(b) whether they show symptoms of a disease or a disorder of their general condition which is likely to make the meat unfit for human consumption;

(c) whether they are tired or agitated.

12. Animals may not be slaughtered for intra-Community trade in fresh meat: (a) which show any of the conditions listed in paragraph 11 (a) and (b);

(b) which have not been rested for an adequate period of time which, for tired or agitated animals, must not be less than twenty-four hours;

(c) in which any form of tuberculosis has been found or which react positively to tuberculin and are thus found to be suffering from tuberculosis.

CHAPTER V Slaughter and cutting hygiene

13. Slaughter animals brought into slaughter premises must be slaughtered immediately.

14. Bleeding must be complete ; blood intended for human consumption must be collected in absolutely clean containers. It must not be stirred by hand and only with instruments which meet hygiene requirements.

15. Immediate and complete skinning shall be compulsory, except for pigs. When not skinned, pigs shall have their bristles removed immediately.

16. Evisceration must be carried out immediately and completed not later than half an hour after bleeding. The lungs, heart, liver, spleen and mediastinum may either be detached or left attached to the carcase by their natural connections. If detached, they must be numbered or identified in some way to enable them to be recognised as belonging to a given carcase ; this shall also apply to the head, tongue, digestive tract and any other part of the animal required for inspection. The above-mentioned parts must remain near the carcase until the inspection is complete. For all species the kidneys must remain attached to the carcase by their natural connections but be removed from their fatty covering.

17. Cleansing of meat by wiping with a cloth, and inflation, are prohibited.

18. Carcases of solipeds, pigs and bovine animals except calves must be submitted for inspection split lengthwise into half carcases down the spinal column. In the case of pigs and solipeds, the head shall also be split lengthwise. If the inspection so necessitates the official veterinarian may require any carcase to be split lengthwise.

19. Cutting up the carcase or removal or treatment or any part of the slaughtered animal before the inspection has been completed is prohibited.

20. Detained or seized meat, stomachs, intestines, hides, skins, horns and hooves must be removed as soon as possible to special premises.

21. If the blood of several animals is collected in the same container, the entire contents shall be excluded from intra-Community trade if the meat of one of the animals in the consignment has been declared unfit for human consumption.

22. Cutting into pieces smaller than half carcases or quarters shall be allowed only in cutting plants.

CHAPTER VI Post mortem health inspection

23. All parts of the animal, including blood, must be inspected immediately after slaughter.

24. The post mortem inspection must include: (a) visual inspection of the slaughtered animal;

(b) palpation of certain organs, in particular the lungs, liver, spleen, uterus, udder and tongue;

(c) incisions of organs and of lymph nodes;

(d) investigation of anomalies in consistency, colour, smell and, where appropriate, taste;

(e) where necessary, laboratory waste.

25. The official veterinarian must examine, in particular: (a) the colour of the blood, its coagulation properties and the possible presence of foreign bodies in the blood;

(b) the head, throat, retro-pharyngeal submaxillary and parotid lymph nodes, (Lnn. retro-pharyngiales, mandibulares and parotidei) and the tonsils, the tongue having been freed to permit a detailed inpection of the mouth and the fauces. The tonsils must be removed after inspection;

(c) the lungs, trachea, oesophagus, bronchial and mediastinal lymph nodes (Lnn. bifurcationes, eparteriales and mediastinales), the trachea and the main branches of the bronchi having been opened lengthwise and the lungs having been incised in their last third, perpendicular to their main axes;

(d) the pericardium and the heart, the latter being incised lengthwise so as to open the ventricles and to cut through the inter-ventricular septum;

(e) the diaphragm;

(f) the liver, gall-bladder and bile ducts and the hepatic and pancreatic lymph nodes (Lnn. portales);

(g) the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (Lnn. gastrici mesenterici, craniales and caudales);

(h) the spleen;

(i) the kidneys and their lymph nodes (Lnn. renales) and the bladder;

(j) the pleura and peritoneum;

(k) the genital organs ; in cows, the uterus shall be opened by a lengthwise incision;

(l) the udder and its lymph nodes (Lnn. supramammarii) ; in cows, the udder shall be opened by a long, deep incision as far as the lactiferous sinuses;

(m) the umbilical region and joints of young animals ; in case of doubt, the umbilical region must be incised and the joints opened.

The lymph nodes referred to above must be systematically freed and sliced as thinly as possible along their main axes.

In case of doubt the following lymph nodes must also be incised in the same way : superficial cervical, prescapular (Lnn. cervales superficiales), axillaries (Lnn. axillares proprii et primae costae), substernal (Lnn. sternales craniales), deep cervical (Lnn. cervicales profundi), costocervical (Lnn. costocervicales), popliteal (Lnn. poplitei), precrural (Lnn. subiliaci), ischiatic (Lnn. ischiatici), iliac and sublumbar (Lnn. iliaci et lumbales).

In sheep and goats, the opening of the heart and incision of the lymph nodes of the head must only be carried out in case of doubt.

26. In addition, the official veterinarian must systematically carry out: A. An investigation for cysticercosis: (a) in bovine animals over six weeks old, at the level of: - the tongue, of which the musculature must be incised lengthwise on the lower surface, without damaging the organ excessively;

- the oesophagus, which must be freed from the trachea;

- the heart, which, in addition to the incision provided for in paragraph 25 (d), must be split from two opposite points from the auricles to the apex of the external and internal masseters, which shall be incised along two planes parallel to the manible from its lower edge to its upper muscular insertion;

- the diaphragm, the muscular part of which must be freed from the serous part;

- the muscular surfaces of the carcase which are directly visible;

(b) in swine, at the level: - of the directly visible muscular surfaces, in particular at the level of the thigh muscles, the abdominal wall, the psoas muscles freed from fatty tissue, the pillars of the diaphragm, the intercostal muscles, the heart, tongue, and larynx.

B. An investigation for distomatosis in bovine animals, sheep and goats by means of incisions on the gastric surface of the liver to examine the bile ducts and by means of a deep incision at the base of the Spiegel lobe.

C. An investigation for glanders in solipeds by means of careful examination of mucous membranes from the trachea, larynx, nasal cavities, sinuses and their ramifications, after splitting the head in the median plane and excision of the nasal septum.

CHAPTER VII Stamping

27. Stamping must be carried out under the responsibility of an official veterinarian.

28. The stamp must be an oval mark 6 75 cm wide by 4 75 cm high. The following information must appear on the mark in perfectly legible characters: - on the upper part, the name of the exporting country in capitals,

- in the centre, the veterinary approval number of the slaughterhouse,

- on the lower part, one of the following sets of initials, CEE, EEG or EWG.

The letters must be 0 78 cm high and the figures 1 cm high.

29. Carcases shall be marked in ink with a stamp in accordance with 28: - those weighing more than 60 kilogrammes must be stamped on each half-carcase, in the following places at least : external surface of the thigh, loins, back, breast, shoulder and pleura in the dorsal region;

- other carcases must be stamped in at least four places, on the shoulders and on the external surface of the thighs.

30. Heads, tongues, hearts, lungs and livers must be marked with ink or hot-branded with a stamp in accordance with paragraph 28. However, in the case of sheep and goats, stamping of tongues and hearts shall not be

compulsory.

31. Cuts obtained in the cutting plants from properly stamped carcases must, where they do not bear a stamp, be marked with ink or hot-branded with a stamp in accordance with paragraph 28 which shall bear in its centre the number of the cutting plant instead of the veterinary approval number of the slaughterhouse.

32. When cuts from carcases or offal are consigned in packages, a stamp as provided for in paragraphs 28 and 31 must be affixed to a clearly visible label attached to the package.

This label shall, in addition, bear the following information: - a serial number;

- the anatomical description of the cuts or offal;

- the indication of the animal species to which the cuts or offal belong;

- the net weight of each package.

A duplicate of this label must be placed inside each package.

33. Only methyl violet may be used for stamping with ink.

CHAPTER VIII Health certificate

34. The health certificate accompanying meat during transportation to the country of destination must be issued by an official veterinarian at the time of loading. It must be expressed in the language of the country of destination at least and contain the information specified in the model in Annex II.

CHAPTER IX Storage

35. Fresh meat intended for intra-Community trade must be chilled immediately after the post mortem inspection and kept at a constant temperature of not more than + 7 °C for carcases and cuts and + 3 °C for offal.

CHAPTER X Transport

36. Fresh meat must be transported in sealed vehicles or containers, designed and equipped in such a way that the temperatures specified in Chapter IX are maintained throughout transportation.

37. Vehicles or containers intended for transporting such meat must meet the following requirements: (a) their inside surfaces or any other part which may come into contact with the meat must be of non-corrodible material which cannot affect the organoleptic character of the meat nor render it harmful to human health ; these surfaces must be smooth and easy to cleanse and disinfect;

(b) they must be provided with efficient devices for protecting the meat against insects and dust and be watertight to prevent drainage of liquids;

(c) for transporting carcases, half-carcases or quarters, they must be equipped with non-corrodible fittings for hanging the meat fixed at such a height that the meat cannot touch the floor ; this provision shall not apply to frozen meat in hygienic packing.

38. Vehicles or containers intended for transporting meat may in no case be used for transporting live animals or any product likely to affect or contaminate meat.

39. No other product may be transported at the same time as the meat in the same vehicle or container. In addition, stomachs may not be transported therein unless scalded, and heads and feet unless they are skinned or scalded and depilated.

40. Vehicles or containers used for the transport of meat must be cleansed and disinfected immediately after unloading.

41. Carcases, half-carcases and quarters, excluding frozen meat packed in accordance with hygiene requirements, must always be hung up for transportation. Other cuts and offal must be hung or placed on supports if not packed or contained in non-corrodible containers. Such supports, packagings or containers must meet hygiene requirements. The viscera must always be transported in strong waterproof and greaseproof packaging which may only be re-used after cleansing and disinfection.

42. The official veterinarian must ensure before consignment that transport vehicles or containers and loading conditions meet the hygiene requirements of this Chapter.

ANNEX II

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（参考資料）

・日本と米国のサーベイランスの対比

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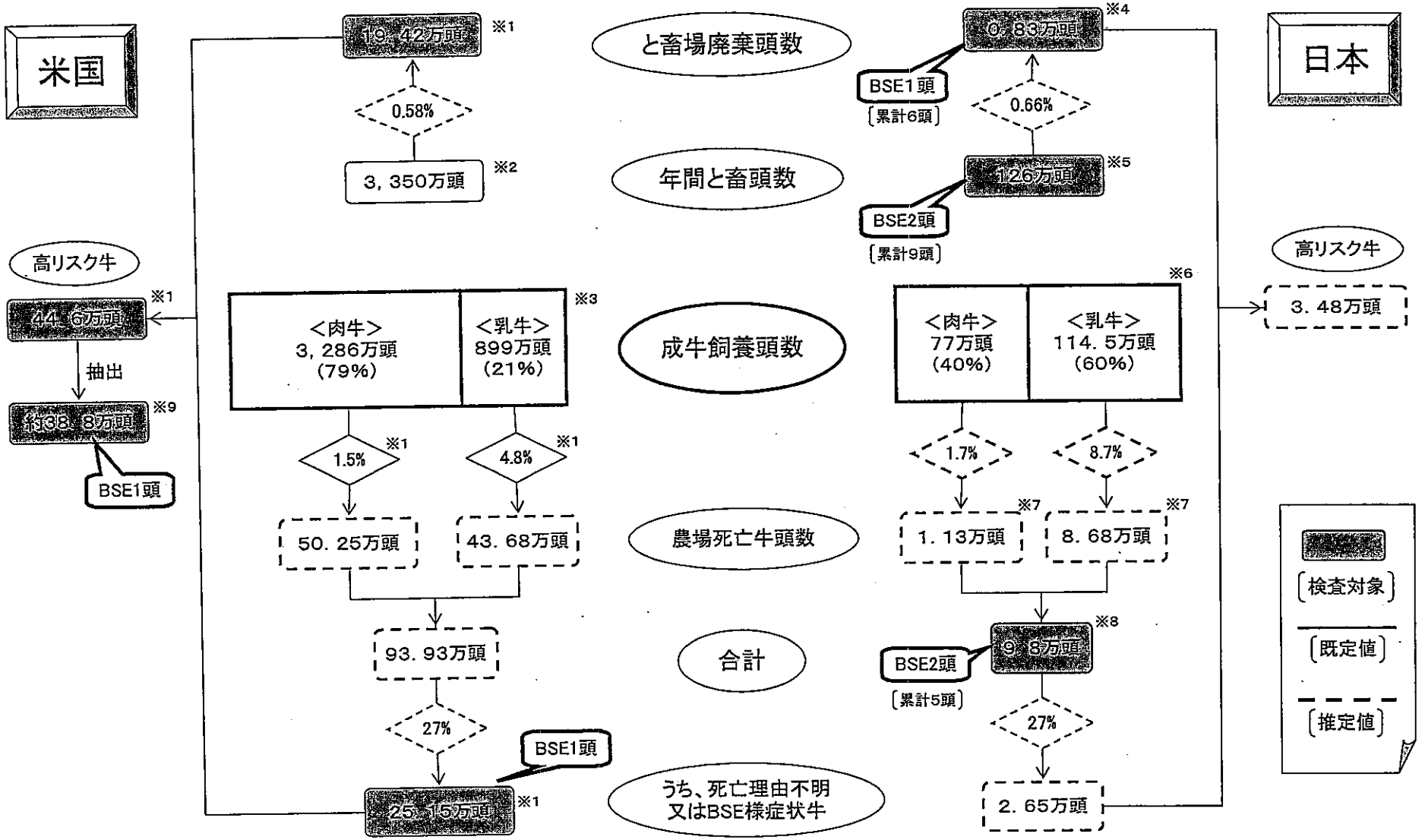

※1 【Bovine Spongiform Encephalopathy (BSE) Surveillance Plan(2004.3.15 APHIS)】(諮問参考資料27)
※2 【Livestock Slaughter 2004 Summary(NASS USDA)】(諮問参考資料15)
※3 【United States and Canadian Cattle (Agricultural Statistics Board NASS USDA)】(諮問参考資料14)
※4 【牛海綿状脳症(BSE)のスクリーニング検査結果について(週報)】(厚生労働省ホームページ)
※5 【平成16年畜産物流通統計】(諮問参考資料17)
※6 平成17年畜産統計
※7 死亡牛の届出資料より、利用可能なものからの推計値
※8 平成16年度死亡牛届出頭数
※9 米国のBSEサーベイランス実績(H16.6～H17.6.21)

＜委員限り＞

（参考資料）

・カナダにおけるＢＳＥ感染牛の診断、サーベイランスの年齢分布等