資料 9

平 成 １ ７ 年 ６ 月
食品安全委員会事務局

# 米国におけるＢＳＥ（２例目）の確定について

１．６月２４日（現地時間）、米国農務省（ＵＳＤＡ）から、ＢＳＥ疑似陽性牛の確認検査の結果に関し、次の内容の発表があった。

（１）６月１０日（現地時間）に公表された、ＢＳＥ疑似陽性牛に関する、英国（ウェイブリッジ）の研究所における確認検査の結果、当該牛はＢＳＥ陽性であると確認されたこと。

（２）今後、一次検査の結果擬陽性となった牛に関し、免疫組織化学的検査（ＩＨＣ）及びウェスタンブロット法による検査（ＷＢ）の両方で確認検査を行うことを指示した。本日以降、擬陽性牛は、ＩＨＣ及びＷＢ両方で確認検査を行い、いずれかの検査結果が陽性となった場合には、ＢＳＥ陽性と判定されること。

（３）当該牛に関する疫学的調査を実施する。なお、当該牛は飼料規制以前の牛であり、食用が禁止されている歩行困難牛（ダウナー）であったこと。

２．同日、１に関連し、米国農務省動植物検査局（ＡＰＨＩＳ）から、米国農務省が昨年１１月に行った確認検査で陽性と判断できなかった理由等に関し、次の内容のファクトシートの公表があった。

（１）当該牛は、非常に弱い陽性であり、農務省のＩＨＣの感度では、発見できなかった可能性があること。

（２）当該牛の脳の異常プリオンの分布は均等ではなく、隣接した箇所を検査しても同一の結果が得られない可能性があること。

（参考１）米国において確認された一次検査陽性牛

| | 一次検査 | | | 確認検査 | | | 判定 |
|---|---|---|---|---|---|---|---|
| | 検査日 | 検査方法 | 結果 | 確定日 | 確認検査法 | 結果 | |
| 1 | 2004年6月25日 | エライザ法 | 陽性 | 2004年6月30日 | 免疫組織化学的検査 | 陰性 | 陰性 |
| 2 | 2004年6月29日 | エライザ法 | 陽性 | 2004年7月2日 | 免疫組織化学的検査 | 陰性 | 陰性 |
| ③ | 2004年11月18日 | エライザ法 | 陽性 | 2004年11月23日 | 免疫組織化学的検査 | 陰性 | 陰性 |

（注）当該牛は③の牛である。

（参考２）

# 米農務省による記者発表資料のポイント（２４日）

１．検査結果及び今後の検査手法の検討

（１）農務省は、英国ウェイブリッジにある獣医学研究所から、最終的な検査結果を受領し、当該（昨年１１月に採取された）サンプルは、ＢＳＥ陽性であると確認した。

（２）米農務省は、新たな検査プロトコールを作成する。今後（簡易迅速な検査により）結論できない(inconclusive)結果が得られた場合には、確認検査として、免疫組織化学検査（ＩＨＣ）及びウェスタンブロット法（ＷＢ）の両方の検査を行い、いずれか一方の検査結果が陽性であれば、ＢＳＥ陽性とされる。

２．疫学調査

（１）当該牛の生まれた群れを確認するための疫学調査（トレース調査）を開始したが、未だ完了していない。

（２）当該牛は、飼料規制が導入された９７年以前の産まれである。

３．当該牛の特徴及びＢＳＥ検査の経緯

（１）昨年１１月、ＢＳＥリスクが高いとみなされる歩行できない牛（へたり牛(downer)）であったため、検査対象とされた。

（２）昨年１１月の時点で、農務省が確認検査としてＩＨＣを実施し、ＢＳＥ陰性との結果を得た。

（３）今月の初めに、農務省の監査局長が、もう一つの確認検査手法であるＷＢを実施することを勧告した。ＷＢにより、ＢＳＥ陽性との結果が得られたため、米農務省は、英国の獣医学研究所に当該サンプルを送付し、更なる分析を依頼した。

（４）へたり牛は、２００４年１月より暫定的最終規則(interim final rule)により、人の食料供給に入ることが禁じられている。

４．米国におけるＢＳＥ対策の検討

（１）米国の消費者と家畜をＢＳＥから守るために、農務省はコミットしており、強化されたサーベイランスによりＢＳＥを見つける努力を継続する。

（２）十分なデータが蓄積されれば、農務省は、外部の専門家と分析し、現行のＢＳＥ対策に変更が必要か否か決定する。

５．情報提供

ＢＳＥ陽性牛が確認されたことは、食料供給の安全性に全く影響はない。疫学的調査が進めば、農務省は適時適切に情報を公開する。

（参考３）

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# USDA ANNOUNCES BSE TEST RESULTS AND NEW BSE CONFIRMATORY TESTING PROTOCOL

WASHINGTON, June 24, 2005 -- Agriculture Secretary Mike Johanns today announced that the U.S. Department of Agriculture has received final test results from The Veterinary Laboratories Agency in Weybridge, England, confirming that a sample from an animal that was blocked from the food supply in November 2004 has tested positive for bovine spongiform encephalopathy (BSE). Johanns also directed USDA scientists to work with international experts to thoughtfully develop a new protocol that includes performing dual confirmatory tests in the event of another "inconclusive" BSE screening test.

"We are currently testing nearly 1,000 animals per day as part of our BSE enhanced surveillance program, more than 388,000 total tests, and this is the first confirmed case resulting from our surveillance," Johanns said. "I am encouraged that our interlocking safeguards are working exactly as intended. This animal was blocked from entering the food supply because of the firewalls we have in place. Americans have every reason to continue to be confident in the safety of our beef."

Effective immediately, if another BSE rapid screening test results in inconclusive findings, USDA will run both an IHC and Western blot confirmatory test. If results from either confirmatory test are positive, the sample will be considered positive for BSE.

"I want to make sure we continue to give consumers every reason to be confident in the health of our cattle herd," Johanns said. "By adding the second confirmatory test, we boost that confidence and bring our testing in line with the evolving worldwide trend to use both IHC and Western blot together as confirmatory tests for BSE."

USDA has initiated an epidemiological investigation to determine the animal's herd of origin. That investigation is not yet complete. The animal was born before the United States instituted a ruminant-to-ruminant feed ban in August 1997, which prevents the use of most mammalian protein in cattle feed. According to internationally accepted research, feed containing meat-and-bone meal is the primary way BSE is transferred to the cattle population.

The animal was selected for testing because, as a non-ambulatory animal, it was considered to be at higher risk for BSE. An initial screening test on the animal in November 2004 was inconclusive, triggering USDA to conduct the internationally accepted confirmatory IHC tests. Those test results were negative. Earlier this month, USDA's Office of the Inspector General recommended further testing of the seven-month-old sample using another internationally recognized confirmatory test, the Western blot. Unlike the IHC, the Western blot was reactive, prompting USDA to send samples from the animal to the Weybridge laboratory for further analysis.

The laboratory in Weybridge, England, is recognized by the World Animal Health Organization, or OIE, as a world reference laboratory for BSE. Weybridge officials this week conducted a combination of rapid, IHC and Western blot testing on tissue samples from the animal in question. At the same time these diagnostic tests were being run by Weybridge, USDA conducted its own additional tests.

As a non-ambulatory, or "downer" animal, the cow was prohibited from entering the human food supply, under an interim final rule in effect since January 2004. Research has shown that BSE is most likely to be found in older non-ambulatory cattle, animals showing signs of central nervous system disorders, injured or emaciated animals, and cattle that have died for unexplained reasons. USDA's testing program targets these groups of animals for testing.

The system of human health protections includes the USDA ban on specified risk materials, or SRM's, from the food supply. SRM's are most likely to contain the BSE agent if it is present in an animal. Additional measures, such as a longstanding ban on importing cattle and beef products from high-risk countries, a ruminant-to-ruminant feed ban, U.S. slaughter practices, and aggressive surveillance provide a series of interlocking safeguards to protect U.S. consumers and animal health.

USDA remains committed to protecting both U.S. consumers and U.S. livestock from BSE, and to that end continues efforts to detect the disease through its enhanced BSE surveillance program. Once sufficient data from the surveillance program has been accumulated, USDA will consult with outside experts to analyze it and determine whether any changes to existing risk management measures are necessary.

This confirmed case of BSE in no way impacts the safety of our nation's food supply. As the epidemiological investigation progresses, USDA will continue to communicate findings in a timely and transparent manner.

APHIS Factsheet

Veterinary Services June 2005

# The IHC Test Variables:

- IHC has been the primary confirmatory test for USDA's BSE surveillance program and is recognized by the World Organization for Animal Health, or OIE.
- IHC allows scientists to determine if a sample is positive for BSE in two distinct ways:
  1.) A staining technique (presence of abnormal prion protein) that uses antibodies to detect abnormal prion protein in the brain.
  2.) A visual examination to determine whether there are lesions (holes or "spongy" appearances) present in the brain.
- **Several variables could yield conflicting results:**
  - IHC is not a standardized, commercially available test. It involves variables, including several options in types of antibodies and other reactive agents. The sensitivity of any given test is influenced by those variables.
  - If the level of infectivity in the animal is extremely low, the abnormal prion in the brain will be minimal and therefore more difficult to detect.
  - Variations in the conditions under which the staining process is performed, such as chemicals and reactive agents used, temperature and length of antibody exposure, can also cause the test to yield different results.

## Testing History on This Animal:

- In November 2004, a sample from this animal returned inconclusive for BSE on a Biorad screening test.
- The sample was subjected to an IHC confirmatory test, which returned negative.
- USDA scientists also ran an additional, experimental IHC "rapid" tissue fixation test for academic purposes, which can be conducted more quickly than the IHC confirmatory test and is therefore of interest to the scientific community, but it has not been approved internationally.
- While some abnormalities were noted in the experimental IHC test results, because the test was not a validated procedure, and because the two approved IHC tests came back negative, the results were not considered to be of regulatory significance and therefore were not reported beyond the laboratory.
- A Western blot test conducted the week of June 5, 2005, returned positive for BSE.
- An additional IHC confirmatory test conducted the week of June 13, 2005, by USDA scientists utilizing different antibodies from the November 2004 test, confirmed this case as weakly positive for BSE.
- The Veterinary Laboratories Agency in Weybridge, England, conducted a series of diagnostic tests including an IHC, using different antibodies from those used by USDA in November 2004, which returned positive results for BSE.
- Experts from the Weybridge lab confirmed the accuracy of the results of USDA's November confirmatory IHC test, concurring that the case could not have been confirmed on the basis of this sample.
- Weybridge experts also examined the November experimental IHC test and interpreted the results to be positive.

## Potential Causes of Conflicting Results:

- USDA scientists are consulting with Weybridge scientists to determine the cause of the conflicting IHC test results.
- Several factors could cause or contribute to the discrepancy as follows:
  - This animal had a very low level of infectivity and therefore the sensitivity of USDA's routine IHC test might not have been sufficient to detect the disease.
  - Weybridge experts indicate that deposits of abnormal prion in the brain tissue were not uniformly distributed and were present at low concentration, which means that even adjacent samples of brain tissue might not give identical results.

## USDA Protocol Review:

- USDA will develop a protocol to conduct dual confirmatory tests, the IHC and the Western blot, when the screening test, the Biorad, returns an inconclusive result.

- USDA and Weybridge scientists are in agreement that the Biorad test is a very effective and appropriate screening test.

- USDA scientists will consult with Weybridge scientists to assess the array of antibodies available for use in IHC confirmatory tests to determine the most appropriate for use in United States confirmatory tests. Those consultations will be repeated periodically.

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