米国厚生省
プレス発表

2004年1月26日

現在のBSE伝染防御対策強化のための拡充保護対策

厚生省長官が幾つかの新しい公衆衛生上の施策を発表した。施策はFDAによって実施されるもので国民をBSEの原因物質への曝露から保護するために設けられている現在の多層的な防護壁を大幅に強化するものである。

現在の何重にも渡る防護壁はUSDAとFDAによって設けられたものであり、BSEから米国の消費者を守るために非常に有効に働いてきた。最初の防護壁は1989年の輸入管理である。第二はUSDAのBSE牛のサーベイランスプログラムである。第三はFDAによる1997年の牛を含む反芻動物飼料への肉骨粉禁止である。第四は最近USDAより発表されたBSEのリスクの高い牛の部位をヒトの食用への流通を禁止するものである。第五はBSE陽性牛が発見された場合の潜在的被害に対する有効な対応計画である。今回12月23日に発見された際にこの非常事態対策は直ちに開始された。

本日発表される新しい安全対策は科学に基づき、既に有効に機能している安全対策を更に強化する。

具体的にはHHSはヒトの食品（サプリメントを含む）および化粧品への特定の牛由来の成分の使用禁止である。これにより既に米国人のBSEへの曝露対策として規制されているUSDA管轄下製品にFDAが規制する製品が加わる。

FDAは更に現在許可されている特定の牛や他の反芻動物飼料製造基準を禁止する。これにより1997年のFDAの動物飼料法はさらに強化される。

動物飼料法の順守率は99%に上っているがこれを更に上げるための努力をする。最後に将来のBSE予防に寄与する新しい技術の改良と開発を継続する。

新しい防御措置の実施のため、FDAは公告により有効となる2件の暫定最終法規を発表する。

第一の暫定最終法規は次の材料をヒトの食品（サプリメントを含む）および化粧品として使用することを禁止する。

- “歩行不能牛”からの全ての材料
- “死亡牛”からの全ての材料（農場で死亡した牛：処分場につく以前に死亡した牛）
- 特定危険部位（30ヶ月令以上牛の頭蓋骨、脳、三叉神経節、眼球、脊椎柱、脊髄索、背部神経節根、及び全ての年齢牛の小腸・扁桃腺）
- 危険部位を含む可能性のある機械解体処理牛肉製品。ただしUSDAにより危険部位の混入が規制されている高度肉回収装置（AMR）による肉は使用可能。

第二の暫定最終法規は誤って、ないしは意図的に牛に禁止肉骨粉飼料を与えるリスクを低減するためのものである。

この暫定最終法規はFDAの現行の飼料法に4点の改正を伴うもので、第一は現在の哺乳動物の血液、血液製品の反芻動物飼料への使用許可の撤廃。最近の研究でBSEは血液を介して伝染する可能性が示唆された。

第二は“家禽くず”を反芻動物の飼料として与えることの禁止。“家禽くず”は敷き藁、えさのこぼれ、羽、糞など家禽小屋から集められたもの。これは家禽飼育場と牛飼育場が近接している一部地域で実際に行われている。家禽用飼料には反芻動物には禁止されている肉骨粉などが含まれている。

第三は“食べ残し”の反芻動物飼料への使用禁止。レストランチェーンから回収されるもので肉や肉のかけらを含み、レンダリング処理され飼料となる。“食べ残し”の使用はFDAの飼料分析能力を混乱させ、十分な実施を危うくする。

第四は反芻動物飼料と非反芻動物飼料の交叉汚染の可能性を最小にするもので設備機器、生産ラインの兼用を禁じ、動物たんぱく質を使用する場合には非反芻動物専用とすることを求める。現在は一部設備機器、生産ラインが共用されており交差汚染に結びつく可能性がある。

これら新しい対策と同時にFDAは飼料工場やレンダリング施設など動物飼料を扱う施設の検査を強化する。FDAにより2800箇所、州当局との協力で3100箇所を外部発注。連邦政府より700箇所の検査データを入手。以上から2004年だけで3800箇所の契約による検査が強化される。

更にBSE陽性牛の発生農場に関係する22箇所の試料工場、農場、と畜場など全てが飼料法を順守していた。

FDA は飼料から動物たんぱく質を早く、安く、高い信頼性で検出できるテスト方法の開発を支援していく。

Press Release

FOR IMMEDIATE RELEASE
Monday, Jan. 26, 2004

FDA Press Office
301-827-6242

Expanded "Mad Cow" Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission

HHS Secretary Tommy G. Thompson today announced several new public health measures, to be implemented by the Food and Drug Administration (FDA), to strengthen significantly the multiple existing firewalls that protect Americans from exposure to the agent thought to cause bovine spongiform encephalopathy (BSE, also known as mad cow disease) and that help prevent the spread of BSE in U.S. cattle.

The existing multiple firewalls, developed by both the U.S. Department of Agriculture (USDA) and HHS, have been extremely effective in protecting the American consumer from exposure to BSE. The first firewall is based on import controls started in 1989. A second firewall is surveillance of the U.S. cattle population for the presence of BSE, a USDA firewall that led to the finding of the BSE cow in December. The third firewall is FDA's 1997 animal feed ban, which is the critical safeguard to help prevent the spread of BSE through cattle herds by prohibiting the feeding of most mammalian protein to ruminant animals, including cattle. The fourth firewall, recently announced by USDA, makes sure that no bovine tissues known to be at high risk for carrying the agent of BSE enter the human food supply regulated by USDA. The fifth firewall is effective response planning to contain the potential for any damage from a BSE positive animal, if one is discovered. This contingency response plan, which had been developed over the past several years, was initiated immediately upon the discovery of a BSE positive cow in Washington State December 23.

The new safeguards being announced today are science-based and further bolster these already effective safeguards.

Specifically, HHS intends to ban from human food (including dietary supplements), and cosmetics a wide range of bovine-derived material so that the same safeguards that protect Americans from exposure to the agent of BSE through meat products regulated by USDA also apply to food products that FDA regulates.

FDA will also prohibit certain currently allowed feeding and manufacturing practices involving feed for cattle and other ruminant animals. These additional measures will further strengthen FDA's 1997 "animal feed" rule.

"Today's actions will make strong public health protections against BSE even

stronger," Secretary Thompson said. "Although the current animal feed rule provides a strong barrier against the further spread of BSE, we must never be satisfied with the status quo where the health and safety of our animals and our population is at stake. The science and our own experience and knowledge in this area are constantly evolving. Small as the risk may already be, this is the time to make sure the public is protected to the greatest extent possible."

"Today we are bolstering our BSE firewalls to protect the public," said FDA Commissioner Mark B. McClellan, M.D., Ph.D. "We are further strengthening our animal feed rule, and we are taking additional steps to further protect the public from being exposed to any potentially risky materials from cattle. FDA's vigorous inspection and enforcement program has helped us achieve a compliance rate of more than 99 percent with the feed ban rule, and we intend to increase our enforcement efforts to assure compliance with our enhanced regulations. Finally, we are continuing to assist in the development of new technologies that will help us in the future improve even further these BSE protections. With today's actions, FDA will be doing more than ever before to protect the public against BSE by eliminating additional potential sources of BSE exposure."

To implement these new protections, FDA will publish two interim final rules that will take effect immediately upon publication, although there will be an opportunity for public comment after publication.

The first interim final rule will ban the following materials from FDA-regulated human food, (including dietary supplements) and cosmetics:

- Any material from "downer" cattle. ("Downer" cattle are animals that cannot walk.)
- Any material from "dead" cattle. ("Dead" cattle are cattle that die on the farm (i.e. before reaching the slaughter plant);
- Specified Risk Materials (SRMs) that are known to harbor the highest concentrations of the infectious agent for BSE, such as the brain, skull, eyes, and spinal cord of cattle 30 months or older, and a portion of the small intestine and tonsils from all cattle, regardless of their age or health; and
- The product known as mechanically separated beef, a product which may contain SRMs. Meat obtained by Advanced Meat Recovery (an automated system for cutting meat from bones), may be used since USDA regulations do not allow the presence of SRMs in this product.

The second interim final rule is designed to lower even further the risk that cattle will be purposefully or inadvertently fed prohibited protein. It was the feeding of such protein to cattle that was the route of disease transmission that led to the BSE epidemic in United Kingdom cattle in the 1980's and 1990's.

This interim final rule will implement four specific changes in FDA's present animal feed rule. First, the rule will eliminate the present exemption in the feed rule that allows mammalian blood and blood products to be fed to other ruminants as a protein source. Recent scientific evidence suggests that blood can carry some infectivity for BSE.

Second, the rule will also ban the use of "poultry litter" as a feed ingredient for ruminant animals. Poultry litter consists of bedding, spilled feed, feathers, and fecal matter that are collected from living quarters where poultry is raised. This material is then used in cattle feed in some areas of the country where cattle and large poultry raising operations are located near each other. Poultry feed may legally contain protein that is prohibited in ruminant feed, such as bovine meat and bone meal. The concern is that spillage of poultry feed in the chicken house occurs and that poultry feed (which may contain protein prohibited in ruminant feed) is then collected as part of the "poultry litter" and added to ruminant feed.

Third, the rule will ban the use of "plate waste" as a feed ingredient for ruminants. Plate waste consists of uneaten meat and other meat scraps that are currently collected from some large restaurant operations and rendered into meat and bone meal for animal feed. The use of "plate waste" confounds FDA's ability to analyze ruminant feeds for the presence of prohibited proteins, compromising the Agency's ability to fully enforce the animal feed rule.

Fourth, the rule will further minimize the possibility of cross-contamination of ruminant and non-ruminant animal feed by requiring equipment, facilities or production lines to be dedicated to non-ruminant animal feeds if they use protein that is prohibited in ruminant feed. Currently, some equipment, facilities and production lines process or handle prohibited and non-prohibited materials and make both ruminant and non-ruminant feed -- a practice which could lead to cross-contamination.

To accompany these new measures designed to provide a further layer of protection against BSE, FDA will in 2004 step up its inspections of feed mills and renderers. FDA will itself conduct 2,800 inspections and will make its resources go even further by continuing to work with state agencies to fund 3,100 contract inspections of feed mill and renderers and other firms that handle animal feed and feed ingredients. Through partnerships with states, FDA will also receive data on 700 additional inspections, for a total of 3,800 state contract and partnership inspections in 2004 alone, including annual inspections of 100 percent of all known renderers and feed mills that process products containing materials prohibited in ruminant feed.

"We have worked hard with the rendering and animal feed production industries to try and achieve full compliance with the animal feed rule," said Dr. McClellan, "and through strong education and a vigorous enforcement campaign, backed by additional inspections and resources, we intend to maintain a high level of compliance."

Dr. McClellan also noted that, in response to finding a BSE positive cow in Washington state December 23, FDA inspected and traced products at 22 facilities related to that positive cow or products from the cow, including feed mills, farms, dairy farms, calf feeder lots, slaughter houses, meat processors, transfer stations, and shipping terminals. Moreover, FDA has conducted inspections at the rendering facilities that handled materials from the positive cow, and they were found to be fully in compliance with FDA's feed rule.

To further strengthen protections for Americans, FDA/HHS intends to work with Congress to consider proposals to assure that these important protective measures will be implemented as effectively as possible.

FDA is also continuing its efforts to assist in the development of better BSE science, to achieve the same or greater confidence in BSE protection at a lower cost. For example, to enhance the ability of our public health system to detect prohibited materials in animal feed, FDA will continue to support the development and evaluation of diagnostic tests to identify prohibited materials. These tests would offer a quick and reliable method of testing animal feeds for prohibited materials and for testing other products for contamination with the agent thought to cause BSE.

FDA has publicly discussed many of the measures being announced today with stakeholders in workshops, videoconferences, and public meetings. In addition, FDA published an Advance Notice of Proposed Rulemaking in November 2002 (available online at http://www.fda.gov/OHRMS/DOCKETS/98fr/110602c.htm concerning possible changes to the animal feed rule.

Comprehensive information about FDA's work on BSE and links to other related websites are available at http://www.fda.gov.