Proposed EU Ban on Specified Risk Materials (SMRs): An Action Plan for the American Meat Association

Commercial Diplomacy
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SCENARIO

For the purposes of this project, I assume the fictious role of an independent trade policy consultant hired by a fictitious industry association, the American Meat Association (AMA).

In order to exempt the United States from the proposed European Union (EU) ban on sales of materials that could potentially carry the Bovine Spongiform Encephalopathy (BSE) or "mad cow" virus, I have been asked to create a strategy to gain recognition of the United States as a BSE-free country.

Without BSE-free status, exports of AMA members' products to the EU could be blocked, resulting in potential economic losses of more than $17 billion in U.S. pharmaceutical exports, $125 million in U.S. tallow and tallow derivative exports, $100 million in cosmetics exports, and hundreds-of-millions of dollars in animal feed and human food product exports. This project assumes a report on November 1, 1997.

ISSUE

On July 30,1997, the EU announced plans to ban the sale of products that contain specified risk materials (SRMs) such as brains, spinal cords, tallow and gelatin. Products that would be covered by the ban include certain animal feeds, human foods, cosmetics, and pharmaceuticals. Known as the SRM Directive, the ban is scheduled to be implemented beginning January 1, 1998, and is intended to prevent the spread of Transmissible Spongiform Encephalopathies (TSEs), specifically BSE.

The United States argues that its SRMs are free from BSE since the United States maintains a vigorous monitoring system and no cases of BSE have ever been confirmed in the United States.

If the EU implements the proposed SRM ban in its original form (i.e., without derogations), the United States stands to lose billions of dollars in exports of animal products. For the AMA and its members, this could be a devastating blow. In 1996, the EU was the second largest export destination for U.S. tallow. In the event the EU decides to expand the ban to additional SRMs, the potential impact would increase.

BACKGROUND

Economic Impact of the Ban

The EU ban would cost the United States more than $125 million in U.S. tallow and tallow derivative exports, $17 billion in U.S. pharmaceutical exports, and $100 million in U.S. cosmetics exports to the EU. In addition, hundreds-of-millions of dollars in animal feed and food product exports to the EU also would be lost. Exporters and farmers, as well as Americans working in jobs that support these export activities, would all be affected.

The U.S.-EU trading relationship would also be affected by the ban. The EU and the United States together account for more than 30 percent of world trade and represent almost 60 percent of the industrialized world's GDP. Our bilateral trade and investment flows with the EU equals more than $1 trillion annually. Maintaining good U.S.-EU relations is important to continuing this economic prosperity, particularly for U.S. agricultural exporters because the EU is one of the largest export markets for U.S. farm products.

Political Briefing

Since the ban would have a substantial negative impact on numerous American and EU interest groups, AMA can form a broad coalition of opposition to the ban. Within the United States, AMA can expect the support of the Pharmaceutcial Research and Manufacturers of America (PhRMA), the Cosmetics, Toiletry and Fragrance Association (CTFA), the National Renderer's Association (NRA), the National Cattlemen's Beef Association, the U.S. Meat Export Federation, and the American Farm Bureau Federation. All of these organizations represent major industries that would be negatively affected by the ban.

AMA can also expect that the United States Department of Agriculture (USDA) and the Office of the U.S. Trade Representative (USTR) will continue to support AMA. USDA and USTR are already discussing the proposed ban with the EU.

Other less obvious allies are EU member states that have not had native cases of BSE. These allies could prove to be extremely important because of their ability to influence the European Commission. Some member states have told the Commission they deserve to be exempt from the ban because of their low risk for BSE.

Since U.S. animal product exports are used by EU pharmaceutical and cosmetics industries to create products and consumer goods, these companies are another potential set of allies for AMA. EU member states rely on U.S. pharmaceuticals to some degree, but many American companies operate in Europe through subsidiary companies. Since 1995, France has been the number one producer of pharmaceuticals in Europe. U.S. imports account for only eight percent ($234 million) of the French pharmaceutical market. Subsidiaries of U.S. companies operating in France account for about 20 percent of local production. According to Agripharm, a U.S. working group of pharmaceutical companies in France, American pharmaceutical companies account for more than 10 percent of the market in EU member states: France-23 percent, Germany-22 percent, Italy-16 percent, and United Kingdom-12 percent.

AMA should expect the EU Commission and EU member states that have reported BSE cases in native cattle, particularly the United Kingdom, to oppose AMA's efforts. Less clear are the interests of the EU Standing Scientific Committee and other scientific committees that study BSE and advise the Commission. Although these committees are supposed to make decisions based on objective, scientific criteria, they are not necessarily free from political pressure from the Commission and other EU member states.

Scientific Basis and Criteria for Evaluating the Ban

In July 1997, the EU Commission introduced Directive 97/534, known as the SRM Directive, as a follow-up to Directive 97/01, the Cosmetics Directive, of January 1997. Together these Directives ban the sale of all SRMs and SRM-containing products (SRM Directive), as well as beef tallow and tallow-containing products (Cosmetics Directive). The purpose of these Directives is to prevent the spread of BSE, a slowly progressing degenerative disease that affects the nervous system of cattle.

Commonly referred to as "mad cow disease," BSE was first identified in the United Kingdom (UK) in 1986. The scientific community believes that cattle contracted BSE by consuming contaminated meat-and-bone meal in concentrate feed, with sheep or cattle being the original source. The epidemic of BSE in the UK, the only country with a high incidence of the disease, appears to be the result of recycling affected bovine material back to cattle before July 1988 when the UK instituted a ban on using ruminant-derived materials in feed. Ruminants include cattle, sheep and goats.

BSE is one of several different transmissible animal brain diseases known as Transmissible Spongiform Encephalopathies (TSEs). Other TSEs include scrapie, a disease commonly found in sheep; a similar neurological disease in mink and captive North American mule deer and elk; and a neurological disease in household cats and captive ruminant and feline species, the majority of cases of which have occurred in the UK. Although there is no evidence to date that TSEs/BSE can be transmitted either maternally or horizontally to different animal species, scientists worldwide continue to study various aspects of these diseases.

Similar forms of brain spongiform disease have been diagnosed in human beings, including the deadly Creutzfeldt-Jakob disease (CJD). At the time of the BSE epidemic, health officials in the UK diagnosed a new variant of CJD (nv-CJD) in approximately 20 patients. No cases of this disease have been diagnosed in the United States.

Although scientists believe that human exposure to BSE is the most probable cause of nv-CJD, no clear scientific evidence has been found to link this new strain to BSE. Nonetheless, the potential link has raised questions as to whether animal products from BSE-infected cattle could infect human beings or other animals, and it is the potential link that led the EU to ban the sale of SRMs and animal by-products that contain SRMs.

As outlined by the WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), the EU has the right to take measures to protect human, animal or plant health, it is required to base these measures upon sound scientific principles and evidence and to minimize any negative trade effects. The United States maintains that the ban violates the EU's SPS obligations and acts as an unnecessary trade barrier.

The SPS Agreement does not proclaim that the WTO will engage in setting scientific standards for determining the appropriate level of protection or risk related to SPS measures. Instead, it requires all members to ensure that their SPS measures are "based on an assessment . . . of the risks to human, animal or plant health, taking into account the risk assessment techniques developed by the relevant international organizations." The Agreement also refers members to the guidelines developed by international organizations when adapting SPS measures to regional conditions, including disease-free areas. For animal and animal-disease issues (including TSE/BSE), the SPS Agreement refers members to standards set by the International Office of Epizooties (OIE), the international veterinary association. Because the EU ban involves protecting human and animal life, the Codex Alimentarius Commission standards of the Food and Agriculture Organization (FAO) and World Health Organization (WHO) recommendations also must be considered.

Exhibit 1 summarizes these guidelines. Exhibits 2-5 address OIE, CODEX, and WHO guidelines for BSE. These international guidelines and recommendations should be followed in designing and evaluating BSE risk assessments and prevention, surveillance, and response strategies. The guidelines should also be used in determining what materials should be considered to be SRMS.

Risk Assessment

CODEX and OIE identify risk assessment and management as the basis of any country's BSE management/surveillance program. CODEX combines recommendations for risk assessment with guidelines for effective management and communication of BSE risk levels (Exhibit 5).

The OIE International Animal Code provides a detailed outline of the risks specific to BSE and provides guidelines for countries to follow when identifying the potential for BSE occurrence, including:

- The risk arising from imports of animals potentially infected with TSEs and potentially contaminated animal feedstuff;
- The indigenous risks of cattle consuming animal-derived proteins from TSE-infected animals and rendering processes that do not inactivate the agent; and
- The potential vertical transmission of BSE from cows originating from infected countries.

Prevention

International recommendations for preventing the spread and introduction of BSE include:

- Banning (or placing restrictions on) the use of feeds that contain ruminant-animal-derived materials from TSE-infected countries (OIE, WHO, CODEX);
- Taking measures to ensure that rendering procedures eradicate TSEs, particularly when dealing with SRMs (WHO); and
- Preventing parts of any animal (including tissues) that has shown TSE symptoms from entering any human or animal food chain (WHO, CODEX).

Surveillance

International recommendations for domestic BSE surveillance programs include:

- Establishing continuous BSE surveillance monitoring systems (OIE, WHO);
- Declaring compulsory notification for BSE cases (OIE, WHO); and

- Completing clinical investigations of suspect cases by post-mortem examination of brain material (OIE).

Response

To prevent the spread of BSE, these international organizations recommend that animals confirmed to be infected with BSE be completely incinerated or otherwise effectively destroyed.

SRMs

The EU must also consider WHO safety recommendations concerning certain bovine by-products and SRMs. The EU ban seems to disregard WHO findings that:

- Gelatin is considered safe for human consumption because its preparation involves a chemical extraction process that destroys BSE infectivity;
- Tallow is considered safe if it is produced using effective rendering procedures; and
- With respect to medicinal products (which differ from food in that they can be injected as well as taken orally), the risk of transmitting the BSE agent can be minimized by using only SRM materials that come from countries that have surveillance systems in place and report either no or only sporadic cases of BSE.

The United States' BSE Risk

Although the United States already has proven its BSE-free status in international fora, the EU has refused to exempt the United States from the ban for two reasons:

- An EU scientific committee studying the BSE issue has argued that the lengthy BSE incubation period would require inspections over a 60-month period to verify a country's BSE status; and
- Granting the United States BSE-free status would open the door for some EU member states to ask for the same status, something the EU Commission wants to avoid.

However, the EU must recognize and follow OIE guidelines to determine a country's BSE status. According to the OIE Code, a country may be considered free of BSE if it:

- implements a comprehensive BSE risk management strategy and bans the feeding of meat-and-bone meal to cattle (derived either from ruminant animals from TSE-infested countries or countries that do not maintain a BSE surveillance program);
- certifies that there have been no clinical cases of BSE in the country, makes BSE a notifiable disease, and maintains an effective surveillance and monitoring system; and
- (if BSE has been confirmed within a country) proves that all cases of BSE originated from BSE-infected countries and ensures that all suspect animals are destroyed.

The United States not only meets these guidelines but also meets the international recommendations for preventing the spread and introduction of BSE by establishing both monitoring and response systems for BSE.

The U.S. BSE Monitoring System

Although no cases of BSE have been confirmed in the United States, the U.S. Department of Agriculture (USDA), in conjunction with the U.S. Food and Drug Administration (FDA), maintains a detailed monitoring system for BSE. USDA's Animal and Plant Health Inspection Service (APHIS) and the Food Safety Inspection Service (FSIS) are the main agencies responsible for developing and implementing this system. The monitoring system is divided into four components: prevention, surveillance, education, and response.

Prevention Through Import Restrictions

Recognizing the potential risk of introducing BSE into the United States through imports of animals and potentially contaminated animal feedstuff, USDA maintains a series of import restrictions. To prevent BSE from entering the country, APHIS prohibits imports of live ruminants from countries having confirmed cases of BSE in native cattle. In addition, USDA prevents other products derived from ruminants from entering the United States unless permission or a USDA permit is granted due to special conditions or for scientific research purposes. Products included under this ruminant derivative ban include beef, fetal bovine serum, bone meal, meat-and-bone meal, blood meal, offal, fats, and glands. The United States does not allow imports from slaughter plants in countries with confirmed BSE cases.

Recognizing that Europe's recent outbreak of BSE was probably caused by TSE-contaminated ruminant feed for cattle, the FDA prohibits the inclusion of ruminant and mink protein in ruminant feed. This rule came into force on August 4, 1997, and is consistent with safety recommendations set forth by the OIE, WHO, and CODEX.

Education and Training Initiatives

The education component of the United States' BSE monitoring system includes efforts to ensure that a variety of groups and individuals are aware of the disease. APHIS educates the veterinary community, including veterinary practitioners and veterinary laboratory diagnosticians, on the clinical signs and pathology of BSE. APHIS also provides educational/training briefings for U.S. cattle industry groups and producers. APHIS veterinary pathologists and field investigators receive BSE diagnosis training from their British counterparts.

Surveillance

In accordance with the guidelines established by OIE, APHIS leads the United States' comprehensive BSE surveillance program (Exhibit 6). Since the only proven test for BSE is a post-mortem examination of brain tissue, well-trained APHIS staff and other veterinary laboratories examine brains from adult cattle that have exhibited neurological signs which could signal BSE or another form of TSE. After cattle exhibiting these signs (and rabies-negative cattle) are identified on the farm or at slaughter, brain samples are submitted for testing to veterinary diagnostic laboratories and teaching hospitals. As of April 30, 1997, BSE-diagnostic tests on a total of 5,621 brains from 48 states and Puerto Rico have shown no evidence of BSE or other TSE.

Also included in the surveillance program is a monitoring system for cattle that were imported from Great Britain between 1981 and 1989 (before the ban on imports went into effect). As of February 26, 1997, 463 (93 percent) of the 496 cattle imported from the UK had been identified. Twenty-five of these animals have been confirmed to be alive, and APHIS is attempting to purchase them for diagnostic research purposes. To date, no evidence of the disease has been detected. Based on the ages of the remaining cattle, APHIS estimates that most of them are dead. However, APHIS continues efforts to locate them.

Response

To be prepared in the event that BSE is detected in the United States, a joint APHIS/FSIS working group drafted the USDA BSE Response Plan in August 1996. The plan provides a step-by-step set of actions designed to minimize the spread of the disease.

APHIS also established a TSE Working Group to monitor and assess all on-going events and research findings regarding TSEs to determine if and when steps should he taken to revise U.S. prevention and diagnostic measures. The group also responds to questions about TSEs.

Present Situation (November 1, 1997)

The United States continues to meet with the EU to discuss the proposed ban. Although the EU still refuses to consider granting the United States BSE-free status, it is considering exempting some products from the ban.

The EU announced plans to consider exempting U.S. tallow and tallow-containing products from the ban following the release of an EU Scientific Committee on Cosmetology report that confirmed U.S. assertions concerning tallow; if produced under certain heat and pressure conditions, tallow and tallow-containing products should be considered free of BSE. The Commission, however, has not yet approved the proposed amendment.

The EU is also considering a partial exemption for certain "lifesaving" pharmaceuticals deemed necessary for obvious medical and health reasons. However, since none of these exemptions has been presented in writing to the United States, AMA members' exports remain threatened.

WHITE PAPER

The EU plans to ban imports of animal products that contain animal proteins or animal parts to guard against the spread of "mad cow disease," or Bovine Spongiform Encephalopathy (BSE). The EU fears that these animal products, called specified risk materials, may contain the disease.

The United States understands and shares the EU desire to prevent the spread of BSE, but the EU is not justified in enacting the ban. The ban does not adhere to international guidelines set forth by the World Trade Organization (WTO) and other international organizations, including the international veterinary association, the Office of International Epizootics. As required by international guidelines, the United States has already set up a strict and comprehensive monitoring system to detect and prevent the spread of BSE, and no cases of the disease have been detected in the United States.

The ban would block hundreds-of-millions of dollars in U.S. animal feed and food products from entering the EU and cost U.S. exporters billions of dollars. Other animal products that the EU plans to ban, including tallow and gelatin, are also extremely important to U.S. companies and consumers worldwide.

- Tallow is a white, nearly tasteless, solid fat from cattle (and sheep) that is used by cosmetics manufacturers and others to make products such as soap, margarine, and candy. Although scientists have found that tallow is free from BSE if processed under certain temperature and pressure conditions, the EU still plans to ban more than $125 million in U.S. tallow exports and $100 million in U.S. cosmetics exports that contain tallow.

- Gelatin is a gummy material obtained by boiling animal tissues. U.S. pharmaceutical companies use gelatin in 80 percent of their medicines, such as capsules and gelatin-coated tablets. The ban would

prevent nearly $17 billion in U.S. pharmaceutical products from reaching EU consumers and could potentially endanger the lives of many patients.

Because the United States maintains a rigorous monitoring system and has not found any cases of the disease, the United States has asked the EU to grant it BSE-free status and to allow U.S. companies to continue to export to the EU. The United States has proven to international organizations that it meets the guidelines for recognition as a "BSE-free country." As mandated by the WTO, the EU must take into consideration these same international guidelines when determining EU human/animal health and safety standards, including the EU ban on animal products. However, the EU still refuses to follow these guidelines and recognize the United States as BSE-free.

As the world's largest trading partners, the EU and the United States must work together to resolve this issue and maintain their strong economic and politically important relationship. The EU and the United States together account for more than 30 percent of world trade, represent almost 60 percent of the industrialized world's GDP. Their bilateral trade and investment flows equal more than $1 trillion annually. Maintaining good relations with the EU will continue this economic prosperity. This is especially important for United States agricultural exporters since the EU is one of the largest export markets for U.S. farm products. The United States also relies on the EU for support in other areas such as international security and drug programs. For these reasons, the United States should continue to work with the EU to find a mutually-beneficial solution to this important trade issue.

STRATEGY PAPER

AMA's goal is to secure the EU's recognition of the United States as BSE-free. Obtaining this recognition will protect U.S. exports to the EU and set an important precedent to ensure that other countries also recognize the United States as BSE-free. Since the EU Commission has the authority to grant BSE-free status to the United States, the ultimate objective of AMA's strategy must be to pressure the EU Commission to accept the United States' scientific data proving it should be granted this status. Accordingly, AMA must implement a dual-track strategy that mobilizes support from domestic and European communities.

A major component of the strategy is to use the media. Exhibit 7 explains the specifics of the media strategy.

Domestic Strategy

In order to bring more pressure to bear on the EU, AMA should first concentrate on building a broad base of domestic support for its efforts. The Office of the U.S. Trade Representative (USTR) and the U.S. Department of Agriculture (USDA) already agree that the EU ban is a problem and have been meeting with the EU to discuss the issue. AMA should ensure that both agencies continue to give this issue high priority. Additionally, AMA needs to increase coordination with other domestic stakeholders and lobby Congress to put pressure on the administration to resolve the problem.

Increase Coordination with Other Domestic Stakeholders

The following organizations are likely to support our position:

- Pharmaceutical Research and Manufacturers of America (PhRMA);
- Cosmetics, Toiletry and Fragrance Association (CTFA);
- National Renderers' Association; and
- National Cattlemen's Beef Association.

AMA should write letters to these parties proposing the establishment of a coalition that would work toward gaining BSE-free status for the United States (Exhibit 8 provides a sample letter).

By working together, AMA and its allies can:

- Protect their shared interest in ensuring access to the EU market;
- Coordinate the sharing and dissemination of scientific information that illustrates the steps the United States is taking to ensure its products are safe;
- Work together to educate Congress on the importance of this issue for a number of U.S. industries; and
- Share the organizational and financial burden associated with the campaign.

Build Awareness of the Issue within Congress

Although AMA should continue current efforts to communicate directly with Congress, it should also work with the coalition to:

- Provide members of Congress and their staff with 1) scientific data relevant to BSE status in the United States, and 2) trade figures that illustrate the impact of the proposed ban;
- Ensure that those members of Congress that might agree with the objective of the EU ban realize that there is no proper scientific basis for the ban; and
- Encourage Congress to support AMA's position with the ultimate goal of convincing Congress to urge the Administration's action on this issue.

AMA should send letters (Exhibit 9) to key members of Congress and provide testimony (Exhibit 10) to the House Subcommittee on Livestock, Dairy and Poultry and the Senate Committee on Agriculture, Nutrition and Forestry. The letters and testimony should emphasize the importance of gaining BSE-free status for the United States, as well as the potential impact of the EU ban. The legislative strategy document (Exhibit 11) contains more details on preparation for this testimony.

Encourage USDA/USTR to Push Harder for BSE-free Status

Congressional support will assist AMA in encouraging USTR and USDA to step-up their campaign for BSE-free status. However, since USTR, along with USDA, are the agencies that represent U.S. concerns directly to the EU, AMA will also want to work closely with USTR and USDA. AMA should write letters (Exhibit 12) and maintain daily contact via telephone, fax, and e-mail with appropriate personnel at these two agencies in order to:

- Acknowledge progress made;
- Provide relevant scientific information about the safety of U.S. products; and
- Keep this issue on the front burner.

AMA also should provide the U.S. government with a strategy for approaching negotiations with the EU (Exhibit 13).

EU Strategy

In addition to encouraging the U.S. government to make the ban a priority issue, AMA should also build EU allies, including EU consumers, EU member states without native BSE cases, and EU industries that rely on U.S. imports or would be otherwise negatively impacted by the ban. AMA needs to alert these allies to the potential effects of the ban and ensure that they will support the U.S. request for BSE-free status. AMA should hold a press conference (Exhibits 14) to provide information to EU parties that both support and oppose the ban.

Influence EU Consumers

Given the general consumer fear of BSE in the EU, AMA should provide scientific and safety information to reassure EU consumers that U.S. products are safe. A general public advocacy campaign, using advertisements (Exhibits 15) and op-ed pieces in EU newspapers, should help assure consumers that U.S. products do not pose BSE risks. EU consumer support can be used to remind the EU Commission of the impact that this ban would have on EU citizens.

Align with EU Member States without Native BSE Cases

AMA should encourage EU member states that have not identified BSE in native cattle to support the United States position. Because member states can influence the Commission's decision regarding the ban, AMA should encourage these countries to propose that the Commission grant exceptions for trading partners that are BSE-free. Through op-ed pieces, letters (Exhibit 16), and personal contact with these countries, AMA can demonstrate that they share an interest in securing BSE-free status.

Initiate Dialogues with EU Industries

The EU pharmaceutical and cosmetics industries are potential allies for AMA since these companies use U.S. animal products in their products and consumer goods. As for U.S. pharmaceutical imports, some member states rely on U.S. pharmaceuticals to a degree, but many American companies operate in Europe through subsidiaries. AMA must reassure these industries that U.S. products are safe and encourage their support in getting the EU to recognize the United States as BSE-free. Another industry that should be targeted is the medical industry, which could be affected by price increases that would likely result if the ban is implemented. AMA should write letters to these industries to solicit their support (Exhibit 17).

Some EU industries will want to use the ban to take back market share previously held by foreign imports. Although these industries may not respond well to our overtures, we should contact them to explain that they, too, will benefit from convincing the Commission to recognize BSE-free status of some trading partners. For industries in countries that do not have native cases of BSE, this recognition would legitimize the safety of the industry's products.

EXHIBITS

EXHIBIT 1

INTERNATIONAL ORGANIZATION GUIDELINES FOR MINIMIZING BSE RISK

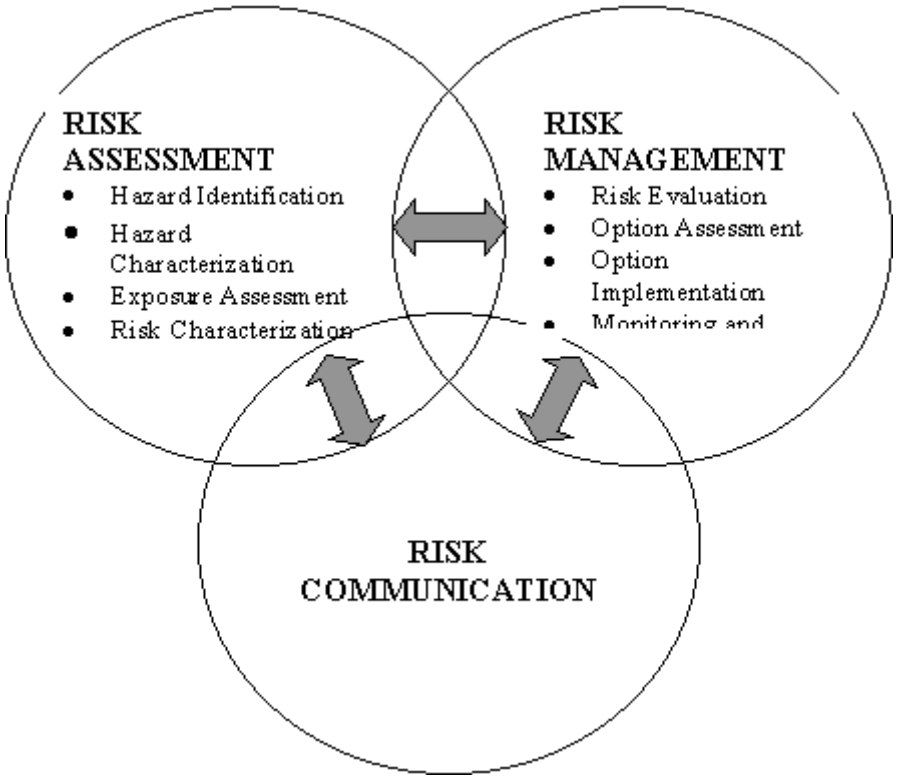
RECOMMENDATION OR GUIDELINE AREA	ORGANIZATION		
	OIE	WHO	CODEX

1. Compulsory notification of BSE	X	X	
2. Mandatory examination of brain specimens from suspicious cattle	X		
3. Mandatory ban on using ruminant-containing feeds from TSE-infected countries	X	X	X
4. Establishment of continuous BSE surveillance monitoring system	X	X	
5. Incineration of confirmed BSE-infected tissues/animals		X	X
6. Measures to ensure that rendering procedures eradicate TSEs			
7. Follow guidelines to determine BSE-free status	X		
8. Establishment of a risk assessment/management program for TSE	X		

Source: WHO, OIE, FAO/CODEX ALIMENTARIUS COMMISSION

EXHIBIT 2

STRUCTURE OF RISK ANALYSIS RECOMMENDED BY THE FAO



Source: FAO/CODEX ALIMENTARIUS COMMISSION

EXHIBIT 3

OFFICE OF INTERNATIONAL EPIZOOTICS
BSE RECOMMENDATIONS

The Office of International Epizootics' (OIE's)1[1] International Animal Health Code sets out minimum surveillance and monitoring requirements for BSE. These requirements are:

1. Compulsory notification and clinical investigation of suspect cases.
2. Risk assessment that identifies potential hazards for BSE occurrence, including:
    a. risk arising by:
        i) importation of animals or embryos/ova which are potentially infected with a transmissible spongiform encephalopathy (TSE); or
        ii) importation and feeding of potentially contaminated animal feedstuff to cattle;
    b. indigenous risks of:
        i) consumption, by cattle, of contaminated, animal-derived proteins arising from TSE-infected animals and rendering processes that do not inactivate the agent; or
        ii) potential vertical transmission of BSE from cows originating from infected countries.
3. Continuous BSE surveillance and monitoring with emphasis on the risks identified in point 2 above.
4. Examination in an approved laboratory of brain material from cattle older than 20 months displaying signs of progressive neurological disease in accordance with the diagnostic techniques set out in the Manual. A sufficient number of investigations as indicated in Table I of the Guidelines for Continuous Surveillance and Monitoring of BSE (Appendix VUlb of document 65 SG/ 12/CS1) should be carried out annually in countries where progressive neurological disease incidence is low. Surveillance should be targeted at cattle older than four years of age that display other progressive disease conditions.
5. Maintenance of seven years of records that track the number and results of investigations.

In addition, the OIE's International Animal Health Code offers guidelines for determining a country's BSE status. According to Chapter 3.2.13.2 of the Code, countries may be considered free of BSE if:

1. They have implemented a risk management strategy to address any risk, as identified in Article 3;2.13.1 point 2); and

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1[1] An international veterinary organization.

2. They have effectively enforced a ban on feeding cattle meat-and-bone meal derived from ruminants from TSE-infected countries or countries that do not have an effective and continuous surveillance and monitoring system as described in Article 3.2.13.1points 3) and 4);

AND

1. There has been no clinical case of BSE, the disease is notifiable, and an effective and continuous surveillance and monitoring system is practiced, as described in Article 3.2.13.1 points 3) and 4); or

2. All cases of BSE have been clearly demonstrated to originate directly from the importation of live cattle originating from BSE-infected countries, provided that the disease is made notifiable and suspect animals are slaughtered, investigated and, if disease is confirmed, completely destroyed and an effective and continuous surveillance and monitoring system is practiced, as described in Article 3.2.13.1 points 3) and 4), or

3. BSE has been eradicated (under study).

EXHIBIT 4

WORLD HEALTH ORGANIZATION
BSE RECOMMENDATIONS

In order to protect public health from any potential risk from animal TSEs, the World Health Organization (WHO) recommends that:

- No part of any animal which has shown signs of a TSE should enter into any food chain—human or animal;
- All countries should ensure the killing and safe disposal of all parts or products of such animals so that TSE infectivity cannot enter any food chain; and
- All countries should review their rendering procedures to ensure that they effectively inactivate TSE agents.

With regard to surveillance and other BSE issues, WHO has recommended that:

- All countries should establish continuous surveillance and compulsory notification for BSE according to recommendations established by the OIE in Paris. In the absence of surveillance data, a country's BSE status must be considered as unknown.
- Countries where BSE exists in native cattle should not permit tissues that are likely to contain the BSE agent to enter any food chain—human or animal.
- All countries should ban the use of ruminant tissues in ruminant feed.

EXHIBIT 5

CODEX
BSE RECOMMENDATIONS

The WTO Agreement on Sanitary and Phytosanitary Measures (SPS) refers to the standards, guidelines, and recommendations established by the FAO Codex Alimentarius Commission relating to various food safety issues.

At an FAO Expert Consultation on Animal Feeding and Food Safety held in Rome March 10-14, 1997, guidelines for the control of feed-borne hazards were introduced. Although it has not been proven that BSE is a feed-borne hazard, the Expert Consultation concluded that it would not be "prudent" to exclude BSE as a "potential food-borne hazard." The group concluded that "the risk that arises from [BSE] should be assessed and managed in exactly the same way as other food-borne hazards."

Codex provides guidelines for analyzing this risk, based upon structured risk assessment, risk management, and risk communication.

Specific guidance given with respect to BSE includes taking the following measures:

- All tissues from cattle with clinical BSE should be incinerated so that they are eliminated from all feed and food chains.
- In all countries where BSE has occurred, depending upon its incidence (as determined by a "competent authority and an appropriately structured surveillance program"), consideration should be given to placing restrictions on the use of meat-and-bone meal derived from specific bovine tissues in ruminant feeds. A similar consideration should be made in countries where a risk assessment indicates that the cattle population has been exposed to infection.
- In countries where BSE and sheep scrapie have occurred, consideration should be given to placing restrictions on the use of ruminant-derived protein in feeds for ruminants.
- In countries where BSE has not occurred, but where sheep scrapie is present, consideration should be given to placing restrictions on the feeding of bovine-derived protein to ruminants—depending on the incidence (as determined by a "competent authority and an appropriately structured surveillance program") of scrapie and the time/temperature processes used for the rendering of bovine carcasses and tissues.

EXHIBIT 6

U.S. BSE SURVELLANCE PROGRAM

ACTIVE SURVEILANCE	PASSIVE SURVELLANCE
• **Education** APHIS educates veterinary practitioners, veterinary laboratory diagnosticians, and industry producers on the clinical signs and pathology of BSE. • **UK Cattle Monitoring** APHIS monitors the cattle imported from the United Kingdom before the United States' ban on cattle imports went into effect. • **Laboratory Examination of Cattle Brains for BSE** Every year since 1990, USDA's National Veterinary Services Laboratories along with more than 60 veterinary diagnostic laboratories across the United States have examined hundreds of brains from adult cattle displaying neurological abnormalities either at slaughter or on the farm. FSIS performs ante-mortem slaughter inspection at all federally inspected slaughter establishments, and inspectors are alert for central nervous system disorders. Any suspect animals are condemned and tested. As of April 30, 1997, a total of 5,621 brains from all over the United States had been examined. No evidence of BSE has been detected.	• **Referral of Unusual Cases to Veterinary Laboratories** The network of private veterinary practitioners that refers unusual cases to veterinary schools or state diagnostic laboratories around the United States provides an informal but extensive and important surveillance system. • **BSE Diagnosis Training for Veterinarians** USDA has trained over 250 state and federal field veterinarians to recognize and diagnose foreign animal diseases, including BSE. • **Veterinary Data Bases** The Veterinary Medical Data Base maintained by Purdue University compiles diagnoses submitted by 27 U.S. veterinary schools. The data base includes many neurological cases. The Veterinary Diagnostic Laboratory Reporting System (VDLRS)* maintains a data base on selected disease conditions submitted by 29 state and university veterinary diagnostic laboratories throughout the United States, including the results of histologic examinations for BSE. • **BSE Examination Conducted on Zoo Animals** Since BSE-like encephalopathies have been diagnosed in seven species of exotic Bovidae at zoos in England, Veterinary pathologists at zoos in the United States routinely conduct post-mortem examinations on the brains of zoo animals exhibiting neurological abnormalities.

* The VDLRS is a cooperative effort of the American Association of Veterinary Laboratory Diagnosticians, the United States Animal Health Association, USDA/APHIS/VS Centers for Epidemiology and Animal Health, and the 29 laboratories that submit data.	

EXHIBIT 7

MEDIA STRATEGY

An important part of AMA's strategy for convincing the EU to grant the United States BSE-free status is to use the media to mobilize support from domestic and European communities.

Domestic Strategy

AMA must balance its domestic strategy very carefully. Any media attention could confuse the public about the safety of U.S. beef. Accordingly, AMA may want to keep a low profile and avoid using the media. On the other hand, AMA could use the media to reassure the public that U.S. beef is safe.

Since the U.S. government already supports our position, AMA could use a Washington-focused media strategy to help ensure that the government gives this issue top priority. Such a strategy would target Congress and the Administration and would include placing op-ed pieces and letters to the editor in D.C. publications. Additionally, AMA could post information about meat industry safety on AMA and coalition web sites, as well as provide links to other resources, such as APHIS and FSIS.

European Strategy

The main priority with respect to the media should be to convince the EU public of the safety of U.S. animal products. AMA must implement a comprehensive media strategy that reassures opponents and gives our EU allies adequate facts to bolster their domestic efforts. AMA should:

- Conduct a press conference with other coalition members to share the facts about the United States' clean BSE record and the potential consequences of the EU's ban;
- Purchase advertising time on radio and television and in prominent publications (newspapers, journals, magazines) that target European consumers, governments, industries, and the Commission;
- Target editorial writers in publications such as the *Financial Times*, which is widely read by those involved in EU decision-making;
- Publish op-ed pieces and letters to the editor in European publications to target EU consumers, governments, industries, and the Commission;
- Post information about meat industry safety on AMA and coalition web sites in European languages, as well as provide links to other resources, such as APHIS and FSIS;
- Publish op-ed pieces and letters to the editor in European publications to inform the public, as well as EU industries and governments, about the safety of U.S. animal products.

EXHIBIT 8

SAMPLE LETTER TO A POTENTIAL U.S. COALITION MEMBER

Dear Sir or Madame:

As your organization is well aware, the European Union is planning to ban the sale of products that may contain, or are made using, specified risk materials for Bovine Spongiform Encephalopathy (BSE). Our organizations have much to gain from preventing implemention of this costly trade barrier.

I am writing to propose that we explore opportunities for forming a coalition to ensure that the EU ban does not block our exports. Together we can make certain the U.S. government makes this issue a high priority and continues to pressure the EU to exempt the United States from its ban based on our BSE-free status.

The ultimate goal of our coalition would be to ensure that the EU grants the United States BSE-free status and does not disrupt the flow of U.S. exports to the EU. Our intermediate goal would be to increase political awareness of this issue in Washington. We can coordinate our efforts to educate members of Congress, providing them the real facts about (1) the safety of U.S. animal products subject to the EU ban, and (2) the potential negative impact the EU ban will have on U.S. exports and U.S. jobs. More importantly, we can work together to secure allies in the EU and reassure EU consumers, industries, the European Commission, and EU member states about the safety of our products.

With your support we can begin immediately to coordinate our efforts and ensure that the EU recognizes the United States as BSE-free. A coordinated effort will undoubtedly go a long way toward protecting the interests of our members and promoting safe U.S. products. Thank you for your time and support.

Sincerely,

President
American Meat Association

EXHIBIT 9

SAMPLE LETTER TO MEMBER OF CONGRESS

Dear Senator:

I am writing to you on behalf of the American Meat Association concerning the proposed EU ban on animal products that contain specified risk materials for Bovine Spongiform Encephalopathy (BSE), the so-called “mad cow disease." If implemented, this ban will prevent $126 million in tallow exports to the EU. For Americans working in the U.S. livestock and rendering industry, the ban would be devastating.

Since the United States has not had any cases of BSE and maintains a rigorous monitoring system, it qualifies as BSE-free, and international organizations have recognized the United States as such. The EU, however, has refused to recognize our BSE-free status. Moreover, it has not provided scientific evidence to justify this decision—although such evidence is required by the WTO Agreement on the Application of Sanitary and Phytosanitary Measures.

In short, the EU ban is a trade barrier that violates World Trade Organization rules and will prevent us from exporting our products to the EU.

American companies, as well as European consumers, need to be assured that we will be able to continue to provide the EU market with our safe products. We gratefully acknowledge the U.S. government's efforts to resolve this issue with the EU, but we also want to encourage the Administration to step-up its efforts to find a satisfactory solution to the problem.

As you are aware from your past experience working in the livestock industry, our industry is committed to providing consumers around the world with safe products. If implemented, the EU's ban will result in undeniable damage to our industry, as well as animal product dependent industries.

Senator, your support for the swift resolution of this problem would be very much appreciated.

Sincerely,

President
American Meat Association

EXHIBIT 10

SAMPLE CONGRESSIONAL TESTIMONY

Testimony to the U.S. Senate Subcommittee on Livestock, Dairy and Poultry, Committee on Agriculture

Thank you, Mr. Chairman. I am the President of the American Meat Association (AMA). The Institute is a national trade association that represents the interests of packers and processors of 70 percent of the nation's beef, pork, lamb, veal and turkey production, as well as their suppliers across the United States.

We appreciate this opportunity to share with the Subcommittee AMA's views on the proposed EU ban on animal products that contain animal proteins or parts called specified risk materials. Still recovering from its epidemic of Bovine Spongiform Encephalopathy (BSE), the so-called "mad cow disease," the EU fears that animal products that contain specified risk materials may contain this disease.

AMA understands and shares the EU's desire to prevent the spread of BSE, but the EU is not justified in erecting a ban. AMA supports domestic and international food safety policies based on sound science as required by the WTO Agreement on Sanitary and Phytosanitary Measures. The EU ban, however, is not scientifically based. There has never been a U.S. case of BSE, and the United States maintains a highly sophisticated and comprehensive monitoring and surveillance system for BSE.

Accordingly, the U.S. Trade Representative has asked the EU to recognize the United States as BSE-free and to allow U.S. companies to continue to export to the EU. The U.S. Trade Representative has emphasized that the United States meets international guidelines for recognition as a BSE-free country, but the EU refuses to follow these guidelines and accept our exports as BSE-free.

Our industry is committed to providing high-quality, safe products for domestic and international consumers. But an outright removal of the opportunity to export to the EU will mean hundreds-of-millions of dollars in lost exports for our industry. Exports that would be affected by the ban include food products, animal feed and gelatin.

Sales of tallow, one of the most important products for our members, would also be banned. Cosmetic and other companies use tallow to make products such as soap, margarine, and candles. Although international scientists have found that tallow is free from BSE if processed under certain temperature and pressure conditions, the EU still plans to ban more than $125 million in U.S. tallow exports.

The Unites States is by far the world's largest producer and exporter of tallow, and the EU is the second largest export destination for U.S. tallow. The BSE epidemic in the EU greatly affected U.S. tallow exports, and the EU refusal to recognize the United States as BSE-free will only make things worse.

The effects of the ban are already being felt. The mere threat of the ban in early 1997 made EU tallow buyers reluctant to purchase U.S. tallow. For the first seven months of the year, U.S. tallow exports were down 23 percent. If the EU does not recognize our BSE-free status, there is little hope for recovery. For our members, this would be devastating.

What it comes down to is that exports are essential for our industry. We rely upon exports to support industry growth, and we will need increasing exports in the future to ensure economic opportunity for the next generation.

The ban would also affect other Americans. The United States Department of Agriculture has found that each dollar received from agricultural exports in 1996 generated another $1.32 in supporting activities to produce the products we shipped overseas. This means that a loss of $125 million in our exports to the EU would cost Americans $165 million. Clearly these figures show that we must work harder to ensure that U.S. exports will not be blocked.

AMA would like to acknowledge the support that you, Mr. Chairman, and the members of this Subcommittee have given us in the past. Today, we call upon you to continue that support by encouraging the Administration to work harder to stand up for the safety of U.S. beef and animal products. Anything less than a prompt and satisfactory resolution to this issue will seriously injure our industry.

This concludes my testimony, Mr. Chairman. I would be pleased to respond to any questions that you or other members of the Committee might have. I thank you.

EXHIBIT 11

LEGISLATIVE STRATEGY

In order to ensure that USTR and USDA give high priority to gaining the EU's recognition of the United States as BSE-free, AMA must secure domestic support including support of Congress. Increased political awareness of the ban will help USTR and USDA in their discussions with the EU.

In securing the support of Congress, AMA should:

- Provide members of Congress and their staff with 1) scientific data relevant to the United States' BSE status, and 2) trade figures that demonstrate the potential impact of the proposed ban;
- Reassure Congress that the EU has no scientific grounds for implementing the ban;
- Write letters (Exhibit 9) to key members of Congress and meet with them to encourage their support;
- Provide testimony on the importance of establishing BSE-free status for the United States and on the potential impact of the ban (Exhibit 10) to both the Subcommittee on Livestock, Dairy and Poultry of the House Committee on Agriculture, and the Senate Committee on Agriculture, Nutrition, and Forestry; and
- Encourage members of Congress who support our position to consider introducing legislation to ensure that imports into the United States are BSE-free.

Prior to meeting with members of Congress and testifying, AMA should evaluate these members propensities to support our position considering their past support of agricultural export interests and food and livestock safety issues:

House Committee on Agriculture, Subcommittee on Livestock, Dairy and Poultr

Democrats:
Collin C. Peterson, MN (Ranking Minority Member)
Earl F. Hilliard, AL
Tim Holden, PA
Jay W. Johnson, WI
Gary A. Condit, CA
Calvin M. Dooley, CA
Sam Farr, CA
Leonard L. Boswell, IA

Republicans:
Richard W. Pombo, CA (Chair)
John A. Boehner, OH (Vice Chair)
Bob Goodlatte, VA
Nick Smith, MI
Frank D. Lucas, OK
Ron Lewis, KY
John N. Hostettler, IN
Roy Blunt, MO
Charles W. "Chip" Pickering, MS
William L. Jenkins, TN

Senate Committee on Agriculture, Nutrition, and Forestry

Democrats:
Tom Harkin, IA
Patrick J. Leahy, VT
Kent Conrad, ND
Thomas A. Daschle
Max Baucus, MT
J. Robert Kerry, NB
Mary Landrieu, LA
Tim Johnson, SD

Republicans:
Richard G. Lugar, IN (Chair)
Jesse Helms, NC
Thad Cochran, MS
Mitch McConnell, KT
Paul Coverdell, GA
Rick Santorum, PA
Pat Roberts, KS
Charles Grassley, IA
Phil Gramm, TX
Larry E. Craig, ID

EXHIBIT 12

SAMPLE LETTER TO U.S. TRADE REPRESENTATIVE AND U.S. DEPT. OF AGRICULTURE

The Honorable Charlene Barshefsky
United States Trade Representative
600 17th Street, N.W.
Washington, D.C. 20508

Dear Ambassador Barshefsky:

The American Meat Association (AMA) appreciates the attention that you and your staff are giving to an issue of serious concern to the U.S. livestock industry. If implemented, the European Commission Decision of July 30, 1997, to ban certain animal products containing specified risk materials for BSE will cause our industry to lose hundreds-of-millions of dollars in export sales. I am writing to share with you AMA's concerns and recommendations regarding this proposed ban.

The EU's lack of sound scientific evidence in support of its EU ban clearly puts the EU in violation of the WTO SPS Agreement. Indeed, under the International Office of Epizootics' international guidelines concerning BSE, the United States should be considered BSE-free. The EU continues to ignore these guidelines, and it refuses to recognize that the United States' state-of-the-art BSE monitoring system has found absolutely no signs of BSE in U.S. cattle.

Given the United States' clean record on BSE, anything less than a full derogation from the ban for U.S. animal product exports is unacceptable. We recommend that the United States continue to press the EU on this issue in bilateral meetings and other fora. The ban would undoubtedly have a devastating affect on our industry unless we are exempted from it.

Again, I thank you for your attention to this matter and encourage you to continue to press the EU for a satisfactory resolution to this problem. As always, your leadership in protecting the international trade interests of the United States is greatly appreciated.

Sincerely,
President
American Meat Association

EXHIBIT 13

NEGOTIATION STRATEGY

MEMORANDUM

November 1, 1997

To: President, American Meat Association

From: Jeanette Kelly, Trade Policy Consultant

Re: Strategy for U.S. Government Negotiations with EU on Proposed SRM Ban

AMA should share with the U.S. government its ideas for approaching negotiations with the EU on the proposed SRM ban. This memorandum outlines an approach the U.S. government could use in building its negotiation strategy.

PREFERRED OUTCOME

The U.S. objective of these negotiations should be to persuade the EU to recognize the United States as BSE-free. This will protect U.S. exports to the EU and set an important precedent to ensure that other countries also recognize the United States as BSE-free.

ALLIES

The United States should form a coalition with EU industry associations and EU member states that share our interests. Denmark and Germany have already expressed their opposition to the ban. Other potential allies include the cosmetics, pharmaceutical and medical associations in these countries. The attached interest charts (Exhibit 18) provide additional details on potential allies.

BASIC ARGUMENTS

In negotiations with the EU, the United States should base its arguments on the following facts and background information:

- The United States understands and shares the EU desire to prevent the spread of BSE.
- The United States acknowledges that the EU has the right under the SPS Agreement to take measures (SPS measures) to protect human and animal health.
- The United States maintains a sophisticated monitoring and surveillance program to protect U.S. beef from BSE. This system has not found any cases of BSE in the United States.
- No cases of the new variant strain of Creutzfeldt-Jakob (nv-CJD) disease have been diagnosed in the United States.

- The SPS Agreement calls for SPS measures, such as the EU ban, to be based on scientific evidence.
- The SPS Agreement calls for SPS measures to take into consideration relevant international standards.
- With respect to BSE, the international veterinary organization (OIE) has defined guidelines for determining BSE status, and OIE has recognized that the United States meets these guidelines.
- Because the United States has a lower level of risk for BSE than any other country, U.S. products deserve to be treated differently than products from countries with higher BSE risks.
- The United States believes that it has provided ample scientific evidence to show that it has no BSE.

NEGOTIATION TACTICS

The United States should consider using the following negotiation tactics to show the EU it is serious about achieving BSE-free status:

- Reveal what the United States will do if agreement is not reached. (The United States could present a very strong case to a WTO Dispute Settlement Panel.)
- Remind the EU that Congress is following this issue and may decide to retaliate if this issue is not resolved.
- Focus on the negative impact the ban will have on EU consumers, particularly medical patients.

If the United States is not successful in these negotiations, it should continue to communicate with the EU. We must identify all possible options for coming to a mutually beneficial solution to this problem. If the EU refuses to accept the arguments we have given to justify our BSE-free status, the United States can apply pressure on the EU by emphasizing that:

- The United States deserves access to any scientific evidence that allows the EU to disregard guidelines established by international organizations concerning the safety of SRMs.
- The United States deserves a full explanation of the EU method of risk analysis (to enable a comparison of the EU methods with those recommended by the OIE International Animal Health Code).

If the EU refuses to provide this information, we must again emphasize that our final alternative, if an agreement is not reached, is to ask the WTO to form a DSB panel.

EXHIBIT 14

SAMPLE PRESS RELEASE

MEDIA ADVISORY
American Meat Association

EU Violates Global Rules, Has No Scientific Evidence to Ban U.S. Animal Products

U.S. industries deserve the right to provide EU suppliers and consumers with high-quality, safe products.

WHAT: Representatives from the U.S. meat, pharmaceuticals and cosmetics industries to brief press on the proposed EU ban on animal products and its impact on U.S. exports.

WHEN: Monday, November 1, 1997, 9:00-10:00 a.m.

WHERE: American Chamber of Commerce
Avenue des Arts 50-55 Kuntslaan, 1000 Brussels

WHO: AMA President
National Renderer's Association President
Pharmaceutical Research and Manufacturer's Association (PhRMA) President

Call the American Chamber of Commerce at XX/XXXX to confirm your attendance.

EXHIBIT 15

SAMPLE ADVERTISEMENT AIMED AT EU CONSUMERS

U.S. MEAT PRODUCTS:
PROVEN QUALITY AND SAFETY

The American meat industry has extremely strict standards for safety and, in conjunction with the U.S. Department of Agriculture, diligently works every day to monitor the health of U.S. cattle. The United States' food safety surveillance program for meat is one of the most comprehensive and effective in the world.

The American meat industry is committed to providing high-quality, safe products for domestic and international consumers.

Anyone that challenges the safety of our products does not have all of the facts:

- Scientific studies conducted by the U.S. government confirm that the United States has never had a case of "mad cow disease" or Bovine Spongiform Encephalopathy (BSE).
- The United States meets international guidelines for being considered BSE-free.
- The United States' system for monitoring the health and safety of its cattle population is sophisticated and comprehensive.

These are the facts, plain and simple. Choose the proven quality and safety of U.S. meat products.

To learn more about the safety of U.S. meat and animal products, please write to the American Meat Association, P.O. Box ABC, Washington, D.C., 12345 or visit our website at www.abcdefghijk.

Sponsored by the American Meat Association

EXHIBIT 16

SAMPLE LETTER TO EU MEMBER STATES

November 1, 1997

His Excellency K. Erik Tygesen
Royal Danish Embassy
3200 Whitehaven St. NW
Washington, D.C. 20008

Dear Ambassador Tygesen:

As Denmark is well aware, the European Union is planning to ban the sale of products that may contain, or are made using, specified risk materials for Bovine Spongiform Encephalopathy (BSE). The American Meat Association is a national trade association that represents the interests of packers and processors of 70 percent of U.S. beef, pork, lamb, veal, and turkey production, as well as their suppliers. We believe that our organization and your country have similar interests: securing BSE-free status for our countries to certify the safety of our animal products. On behalf of AMA, I am writing to ask for your support concerning this issue.

The United States has already begun meeting with the Commission to discuss the proposed ban. We believe that if Denmark, the United States and others work together, we can ensure that the EU Commission realizes it has no choice but to alter its decision. The ban should not apply to products from countries that 1) have effective BSE monitoring systems in place and 2) have found no evidence of BSE.

Our industry is committed to providing high-quality, safe products for domestic and international consumers. So far, the Commission refuses to recognize the safety of our products and our BSE-free status. Unless the Commission grants the United States BSE-free status, we will not have the opportunity to provide your consumers with these products. As I am sure you are aware, these products include life-saving pharmaceuticals. Any delay in access to these products could affect the lives of your citizens, and only the Commission can prevent this from happening.

With your support, we can begin immediately to coordinate and ensure that the EU recognizes our countries as BSE-free. Thank you for your time and support.

Sincerely,

President
American Meat Association

EXHIBIT 17

SAMPLE LETTER TO EU INDUSTRIES

November 1, 1997
Dr. Vincenzo Costigliola
European Medical Association

Place de Jamblinne de Meux, 12
B-1040 Brussels, Belgium

Dear Dr. Costigliola:

As the European Medical Association is well aware, the European Union is planning to ban the sale of products that may contain, or are made using, specified risk materials for Bovine Spongiform Encephalopathy (BSE). The ban includes U.S. pharmaceutical products.

The American Meat Association is a national trade association that represents the interests of packers and processors of 70 percent of U.S. beef, pork, lamb, veal and turkey production and their suppliers across the United States. We believe that our organizations have similar interests: preventing implementation of this ban in order to continue supplying the EU with U.S. products, including pharmaceuticals. On behalf of AMA, I am writing to ask for your support concerning this issue.

The United States has already begun meeting with the Commission to discuss the proposed ban. So far, the Commission refuses to recognize the safety of our products and our BSE-free status. We believe that if our organizations work together, we can ensure that the EU Commission realizes it has no choice but to alter its decision and allow the United States to continue supplying the EU medical community with safe and effective products at a reasonable cost.

Our industry is committed to providing high-quality, safe products for domestic and international consumers. Unless the Commission grants the U.S. BSE-free status, we will not have the opportunity to provide EU consumers with these products. As I am sure you are aware, any delay in access to U.S. pharmaceutical products will affect the lives of your patients. Only the Commission can prevent this from happening.

With your support we can begin immediately to coordinate and ensure that the EU recognizes the United States as BSE-free, thus allowing us to continue supplying the EU with life-saving pharmaceuticals. Thank you for your time and support.

Sincerely,

President
American Meat Association

EXHIBIT 18 – INTEREST CHART 1 (of 8)

PARTY	INTERESTS	OPTIONS	OBJECTIVE CRITERIA	BATNA
American Meat Association (AMA)	Prevent EU ban	• Get recognition of U.S. as BSE-free • Pressure USTR/USDA to make this issue a high priority • Work with other parties to pressure/lobby EU • Lobby Congress to support AMA's position	SPS Agreement OIE Guidelines WHO Recommendations CODEX Recommendations	Take to WTO

	Obtain BSE-free status for the U.S.	• Use certification from int'l organizations (OIE) to pressure EU • Produce study to compare US with other countries recognized by the EU as BSE-free (Australia) • Lobby USDA to allow EU to take a role in US inspections • Provide EU with data to prove the U.S.'s BSE-free status according to the OIE International Animal Health Code		
	Prevent the EU ban from affecting additional products	• Inform USDA/USTR on the lack of evidence that BSE can be transmitted to other animals (horizontal transmission) • Ask USDA to fund BSE studies and procedures for other animals, to which the EU might extend the ban • Prove that other products are safe from BSE		
	Promote members' interests at home and abroad; increase exports; protect high-quality reputation of products	• Increase marketing efforts (in EU) • Start a BSE-free label for meat and products • Target new markets, diversify products • Ensure recognition of BSE-free status		
	Ensure implementation of EU commitments to accept US imports	• Lobby USDA/USTR to get assurance from EU • Lobby to allow US to retaliate in event that EU does not carry out its end of any deal • Export to countries that are more likely to accept US imports		

	Make interests of AMA known to the EU public	• Educate public, provide on-line information • Increase active public outreach activities and response plans • Target youngsters • Participate with other interested parties in an education initiative		
	Preserve relationship with USDA and USTR	• Offer support for both agencies efforts while encouraging them to continue to press the EU		
	Provide consumers with safe products	• Initiate a separate inspection program for AMA members • Sponsor or work with APHIS to continue to train processors to identify possible signs of BSE • Offer to provide funding for additional educational programs		

EXHIBIT 18 – INTEREST CHART 2 (of 8)

PARTY	INTERESTS	OPTIONS	OBJECTIVE CRITERIA	BATNA
European Union/ **Commission**	Protect the health of EU animals from BSE	• Implement ban on SRMs • Prevent import of any products/parts that have risk of transmitting disease • Prevent import of products/parts from countries with high risk for BSE	SPS Agreement OIE Guidelines WHO Recommendations CODEX Recommendations	Do nothing; Implement the ban as is and risk being taken to the WTO

	Protect the health of EU citizens from BSE/CJD; ensure availability of medical products; ensure safety of food supply	• Implement the ban on SRMs • Allow import of products necessary to save lives of EU patients, regardless of whether they have SRMs • Establish a certification system for products with no SRMs		
	Maintain good relations with US and other trading partners	• Negotiate derogations for the ban • Implement ban with differing levels of application, depending on risk level • Conduct talks with other trading partners concerning the potential impact of the ban on them		
	Maintain Commission "sovereignty"/authority on EU trade matters	• Try to keep member states out of the negotiations • Try to keep member states happy; build their trust, involve them as much as possible		
	Prevent disagreement/promote agreement between Commission and member states	• Keep US interests in mind • Treat all member states equally		
	Avoid granting exemptions for EU member states	• Don't grant exemptions for any other nation		
	Promote international trade norms; avoid being taken to WTO	• Follow WTO guidelines		

EXHIBIT 18 – INTEREST CHART 3 (of 8)

PARTY	INTERESTS	OPTIONS	OBJECTIVE CRITERIA	BATNA
EU Standing Scientific Committee (SSC)	Use only most reliable scientific evidence when making recommendations	• Follow international guidelines • Don't make far-fetched interpretation of scientific evidence just to meet the needs of the Commission	SPS Agreement OIE Guidelines WHO Recommendations CODEX Recommendations	Maintain status quo
	Advise Commission and ensure SSC's role in decision-making	• Tell Commission what it wants to hear • Work to de-politicize membership, make SSC membership last longer to reduce Commission's ability to pressure SCC and ensure membership is based solely on merit		
	Protect EU animals and human health	• Suggest Commission implement the ban • Follow international guidelines and sound science • Conduct own research on these issues		
	Protect reputation as independent, fair and knowledgeable	• Follow international guidelines • Make decisions based on sound science • Consistently remain independent of Commission		

EXHIBIT 18 – INTEREST CHART 4 (of 8)

PARTY	INTERESTS	OPTIONS	OBJECTIVE CRITERIA	BATNA
EU Pharma-ceutical Community	• Sell its products at home	• Ensure their safety • Don't use SRMs • Develop non-SRM method of production	SPS Agreement OIE Guidelines WHO Recommendations CODEX Recommendations	Maintain status quo
	• Sell products abroad (increase exports)	• Marketing-safety		

	• Ensure safety of products and materials used to create pharmaceutical products • Ensure health, safety of consumers	• Don't use SRMs • Use only BSE-free SRM inputs • Support EU ban		
	• Ensure reputation for providing high-quality products	• Marketing and efforts to distinguish EU products from US (as free from SRMs) • Ensure products are safe		
	• Create new products • Obtain funding for research • Obtain approval for new products	• Increase R&D efforts • Work with US companies		
	• Maintain relationship with EU authorities	• Work with them to ensure safety standards and quality		
	• Prevent imports (protect domestic market share)	• Increase marketing • Support ban		
	• Obtain required inputs from foreign suppliers	• Don't support ban • Use imports from BSE-free countries • Don't use SRMs		

EXHIBIT 18 – INTEREST CHART 5 (of 8)

PARTY	INTERESTS	OPTIONS	OBJECTIVE CRITERIA	BATNA
EU Member States with <u>no</u> Native BSE	Protect reputation of products	• Obtain exemption from ban • Ensure safety, quality, monitoring/prevention/education for BSE	SPS Agreement OIE Guidelines WHO Recommendations CODEX Recommendations	Maintain status quo
	Obtain BSE-free status	• Push Commission to grant status Continue to monitor safety of domestic beef, etc. to demonstrate commitment to remaining BSE-free		
	Protect food supply, consumers, human health	• Inspection of food supply • Implement ban		
	Protect animal health (from BSE)	• Inspection system • Import restrictions-like ban • Prevention, education methods		
	Show Commission the states are important (limit Commission's power/competence)	• Withhold support for ban unless member states with no BSE get exemptions • Ensure members states maintain some authority in trade issues		
	Distinguish themselves from UK	• Uphold support for ban • Demand exemptions		
	Promote exports	• Lobby to remove US ban/limitations on imports • Marketing efforts • Distinguish from UK		
	Promote international trade norms	• Ensure Commission follows WTO guidelines • Communicate with other member states concerning ban		

EXHIBIT 18 – INTEREST CHART 6 (of 8)

PARTY	INTERESTS	OPTIONS	OBJECTIVE CRITERIA	BATNA
United Kingdom	Protect animal health from BSE	• Implement ban on SRMs • Prevent import of any products/parts that have risk of transmitting disease	SPS Agreement OIE Guidelines WHO Recommendations CODEX Recommendations	Maintain status quo
	Protect human health, consumers	• Implement ban on SRMs • Allow products that are necessar to save lives of EU patients, regardless of whether they have SRMs • Establish a certification system for products with no SRMs		
	Increase exports	• Marketing • Ensure safety of products		
	Protect right to establish own, separate ban	• Lobby Commission for support		
	Implementation of EU ban (on April 1)	• Lobby Commission • Lobby other EU member states		
	Prevent spread of BSE	• Scientific inspections • Prevention initiatives • Education initiatives • Support ban		

EXHIBIT 18 – INTEREST CHART 7 (of 8)

PARTY	INTERESTS	OPTIONS	OBJECTIVE CRITERIA	BATNA
United States Trade Represen-tative (USTR)	Prevent EU ban	• Negotiate derogations with EU • Push for BSE-free status	SPS Agreement OIE Guidelines WHO Recommendations CODEX	Take EU to WTO
	Promote US exports	• Marketing • Ensure ban in removed • Bilateral agreements-negotiations		

	Obtain BSE-free status	• Lobby EU • Lobby member states • Work with industries to get science right	Recommendations	
	Ensure implementation of EU exceptions (also only high-quality exceptions)	• Lobby EU • Negotiate with EU • Take EU to WTO		
	Ensure international trade norms used	• Follow WTO obligations, use DSB to take EU to WTO DSB • Encourage EU to follow the WTO obligations		
	Preserve relationship with USDA, EU Commission	• Negotiate with objective criteria as basis • Separate negotiations from personal contacts • Make efforts to preserve relationship outside of negotiations/official busines		

EXHIBIT 18 – INTEREST CHART 8 (of 8)

PARTY	INTERESTS	OPTIONS	OBJECTIVE CRITERIA	BATNA
U.S. Dept. of Agriculture **(USDA)**	Prevent EU ban	Work with USTR to lobby EU and push for BSE-free status	SPS Agreement OIE Guidelines WHO Recommendations CODEX Recommendations	Take EU to WTO
	Promote US exports	Work with USTR to negotiate market access agreements Target new markets Provide exporters with market access information, tips, etc.		
	Obtain BSE-free status	Work with USTR Ensure that US monitoring system meets all guidelines set by the OIE International Animal Health Code		

	Ensure implementation of EU commitments; accept only high-quality exemptions	Work with USTR (see USTR #4)		
	Preserve relationship with USTR, EU	Work to keep personal relationship separate from official business, (see USTR #7)		
	Ensure safety of US food supply (protect human health)	Continue BSE surveillance and monitoring system		
	Ensure animal health (from BSE)	Continue BSE surveillance and monitoring system Protect domestic animals Import controls		