



MAR 12 2001

The Honorable W.J. "Billy" Tauzin
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

Thank you for your interest in the Food and Drug Administration's (FDA or the Agency) role in protecting the United States (U.S.) from bovine spongiform encephalopathy (BSE). This letter is in response to your letter of January 24, 2001, co-signed by Chairman Michael Bilirakis to Bernard A. Schwetz, DVM, Ph.D., Acting Principal Deputy Commissioner of Food and Drugs.

Enclosed are documents responsive to your request. Certain documents provided may contain trade secret, commercial confidential, or other privileged information protected from disclosure to the public under the Freedom of Information Act (Title 5, United States Code [U.S.C.] Section 522), the Trade Secrets Act (18 U.S.C. Section 1905), and FDA regulations. We ask that the Committee not publish or otherwise make public any such confidential information. We would be glad, of course, to discuss with the Committee staff the confidentiality of any specific information. Please be advised that additional records that otherwise may be responsive to your request are not being provided at this time, as they are related to an ongoing investigation. Once the investigation is closed, we will be happy to provide additional information to the Committee.

Your requests or questions are restated, followed by FDA's response.

1. All records dated on or since July 1, 2000 relating to assessments of the public health threat from mad cow disease or BSE, chronic wasting disease, or any other disease that is relevant to assessing or understanding the mad cow disease issue.

Documents are at Tab A.

2. Please itemize and explain the different kinds of import controls that FDA has to prevent imports of products potentially tainted with mad cow disease. Please itemize and explain the different kinds of deficiencies in the import control system that are relevant to preventing imports of products potentially tainted with mad cow disease. Please provide all records dated on or since July 1, 2000 used to support the agency's response.

Import Controls

FDA's Import Program is the primary tool the Agency has to "control imports" of products potentially infected with or at high risk of infection with the agent associated with BSE (i.e., products "potentially tainted with mad cow disease"). On the issue of protecting the U.S. from BSE, FDA and the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) work together in close cooperation with the U.S. Customs Service (Customs), the Federal agency with primary responsibility for administering U.S. laws relating to imports.

Operationally, the import control system provides for the review of information about every product offered for entry into the U.S. and the opportunity for physical examination of the products. The outcome of the review process determines whether a product will be admitted into the U.S., with or without physical examination, or refused admission.

Procedurally, FDA provides Customs with a list of the Harmonized Tariff Schedule (HTS) codes for FDA-regulated products about which we have potential concerns. Customs' Automated Commercial System (ACS) uses these codes to help identify these articles

subject to FDA's jurisdiction when they are presented for entry into the U.S. Customs then either transmits data elements describing the products to FDA ("electronic entries") or insures that the importer notifies FDA of the entry ("paper entries"). Electronic entry data are then screened against entry criteria stored in FDA's Operational and Administrative System for Import Support (OASIS) system prior to review by FDA entry reviewers. Paper entries are reviewed solely by FDA entry reviewers. Entry data are collected at all ports of entry, even those at which FDA staff are not always present.

Generally, if FDA decides to physically examine a product offered for import, an FDA inspector will visit the storage location; examine the packaging, labeling, and storage conditions; may copy or photograph the labeling or marks on the shipping container; and/or, may collect a sample for laboratory analysis. If FDA decides to physically examine the entry after it has left the port area, Customs, under the terms of the importer's entry bond, can order the product redelivered for FDA examination. If the analysis indicates the product is in compliance, the shipment can be released into U.S. commerce. Section 801 of the Federal Food, Drugs, and Cosmetics Act (the Act) authorizes FDA to refuse admission of any article that appears to be in violation of the Act.

If the product is refused admission, the importer is provided an opportunity to submit a petition to recondition the product to bring it into compliance with the law. If the product is ultimately refused admission into this country, the importer is required to either re-export or destroy the article under Customs or other approved supervision. If the refused product is not destroyed or re-exported, Customs issues a notice for redelivery to the importer of record. Failure to redeliver the refused product may result in Customs assessing liquidated damages against the importer's bond.

Import Alerts and Import Bulletins

The sheer volume of imported FDA-regulated products precludes the Agency from physically examining every entry into the U.S. Therefore, other tools are used to help control the entry of products where historical data suggest products are likely to be in violation of the law. Import Alerts and Import Bulletins are used to disseminate information regarding problems or potential problems with imported products. Import Alerts and Bulletins are coordinated closely with APHIS and its prohibitions on the

importation of products of concern about contamination with BSE suspect material.

Import Alerts are a means to disseminate guidance to FDA District offices regarding identified problems with imported products. As a matter of convenience, they are made available on FDA's website (www.FDA.gov). These Alerts are used to identify problem commodities, problem shippers, or problem importers, in addition to providing guidance for import coverage. This guidance is based upon evidence the Agency has developed related to the commodities, shippers or importers. An Alert may cover an individual manufacturer, supplier, or a particular product from an entire country. Import Alerts also may be issued as a follow-up to an inspection, when it is determined that a manufacturer is in violation of good manufacturing practice requirements. Import Alerts recommend that the field offices examine, sample, or detain and, if warranted, refuse entry of the product in question.

Import Bulletins provide early information about potentially violative imported products. Bulletins are usually only advisory. Therefore, they basically advise FDA field offices to contact the appropriate product expert for additional information and advice.

When either an Import Bulletin or an Import Alert is issued, screening criteria describing the product, country of origin, manufacturer, shipper and other relevant information are loaded into OASIS. When product matching these criteria is offered for import, the OASIS system alerts the FDA entry reviewer.

Imports and BSE

FDA has issued the following Import Alerts and Import Bulletin relating to BSE:

- On September 1, 1992, FDA issued Import Bulletin 99-B03, alerting field units to imports, from BSE countries, of animal by-products and regulated products containing animal by-product ingredients.
- On October 19, 1994, FDA issued Import Alert 17-04 (replacing the 1992 Import Bulletin) calling for the detention, without examination, of bulk shipments of

high-risk bovine tissues and tissue-derived ingredients from BSE countries (at that time this included the United Kingdom, France, Ireland, Oman, Switzerland, and Portugal). FDA updated this alert whenever APHIS revised the list of BSE countries it included at Title 9, Code of Federal Regulations (CFR) § 94.18.

- On January 24, 2000, FDA updated the existing Import Alert 17-04, which called for detention of bulk shipments of high-risk bovine tissue from BSE countries to include countries in most of Europe, following APHIS's extension of import restrictions to those countries.
- On December 20, 2000, FDA issued Import Bulletin 71B-02, alerting FDA field personnel of the APHIS restrictions on animal feed ingredients from 31 countries, and instructing them to coordinate entry review with their local APHIS office. This Import Bulletin was cancelled on January 23, 2001, after the issuance of Import Alert 99-25.
- On January 20, 2001, FDA issued Import Alert 99-25, which instructed FDA field personnel to detain animal feed, animal feed ingredients, and other products for animal use consisting of, or containing, ingredients of animal origin.
- On March 1, 2001, FDA issued Import Bulletin 99B-14, alerting FDA field personnel that APHIS further prohibited the importation into the U.S. of certain edible ruminant products from Europe, Oman, and BSE at-risk countries. The Bulletin advises that FDA entry review should include assessment of product ingredients to determine whether they contain or may contain ruminant material subject to the APHIS prohibition.

Copies of the Import Alerts 17-04 (as of January 24, 2000) and 99-25 and Import Bulletins 71B-02 and 99-B14 are enclosed at Tab B1.

Opportunities to Improve Controls

FDA's control of products that could be contaminated with BSE and that are presented for entry could be enhanced by more consistent, complete and reliable data available to FDA for review.

Data Elements

For the most part, FDA entry review is based upon data that are submitted to Customs as required by Customs regulations. FDA does not currently require the submission of additional information outside of Customs' data requirements when an FDA-regulated product is offered for import. Data submitted to Customs at time of entry do not always have the level of specificity necessary for FDA review, thus requiring time and labor including intensive communications with the broker or importer before entry review can be completed. Examples of data that would facilitate screening for BSE material include documentation of the country of origin of the product, a complete list of ingredients for each product, the animal origin of any such ingredients, and the identity of the actual manufacturer (as opposed to the shipper or distributor).

Except in the case of Low Acid Canned Foods, FDA currently does not require in its regulations that foreign food manufacturers register with the Agency, supply processing and materials information, or submit to FDA inspection as a requirement for exporting to the U.S. It should be noted that the number of foreign food manufacturers is estimated to be in the hundreds of thousands.

Data Integrity

Entry data is supplied to FDA (as well as Customs and all other government agencies) on a "self-reporting" basis by importers or their agents. The accuracy and completeness of such data therefore limit the review and regulation of imported products. FDA's experience is that data accuracy has been a problem. In order to achieve and maintain a sufficient level of accuracy in such data, FDA has trained importers and brokers in the submission of such data, and periodically evaluates the quality of such data by comparing the data submitted with the original entry documents.

Filer Evaluations: It is important to note that FDA is dependent upon the import community (brokers, importers, shippers) for the entry and manifest data with which to identify products consisting of, or containing, ruminant material from BSE countries. Products which are mis-declared or mis-described intentionally or unintentionally by importers or brokers, which hides their animal origin or country of origin, may not be detected either by OASIS screening or manual entry review. Because the OASIS Entry Review Process relies on the submission of accurate and complete information from the importers and brokers (collectively referred to as entry "filers"), FDA has initiated a broker/filer evaluation data integrity program and attempts to evaluate the accuracy and validity of each filer's data submissions at least every nine months. This evaluation, however, is a time consuming procedure which consists of selecting a random sample of each filer's data submissions for the previous nine months and comparing the data submitted to FDA with data from the original entry documents in the entry filer's files.

Filer Training: When OASIS (and its progenitor, EEPS) was first implemented, FDA offered training, at Agency expense, to all importers and brokers who would enter data into the system. This training utilized the "train-the-trainer" approach: A cadre of FDA field personnel was trained both in OASIS data entry and how to train importers and filers in such data entry. Recently, FDA has developed an Internet-based training module that allows importers and filers to receive training in their own facilities on their own schedule. Unfortunately, based upon the incidence of inaccurate data submitted to FDA, it appears that many filers have failed to utilize this training opportunity. Individual districts occasionally have offered repeat in-person training courses, but to institute a massive in-person re-training of importers and brokers would require the training of a new cadre of FDA field personnel and then training approximately 4,205 filers (importers and brokers) across the country.

These programs have encouraged import filer compliance. FDA is hopeful that planned enhancements to these programs will provide additional intelligence and subsequently increase enforcement actions for FDA-regulated products, including those products that potentially could be contaminated with BSE. Filer evaluations and filer training are done in line with current

resources. FDA currently does not have the resources that it would like to devote to these programs.

Additional records are at Tab B2.

3. When does FDA expect to complete the reinspections of the 700 U.S. animal feed manufacturers and renderers not in full compliance? Please provide all records relating to the plan of reinspections.

FDA expects to have the reinspections completed by the end of this fiscal year. Following is information on FDA's plans to achieve 100 percent compliance of renderers, protein blenders, and licensed and unlicensed feed mills with the August 4, 1997, Final Rule covering prohibitions of feeding mammalian protein to ruminant animals.

There are approximately 1500 renderers and licensed feed mills in the current inventory of known establishments. As of February 27, 2001, FDA and its State counterpart agencies have performed initial inspections (regarding compliance with 21 CFR 589.2000) of 227 of the 260 renderers and 1069 of the 1240 licensed feed mills.

There also are a large number of unlicensed feed mills in the U.S. It is estimated there are from 6000 to 8000 of these establishments. FDA is contracting with States to help identify unlicensed feed mills within their States and to then conduct inspections if there is no record of an inspection being conducted under FDA's program. As of February 27, 2001, FDA has inspected 922 of these firms and our State counterparts, under FDA contract, have inspected 4142 of these firms.

The Agency recently issued two inspection assignments for further inspections of known establishments. The first assignment, issued on December 20, 2000, covers renderers and FDA-licensed feed mills that have never been inspected. The second assignment, issued on January 12, 2001, covers firms (licensed and non-FDA-licensed feed mills, renderers, and protein blenders) that were determined on their most recent inspection to be out of compliance with the regulations based on evidence that products were not properly labeled, they lacked a system to prevent commingling, or they failed to establish adequate record keeping practices. The total number of inspections ordered as part of these two assignments is 1247 (413 initial inspections, 834 reinspections).

To accomplish this, FDA has implemented a nationwide tracking system and will be coordinating our activities with our State counterparts to ensure the timely completion of these assignments.

The following documents are provided at Tab C1.

"Inspectional Request - Compliance with 21 CFR 589.2000, Animal Proteins Prohibited from Use in Animal Feed" dated 12/20/00.

"Inspection Request - Follow-up Inspections, Firms Not in Compliance with 21 CFR 589.2000, Animal Proteins Prohibited from Use in Animal Feed" dated 1/12/01.

Additional documents are at Tab C2.

4. How are the FDA and all other relevant federal agencies (U.S. Customs Service, the Department of Agriculture, Centers for Disease Control and Prevention, e.g.) cooperating to ensure that imports of products potentially tainted with mad cow disease are not getting into the United States? Is there any reconsideration of admissibility requirements of products currently exempt from the import ban on British meat or meat products? Please provide all records dated on or since July 1, 2000 of all meetings, teleconferences, or any other communications among FDA and other federal agencies relating to mad cow disease or BSE.

There exist working groups and a senior executive interagency steering committee on BSE, as well as a Tri-country group of the U.S., Canada, and Mexico. FDA is a participating Agency on all of these groups, and, in fact, chairs the Senior Executive Interagency Steering Committee. A major goal of these groups is to ensure that imports of products potentially contaminated with the agent associated with BSE do not get into the U.S. Following is a brief overview of these groups and specific information on cooperation on imports.

The Tri-country group of the U.S., Canada, and Mexico has been meeting for three years. The U.S. hosted the first meeting in 1998 and is scheduled to host the meeting this year in September or October. The Tri-country group is comprised of technical

individuals who know the day-in and day-out workings of the programs of their agencies. The Tri-country group makes recommendations that are considered by the participating countries. The group has been successful in terms of harmonizing import policies. All three countries have put into place the last two import bans issued by the USDA.

An Interagency Steering Committee of senior officials assures ongoing coordination between agencies, especially in three main areas: integrated contingency planning in case BSE or variant Creutzfeldt-Jakob Disease (vCJD) disease is found in the U.S, identification of and response to potential vulnerabilities in the U.S. to BSE and vCJD, and coordination of risk communication plans by the various agencies. Organizations represented are: the Department of Health and Human Service's Assistant Secretary for Science Policy, FDA, the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), USDA's APHIS, Foreign Agricultural Service, and Food Safety and Inspection Service (FSIS), White House Office of Science & Technology Policy, U.S. Trade Representative, Customs, Department of State, Department of Defense (DoD), National Association of States Departments of Agriculture, and the Association of American Feed Control Officials.

An interagency working group on BSE started in 1996 with USDA's APHIS, FSIS and Agricultural Research Service (ARS), FDA, NIH, CDC, and DoD represented. The purpose of the group is to share information, evaluate ideas and issues, and take suggestions back to participating agencies. Although import issues have long been addressed in the interagency working group and agencies have coordinated actions on import issues, to further strengthen coordination of import issues, an import subgroup to the interagency workgroup was formed to investigate and make recommendations relating to import issues. On January 17, 2001, FDA attended the initial meeting of the import subgroup (consisting of representatives from APHIS, FDA and Customs) to enhance joint procedures to prevent the importation of BSE material into the U.S.

FDA, APHIS, and Customs have coordinated their response to the potential importation of BSE-related products. After APHIS issued their prohibition on the importation of BSE materials on December 7, 2000, FDA issued Import Bulletin 71B-02 requesting that FDA's field offices notify their local APHIS offices of any import suspected of containing BSE material.

FDA continues to coordinate activities among U.S. Customs, USDA/APHIS and FDA, and is leading the efforts for developing procedures for multi-agency operations. FDA has provided FDA-product codes (those used in OASIS entry screening) to APHIS for their review, and has facilitated APHIS review of Customs HTS codes (used in Customs entry screening) which resulted in Customs issuing a directive to Customs field personnel on January 4, 2000, identifying specific HTS codes for products subject to the APHIS prohibition.

APHIS prohibition of BSE risk products of animal origin is currently the first line of defense to prevent such products from entering the U.S. FDA will continue to review entries of FDA-regulated products that consist of, or may contain, such products and ensure that APHIS has been notified of and has denied entry of such products as appropriate. FDA is continuing to review its own admissibility requirements regarding FDA-regulated products that could pose a BSE-related risk.

Documents are at Tab D.

5. What kinds of data systems does FDA have to deal with imports of products potentially tainted with mad cow disease? What kinds of data systems should FDA have to deal effectively with imports of products potentially tainted with mad cow disease? Please state what resources are needed for FDA to upgrade its import control system to deal with the threat of mad cow disease. Please provide this in both dollar amounts and FTEs if possible.

Current Systems to Deal with Imports of Products Potentially Contaminated with BSE.

The OASIS is FDA's automated system for making admissibility determinations for shipments of foreign-origin FDA-regulated products seeking to enter domestic commerce. FDA re-engineered the business processes that Agency staff utilizes for making admissibility determinations to ensure the safety, efficacy, and quality of foreign-origin FDA-regulated products. OASIS automated those re-engineered processes.

As this Committee knows, OASIS began as a pilot program in 1992 and interfaced with Customs' ACS, screening entries using ACS and providing the initial operational support to FDA users. The interface with ACS and the screening subset of the system (known as EEPS) was implemented nationally by June 1995 and use of the

OASIS system by industry became mandatory in December 1996. The baseline of the current version of OASIS with full basic operational functionality was implemented nationally by October 1997. The system has undergone continuous improvement of operational support. A major change in September 1999 moved screening from ACS to OASIS and expanded screening to cover all data elements.

The OASIS system uses information entered by Custom House Brokers and importing firms to facilitate the screening and/or inspection of imported products that are subject to FDA regulation. As a user-driven system, OASIS depends upon import brokers to provide complete and accurate information. While the OASIS system provides the majority of the information it was designed to provide, it only contains two years worth of data, and does not currently electronically interface with other systems that contain additional information of value to FDA field staff.

Screening information relating to the Imports Alerts and Import Bulletin on BSE has been entered into the OASIS system. Detailed information on Import Alerts and Import Bulletins is available to field personnel through the FDA Import Alert Retrieval System, which has been operational since August 1987.

Systems Enhancements to More Effectively Deal with Imports of Products Potentially Contaminated with BSE.

As the Committee is aware, improving and enhancing the Agency's information technology systems is a high priority. As previously reported to the Committee, last year, FDA hired an outside contractor to assess the Agency's information technology systems. A focus of the review was to find ways to provide more accurate, complete, and timely information to import inspectors. Two overarching efforts that are being pursued in follow-up to that review and that have been discussed with Committee staff are the development of a Secure Enterprise Information Portal to provide a single-route electronic access to all of FDA's regulatory database systems for import inspectors and development of an Agency-wide electronic address book of companies with which FDA has regulatory dealings. At the same time, the Agency is continuously evaluating ways, within available resources, to make enhancements to its existing import information systems.

FDA is not prepared at this time to articulate specific resource needs to upgrade FDA's import control systems to deal with BSE. We acknowledge that enhancements and upgrades to our information systems and other import controls would improve our ability to control the flood of diverse products being presented for entry at our borders. FDA is working with the Administration to identify sufficient resources to be included in the Fiscal Year 2002 budget. Until the President releases the budget, we are not at liberty to discuss resource issues.

Thank you again for your interest in this matter. If the Committee has further questions, or would like a briefing for the Members or your staff, please let us know. A similar letter has been sent to Chairman Bilirakis.

Sincerely,



Melinda K. Plaisier
Associate Commissioner
for Legislation

cc: The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce

The Honorable Sherrod Brown
Ranking Minority Member
Subcommittee on Health
Committee on Energy and Commerce