

specifically address recordkeeping requirements.

Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act") (Pub. L. 107-188), which was signed into law on June 12, 2002. The Bioterrorism Act provides that the Secretary of Health and Human Services (HHS) may require the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive hold, or import food for human or animal consumption in the United States. On May 9, 2003, the Food and Drug Administration (FDA) proposed regulations that would implement these recordkeeping requirements (68 FR 25188). The recordkeeping requirements that will apply under the Bioterrorism Act will not affect the recordkeeping requirements in FSIS' regulations. Therefore, even after the Bioterrorism Act's recordkeeping requirements take effect, the recordkeeping requirements in FSIS' regulations will continue to apply to the parties listed above.

Registration Requirements

The FMIA and PPIA were also amended in 1967 and 1968, respectively, to add sections 203 (21 U.S.C. 643) and 11(c) (21 U.S.C. 460(c)). These provisions prohibit any person, firm, or corporation from engaging in commerce as a meat or poultry products broker, renderer, animal food manufacturer, wholesaler, or public warehouseman, or from buying, selling, or transporting, or importing any dead, dying, disabled or diseased livestock or poultry or parts of the carcasses of livestock or poultry that died otherwise than by slaughter unless they have registered their business as required by the regulations.

Regulations implementing registration requirements were first published in 1970. Sections 320.5 and 381.179 of the current regulations require that the parties listed in the preceding paragraph register with FSIS, unless these parties conduct business only at an official establishment where meat or poultry inspection is maintained.

According to the regulations, parties required to register with FSIS must do so by filing out a form and must provide current and correct information to FSIS, including their name, the address of all locations at which they conduct the businesses that require them to register, and all trade or business names under which they conduct these businesses.

FSIS has developed a new registration form. In addition to requiring the name and addresses of locations at which registrants conduct business, the form

requires that parties disclose the form of their organization (*e.g.*, individually owned or partnership), the nature of their business (*e.g.*, meat or meat products or poultry or poultry products), and the type of business they are engaged in (*e.g.*, domestic broker, import broker, warehouseman, etc). The form also requires that registrants provide their phone number and e-mail address and the hours of operation of any of their subsidiaries, branches, or divisions that conduct the businesses that require them to register. According to the regulations, parties required to register with FSIS must do so within 90 days after they begin to engage in any of the businesses that require them to register.

FSIS' new registration form will be available for use by December 22, 2003. Because this form requires that registrants provide certain information that was not required on the previous form, including e-mail address, phone number, and subsidiaries' hours of operation, all parties required to register, including those that are currently registered, must complete the new form and submit it to FSIS. Parties must submit the form to FSIS by March 22, 2004.

The registration form can be obtained over the Internet at: <http://www.fsis.usda.gov/fsisforms/>. To obtain the form, parties can also write to USDA, FSIS, Program Evaluation, Enforcement and Review (PEER), Evaluation and Enforcement Division (EED), 300 West End Court Building, 1255 22nd Street, NW., Room 300, Washington, DC 20250-3700. The FSIS regulations provide a different mailing address for obtaining the registration form, and state that the registration form can be obtained from "Compliance Programs, Regulatory Programs" (§§ 320.5(a) and 381.179(a)). FSIS intends to update this information in a future rule. The form will also be available from FSIS personnel that visit businesses required to register. Once parties complete the form, they should mail it to USDA, FSIS, Program Evaluation, Enforcement and Review (PEER), Evaluation and Enforcement Division (EED), 300 West End Court Building, 1255 22nd Street, NW., Room 300, Washington, DC 20250-3700 (the same address as for obtaining forms) or fax it to Director, Evaluation and Enforcement Division (EED) at (202) 418-8941.

The regulations require that, whenever any change is made in the registrant's name, business address, or any trade or business name under which it conducts its business, the registrant must report such change in writing to

the Administrator within 15 days after making the change.

The Bioterrorism Act includes a provision that requires the Secretary of HHS to develop regulations mandating domestic and foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the United States to register with the FDA by December 12, 2003. On February 3, 2003, FDA proposed regulations that would implement these registration requirements (68 FR 5378). The registration requirements that will apply under the Bioterrorism Act will not replace the registration requirements in FSIS' regulations. Therefore, even after the Bioterrorism Act's registration requirements take effect, the registration requirements in FSIS' regulations will continue to apply to the parties listed above.

Bovine Spongiform Encephalopathy

Bovine Spongiform Encephalopathy (BSE), commonly referred to as "Mad Cow Disease," is a slowly progressive degenerative disease that affects the central nervous system (CNS) of adult cattle. BSE belongs to the family of diseases known as the transmissible spongiform encephalopathies (TSEs). Other TSEs include scrapie in sheep and goats, transmissible mink encephalopathy, feline spongiform encephalopathy, chronic wasting disease (CWD) in deer and elk, and in humans, kuru, classic Creutzfeldt-Jakob Disease (CJD), Gerstmann-Strausler-Scheinker syndrome, fatal familial insomnia, and variant Creutzfeldt-Jakob Disease (vCJD).

The agent that causes BSE and other TSEs has yet to be fully characterized. There are three main theories on the nature of the BSE agent: (1) The agent is a virus with unusual characteristics; (2) the agent is a prion—an abnormal form of a normal protein known as cellular prion protein; and (3) the agent is a virino—an "incomplete" virus composed of nucleic acid protected by host proteins. The BSE agent is highly resistant to heat, ultraviolet light, ionizing radiation, and common disinfectants that normally inactivate viruses or bacteria. Scientific experts believe that prions most likely cause BSE and other TSEs.

BSE was first diagnosed in 1986 in the United Kingdom (U.K.) and since then has been confirmed in native-born cattle in many other European countries and several countries outside Europe. This animal disease is most likely spread by feeding the rendered parts of cattle infected with the BSE agent to other cattle in the form of meat and bone meal. No cases of BSE have been