

FSIS web site at http://www.fsis.usda.gov/oa/topics/BSE_Thinking.pdf and http://www.fsis.usda.gov/oa/topics/BSE_thinking.htm.

In this paper, FSIS stated that it planned to increase its enforcement of recordkeeping and registration requirements for renderers and persons who engage in the business of buying, selling, and transporting 4-D livestock or parts of the carcasses of any such livestock that died otherwise than by slaughter. In considering measures to minimize human exposure to bovine tissue and products that could contain the agent that causes BSE, FSIS determined that registration information and records from renderers and persons who engage in the business of buying, selling, and transporting 4-D livestock, or parts of the carcasses of any such livestock that died otherwise than by slaughter, would support FDA in enforcing its regulations that prohibit most mammalian protein in ruminant feed.

Parts of carcasses of 4-D livestock are often used in rendering. Renderers produce meat and bonemeal and similar products used in livestock and poultry feed. If any ruminant feed is suspected of containing mammalian protein, FSIS will need and will be able to obtain registration information from the renderers that supplied rendered ruminant product to the animal feed manufacturers and from the producers or businesses that supplied the renderers with 4-D livestock or parts of carcasses of 4-D livestock. FSIS will also require and will have access to their related business records. FSIS will work collaboratively with FDA to locate these producers and businesses and obtain their records.

Should BSE be introduced into the United States, registration information and business records will be crucial in quickly determining and tracking the source of BSE so as to prevent its spread. Registration information and business records would be crucial in tracking transactions involving cattle that are suspected of being, or confirmed to be, infected with BSE and carcasses and products that are suspected of being, or confirmed to be, contaminated with the agent that causes BSE.

FSIS is reminding businesses subject to the PPIA that are required to register or maintain records that they must do so because the registration and recordkeeping requirements in the poultry products inspection regulations are almost identical to those in the meat inspection regulations. Also, FSIS needs to make sure that its information on

registrants is accurate, complete, and current. Therefore, it is important that all businesses required to register under the FMIA or PPIA do so and keep their registrations current. As stated above, in this notice, FSIS is not focusing on egg products businesses because the recordkeeping requirements in the egg products inspection regulations are different from those in the meat and poultry products inspection regulations, because egg products businesses are not required to register with FSIS, and because FSIS is developing a proposed rule on shell eggs and egg products that will address recordkeeping requirements.

Failure To Register or Maintain Records

As FSIS previously stated in its BSE current thinking paper, FSIS intends to increase enforcement of the registration and recordkeeping requirements discussed above. If FSIS determines that a party required to register, or a party required to maintain records, has not done so, FSIS program employees will first remind the party to register immediately or to maintain current and accurate records. If the party continues to violate the registration or recordkeeping requirements, FSIS will then issue a letter of warning. If any party continues to violate the registration or recordkeeping requirements after receiving a letter of warning, FSIS will consider pursuing criminal or other legal action against the violating party.

For violations of the statute such as failure to register with FSIS or to maintain required records, section 406(a) of the FMIA (21 U.S.C. 676(a)) provides that the penalties may be imprisonment for not more than one year, or a fine of not more than \$1,000, or both such imprisonment and fine. The PPIA provides that the same penalties may be imposed for certain violations of the statute, including violation of registration and recordkeeping requirements (21 U.S.C. 461(a)). In addition, both statutes provide that if such violations involve intent to defraud, or any distribution or attempted distribution of an article that is adulterated (except when the product is adulterated for certain reasons, mostly concerning product quality), the penalty can be imprisonment for not more than three years or a fine of not more than \$10,000, or both.

Section 406(a) of the FMIA (21 U.S.C. 676(a)) also provides that persons, firms, or corporations would not be subject to the above penalties for receiving for transportation any article or animal in violation of the FMIA, if the receipt was

made in good faith, unless the person, firm, or corporation refuses to furnish at the request of an FSIS employee the name and address of the person from whom it received such article or animal and copies of any documents pertaining to the delivery of the article or animal to them. Similarly, section 12(b) of the PPIA (21 U.S.C. 461(b)) provides that carriers are not subject to penalties under the PPIA (except for violations of regulations concerning the buying, selling, or transporting of poultry carcasses or parts or products of poultry that are not intended for use as human food) for receiving, carrying, holding or delivering poultry or poultry products owned by another person, in carriers' usual course of business, unless they have knowledge or are in possession of facts that would indicate that the poultry or poultry products were not inspected or marked in accordance with the provisions of the PPIA or were otherwise not eligible for transportation under the PPIA. Carriers are liable, however, if they refuse to furnish at the request of an FSIS employee the name and address of the person from whom they received such poultry or poultry products, and copies of any documents pertaining to the delivery of the poultry or poultry products. These statutory provisions emphasize the importance of carriers' maintaining records of business transactions subject to the FMIA and PPIA and making these records available to FSIS employees.

Under section 404 of the FMIA (21 U.S.C. 674) and section 21 of the PPIA (21 U.S.C. 467c), the United States district courts, the District Court of Guam, the District Court of the Virgin Islands, the highest court of American Samoa, and the United States courts of the other Territories, are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, the FMIA and PPIA (including violations of the registration and recordkeeping requirements).

Paperwork Reduction Act

Title: Registration requirements under the FMIA and PPIA.

Type of Collection: New.

Abstract: FSIS has developed a new registration form and has reviewed the paperwork and recordkeeping requirements associated with this form in accordance with the Paperwork Reduction Act. Existing regulations require that certain parties register with FSIS. See "respondents" below for a list of the parties required to register.

According to the regulations, parties required to register with FSIS must do so by filing a form and must provide current and correct information to FSIS,