

official certification that the above conditions have been met.

Additionally, because offal can encompass a variety of materials, for clarification we would add a definition of offal to § 95.1 to mean the parts of a butchered animal that are removed in dressing, consisting largely of the viscera and the trimmings, which may include, but are not limited to, brains, thymus, pancreas, liver, heart, and kidney.

APHIS Inspection of Processing and Handling Facilities; Certification of Compliance

Although § 95.4 restricts the importation of animal protein, tankage, fat, glands, tallow other than tallow derivatives, and serum from regions where BSE is known to exist or that present an undue risk of BSE (as listed in current § 94.18(a)), paragraph (c) of § 95.4 exempts certain materials from the restrictions, under certain conditions, provided the material is derived from a nonruminant species, or from a ruminant species if the ruminants have never been in a region listed in § 94.18(a). One of the conditions for such importation is that all steps of processing and storing the material be carried out in a facility that has not been used for the processing or storage of any materials derived from ruminants that have been in any region listed in § 94.18(a). A further requirement is that, if the facility processes or handles any material derived from mammals, the facility must have entered into a cooperative service agreement with APHIS to pay for the costs of an APHIS veterinarian to make annual inspections of the facility.

Because we believe the regions we are proposing to include in § 94.18(a)(3) of this proposal present a minimal risk for BSE, we believe that, in lieu of annual APHIS inspections of the facility, such inspections could be carried out by the government agency responsible for animal health in the region, although APHIS would reserve the right to inspect as deemed necessary. Therefore, we are proposing to amend § 95.4(c)(4) to exclude facilities in BSE minimal-risk regions from the requirement for a cooperative service agreement and to require that annual inspections of the facility be carried out by a representative of the government agency responsible for animal health in the region. We would, however, still apply to BSE minimal-risk regions the provisions of § 95.4(c)(5), which require the facility to allow periodic inspections by APHIS.

Additionally, we are proposing to amend § 95.4(c)(6), which currently

specifies that each shipment imported into the United States in accordance with § 95.4(c) be accompanied by an original certificate signed by a full-time, salaried veterinarian of the government agency responsible for animal health in the region of export certifying that the conditions of that section have been met. Because of the reduced risk of such exports from regions we would consider minimal risk, we are proposing to provide in § 95.4(c)(6) that, for shipments of animal feed, the necessary certification may be signed by a person authorized to issue such certificates by the veterinary services of the national government of the region of origin.

Definitions

In addition to adding definitions of *as a group*, *designated feedlot*, *bovine spongiform encephalopathy (BSE)*, *minimal-risk region*, *offal*, and *personal use* to the regulations, as discussed above, we are proposing to define in § 93.400 the term *USDA representative* to mean a veterinarian or other individual employed by the United States Department of Agriculture who is authorized to perform the services required by part 93.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

Under the Animal Health Protection Act of 2002 (7 U.S.C. 8301 *et seq.*) the Secretary of Agriculture is authorized to promulgate regulations to prevent the introduction into the United States or dissemination of any pest or disease of livestock.

On May 20, 2003, the Canadian Food Inspection Agency reported a case of BSE in a beef cow in northern Alberta. To prevent the introduction of this disease into the United States, APHIS issued an interim rule to classify Canada as a region where BSE exists, thereby prohibiting the importation of ruminants and most ruminant products from Canada, effective May 20, 2003.

This proposed rule would amend the regulations by establishing a category of regions that present a minimal risk of introducing BSE into the United States. The rule would set forth factors considered for placing a region in this category, and risk mitigations that would be required for the importation of certain ruminants and ruminant products from such regions. Although the proposed rule would list Canada as

the only BSE minimal-risk region at this time, APHIS would evaluate requests and supporting information submitted by other regions for inclusion in this category.

In accordance with Executive Order 12866 and the Regulatory Flexibility Act, we assessed the potential economic costs and benefits of this rule and potential effects on small entities. Although not addressed in the analysis, Canadian producers/suppliers of ruminants and ruminant products would benefit from the resumption of exports to the United States.

Below is a summary of our economic analysis. A copy of the full economic analysis is available for review in our reading room (see the **ADDRESSES** section at the beginning of this document). You may also view the economic analysis on the Internet by accessing the APHIS Web site at <http://www.aphis.usda.gov>. At the APHIS Web site, click on the "Hot Issues" button. On the next screen, click on the listing for "Bovine Spongiform Encephalopathy (BSE)." On the next screen, click on the listing for "Economic Analysis, Proposed Rule, Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities (APHIS Docket No. 03-080-1)." We do not have enough data for a comprehensive analysis of the potential economic effect of this proposed rule on small entities. Therefore, in accordance with 5 U.S.C. 603, we have performed an initial regulatory flexibility analysis for this proposed rule. We are inviting comments about this proposed rule as it relates to small entities. In particular, we are interested in determining the number and kind of small entities that would incur benefits or costs from the implementation of this proposed rule and the economic effect of those benefits or costs.

Because Canada is the only region we are proposing to include in the BSE minimal-risk category at this time, ruminant and ruminant product imports from Canada that would be reestablished under the proposed rule are the focus of our analysis. However, this minimal-risk category is not limited to Canada and could include other regions in the future. The analysis also considers effects of the rule for U.S. ruminant and ruminant product exports should other countries not consider our minimal-risk requirements sufficient to safeguard against BSE introduction into the United States and/or do not accept our listing of Canada as a region of minimal risk.