

the FMD virus could survive in those exempted products, so we believe that it is necessary to provide specific processing requirements for these products as a condition of their importation. These proposed processing methods are consistent with the Office International des Epizooties (OIE) standards. We are, therefore, proposing to remove the exemptions from importation conditions for the milk products listed in § 94.16(a) and instead would provide specific conditions (*i.e.*, processing methods) under which those products could be imported. These processing methods could also be used for other products that are already eligible for importation under the conditions in § 94.16, including, but not limited to, condensed milk, long-life milks such as sterilized milk, cream, cheeses, whey, casein and caseinates.

Under this proposed rule, the milk products now listed as exempt in § 94.16(a) could be imported into the United States from a region affected with FMD only if they have been produced using one of the processing methods described below:

1. Milk or milk products (other than cheese) that are, or are made from, milk that has been treated at ultra-high temperature (UHT)(298.4 °F (148 °C) for 3 seconds or 284 °F (140 °C) for 5 seconds).

2. Milk or milk products (other than cheese) that are, or are made from, milk that has been treated at a high temperature for a short time (HTST) (161.6 °F (72 °C) for 15 seconds), followed by a second HTST treatment. For milk products made with added fat or added concentrates, the treatment temperature would have to be increased to 167 °F (75 °C).

3. Milk products made from milk that is HTST-treated then brought to a pH of less than 6 for 1 hour.

4. Cheese made from raw milk, aged at a temperature of greater than 35.6 °F (2 °C) with a pH of less than 6 for 120 days prior to export from the country of origin.

5. Cheese made from HTST milk, aged at a temperature of greater than 35.6 °F (2 °C) with a pH of less than 6 for 30 days prior to export from the country of origin.

The scientific evidence available to us indicates that each of the methods described above is sufficient to inactivate the FMD virus in milk and milk products.

We would also require that any milk or milk product imported under these

proposed conditions (*i.e.*, the butter, butteroil, and cheeses that would have to meet one of those conditions, as well as any other milk or milk product for which one of those methods was used as an alternative to meeting the existing importation conditions in § 94.16) be accompanied by an official veterinary certificate endorsed by a full-time, salaried veterinarian employed by the region of origin attesting to the completion of the appropriate processing. The certificate would help ensure that the required processing has been performed by requiring that a representative responsible for animal health in the exporting region verifies that the treatment has been carried out.

Additional Changes

We are proposing to add ice cream and chocolate milk to the examples of milk products in current § 94.16 (b)(3) that may be eligible for importation based on written permission from the Administrator. We are proposing to specifically cite ice cream and chocolate milk as products requiring written permission to minimize the chance that these products may accidentally be diverted into the animal food chain.

We are also proposing to require that the examination, testing, and analysis of small amounts of milk and milk products allowed for importation under current § 94.16(b)(4) occur in a laboratory setting. This action would ensure that untreated samples would not enter the United States to be sold at trade shows or fairs.

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.

We are proposing to amend the regulations regarding the importation of animal products to establish specific processing requirements for certain cheeses, butter, and butteroil imported from regions in which FMD exists. Those processing methods could also be used for other milk and milk products that are already eligible for importation under different conditions, thus allowing their importation under a greater variety of conditions.

Additionally, we are proposing to require that products imported from regions in which FMD exists and processed using one of the proposed methods be accompanied by government certification regarding their processing. We believe these actions are

necessary to ensure that products containing the FMD virus are not imported into the United States.

The establishment of FMD in the United States could result in serious economic consequences, given the size of the Nation's livestock inventories and the volume of animal and animal product sales. Potential losses associated with an outbreak of FMD include production losses at affected establishments, eradication and quarantine costs, and trade restrictions.² Production losses arise from lost production on depopulated premises and in the industries linked to the livestock sector. There would also be additional costs to be borne by producers and slaughterers, as restrictions would be imposed to prevent the spread of FMD and eradicate the disease within the United States. These restrictions and eradication measures would also mean added costs to the government for implementation and enforcement.

FMD outbreaks in the spring of 2001 in the United Kingdom illustrate these costs. Control of FMD in the United Kingdom became a nationwide undertaking, with restrictions on the movement of animals (and people), large-scale slaughter of animals on affected and neighboring farms, and disposal of carcasses through burning, rendering, or burial. The last case of FMD in the United Kingdom was found on September 30, 2001; by the time the United Kingdom declared the outbreak eradicated on January 14, 2002, 586,551 cattle, 3,466,493 sheep, 148,388 pigs, 2,482 goats, 1,021 deer, and 770 other animals had been slaughtered.³ In addition, the European Union banned the export of meat, livestock, and milk products from the United Kingdom. As is shown below, the United States is a major exporter of products whose international movement could be affected by an outbreak of FMD in the United States. In addition to a likely reduction in demand from international consumers, trading partners of the United States would likely impose restrictions on, and reduce imports of, U.S. ruminants, swine, and some of their products in the event of an FMD outbreak in the United States.

According to "Agricultural Statistics 2001," published by National Agricultural Statistics Service (NASS), cattle in U.S. herds in 2000 were valued at \$67.1 billion, with 1999 cash receipts

² Ekboir, Javier M., "Potential Impact of Foot-and-Mouth Disease in California," 1999, Agricultural Issues Center, Division of Agriculture and Natural Resource, University of California.

³ UK Department for Environment, Food & Rural Affairs.

Cunliffe, H.R., *et al.*, "Inactivation of Milkborn Foot- and Mouth Disease Virus at Ultra-High Temperatures," 1979, Journal of Food Protection, Vol. 42, No. 2, pp. 135-137.