

diseases, including swine vesicular disease (SVD). Section 94.12 of the regulations contains requirements for the importation into the United States of pork and pork products from regions where SVD is known to exist. Section 94.17 of the regulations contains requirements for the importation into the United States of dry-cured pork products from regions where SVD, classical swine fever (CSF), foot-and-mouth disease (FMD), rinderpest, and African swine fever exist.

SVD is a highly contagious disease caused by an enterovirus that shows extraordinary resistance to both environmental factors and common disinfectants. SVD rarely results in mortality in infected swine and does not cause severe production losses. Still, the disease can have a major economic impact because eradication is costly and because SVD-free regions often prohibit imports of swine, pork, and pork products from affected regions.

Certain regions in Italy are considered to be affected with SVD and thus are not among those regions designated in § 94.12 as free of the disease. Similarly, certain regions in Italy are not included among the regions designated in §§ 94.9 and 94.10 as free of CSF. Therefore, cooked and dry-cured pork and pork products imported from certain regions in Italy are subject to the requirements in §§ 94.12 and 94.17.

On January 21, 2003, we published in the **Federal Register** (68 FR 2711–2714, Docket No. 02–003–1) a proposal to amend the regulations in § 94.12 by establishing procedures for the importation of pork-filled pasta into the United States from regions affected with SVD. The proposed procedures required that the product contain only cooked or dry-cured pork otherwise eligible to enter the United States under the regulations; that the product not be commingled, directly or indirectly, with products ineligible to enter the United States; and that the product be accompanied by an official veterinary certificate confirming that the product was prepared in accordance with the regulations.

We solicited comments concerning our proposal for 60 days ending March 24, 2003. We received four comments by that date. They were from foreign and domestic producers and representatives of the Government of Italy. All the commenters favored the proposed rule in its broad outlines, but three of the four requested that we modify certain provisions, arguing that the same level of protection against the introduction of SVD into the United States could be achieved in less intrusive ways. The comments are discussed below by topic.

Commenters pointed out that certain of the proposed requirements assumed that the pork-filled pasta would be produced in a facility used both for products eligible for export to the United States and those not eligible for export to the United States. (Such multi-use facilities are referred to as “non-dedicated facilities.”) The commenters specifically cited the requirements pertaining to storage areas for pork for pork-filled pasta products, cleaning and disinfection of machinery, and restricted use of processing lines, which were contained, respectively, in proposed § 94.12(c)(2) through (c)(4). The commenters maintained that the final rule should also provide for products produced in a dedicated facility that would produce only pork-filled pasta products eligible for export to the United States. The commenters suggested that the provisions of proposed paragraphs (c)(2) through (c)(4) would be irrelevant to such a dedicated facility, which should, therefore, be exempted from them.

We agree with the commenters that dedicated processing facilities that are exempt from the requirements in proposed paragraphs (c)(2) through (c)(4) can safely provide pork-filled pasta products for the U.S. market, and are providing for such an exemption in a new § 94.12(c)(7).

The commenters also urged that we modify the requirements contained in proposed § 94.12(c)(2) for the storage of pork intended for use in pork-filled pasta products for export to the United States. This paragraph stated that, at the pasta processing establishment, pork intended to be used for pork-filled pasta products for export to the United States must be stored in a separate room or facility from any meat or meat products not eligible for export to the United States. The commenters contended that an equivalent level of protection could be provided by storing U.S.-import-eligible pork in a dedicated area within existing refrigerated storage cells rather than in fully dedicated cells, provided these areas are separated by at least 1 meter from areas where ineligible meat is stored, marked with signs, and have their borders outlined on the floor. The commenters noted that the Animal and Plant Health Inspection Service (APHIS) has already adopted this approach for use in Italian prosciutto plants that are eligible to export their products to the United States under §§ 94.12 and 94.17.

The commenters also suggested that we modify proposed § 94.12(c)(4), which stated that processing lines working with pork-filled pasta products for export to the United States must process only pasta containing pork

eligible for such exportation and that, when such processing lines are working with pasta products containing pork for export to the United States, other lines may work only on pasta products that do not contain meat. Again citing APHIS’ practices in regard to Italian prosciutto plants, the commenters asserted that the cleaning and disinfection requirements set forth in proposed § 94.12(c)(3) were sufficient to prevent contamination of pork intended for the U.S. market and that requiring dedicated processing lines was unnecessary. The commenters recommended that, instead of requiring dedicated processing lines, the regulations require dedicated processing times, which the commenters said would be a less costly and intrusive but equally effective way to guard against commingling. Specifically, they proposed that a production line be dedicated to producing pork-filled pasta products for export to the United States only for the time necessary to complete a lot destined for the U.S. market, and that, when any line in the facility was processing such a lot, no other processing lines in the same facility be allowed to process products using meat that is not eligible for export to the United States. The commenters stated that these changes would allow the entire facility to be dedicated to producing pork-filled pasta products for export to the United States for the time needed to produce a specified amount of such products and then to be used to make other products.

We are incorporating the changes recommended by the commenters into our final rule. If strictly adhered to, the suggested provisions will prevent the introduction of SVD into the United States via imports of pork-filled pasta products from affected regions, while offering processors greater flexibility in the utilization of their facilities than the corresponding paragraphs in the proposed rule would have. However, to ensure that these changes will not increase the risk of introducing SVD into the United States, we consider it necessary to augment some of the requirements of the proposed rule.

We consider a more rigorous inspection requirement than that prescribed in the proposed rule to be necessary to ensure that processors comply with the regulations. The proposed rule, in § 94.12(c)(6), provided for periodic inspections of processing facilities and their records and operations by APHIS inspectors. In place of that general requirement, this final rule describes the terms of a cooperative service agreement, modeled on similar provisions for certain