

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. Paragraph (c)(3) would state that all equipment and machinery that will come in contact with the pork or other ingredients of pork-filled pasta products intended for export to the United States must be cleaned and disinfected before each use. Paragraph (c)(4) would state that processing lines working with pork-filled pasta products for export to the United States must process only pasta containing pork eligible for such exports and that when such lines are working with these pasta products, the remaining lines may work only on pasta products that do not contain meat.

Paragraph (c)(5) would set out cooking and other requirements for pork-filled pasta being exported to the United States to ensure that the product would be shelf stable without refrigeration. Specifically, we would require that during processing, the pork-filled pasta would have to be steam-heated to a minimum internal temperature of 90 °C, then dried, cooled, and packed to make the product shelf stable without refrigeration.

Paragraph (c)(6) would give the Animal and Plant Health Inspection Service the right to conduct periodic inspections of establishments that manufacture pork-filled pasta products for export to the United States in order to verify compliance by these establishments with the regulations in this section.

Paragraph (c)(7) would set out recordkeeping requirements for pork or pork products used in pork-filled pasta products being exported to the United States. A processing facility would have to maintain under lock and key, for a minimum of 2 years, an original record of each lot of pork or pork products used for meat-filled pasta products for U.S. export. Each record would have to include the date that the cooked or dry-cured pork product was received in the processing facility; information on the number of packages, the number of hams or cooked pork products per package, and the weight of each package; a lot number or other identification marks; the health certificate that accompanied the cooked or dry-cured pork product from the slaughter/processing facility to the meat-filled pasta product processing facility; and the date that the product started dry curing (if the product used is a dry-cured ham) or the date that the product was cooked (if the product used is a cooked pork product). These recordkeeping requirements would be consistent with those set out in § 94.17

for exports of dry-cured pork products to the United States.

Finally, paragraph (c)(8) would require that pork-filled pasta arriving in the United States be accompanied by a certificate issued by an official veterinarian of the National Government of the region in which the pasta product is processed stating that the product has been processed in accordance with the requirements discussed in the preceding paragraphs. This certificate would provide further assurance that the processing facilities are complying with our regulations.

#### **Executive Order 12866 and Regulatory Flexibility Act**

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This proposed rule would amend the regulations in § 94.12 that deal with the importation of pork and pork products from regions affected with SVD by establishing procedures for the safe importation of pork-filled pasta into the United States from Italy and other affected regions. These proposed procedures would allow the importation of this product into the United States while ensuring that the health of the U.S. swine population and the economic viability of the U.S. swine and pork and pork products industries would not be threatened by an incursion of SVD.

These industries play an important role in the U.S. economy. There was a total inventory of 58.698 million swine in the United States as of March 1, 2002.<sup>2</sup> Cash receipts from swine farming in 2001 were about \$12.1 billion.<sup>3</sup> The industry marketed 26.7 billion pounds of pork in 2001. Additionally, the United States earned a substantial amount of money from exports of swine and swine products. The United States exported 1.075 billion pounds of pork, valued at \$1.283 billion, in 2001. Also 64,912 live swine were exported, which were valued at about \$12 million. The United States also imported 717 million pounds of pork in 2001, valued at \$771 million, and imported 5,337,088 live swine, all from Canada, valued at \$349 million. Domestically, other related agricultural and non-agricultural sectors are dependent on the swine and the swine-product industries for their

economic activity. These activities provide employment and income to many households. Maintaining the stability of these industries depends in part on continued efforts to prevent any introduction of SVD into the United States.

The Regulatory Flexibility Act requires that agencies specifically consider the economic impact of their rules on small entities. The domestic entities most likely to be affected by allowing importation of pork-filled pasta products from Italy are durum wheat producers and pasta manufacturing companies.

In 1997, 6,887 farms, over 99 percent of which were considered small,<sup>4</sup> produced about 5.160 billion pounds of durum wheat.<sup>5</sup> In 2001 durum wheat production was estimated at about 5.013 billion pounds on 2.789 million harvested acres.<sup>6</sup> In 2001, the United States exported 3 billion pounds of durum wheat, valued at \$215 million. The major destinations were Italy (39 percent), Tunisia (10 percent), Algeria (9 percent), and Mexico (7 percent).<sup>7</sup>

As a new product, dry, shelf-stable, pork-filled tortellini is expected to have a small market. The impact, if any, on durum wheat producers of importation of this product into the United States is also likely to be small. Producers of durum wheat could benefit in the future from any expansion of product range that results from these imports.

There were 141 pasta manufacturing plants in the United States in 2000. Of these, five companies accounted for 55 percent of the sales. The total domestic capacity is estimated to be about 3.4 billion pounds of pasta.<sup>8</sup> Pasta producers are considered small businesses if they employ 500 workers or fewer.<sup>9</sup> Most U.S. pasta manufacturers can be considered small.

<sup>4</sup> North American Industry Classification System (NAICS) code 111140, Wheat Farming. The Small Business Administration has established guidelines for determining which types of firms are to be considered small under the Regulatory Flexibility Act. A wheat farm is considered small if it has annual receipts of \$750,000 or less.

<sup>5</sup> USDA/NASS, 1997 Census of Agriculture (for AZ, CA, MN, MT, ND, and SD). These are durum wheat-producing States.

<sup>6</sup> USDA/NASS, Crop Production 2001 Summary, Agricultural Statistics Board, January 2002.

<sup>7</sup> Global Trade Information Services, Inc., World Trade Atlas, United States Edition, December 2001.

<sup>8</sup> Michael Boland and David Barton, "How Dakota Growers Pasta co-op found success in a highly competitive market," July 2001

([www.rurdev.usda.gov/rbs/pub/jul01/niche.htm](http://www.rurdev.usda.gov/rbs/pub/jul01/niche.htm)). About 80 million bushels of durum wheat were allocated for food use in 2001. Assuming a bushel of wheat yields 42 pounds of pasta, the amount of wheat in food use equals 3,360 million pounds of pasta.

<sup>9</sup> NAICS code 311823, dry pasta manufacturers.

<sup>2</sup> USDA/NASS, Quarterly Hogs and Pigs, Agricultural Statistics Board, March 2002.

<sup>3</sup> USDA/ERS, U.S. farm sector cash receipts from sales of agricultural commodities, 1998–2002, February 2002.