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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Ch. I

[Docket No. 01–068–1]

RIN 0579–AB43

Risk Reduction Strategies for Potential BSE Pathways Involving Downer Cattle and Dead Stock of Cattle and Other Species

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: We are soliciting public comment to help us develop approaches to control the risk that dead stock and nonambulatory animals could serve as potential pathways for the spread of bovine spongiform encephalopathy, if that disease should ever be introduced into the United States.

DATES: We will consider all comments that we receive on or before March 24, 2003.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 01–068–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1231. Please state that your comment refers to Docket No. 01–068–1. If you use e-mail, address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 01–068–1'' on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Dr. Lisa Ferguson, Emergency Programs, VS, APHIS, 4700 River Road, Unit 41, Riverdale, MD 20737–1237; (301) 734–8073.

SUPPLEMENTARY INFORMATION:

Background

We are soliciting comments to help us develop an approach to control risks associated with disposal of nonambulatory and dead livestock. These animals could serve as potential pathways for the spread of bovine spongiform encephalopathy (BSE), if that disease should ever be introduced into the United States.

It is well established that domestic and wild animals may contract diseases—especially viral and bacterial diseases—from animals that die on the farm and do not receive proper disposal. Direct exposure to improperly buried dead stock [1] and consumption of feed or grass contaminated by run-off that passed over such animals are some of the routes of potential exposure for these diseases.

Bovine spongiform encephalopathy (BSE) is a disease of cattle and is a member of a class called transmissible spongiform encephalopathies (TSE's). Other TSE's also cause various diseases in animals and humans. BSE was first documented in the United Kingdom in 1986 and has since spread to approximately 21 other countries in Europe, and to Israel and Japan. There has never been a case of BSE identified in the United States. However, other types of TSE diseases have affected U.S. livestock and wildlife, including scrapie in sheep and goats and chronic wasting disease (CWD) in both captive and free-ranging elk and deer.

In many ways, TSE diseases present a more difficult problem than other animal diseases with regard to controlling the spread of disease through dead stock. This is due to the nature of TSE diseases, the general lack of live-animal tests for them, and the extreme hardiness of TSE agents. These issues are discussed in some detail below.

Surveillance programs in European countries where BSE exist have found that BSE is present in a higher percentage of nonambulatory and dead livestock than in the general cattle populations. An animal at the point of death from BSE is also generally in its most infectious state, with a high concentration of the BSE agent in certain tissues. Studies by the U.S. Department of Agriculture (USDA), independent researchers, and the Harvard Center for Risk Analysis (discussed below) concur that if BSE were introduced into the United States, dead stock that were rendered and allowed into the animal feed chain would pose a risk of spreading the disease. In January 2001, the Food and Agriculture Organization of the United Nations issued a press release urging countries to take steps to reduce BSE risks; one of the recommended practices was correct disposal of dead stock. Diseases other than BSE are also an issue in the disposal of dead stock.

The BSE agent is remarkably hardy and resistant to destruction by standard cooking practices, sterilization procedures, and rendering processes. Generally, the rendering processes used in the United States will reduce the infectivity of a TSE agent in the rendered material by a factor of 1 to 3 logs.[2] The continuous rendering processes most widely used in the United States reduce infectivity by 2 logs or less; batch processing, used for less than 5 percent of rendered animals, can reduce infectivity by 3 logs. Since some BSE agent survives rendering, if BSE were to be present in a rendered product that is used in cattle feed (in deliberate or accidental violation of the feed ban imposed by the U.S. Food and Drug Administration (FDA)) it could lead to the amplification and spread of

[1] Dead stock are livestock that die or are killed before being sent to slaughter; they are sometimes referred to as ''on-farm deads.'' When used in this notice in reference to cattle, this term refers to adult cattle over 24 months of age, since cattle that die at a younger age present a greatly reduced likelihood of harboring BSE infectivity.

[2] A 1-log reduction is reduction by a factor of 10, 2 logs = 100, 3 logs = 1000, etc.

BSE among cattle consuming that feed. There is also a possibility that animal feed containing a TSE agent from the rendered protein of one species (*e.g.*, scrapie in sheep) could cause development of disease in animals of another species consuming that feed (*e.g.*, cause BSE in cattle). This is, in fact, the leading theory for how BSE originated in the United Kingdom.

Given this situation, the Animal and Plant Health Inspection Service (APHIS) wants to take steps to limit the potential pathways through which BSE could spread in U.S. animal populations, in case it is introduced despite efforts to keep it out of the United States.

TSE Disease Surveillance

Data from APHIS animal disease surveillance programs can be used to detect occurrences of disease, provide information for better policy decisions, and better understand the diseases. Most surveillance programs are based on data from live-animal tests; however, since such tests are generally unavailable for TSE's, in this area APHIS generally relies on observation of animals exhibiting signs of TSE's and tissue samples from dead animals. Since 1990, animals targeted for BSE surveillance by APHIS include cattle exhibiting signs of neurological disease in the field (*i.e.*, prior to being brought to slaughter), cattle condemned at slaughter for neurologic reasons, rabies-negative cattle submitted to public health laboratories,[3] neurologic cases submitted to veterinary diagnostic laboratories and teaching hospitals, nonambulatory cattle (''downer cattle'') over 24 months of age at slaughter, and adult cattle dying from unknown causes on farms. The primary reason we target downer animals is that surveillance data from European countries in which BSE has been detected indicate that downer cattle have a greater incidence of BSE.[4] If BSE enters the United States, downer cattle testing programs are likely to first reveal it.

APHIS' current approach to BSE surveillance takes into account regional differences in the movement of animals, *i.e.*, surveillance is scaled to take into account where most cattle are raised and where they are slaughtered. On this basis the United States is divided into eight regions[5] for BSE surveillance. For years, APHIS has calculated regional surveillance goals for BSE to exceed international standards recommended by the Office International des Epizooties, the world organization for animal health. APHIS continues to increase postmortem testing for BSE, with more than 19,990 cattle samples tested in fiscal year 2002'up from 5,200 during fiscal year 2001. Overall, our surveillance program targets the segment of the cattle population where BSE would most likely be found if it were to occur, *i.e.*, downer animals and dead stock.

Limiting Possible Pathways for Spread of BSE

By their nature, downer animals and dead stock include many animals dead or dying from communicable diseases. They therefore represent a significant pathway for spread of disease if they are not handled or disposed of with appropriate safeguards. Over time, USDA and industry have developed methods to mitigate, if imperfectly, the risks presented by dead stock and downer animals affected by the older, better-known animal diseases.

With regard to limiting the potential pathways through which BSE could spread in U.S. animal populations if it were introduced, we believe that dead stock and downer animals represent the most significant potential pathway that has not been addressed in previous efforts to reduce BSE risks. The remainder of this advance notice of proposed rulemaking discusses why we think this is so and identifies topic areas where we are seeking more information in order to develop rulemaking on the subject of dead stock.

The Harvard Risk Analysis

In April 1998, in order to better characterize the potential for BSE to be introduced and spread in the United States, and the potential threat to human health should this happen, USDA commissioned the Harvard Center for Risk Analysis to conduct a risk analysis (referred to below as the Harvard study). The Harvard study was completed and released on November 30, 2001.[6] The summary of the Harvard study stated its findings that the United States is highly resistant to any introduction of BSE or a similar disease. It also found that BSE is extremely unlikely to become established in the United States, and if introduced, it is likely to be quickly eliminated following its introduction.

The Harvard study investigated potential pathways by which BSE or other TSE's could enter U.S. cattle populations, using a quantitative simulation model to characterize how the introduction of BSE would spread over time, and the extent to which it could result in human exposure to contaminated food products. The study's model quantified some aspects of BSE's potential progress if introduced into the United States—*e.g.*, the number of animals that would be infected over time, and the resulting quantity of the BSE agent in food that would potentially be available for human consumption—but it did not quantify the probability that BSE will be introduced, nor did it estimate how many people would contract vCJD if BSE were introduced. The study omitted quantitative treatment of both of these issues because the available information is inadequate.

The Harvard study has helped APHIS identify those risk management control options that most influence the introduction and spread of disease, and to identify those sources of uncertainty that have the greatest impact on our programs to control BSE risks. This information can be used to help identify the most important control measures and to prioritize data collection and research efforts.

The Harvard study finds that the United States is highly resistant to the introduction of BSE. In addition, should BSE occur in this country, measures taken by government and industry make

[3] We test rabies-negative cattle because these animals often have clinical signs that could be consistent with BSE. If the public health tests show the animal does not have rabies, the samples may be forwarded to APHIS for BSE testing.

[4] For instance, surveillance in Germany in 2001 showed that animals subjected to normal slaughter had a BSE incidence of 0.002 percent, while fallen animals (in the United States, these would be called dead stock, or animals not presented for slaughter for human consumption) had an incidence of 0.02 percent, and emergency slaughters (in the United States, animals presented for slaughter for human consumption and found to show signs of neurological illness) had an incidence of 0.48 percent. ''Final Report of a Mission Carried Out in Germany from 28/05/2001 to 01/06/2001 in Order to Evaluate the Implementation of Protective Measures Against Bovine Spongiform Encephalopathy,'' available at *http://europa.eu.int/comm/food/fs/inspections/vi/reports/germany/vi_rep_germ_3302–2001_en.pdf.*

[5] These divisions were established essentially for epidemiological surveillance reasons and are not intended for the purposes of Chapter 1.3.4 of the International Animal Health Code, *i.e.*, ''defining geographical areas of different animal health status within its territory for the purpose of international trade.'' The regions were established because State-by-State reporting did not provide very useful data, and caused underestimation and overestimation of States' cattle populations, due to the common practice of moving cattle interstate for feeding and slaughter. Often an animal actually comes from one state (*e.g.*, New Jersey) but is slaughtered in another state (*e.g.*, Pennsylvania), so therefore slaughter surveillance on a State-by-State basis would report the animal as originating from Pennsylvania. To make our estimations and calculations as scientifically sound as possible, we changed to a regional system, with States grouped into regions based on typical animal populations and their movement to regional slaughterhouses.

[6] Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States; Harvard University and Tuskegee University, November 26, 2001. Available at http://www.aphis.usda.gov/oa/bse/.

the United States robust against the spread of BSE to animals or humans.

The report identified three pathways or practices that could contribute most either to increased human exposure to the BSE agent or to the spread of BSE if it should be introduced into the United States. The three pathways are:

- Noncompliance with the FDA feed ban, including misfeeding on the farm and the mislabeling of prohibited feed and feed products;
- Inclusion of high risk material, such as brain and spinal cord, in edible products;
- Rendering of animals that die on the farm and use (through illegal diversion or cross-contamination) of the rendered product in ruminant feed.

FDA and FSIS are taking action to address the first two pathways. FDA is enhancing its enforcement of the feed ban and is evaluating whether further rulemaking is needed. FSIS published a notice in the **Federal Register** on January 17, 2002 (67 FR 2399, Docket No. 01–027N) announcing the availability of a BSE Current Thinking Paper that discusses measures that it is considering implementing to minimize human exposure to bovine materials that could potentially contain the BSE agent. Measures under consideration by FSIS include prohibiting certain high risk materials, such as brain and spinal cord, from specified cattle for use as human food and prohibiting the incorporation of CNS tissue in boneless beef products, including meat from advance meat recovery (AMR) systems. Commenters on this advance notice of proposed rulemaking may wish to explore whether there are cross-cutting issues between safe disposal of these specified risk materials and safe disposal options for downer and on-farm dead animals.

Because APHIS has primary authority [7] for animal disease risks posed by both live and dead animals on the farm, including matters where carcass disposal may pose animal health risks, APHIS is publishing this advance notice of proposed rulemaking to open discussion concerning the third pathway, rendered material from animals that die on the farm and its possible inclusion in ruminant feed. We are publishing this notice to fulfill the Secretary's statement, upon release of the Harvard study, that ''USDA will publish an advance notice of proposed rulemaking to consider disposal options for dead and downer animals, because such cattle are considered an important potential pathway for the spread of BSE in the animal chain.''

The Harvard study considers dead stock to be an especially significant potential pathway for BSE. The base case for the Harvard study's model examined what would happen if 10 animals infected with BSE were imported into the United States, assuming current Government regulations and controls are in place. In this scenario, it could be likely that one or more of these animals will succumb to the disease on the farm, or become sick enough to be killed rather than sent to slaughter. The worst possible outcome at this point in the scenario would be for an animal with BSE to be rendered, and for the rendered product to be mixed into ruminant feed (in violation of the FDA feed ban). Rendering an animal that has reached the clinical stage of BSE introduces the maximum amount of infectivity into rendering and potentially into feed. This could result in many more cattle contracting BSE through consuming that contaminated feed, or consuming feed that was cross-contaminated during production or storage, if the feed ban was violated.

The Harvard study's model estimates that keeping this from occurring, by prohibiting the rendering of animals that die on the farm or by ensuring that no rendered product from such animals is ever mixed with ruminant feed, would greatly reduce the potential for contamination in the animal feed chain and reduce the average predicted new cases of BSE following introduction of 10 infected cattle from 2.9 new cases to 0.68 new cases. The Harvard study found that safely disposing of on-farm dead livestock is predicted to greatly reduce BSE spread due to the high levels of BSE agent expected in animals that die from BSE on the farm. It is important to keep such animals from directly entering animal feed chains (*e.g.*, through using rendered products derived from them in feed), and it is important to dispose of their carcasses in ways that keep other livestock and wildlife from contacting them.

Note that the Harvard study by design considered risk factors for BSE one at a time, not in combination. In other words, the prediction that keeping rendered dead stock out of ruminant feed would lower new cases of BSE following introduction of 10 infected cattle from 2.9 to 0.68 new cases does not take into account the marginal and cumulative effects of other BSE risk reduction activities. Other actions by Federal agencies and industry—*e.g.*, more effective enforcement of the feed ban and import restrictions applied to countries with BSE—will also be acting to mitigate BSE risks, to a cumulative degree not calculated by the Harvard study.

The Harvard study suggests prohibiting rendering of dead stock as one way to mitigate this risk, but it does not go on to evaluate the associated negative effects such a policy could have on preventing the spread of BSE and other diseases. Eliminating rendering as a disposal option for dead stock would mean owners would have to find other disposal options, many of which pose their own risks of spreading disease. These risks are discussed later in this document.

Issues in Disposal of Downer Cattle and Dead Stock

Downer Cattle

Downer cattle—animals that cannot rise from a recumbent position due to injury or illness—may be sent for slaughter at plants inspected by FSIS.[8] Sometimes the FSIS antemortem inspection reveals that the downer animal clearly is affected by a particular disease, but more often diseases are revealed only when characteristic lesions (*e.g.*, of tuberculosis, swine erysipelas, or infectious anemia) are seen within the carcass after slaughter. However, TSE diseases do not cause grossly observable lesions, so FSIS inspectors instead observe the live downer animals for signs of a CNS disorder. FSIS has the lead role in ensuring that downer cattle presented for slaughter that exhibit clinical signs of BSE are diverted from slaughter. Cattle with clinical signs of a CNS disorder and cattle that died otherwise than by slaughter are already prohibited from use as human food. All downer cattle presented for slaughter are

[7] Generally, APHIS does not directly regulate businesses engaged in animal disposal through rendering, incineration, burial, or other methods. However, such businesses could be affected if APHIS regulates how the owners of animals may move or dispose of dead stock; *e.g.*, disposal businesses could choose to alter their practices to provide the types of disposal APHIS requires the owners of animals to employ. See the Animal Health Protection Act of 2002 (Subtitle E of the Farm Security and Rural Investment Act of 2002, Pub. L. 107–171). Section 10406 states that the Secretary of Agriculture may prohibit or restrict ''the movement in interstate commerce of any animal, article, or means of conveyance if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction or dissemination of any pest or disease of livestock.'' Section 10409 states that the Secretary ''may carry out operations and measures to detect, control, or eradicate any pest or disease of livestock * * * including animals at a slaughterhouse, stockyard, or other point of concentration.''

[8] Any FSIS-inspected facility may slaughter downer cattle if the animal passes ante mortem inspection. Although some slaughter facilities will not accept downers for slaughter, FSIS does not restrict or approve where downers may be slaughtered.

automatically suspected of being affected with a disease or condition that may require condemnation of the animal, in whole or in part, and are identified as ''U.S. Suspects.'' Such cattle must be examined by an FSIS veterinarian, and a record of the veterinarian's clinical findings must accompany the carcass to postmortem inspection if the animal is not condemned. Post mortem inspection on the carcasses of all cattle classified as ''US Suspects,'' including downer cattle, must be performed by a veterinarian rather than a food inspector, and the results of this inspection must be recorded as well.

Downer cattle presented for slaughter that pass antemortem inspection may be slaughtered and, if passed on postmortem inspection, the meat and meat products from such cattle can be used for human food. However, surveillance for BSE in Europe has shown that downer cattle infected with BSE often cannot be found by looking for the typical clinical signs associated with BSE, because the signs of BSE often cannot be differentiated from the signs of the many other diseases and conditions affecting downer cattle. Thus, if BSE were present in the United States, downer cattle infected with BSE could potentially be offered for slaughter and, if the clinical signs of the disease were not detected, pass antemortem inspection. These cattle could then be slaughtered for human or animal food. Although the muscle tissue from BSE-infected downer cattle has not been found to contain the BSE agent, other tissues could contain the BSE agent and the muscle tissue could be cross-contaminated during slaughter and processing.

As noted above, FSIS is considering placing restrictions on specified risk materials from certain categories of slaughtered cattle, including downer cattle, to address this scenario. We are seeking suggestions on actions APHIS could take to prevent downer animals potentially affected by BSE (should it be introduced) from spreading the disease; *i.e.*, actions that could be taken on the farm or at other stages prior to slaughter. We are looking for actions we could take now, rather than actions to be taken if and when BSE is ever introduced. Commenters may wish to describe how risk factors should be considered when sending downer cattle to slaughter, *e.g.*, age, physical condition, source and type of cattle, etc.

Commenters should bear in mind that we currently rely on collecting samples from downer animals, at slaughter and other locations, as a key part of BSE surveillance. We would like commenters to address how APHIS could continue to obtain samples for testing from downer cattle, since such cattle are an important part of our surveillance program for BSE.

Dead Stock

In addition to comments regarding downer animals, we seek comments regarding dead stock. Disposal methods for dead stock is the most important issue addressed by this advance notice of proposed rulemaking. Dead stock are a potential source of infection for many animal diseases, including BSE. Past experience with disease outbreaks in livestock has demonstrated the need for carcass disposal methods that are cost-effective, safe, fast, complete, and environmentally acceptable.

If an animal dies on the farm, or becomes so sick or injured that it must be destroyed on the farm, it immediately loses most or all of its economic value. It is prohibited from being sold for human food. It might be sold to be rendered, or to be processed as pet food, but in most cases the fee for picking up and transporting a dead animal exceeds the salvage value (*i.e.*, the payment for its value as rendered product or pet food). Thus, producers have a strong business reason for finding ways to dispose of dead stock as cheaply as possible.

This incentive to find cheap means of disposal for dead stock is directly in conflict with certain public interest needs. We will note, but not directly address in this advance notice of proposed rulemaking, that dead stock disposal can have significant impacts on environmental quality and on the capacity of existing solid waste management disposal systems (landfills, incinerators, etc.). We are also aware that there are varying costs associated with different methods of dead stock disposal, but we have not analyzed these costs because we have insufficient data, and we request commenters to submit data on these costs. The focus of this advance notice of proposed rulemaking is on how dead stock disposal relates to the public interest in controlling animal disease risks.

Many animal health programs depend on collecting good data about how livestock become sick and die. This data collection would obviously become even more important if BSE were introduced into the United States. When dead stock is treated as an economic burden and disposed of as cheaply as possible, this data collection suffers. The cheapest methods for dead stock disposal include ignoring the carcass (possible in some cattle range situations) or burying it on-site. Both of these means are legal in some States, and in other States that have specific disposal requirements, the requirements are often loosely enforced. Some producers have disposed of dead stock creatively and illegally by abandoning it on public or private land in ravines, rivers, culverts, dumpsters, and other locations. In all of these situations, information about the animal and its possible cause of death is unlikely to make its way to State or Federal animal health authorities.

In addition to making it harder to collect animal health data, inappropriate disposal of dead stock increases the possibility that humans, livestock, or wildlife will come into contact with pathogens associated with the dead stock. Human and animal health concerns, along with environmental quality concerns, are the major reasons existing State laws on carcass disposal were enacted.

While State laws regarding dead stock disposal vary widely, most have the following features in common. They establish a time limit within which disposal must take place—usually 24 or 48 hours after death. They limit disposal methods to those authorized by law, and sometimes rank the methods in the order the State prefers they be used. Typically, this is the preferred order:

Rendering at a licensed and approved rendering facility. This method maximizes the government's ability to monitor and regulate dead stock disposal, by working with relatively few companies that pick up and render the dead stock. However, as discussed below, dead stock pickup by renderers has become less available in many areas and has become more expensive. (In the past renderers would pick up dead cattle for free, or pay the producer for the dead animals; now there is typically a fee of $20 or more for this service, when it is available at all.) There are also TSE risk issues associated with rendering, and with the renderers' ability to segregate higher-risk materials and divert them to products that are not for use in humans or animals.

However, the existence of markets for use of rendered products for industrial purposes that present no risk of contact with animal or human products does provide a possible avenue for disposal of rendered products from animals that may be infected with a TSE. Such products may be diverted into production of paints, adhesives, or other products. Rendered fat products and meat and bone meal (MBM) may also be used as either a primary fuel or a fuel supplement for heat and power production (especially co-combustion in coal-fired plants), or as an ingredient in cement (MBM is currently used in

cement production in Belgium, France, Germany, Japan, and possibly other countries.) Naturally, diversion of large quantities of rendered products into new uses raises significant economic issues, and many diversion uses may not currently make sense in purely economic terms, as other nations that practice such diversion have found.[9] For example, MBM, when burned, generates only about half the energy obtained from burning coal, yet MBM sells for about 12 times the price of coal.

Although many industrial products are produced mainly from rendered fats and oils, rather than rendered protein, some products utilize rendered protein. In other cases, a percentage of rendered protein can be included as a harmless additive with the rendered fat or oil product. If such diversion into non-food uses is effectively accomplished, it could provide a safe means of dead stock disposal for animals that might spread TSE's if disposed of in other ways.

Composting of dead stock in a properly designed and sized dead animal composter. Composting of dead stock allows the end product to be recycled back to the land as a fertilizer. Poultry and swine industries use this technology effectively. Composting is used to dispose of some cattle and other large species, but large-scale cost-effective approaches are still under development. Composting requires careful planning and monitoring to be successful. Issues include moisture and temperature control and proper admixture of plant matter (often straw or old feedstuffs) to raise the carbon-nitrogen level to a point where proper composting can occur. Composting also takes time; decomposition of a mature cattle carcass takes about 6 to 8 months. The remaining bony matter is soft and easily broken for land application or other final disposal. One successful composting approach uses a three-bin system, which is best located downwind from nearby residences and away from waterways and ponds. Permanent composting facilities have significant start-up costs of $5,000 or more. Composting operations must also take steps to control the potential risk of disease spread by wild and feral animals.

Composting is problematic with regard to BSE infectivity; it may be effective, or it may reduce but not destroy infectivity. Composting does not usually raise material temperatures over 160 °F, a temperature the BSE agent is known to survive for long periods. Further research is needed to characterize the effectiveness of composting with regard to BSE. The United Kingdom's Department for Environment, Food, and Rural Affairs is currently preparing a risk assessment, to be completed in the near future, that may help resolve this question.

Dead stock disposal in an approved sanitary landfill. Most municipal landfills are permitted to accept dead animals but may limit their numbers. To minimize pathogen contamination of groundwater, modern sanitary landfills are designed and operated to prevent leaching into groundwater or surface waters. Drawbacks include limited capacity and expense—many landfills charge over $100 a head to dispose of cattle. However, properly operated landfills will keep infectious material away from livestock.

Incinerating dead stock. Incineration is very effective but is costly and energy intensive, and it may pollute the environment if the incinerator is not operated and maintained properly. Incinerators generally must be licensed by a State government. Open burning of dead animals is not allowed in most States without a permit.

A subset of incineration technology that is gaining popularity is on-site disposal using either complete mobile incinerators or air curtain trench burners. There are cost and air quality issues associated with both of these technologies, and they are usually considered most suitable for short-term disposal projects (such as depopulating a herd) rather than long-term use. However, air curtain trench burners in particular have been gaining use in recent years for on-site disposal of diseased animals. They have been used in Great Britain for disposal of animals during the recent foot-and-mouth disease outbreak, and they have been used in Montana and Colorado to dispose of elk implicated in CWD outbreaks. When properly used, this technology produces ash that presents no disease risk when disposed of properly.

Air curtain trench burners are essentially giant blowers that direct powerful airstreams onto trenches in which carcasses are burned on firewood fuel. This superheats the fire to temperatures steadily above 1,000 °C., resulting in total carcass incineration in approximately 20 minutes. (Cadaver incineration times will vary with factors such as fat content, moisture content, firebox or pit temperature, type of wood waste used, etc.) Site selection is important for air curtain trench burners, and soil type, underground water table, and prevailing wind direction should be carefully considered. High water table areas and sandy soil types should be avoided. Stable vertical trench walls with minimum entry of underground water into the burn area are needed for steady high incineration temperatures.

Burial on premises. Many States specify requirements for owners who bury their dead stock on their own premises. Typically, State laws limit the number of animals that may be buried, require adequate topsoil covering the animals (usually 2 or 3 feet), and attempt to restrict burials in areas where runoff passing over the animals would contaminate groundwater or aquifers.

Tissue digestion. Because this is a new and relatively expensive technology, most State laws do not yet recognize or recommend it as a means of dead stock disposal. Tissue digesters are essentially large ''pressure cooker'' devices that use boiling sodium hydroxide solutions to degrade proteins and fats and result in a sterile liquid suitable for municipal sewage systems, and a sterile, crumbling calcium phosphate residue from the bones and teeth of the animals. Research has shown this method to very effectively reduce levels of TSE infectivity. A typical digester costs several hundred thousand dollars, could process several cattle cadavers simultaneously, and takes several hours to complete a processing cycle. Currently, most digesters in the United States are located at major veterinary research centers or veterinary teaching hospitals.

Preferred Methods for Dead Stock Disposal

APHIS is seeking comments on which approaches for safe disposal of dead stock should be encouraged or required. The primary issue we would like commenters to address is how to develop a combination of regulatory requirements, incentives, and cooperative relationships with production and disposal industries that

[9] ''In Germany all fallen animals and all animals unfit for human consumption must be disposed of at rendering plants. The renderers collect the animals. All fallen and sick bovines over 24 months are BSE tested * * * If the results of the test have not come through then the whole carcass must be processed into MBM under the standard procedure at 133°C and 3 bar. Since the introduction of the MBM feed ban all MBM must be burnt either in waste incinerators, power stations, or as fuel for cement producers * * * Since the introduction of the MBM feed ban rendering operations run at a loss. Federal and Land Governments are still discussing the coverage of the extra costs brought about by the BSE crisis. The Federal Government has so far resisted the wish of the Land Governments that the Federal Government should pay all BSE follow-up costs including the disposal costs of MBM.''—British Embassy Bonn Office Agriculture Note: September 2001, available at *http://www.britischebotschaft.de/en/embassy/agriculture/Agni-Note-Fallen%20Stock.htm.*

will result in sustainable procedures for the safe disposal of dead stock.

Commenters are also asked to consider the costs associated with any such solutions, and any trade-offs that might result by requiring particularly stringent disposal methods to protect against BSE, when easier disposal methods might be adequate protection against other animal diseases. Such comments could also address whether moving to a disposal system designed with BSE in mind might reduce the availability of other types of disposal services which might be needed in situations where it is necessary to dispose of large quantities of carcasses that do not present a BSE risk (*e.g.,* an FMD or pseudorabies outbreak).

Commenters should bear in mind that our current BSE surveillance includes collecting samples from cattle that die on-farm. We would like commenters to address how APHIS could continue to obtain and increase our samples for testing from dead stock.

When dead stock are disposed of unsafely, it is because safe disposal is unavailable, expensive, or inconvenient. One approach to dead stock disposal could be to require certain methods of disposal (*e.g.*, incineration, landfill burial, digestion, or composting, at licensed facilities) under Federal or State laws. But requiring certain disposal methods does not automatically make them available, inexpensive, or convenient. Also, some disposal methods have been very useful for disposing of small numbers of animal carcasses, but their use for the disposal of large numbers of carcasses may result in an increased disease risk to other livestock producers in an area. The short term savings from these methods can easily result in an increased cost later on, which could have been reduced or eliminated if the right techniques had been used initially.

As discussed above, different disposal methods result in different levels and types of risk that cattle could contract BSE from a disposed animal. There are very effective and usually expensive disposal methods that reliably inactivate any infectious agent, including BSE, in a destroyed cadaver. These methods include incineration (on-farm or at a remote incinerator) and tissue digestion. Other disposal methods are known to be partially effective in deactivating the BSE agent, thus reducing but not eliminating risk. These methods include rendering (known to reduce BSE infectivity, with the extent of reduction related to the process used) and composting (apparently reduces infectivity, but to what degree is not well characterized). In both of these methods, an important element may be diversion of the end-product to uses that will not bring it into contact with animal feed. Other methods such as open burning, burial, and landfill disposal have great variations in their effectiveness due to the great variations in how they are implemented at different times and places.

An important aspect of disposal methods is that they can achieve the desired end either by deactivating the BSE agent or by isolating it. The BSE agent in dead stock need not be inactivated if it is reliably kept from contact with animals that it might infect. Another aspect to consider regarding disposal methods is the extent to which they create further disposal problems downstream. Incineration reduces animals to a small volume of ash, but the ash must be spread somewhere. Tissue digesters produce innocuous liquid waste and some calcium phosphate. Burial and landfill disposal do not immediately reduce the volume of the animal and create enduring concerns about scavengers and leaching into the water table. Rendering greatly reduces the volume of the processed product by removing water content and places the end-product in containers, but it has labeling and use concerns because the product may still be infectious.

We are seeking comments to help us balance these considerations in developing good dead stock disposal practices. We have better information on the issues associated with rendering, compared to other disposal methods, because rendering businesses are few in number and uniform in operation compared to the great variety of businesses operating landfills, incinerators, and composting services. While the following discussion directly addresses some issues associated with rendering, we hope commenters will help us develop similar data regarding other disposal methods.

Here are some of the questions regarding whether rendering is a useful disposal method for dead stock that could harbor TSE's: Since rendering does not completely destroy TSE agents, can we be sure rendered products from possibly-infected dead stock would all be used in ways that would not spread TSE's? Given the capacity and distribution of rendering plants, is rendering of dead stock a viable option nationwide, or are there areas where it is practically unavailable? If rendering is a desirable disposal method, what sorts of requirements, partnerships, or incentives could increase its use?

There are approximately 100 million cattle in the United States, including beef, dairy, and other categories. Over a million post-weaning calves and adult cattle die or are killed each year before being sent to slaughter. The National Renderers Association estimates that about 44 percent of these carcasses were sent for rendering last year but notes that this percentage is declining, as the profitability of rendering dead stock declines. North American renderers process more than 50 billion pounds of animal and poultry material each year, including dead stock, offal, and waste from slaughter and packing plants, and animal waste from food processing, supermarket, and restaurant industries. Rendering reduces the volume of this material by 64 percent, mostly by reducing the water content, which makes the resultant products much easier to package and transport—whether for sale, or for disposal. The value of rendered products in the United States in 1998 was approximately $3.2 billion, and consisted of 9 billion pounds of protein concentrate (largely meat and bone meal, or MBM) and 9 billion pounds of animal fat such as tallow.

Historically, the bulk of rendered products has been used by the feed industry, which adds MBM and high-energy fats to feed mixes for cattle, swine, poultry, and pets. MBM is an attractive feed supplement because it is high in protein, calcium, and phosphorus. The chief supplements that compete with MBM are soybean meal and corn gluten meal. Neither of these plant-based supplements has significant levels of calcium or phosphorus, although corn gluten meal has a higher crude protein content than MBM (60 percent compared to 50 percent). Wholesale prices for MBM and soybean meal have traditionally tracked each other closely, but with MBM commanding a slight premium presumably due to its better mineral content. From January 1988 through February 1996, ruminant MBM sold for an average of $16.05 per ton above the price of soybean meal, but since March 1996, the average price of ruminant MBM has been $1.20 below the price of soybean meal. This price reduction probably results largely from the FDA feed ban, although greater production of soy and corn may also be a factor.

Steady decreases in the price brought by MBM, coupled with increases in transportation and processing costs, act to reduce renderers' traditional role as the primary means for producers to dispose of dead stock. In the past, renderers paid farmers for their dead stock, but recovered that cost by selling the byproducts at a profit. Farmers got rid of their dead animals without cost or

difficulty. Now, however, the rendered product derived from a dead stock cow is worth perhaps $20; to cover collection and processing costs and profit, renderers charge the owner a pickup fee of from $15 to $35 for each animal. This causes producers to seek cheaper means of disposal. It has also caused some renderers to stop offering dead stock pickup when they do not find it cost effective; renderer pickup is very difficult to arrange in Ohio and Michigan, among other places.

We have not yet been able to obtain accurate national figures to indicate the fall-off in renderer pickup of dead stock, but we do have illustrative data from one State, California. The California Department of Food and Agriculture recently required renderers to submit annual reports on how much of their raw material came from dead stock. These reports show that between fiscal years 1999–2000 and 2000–2001, the number of dead stock (poultry excluded) that was collected by renderers declined by 20 percent—from 686,434 head to 553,974 head.

To help commenters focus their comments on the role of rendering in dead stock disposal, we are providing certain basic information about how rendering industries are regulated, their business situation, and certain rendering industry initiatives relevant to dead stock disposal. Persons interested in obtaining more information on rendering industries may wish to visit the National Renderers Association website at *http://www.renderers.org*.

Renderers generally must be licensed by each State in which they do business. Licensing and operating requirements for renderers vary from State to State. With regard to Federal regulations, renderers, like any business, must comply with numerous regulations regarding employment, worker safety, environmental quality, and so on. Renderers of livestock species subject to the FMIA are required to register their businesses with the FSIS, in accordance with 21 U.S.C. 643 and 9 CFR 320.5. (Renderers who do business solely at official slaughter, packing, or other establishments inspected by FSIS are exempt from this registration requirement.) Renderers are also subject to FDA regulations at 21 CFR 589.2000—the ''feed ban'' regulations—that impose requirements on renderers that produce products for use in animal feed. The FDA regulations include requirements for labeling, recordkeeping, separation of raw materials based on species type, and related matters to ensure mammalian protein (with certain exceptions) does not go into ruminant feed.

The rendering industry and individual renderers have taken several actions affecting dead stock disposal and TSE issues. Starting in 1991, most renderers elected not to pick up dead sheep, due to the possible scrapie/BSE link, as a means of keeping sheep dead stock protein out of ruminant feed. That industry-elected action became irrelevant in 1997 with the FDA ruminant feed ban, but dead sheep pickup is still not happening because: (1) Many contracts from product end-users specify that no adult ovine protein is allowed in the product, and (2) the same economic conditions that make it marginal for renderers to pick up any dead stock (cattle, swine, etc.) make it a low priority for renderers to resume picking up sheep. However, renderers have stated that they could reinstitute sheep pickup if it becomes economically viable to do so.

Rendering industry representatives cooperated with FDA in developing the feed ban regulations and have monitored compliance with the ban within the rendering industry. Beginning in April 2001, the Animal Protein Producers Industry (the biosecurity arm of the rendering industry) started an inspection audit of all animal protein producers to ascertain compliance with the FDA feed ban. This was a third-party audit performed by an independent auditing firm, Cook & Thurber of Madison, WI.

Currently, a major concern of renderers is identifying markets for MBM and other rendered protein products that contain ruminant protein. Year 2000 production of MBM was nearly 6.7 billion pounds, of which 5 billion pounds, or 75 percent, contained ruminant protein. All of the ruminant protein MBM production has been diverted from use in ruminant feed, with most going to swine, poultry, and pet feed. Export markets for MBM have also increased more than four-fold in the past 10 years, to 979 million pounds in the year 2000. However, oversupply of MBM compared to the demand for its allowed uses continues to drive MBM prices down. The industry believes it would be physically possible for independent rendering plants to install separate processing lines that would allow them to reduce the amount of MBM containing ruminant protein, and increase the amount of ruminant-free MBM, by roughly 1.5 billion pounds a year. However, the capital expenditure and operating costs to do this would mean that renderers would lose money with each year additional separate processing lines are operated, given prevailing prices for MBM.

Renderers continue to seek new, non-feed markets for their rendered product. However, the market opportunities seem to be much greater for rendered fat and oil product lines than for rendered protein product lines. For example, there is a growing market for biodiesel fuels that can be produced from animal (as well as plant) fats and oils. The USDA's Foreign Agricultural Service has reported that, to address MBM disposal in Europe, ''New uses are being pursued, such as burning MBM in power plants to produce electricity or burning it in kilns to produce construction materials such as cement.''[10]

We are interested in receiving comments that discuss whether rendering can be an effective means for safely disposing of dead stock in a manner that minimizes risks of spreading BSE and other animal diseases. We hope that commenters will address the full range of technical, economic, regional, environmental, and practical business issues associated with this question. At this time, APHIS believes that the key issues associated with using rendering as a safe means of disposal for dead stock are:

- Should dead stock ruminants be segregated at rendering from material being rendered for animal feed use?
- If so, can the rendering industry successfully implement this degree of raw material and product segregation and labeling? What would the cost implications be?
- If the cost of rendering dead stock exceeds the value of the rendered product, who should pay the excess cost? The producer, State or local government, Federal Government, or someone else?
- What could be done through cooperation between industry and government to decrease the cost of picking up dead stock for rendering (*e.g.*, harmonization of licensing and regulations, creation of regional pickup centers, etc.)?

Compliance, Enforcement, and Incentive Issues

We are also interested in receiving comments on ways to ensure compliance with any dead stock disposal requirements that may eventually be established through rulemaking. Vigorous enforcement, with civil and criminal penalties for violators, is one means to encourage compliance. However, there are obvious limits to APHIS' ability to directly monitor and enforce dead stock disposal

[10] ''International Agricultural Trade,'' February 5, 2002, p.3. Foreign Agricultural Service, USDA.

requirements. Our inspectors cannot directly observe, or even be aware of, all the thousands of animal disposal incidents that occur each day. In addition to enforcement and penalties, there may be a role for incentives to help achieve compliance in dead stock disposal practices.

One possible incentive may be a program to help owners pay for the cost of dead stock disposal under certain circumstances. In a January 2002 report [11] about strengthening regulatory efforts to prevent BSE in the United States, the Government Accounting Office (GAO) noted that USDA sometimes subsidizes animal disposal costs in order to obtain sufficient tissue samples for its BSE surveillance program. The report notes that ''In 1998 USDA implemented a cooperative program with the rendering industry to ensure that carcasses of animals condemned at slaughter for signs of neurological disease are held until test results are completed. Under this program, USDA may share the expenses to store or dispose of carcasses during the testing period.''

Similar programs haves used State, Federal, and industry subsidies to obtain surveillance samples and to encourage responsible dead stock disposal. For example, when cattle with neurological signs of illness are identified at ante mortem inspection in several States, the costs of sample collection and carcass disposal are shared between State government, Federal agencies, and renderers. We are seeking more data on the rationale and operations of these and similar programs, especially including any studies of their overall costs and benefits. We hope to assemble enough data to evaluate the costs and benefits associated with possible dead stock disposal programs that could be designed to maximize benefits to the general public, cattle producers, disposal industries, and others. One possible design for a voucher-subsidized ''multi-benefit'' dead stock disposal program is discussed below.

Consider a program where the Federal or State Government issues qualifying producers a certain number of ''stock disposal vouchers'' each year. If one of the producer's animals dies on-farm, or becomes so ill or injured the producer decides to euthanize it, the producer could use a voucher to cover some or all of the costs of disposing of the animal. The government that issued the vouchers may make arrangements with incinerator operators or other disposal businesses that will honor the vouchers. Dead stock transporters may also be involved in the voucher system. In all cases, businesses may benefit from increased formal disposal of dead stock that, without the voucher system, might be buried on-farm. Solid waste disposal systems may benefit as fewer animals are taken to limited landfill spaces and more animals are incinerated. Public health and environmental values may benefit from fewer casual or illegal animal disposals that pollute groundwater and spread disease.

Such a voucher system could also benefit USDA disease surveillance programs if it includes a requirement to allow USDA to examine and collect samples from the animals for which vouchers are used. USDA staff or accredited veterinarians could be used to examine animals prior to euthanasia and to collect samples from dead animals prior to their disposal.

As an alternative to a predefined voucher system for dead stock disposal, Federal or State agencies could concentrate on identifying, and paying disposal costs for, downer animals that would be euthanized on the farm. This approach might offer a bounty or reward payment for owners who report certain types of animals in their herds—*e.g.*, adult cattle showing certain signs indicative of CNS conditions. The Federal or State agency could then examine the animal, euthanize it, take samples if the examination showed a reason to do so, and arrange to dispose of the cadaver. The owner would receive a small bounty payment and would avoid any disposal costs he might otherwise have faced if he euthanized the animal without government assistance.

The above are just two examples of a design for a ''multi-benefit'' dead stock disposal program; we encourage commenters to suggest others. If your comment suggests a system for dead stock disposal, please include your thoughts on what businesses, levels of government, or other parties should be involved. We are particularly interested in hearing comments on whether such programs should be organized on the county or State level, a regional level, or a national level, and what role the Federal Government should play.

Dead Stock Disposal for Species Other Than Cattle

While this notice primarily addresses disposal of cattle, there are obviously related issues for other species. In particular, commenters may wish to address disposal of sheep and goats with regard to scrapie, disposal of captive elk and deer with regard to CWD, and disposal of all types of livestock with regard to communicable non-TSE diseases. We hope commenters will help us to understand what dead stock disposal issues are common to all of these species, what issues are of particular importance to different types of producers, and the possible costs to involved parties (including producers and taxpayers) of addressing these issues.

Summary of Issues Open for Comment

- What is the preferred approach and associated costs to affected parties for controlling risks associated with disposal of nonambulatory and dead livestock?
- Are there any cross-cutting issues between safe disposal of specified risk materials such as brain and spinal cord and safe disposal options for downer and on-farm dead animals?
- Are there practical ways to cull higher-risk downer cattle, *e.g.* cattle that may have a non-obvious CNS condition, before they are sent to slaughter? How should risk factors such as age, physical condition, and the source and type of cattle be considered when sending downer cattle to slaughter? What would such culling cost affected parties?
- Since APHIS currently relies on collecting samples from downer animals, at slaughter and other locations, as a key part of BSE surveillance, how could we continue to obtain samples for testing from downer cattle if they are not sent to slaughter?
- What carcass disposal methods are safe, fast, complete, and environmentally acceptable? What combination of regulatory requirements, incentives, and cooperative relationships with production and disposal industries would result in sustainable procedures for the safe disposal of dead stock, and what are the costs associated with such solutions?
- Can rendering be an effective means for safely disposing of dead stock in a manner that minimizes risks of spreading BSE and other animal diseases? Under what conditions? What are the associated technical, economic, regional, environmental, and practical business issues?
- What are equitable ways to share the costs of dead stock disposal, to concentrate and increase economic opportunities and social benefits that can be associated with responsible dead stock disposal?
- What businesses, levels of government, or other parties should be involved in dead stock disposal? Should such programs be organized on the

[11] ''MAD COW DISEASE: Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts,'' GAO–02–183, Government Accounting Office, January 2002.

county or State level, a regional level, or a national level, and what role should the Federal Government play?

• Is there a need to particularly address disposal of sheep and goats with regard to scrapie, and disposal of captive elk and deer with regard to CWD? What dead stock disposal issues are common to all species, and what issues are of particular importance to different types of producers?

Done in Washington, DC, this 15th day of January 2003.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 03–1210 Filed 1–17–03; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 02–003–1]

Importation of Pork-Filled Pasta

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations regarding the importation of pork and pork products from regions affected with swine vesicular disease by establishing procedures for the importation of pork-filled pasta into the United States. The proposed procedures would require that the product contain only cooked or dry-cured pork otherwise eligible to enter the United States under the current 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 has been prepared in accordance with the regulations. This action would provide for the importation of pork-filled pasta under conditions designed to prevent the introduction of swine vesicular disease into the United States.

DATES: We will consider all comments that we receive on or before March 24, 2003.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 02–003–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 02–003–1. If you use e-mail, address your comment to *regulations@aphis.usda.gov.* Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 02–003–1'' on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Dr. Masoud Malik, Senior Staff Veterinarian, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231; (301) 734–3277.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations) prohibit or restrict the importation of specified animals and animal products into the United States to prevent the introduction into the U.S. livestock population of certain contagious animal diseases, including swine vesicular disease (SVD). Section 94.12 of the regulations provides 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 provides requirements for the importation into the United States for dry-cured pork products from regions where SVD, hog cholera (also known as classical swine fever), 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.

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

The Italian Government has requested that facilities in Italy be allowed to export to the United States tortellini (pasta) that is filled with pork. In order to allow this product to enter the United States without increasing the risk of the introduction of SVD, we are proposing to amend § 94.12 to establish procedures that processing facilities in SVD-affected regions would have to follow to ensure that this particular product would be safe to import into the United States. While a specific request from Italy provided the impetus for this proposed rule, the requirements we are proposing would apply to pork-filled pasta products imported into the United States from any region affected by SVD.

Specifically, we are proposing to add a new paragraph (c) to § 94.12 that would delineate processing, recordkeeping, and certification requirements for pork-filled pasta products exported to the United States from SVD-affected regions. Paragraph (c)(1) would stipulate that pork-filled pasta products processed for export to the United States would have to contain only pork or pork products that are otherwise eligible for importation into the United States, *i.e.,* that meet all requirements that apply to cooked pork products under § 94.12 (b)(1)(i), (ii), or (v)[1] or to dry-cured pork products under § 94.17.

The provisions of proposed paragraphs (c)(2), (c)(3), and (c)(4) are intended to prevent contamination via the commingling of ineligible pork or other meat products with pork or pork products eligible for use in pork-filled pasta products for export to the United States. Paragraph (c)(2) would stipulate that pork intended to be used for pork-filled pasta products for export to the

[1] While pork and pork products that meet the requirement of § 94.12(b)(1)(iii) and (iv) are also eligible for importation into the United States, proposed paragraph (c)(1) would not provide for their use in pork-filled pasta products. As neither paragraph requires the pork or pork products to be fully processed in the region of origin, such pork and pork products are not suitable for inclusion in a completed product such as pork-filled pasta.