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May 7, 2004

Docket Clerk
Food Safety Inspection Service
United States Department of Agriculture
Docket No. 03-0381F
Room 102, Cotton Annex
300 12th Street, S.W.
Washington, DC 20250-3700

Dear Docket Clerk:

The National Pork Producers Council (NPPC) appreciates the opportunity to comment on Docket No. 03-0381F, 9 CFR Part 301, 309, et al. "Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems; Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter; Bovine Spongiform Encephalopathy Surveillance Program; Interim Final Rules and Notice."

NPPC is a federation of 44 state pork producer organizations and represents the federal interests of U.S. pork producers. The U.S. pork industry represents a major value-added activity in the agricultural economy and is a major contributor to the overall U.S. economy.

NPPC understands that these Interim Final Rules are an emergency regulatory response to a December 23, 2003 positive Bovine Spongiform Encephalopathy (BSE) diagnosis of a single Canadian-born adult cow by the U.S. Department of Agriculture (USDA).

NPPC has concerns about the changes contained in these Interim Final Rules. We are concerned about the amendments to the Food Safety Inspection Service (FSIS) regulations that prescribe requirements for definitional changes to the term "downer". We are also concerned about the inclusion of pork and pork products in the Advanced Meat Recovery (AMR) section of these Interim Final Rules. Both of these changes could negatively impact U.S. pork producers without providing the public any additional safety assurances and could, in fact, undermine consumer confidence in pork by raising questions about pork as a potential source of BSE.

NPPC is very concerned about the changes to 9 CFR 309.2 that replace the reference to "seriously crippled animals commonly termed 'downers'" in 309.2 (b) with the term "non-ambulatory disabled livestock" and FSIS' subsequent definition. The definition, as written, includes not only non-ambulatory disabled and diseased swine but also healthy swine with injuries such as a broken appendage or severed tendons and temporary fatigue, or reversible metabolic conditions that are specific to swine.

The Global Voice for the U.S. Pork Industry

The stated objective in these Interim Final Rules is to “minimize human exposure to materials that scientific studies have demonstrated as containing the BSE agent in cattle infected with the disease.” Therefore, FSIS has declared that all “non-ambulatory disabled” cattle are unfit for human consumption under section 1 (m)(3) of the Federal Meat Inspection Act (FMIA) and is requiring that all “non-ambulatory disabled” cattle should be condemned.

FSIS asserts it is making this modification because there is currently no regulatory definition of “downer” and the new definition more accurately describes “cattle that it believes that should be prohibited for human food.” FSIS then goes on to define “non-ambulatory disabled livestock,” not just cattle, but “livestock that cannot rise from a recumbent position or that cannot walk, including those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.” FSIS goes on to state that this definition would include *all* livestock that are non-ambulatory due to acute injury en route to the processing facility as well as those with an underlying pathological condition.

Research conducted in the United Kingdom during the height of the BSE epidemic demonstrated that swine are resistant to BSE following oral exposure with large doses of infective material.ⁱ In addition, no case of naturally acquired Transmissible Spongiform Encephalopathy has ever been demonstrated in swine. This has been scientifically documented in areas where there were many cases of BSE in cattle, where both swine and cattle had been exposed to the same feedstuffs.ⁱⁱ

The Rules make reference to the Harvard Risk Assessment discussion regarding pork. The Assessment validates the research findings from the United Kingdom. Further, the Risk Assessment also indicates that there is no demonstrated risk for human exposure to materials that scientific studies have demonstrated as containing the BSE agent in pork and pork products.

NPPC believes that because BSE, the disease of concern in these Interim Final Rules, is not relevant to swine, the amended language contained in the Rules must be clarified to be more species-specific. **Without such clarification the definitions contained in these Interim Final Rules are not scientifically defensible and present very serious negative economic consequences for U.S. pork producers without providing accurate or additional food safety or public health assurances for U.S. consumers.**

NPPC requests that FSIS consider species-specific language that reflects why swine can be “temporarily disabled”. The pork industry commonly refers to swine that become “temporarily disabled” but are not “diseased” as *stressed* or *fatigued*.

Porcine Stress Syndrome (PSS) is a scientifically recognized, genetic-based, metabolic stress condition that occurs in a small proportion of animals in the swine population. Animals with PSS express *temporary* ambulatory interruption and dysfunction when subjected to stressful types of conditions (i.e., change in environment, weather change, moving/trucking, etc.). Levels of severity vary and extreme cases can result in the death of the animal. When afflicted, animals may be unable to move or rise for a short-term period; however, if given time to rest, these animals will generally recover. Another condition occasionally seen in young swine is “metabolic exhaustion”. This is likely caused by a combination of unique genetics coupled with feeding practices. When exposed to environmental change or stress, the animal experiences an

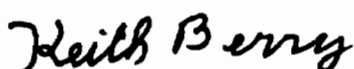
increased metabolic activity that results in elevated serum lactic acid. Body temperatures may also become elevated. Severely afflicted animals lay or sit down and refuse to move. This condition is often reversible when affected swine are allowed to recover and presents no risk to food safety. These animals have been inappropriately termed “downers”, and this Interim Final Rule may require FSIS to include more science-based supporting information with respect to the effect and diagnosis of metabolic exhaustion, and/or PSS.

A second issue of concern raised by the Interim Final Rules is that of extending the restrictions on Advanced Meat Recovery (AMR) to cover pork products. We believe that this action questions the scientific conclusions and the validity of the Harvard Risk Assessment. Neither the Agency nor the Risk Assessment have found scientific evidence indicating that pork is a potential risk to human health. We believe that as written, the “Rules” will undermine consumer confidence in pork and pork products by raising questions about pork as a potential source of BSE. In addition, the loss of AMR processes and products presents additional costs across the pork chain. Pork producers at the beginning of the chain will be forced to bear these costs.

NPPC appreciates the opportunity to present comments on behalf of America’s pork producers. We are concerned that FSIS has gone beyond what is scientifically defensible and the Rules’ stated purpose to “minimize human exposure to materials that scientific studies have demonstrated as containing the BSE agent in cattle infected with the disease.” The Rules, as written, have the potential to undermine consumer confidence in pork by raising questions about pork as a potential source of BSE. Further, the Rules will impose undue economic hardship on U.S. pork producers without any additional public health assurances about pork and pork products.

If you have any additional questions, please contact Ms. Audrey Adamson, Director, Government Relations, at (202) 347-3600.

Sincerely,



Keith Berry
President

ⁱ Wells GA, Hawkins SAC, Austin AR, et al. 2003. Studies of the transmissibility of the agent of bovine spongiform encephalopathy to pigs. *Journal of General Virology*, 84, pp. 1021-1031.

ⁱⁱ MAFF. 2000. MAFF BSE Information, <http://www.maff.gov.uk/animalh/bse/index.html>.