Points to Consider for OMB on the proposal by FSIS, USDA of the New Swine Inspection System

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My background:

I am a retired veterinarian, with over 45 years experience in public health, including **over 35 years service in USDA, FSIS**. Starting my career in FSIS as an in-plant Veterinary Medical Officer, I rose up the ranks over the years and retired as the top veterinarian for the Agency - the **Chief Public Health Veterinarian**. Also, I had a dual senior service appointment in FSIS as the **SL for Chemistry, Toxicology and Related Sciences**, and served as a lead member of the US Delegation in at least two Codex Committees related to veterinary drugs and pesticides.

During my Federal career, I received multiple outstanding ratings and almost every civilian awards, including the USDA Superior Service Award and the USDA Unsung Hero Award.

I retired from FSIS on Friday, January 6th, 2018; the proposed New Swine Inspection System (NSIS) was publicly announced by FSIS the following week.

Executive summary:

FSIS issued a Federal Register Notice (FR: Volume 83, Issue 22, dated February 1, 2018) that purportedly "modernizes" swine slaughter inspection. While I have been actively involved with FSIS inspection updates in the past, and support previous any attempts by the Agency to streamline the current inspection systems. However, any attempt to "modernize" must start by updating the **Federal Meat Inspection Act (FMIA) of 1906**. This is just what FDA has done with their new Food Safety Modernization Act (**FMSA**) of 2011.

FMIA demarcates FSIS inspection and legal oversight from the slaughterhouse gates to the loading dock of a Federally licensed establishment. If the final product is deemed safe, it is stamped "USDA Inspected & Passed" with the establishments number in the stamp. Since FSIS has not incorporated any modern microbiology screening tools, and the Agency does not use a hold-and-test policy other than for residues, all tests for pathogens are conducted when samples are sent to the FSIS laboratories. Since the results of such tests are available usually after the product has left usual the official premises, FSIS has to announce a voluntary recall for this contaminated product.

Modernization has everything to do with the update of FMIA and adding the latest detection technology, such as one's developed by the USDA/ARS and currently used by the Army. It has nothing to do with removing qualified and trained FSIS Inspection Program Personnel (IPP) from critical duties (required under the law) and replacing them with unqualified and untrained minimum-wage plant employees, and then allowing these plants to run their slaughter lines at any line-speed.

The changes proposed by FSIS to create the **New Swine Inspection System (NSIS)** is not the definition of "modernization"; it is the definition of a public health, food safety, and an economic disaster for all United States citizens and the consumers of U.S. product exported worldwide.

In addition to **updating the 1906 FMIA,** as mentioned above, the following must be completed before the NSIS, can "modernize" the US meat inspection program:

1) **Mandatory Animal ID for all Food Animals**, as is required by all advanced countries worldwide and the U.S. trading partners. This will enable the traceback and correction of serious public health and food safety issues detected in any plant. This includes traceback for swine infected with resistant bacteria, foreign animal diseases or illegal drug use (under the FDA laws and regulations), before they spread and become a national crisis affecting human and/or animal health and a create a financial burden for the entire country.

2) **Peer-reviewed Risk Assessment (RA)**, that covers not only the chance of *Salmonella* contamination of the meat, but address other important food and animal pathogens, including those causing zoonotic or foreign animal diseases. Also needed is the RA to address checks for compliance with FDA Guidance #209 and #213 and 21 CFR 556, to identify possible misuse of antibiotics and the presence of antimicrobial resistance (AMR) organisms that cause serious infections and death to a vulnerable population consuming this contaminated product.

3) **A true Cost-Benefit Analysis**, that thoroughly estimates and compares the potential economic costs and benefits resulting from the promulgation of this new rule. This must include:
   - The real cost for each swine slaughter establishment, were they to do as they should if they want this sort of system and hire employees who match the education and qualification of the FSIS-IPP and can be trained to assist the Federal employees in mandated inspection tasks.
   - The real cost for each swine slaughter establishments to create and deliver the required training to its employees in English or in their native languages.
   - The economic impact for any FAD outbreak, which is estimated by experts to be between $2.6-4.1 billion for classic swine fever to $188+ billion for foot-and-mouth disease.
   - The cost to the consumer's health and the increase in AMR created by uncontrolled drug-use caused by the significant reduction in IPP-generated residue sampling as noted in the current HIMP plants.
   - The benefits, if any, to the tax payers that can override the expenses mentioned above.

Self NSIS Review Summary:

At the request of my supervisor, Dr. David Goldman, Assistant Administrator of the Office of Public Health Science (OPHS), I reviewed the draft FRN prepared to announce the New Swine Inspection Program and provided him a detailed response. On October 4th 2016, in my annual accomplishment report for the year submitted to Dr. Goldman, I summarized my draft NSIS FRN review results as follows:

- The Swine HIMP project originally started in 1997 with 5 plants market hog plants who all volunteered. The project oversight was by a few OPPD staff members in Omaha, NE.

- Even though I had requested the opportunity to review this project (on site, in person), this request was repeatedly denied.

- I was finally afforded the opportunity to review the draft FRN on March 7th, 2016, created to announce the implementation of this project nationwide in ALL hog slaughter plants.

- Using the May 2013 OIG Audit report on the multiple deficiencies noted in this project, I then started comparing the residue and pathology data from PHIS in these 5 pilot plants to 5 similar plants in the same District. The data showed significant public health-related deficiencies in all the pilot plant compared to the similar plants.

- My conclusion demonstrated that:
  (1) almost none of the 5 pilot plants were in compliance with FSIS regulations;
  (2) the in at least two plants, there was no record of any pathology found or residue test conducted for multiple years;
  (3) that the data comparison between the 5 market hog plants and any other sow or roster pig plant was invalid.

- As a result of my extensive effort, this FRN is now on hold, while the project proposal in being reevaluated to cover market hogs only.

My major concerns with NSIS include:

- Removing infectious or foreign animal diseases at ante mortem (AM) prior to IPP checks by untrained and/or unqualified plant employees.

- Bypassing mandatory **9 CFR 309.13(d)** requirements by removing any "unfit" animal from the AM pen by untrained and/or unqualified plant employees.

- Removing "bruises and defects" by untrained and/or unqualified plant employees prior to IPP on-line PM inspection, which automatically results in loss of pathology "markers" and reduction of residue sampling in swine that is NOT being marketed as "*No antibiotics - ever*", as in the case of poultry.

- Emphasizing PHR checks to improve food safety, where every one of the pathogenic microbiology sampling results is available to FSIS only AFTER the product has left the plant premises with the official "**USDA Inspected & Passed**" stamp. This leads to what I term - "**Inspection by Recall**", where (unlike FDA) FSIS has no authority for a mandatory recall. In other words, the proposed increase in the "**Offline Verification Inspection**" by FSIS (as specified in the FR: pp15-16) would have zero effect on the food safety of the product being marketed that day.

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