



Consumer Federation of America

March 21, 2013

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
Patriots Plaza 3
1400 Independence Avenue SW
Mailstop 3782, Room 8-163A
Washington, DC 20250-3700

RE: Docket No. FSIS-2012-0049

To Whom It May Concern:

The Consumer Federation of America (CFA)¹ appreciates the opportunity to comment on the Food Safety and Inspection Service's (FSIS) Federal Register notice regarding Ongoing Equivalence Verifications of Foreign Food Regulatory Systems (**Docket No. FSIS-2012-0049**).

Transparency

CFA has previously praised FSIS' foreign equivalency program as a robust program for ensuring the safety of imported foods. However the changes proposed by FSIS and the manner in which those changes were made raises concerns about whether the foreign equivalency program will continue to provide adequate assurances of safety.

FSIS states in the Federal Register notice that the agency modified its approach to equivalence of foreign food regulatory systems in 2009. Yet the agency did not inform the public of these changes until publication of the notice on January 25, 2013. The public only first found out about changes to the foreign equivalency program from an investigative report by *Food Safety News*² which revealed that the number of countries audited by FSIS each year had declined by more than 60 percent since 2008. According to the report, from 2001-2008 FSIS audited an average of 26.4 countries per year. However from 2009-2012 FSIS audited an average of only 9.8 countries per year. In addition, FSIS had failed to post foreign audit reports in a timely fashion and had stopped posting individual plant audit reports.

¹ CFA is an association of nearly 300 non-profit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy and education. Member organizations include local, state, and national consumer advocacy groups, senior citizen associations, consumer cooperatives, trade unions and food safety organizations. CFA's Food Policy Institute was created in 1999 and engages in research, education and advocacy on food safety, food and agricultural policy, agricultural biotechnology, and nutrition.

² Bottemiller H, "Investigation: USDA Quietly Eliminated 60 Percent of Foreign Meat Inspections." *Food Safety News*, November 1, 2012.

It is a serious problem that FSIS did not inform the public of changes to its foreign equivalency program for nearly four years. Substantial changes such as these should have been released to the public for public comment *prior* to FSIS moving forward. Instead stakeholders are left to comment on a process that has already been operating for four years. The Federal Notice is perfunctory, rather than an honest effort to engage the public. Such actions are not transparent and do not engender confidence or trust in future agency actions.

On-Site Audits

The three components – document reviews, on-site audits, and point-of-entry inspections – are all essential elements of FSIS' foreign equivalency program. While FSIS' new Self Reporting Tool appears to be a useful way to gather information from foreign countries on an ongoing basis, self-reporting cannot provide the same level of assurance as in-person verification. FSIS must still send staff to foreign countries to conduct on-site audits to verify that what is being reported is actually occurring on the ground.

FSIS has made the determination that countries will receive less frequent on-site audits – once every three years instead of annual audits. Yet the agency has provided no data in the Federal Register notice or the accompanying documentation to justify that decision. FSIS claims that this new approach provides “the same level of public health protection as FSIS’ previous approach with annual on-site audits”, yet the agency provides no data to support that statement. Until FSIS can demonstrate with data that an audit every three years provides the same public health protection as annual audits, the agency should continue to conduct annual audits of all foreign countries.

FSIS justifies its new performance-based approach by stating that it is following the recommendations by the National Advisory Committee on Meat and Poultry Inspection. However, the reports issued by NACMPI in 2008 are more general in nature and did not endorse shifting annual on-site audits to every three years. While the NACMPI reports do suggest that audits could be based on risk, neither of the reports specifically recommends that FSIS should substantially reduce the frequency of its on-site audits.

FSIS implies, but does not state, that the transparency of a foreign country’s food safety system and outcomes will be essential for the agency to make adequate determinations about the country’s equivalency. FSIS should take necessary steps, including delisting plants or revoking an equivalency determination, for any country which does not provide adequate information or provides false information. In addition, plants should be delisted or equivalency determinations revoked if the basic components of our system are not met, such as instances of direct product contamination, lack of sanitation standard operating procedures, lack of a HACCP plan, less than continuous inspection coverage, and other fundamental elements of equivalence.

One consequence of reducing the frequency of in-person audits is that the data being collected and analyzed by FSIS will be less robust. FSIS states that the agency performs a statistical analysis of country compliance based on the compilation of findings from five sources of information: on-site audits of government offices; on-site audits of establishments; on-site audits of laboratories; review of foreign country Self-Reporting Tool; and point-of-entry (POE) inspections. If FSIS shifts from annual audits to audits every three years, the agency will have fewer data points from the on-site sources of information than for the SRT and POE sources of information.

As a result, the agency will be relying more heavily on the SRT and POE data in its decision-making, both of which have limitations. SRT data is subjective, as it is provided by the foreign country, until it can be

verified more objectively by FSIS through on-site audits. POE inspections provide a check on a foreign country's food safety system, but provide little data about that system as a whole. Further, the information FSIS uses to make decisions in its foreign inspection program is all interrelated. POE inspections rely on data from the agency's country performance assessments, which in turn, rely partly on compliance data from POE re-inspections and on-site audits. If the data from some of those sources is less robust, the entire system becomes less robust.

Rather than the approach outlined in the Federal Register which reduces the frequency of annual audits, FSIS could develop an approach in which the agency conducts audits each year, but the scope of those audits could change. Provided the information collected from a foreign country was sufficient to make such determinations, foreign country audits could focus on specific areas of concern or areas in which FSIS needed additional information. If, during the course of an audit, the agency identified problems that indicated a need for a more comprehensive audit, the agency could easily widen the scope of the audit. This approach would assure that FSIS was auditing foreign countries on a regular basis but would allow the agency some flexibility in terms of the areas on which it would focus.

CFA appreciates the opportunity to provide comments to the agency.

Sincerely,



Chris Waldrop
Director, Food Policy Institute