



January 28, 2016

Secretary Tom Vilsack
United States Department of Agriculture
Room 200, Jamie L. Whitten Building
12th Street & Jefferson Drive, S.W.
Washington, DC 20250

Transmitted via facsimile: (202) 720-6314

Dear Secretary Vilsack:

On behalf of the non-profit public interest advocacy organization Food & Water Watch, I am writing to express my concern regarding the state of the equivalency determination process and the import inspection program at USDA's Food Safety and Inspection Service (FSIS). What was once touted to be a model for other nations to emulate has degenerated into a travesty. It is unconscionable that the Obama Administration has allowed this to happen in light of the aggressive trade agenda it has pursued that will undoubtedly increase the volume of imported food items coming to the U.S. that might put our consumers at risk.

Specifically, I would like to bring to your attention several recent incidents that have sparked our concern.

The Process for Determining On-Going Equivalence

As you recall, a controversy erupted in November 2012 when *Food Safety News* reported that 60 percent of the foreign equivalency audits had been eliminated by FSIS.¹ The agency admitted in that article that it had, in fact, changed its approach to assessing on-going equivalency, but that "it had dropped the ball" in not announcing the change publicly. Prior to 2009, the agency would conduct annual verification audits of countries that had achieved equivalency status.

At the January 16, 2013 meeting of the National Advisory Committee on Meat and Poultry Inspection, FSIS announced that there would be a Federal Register Notice published that would explain the agency's new process for determining on-going equivalence for countries that were already exporting meat, poultry, and/or egg products to the U.S.²

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

² United States Department of Agriculture, Food Safety and Inspection Service. National Advisory Committee on Meat and Poultry Inspection. Plenary Session, Transcript, January 16, 2013, p. 29.

On January 25, 2013, FSIS published a Federal Register Notice, “Ongoing Equivalence Verifications of Foreign Food Regulatory Systems,” in which it outlined a “performance-based” approach to equivalence audits and port-of-entry inspections of imported products.³ The agency solicited public comments on this “new” approach that it had already been using since 2009. The agency explained that it was instituting a rating system to assess the inspection systems of exporting countries. The ratings would dictate how frequently in-country audits would be conducted and the level of scrutiny imported shipments from each country would receive at ports-of-entry. The new process was described in a document entitled, “Performance-Based Approach to Foreign Country Equivalence Verification Audits and Point-of-Entry (POE) Reinspections.”⁴

Using a statistical formula, the agency stated there would be three possible ratings: well-performing, average, and adequate. According to FSIS, “well-performing” countries would receive less intensive and less frequent audits and a lower frequency of point-of-entry re-inspections and sampling. “Average” performing countries would receive a “normal” level of audits and a “normal” level of point-of-entry re-inspections. “Adequately” performing countries (i.e., countries that meet FSIS’ eligibility requirements for exporting meat and poultry products to the U.S. but that are performing worse than their peers with respect to food safety requirements) would receive the most comprehensive and most frequent equivalence verification audits and the highest frequency of point-of-entry re-inspections and sampling.⁵

At the January 13, 2015 meeting of the National Advisory Committee on Meat and Poultry Inspection, Jane Doherty, International Coordination Executive, made the following statement:

“...if a country is a well-performing country, they’ll be audited every three years. If a country is doing an average job, they will be audited every two years. And everyone who is not meeting or just meeting our standards will be audited every year. ***Right now most countries are being audited every year. We’re just not comfortable that anyone has met those higher criteria***” (emphasis added).⁶

In reality, that has not happened. FSIS continues to post reports of audits that are two years old or older.⁷ We also noticed that, beginning with the most recent audit report for Poland that was posted on November 5, 2015, there was no rating for that country’s meat

³ 78 FR 5409-5413.

⁴ See http://www.fsis.usda.gov/wps/wcm/connect/c10d362b-c978-4578-8b9e-93f956601ccf/Performance_Based_Approach_Equivalence_Verification_0213.pdf?MOD=AJPERES

⁵ Ibid.

⁶ United States Department of Agriculture, Food Safety and Inspection Service. National Advisory Committee on Meat and Poultry Inspection. Plenary Session, Transcript, January 13, 2015, pp. 69-70.

⁷ See <http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports>

inspection system.⁸ Food & Water Watch received information that the reason Poland's meat inspection system did not have a rating was due to the fact that Canada, our largest trading partner, had objected to the rating of "adequate" that FSIS had concluded from the audit the agency conducted of that country's meat inspection system in 2014. When confronted with that information by Food & Water Watch on January 14, 2016, agency officials scurried to withdraw the audit report that had been transmitted to Canada, and substituted in its place the audit report that was eventually posted on the agency website on January 20, 2016.⁹ That report does not contain a rating for Canada's inspection system and Canada's response to the FSIS draft final audit report clearly shows that officials from the Canadian Food Inspection Agency (CFIA) had objected to the "adequate" rating.¹⁰ FSIS capitulated and there was no rating for the Canadian inspection system.¹¹

So, that raises several questions: Has the agency changed its policy once again on how it conducts audits of foreign meat, poultry, and egg products inspection systems? Will that impact how frequently it conducts on-site audits of foreign inspection systems? Will that change in policy be reflected in a Federal Register Notice? If not, why not?

The 2014 Canadian Audit Report Findings

Even though FSIS concluded in its 2014 audit report that Canada could continue to export meat, poultry, and egg products to the U.S., the audit report contains this ominous statement:

"...FSIS identified three operational (or procedural) weaknesses related to government oversight, sanitation, and microbial testing that raise significant questions about the Canadian system's (sic) will need to be addressed by the (Canadian Food Inspection Agency) in order to maintain on-going equivalence to the United States' system."¹²

Many of the FSIS concerns regarding government oversight were in Canadian establishments that had adopted alternate inspection models – the High Linespeed Inspection System (HLIS) in beef slaughter and the HACCP-based Inspection Program (HIP) in pork slaughter – that are similar in structure to the HACCP-based Inspection Models

⁸ United States Department of Agriculture, Food Safety and Inspection Service. "Final Report of an Audit Conducted in Poland April 21 to May 8, 2015 Evaluating the Food Safety Systems Governing Meat Products Exported to the United States," p. 15.

⁹ United States Department of Agriculture, Food Safety and Inspection Service. "Final Report of an Audit Conducted in Canada May 28 to June 13, 2014 Evaluating the Food Safety System Governing the Production of Meat, Poultry, and Egg Products (sic) Intended for Export to the United States of America," posted January 20, 2016, see <http://www.fsis.usda.gov/wps/wcm/connect/13607606-3ff1-40ab-a63e-8f8bb191ae4a/2014-Canada-FAR.pdf?MOD=AJPERES>.

¹⁰ Ibid., "Appendix: Response of the Canadian Food Inspection Agency (CFIA) to Findings Identified in the United States Department of Agriculture, Food Safety and Inspection Service (USDA-FSIS) Draft Audit Report on the Equivalency of the Canadian Meat, Poultry and Egg Products Inspection System," p. 13.

¹¹ Ibid, pp. 17-18.

¹² Ibid.

Project (HIMP) in pork slaughter here in the U.S. These are all privatized inspection systems in which many inspection responsibilities are turned over to company employees to perform and the government plays a verification role. FSIS found HLIS and HIP equivalent in 2006 based on the five-plant HIMP pilot project in hog slaughter in the U.S.¹³ It should be noted that one of the HLIS plants in Canada – Establishment 38 – was involved in the largest meat recall in Canadian history in 2012.¹⁴ One of the HIP plants – Establishment 7 – continues to incur point of entry rejections at our border inspection stations for visible contamination (see Attachment A).

Sanitation issues surfaced in several of the Canadian plants audited, including in two of the ready-to-eat plants. As you know, there was a major listeriosis outbreak involving deli meats in Canada in 2008, in which 22 Canadian consumers died.¹⁵ Improper sanitation was found to be a major contributor to the contamination. CFIA's program to control *Listeria monocytogenes* in meat production has been an on-going problem, and it seems to continue in spite of the 2008 outbreak.

Furthermore, FSIS auditors found that CFIA's sampling and testing program for *Listeria monocytogenes* in ready-to-eat products is not equivalent to that of the U.S. Specifically, CFIA does not require ongoing sampling and testing of non-contact food surfaces for *Listeria monocytogenes* as we require of our plants here in the U.S. This raises some areas of concern. First, control of *Listeria monocytogenes* for ready-to-eat products is a continual bone of contention between CFIA and FSIS that does not seem to have a resolution, yet we continue to import ready-to-eat products from Canada. Second, the U.S. Food and Drug Administration (FDA) and CFIA have been engaged in discussions for over three years on a systems recognition agreement in which the two agencies would find each other's food safety systems to be "comparable" for the food products under FDA's jurisdiction.¹⁶ It seems to us that CFIA's microbiological testing program is a major issue, so we would hope that FSIS is sharing its findings with FDA so that there is not a disparity in the approaches that our food safety agencies take when dealing with imported food products from Canada. The fact that FSIS has identified some major problems in Canada's inspection system for meat, poultry, and egg products – and some of these issues are recurring from past audits – raises the question of why the decision was made to continue to recognize Canada as having an equivalent food safety system regardless of whether it has a rating or not.

Australia

It is our understanding that FSIS conducted an audit of the Australian meat inspection system in November and December of 2014. The audit report still has not been posted

¹³ United States Department of Agriculture, Food Safety and Inspection Service. "Final Report of an Audit Conducted in Canada October 22 Through November 9, 2012 Evaluating the Food Safety Systems Governing the Production of Meat Products Intended for Export to the United States of America," p. 14.

¹⁴ See http://www.foodsafety.gc.ca/english/xl_reprt-rapprte.asp

¹⁵ See http://www.cpha.ca/uploads/history/achievements/09-lirs-rpt_e.pdf

¹⁶ See <http://www.inspection.gc.ca/about-the-cfia/transforming-the-cfia/regulatory-modernization/regulatory-cooperation-council/food-safety/eng/1431366847455/1431366848204>

because there are on-going discussions with the officials of the Australian Department of Agriculture and Water Resources over the conclusions reached in that audit – over one year after the audit was conducted. As you know, Australia shifted to a privatized inspection model in 2011 and 2012 called the Australian Export Meat Inspection System (AEMIS) for red meat products exported to the U.S. FSIS recognized that inspection system as being equivalent in 2011, again, based on the hog HIMP pilot here in the U.S.¹⁷ We have written to you in the past and raised serious issues with the implementation of AEMIS since the number of import rejections has increased substantially after most beef and mutton slaughter facilities in Australia shifted to this inspection model.¹⁸ As you know, the European Union rejected AEMIS, citing conflict-of-interest concerns with having company employees perform food safety responsibilities while also being held accountable by their employers to maintain production.¹⁹ Rather than return to full government inspection, the Australian Department of Agriculture and Water Resources opted to recognize private third party employment firms to supply meat inspectors to slaughter facilities. We affectionately refer to this scheme as the “rent-an-inspector” model. Fortunately, to this point, FSIS has rejected this model and so have some of the Australian meat processors who have opted to return to full government inspection.²⁰ So, Australia is now using three different inspection systems for exported meat products making for a very confusing situation.

There is also evidence that FSIS is confused about what it approved when it recognized AEMIS as an equivalent inspection model. We have attached a December 23, 2015 communication (see Attachment B) from the Australian Department of Agriculture and Water Resources to FSIS. Australian officials argue that concerns FSIS raised in the 2014 Australian audit (the report for which still has not been published) about the manner in which AEMIS was operating were unfounded because FSIS did not understand how the new inspection model actually worked. That raises a very significant question: Did FSIS really know what it approved in 2011? That letter also refers to the continuing problem of import rejections of Australian meat shipments due to fecal and ingesta contamination. Even more alarming, the letter refers to import rejections due to microbiological contamination from dangerous STEC forms of E. coli.

Australia is a major trading partner. Due to the liquidation of our livestock herds because of persistent drought in our western states, the volume of exported meat products from Australia has grown substantially in recent years. This growth in exports occurred while

¹⁷ 76 FR 11752-11755

¹⁸ See

https://www.foodandwaterwatch.org/sites/default/files/au_meat_equivalent_usda_letter.pdf; https://www.foodandwaterwatch.org/sites/default/files/vilsack_letter_aemis_july_2013.pdf; https://www.foodandwaterwatch.org/sites/default/files/vilsack_letter_austr_canada_oct_22_2013.pdf

¹⁹ European Commission, Health and Consumers Directorate-General, Food and Veterinary Office. “Final Report of an Audit Carried Out in Australia From 12 to 24 October 2012 in Order to Evaluate the Operation of the Public Health Control Systems and Certification Procedures over the Production of Fresh Ovine, Equine and Wild Game Meat Destined for Export to the European Union.”

²⁰ Locke, Sarina. “Cost of Privatising Meat Inspection Creeps Up as Europe Rejects Industry Inspection Model,” Australian Broadcasting Corporation, November 5, 2014.

Australia was transitioning to the privatized inspection model that does not seem to be working or understood by FSIS staff. We believe that this is a recipe for disaster, and we urge you to reconsider the equivalency determination for AEMIS. We also urge you to publish the report of the 2014 audit so that we can fully understand why FSIS is raising concerns about AEMIS.

Equivalency Determination for Processed Poultry Exports from the People's Republic of China

Nothing makes less sense to us than the decision by FSIS to grant equivalency status to the poultry inspection system in the People's Republic of China (PRC). We know that the issue is inextricably tied to our efforts to reopen beef exports to the PRC that were halted in 2003. The Chinese poultry issue has been debated for over a decade, as there are still doubts about the PRC's food safety system. The PRC is still suffering repercussions from the melamine contamination of dairy products in 2008 that killed 6 infants and hospitalized 300,000 consumers. There are almost daily stories in the Australian press about Chinese consumers who are hoarding infant formula manufactured in Australia because they have no confidence in the safety of domestic milk products.²¹ There are news accounts about a recent crackdown by Chinese authorities against restaurants that are lacing dishes with opium poppy.²² There is the recent trial of employees of U.S.-based OSI that operates plants in the PRC who are charged with selling adulterated poultry meat to Chinese restaurants, including KFC and MacDonald's.²³ Our FDA has been very quietly issuing import alerts against Chinese pet food manufacturers who are using poultry (chicken and duck) that has been raised with antibiotics and other chemicals not approved in the U.S. to make jerky pet treats for export.²⁴ And, as you know, there have been over 1000 canine deaths that seem to be tied to the consumption of poultry jerky pet treats imported from the PRC.²⁵

There is a recent emphasis among food safety professionals on the importance of creating a "food safety culture" in the manufacture and preparation of food. That concept seems to be lost on the PRC. That is why we find it unconscionable for FSIS to have finalized a rule in 2006 to permit the PRC to export processed poultry to the U.S.²⁶ While there were restrictions placed on the source of the raw poultry that was to be used for processing for export to the U.S., there are still major food safety issues in the PRC that have not been resolved.

²¹ Huffadine, Leith. "Chinese Navy 'Picked up Boxes of Baby Formula While Docked at Brisbane' After Australian Supermarkets Limit Customer Purchases as Supplies Run Short," Daily Mail Australia, January 9, 2016.

²² Hunt, Katie and Kevin Lui. "China Busts 35 Restaurants for Seasoning Food with Opium Poppy," CNN, January 22, 2016.

²³ Keefe, Linda M. "OSI Trial Begins in Shanghai," MeatingPlace, December 28, 2015.

²⁴ See http://www.accessdata.fda.gov/cms_ia/importalert_1140.html

²⁵ See <http://www.fda.gov/animalveterinary/safetyhealth/productsafetyinformation/ucm360951.htm>

²⁶ 71 FR 20867 - 20871

It is our understanding that the PRC still has not exported processed poultry products to the U.S. under the 2006 rule, but we are growing suspicious that this may be about to change. There are several reasons that have contributed to the delay: 1) the PRC itself has been resistant to export under the restrictions of the 2006 rule pending completion of the equivalency determination of its poultry slaughter inspection system; 2) there have been no companies in the U.S., Canada, Chile or in any other country whose poultry slaughter inspection system has been found to be equivalent to ship raw poultry to the PRC for processing so that it could be re-exported to the U.S.; 3) congressional action blocking FSIS from implementing any regulation that would permit the PRC to export poultry products to the U.S. That restriction was lifted in 2010 due to a World Trade Organization ruling²⁷; 4) the PRC's procrastination in scheduling FSIS on-site audits of its poultry processing facilities; 5) the length of time it took the PRC to certify poultry processing facilities to export under the 2006 rule.

Ever since the PRC certified four poultry processing plants in November 2014 (one plant was subsequently delisted in March 2015)²⁸ to be able to export to the U.S. under the 2006 rule, Food & Water Watch has filed a monthly Freedom of Information Act (FOIA) request with FSIS requesting the veterinary health certificates from any of those plants to determine whether they actually exported to the U.S. Up until December 2015, FSIS has responded within a couple of weeks of our submitting the request indicating that no such records could be located. To date, we have not received responses to our December 4, 2015 and January 5, 2016 FOIA requests. That raises a concern that the PRC has or is about to commence exports of poultry products to the U.S. Furthermore, comments attributed to you during your recent visit to the PRC have also raised our suspicions.²⁹

But there is another recent development that has added a new wrinkle to the Chinese poultry trade issue. We knew that FSIS had conducted on-site audit visits of poultry processing and slaughter facilities in 2015. On August 13, 2015, an article appeared in WATTAgNet.com entitled, "Cargill Anhui Cleared to Export Poultry Meat to U.S."³⁰ The article stated that FSIS had cleared that plant for export to the U.S. When we asked FSIS staff about the veracity of the article, they responded that while the Cargill plant was part of the audit visit FSIS made to the PRC, only the PRC could certify Chinese poultry plants for export to the U.S. In addition, for the PRC to be able to export its own poultry to the U.S., FSIS still needed to propose a rule finding the poultry slaughter inspection system to be equivalent to ours.

We then learned of a visit by PRC food safety officials to the U.S. in November 2015 underwritten by Cargill Meat Solutions. On November 10, 2015, the Deputy Bureau Chief of Safety of Import and Export Food Products of the General Administration of Quality

²⁷ See https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds392_e.htm

²⁸ See http://www.fsis.usda.gov/wps/wcm/connect/21458caf-2efc-4bc3-9f30-8c9adb3cbb97/China_establishments.pdf?MOD=AJP

²⁹ The Poultry Site. "China, U.S. Discuss Bilateral Poultry Trade," November 26, 2015, see <http://www.thepoultrysite.com/poultrynews/36217/china-us-discuss-bilateral-poultry-trade>.

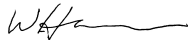
³⁰ See <http://www.wattagnet.com/articles/23859-cargill-anhui-cleared-to-export-poultry-meat-to-us>

Supervision, Inspection and Quarantine of the PRC sent a memo to Deputy Undersecretary for Food Safety Alfred Almanza that responded to some of the issues raised in the 2015 audits conducted by FSIS of the PRC poultry processing and slaughter inspection systems. The memo also identified 5 poultry processing and 5 poultry slaughter facilities that the PRC intended to certify as being eligible to export to the U.S. That memo listed one Cargill poultry processing facility and the Cargill slaughter facility in Anhui among the ten (see Attachment C). The only conclusion that we can reach from this memo is that the fix is in. The equivalency determination process has been turned into a sham. The subversion of the process must be part of a "China-Is-Too-Big-To-Fail" policy to help the PRC out of its current economic doldrums. Using a multinational corporation such as Cargill, that is undermining our domestic poultry industry by outsourcing processing in the PRC, as a fig leaf will not hide the endemic food safety system weaknesses in the PRC.

All of the matters that we have raised in this letter lead us to believe that the equivalency determination process at FSIS is in shambles and has been undermined by a trade agenda that will put U.S. consumers at risk. We sincerely hope that you will investigate the issues we have raised and take remedial actions to strengthen the international program at FSIS.

We look forward to your response.

Sincerely,



Wenonah Hauter
Executive Director

Attachments

cc: Senator Pat Roberts
Senator Debbie Stabenow
Senator Ben Sasse
Senator Kirsten Gillibrand
Senator Thad Cochran
Senator Barbara Mikulski
Senator Jerry Moran
Senator Jeff Merkley
Representative Michael Conaway
Representative Collin Peterson
Representative David Rouzer
Representative Jim Costa
Representative Harold Rogers
Representative Nita Lowey
Representative Robert Aderholt
Representative Sam Farr
Representative Rosa DeLauro
USDA Inspector General Phyllis Fong