



United States Department of Agriculture

Food Safety and
Inspection Service

1400 Independence
Avenue, SW.
Washington, D.C.
20250

AUG 22 2014

Ms. Wenonah Hauter
Executive Director
Food & Water Watch
1616 P Street NW, Suite 300
Washington, DC 20036

Dear Ms. Hauter:

This letter is in response to your petition, dated January 28, 2008, requesting that the Food Safety and Inspection Service (FSIS) remove Canada as a country that is eligible to export meat and poultry products to the United States (9 CFR 327.2(b), 9 CFR 381.196(b), and 9 CFR 590.910 (b)). The petition was forwarded to FSIS' Office of Policy and Program Development (OPPD) on September 18, 2012, and assigned petition number 12-09.

The petition asserts that this action is needed because you believe that there are multiple deficiencies in the Canadian food safety system. Specifically, the petition cites past recalls involving imported Canadian meat and poultry products; FSIS' findings from previous audits of Canada's system conducted from 2003-2007; and Office of the Inspector General (OIG) audit reports on FSIS' verification of Canadian meat, poultry, and egg product equivalence. The petition also expresses concern that FSIS is evaluating a proposal by Canada that would not meet FSIS equivalence requirements for daily inspection coverage. We have considered the issues raised in your petition, as well as the outcome of additional audits conducted after you submitted your petition, that verified Canada's continued equivalence status and find that there is no merit to the assertion that Canada's food safety system is not equivalent to that of the United States. Therefore, for the reasons discussed below, we are denying your petition.

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 620) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 466) prohibit the importation of meat and poultry products into the United States if such products are adulterated or misbranded, and unless they comply with all the inspection and other provisions of the Acts and regulations that are applied to U.S. domestic products. The Egg Products Inspection Act (EPIA) (21 U.S.C. 1046) prohibits the importation of egg products unless they have been processed under an approved continuous inspection system of the government of the foreign country of origin and comply with all other provisions of the Act and regulations that apply to U.S. domestic products. These Acts provide the statutory basis for FSIS' regulatory approach

to ensuring that imported meat, poultry, and egg products are safe, wholesome, and correctly labeled.

In 1994, the concept of equivalence was introduced in the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), which appears in the Final Act of the Uruguay Round of Multilateral Trade Negotiations signed in Marrakech. The SPS Agreement became effective in January 1995, concurrently with establishment of the World Trade Organization (WTO), which superseded the General Agreement on Tariffs and Trade (GATT) as the umbrella organization for international trade. Because the United States is a signatory to the SPS Agreement and a member of the WTO, FSIS amended its regulations to require foreign meat and poultry food regulatory systems to be “equivalent to” comparable U.S. requirements (60 FR 38667; July 28, 1995). In the late-1990’s, FSIS shifted the emphasis of its on-site audits from inspecting establishments to assessing a country’s food regulatory system. This change was announced in the *Federal Register* on December 17, 1999 (64 FR 70690; December 17, 1999). Under this approach, the scope of on-site audits was broadened to include country laws and documents related to program implementation; records of establishment operations, inspection results and enforcement activities; chemical residue controls from farm to slaughter; microbiological and chemical testing programs; laboratory support, sampling programs, and sampling and testing methodologies; and other U.S. import requirements such as pathogen reduction and Hazard Analysis and Critical Control Point (HACCP) programs.

Since the 1990s, FSIS has had almost 20 years of experience in determining and verifying equivalence. By leveraging this accumulated experience, FSIS continues to refine its triad-approach to more systematically verify a country’s equivalence status. Specifically, after a country is initially deemed equivalent, FSIS continually reviews the country’s equivalence status by using a three-part approach that includes on-going document reviews, periodic on-site system audits, and port-of entry (POE) reinspection. FSIS determines the scope and frequency of on-site systems audits and POE reinspections through analysis of the results of the triad approach referenced above. By using a performance-based approach, FSIS is able to direct its resources to foreign food regulatory systems that pose greater risk to public health; make its international program more consistent with its domestic inspection system; and ensure the continued equivalence of foreign countries’ inspection systems by improving the linkage between POE reinspections, on-site audits, and document reviews. Taken together, these data allow FSIS to make an informed assessment, based on our statutory mandate to ensure food safety, of a country’s equivalence status (78 FR 5409, January 25, 2013). Consistent with this process, from October 22, 2012, to November 9, 2012, the Agency conducted a thorough and detailed on-site audit which verified that Canada’s meat and poultry inspection system remains equivalent to the U.S. system. Since 2005, FSIS has conducted nine on-site audits in Canada. In the 2012 audit, FSIS found that Canada is maintaining equivalence and meeting all six equivalence components (government oversight, statutory and regulatory authority, sanitation, HACCP systems, chemical

residues, and pathogen testing). In the audit, FSIS identified areas of improvement for Canada, particularly in HACCP verification, sanitation, and humane handling. However, Canada has implemented corrective actions. In June 2014, FSIS conducted an on-site audit of the Canadian meat and poultry inspection system to verify ongoing equivalence and implementation of corrective actions from prior audits, including the 2012 audit. FSIS found that Canada continues to meet U.S. equivalence criteria and is maintaining its equivalence status. FSIS will post the final audit report for the 2014 audit when it is completed. The 2012 audit report, which was posted to FSIS' website on December 11, 2013, can be found here: http://www.fsis.usda.gov/wps/wcm/connect/6badd5fa-b120-4c15-b2b8-1498532c44ce/Canada_FAR_2012.pdf?MOD=AJPERES

You cite a 2005 Office of the Inspector General (OIG) report that identified areas of improvement for FSIS' verification of Canada's equivalence status. FSIS recognized the importance of OIG's findings, agreed with them, and addressed them, as detailed in the final report (Report No. 24601-05-Hy, December 2005). OIG accepted FSIS' actions to resolve the findings. Regarding the issues raised in your petition and the OIG report, Canada has implemented once per shift inspection at processing establishments and carcass-by-carcass inspection at slaughter establishments as well as finished product and environmental (food contact and non-food contact surfaces) sampling for *Listeria Monocytogenes*.

You also highlight multiple findings in previous FSIS audit reports of Canada. In its audit reports, the Agency has, as you state, "discovered and documented" instances that required corrective actions, which were reviewed, accepted, and verified by FSIS. During the 2012 audit, some of these corrective actions were immediately implemented by CFIA during the course of the audit, while others have been reviewed and accepted through document review. As noted above, FSIS conducted an on-site audit of the Canadian meat and poultry inspection system in June 2014 to verify ongoing equivalence and implementation of corrective actions from prior audits, including the 2012 audit. FSIS found that Canada continues to meet U.S. equivalence criteria and is maintaining its equivalence status. This "discovery and documentation," along with confirming implementation of corrective actions, is precisely what FSIS seeks to achieve through the ongoing equivalence verification process – identifying any deficiencies, communicating those deficiencies to the foreign government, and ensuring that corrective actions are taken. The instances identified by FSIS, including those you cite, do not rise to a level of concern that would require removing Canada from the list of countries eligible to export to the United States – particularly as Canada acts to address these issues, and FSIS verifies the corrective actions.

It is important to note that removing a country's eligibility to export is only one action that FSIS could take in responding to a country's deficiencies, depending on the severity of the situation. Other actions include increasing POE reinspections for specific products (physical product examinations, condition-of-container reinspections, and laboratory sampling), which FSIS has implemented in nine specific instances for Canada since

Fiscal Year 2012. This increased reinspection is made possible by collecting and analyzing product-specific PHIS data that provides a real-time look at the country's performance. FSIS may also delist specific establishments or products from export eligibility. Another potential action is conducting a targeted, for-cause audit that allows FSIS experts to view the country's inspection system in operation. These audits are designed to address repetitive POE findings of public health significance or other conditions representing a lack of process control within a country's food safety system. As it does with all countries, FSIS also verifies Canada's equivalence status by reviewing in detail CFIA's responses to systemic questions from FSIS, as well as analyzing all applicable laws, regulations, and other written documentation. These verification activities (POE reinspection, on-site audits, and document reviews) are linked to each other and work together to help FSIS ensure whether or not a country's system remains equivalent to the United States. Ultimately, however, FSIS retains the option of removing a country's eligibility to export for serious public health situations in which the exporting country must take immediate, systemic, and potentially time-consuming steps to address major deficiencies identified by the Agency that could allow adulterated product to enter U.S. commerce. Furthermore, FSIS can and has suspended a country's eligibility to export without removing it from the Code of Federal Regulations.

With regard to your statement that FSIS is seriously entertaining a proposal by Canada that would compromise FSIS' requirement for daily inspection of regulated establishments, the Agency is not considering any such proposal and has both communicated to Canada the need for once per shift inspection in processing establishments and carcass-by-carcass inspection in slaughter establishments, and verified that such inspection is taking place.

Finally, you state that FSIS treats Canada deferentially. FSIS continues to work with Canada, as it does with all equivalent countries, in verifying that FSIS's requirements are being met and any outstanding issues are addressed. FSIS conducted its equivalence process for Canada in the same way it has conducted the process for all other countries.

For the reasons discussed above, we have concluded that your petition does not provide an appropriate basis to institute an action to remove Canada from the list of countries eligible to export meat and poultry products to the United States. Therefore, as stated above, we are denying your petition. While FSIS will continue to carefully scrutinize product from Canada and the Canadian meat, poultry, and egg product food safety systems, Canada continues to maintain equivalence with the U.S. food safety system at this time.

In accordance with FSIS regulations, your petition was posted on the FSIS Website in September 2012. We intend to post this response as well.

If you have questions on the information in this letter please contact Dr. Andreas Keller at (202) 690-5646.

Sincerely,

A handwritten signature in blue ink, appearing to read "Daniel L. Engeljohn". The signature is fluid and cursive, with a large initial "D" and "E".

Daniel L. Engeljohn, PhD
Assistant Administrator
Office of Policy and Program Development