2011-2012 AFDO FINAL COMMITTEE REPORT

International & Governmental Relations Committee

***Co-Chair:** Melinda Plaisier, U.S. Food & Drug Administration, Chicago, IL
Co-Chair: Bob Scales, Health Products & Food Branch, Health Canada, Winnipeg, MB

Charge 1: Identify and report on the efforts of FDA and other international regulatory authorities to address the potential impact of radiation from the nuclear power plant in Japan on imported food products

Discussion:

FDA - During the Fukushima event FDA collaborated with a number of foreign governments and US government Agencies. An FDA expert in radiation and health physics was deployed to the US Embassy in Japan to share information between the US government and the Government of Japan. FDA's Winchester Engineering Analytical Center (WEAC) provided radiation pagers and personal dosimeters along with on the spot radiation safety training via webinar to government officials and import staff in Guam and the Commonwealth of the Northern Marianna Islands. The FERN was placed on alert and methods validations were performed between FDA and state radiation laboratories in anticipation of a potential surge in sample analysis for radiation contamination that could exceed the analytical capacity of FDA's WEAC lab and result in FDA needing assistance from FERN labs to increase through put of analytical samples. Twenty –nine samples of food rations issued to servicemen by the US military were analyzed by WEAC for DOD. Eight samples of sake were analyzed by WEAC for the Treasury Department's Alcohol, Tobacco Tax, and Trade Bureau. FDA participated on the Federal Advisory Team for Environment, Food and Health which provided protective action recommendations to decision makers responding to the event. FDA's Emergency Operations Staff worked with EPA and USDA to share and coordinate public messaging so that public messages did not contain conflicting information. And lastly the FDA Pacific Region initially held daily calls, and later scaled back to weekly calls with representatives from the Pacific Islands including government officials from Guam. FDA issued import alerts for FDA regulated products coming into the US from Japan. In all FDA field staff performed 29,000 field exams. FDA's Winchester Engineering Analytical Center (WEAC) analyzed over 1200 samples of drugs, devices, and foods imported from Japan. FDA continues to monitor imported products from Japan.

Canadian Food Inspection Agency - Following the March 11 earthquake in Japan, the Canadian Food Inspection Agency (CFIA) took several measures to assess and protect the Canadian food supply from potential effects of Japan's nuclear crisis. In coordination with the Canada Border Services Agency (CBSA) and other government and international partners, the CFIA implemented enhanced import controls, which did not allow food and animal feed products from affected areas in Japan to enter Canada without acceptable documentation or test results verifying their safety.

The CFIA also launched a sampling and testing strategy to monitor radiation levels of imported food from Japan, domestic milk and domestic fish off the coast of British Columbia. More than 200 food samples were tested and all were found to be below Health Canada's actionable levels for radioactivity. As such, enhanced import controls have been lifted and no additional testing is planned.

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Health Canada - The damaged nuclear power reactors in Japan do not pose a health risk to residents of British Columbia or the rest of Canada. Given the thousands of kilometers between Japan and Canada's west coast, any radioactive material that might have been carried eastward via wind currents was dispersed and diluted over the ocean long before it reached Canada.

Health Canada has monitoring stations across the country in strategic locations and major population centres and will continue its regular radiation surveillance and monitoring activities.

Recommendation/Outcome: The Committee views this Charge as complete and no further action needed.

Executive Committee Action:

Approval ☒ Disapproval ☐ Date 5/23/12

Charge 2: Monitor and report on new import initiatives and activities that are proposed or instituted as a result of the enactment of the new Food Safety Modernization Act (FSMA).

Discussion: FSMA was signed into law in January 2011, representing the most sweeping change to US food safety law in more than 70 years. Title 111 is focused on Improving the Safety of Imported Food. The FDA is doing considerable outreach on the implementation of FSMA and has established a website that provides current information. Specific to imports, globalization of the food supply makes reliance on port-of-entry inspection too costly and infeasible to handle the increasing volume of imports. FSMA represents a groundbreaking shift, in that importers will now be responsible for ensuring that their foreign suppliers have adequate preventive controls in place and FDA will now have unprecedented authority to ensure that imported products meet U.S. standards. The new law explicitly states that importers are responsible for ensuring that their foreign suppliers have adequate preventive controls in place. So the prevention-based focus is being applied to imports as well as to domestically produced products. The scope of Title III is broad, including: Foreign Supplier Verification Program, Voluntary Qualified Importer Program, Authority to Require Import Certification for Food, Prior Notice of Imported Food Shipments, Capacity Building, Inspection of Foreign Food Facilities, Targeting of Inspection Resources, Accreditation of Third-Party Auditors, Establishing Foreign Offices, and working to prevent smuggled food.

Recommendation/Outcome: The Committee notes that FDA's Deputy Commissioner for Foods, Mike Taylor, is speaking on FSMA at the 2012 Conference. The Committee recommends AFDO continue to keep FSMA on the agenda in the coming year, as FDA continues to implement the new law.

Executive Committee Action:

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Charge 3: Assist the Conference Program Chair by identifying topics of interest and international speakers for the AFDO Annual Educational Conference.

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Discussion: The Committee notes this year's agenda includes senior leaders from the US and Canada. Deb Autor, Deputy Commissioner for Global Regulatory Operations and Policy, FDA (*Glenn W. Kilpatrick Memorial Address*); Dara Corrigan, Associate Commissioner for Regulatory Affairs (*FDA Keynote*); Paul Glover, Assistant Deputy Minister, Health Canada, Health Products and Food Branch (*Health Canada Keynote*); Cameron Prince, Vice-President, Canadian Food Inspection Agency, Inspection Modernisation (*Canadian Food Inspection Agency Keynote*); Alexis Grolla, Health Canada, Manager, Inspectorate Program (Drug GMP Inspection Program Review and Medical Devices Foreign Site Inspection Pilot); Paul Mayers, Association Vice-President, Programs, Canadian Food Inspection Agency (Import/Export Issues within North America).

Recommendations: The Committee will continue to work with the AFDO Planning Committee to identify potential key speakers for the 2013 Conference.

Executive Committee Action:

Approval ☒ Disapproval ☐ Date 5/23/12

**Responsible for submission of reports*