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August 10, 2015

Stephen Ostroff, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10901 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Ostroff:

I'm writing to request further information on FDA's policy and practice regarding oversight on imported seafood. Since the release of the GAO report titled "Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources[i]", published in April 2011, there have been numerous studies done which demonstrate that the amount of imported seafood, specifically shrimp, with a presence of bacteria or antibiotic residue is alarmingly high.

One study[ii] was completed in 2012 by a Louisiana State University student as a Master of Science thesis. In her study she found that 92% of imported, farm-raised shrimp samples tested positive for at least one drug that is banned for use in food-producing animals in the US.

In another study, a report[iii] released in April by Consumer Reports found that, as an aggregate, the number of shrimp tested for bacteria and drug residue was very high. In one section of the study, 16% of cooked, ready-to-eat shrimp was found to have several bacteria, including vibrio and E. coli.

Since over 90% of the shrimp consumed in the US is imported, the safety measures prior to domestic consumption must be of all time importance. In the 2011 report, GAO highlighted the limited scope of FDA's import food sampling program and the agency's use of resources for its aquaculture drug residue testing laboratory activities. GAO found that FDA could better ensure the safety of imported seafood by improving its import sampling program and use of resources by fully leveraging FDA's laboratory capabilities. In light of the studies cited above, and understanding that implementation of rules and regulations in the Food Safety Modernization Act are ongoing, I respectfully request that the FDA answer the following questions:

1. In testing for unapproved residue, the 2011 GAO report stated that FDA repeatedly fell short of the agency's sampling performance goals, failing to test for unapproved drugs and to utilize available laboratories.
    - What are FDA's current or targeted performance goals for testing imported seafood, including shrimp? Is the agency on track to meet such performance goals? If not, please provide details on the agency's plan to meet its targeted performance goals.
    - How has FDA improved in its laboratory activities to ensure full utilization of labs to provide better sampling of imported seafood? Please provide details on FDA's current use of laboratory capacity.
    - What criteria does FDA use in applying a risk-based approach for testing or sampling shrimp products from foreign importers, specifically in determining or identifying the presence of unapproved drug residues?

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- How does the recently proposed rule, "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" propose to support and improve imported seafood oversight to ensure increased residue monitoring of imported shrimp?
- Under FDA's HACCP inspection regulations and requirements, what tools does FDA use to ensure seafood imports, particularly shrimp, have been tested or sampled for unapproved drug residue or other hazards, such as bacteria, in a risk-based manner?

2. What is an importer required to include in its HACCP plan with respect to providing assurances that imported seafood does not contain hazards, such as unapproved drug residue?

3. In reference to the FY2012 Online Performance Index[iv] what countries or health systems has the FDA received performance assessments from?

4. Under the agency's proposed rule, FDA would require a comprehensive risk evaluation for foreign suppliers of food to be imported
   - In evaluating the risk factors of an importer, will the FDA take into consideration the foreign country's food safety program and its performance as a risk factor as part of its hazard analysis?
   - What criteria does FDA consider under the agency's assessments of foreign countries prior to a country-wide import alert for specific seafood products?
   - How does FDA apply or consider the results of a foreign country assessment within its risk-based inspections, sampling, or other testing activities under its seafood HACCP inspections of foreign importers?

5. What accountability mechanisms does FDA use to ensure that food importers or processors are effectively and adequately following their HACCP plan, particularly given that there is no requirement that FDA approve a food importer's HACCP plan? Please describe in detail.

6. In reviewing a foreign country's food safety program, what, if any, subjective variables such as country's government and social structure, are taken in account.

7. In addition to the performance assessments, does the FDA specifically encourage or require discussions on best practices with other large systems such as the European Medicines Agency or Canada Food Inspection Agency?

Thank you for your timely response. I look forward to hearing from you. If you have any questions please reach out to Christine Lofgren and Christine_Lofgren@cassidy.senate.gov or at 202-224-6820.

Sincerely,

B. Cassidy

Bill Cassidy, M.D.
United States Senator

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[i] http://www.gao.gov/assets/320/317734.pdf
[ii] http://etd.lsu.edu/docs/available/etd-04082014-144051/
[iii] http://www.consumerreports.org/cro/magazine/2015/06/shrimp-safety/index.htm
[iv] www.fda.gov/downloads/.../UCM242730.pdf#page=15