



The Honorable Bill Cassidy, M.D.  
United States Senate  
Washington, D.C. 20510-1804

NOV 10 2015

Dear Dr. Cassidy:

Thank you for your letter of August 10, 2015, regarding oversight of imported seafood. You express concern about the presence of bacteria and antibiotic residues in imported seafood and ask a number of questions about how the Food and Drug Administration (FDA or the Agency) ensures the safety of imported seafood. Please be assured that FDA shares your interest in protecting the public health and making sure that imported seafood is as safe as domestic seafood.

By way of background, FDA has had a strong regulatory program in place since the mid-1990s to ensure the safety of domestic and imported seafood. Processors of fish and fishery products are subject to FDA's Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, commonly known as the Seafood Hazard Analysis and Critical Control Point (HACCP) regulation. This regulation requires both domestic and foreign processors of fish and fishery products to understand the food safety hazards associated with their process and product and, through a system of preventive controls, to implement controls for those hazards. The hazard analysis and risk-based preventive controls framework of FDA's seafood safety program is a basis for the preventive controls requirements for other FDA-regulated foods called for in the FDA Food Safety Modernization Act (FSMA), enacted in 2011. FSMA specifically exempts facilities subject to and in compliance with the seafood HACCP regulation from the Foreign Supplier Verification Program (FSVP) provisions of the act (section 301), among others. We note, however, that FSMA also provides the Agency with a number of new authorities that will help improve the safety of domestic and imported FDA-regulated foods, including seafood.

FDA's risk-informed seafood safety program is designed to promote the overall safety of all seafood and to address areas that are most likely to have an impact on consumer health. The program relies on various measures of compliance with its seafood HACCP regulations. For imported seafood, these measures include:

- Screening 100 percent of import entries electronically prior to the products' entering the country,
- inspections of foreign processing facilities,
- examination and sampling of seafood offered for import into the United States,
- domestic surveillance sampling of imported products,
- inspections of seafood importers,
- evaluations of filers of seafood products,

- foreign country program assessments,
- information gathering from our foreign partners and FDA overseas offices, and
- import controls, known as Import Alerts, over product from firms, importers, and countries found to be in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA's Office of Partnerships provides funding to states that participate in the imported foods sampling elective within the state food contract program. Additionally, some states have their own programs that independently collect imported product in domestic commerce, analyze the imported product, and share the findings with FDA. The Agency has tools which allow sharing of information, including information-sharing agreements and the commissioning of officials in the state. You may be interested to know that FDA has these information-sharing agreements with the Louisiana Department of Agriculture and Forestry (LDAF) and the Louisiana Animal Disease Diagnostic Laboratory, which allows FDA to share certain non-public information with partners in these agencies. Additionally, several officials from LDAF, as well as the Louisiana Department of Health and Hospitals (LA DHH) and the Louisiana Department of Environmental Quality, are commissioned by FDA, including some who are credentialed by FDA to conduct inspections on the Agency's behalf. FDA's partnership with the state of Louisiana is essential to our nationwide Integrated Food Safety System and is accomplished through various contracts and other agreements related to food and feed.

We have restated your questions below in bold, followed by our responses.

**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.**

In recent years, FDA has assigned approximately 1,000 samples of imported and 100 samples of domestic aquaculture products to be collected per year and tested for various drug residues. In Fiscal Year (FY) 2013, a total of 1,141 samples of aquaculture products were collected and tested, which included 1,056 imports and 85 domestic samples. In FY 2014, a total of 928 samples of aquaculture products were collected and tested, which included 858 imports and 70 domestic samples. As of July 2015, a total of 1,091 samples of aquaculture products were collected and tested for FY 2015, which included 1,047 imports and 44 domestic samples. In terms of seafood overall, in FY 2014, FDA screened approximately 938,000 entries of imported seafood, while our field staff performed nearly 26,000 physical examinations of seafood imports and collected over 5,600 samples of domestic and imported seafood for analysis at FDA field laboratories.

By way of background, FDA's routine drug residue testing program for chemotherapeutic agents in domestic and imported farmed seafood is an integral part of a comprehensive, prevention-

oriented food safety system for all fish and fishery products under the provisions of the FD&C Act. The drug residue testing program is a verification tool, providing information on the degree of application of good aquaculture practices and controls and their effectiveness within the entire production system.

The program results are evaluated annually, and a new collection schedule is issued at the beginning of each fiscal year. Since it is neither feasible nor an effective use of resources to sample every entry of seafood products, the program incorporates a risk-based approach identifying types of commodities, countries of interest, and specific drug residues to test.

The overall number of samples is based on the program's accomplishment data and availability of resources. The program collection schedule provides a total number of samples per commodity of interest, and countries are identified based on non-compliance historical data, the volume of export of specific aquaculture products from a particular country to the United States, and any additional information gathered during FDA foreign country program assessments, foreign regulatory inspections, and review of publicly available information, such as that reported by other countries. The sampling plan is adjusted if there is an indication of problems with a specific product from a particular country or geographical area.

- **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.**

In recent years, FDA has developed a number of new methodologies for analyzing residues of unapproved antibiotics and antifungal agents in imported aquaculture products, including multi-residue screening methods. The methods developed are able to detect and confirm drug residues at low concentrations at the parts-per-billion (ppb) level. These methods were implemented in the FY 2014 and FY 2015 sampling programs. Currently, FDA has five field laboratories testing imported seafood for drug residues in shrimp, finfish, and other aquaculture species. These five labs are geographically dispersed throughout the United States to best handle imported seafood. While FDA has optimized the number of laboratories currently analyzing seafood, other FDA labs experienced in performing the required methodologies can be brought online, if needed, for additional testing capacity.

In addition, progress has been made in evaluation of performance parameters for the different types of commercially available test kits for screening for common residues in aquaculture species. FDA is planning evaluation work to determine if there is the potential to use the kits to increase the screening of shipments of imported seafood products. This evaluation work is essential because the analytical methods used for the testing of drug residues in seafood, to serve the Agency's regulatory purposes, must be rigorous, validated, and confirmatory. Such testing requires a high degree of analytic proficiency, relies on the most advanced laboratory instrumentation, and is supported by significant research efforts.

FDA laboratory analysts are also actively engaged in reviewing and approving the analytical packages submitted to FDA by private laboratories. Importers and consignees submit these packages to FDA to provide testimony to show an imported product, previously denied entry into

the United States, is now fit for entry. As is typical with any testimony submitted to the Agency, FDA lab analysts evaluate these analytical packages for scientific validity. These evaluations continue to grow in number as does the time required to perform them. FDA continues to ensure that these evaluations are done as efficiently and uniformly as possible through increased training of FDA analysts and standardization of package reviews.

- **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?**

Currently, FDA tests for drug residues in shrimp, finfish, and other aquaculture species. The drugs tested for are 1) the most frequently used on farms because they are considered to be effective, inexpensive, and easily accessible, 2) not approved for use in aquaculture in the United States, 3) in some cases, prohibited for extra label use, and 4) those for which there are the most significant concerns of potential adverse consequences to human health. Sampling and testing is determined based on results of regulatory inspections and the prevalence of non-complying results in products sampled in the previous year, and other factors.

- **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?**

The accredited third-party certification program (third-party program) is one of several new FSMA tools that, under certain circumstances, will provide additional assurances that imported foods are as safe as domestic foods.

The third-party program is voluntary and is focused on the issuance of certifications that may be offered to FDA for two purposes: 1) to help demonstrate eligibility for the Voluntary Qualified Importer Program (VQIP) for the expedited review and importation of foods from importers who achieve and maintain a high level of control over the safety and security of their supply chains, and 2) to satisfy a condition of admissibility of an imported food subject to an FDA risk determination under section 801(q) of the FD&C Act (21 U.S.C 381(q)). The third-party program will serve as an important component of FDA’s modernized imports system for helping ensure that foods entering the United States are safe. Unlike FSVP, facilities subject to and in compliance with seafood HACCP requirements can participate in the third-party program.

When finalized, the third-party certification rule will establish requirements for the competency and impartiality of accredited third-party certification bodies, which will audit eligible foreign entities to determine compliance with applicable food safety requirements of the FD&C Act, such as the seafood HACCP regulations.

- **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?**

As mentioned above, the Agency has a variety of tools to ensure compliance with seafood safety requirements. As part of the Agency's surveillance work at the border, FDA utilizes a risk-based approach to allocate resources, with priority given to high-risk food safety issues. FDA screens all import entries electronically prior to the product entering U.S. commerce, and a subset of those are physically inspected or tested at varying rates, depending on the potential risk associated with them. FDA conducts inspections of domestic and foreign processing facilities, examination and sampling of domestic seafood and seafood offered for import into the United States, domestic surveillance sampling of imported products, inspections of seafood importers, evaluations of filers of seafood products offered for import, foreign country program assessments, and issues Import Alerts.

There is no acceptable level for any residue of animal drugs not approved for use in farmed fish in the United States; therefore, any amount of unapproved drugs detected in the product renders the product adulterated. If FDA has established an import tolerance for a drug not approved in the United States, seafood imported into the United States containing residues at or below the import tolerance would not be adulterated. To prevent adulterated fishery products from entering domestic commerce, FDA has a monitoring program to test for residues of unapproved drugs. Upon discovering any use of an unapproved drug through the testing program (or during an FDA foreign inspection), FDA typically employs several tools: Import Alerts, communication to the foreign government's competent authority, increased surveillance by FDA of the potentially adulterated products, and regulatory enforcement actions.

FDA's general policy is to place certain violators on an Import Alert, which informs FDA field personnel that the Agency has sufficient evidence or other information to detain without physical examination future shipments of an imported article (i.e., that future shipments appear to be violative). Positive analytical results are but one type of evidence that can be used to place a firm on Import Alert; the Agency has also used evidence of unapproved drug use obtained during a facility inspection or a country's assessment to place firms on Import Alert.

When an Import Alert is issued and FDA detains a shipment, the importer has an opportunity to introduce evidence to demonstrate that the product is not violative. An Import Alert shifts the burden to the importer to conduct testing to demonstrate that the product meets FDA regulatory requirements. FDA decisions to remove a product, manufacturer, packer, shipper, grower, country, or importer from detention without physical examination are based on evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved, and the Agency has confidence that future entries will be in compliance with the FD&C Act.

**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?**

The foreign processor, rather than the importer, is required to conduct a hazard analysis and to have and implement HACCP plans. Importers are required to have verified that seafood products offered for import are processed in accordance with the seafood HACCP requirements found in 21 *Code of Federal Regulations* (CFR) part 123. An importer can demonstrate



verification by obtaining a fish or fishery product from a country that has an active MOU with FDA that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, as described in 21 CFR 123.12(a)(1), or by having and implementing written verification procedures as described in 21 CFR 123.12(a)(2). These procedures include maintaining product specifications that are designed to ensure that the product is not adulterated under section 402 of the FD&C Act and performing one or more affirmative steps specified in 21 CFR 123.12(a)(2)(ii) to assure that the seafood offered for entry has been processed in accordance with FDA's requirements in 21 CFR Part 123. Acceptable aquaculture drug residues and usage or other safety limits should be defined in the product specifications. Affirmative steps help ensure that foreign processors have and implement a seafood HACCP program in accordance with FDA requirements. A HACCP plan must, among other things identified in 21 CFR 123.6(c), list the critical control points for each of the identified food safety hazards.

**3. In reference to the FY 2012 Online Performance Index, what countries or health systems has the FDA received performance assessments from?**

With respect to Measure 214207 of the "FY 2012 Online Performance Appendix"<sup>1</sup> (i.e., the number of assessments/questionnaires completed to initiate the process of establishing comparability of foreign country food safety systems to that of the United States relative to public health outcomes), FDA continues to develop a process for conducting systems-recognition assessments (previously called comparability assessments).<sup>2</sup> New Zealand, Canada, Australia, and Europe have expressed interest in systems recognition assessments and are working with the Agency. FDA has signed an agreement with New Zealand and has completed assessments of the Canadian and Australian food safety systems.

The Agency has also done commodity-specific assessments. For example, the Agency has conducted foreign country assessments to evaluate the country's laws for, and implementation of, good aquaculture practices. Specifically, FDA evaluates the country's controls, including licensing and permitting, inspections, and training programs for aquaculture products. FDA uses the information from country assessments to better target surveillance sampling of imported aquaculture products, inform its planning of foreign seafood HACCP inspections, provide additional evidence for potential regulatory actions, such as an Import Alert, and improve collaboration with foreign government and industry contacts to achieve better compliance with FDA's regulatory requirements. For example, the country assessments for China in 2006, Chile in 2009, and India in 2010 resulted in increased sampling and testing for aquaculture products from these countries (e.g., eel from China, salmon from Chile, and shrimp from India).

**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?**

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<sup>1</sup> <http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/budgetreports/ucm242730.pdf>

<sup>2</sup> <http://www.fda.gov/Food/InternationalInteragencyCoordination/ucm367400.htm>

As mentioned above, FSMA exempts from the FSVP requirements seafood facilities subject to and in compliance with the seafood HACCP regulations. FDA's seafood HACCP regulation requires both domestic and foreign processors of fish and fishery products to understand the food safety hazards associated with their process and product and, through a system of preventive controls, to implement controls for those hazards.

Under the FSVP proposed rule for importers of food for humans and animals subject to the regulation, the FSVP importer would be responsible for conducting supplier verification activities to provide assurance that the food and feed products they import are produced in compliance with the preventive controls and produce safety provisions of FSMA (as applicable) and in compliance with sections 402 and 403(w) of the FD&C Act. Under the proposed rule, it would be the responsibility of the importer to identify hazards associated with a product and take this into consideration, along with the characteristics of potential foreign suppliers, in approving suppliers and determining appropriate supplier-verification activities to conduct.

- **What criteria does FDA consider under the Agency's assessments of foreign countries prior to a country-wide import alert for specific seafood products?**

As described above, the Import Alert is one of FDA's tools to prevent potentially violative imported foods from entering U.S. commerce. Import Alerts may reference affected products from the listed manufacturer, shipper, grower, or geographic area. For example, FDA imposed a country-wide Import Alert on all farm-raised catfish, basa, shrimp, dace, and eel from China in June 2007, due to the presence of unapproved animal drugs and/or unsafe food additives.

FDA's procedures for implementing a country-wide alert are defined in the Agency's Regulatory Procedures Manual (RPM). The criteria in the RPM indicate that FDA's field staff may recommend detention without physical examination for specific products from a country or a specific geographic area when there are at least 12 detentions in a recent six-month period or less, these detentions represent at least 25 percent of the total shipments of that product examined in that time period known to that FDA district office, and these detentions represent a significant number of firms that manufacture, ship, or grow the product from the geographic area or country.<sup>3</sup> The Agency may consider additional information in conjunction with sample analysis, when considering whether to recommend products from a geographic area or country for detention without physical examination, such as the results of foreign inspections and foreign country program assessments that include, for example, information on sampling and analytical results.

- **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?**

Foreign country program assessments give FDA unique information necessary to understand a country's animal drug residue program for aquaculture products. Their purpose is for FDA to gain knowledge of a country's seafood safety laws and regulations, specific to aquaculture, and

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<sup>3</sup> <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179271.htm>

to become familiar with the controls a country's competent authority is implementing for the distribution, availability, and use of animal drugs in aquatic animals to meet requirements of FDA's HACCP requirements and other relevant laws and regulations in order to ensure the safety of aquaculture products intended for the U.S. market.

FDA looks at the operational criteria the competent authority has in place to ensure its impartiality and effectiveness. The criteria include having a number of qualified and experienced staff to carry out official controls at the central, regional, and local levels; routine surveillance checks; inspections; verifications; investigations of non-compliance; sampling; and testing. The competent authority should ensure that all units involved in implementation of controls have effective and efficient coordination and communication in place. Laboratories involved in the analysis of samples should work in accordance with internationally approved procedures, use validated methods, and have equipment that enables the correct determination of residue levels. FDA also is interested in the interaction between the competent authority and industry. This is accomplished through interviews with the country's competent authority officials and industry during visits to farms, processing plants, laboratories testing for drug residues, and animal drug and fish feed-selling centers/stores.

The information gathered during the foreign country assessment trip is used in a variety of ways by FDA:

- the information helps to enhance the design of the surveillance sampling program to target aquaculture species and countries of concern,
- the drug use information obtained during the assessment helps the Agency identify residues for which a new methodology needs to be developed,
- any noncompliant trends observed at processing facilities are taken into consideration in the planning of foreign regulatory seafood HACCP inspections, and
- observations made during the assessment are taken into consideration before the issuance of a country-wide Import Alert.

These visits are also a forum for exchanging information with regard to FDA requirements for importing seafood products into the United States and lead to capacity-building opportunities such as the train-the-trainer programs in Good Aquaculture Practices.

**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.**

FDA obtains assurances of compliance through accountability mechanisms such as record reviews and physical inspection of importers and processors. FDA's regulatory approach considers the entire seafood HACCP program as a whole unit that incorporates the written procedures, the actual implementation of those procedures, and the maintenance of written records that accurately reflect the implementation of the program.



As mentioned above, FDA uses a risk-based prioritization system to select processors and importers for inspection. FDA utilizes its entry data to determine what products to inspect. The investigator confirms whether an importer of fish or fishery products meets the requirements of 21 CFR 123.12 for the products that have been offered for entry into the United States. This section of the regulation requires that importers demonstrate verification by obtaining a fish or fishery product from a country that has an active MOU with FDA that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, as described in 21 CFR 123.12(a)(1), or by having and implementing written verification procedures as described in 21 CFR 123.12(a)(2) for ensuring that the fish and fishery products that they offer for import into the United States were processed in accordance with the seafood HACCP requirements of 21 CFR Part 123. This may include obtaining written assurances from the foreign processors that they have met the requirements of the seafood HACCP regulation.

FDA utilizes information from importers to target foreign processors for inspection. During an FDA inspection, the investigator assesses the processor's written HACCP plan. In accordance with 21 CFR 123.12(d), FDA will deny entry of product that appears to be adulterated in instances where assurances do not exist that imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under 21 CFR Part 123.

**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?**

FDA considers a country's food safety program in a number of ways, including food safety oversight by the food safety authority, regulatory decision-making, capacity building, laws, infrastructure, training programs, and systems recognition. For capacity building, FDA uses data from assessments to inform its planning process and whether/how to engage with another country.<sup>4</sup> For systems recognition, FDA uses data from assessments to inform its ability to recognize another country's food safety system as comparable to FDA's.

The FDA aquaculture drug residue program is an important part of the Agency's overall seafood safety prevention strategy. The assessment program provides FDA with unique information necessary to understand a country's animal drug residue program for aquaculture products.

**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?**

Seafood is one of the most highly traded commodities in the world. The Agency recognizes that success in protecting the American public depends increasingly on our ability to reach beyond U.S. borders and engage with its government regulatory counterparts in other nations, industry, and with regional and international organizations to encourage the implementation of science-based standards to ensure the safety of products before they reach the United States. FDA

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<sup>4</sup> See FDA's International Food Safety Capacity Building Plan, Objective 2.2, available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM341440.pdf>.

regularly considers other countries' food safety systems and best practices and engages in dialogue with those countries for awareness, and to gain knowledge and inform decision-making.

Thank you, again, for contacting us concerning this matter. If you have further questions or concerns, please let us know.

Sincerely,

A handwritten signature in dark ink, appearing to read "Dayle Cristinzio", with a stylized flourish at the end.

Dayle Cristinzio  
Acting Associate Commissioner  
for Legislation