FDA's Evaluation of the Seafood HACCP Program for Fiscal Years 2006 – 2014

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SUMMARY

This evaluation covers the status of domestic seafood processors and importers and foreign seafood processors in Fiscal Years 2006 through 2014 with regards to implementing food safety controls in accordance with the Food and Drug Administration's (FDA or Agency) Hazard Analysis Critical Control Point (HACCP) requirements defined in Title 21 of the Code of Federal Regulations, Part 123 (21 CFR 123). These fiscal years represent the ninth through seventeenth years for the implementation of the seafood HACCP program.

The seafood HACCP regulation took effect on December 18, 1997. This is the fifth such evaluation. The previous evaluations, beginning with the first issue in December 2000, included all the data collected since 1998, the first year of mandatory Seafood HACCP controls.

PROGRAM OBJECTIVE

HACCP is a science-based food safety system that commercial fish and fishery products (seafood) processors must use to identify potential food safety hazards and keep them from occurring. Processors are required to implement those written HACCP plan controls to reduce the risk of the identified hazards from occurring. The seafood HACCP program further requires importers of seafood products to develop written verification procedures to assure the seafood they import has been processed in accordance with seafood HACCP requirements. The FDA Seafood HACCP program was designed to increase the margin of safety and to reduce those illnesses that do occur to the lowest possible levels.

COMPLIANCE PROGRAM OBJECTIVE

The objective of the seafood processor and imported seafood compliance programs is to ensure the safety of fish and fishery products consumed in the United States (U.S.) This is done by determining compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and its supporting regulations by conducting inspections that evaluate the food safety controls (HACCP) implemented by seafood processors (Processor is defined in 21 CFR 123.3(l) on website: https://www.gpo.gov/fdsys/pkg/FR-1995-12-18/pdf/FR-1995-12-18.pdf) and importers of seafood products.

The seafood HACCP program utilizes two compliance programs, one for processing facilities (CP 7303.842) and one for imported seafood products (CP 7303.844). FDA further utilizes compliance Programs specific to raw molluscan shellfish (CP 7318.004) and the surveillance of aquacultured seafood products (CP 7304.018). This evaluation focuses on the compliance programs for processing facilities and imported seafood products.

PROCESSING FACILITIES

COMPLIANCE PROGRAM BACKGROUND

The Seafood Processor Inspection Program – Domestic and Foreign Facilities (CP 7303.842) supports the regulatory coverage of seafood processors by FDA and State inspectors operating under contract or partnership agreements with FDA. It includes procedural guidance to the field for determining compliance with seafood HACCP requirements by processors that distribute fish and fishery products in interstate commerce or export product to the U.S. Following the promulgation of 21 CFR 123, "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products" Final Rule (the seafood Hazard Analysis and Critical Control Point regulation) in December 1995, the Agency has performed HACCP compliance inspections of both domestic and foreign seafood processing facilities. These inspections verify that the inspected seafood processors have developed and implemented a written system of preventive controls which meet the requirements of 21 CFR 123, including compliance with the Good Manufacturing Practice Regulation, 21 CFR 110 which was in effect during the time covered by the evaluation. The compliance program applies to both domestic and foreign processors, with foreign processors being held to the same requirements as domestic processors. In addition to CP 7303.842, other compliance programs may apply depending on the product and processing activities at the facility.

In addition to the compliance program, another critical tool utilized during inspections is the *Fish and Fishery Products Hazards and Controls Guidance* (the Guide), a scientific reference tool. This is a peer reviewed compilation of information based on scientific literature that identifies potential food safety hazards, the conditions that result in the hazards occurring, and controls to prevent or eliminate the hazards. FDA investigators and State inspectors use this guidance document to evaluate the adequacy of HACCP controls during inspections of processors and importers.

When selecting foreign processors for inspection, FDA takes into consideration the volume and type of seafood shipped, the food safety risks associated with the products they ship to the U.S., which are prioritized in the compliance program, and the processor's individual compliance history. Processors of higher-risk products and processes identified during surveillance activities are assigned a higher priority for inspection. For example, inspections of U.S. importers can identify foreign processors that potentially have significant problems with their HACCP programs based on the foreign processor's HACCP paperwork reviewed during the inspection.

The safety of fresh and frozen molluscan shellfish is controlled in accordance with guidelines established in the National Shellfish Sanitation Program (NSSP). The NSSP is a federal/state cooperative program that is recognized by FDA as the primary program for the sanitary control of shellfish produced and sold in interstate commerce for human consumption in the U.S. Requirements upon both the shellfish industry and state shellfish control authorities are provided within the NSSP Model Ordinance, which incorporates the requirements of the seafood HACCP regulation. Regulatory requirements on the harvest and source of raw molluscan shellfish published as part of the Seafood HACCP regulations are intended to strengthen safety controls and provide additional support to the NSSP. Since 1925, when the NSSP was established, FDA has recognized state shellfish control authorities as the principal regulatory authority over the safe growing, processing, storing, and shipping of molluscan shellfish in interstate commerce. FDA's seafood HACCP regulation provides the Agency with the regulatory

authority to manage shellfish safety should a state(s) fail to control the safety of molluscan shellfish in accordance with the NSSP. The seafood HACCP regulation is not intended to override the NSSP.

Processors of raw molluscan shellfish are covered under The Molluscan Shellfish Compliance Program (CP 7318.004) in States participating in the Interstate Shellfish Sanitation Conference (ISSC). CP 7303.842 applies to raw molluscan shellfish processors and products located in non-participating ISSC inland states and thus not covered under the NSSP and are therefore not covered under the Molluscan Shellfish Compliance Program (CP 7318.004).

IMPORTED SEAFOOD

COMPLIANCE PROGRAM BACKGROUND

Historically, FDA has controlled imported fish and fishery products by reviewing customs entries, conducting field examinations, collecting samples for laboratory analysis, recommending detentions, and ultimately placing products and processors with a history of problems on detention without physical examination. With the promulgation of the seafood HACCP regulation, there is now a second component in the import control strategy. Under the seafood HACCP system of controls, an importer assumes the responsibility for the safety of the seafood products they import into the U.S. Importers are required to take steps to verify that their imported products are obtained from foreign processors that comply with FDA's seafood HACCP regulation. The Imported Seafood Products Compliance Program (CP 7303.844) provides instructions for both the inspection of U.S. importers of seafood products and the sampling and analysis of seafood offered for entry into the U.S.

OVERALL PROGRAM DESIGN AND METHODOLOGY

The seafood processor and imported seafood compliance programs provide instructions for the inspection of processing facilities and importers, analytical references, sample collection guidance, and enforcement strategies. The instructions include a prioritization for the selection of facilities and commodities for surveillance based on a combination of the potential safety risks associated with the products, industry compliance history, and the compliance history of the individual processor.

The data presented in this report is obtained from actual inspections conducted during each fiscal year and is not the total number of firms in the FDA official establishment inventory. Since the current evaluation covers nine fiscal years, the data from previous evaluations has not been used for comparison to identify trends.

The seafood HACCP compliance programs direct inspectors to complete data collection reports, FDA Form 3501 for both domestic and foreign processing facilities and FDA Form 3502 for importer inspections. The data collected is specific to the seafood HACCP regulation and is maintained in a separate data system. As part of a seafood HACCP inspection, an inspector will select a specific seafood product that is the target of their inspection based on the risk and volume produced. They observe the process for that product and the HACCP documentation related to the selected product. The information in the FDA 3501 and 3502 reports is based on the findings of the inspector during their observation of the selected product's process and the reviewed HACCP documentation. The inspections may be conducted by either FDA personnel or State inspectors who are operating under contract or in partnership agreements with FDA. FDA uses the data in the FDA 3501 and 3502 reports to identify trends within a portion of the industry with regards to the identification and implementation of HACCP controls. FDA then utilizes this information to prioritize commodities and facilities for surveillance activities (i.e., inspection and product sampling) in the compliance programs.

The evaluation tables included in this report that cover compliance with the seafood HACCP requirements reflect the FDA Form 3501/3502 data, which identifies the most significant HACCP elements and provides the percentage of processors or importers that succeeded in meeting FDA's requirements for each of these elements. The accompanying narrative addresses specific aspects of the data, including noteworthy trends and issues that are emerging or continuing.

The data related to the number of inspections performed and final classification of the inspection report was obtained from FDA's FACTS database and reported under the FACTS Accomplishments generated by CFSAN's Office of Compliance. In our reviews of facility compliance, firms are classified by FDA as "no action indicated" (NAI), "voluntary action indicated" (VAI) or "official action indicated" (OAI). Traditionally, FDA considers a firm "in compliance" when the most recent inspection was classified NAI or VAI.

FINDINGS

Domestically, the number of inspections decreased dramatically from FY 2006 to FY 2014. Conversely, foreign inspections and the number of countries visited by FDA increased, albeit modestly, over that same period. As expected, the number of domestic inspections was significantly larger than the number of foreign inspections. The classification percentages for NAI and VAI inspections of domestic processors reported in this evaluation were similar. The number of domestic inspections of processors of lower risk products or who have a good compliance history increases the likelihood of VAI and NAI classifications. Since foreign processors are selected based on increased risk either by the hazards associated with the product or factors associated with the processor or country, there is an increased likelihood that the inspection classification will be VAI or OAI for those inspections. Our evaluation found the inspection classifications for foreign inspections were predominately VAI.

FDA's seafood HACCP compliance program has been in place since FY 1998, when FDA began to actively enforce the seafood HACCP regulation. As industry has become familiar with FDA's requirements the compliance (success) rates for domestic processors have stabilized. Our current evaluation found no distinct increase or decline in compliance unless mitigating factors are introduced, such as the revision of the *Fish and Fishery Products Hazards and Controls Guidance, Fourth Edition* in April 2011 and the introduction of new guidance. The issuance of the Guide in April 2011 resulted in a slight decline with regards to compliance of HACCP plan content for domestic processors as industry adjusted to the new information.

The current evaluation found the overall success rates with regards to plan content and implementation for domestic processors exceeded that of foreign processors. The success rates for domestic processors in the identification of appropriate written HACCP plan controls was slightly higher when compared to the success rates for foreign processors. The success rates for implementation of the written HACCP plans fluctuated slightly from year to year but were similar when comparing overall rates for both domestic and foreign processors.

Performance of importers with regards to having written verification procedures and implementing adequate affirmative steps was significantly lower when compared to domestic and foreign processors having adequate HACCP plans and implementing them. The data for importers does not identify a specific trend for an increase or decrease in compliance. The low rate of inspection is a likely contributing factor.

DOMESTIC INDUSTRY PROGRESS

Not all domestic firms are inspected annually. Because of the large inventory of domestic seafood processors, the processors are prioritized for inspection based on a combination of the potential safety risks associated with the products and the compliance history of the processor. FDA's risk-based approach allows FDA to concentrate

its inspectional resources on the processors of higher risk commodities and on previously noncompliant firms first, followed by lower risk processors and processors with minor deficiencies. Processors of lower risk products continue to be inspected as resources allow. Section 201 of the Food Safety Modernization Act (FSMA) (website: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247548.htm#SEC205) published in January 2011 now defines the minimum frequency for inspections based on product food safety risk.

a) "Compliance Rate"

Figure 1 shows the total number of seafood processor inspections completed in each fiscal year and a breakdown of the inspections by classification. Although, FDA identifies the classification of most inspections (i.e., NAI, VAI, or OAI), some inspections may remain unclassified and are therefore not included in the calculations. Our evaluation determined that the number of inspections each fiscal year decreased by 64% over the nine-year evaluation, from 2338 inspections in FY 2006 to 845 inspections in FY 2014. Figure 2 converts Figure 1 numbers into the percentages of the total inspections for each fiscal year. The use of percentages overcomes the significant change in the number of inspections and allows a comparison of performance. The majority of inspections were classified as NAI and VAI. However, there are two noticeable trends, the decrease in the percentage of NAI classifications and the increase of the percentage OAI classifications in the overall number of inspections for each fiscal year. We hypothesize the increase in OAI classification percentages is due to FDA assigning a higher priority for inspection to processors of higher risk commodities based on the associated hazards and/or the compliance history of the product or processor.

Figure 1

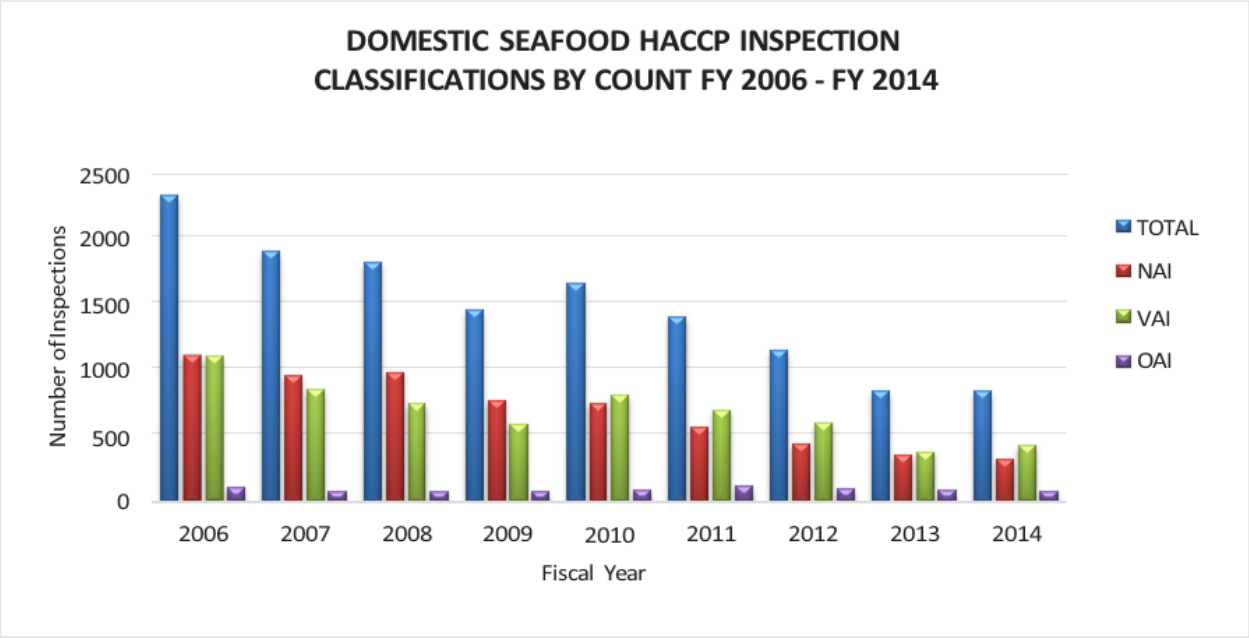
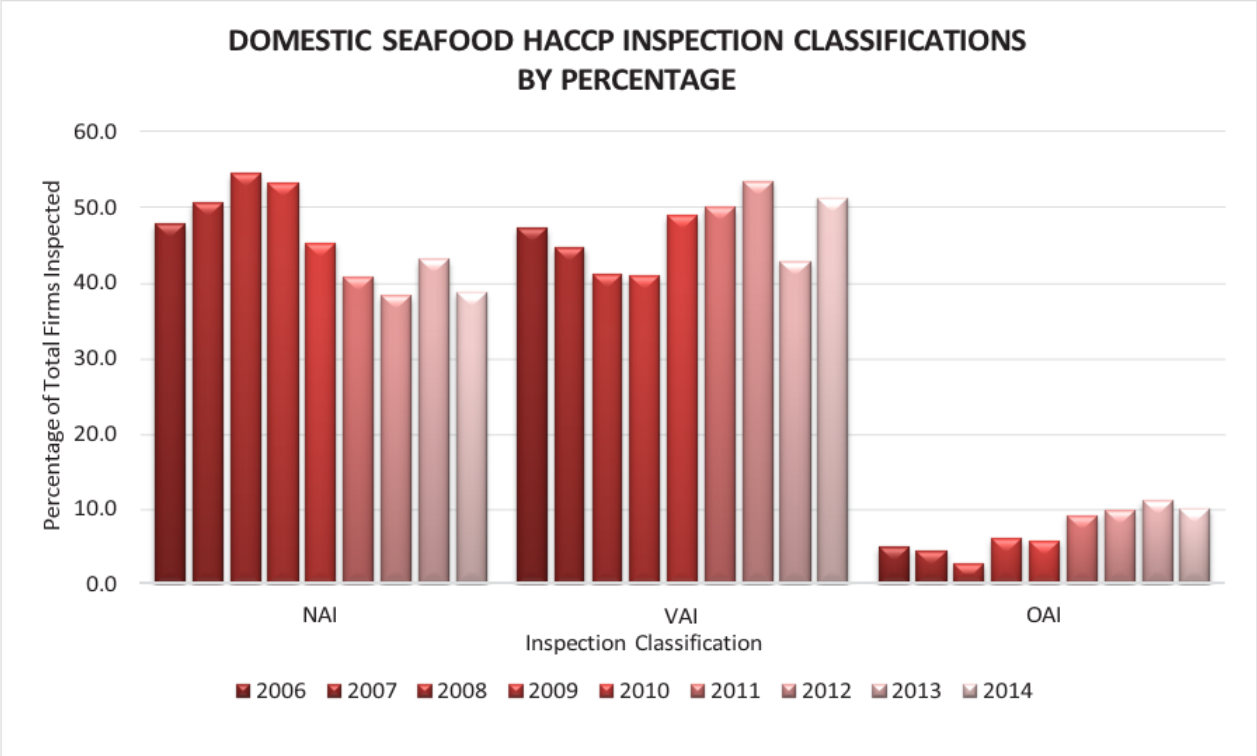


Figure 2



b) <u>Success on individual Elements: Domestic Industry Overall</u>

As with the previous evaluations, this evaluation continues to list the most significant elements of the seafood HACCP regulation in tables and provides the percentage of processors that successfully accomplished the listed elements for each of the fiscal years. The accompanying narrative addresses specific aspects of the data, including noteworthy trends and issues that are emerging. In addition to the individual elements, the tables also show three broad categories which include the contents of the HACCP plan, the implementation of the HACCP plan, and sanitation monitoring controls.

The inspection numbers in Table 1 are based on the information entered in the data collection report, FDA 3501 relating to commodities targeted during the inspection, and may not agree with the number of inspections reported in Figures 1 which were obtained from the FACTS data system and represent facility inspections. Because a processor may have more than one HACCP plan for different processes or products, there may be several FDA 3501 collection reports for one facility inspection. Table 1 sorts success rates into individual elements that address HACCP plan content, HACCP plan implementation, GMP conditions, and sanitation monitoring.

The overall success averages for HACCP plan content and implementation (line 1) in Table 1 show success rates exceeding 80 percent. The averages represent an average of the individual success rates listed in lines 2 through 15. From FY 2006 to FY 2010, there is no appreciable trend upward or downward for success rates for the individual elements addressing the contents of the HACCP plans, implementation of the plans, or sanitation monitoring controls for each fiscal year (lines 3 to 20). With regards to sanitation monitoring elements (lines 16 to 20), the stability of the results continues through FY 2014. However, a noticeable decrease in the success rates related to the HACCP plan content elements (lines 5 – 9), can be seen from FY 2011 to FY 2014 which impacted the overall success rates (line 1) and resulted in a decline in success rates. This decline in overall success rates also corresponds with the increase in the percentage OAI classifications shown in Figures 2 during that time (FY 2011 to FY 2014).

The update in the *Fish and Fishery Products Hazards and Controls Guidance* in April 2011 coincides with the decrease in inspections successfully identifying appropriate HACCP plan controls (lines 5 – 9). We hypothesize that the decrease occurred as industry adjusted to changes in safety guidance.

Another related decrease occurred with the number of inspected firms that did not need a HACCP plan (line 3). That number decreased from a high of 28 percent in FY 2009 to 10 percent in FY 2014. This can be attributed to the new Guide's clarification on FDA's policy with regards to the control of the food safety hazard of allergens. The Guide was modified to specifically require HACCP plan controls for allergen labeling. Processors that previously did not have HACCP plans were now required to develop and implement plans.

Sanitation monitoring success rates (line 17) ranged between 69 and 80 percent. These success rates were determined by evaluating data resulting from a processor's failure to identify GMP deficiencies during sanitation monitoring activities required by the seafood HACCP regulation. Maintenance of adequate sanitation monitoring records documenting observations (line 18) was slightly higher than monitoring results, between 77 and 84 percent. The highest success rates were identified for taking appropriate corrective actions when deficiencies were noted and documenting it (lines 19 - 20). "Adequate sanitation controls" (line 16) considers when the inspection identifies no deficiencies for any of the sanitation elements (lines 17 – 20) which includes GMP conditions, sanitation monitoring, sanitation records, and corrective actions. Success rates ranged between 63 and 72 percent although the individual elements (lines 17 – 20) showed higher success rates because they were for single elements, not multiple elements. No definitive trends of increase or decrease in success rates for the sanitation monitoring program were identified in any of the elements (lines 17 – 20).

TABLE 1
Domestic Industry Progress –
Percentages of Seafood HACCP and Sanitation Controls
by Regulatory Provisions (FY 2006 – 2014)

Mandatory HACCP/Sanitation Provision (All inspections)

	HACCP Program Areas	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
1	**Average covering overall success with plan content and implementation (5-9, and 12-15).**	86	86	88	88	84	83	82	82	80

HACCP Plan Content

	HACCP Program Areas	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
2	**Overall average of elements 5-9, plan content**	88	89	89	88	86	83	81	80	79
3	No HACCP plan needed.	25	23	24	28	26	25	21	20	10
4	HACCP plan present when needed.	87	88	89	91	91	86	80	84	86
5	All significant hazards listed in written plan – all inspections.	90	91	91	88	85	81	79	76	80
6	All critical control points identified in written plan – all inspections.	90	90	92	89	88	85	82	82	82
7	Adequate identification of critical limits in written plan.	84	85	84	86	84	81	77	80	79
8	Adequate identification of monitoring procedures in written plan - all inspections.	87	88	89	87	86	83	81	80	74

	HACCP Program Areas	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
9	Adequate identification of corrective actions in written plan - all inspections.	90	90	91	89	86	83	84	82	81
10	Meet training requirement - all inspections.	88	89	90	90	90	88	86	81	88

HACCP Plan Implementation

	HACCP Program Areas	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
11	**Overall average of elements 12–15, plan implementation.**	84	84	86	87	83	83	83	83	82
12	Adequate implementation of HACCP monitoring procedures listed in the plan.	78	79	80	83	78	75	75	76	74
13	Adequate HACCP monitoring records listed in the plan.	79	78	80	83	78	75	77	77	74
14	Adequate corrective actions taken when needed.	92	93	95	94	90	90	89	89	88
15	Adequate corrective action records when corrective actions taken or no corrective actions needed.	87	88	89	88	85	90	92	91	92

Sanitation Monitoring

	HACCP Program Areas	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
16	Adequate sanitation controls (All GMPs, sanitation monitoring, & record keeping).	69	70	72	67	65	63	63	65	71
17	Adequate sanitation monitoring.	78	77	80	73	72	71	69	71	77
18	Adequate sanitation monitoring records.	78	80	81	77	78	79	82	79	84
19	Adequate sanitation corrections taken when sanitation deficiencies noted or no sanitation corrections needed.	92	91	93	85	90	91	93	90	95
20	Adequate sanitation correction records when sanitation corrections taken or no sanitation corrections needed.	92	92	93	85	90	91	93	91	95

c) Success on Individual Elements: Specific Domestic Industry Sectors

Seafood HACCP controls can vary due to the type of food safety hazards associated with a seafood product. Table 2 represents the seafood HACCP inspection data sorted into sections by the associated food safety hazards. The data has been broken down in this manner to help identify industry sectors having difficulties in meeting FDA requirements so that FDA can better prioritize resources. The "adequate plans and implementation overall" success rates (i.e., lines 1- 8) represent when no deficiencies for any of the individual elements were identified during an inspection and may be lower than the individual element percentages.

Each section in Table 2 lists the overall industry success in controlling a single food hazard, which is then followed by a breakdown of the elements with regards to the content and implementation of the HACCP plan controls for that single hazard. Conversely, Table 1 shows the success of inspected processors in controlling all hazards addressed in the HACCP plan for the inspected commodity. These differences make it difficult to compare an industry sector's performance in Table 2 to the results in Table 1. A more meaningful comparison is to compare success rates for specific hazards within Table 2.

Table 2 results show that industry has been largely successful in identifying and implementing HACCP plans to

control hazards that require less complicated control systems. The majority of results for overall and individual program elements are between 97 and 100 percent for the hazards of veterinary drugs (section 3), marine toxins (section 4), environmental chemicals (section 5), metal/glass inclusion (section 6), allergens/food additives (section 7), and parasites (section 8). Success rates for the control of veterinary drugs were the highest overall, between 99 and 100 percent. One notable difference occurs with the results for allergens/food additives where success rates decreased significantly in FY 2012, FY 2013 and FY2014. The 2011 edition of the Guide clearly identified that HACCP plans must include allergen declaration controls. The reduction in success rates for allergen/food additives is likely attributable by the adjustment of industry to this modification in guidance.

The success rates for having and implementing HACCP plan controls for the hazards of pathogen growth/toxin formation (section 1) and scombrotoxin (section 2) were noticeably less than those for the other hazards. Prevention or elimination of pathogen growth/toxin formation or scombrotoxin hazards may require more complex controls which can involve multiple critical control points, consideration of cumulative exposure conditions, process studies, and consideration of the interaction of differing time/temperature safety controls. This can be challenging with regards to the identification of HACCP plan controls and plan implementation.

Scombrotoxin (histamine) formation is associated with specific species of fish and is prevented through time and temperature controls after harvest and during processing and storage. Overall plan and implementation (line 2) success rates for the control of histamine were significantly higher than the rates for pathogen growth/toxin formation, between 85 and 89 percent. HACCP plan controls (lines 2.1 through 2.5) ranged between 95 and 98 percent. The lowest success rates, 91 to 96 percent, were associated with the implementation of the plan and recordkeeping (lines 2.1 through 2.7). No definitive trends of increase or decrease in rates were identified overall or in any of the other individual elements.

Control of pathogen growth/toxin formation is associated with a broad range of mostly ready-to-eat products including, but not limited to cooked, pasteurized, smoked, vacuum packaged, acidified, salted/brined, cured, fermented, battered/breaded, salads, sandwiches, soups/chowders, and raw ready-to-eat seafood products. Pathogens of concern include, but are not limited to, *Listeria monocytogenes*, *Vibrio vulnificus*, *Vibrio parahaemolyticus*, *Escherichia coli*, *Salmonella* spp., *Staphylococcus aureus*, *Clostridium perfringens*, and *Clostridium botulinum*. Chapter 12 of the Guide (website: https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM252415.pdf) provides a comprehensive list and description of the pathogens of concern.

Success rates for the control of pathogens were significantly lower when compared to success rates for other hazards. The overall plan and implementation (line 1), success rates varied from 56 to 77 percent. Success rates for the individual elements (HACCP plan controls, implementation, recordkeeping) were higher, between 76 and 96 percent (lines 1.1 to 1.7) with slightly lower rates from FY 2011 to FY 2014. The lowest success rates were consistently associated with implementation of the plan, including recordkeeping, between 76 and 88 percent. Higher success rates occurred with the identification of HACCP plan controls (lines 1.1 through 1.5), 81 to 95 percent.

TABLE 2
Domestic Industry Progress –
Percentages of Seafood HACCP and Sanitation Controls
For Specific Hazards (FY 2006 – 2014)

Pathogen Growth/Toxin Formation

	HACCP Program Areas	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
1	**Adequate plans and implementation overall.**	**73**	**73**	**77**	**74**	**72**	**67**	**64**	**66**	**56**
1.1	Hazards properly identified.	94	95	95	94	91	91	89	89	90
1.2	CCP(s) properly identified.	94	94	95	93	92	91	89	91	90
1.3	CL(s) properly identified.	90	91	93	91	91	87	85	88	85
1.4	Monitoring procedures properly identified.	92	93	94	92	91	88	87	88	81
1.5	Corrective action properly identified.	95	94	96	93	92	90	90	89	87
1.6	Plan properly implemented.	85	85	88	88	86	83	80	83	76
1.7	Records properly maintained.	86	86	89	88	86	83	83	84	79

Scombrotoxin

	HACCP Program Areas	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
2	**Adequate plans and implementation overall.**	**85**	**87**	**87**	**89**	**86**	**84**	**85**	**86**	**85**
2.1	Hazards properly identified.	98	99	99	98	97	98	96	97	98
2.2	CCP(s) properly identified.	97	98	98	98	97	97	96	96	98
2.3	CL(s) properly identified.	95	96	95	97	95	95	93	95	96
2.4	Monitoring procedures properly identified.	96	96	97	97	97	97	96	96	96
2.5	Corrective action properly identified.	96	96	96	97	96	94	94	95	95
2.6	Plan properly implemented.	92	92	92	96	92	91	91	91	92
2.7	Records properly maintained.	92	91	94	95	92	92	93	92	94

Veterinary Drugs

	HACCP Program Areas	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
3	**Adequate plans and implementation overall.**	**99**	**100**	**99**	**100**	**99**	**99**	**99**	**99**	**99**
3.1	Hazards properly identified.	100	100	100	100	100	99	100	100	100
3.2	CCP(s) properly identified.	100	100	100	100	100	100	100	100	99
3.3	CL(s) properly identified.	100	100	100	100	100	100	100	100	100
3,4	Monitoring procedures properly identified.	100	100	100	100	100	100	100	100	100
3.5	Corrective action properly identified.	100	100	100	100	100	100	100	100	100
3.6	Plan properly implemented.	100	100	100	100	100	100	100	100	100
3.7	Records properly maintained.	100	100	100	100	100	100	100	100	100

Marine Toxins

	HACCP Program Areas	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
4	**Adequate plans and implementation overall.**	**99**	**99**	**98**	**98**	**99**	**98**	**98**	**100**	**100**
4.1	Hazards properly identified.	99	100	100	99	100	99	99	100	100
4.2	CCP(s) properly identified.	100	100	100	100	100	100	100	100	100
4.3	CL(s) properly identified.	100	100	99	99	100	100	99	100	100
4.4	Monitoring procedures properly identified.	100	100	99	100	100	100	99	100	100
4.5	Corrective action properly identified.	100	100	100	100	100	99	100	100	100
4.6	Plan properly implemented.	99	100	99	99	99	99	100	100	100
4.7	Records properly maintained.	99	99	99	99	100	99	99	100	100

Environmental Chemicals

	HACCP Program Areas	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
5	**Adequate plans and implementation overall.**	**96**	**97**	**97**	**96**	**95**	**92**	**95**	**96**	**96**
5.1	Hazards properly identified.	99	99	99	97	97	96	97	99	99
5.2	CCP(s) properly identified.	99	99	99	99	98	98	98	99	98
5.3	CL(s) properly identified.	99	99	99	99	99	99	98	99	98
5.4	Monitoring procedures properly identified.	99	99	99	99	99	99	99	99	99
5.5	Corrective action properly identified.	99	100	100	99	99	99	99	99	99
5.6	Plan properly implemented.	98	99	99	99	98	98	99	98	99
5.7	Records properly maintained.	98	99	99	99	98	98	98	99	98

Metal/Glass Fragments

	HACCP Program Areas	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
6	**Adequate plans and implementation overall.**	**98**	**98**	**97**	**97**	**96**	**95**	**95**	**95**	**95**
6.1	Hazards properly identified.	99	99	99	98	98	97	98	98	98
6.2	CCP(s) properly identified.	99	99	99	99	99	98	98	98	98
6.3	CL(s) properly identified.	100	99	100	99	99	99	98	99	99
6.4	Monitoring procedures properly identified.	100	99	100	99	99	99	99	99	99
6.5	Corrective action properly identified.	99	99	100	99	99	99	99	99	99
6.6	Plan properly implemented.	99	99	99	99	99	99	99	98	99
6.7	Records properly maintained.	99	99	99	99	99	99	99	98	99

Allergens/Food Additives

	HACCP Program Areas	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
7	Adequate plans and implementation overall.	97	97	97	97	95	93	89	79	77
7.1	Hazards properly identified.	99	99	99	98	98	97	93	87	88
7.2	CCP(s) properly identified.	99	99	99	99	98	98	96	91	92
7.3	CL(s) properly identified.	99	99	100	99	99	99	98	95	95
7.4	Monitoring procedures properly identified.	99	99	99	99	99	99	98	95	95
7.5	Corrective action properly identified.	99	100	100	99	99	99	98	97	98
7.6	Plan properly implemented.	99	99	99	99	98	99	98	95	96
7.7	Records properly maintained.	99	99	99	99	98	98	98	95	93

Parasites

	HACCP Program Areas	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
8	**Adequate plans and implementation overall.**	**99**	**99**	**99**	**99**	**98**	**98**	**98**	**97**	**98**
8.1	Hazards properly identified.	100	100	99	99	99	99	99	98	99
8.2	CCP(s) properly identified.	100	100	100	99	100	100	99	99	100
8.3	CL(s) properly identified.	100	100	99	99	100	100	99	99	99
8.4	Monitoring procedures properly identified.	100	100	99	99	100	100	99	99	99
8.5	Corrective action properly identified.	100	100	99	100	100	100	99	99	100
8.6	Plan properly implemented.	100	99	99	99	99	100	99	99	99
8.7	Records properly maintained.	100	100	99	99	99	100	99	99	99

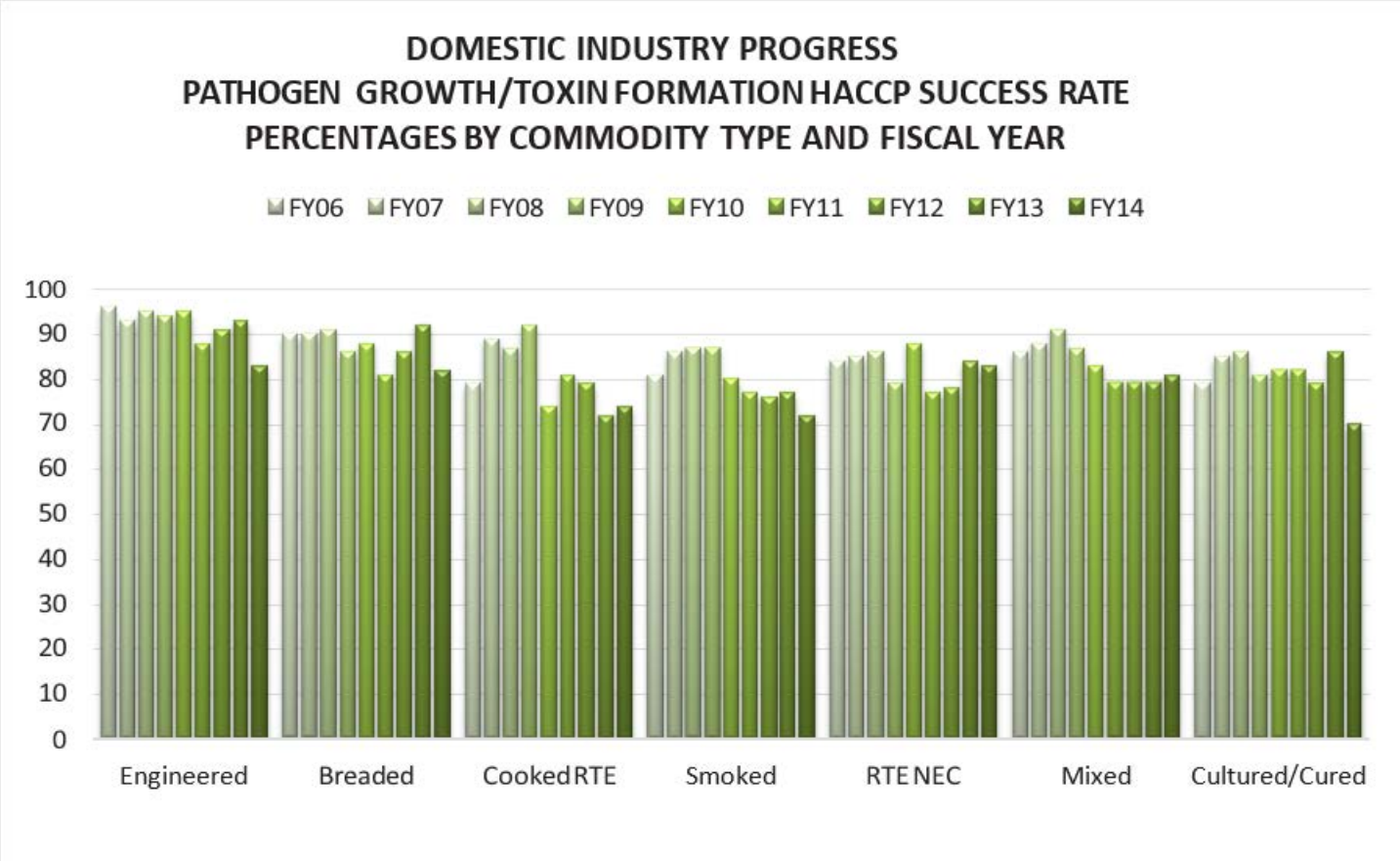
Due to the large variety of commodities associated with the hazard of pathogen growth/toxin formation, we further broke down the data based on commodity-type categories to evaluate the performance of different sectors of the industry in Figure 3. The categories selected are associated with the food safety hazard of pathogen growth/ toxin formation where HACCP controls are normally necessary to prevent its occurrence. There are 7 different commodity types identified:

1) Surimi based fishery products (i.e., imitation seafood and surimi);
2) Breaded fishery products that include breaded and battered seafood, stuffings, cakes, and balls;
3) Cooked Ready-to-Eat (RTE) seafood which includes cooked and pasteurized fishery products;
4) Smoked fishery products (hot and cold smoked);
5) RTE Not Elsewhere Classified (NEC) fishery products that includes pastes, sauces, roe, and broths;
6) Mixed fishery products that includes soups, pasta, eggrolls, meals, hors d'oeuvre, chowders, salads; and
7) Cultured/Cured fishery products that includes salted, fermented, brined and pickled seafood, excluding smoked fish.

Figure 3 shows each individual commodity broken down further into fiscal year success rates by percentage. The data reflects an average of the success rates of 7 of the individual elements (i.e., hazard identified, critical control points, critical limits, monitoring procedures, corrective actions, implementation, recordkeeping) for each fiscal year.

Surimi based products and Breaded fishery products showed the highest success rates of the 7 commodity types, all fiscal year averages exceeding 80 percent, with Engineered fishery products success rates exceeding 90 percent 7 out of the 9 fiscal years. Success rates for each of the other commodities exceeded 80 percent for the majority of the 9 fiscal years except for the Cooked RTE fishery products where 80 percent was met or exceeded in only 4 of the 9 fiscal years. The data does not show a distinct trend in success rates overall, however, the success rates for Cooked RTE, Smoked, and Mixed fishery products did show a slight and inconsistent decrease in success rate percentages after FY 2009. Success rates for all commodities in all fiscal years met or exceeded 70 percent.

Figure 3



Domestic Molluscan Shellfish Industry Progress

Tables 1 and 2 do not contain data for processors of raw bivalve molluscan shellfish (e.g.., oysters, clams, mussels). State shellfish control authorities inspect processors in participating states under the National Shellfish Sanitation Program (NSSP) and the results are not entered into FDA's National Seafood HACCP Inspection Database. The NSSP is a Federal/State cooperative program for the regulation of the raw molluscan shellfish industry. State regulatory authorities license/permit and inspect these processors. Industry performance is monitored through the NSSP program. FDA shellfish specialists accompany State inspectors biennially on several routine inspections and FDA audits each participating State's regulatory program.

Foreign Industry Progress

FDA's seafood HACCP program applies to imported, as well as domestically produced seafood. In 2014, approximately 94 percent of the seafood consumed in the U.S. was imported (website:

https://www.st.nmfs.noaa.gov/Assets/commercial/fus/fus14/documents/09_PerCapita2014.pdf). FDA's traditional food safety strategy has been to review entries of products being offered for importation into the U.S. and then select products for examination at ports-of-entry. The examination is primarily directed toward determining whether the product is misbranded, decomposed, or contains substances that would cause it to be adulterated under U.S. law. FDA recognized that while surveillance sampling is a valuable tool, ensuring that foreign processors implement effective seafood safety programs will provide a more comprehensive safety assurance for the U.S. consumer.

With the implementation of the seafood HACCP regulation in 1997, FDA created two additional strategies to augment port-of-entry examinations. The first strategy requires that U.S. importers develop written verification procedures that include an "*affirmative step*" that assures imported seafood products have been processed in accordance with U.S. seafood HACCP regulation and are safe.

The seafood HACCP regulation identifies seven options for an affirmative step and importers are obligated to implement only one for each foreign source and type of seafood product imported. FDA currently inspects importers at their places of business to confirm they are meeting their written verification procedures and affirmative step obligations. This topic is further discussed in the next section of this report.

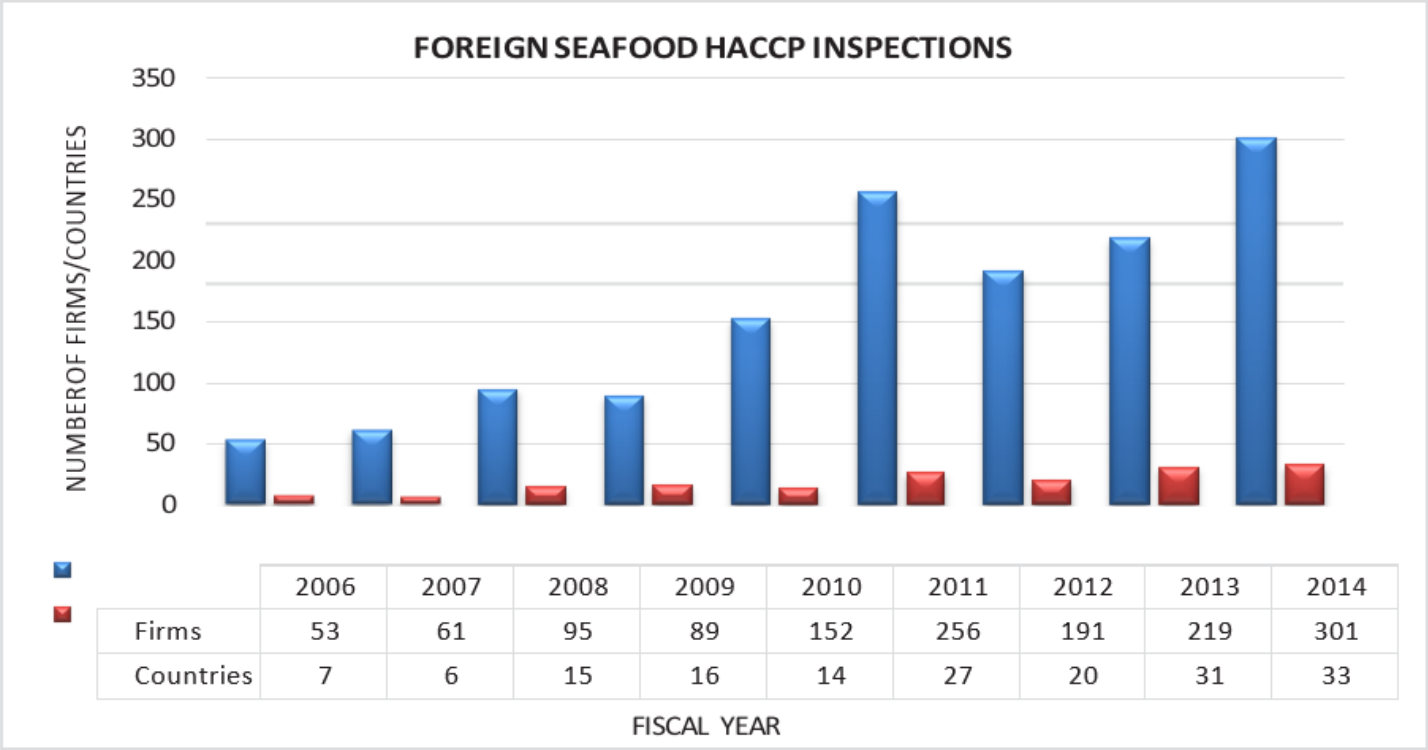
The second strategy involves on-site seafood HACCP inspections of foreign processors by FDA investigators. FDA's primary mission is to evaluate the seafood HACCP program of the selected processors; however, the inspections also serve as a venue for educating industry and foreign competent authorities in FDA's most current requirements with regards to seafood safety. Each year FDA selects countries where FDA investigators are sent to inspect targeted processors who export seafood directly to the U.S. The annual number of countries and inspections varies with the resources available to FDA. Selection criteria for countries and processors include the volume of entries offered for importation, U.S. outbreak data, entry sampling data, information obtained from importers, industry compliance history, follow-up enforcement activities, and emerging issues.

Although foreign seafood processors are subject to the same U.S. regulatory requirements as domestic firms, FDA anticipates that the rate of compliance with the seafood HACCP regulation by foreign processors will be lower than that of domestic processors and to vary from country to country. There are several reasons for these differences. First, FDA investigators and compliance officers provide direct, routine oversight and communication to domestic processors which helps to educate industry in our requirements. Foreign processors are inspected less frequently and language differences may impede communication. Although some FDA guidances have been translated into other languages, they are primarily available only in English. Second, local food safety requirements may differ from FDA's. A foreign processor can be compliant with their country's regulatory requirements and not meet FDA's requirements. FDA's strategy to help overcome these disadvantages is to continue its foreign inspection program, continue working with local regulatory officials to improve their understanding of our requirements, and to participate in the development of outreach programs.

a) "Compliance Rate"

As with domestic inspections, most foreign inspections are classified as NAI, VAI, or OAI, however some inspections do remain unclassified and are therefore not included in these calculations. Figure 4 compares the number of firms inspected and the number of countries visited during inspections for each fiscal year. From FY 2006 to FY 2014, FDA increased the number of facility inspections from 53 firms to 301 firms and the number of countries visited from 7 to 33.

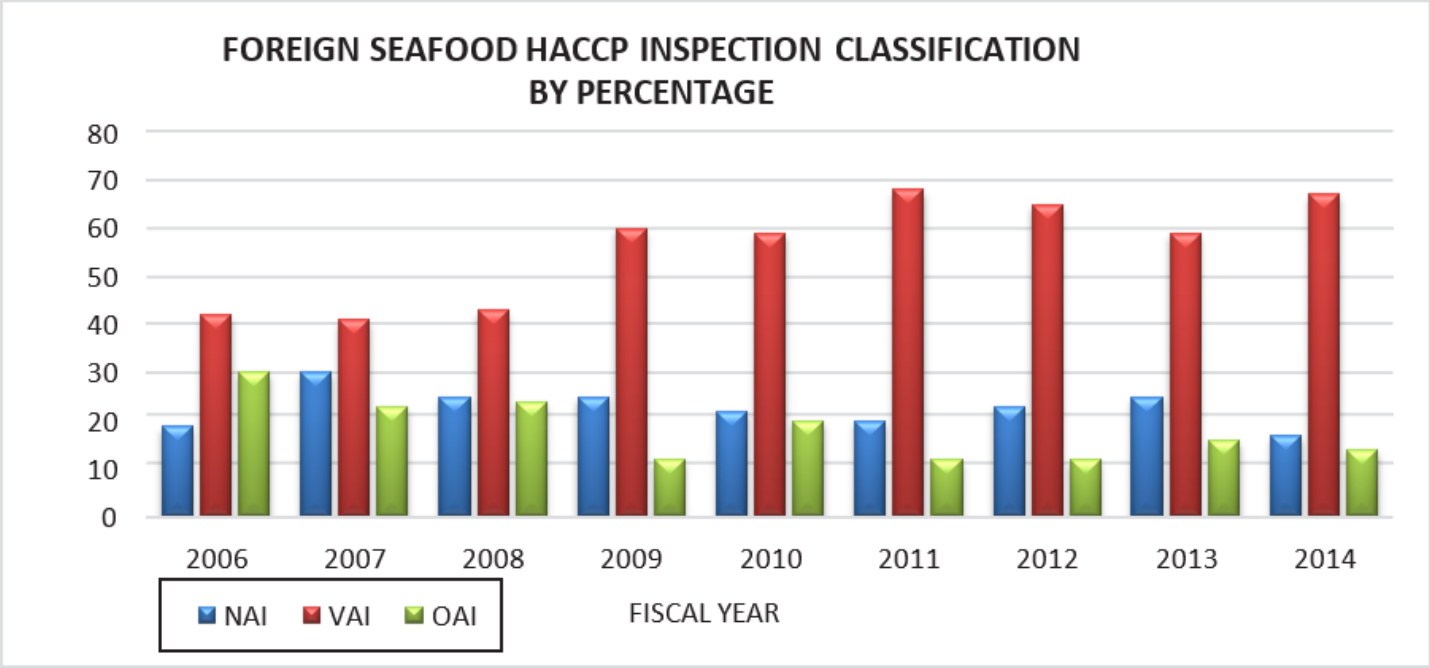
Figure 4



	2006	2007	2008	2009	2010	2011	2012	2013	2014
Firms	53	61	95	89	152	256	191	219	301
Countries	7	6	15	16	14	27	20	31	33

Figure 5 compares the inspection classification percentages for each fiscal year. Results are presented as percentages to accommodate the difference in number of inspections per fiscal year. The majority of inspections were classified as VAI, with VAI classifications increasing from FY 2006 to FY 2014. OAI classifications percentages have slightly decreased, while inspection numbers have increased. NAI classifications decreased from FY 2006 to FY 2009, but only fluctuated from FY 2009 to FY 2014, with no significant trend up or down.

Figure 5



b) <u>Success on Individual Elements: Foreign Industry Overall</u>

Table 3 provides a summary of observations made during the foreign inspections of FY 2006 through 2014 and is limited to the HACCP plan content and implementation. The countries targeted for processor inspections and the regions of those countries visited vary from year to year which makes it difficult to identify an overall trend for foreign industry success rates. Conditions and compliance rates can vary widely between countries based on available resources, local requirements, familiarity with FDA's requirements, and language challenges. The data provides a broader perspective on the understanding of FDA's HACCP requirements outside the U.S and can be compared against Table 1.

There were a significantly larger percentage of domestic processors who were not required to have a HACCP plan (Table 1, line 3) as compared to foreign processors who were not required to have a HACCP plan (Table 3, line 3) for 8 of the 9 fiscal years. Since FDA foreign inspections target foreign processors and products with a higher food safety risk potential, it is likely that a larger percentage of the inspections will determine that a HACCP plan is necessary. Identification of adequate controls in the HACCP plans of foreign processors (line 2) showed an average success rate of between 60 and 76 percent while domestic processors success rates (Table 1, line 2) ranged between 79 and 89 percent. Foreign processor implementation of their written plans (line 11) was, for the most part, between 81 and 90 percent, which is similar to the domestic industry (Table 1, line 11). The foreign industry's success rates for implementation of their HACCP plans (lines 12 and 13) were slightly higher than their success rates for identifying appropriate HACCP plan controls (lines 5 through 9). The overall success (line 1) of the foreign processor's HACCP plans and implementation varied between 68 and 82 percent while the domestic industry was consistently between 80 and 90 percent.

TABLE 3
Foreign Processor Progress –
Percentages of Seafood HACCP and Sanitation Controls
by Regulatory Provisions (FY 2006 – 2014)

Mandatory HACCP/Sanitation Provision (All inspections)

	HACCP Program Areas	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
1	**Average covering overall success with plan content and implementation (5-9, and 12-15).**	**73**	**76**	**76**	**77**	**82**	**80**	**68**	**77**	**81**

HACCP Plan

	HACCP Program Areas	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
2	**Overall average of elements 5-9, plan content.**	**64**	**71**	**67**	**72**	**76**	**73**	**77**	**69**	**72**
3	No HACCP plan needed.	10	10	21	10	9	10	2	7	5
4	HACCP plan present when needed.	82	75	68	86	82	89	82	90	89
5	All significant hazards listed in written plan – all inspections.	66	74	61	61	65	65	51	52	48
6	All critical control points identified in written plan – all inspections.	56	61	59	70	73	65	67	64	71
7	Adequate identification of critical limits in written plan.	63	67	67	72	80	77	80	77	84
8	Adequate identification of monitoring procedures in written plan.	46	59	61	68	76	74	71	73	77
9	Adequate identification of corrective actions in written plan.	88	93	87	90	85	82	88	81	79
10	Meet training requirement.	86	80	90	95	91	92	90	89	90

Plan Implementation

	HACCP Program Areas	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
11	**Overall average of elements 12–15, plan implementation.**	**82**	**81**	**84**	**82**	**88**	**87**	**91**	**85**	**90**
12	Adequate implementation of HACCP monitoring procedures listed in the plan.	66	70	70	64	76	79	84	77	85
13	Adequate HACCP monitoring records listed in the plan.	71	74	72	77	84	83	88	81	90
14	Adequate corrective actions taken when needed.	95	89	98	91	94	92	95	90	94
15	Adequate corrective action records when corrective actions taken or no corrective actions needed.	95	91	96	94	96	94	97	91	92

c) Success on Individual Elements: Specific Foreign industry Sectors

Table 4 further breaks down the success rates of foreign processors addressing specific hazards in their HACCP programs. The overall success rates of foreign processors are significantly less and more variable from year to year than the overall success rates for domestic processors. Overall success rates are based on written HACCP plans and plan implementation where no deficiencies were observed in any of the key HACCP elements (Table 3, lines 5 – 9 and 12 – 15). As with domestic processors, the lowest success rates were associated with the controls for the hazards of scombrotoxin and pathogen growth/toxin formation (Pathogens). Success rates for scombrotoxin controls showed improvement during the evaluation period. A significant decrease in the success

rate for controls of allergens/food additives, which is similar to the domestic industry. Success rates for the control veterinary (Vet.) drugs, marine toxins, and parasites met or exceeded 90 percent, apart from veterinary drugs in FY 2006. Success rates for HACCP controls for metal/glass and environmental (Env.) chemicals exceeded 80 percent, with the exception of environmental chemicals in FY 2008.

TABLE 4
Foreign Processor Progress –
Percentages of Adequate Plans and
Implementation Overall for Specific Hazards (FY 2006 – 2014)

Hazards

	HACCP Program Areas	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
1	Pathogen Growth/Toxin Formation	59	76	85	84	54	74	53	63	64
2	Scombrotoxin	66	52	57	54	73	68	78	77	76
3	Allergens/Food Additives	98	96	89	96	93	85	74	61	58
4	Metal/Glass Fragments	100	87	96	83	96	86	89	81	81
5	Environmental Chemicals	88	91	78	93	87	91	93	95	89
6	Veterinary Drugs	88	91	96	100	97	90	97	98	90
7	Marine Toxins	98	96	98	100	99	96	99	100	100
8	Parasites	98	100	100	100	100	98	99	99	98

Importer Progress

As mentioned above, U.S. importers of seafood must comply with requirements that are designed to ensure the products they offer for entry are processed in accordance with the Seafood HACCP Regulation. Importers are required to have written verification procedures which describe how they will ensure that the seafood products they import are safe, develop written product specifications addressing product safety issues, and implement one or more “affirmative steps” as a method of ensuring that their foreign sources have implemented seafood HACCP controls. They must maintain these records and provide them to FDA during inspections or upon request.

With the advent of Prior Notice requirements and mandatory food facility registration, FDA’s ability to identify U.S. importers has improved. FDA currently estimates that there are several thousand seafood importers operating in the United States. These importers are subject to FDA inspection for compliance with the Seafood HACCP Regulation. FDA investigators conducting inspections of importers complete a data form, FDA 3502, that reports inspection findings to the National Seafood HACCP Database.

Most importer inspections are classified as NAI, VAI, or OAI; however, a small number of inspections remain unclassified and are therefore not included in these calculations. Figure 6 represents the total number of importer seafood HACCP inspections and the inspection classifications for each fiscal year. Figure 7 shows Figure 6 inspection classification numbers as percentages to facilitate comparison between fiscal years. Importer seafood HACCP inspections have decreased over the 9 fiscal years represented. Figure 7 shows that the inspection classifications by percentage are predominately NAI and VAI, however, there is no distinct trend in the percentages increasing or decreasing within each of the 3 types of classifications.

Figure 6

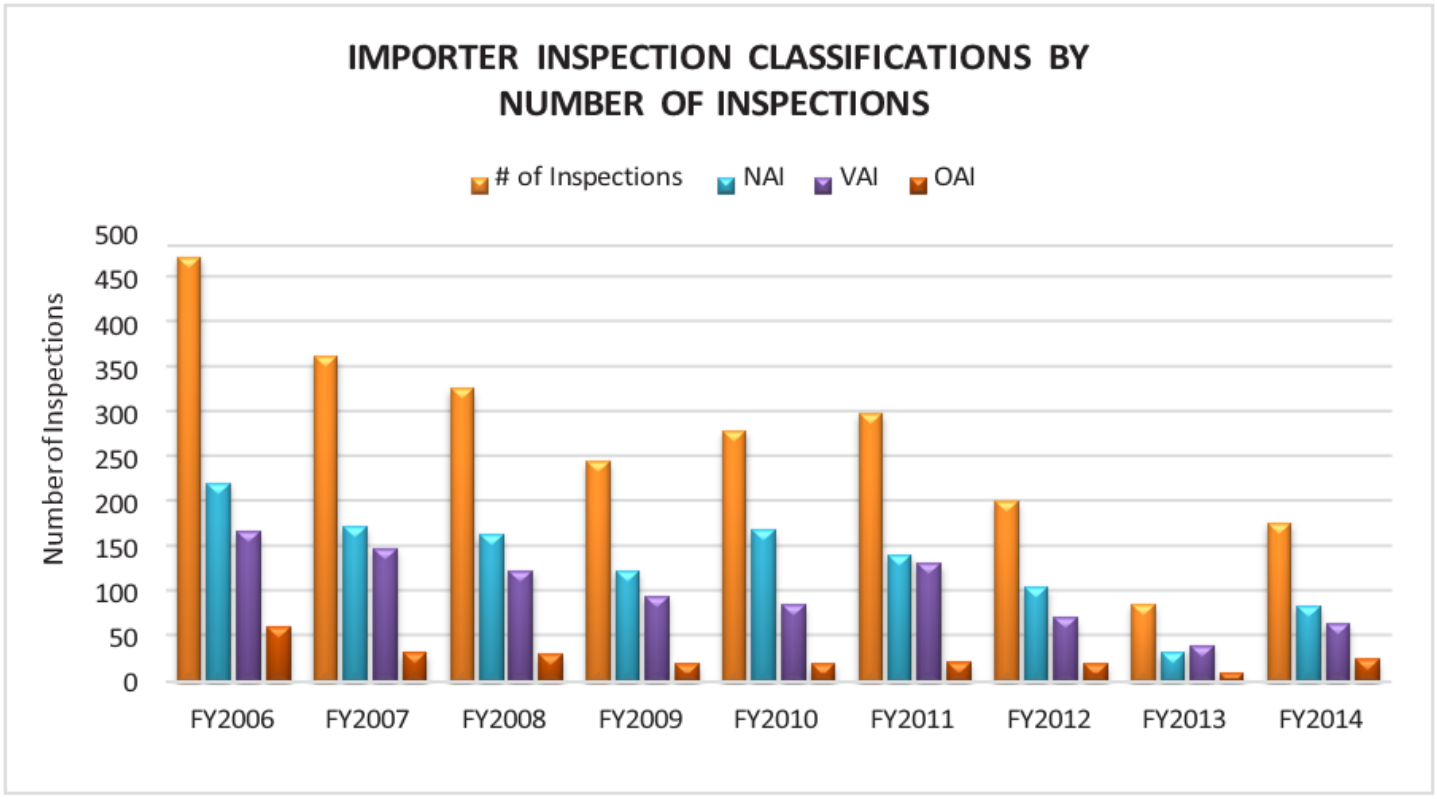


Figure 7

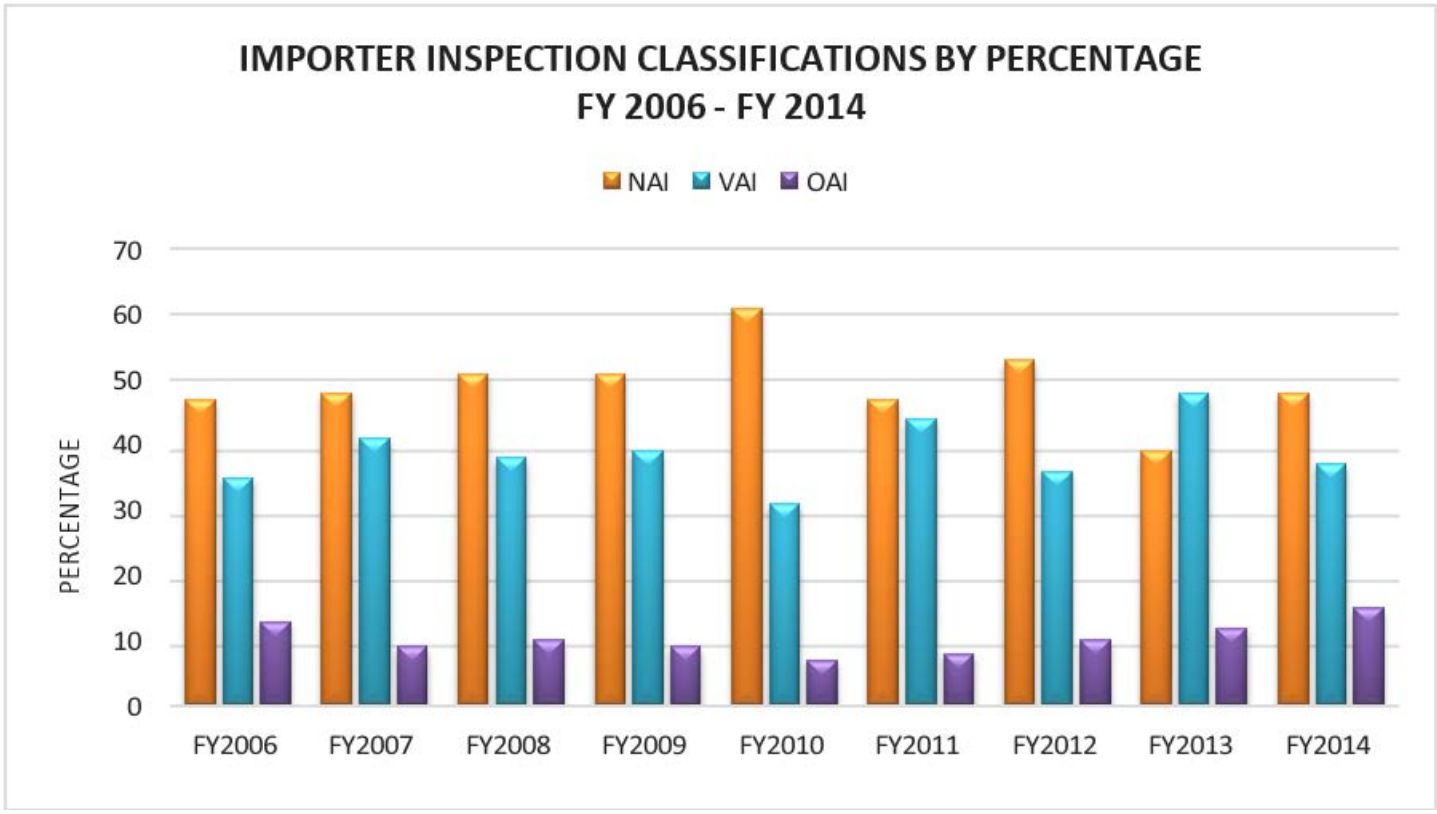


Table 5 shows importers' success in maintaining written verification procedures and adequately implementing the affirmative step(s) they have selected as a control. Compliance rates for maintaining written verification procedures and product specifications fluctuated between 44 and 74 percent (line 1), with 6 of the 9 years between 50 and 60 percent (line 1). Implementation of adequate affirmative steps was, for 6 of the 9 fiscal years, near 80% (line 2). As the data shows below, there has been a significant drop in the compliance rate of Importers having written verification procedures; however, for those who did have the written procedures their implementation of those procedures increased significantly.

TABLE 5
Domestic Industry Progress –
Percentages Focusing on Seafood Importers (FY 2006 – 2014)

	Special Requirements for Imported Products	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
1	Importer has written verification procedures, including product specifications.	74	59	56	52	57	49	60	51	44
2	Adequate implementation of affirmative steps.	48	79	77	78	78	63	59	78	78

RECOMMENDATIONS

The previous FY 2004/2005 Seafood Program Evaluation listed recommendations to improve the program and industry success rates. In response to those recommendations the following adjustments to the seafood compliance program have been implemented:

1) *Recommendation* - Continue to prioritize all processors of high risk potential fishery products, particularly processors of scombrotoxin forming species and cooked ready-to-eat products, for annual inspection.

   Response - Compliance Programs include risk-based prioritizations for seafood commodities which include ready-to-eat cooked products and scombrotoxin forming species with an increased inspection frequency. Foreign inspections are also prioritized based on the compliance program ranking.

2) *Recommendation* - Increase the inspectional priority of processors and importers of aquaculture products.

   Response - Seafood Processor and Imported Seafood Compliance Programs identify aquacultured seafood and processors of aquacultured seafood as "higher risk potential" and an increased priority for inspection. In addition, FDA has developed and implemented a Compliance Program specific to aquacultured seafood. Sampling of imported products is monitored under this program. FDA conducts assessments of foreign food safety systems that oversee the control of aquacultured seafood and provides feedback to foreign competent authorities on their findings. Processors of aquacultured fish have an increased priority for inspection.

3) *Recommendation* - Issue the fourth edition of the *Fish & Fishery Products Hazards and Controls Guidance* to facilitate compliance by processors of scombrotoxin forming species.

Response - The *Fish & Fishery Products Hazards and Controls Guidance* (the Guide) Fourth Edition was issued in April 2011.

4) *Recommendation* - Work on developing strategic, measurable goals for industry segments that have traditionally lagged behind.

   Response - FDA continues to monitor industry performance and adjust inspectional priorities based on performance. FDA modified the format and safety recommendations in the 3rd Edition of the Guide to facilitate the use of the Guide and published the 4th Edition of the Guide.

5) *Recommendation* - Increase the number of importer inspections to reflect a more accurate representation of the size of the industry.

   Response - Importer inspections declined from FY 2006 to FY 2014. FDA has implemented a risk-based approach and resources have been allocated to other areas. FDA will revisit this allocation of resources.

6) *Recommendation* - Implement outreach programs to educate importers with regards to their responsibilities and the options available to them.

   Response - Outreach programs are provided through organizations outside of FDA, such as trade associations, consultants, and through conventions. FDA participates in the development of guidance and in meeting panels when requested by those organizations.

7) *Recommendation* - Develop a system that creates a follow-up mechanism for foreign inspections based on domestic importer inspectional findings.

   Response - FDA has implemented a regulatory strategy that links the findings from importer inspections to foreign inspections for follow-up.

8) *Recommendation* - Continue foreign inspections targeting processors of high risk products. Implement outreach programs for foreign competent authorities and industry groups to provide guidance in FDA's safety recommendations.

   Response - FDA identifies foreign countries and inspects selected foreign establishments based on risk factors. FDA partners with trade groups, the Seafood HACCP Alliance (SHA), the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), and National Oceanic and Atmospheric Administration (NOAA) in providing guidance, training, and information to industry.

9) *Recommendation* - Continue to plan and implement the "Histamine (Scombrotoxin Forming) Outreach Project".

   Response - FDA participates with the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) in developing and providing training in good fishery vessel practices (GFvP) for histamine forming species, good aquacultural practices (GAqP), seafood HACCP training, and training for foreign inspectors which is similar to FDA investigator training in conducting inspections of seafood processors.

Based on our current evaluation, CFSAN advises:

1) Assign a higher priority for inspection in compliance programs to processors and products associated with the hazard of pathogen growth and toxin formation, followed by products for which scombrotoxin formation is a reasonably likely hazard. Continue to rank inspections for commodities associated with other hazards based on the associated hazard and on probability factors.

2) Increasing the number of importer inspections as resources permit to reflect a more accurate representation of the size of the industry and to facilitate in identifying foreign processors for inspection.

3) Continue to collaborate with industry, government, and academic stakeholders in developing education and outreach tools for processors and U.S. importers.

4) Continue to increase the number of foreign inspections to reflect the increased volume of imported seafood using a risk-based system for identification of countries and facilities.

5) Continue to conduct program evaluations to monitor industry progress.