

# Activities for the Safety of Imported Seafood

February 2023



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## Introduction

The Food and Drug Administration (FDA or “agency”) is responsible for ensuring the safety of the majority of the nation’s food supply, which is increasingly becoming more diverse, abundant, and global. Seafood has become one of the most highly traded food commodities in the world with total imports in 2018 accounting for approximately 94% of the volume of seafood sold in the United States.<sup>1</sup> In comparison, 55% of fresh fruits and 32% of fresh vegetables consumed in the United States were imported from other countries in the same year.<sup>2</sup> Food safety requirements apply to food imported from other countries in the same way they apply to food produced domestically. In February 2019, the agency released the [FDA Strategy for the Safety of Imported Food \(Import Strategy\)](#) to describe a comprehensive approach to imported food safety. The approach includes integrating new import oversight tools with existing tools and is guided by four main goals:

- Goal 1: Food Offered for Import Meets U.S. Food Safety Requirements
- Goal 2: FDA Border Surveillance Prevents Entry of Unsafe Foods
- Goal 3: Rapid and Effective Response to Unsafe Imported Food
- Goal 4: Effective and Efficient Food Import Program

Today the United States imports seafood from more than 144 countries or territories and approximately 10,202 exporting food facilities plus aquaculture farms.<sup>3</sup> From 2012-2019, the percentage of seafood lines imported into the United States was on average the highest from Canada ( $22.0 \pm 2.7\%$ ), followed by Japan ( $16.3 \pm 3.6\%$ ), Mexico ( $6.0 \pm 0.6\%$ ), China ( $5.5 \pm 0.9\%$ ), and Chile ( $4.9 \pm 0.5\%$ ) (Figure 1). Expressed as volume, however, NOAA reported that the average majority of seafood imports into the United States during the same timeframe came from China ( $21.5 \pm 2.6\%$ ), followed by Canada ( $11 \pm 0.9\%$ ), Thailand ( $9.1 \pm 1.9\%$ ), India ( $9.0 \pm 2.2\%$ ), and Vietnam ( $8.6 \pm 0.7\%$ ).<sup>4</sup> In total, the United States imported an average of  $5.7 (\pm 0.3)$  billion pounds of edible fishery products annually from other countries.<sup>5</sup> Shrimp accounted for the highest percentage of imported pounds (averaging  $23.3 \pm 1.7\%$ ), followed by fresh/frozen salmon, fresh/frozen tuna, and canned tuna (Figure 2).

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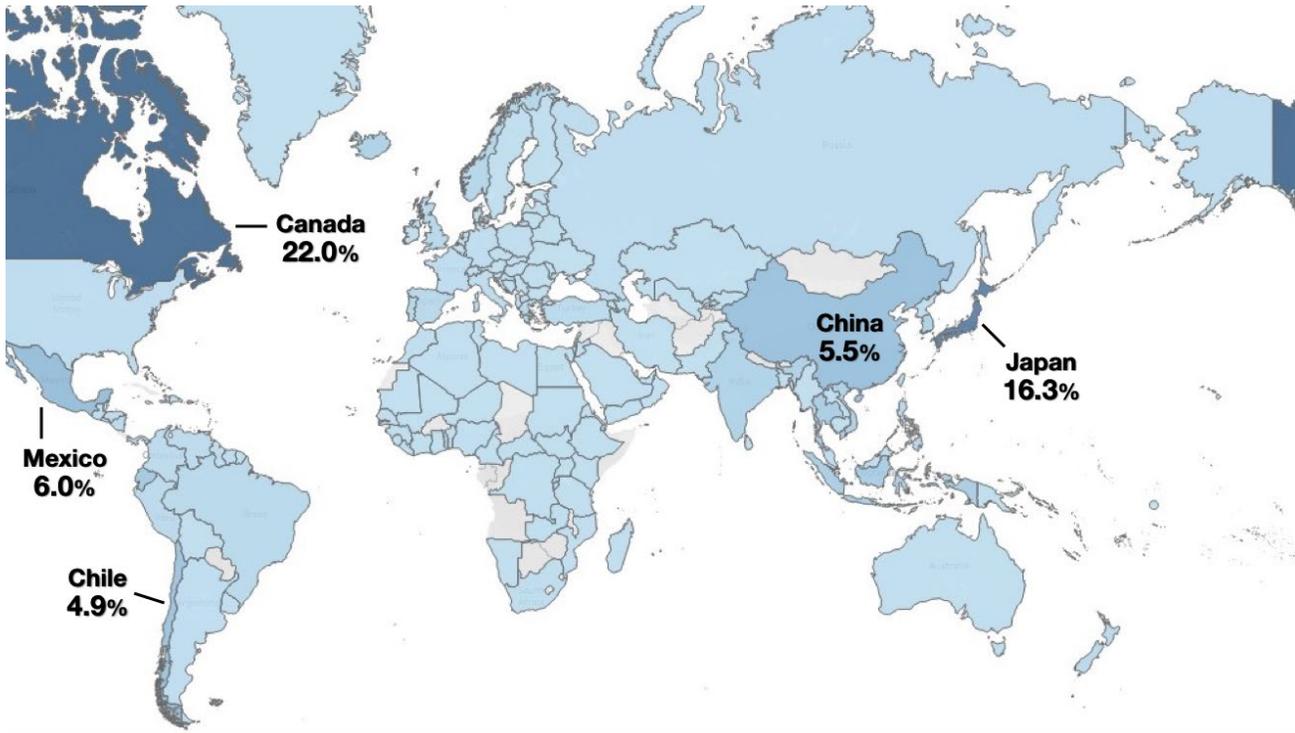
<sup>1</sup> NOAA, 2018. [Fisheries of the United States](#). The percentage of imports in the U.S. supply of edible fishery products was calculated as the volume of imports divided by the total volume in the U.S. (where the total reflects U.S. landings minus exports plus imports). The average percentage of edible fishery products imported to the United States from 2010-2020 was  $91.8\% (\pm 2.3)$ .

<sup>2</sup> Import share of fresh fruit consumption by volume: 55.1% in 2017, [USDA-ERS Fruit and Tree Nuts Yearbook 2018](#), Table H-1; Import share of vegetable consumption by volume: 31.6% in 2017, [USDA-ERS Vegetables and Pulses Yearbook 2018](#), Table 12.

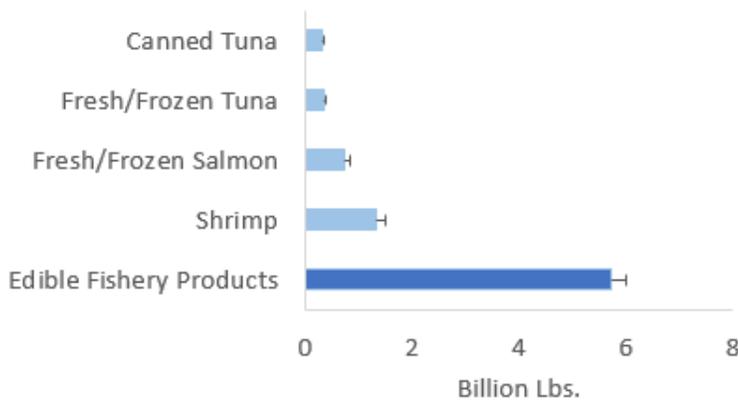
<sup>3</sup> FDA’s Online Reporting Analysis Decision Support System (ORADSS) data from 5/3/2021 through 5/3/2022.

<sup>4</sup> NOAA, 2012-2019. Fisheries of the United States.

<sup>5</sup> NOAA, 2012-2019. Fisheries of the United States.



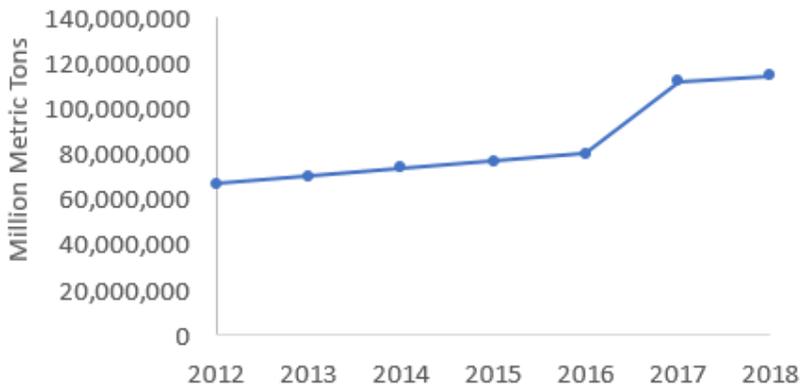
**Figure 1.** Countries from which seafood were imported into the United States from 2012-2019 (based on the number of shipments according to FDA’s ORADSS data accessed on 6/10/2022). Darker shades of blue reflect the countries that account for the largest percentage of shipments.



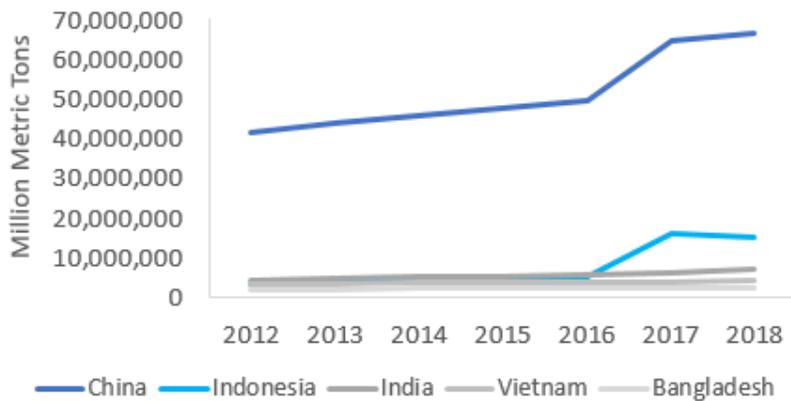
**Figure 2.** Average annual volume (billion lbs.) of total edible fishery products imported into the United States between 2012-2019. Of the total edible fishery products imported into the United States, shrimp represented the highest volume, followed by salmon and tuna.

In addition to the high volumes of seafood imported into the United States, increases in global [aquaculture](#) production add to the complexity of the oversight required. While aquacultured and wild-caught seafood are held to the same FDA food safety standards and regulatory requirements, certain potential hazards associated with aquaculture are unique given that aquaculture is vulnerable to the impact of constantly changing environmental conditions and stress factors that make fish more susceptible to diseases. Global aquaculture production almost doubled from 2012 (66,633,253

million metric tons) through 2018 (114,508,042 million metric tons) (Figure 3).<sup>6</sup> The top five producing countries during this time were China, Indonesia, India, Vietnam, and Bangladesh. Changes in aquaculture production have been more sharply observed over the years for China and Indonesia, whereas general and slight increases have occurred in India, Vietnam, and Bangladesh (Figure 4). NOAA reported that carp, clams, oysters, tilapia, shrimp, and salmon were among the fish and shellfish types with the highest global aquaculture production (Figure 5). While the United States is not a major aquaculture producing country, ranking 14<sup>th</sup> to 17<sup>th</sup> in aquaculture production (averaging  $437,884 \pm 16,222$  million metric tons), over half of the imported seafood into the United States comes from aquaculture.

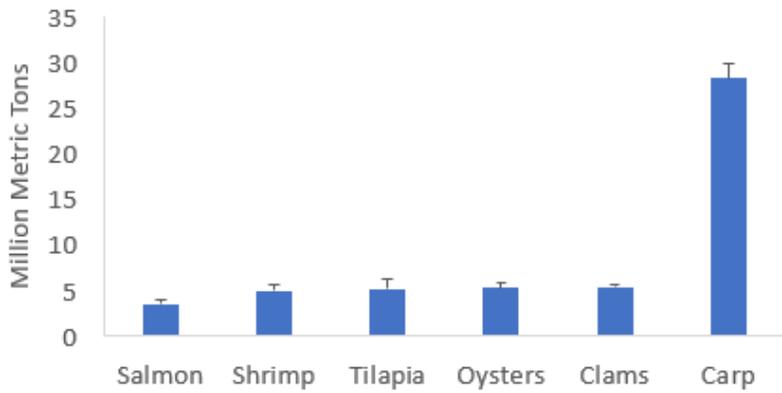


**Figure 3.** Total global aquaculture production (million metric tons) from 2012 through 2018.



**Figure 4.** Aquaculture production (million metric tons) by country from 2012 through 2018.

<sup>6</sup> NOAA, 2013-2019. Fisheries of the United States. Note: Aquaculture data in the NOAA Fisheries of the United States reports lag other data by one year (i.e., 2012 aquaculture data are presented in the 2013 report).

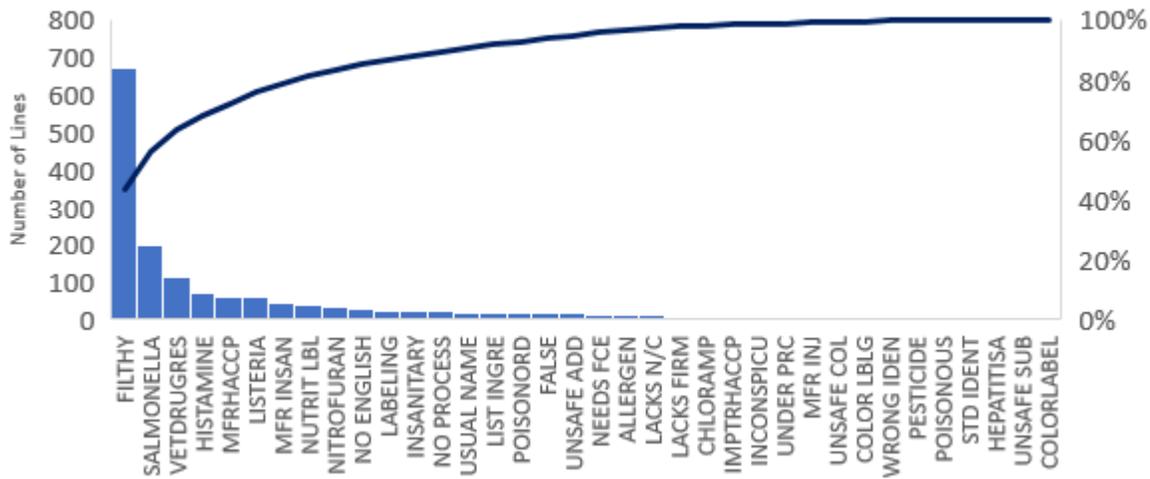


**Figure 5.** Fish and shellfish most globally produced by aquaculture (million metric tons) from 2012 through 2018.

The wide range of known and emerging microbiological and chemical hazards that may impact seafood further adds to the complexity of imported seafood safety oversight. Since many seafood hazards are introduced at the source – in growing areas, in aquaculture farms, and on fishing vessels – this presents a unique challenge to prevent seafood contamination, especially for imported products. Seafood, the type of food with the largest percentage of imports to the United States, is also the commodity that is more often held at the border for data or document review (65% for seafood compared to 45% for all food lines) as FDA seeks to ensure imported products comply with our laws and regulations. In terms of refusals, in 2019 seafood accounted for ~10% of the total line (shipment) entries refused of human foods presented at the border for import.<sup>7</sup> Brazil (214), Vietnam (96), Indonesia (77), and China (60) had the highest number of line entries refused for a single type of refusal charge, in these cases filth represented the charge code. Filth was among the highest of refusal charges (charged to 671 line entries). Other charges for refusals included Salmonella (197 lines), Listeria (60), histamine (72), veterinary drug residues (115), nitrofurans (33), and chloramphenicol (6) (Figure 6). This document (Activities for the Safety of Imported Seafood) builds upon the Import Strategy and specifically describes the agency’s comprehensive approach to providing oversight for the safe importation of a complex commodity: seafood.

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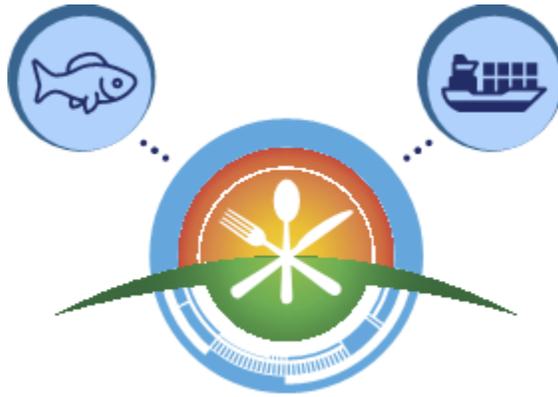
<sup>7</sup> OASIS Refusals FY2019.



**Figure 6.** The number of seafood lines refused (Left y-axis) at the border in 2019 according to charge in descending order of frequency with the cumulative total percentage (right y-axis).

The agency employs a range of tools to ensure the safety of imported seafood. As a primary example, [Hazard Analysis and Critical Control Points](#) (HACCP) regulations embody a multifaceted and risk-informed seafood safety program. In this management system, seafood safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement, and handling, to manufacturing, distribution, and consumption of the finished product. Oversight of imported seafood for compliance with the regulations include inspections of foreign processing facilities, 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 food safety program assessments, and review of relevant information from our foreign partners and FDA overseas offices.

Additional oversight activities to ensure the safety of imported seafood include measures aimed at prevention of contaminated seafood products being shipped to the United States, import screening at the port of entry, and effective response to unsafe imported seafood. For example, increasing the number of [foreign inspections](#) and global presence, utilizing [foreign country assessments](#) as an overview of the ability of the country’s industry and regulatory infrastructure to control aquaculture drugs, and relying on recently expanded statutory authority by the [Food Safety Modernization Act](#) (FSMA) aid prevention efforts. Implementation of the [Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting](#) (PREDICT) currently addresses the screening of imports, while the [national residue monitoring program](#) ensures that seafood is not contaminated with illegal animal drug residues. Sharing [consumer information](#) related to recalls and food safety alerts and having an [integrated food safety system](#) approach strengthens our ability to respond to unsafe imported seafood when the need arises.



Soon after the release of the Import Strategy, FDA announced its [New Era of Smarter Food Safety](#) initiative that focuses on creating a more digital, traceable and safer food system to build on FSMA's successes. The New Era blueprint creates a 10-year roadmap for reaching this goal through tech-enabled traceability, smarter tools and approaches for prevention and outbreak response, new business models and retail modernization and establishing a culture of food safety. Many of the new import oversight tools incorporated into the Activities for the Safety of Imported Seafood align with activities under the New Era initiative. For example, the artificial intelligence (AI) seafood import pilot is exploring the use of smarter tools and approaches for prevention by examining ways to improve targeting seafood samples at the border for collection and analysis. The incorporation of this new tool and others aimed to improve the safety of imported seafood to achieve the goals presented in the Import Strategy are described below.

## Goal 1: Seafood Offered for Import Meets U.S. Food Safety Requirements



To ensure that imported seafood meets U.S. food safety requirements at the time it is offered for import, FDA focuses on preventing unsafe product from reaching our border by using verification, enhanced compliance, and increased data- and information-sharing.

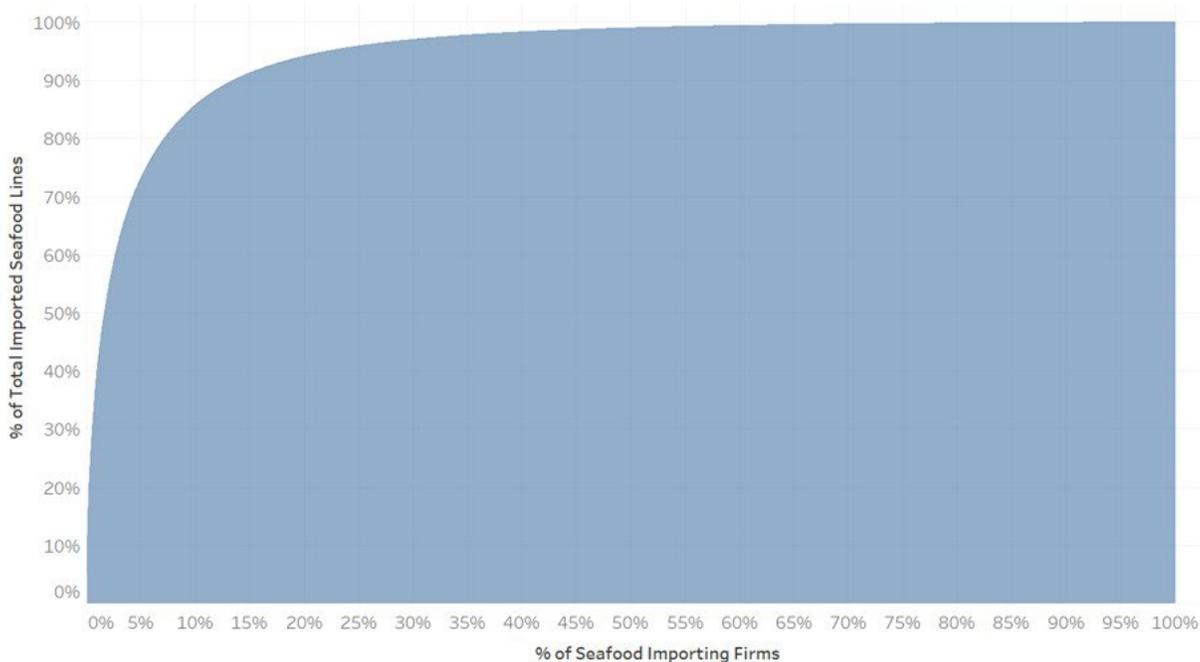
### Objective 1.1: Optimize use of foreign inspections

FDA continues to improve our knowledge and sources of data and information together with the development of sophisticated analytical tools to optimize the use of foreign inspections based on risk. New analytical tools that are being incorporated include expanding our use of AI, specifically targeting inspections based on machine learning (ML) model predictions of violative inspection, performing remote regulatory assessments (a voluntary, document-based, record-review process that complements routine facility inspections as presented in the [Resiliency Roadmap for FDA Inspectional Oversight](#)), and strengthening engagement with foreign regulatory partners. For example, the agency is using ML models to identify the drivers of potential violations. Our modeling efforts have found that firms that are currently registered are less likely to produce violative food. Such insight informs opportunities to focus on non-registered firms with training and inspection.

## Objective 1.2: Ensure importer implementation of special requirements for imported fish and fishery products (21 CFR 123.12)

Importers of seafood that is produced in compliance with Seafood HACCP are exempt from FDA's [Foreign Supplier Verification Program](#) (FSVP) for importers of food, because there are specific requirements for importers of fish and fishery products under Seafood HACCP ([21 CFR 123.12](#)). Every importer of fish and fishery products must either obtain the product from a country that has a Memorandum of Understanding (MOU) or similar arrangement with FDA or have and implement verification procedures to ensure the product they offer for import has been processed in accordance with HACCP requirements.

Importer inspections provide a significant degree of oversight of imported seafood. For example, the largest 10% of importers (by lines) import approximately 85% of imported seafood (Figure 7). Further, the largest 20% of importers (by lines) import approximately 94% of imported seafood. Focusing inspections on these largest importers allows oversight to reach into products originating from many different manufacturers.



**Figure 7.** Running percentage of imported seafood lines imported by the percentage of seafood importers for one year (3/2021-3/2022).

## Objective 1.3: Take into account the results of reliable audits such as those issued under FDA's Accredited Third-Party Certification Program or pursuant to other assurance programs aligned with FDA seafood safety requirements

FDA's [Accredited Third-Party Certification Program](#), a voluntary program in which FDA recognizes accreditation bodies (ABs) with the responsibility of accrediting third-party certification bodies (CBs), are used to establish eligibility to participate in FDA's Voluntary Qualified Importer Program (VQIP) and in some cases to prevent a potentially harmful food from entering the country. Under this program, CBs will conduct food safety audits and issue certifications of foreign food facilities. Our Accredited Third-Party Certification Program continues to develop and will include audits for seafood that will further inform our regulatory oversight activities. Currently, FDA recognizes four ABs, two of which

include Seafood HACCP under their scope. There are 13 CBs, seven of which include Seafood HACCP under their scope.<sup>8</sup> Increasing the use of reliable third-party audits is identified in the New Era blueprint as a focus to strengthen inspection, training, and compliance tools.

#### Objective 1.4: Incentivize importers to use verified suppliers of safe seafood through the Voluntary Qualified Importer Program

VQIP is FDA's voluntary, fee-based program that enables expedited review and import entry of foods into the United States for participating importers. Of the four companies that have been approved as VQIP importers, two include seafood products among their imports.<sup>9</sup> To participate in VQIP, importers must meet the following eligibility criteria: having a three-year history of importing food into the United States; having a data universal numbering system (DUNS) number; using paperless filers/brokers who received an acceptable rating during their last FDA filer evaluation; not being subject to an import alert or Class 1 recall at the time of application; not being subject to an ongoing FDA administrative or judicial action or having a history of significant non-compliances relating to food safety with no documentation of appropriate corrective actions; being in compliance with the supplier verification and other importer responsibilities under applicable regulations (e.g., HACCP); having a current facility registration for each foreign supplier of the food intended for import under the VQIP; developing and implementing a VQIP quality assurance program; having not been the subject of any U.S. Customs and Border Protection penalties, forfeitures, or sanctions within the past three years that are related to the safety and security of any FDA-regulated product imported or offered for import; and paying user fees. The VQIP importers benefit from the program through expedited review and entry of products, limited examination and sampling, sampling at locations preferred by the VQIP importer, faster lab results through sample prioritization, and access to a VQIP specific help desk.

#### Objective 1.5: Leverage the oversight efforts of regulatory counterparts with strong food safety systems

FDA employs a few mechanisms for establishing partnerships with competent authorities in countries with strong food safety systems. [Systems Recognition](#) (SR) is a partnership between FDA and a foreign regulatory counterpart with a strong food safety system, whereby the agencies conclude that they operate comparable regulatory programs (including seafood) that yield similar food safety outcomes. FDA developed the [International Comparability Assessment Tool](#) (ICAT) to systematically assess another country's food safety system. At the same time, FDA's foreign counterpart assesses FDA's oversight of the U.S. food safety system. It is necessary for each agency to reach an independent determination that the other system is comparable for the agencies to formally establish a regulatory partnership in a SR arrangement. As of 2022, FDA has SR arrangements that include seafood with Australia, Canada, and New Zealand.

FDA has additional mechanisms available for partnerships with foreign regulatory counterparts, including for bivalve molluscan shellfish. FDA currently utilizes compliance arrangements and equivalence determinations to ensure the safety of imported bivalve molluscan shellfish. These arrangements ensure that imported products meet the requirements of the National Shellfish Sanitation Program (NSSP), whereas equivalence determinations recognize that another country's food safety requirements for these products, though different from FDA's, provide at least the same level of public health protection. As of 2022, FDA has arrangements on bivalve molluscan shellfish with Canada, the

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<sup>8</sup> Data on ABs and CBs were accessed using the [FDA Data Dashboard](#) on 5/25/2022.

<sup>9</sup> Data on VQIPs were accessed using the [FDA Data Dashboard](#) on 5/25/2022.

European Union (Spain and Netherlands), Korea, Mexico, and New Zealand. FDA has made a final equivalence determination for raw molluscan shellfish harvested from certain waters in [Spain and the Netherlands](#), finalized in 2022, which was the agency's first ever equivalence determination. FDA's equivalence determination facilitates the resumption of bivalve molluscan shellfish trade between the United States and the EU for the first time in over a decade.

### Objective 1.6: Establish regulatory partnerships with foreign competent authorities that FDA has assessed to have seafood commodity-specific oversight systems

In addition to FDA's formal SR partnerships, FDA seeks engagement with all regulatory counterparts in countries that export to the United States. The agency is strengthening such relationships through the development of [regulatory partnership](#) arrangements. For example, in 2021 FDA began engaging with [regulatory partners in Ecuador, India, and Indonesia](#) (the top three foreign suppliers for aquacultured shrimp) to improve oversight of imported shrimp as directed in the Consolidated Appropriations Act, 2021 (P.L. 116-260).

These new international arrangements would embody a formal level of cooperation with the competent authorities in each country, leveraging their oversight of shrimp exported to the United States. Such arrangements would establish mutual goals to reduce contaminated shrimp from foreign suppliers, increase transparency and data sharing through confidentiality commitments, increase monitoring of potentially contaminated shrimp, and each country to address issues "upstream" in the supply chain and redirect their own resources to areas of highest risk. Confidentiality commitments will allow FDA to share with food safety authorities in each of these countries non-public information, which should improve the reaction time to foodborne outbreaks and other food safety incidents, and the food safety regulators' ability to address firms, processes, and facilities that may otherwise not be aware of problems in their establishments.

The development of regulatory partnership arrangements that enable the sharing of data and information aligns with the New Era blueprint to "increase the amount and quality of data FDA has through mechanisms that include expanded use of information-sharing arrangements with regulatory and public health partners, academic institutions, industry and others." In the cases of outbreak response, this activity also aligns with enhancing "early warning mechanisms by facilitating information exchange with and between other countries on reported foodborne illnesses and pathogens isolated from food samples."

### Objective 1.7: Increase awareness of and training on FDA seafood safety requirements and strengthen the capacity of foreign suppliers to produce safe seafood

FDA offers a variety of training opportunities related to seafood safety that are available to the public and designed for foreign suppliers and authorities. For example, learning modules on marine biotoxin management for molluscan shellfish and seafood HACCP can be accessed through the FDA's [Seafood webpage](#). FDA's online training opportunities align with the New Era directive to "expand the availability of industry and regulatory training to include, where appropriate, computer-based and distance learning models."

FDA works through the [Seafood HACCP Alliance](#) (SHA) to offer extensive overseas training in seafood HACCP. The primary purpose of this training is to assist the implementation of HACCP programs in commercial and regulatory settings. Other courses offered through SHA include Sanitation Control Procedures and a Seafood HACCP Train-the-Trainer course. Target audiences include the seafood processing and importing industry and U.S. regulatory officials.

FDA is working through a cooperative agreement with the [Joint Institute for Food Safety and Applied Nutrition](#) (JIFSAN) to assist with training in Good Aquaculture Practices (GAQP), hazard analysis, assessment of the effectiveness of training

and processor control strategies, and country assessments in support of formal seafood regulatory partnership programs with foreign competent authorities. JIFSAN also offers training in [Good Fishing Vessel Practices](#) (GFvP) and Seafood HACCP.

FDA's [Office of Training Education and Development](#) (OTED) offers a wide range of courses related to seafood and specifically on molluscan shellfish. Examples include seafood HACCP regulation, shellfish growing areas, shellfish control of harvest, shellfish plant sanitization, shellfish plant standardization, and shellfish laboratory methods and evaluation.

Additionally, FDA translates seafood safety material into other languages. For example, FDA's advice about eating fish for those who might become or are pregnant or breastfeeding and children ages 1-11 years is available in [eleven different languages](#). Training materials on the [Fish and Fishery Products Hazards and Controls](#) guidance, compliance documents, and other guidance documents are being translated for the regulatory partnership program with Ecuador, India, and Indonesia accordingly.

**Public Health Outcome: Reduced seafood safety problems in the foreign supply chain**

## Goal 2: FDA Border Surveillance Prevents Entry of Unsafe Seafood



Surveillance tools such as screening, examination, sampling, and testing are integral components of FDA's strategy to ensure the safety of imported seafood. FDA is focused on incorporating new tools and sources of information to improve our ability to find and prevent the entry of unsafe seafood into the United States.

### Objective 2.1: Continue to enhance and refine FDA's import screening and entry review processes

FDA uses [Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting](#) (PREDICT) as the primary tool to screen seafood presented for import into the United States and target the seafood shipments that are likely to be in violation of the U.S. Federal Food, Drug and Cosmetics Act (FD&C Act) for sampling. The aim of PREDICT is to prevent the entry of adulterated, misbranded, or otherwise violative goods and expedite the entry of non-violative goods. Exploring the use of AI, specifically ML, has been at the forefront as a new tool to enhance import screening. In 2019, FDA launched a pilot program using AI/ML to augment PREDICT in the seafood import process. The [initial phase of the AI imported seafood pilot](#) was a proof-of-concept to evaluate our ability to improve targeting of unsafe seafood for screening at the border. The promising results of the proof-of-concept led to a [second phase of the AI imported seafood pilot program](#). This operational phase was implemented at all ports of entry across the country and ran from February 1 through July 31, 2021. Efforts continue to improve and expand the application of AI/ML to imported seafood. For example, in response to Section 787 of the Consolidated Appropriations Act, 2021 (P.L. 116-260), opportunities to utilize

the tool for screening and targeting imported shrimp are being examined. Given the likely hazards associated with imported shrimp, an AI/ML model was developed for predicting the probability of imported aquacultured shrimp to be adulterated with animal drug residues. Funding from Section 787 enabled FDA to acquire additional software and staffing to focus on this work.

Lessons learned from the AI/ML work on seafood is informing the application of this tool to other commodities. The New Era blueprint directs the agency to “advance FDA’s predictive analytics capabilities through expanded use of artificial intelligence and machine learning tools, beginning with expanding the proof-of-concept completed by the agency using AI for screening of imported foods at ports of entry.”

Another initiative for enhancing import screening and entry review is the development of the CFSAN Data Warehouse (CDW). The CDW will function as a centralized repository for the data used to execute CFSAN’s mission. It will contain data from both CFSAN systems and systems managed by other Centers, including FDA’s Office of Regulatory Affairs (ORA). Longer term, the CDW will also contain relevant data from other Federal agencies or external entities as needed. A published Data Catalog will identify and describe the data assets available via the CDW. Users will access the data in CDW through business intelligence, reporting, and analytics tools as needed; Tableau, SAS, and ThoughtSpot were the focus for the initial phases of development. FDA utilized Section 787 funds to prioritize imports data from ORA into the CDW for ease of access and use for AI/ML model development and other applications. The CDW development aligns with the New Era initiative aimed to “increase the amount and quality of data FDA has through mechanisms that include expanded use of information-sharing arrangements with regulatory and public health partners, academic institutions, industry and others.”

## Objective 2.2: Optimize use of physical examination and sampling of imported seafood

FDA implements sampling and testing through planned surveillance work and in response to notifications about potential seafood safety risks. Sampling and testing can help us to discover and respond to food safety issues, inform and identify trends, and provide data that can aid in the agency’s risk-based decision-making processes. FDA establishes annual domestic and foreign sampling priorities through Sample Collection Operations Planning Efforts (SCOPE). SCOPE establishes annual sampling priorities utilizing a sampling request process, with input from various FDA program experts as well as state and other partners.

In 2021-2022, FDA conducted a survey of [per- and polyfluoroalkyl substances](#) (PFAS) in seafood, representing an example of imported seafood sampling. This targeted survey aimed to understand the potential dietary exposure to PFAS from the most consumed seafood (shrimp, salmon, canned tuna, tilapia, pollock, cod, crab, and clams) imported from the top three exporting countries per seafood type. PFAS are a diverse group of manufactured chemicals that are used in a wide range of industrial applications and in consumer goods. Given their stability, PFAS may accumulate and persist many years in the environment. The targeted seafood survey was intended to enhance our scientific knowledge base on PFAS, and results are being used to inform additional efforts to sample for PFAS.

Another strategy for optimizing sampling of imported seafood is through retail sampling. In 2021 FDA began increasing the sampling of shrimp at the retail level, focusing on the countries with the greatest volume of imports. This activity involves retail shrimp sample collection by a third party with analysis by FDA as well as third-party sampling and analysis. The focus is on residues of animal drugs in imported aquacultured shrimp from countries contributing to the greatest volume of U.S. imports. The data received from that sampling assignment, together with our current level of examination and sampling at the port of entry, augmented by the AI seafood import pilot, will help inform future rates of examination and sampling. More importantly, we anticipate that having better information via predictive analytics

will make future examination and sampling more impactful by focusing our resources on those shipments that are most likely to be violative.

Investments in improving laboratory capabilities and data analytics also will help us maintain and advance the public health impact of examination and sampling. Investments in data infrastructure will help us use this information for other oversight activities, including advancing our dialogue with foreign regulatory counterparts. FDA has developed the [Laboratory Flexible Funding Model Cooperative Agreement Program](#) (LFFM) to enhance the capacity and capabilities of state human and animal feed testing in support of an integrated food safety system. This program strengthens FDA's ability to prevent foodborne outbreaks by increasing sample testing capacity. LFFM, which is being applied to imported seafood, aligns with the New Era blueprint focus on domestic mutual reliance.

### Objective 2.3: Strategically utilize import alerts and import certifications

[Import Alerts](#) inform the agency's field staff and the public that there is enough evidence to allow for Detention Without Physical Examination (DWPE) of products that appear to violate FDA's laws and regulations. FDA continues to update and adjust import alerts related to seafood to address new and developing food safety concerns. FDA will continue to develop guidance for imported seafood and import alerts to improve consumer protections.

FSMA gave the FDA authority to require [import certification](#) for certain imported food (FSMA Section 303(b); 21 USC 381(q)). In such cases, as a condition of granting admission to a food imported or offered for import into the United States, a certification or other assurances as deemed appropriate that the food complies with applicable requirements may be required. Certifications may be in the form of shipment-specific certificates, a listing of certified facilities that manufacture, process, pack, or hold such food, or any other form as specified by FDA. The determination of whether a certification will be required for a food is based on risk of the food, which includes consideration of the following factors: known safety risks associated with the food; known food safety risks associated with the country of origin; and a finding, supported by scientific, risk-based evidence, that the food safety programs in the country of origin are inadequate to ensure that the food is as safe as a similar food originating in the United States. The FDA has not yet used this authority to require certification for imported seafood, but this is another tool the agency may use to ensure the safety of imported seafood.

### Objective 2.4: Develop and update regulations and guidance to improve the safety of imported seafood

FDA updates regulations and guidance as science and technology advance and as new hazards are identified. FDA's [Fish and Fishery Products Hazards and Controls Guidance](#) is intended to assist processors of fish and fishery products in the development of the HACCP plans. Individual chapters are updated as needed based on the best available science. For example, Chapter 3: Potential Species-Related and Process-Related Hazards and Chapter 11: Aquaculture Drugs were updated in June 2021, along with several appendices. In April 2022, FDA also released updated [Guidance for Industry: Reconditioning of Fish and Fishery Products by Segregation](#) that can be applied to imported seafood. This updated guidance clarifies the steps that owners of fish and fishery products can take to segregate non-violative seafood products from products adulterated with pathogens, unlawful drugs, scombrototoxin (histamine), and decomposition, to demonstrate compliance with the FD&C Act.

FDA is also considering the use of new authorities provided to the agency under FSMA and their potential application to seafood. For example, the [Laboratory Accreditation for Analyses of Foods](#) final rule establishes a laboratory accreditation program for the testing of food in certain circumstances. FDA will recognize accreditation bodies that will accredit laboratories to the standards established in the final rule. The final rule establishes the eligibility requirements

for participation in the program. The program covers tests supporting the removal of food from an import alert through successful consecutive testing requirements and tests supporting admission of an imported food detained at the border because such food is or appears to be in violation of the FD&C Act.

### Objective 2.5: Improve testing methodologies and tools used to determine admissibility of seafood offered for import

FDA is exploring geographic information system (GIS) tools to help identify potential hazards in imported seafood. For example, RAFT-MAP is a custom mobile GIS tool that was developed by FDA to facilitate field data collection by providing real time mapping and analysis tools to assess pollution source impacts to shellfish growing areas. This technical assistance/training tool, first implemented in March 2020, assists states and MOU countries in conducting sanitary surveys with a higher level of efficiency and accuracy, thereby safeguarding the public and meeting compliance aspects of the program. The RAFT-MAP tool will continue to be updated, along with associated guidance/training materials, as science advances to continue to facilitate public health protection.

Another GIS tool under development that can help identify sources of marine biotoxins is the GIS biotoxin visualization tool. Presently, there is no all-encompassing visualization tool comprising all shellfish growing area marine biotoxin geospatial information. Paralytic, amnesic, neurotoxic, diarrhetic, and azaspiracid shellfish poisoning toxin data are required for biotoxin control. The objective of this project is to develop a GIS based visualization tool that can be used to assess the suitability of certain regions for molluscan shellfish harvest. The project has been focused on growing areas in U.S. waters; however, we are exploring opportunities to expand the tool internationally. The tool will serve as a valuable resource that can be used to identify foreign growing areas where marine biotoxin control is needed and inform import screening of products that may contain marine biotoxins.

Activities related to the development of GIS tools for improving the safety of imported seafood align with the New Era blueprint to “develop processes to analyze big-data and non-traditional data sources of information, such as environmental conditions (rain, temperature, wind, etc.), that could be used by the public and private sectors to strengthen foodborne predictive capabilities and make more informed risk management decisions.”

To enhance laboratory testing methodologies, additional instrumentation (liquid chromatography with tandem mass spectrometry, or LC-MS/MS) was purchased in late FY 2021 and delivered to the FDA Gulf Coast Seafood Laboratory (GCSL) in Dauphin Island, AL, in early FY 2022. In addition, two FDA servicing laboratories, Arkansas Laboratory and Denver Laboratory, analyzed samples using a combination of existing methodologies used for regulatory purposes and a new screening method for horizon scanning. The updated screening method was published in November 2021 and allows for testing 98 unique chemical residues, which adds to FDA’s arsenal of effective tools for oversight of the safety of imported shrimp products.

### Objective 2.6: Maximize the benefit to border surveillance from state and other partnerships

The agency seeks to maximize border surveillance by sharing data and leveraging relationships with states and other regulatory partners. Examples include the [Food Emergency Response Network](#) (FERN), the [Laboratory Flexible Funding Model](#) (LFFM), and the [GenomeTrakr Network](#). FERN is a national network of food laboratories designed to integrate the nation’s local, state, and federal food testing laboratories to detect, identify, respond to, and recover from a bioterrorism or public health emergency/outbreak involving the food supply. FDA has initiated sampling assignments through FERN laboratories that include both domestic and imported seafood. The FDA funds numerous state laboratories through the LFFM to support and augment laboratory testing within the agency for domestic and imported food, including seafood. The LFFM is also funding laboratories to implement a new system of laboratory data exchange

(National Food Safety Data Exchange; NSFDX) that will allow state laboratory data to be more easily exchanged with FDA. The FDA’s GenomeTrakr consists of a network of laboratories throughout the world that utilize Whole Genome Sequencing (WGS) to identify pathogen isolate sequences that can be archived in the [National Center for Biotechnology Information](#) (NCBI) database. Inputs from food and environmental isolate sequences through GenomeTrakr can be used to find potential contamination sources of current and future outbreaks, better understand the environmental conditions associated with the contamination of products, and help develop new, rapid testing methods. Relationships with regulatory partners such as FERN, LFFM, and GenomeTrakr enhance overall seafood analysis capacity.

Additionally, FDA routinely communicates with other federal agencies with missions related to seafood safety. Specifically, FDA works closely with seafood counterparts in the United States Department of Agriculture (USDA), Environmental Protection Agency (EPA), and National Oceanic and Atmospheric Administration (NOAA) to share information related to imported seafood safety. FDA engages with federal agencies on a range of interagency committees and working groups, including the [National Science and Technology Council](#) (NSTC) Subcommittee on Aquaculture and the Subcommittee on Ocean Science and Technology, the Interagency Working Group on [Harmful Algal Blooms and Hypoxia Research and Control Act](#) (IWG-HABHRCA), the Federal Waters Shellfish Biotxin Advisory Board, [One Health Harmful Algal Bloom System](#) (OHHABS), the [Joint FDA/NOAA Vibrio Ecological Forecasting Workgroup](#), the [National Nanotechnology Initiative](#) Nanoplastics Community of Practice, and the Interagency Marine Debris Coordinating Committee (IMDCC). Some of these working groups were initiated through legislation. For example, the IWG-HABHRCA was formed in response to Public Law 115-423 and the IMDCC is working on directives in Section 132 of the Save Our Seas 2.0 Act. Bringing interagency experts together to address and find smart solutions for potential seafood safety challenges such as aquaculture drug residues, harmful algal blooms, and micro- and nanoplastics is consistent with the People-Focused and Led Principle described in the New Era blueprint.

Such domestic mutual reliance is a core focus in the New Era blueprint. For example, the agency is directed to “further develop and enhance the mechanisms for appropriate data and information sharing to enable FDA and states with comparable regulatory and public health systems to more fully rely on, coordinate with and leverage one another’s work, data, and actions.”

**Public Health Outcome: More efficient interdiction of unsafe seafood at ports of entry**

### Goal 3: Rapid and Effective Response to Unsafe Imported Seafood



In the event that unsafe seafood enters the country, FDA is poised to respond quickly and efficiently to reduce the duration and public health impact of any imported seafood-related outbreak of illness. Once seafood has been imported, FDA may employ the same tools available for domestically produced products, including recalls.

## Objective 3.1: Maximize effectiveness of FDA response to an event involving imported seafood

FDA's [Coordinated Outbreak Response and Evaluation \(CORE\)](#) network manages foodborne illness outbreak surveillance, response, and post-response activities linked to certain FDA-regulated human food. The CORE Signals and Surveillance Team evaluates emerging outbreaks and disease surveillance trends, working in collaboration with CDC, FDA field offices, and state agencies. The CORE Response Teams have one goal: to control and stop the outbreak. Response Teams work directly with FDA field offices, FDA subject-matter experts, the CDC, and state partners on a response strategy. The CORE Communications Team monitors emerging and active incident investigations. If there is an ongoing risk to the public and actionable steps can be taken to reduce risk of illness, the FDA will issue public warning.

While large seafood-related outbreaks are managed by CORE, seafood-related illnesses caused by natural toxins and scombrototoxin fish poisoning in fish other than molluscan shellfish have a unique reporting mechanism. FDA's Division of Seafood Safety has developed a process for [how to report seafood-related toxin and scombrototoxin fish poisoning illnesses](#).

In December 2021, the agency released FDA's [Foodborne Outbreak Response Improvement Plan](#) as a part of the New Era initiative. The plan focuses on improvements in three specific areas: product tracing, root cause investigations, and the use of CORE data. In the plan, FDA commits to enhance the speed, effectiveness, coordination, and communication of outbreak investigations.

FDA is taking further action to help prevent outbreaks of foodborne illnesses associated with certain foods through the development of [prevention strategies](#) to enhance food safety. A prevention strategy is an affirmative, deliberate approach undertaken by the FDA and stakeholders to help limit or prevent future outbreaks linked to certain FDA-regulated foods. The prevention strategies examine commodity-hazard pairings, potential sources and routes of contamination, and what can be done to reduce incidences of foodborne illness in the future. They also identify existing knowledge gaps and needed areas of focus to inform and promote research and engagement with external stakeholders on steps that can be taken, collaboratively, to protect public health and prevent future outbreaks.

The New Era blueprint encourages the agency to "increase awareness and training to facilitate opportunities to speed whole genome-sequencing of pathogens by public and private labs." Consistent with this initiative, FDA is exploring whole genome-sequencing training and capacity building in foreign countries, beginning with the three countries that export the largest volume of shrimp to the United States.

FDA recently published a final rule that establishes additional traceability recordkeeping requirements for certain foods. The [Food Traceability Final Rule](#) establishes additional traceability requirements for persons who manufacture, process, pack, or hold foods that the agency has designated for inclusion in the [Food Traceability List \(FTL\)](#). Finfish (including smoked finfish), crustaceans, and bivalve molluscan shellfish are included in the FTL, although under many circumstances bivalve molluscan shellfish are [exempt](#) from the requirements of the rule. The compliance date for all entities covered by the final rule is January 20, 2026.

## Objective 3.2: Enhance the efficiency and effectiveness of imported seafood safety recalls

FDA relies on responsible parties, such as an importer, distributor, or farm, to voluntarily recall their seafood when they discover an associated violation or potential health hazard. FDA ensures an industry or FDA press release is published regarding a recall and distributes alerts and public notices to inform consumers and retailers, when appropriate. FDA also works with the [Interstate Shellfish Sanitation Conference \(ISSC\)](#) for postings on their webpage related to recalls associated with molluscan shellfish imported from MOU countries.

The agency will explore mechanisms and tools for recall modernization in alignment with the New Era initiative. Activities to modernize seafood-related recalls may include exploring “mechanisms to harmonize how FDA and USDA communicate recall information to consumers” and enhancing “connectivity of data from Reportable Food Registry submissions and food recalls.”

### Objective 3.3: Use information-sharing opportunities to prepare for and respond to the entry of unsafe imported seafood

FDA engages in data sharing opportunities domestically and with other countries. The [Reportable Food Registry for Industry](#) is an electronic portal where industry can report when there is a reasonable probability that an article of domestic or international food will cause serious health consequences. The agency has developed an [ORA Data Exchange](#) platform (ORA DX) for the secure sharing of data between FDA and state and local regulatory partners. Information-sharing related specifically to molluscan shellfish is also achieved through the [ISSC webpage](#) as well as ISSC notifications to its members. Seafood safety data sharing with other countries also occurs via Systems Recognition and other arrangements as described above.

Under the New Era initiative, there is a domestic mutual reliance effort to “further develop and enhance the mechanisms for appropriate data and information sharing to enable FDA and states with comparable regulatory and public health systems to more fully rely on, coordinate with, and leverage one another’s work, data, and actions.” The New Era blueprint also directs the agency to “advance an integrated, public health focused approach to emergency and incident response coordination by further expanding our federal-state rapid response teams, including recall oversight, investigations of outbreaks and complaints, and supply chain disruptions.”

**Public Health Outcome: More rapid and effective response to unsafe imported seafood**

### Goal 4: Effective and Efficient Seafood Import Program



To improve the effectiveness and efficiency of the seafood import program, FDA will implement an adaptive, risk-informed, cost-effective comprehensive approach with built-in metrics for accountability.

## Objective 4.1: Optimize resource allocation by developing a comprehensive global inventory of seafood facilities and farms and assessing the cumulative oversight applied to the global inventory

FDA will employ the comprehensive oversight tools presented in this document across the global inventory of seafood facilities and aquaculture farms. This will require an improved understanding of the cumulative value of oversight using these tools to optimize FDA's resource allocation towards imported seafood with the highest risk. The establishment of regulatory partnership arrangements, described above, will inform the FDA of foreign competent authority oversight of specific commodities such as shrimp, thereby improving FDA's access to information regarding facility and aquaculture farm inventories.

## Objective 4.2: Ensure effectiveness of import activities through performance assessment and continuous improvement

Existing tools that are useful for evaluating performance include [FDA-TRACK](#), an agency-wide performance management system that monitors FDA Centers and Offices through key performance measures and projects, as well as the CFSAN Center Initiatives Coordination (CIC), which is a selection of projects prioritized and optimized to support strategic priorities.

Performance metrics will be established for individual imported seafood safety activities. For example, for imported seafood safety activities, the FDA will identify performance metrics to evaluate such as violations rates, recidivism rates, field utility measures, and regulatory actions. These metrics enhance the agency's ability to measure the degree to which the New Era initiative and the use of smarter tools and approaches improves the targeting of violative seafood samples entering the country but also improvements in resource efficiency.

The [FDA Data Dashboard](#) is an external facing dataset that increases transparency and accountability by displaying and allowing the analysis of public FDA data through easy to use, visually accessible, customizable, and understandable graphics. Compliance dashboards are available for inspections, compliance actions, recalls, imports summary, import refusals, and imports entry data.

FDA will provide ongoing communications to stakeholders on the progress of all of these imported seafood safety activities.

## Seafood Research

As mentioned below in the Appendix, FDA maintains scientific expertise as the foundation for seafood safety. FDA conducts research to answer outstanding and new policy questions, address knowledge gaps, and develop methods and tools to further strengthen seafood safety. Primary areas of focus include hazard identification and characterization; hazard prevention, control, and risk reduction; method development and validation; risk assessments; development of GIS tools and ecological forecasting; cross-contact and cross-contamination; and computational modeling. Examples of research that may relate to imported seafood safety include the development of methods for viruses, bacteria (including *Vibrio* spp.), marine biotoxins, seafood decomposition, toxic elements, and aquaculture drugs; genome sequencing of pathogenic bacteria (including *Vibrio* spp.) and strains of toxic algae; investigating potentially emerging seafood hazards (e.g., PFAS); developing data visualization tools for geospatial information (e.g., marine biotoxins and pollution sources) related to seafood harvest areas; and improving understanding of time and temperature requirements for seafood storage.

## Conclusion

This document presents the comprehensive approach that FDA is taking to ensure that imported seafood consumed in the United States meets the standards of domestically produced seafood. This approach augments existing oversight tools with smarter, more efficient technologies and processes, thereby allowing greater flexibility of oversight mechanisms for imported seafood. Most of FDA's activities in the Activities for the Safety of Imported Seafood are targeted towards prevention (Goals 1 and 2). These include proactively engaging and establishing partnerships with regulatory counterparts in countries that export seafood to the United States, exploring the use of AI/ML to strengthen predictive analytics, developing new tools that leverage technology such as GIS to provide spatial intelligence about potential seafood hazards, and utilizing the LFFM to increase sample testing capacity and capabilities. While preventing contaminated seafood from entering the country is the priority, FDA aims to enhance the speed, effectiveness, coordination, and communication of outbreak investigations when unsafe seafood does enter the United States.

## Appendix A: Guiding Principles of the Activities for the Safety of Imported Seafood

Guiding principles were established in the Import Strategy to ensure that the same food safety requirements were applied to food consumed in the United States, regardless of where it was sourced. These same guiding principles apply to imported seafood safety.

- **Protecting public health is the first priority:** All imported seafood safety activities are carried out with the end goal of protecting and promoting public health.
- **Partnering with others to build prevention-based systems is the key to success:** FDA must partner with a variety of stakeholders to ensure that safety is built into seafood harvesting, production, and processing from growing areas, aquaculture farms, and fishing vessels to table, preventing seafood-borne illness and injury before they begin. Regulatory partners here in the United States and abroad play an important role in FDA identifying and rejecting unsafe seafood offered for import into the country as well as marshalling effective responses when seafood-borne illness or injury does occur.
- **Maintaining scientific expertise and innovation as the foundations of FDA's seafood safety work:** Science drives FDA's imported seafood activities, from testing for compliance with seafood safety controls, to developing new testing methodologies for detecting pathogens or contaminants on seafood offered for import, to establishing an expanded network of laboratories with the capability and capacity to ensure that imported seafood meets U.S. safety requirements.
- **Sustaining a level playing field for domestic and foreign seafood producers:** FDA must apply the full range of oversight tools to ensure that seafood imported from abroad is as safe as seafood produced domestically. Although the tools may differ in the foreign and domestic arenas, they ultimately create a multilayered seafood safety net strengthened with areas of overlap and interconnection.
- **Allocating resources according to risk is the most effective method for protecting public health, and data analytics is the key to prioritizing according to risk:** FDA maximizes the public health benefit of its regulatory oversight by putting more resources toward riskier areas and fewer resources toward lower-risk areas. The agency understands where areas of greater risk are through effective collection and comprehensive consideration of intelligence from a range of sources regarding multiple risk factors. Supported by an improved facilities and aquaculture farm inventory, FDA will strategically allocate resources across all foreign seafood facilities and aquaculture farms and at the border.
- **Requiring measurement and ongoing refinement to ensure success:** Development of performance measures and outcome indicators for imported seafood safety will improve and maximize the success of imported seafood safety activities.
- **Establishing transparency as the standard:** FDA will publish non-confidential data related to inspections of foreign suppliers and importers, examination and sampling, or other imported seafood safety activities in support of our commitment to operate transparently.