

SEAFOOD FRAUD

Analysis of Legal Approaches
in the United States

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JUNE 2022



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The report benefited from significant research, writing, and editing support from **Cydnee Bence** JD'20, LLM Fellow, Center for Agriculture and Food Systems, **Alexia Basile** MFALP'19 and **Paige Beyer** JD'21.

Acknowledgments

This report was produced by the Center for Agriculture and Food Systems at Vermont Law School, with support from the National Agricultural Library, Agricultural Research Service, US Department of Agriculture. Research for this report was funded in part by FAO. Views expressed in this report are those of the authors and do not necessarily reflect the views of institutional funders.

The report would not have been possible without the assistance, cooperation, and production support of the Center for Agriculture and Food Systems: **Claire Child**, Assistant Director; **Molly McDonough**, Environmental Communications Specialist; **Lihlani Nelson**, Associate Director; and **Whitney Shields**, Project Manager. In addition, we thank the following individuals for their assistance and support: **Max de Faria** MFALP'22 and **Jenileigh Harris** MFALP'18.

We would like to thank the following reviewer for providing feedback on an early draft of this report. Reviewers do not necessarily concur with the report’s recommendations but advised on portions of its content: **Meghan Jeans**, Foghorn Strategies.

The authors gratefully acknowledge participants in FAO’s 2019 expert meeting on food fraud. Discussions from that meeting have informed our thinking on legal and enforcement approaches to this issue.

Finally, we would like to thank those who were interviewed prior to and during the drafting of this report who provided valuable input on its content but do not necessarily concur with its recommendations: **Janice Plante**, Public Affairs Officer, New England Fishery Management Council; **Alexa Cole**, Director, NOAA Fisheries Office of International Affairs, Trade, and Commerce; and Lieutenant Commander **David Stutt**, US Coast Guard.

Report Layout and Design: **Kelly Cochrane-Collar**, Mad River Creative



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ACRONYMS GLOSSARY

ACE	Automated Commercial Environment
AIS	Automatic Identification System
CBP	US Customs and Border Protection
CCAMLR	Commission for the Conservation of Antarctic Marine Living Resources
CCPs	Critical Control Points
CGMPs	Current Good Manufacturing Practice regulations
CoC	Chain of Custody
CTEs	Critical Tracking Events
CTSCA	California Transparency in Supply Chains Act
DWPE	Detention Without Physical Examination
EAR	Enforcement Action Report
EMA	Economically Motivated Adulteration
EEZ	Exclusive Economic Zone
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FSIS	US Department of Agriculture Food Safety Inspection Service
FSMA	Food Safety Modernization Act
FTC	Federal Trade Commission
FTCA	Federal Trade Commission Act
GAO	US Government Accountability Office
GFSI	Global Food Safety Initiative
GRAS	Generally Recognized As Safe
GSSI	Global Sustainability Seafood Initiative
HACCP	Hazard Analysis and Critical Control Points
HARPC	Hazard Analysis and Risk-Based Preventive Controls
HHS	US Department of Health and Human Services
ICCAT	International Commission for the Conservation of Atlantic Tunas
IMO	International Maritime Organization

INFOSAN	International Food Safety Authorities Network
ISEAL	International Social and Environmental Accreditation and Labelling Alliance
ISO	International Organization for Standardization
ITC	International Trade Centre
ITDS	International Trade Data System
IUU	Illegal, Unreported, or Unregulated
JECFA	Joint FAO/WHO Expert Commission on Food Additives
KDEs	Key Data Elements
MOU	Memorandum of Understanding
MSA	Magnuson-Stevens Fishery Conservation and Management Act
MSC	Marine Stewardship Council
NMFS	US National Marine Fisheries Service (also known as NOAA Fisheries)
NOAA	US National Oceanic and Atmospheric Administration
NSSP	National Shellfish Sanitation Program
OSHA	US Occupational Safety and Health Administration
PSMA	Agreement on Port State Measures to Prevent, Deter, and Eliminate Illegal, Unreported, and Unregulated Fishing
PVP	US Department of Agriculture's Process Verified Program
RFE	Regulatory Fish Encyclopedia
RFMCs	Regional Fisheries Management Councils (US)
RFMOs	Regional Fisheries Management Organizations (international)
SIMP	Seafood Import Monitoring Program
SOLAS	IMO Convention for the Safety of Life at Sea
TACCP	Threat Assessment and Critical Control Point
UCL	Unfair Competition Law
UDAP	Unfair and Deceptive Acts and Practices
USCG	US Coast Guard
USDA	US Department of Agriculture
VACCP	Vulnerability Assessment and Critical Control Point
VMS	Vessel Monitoring System
WHO	World Health Organization

TABLE OF STATUTES & REGULATIONS

OFFICIAL TITLE	REPORT ABBREVIATION	CITATION
Public Health Security and Bioterrorism Preparedness Response Act	Bioterrorism Act	Pub. L. 107-188, 116 Stat. 594-697 (2002).
Current Good Manufacturing Practice regulations	CGMPs	21 C.F.R. § 314. 21 C.F.R. § 210. 21 C.F.R. § 211. 21 C.F.R. § 212. 21 C.F.R. § 600.
California Transparency in Supply Chains Act	CTSCA	S.B. 657, 145th Reg. Sess. (Cal. 2010). Cal. Civ. Code § 1714.43. CAL. REV. & TAX. CODE §19547.5.
Federal Food, Drug, and Cosmetic Act	FFDCA	21 U.S.C. §§ 301-392.
Food Safety Modernization Act	FSMA	21 U.S.C. §§ 2201-2252.
Federal Trade Commission Act	FTCA	15 U.S.C. §§ 41-58.
Mitigation Strategies to Protect Food Against Adulteration	Intentional Adulteration Rule	21 C.F.R. § 121.
Magnuson-Stevens Fishery Conservation & Management Act	MSA	16 U.S.C. §§ 1801-1891d.
Occupational Safety and Health Act	OSH Act	29 U.S.C. §§ 651-678.
Risk-Based Preventive Controls for Human Health	Preventative Controls Rule	21 C.F.R. § 117.
Maritime Security and Fisheries Enforcement Act	SAFE Act	16 U.S.C. §§ 8001-8041.
Security and Accountability for Every Port Act	SAFE Port Act	6 U.S.C. §§ 901-1003.



INTRODUCTION

ADVANCES IN FOOD PRODUCTION ACROSS THE GLOBE have led to a remarkably complex and uncoordinated global supply chain marked by limited transparency and traceability. This has increased incidences of food fraud, sometimes with devastating consequences. A recent survey conducted by the International Food Safety Authorities Network (INFOSAN), managed by the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO), indicated that food safety authorities and regulators around the globe need information and best practices to address food fraud.¹ Industry has also attempted to respond to the issue through private mechanisms related to food safety, vulnerability, and defense. Food fraud in the seafood sector is particularly rampant due to the many drivers that cause individuals to consider fraud coupled with the ample opportunities presented by the complexities in the seafood supply chain. Seafood fraud implicates myriad policy concerns, including food safety and public health, consumer trust in the seafood industry and the corresponding responsible regulators, the viability of law-abiding fishers' livelihoods, countries' international reputations in the global fishing industry, and ongoing national and international conservation efforts and fishery management. Among types of food fraud, seafood fraud is distinct due to its close connection with natural resource management.



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CATEGORIES OF SEAFOOD FRAUD

Seafood fraud can be grouped into five categories capturing different types of consumer deception related to seafood attributes.

The first two types are forms of adulteration:

- species substitution
- undeclared processing methods

The remaining three types involve deception about a product's provenance:

- fishery fraud
- illegal, unreported, and unregulated (IUU) substitution
- ethical claims fraud

Each type of seafood fraud confers economic gain on the fraudster, either from selling a lower quality product at a higher price² or by avoiding costs.³ The extent of fraud in the seafood sector is difficult to ascertain because much fraudulent activity likely goes undetected. However, several studies in multiple countries have uncovered high rates of mislabeled seafood species.⁴ Given the significant seafood market share associated with popular seafood products, even low rates of some mislabeled products may result in consumers purchasing significant quantities of fraudulent seafood.⁵

FAO's most recent estimate puts global fish and seafood production at 172.6 million tons, with approximately 54 percent coming from capture production and the remaining 46 percent from aquaculture.⁶ Over one-third of all fish production enters international trade.⁷ In some countries, the proportion of seafood coming from international supply chains is much higher; in the United States, over 80 percent of all seafood is imported.⁸ It is not uncommon for seafood to pass through a country of harvest, a separate country of processing, and a third for sale and distribution to consumers. In some cases, domestic seafood is exported to another country for processing, then reimported to the original harvesting country for sale.⁹ These complex and opaque supply chains provide multiple opportunities for individuals and entities to engage in fraud.

This report examines the issue of seafood fraud with a particular emphasis on the United States to provide a set of recommendations for states attempting to address the issue. Consequently, the report includes discussion of key US laws, regulations, and programs that operate together as an informal seafood fraud prevention and detection framework. As will be discussed later, there are both benefits and consequences associated with this conceptual approach used by the United States. The report concludes with a set of recommendations and considerations for policymakers related to the legal meaning of seafood fraud, prevention and detection, enforcement, and measures tailored to the complexities of the seafood supply chain.



LEGAL APPROACHES TO THE PROBLEM OF SEAFOOD FRAUD

POLICYMAKERS ATTEMPTING TO ADDRESS SEAFOOD FRAUD through legal mechanisms can do so using two main approaches: a definition-based approach and a piecemeal approach. Each approach presents strengths and drawbacks policymakers should consider when determining the most effective means of combating seafood fraud in their national context.

A definition-based approach uses legislation to establish and define the offense of “seafood fraud” or, more likely, the broader category of “food fraud.” The legal definition establishes the required elements of the offense, which may be criminal, civil, or a combination of the two. Defining “food fraud” in legislation is not common practice.¹⁰ However, FAO observes that nonlegislative definitions found in international guidance and applied by various national jurisdictions commonly integrate three key elements: *intentionality*, *deception*, and a motive of gaining *undue advantage*.¹¹

- **Intentionality:** The intentionality element distinguishes fraudulent acts from forms of non-compliance due to mistake or negligence. Intentionality is considered an indicator of the severity of acts of food fraud as compared to unintentional acts that misidentify foods or mischaracterize their value.
- **Deception:** The deception element requires that information provided about the food product is untruthful or misleading to the consumer.
- **Undue Advantage:** Lastly, food fraud definitions include a motive element. FAO describes undue advantage as encompassing the motive of economic gain while providing a somewhat wider scope that includes other forms of personal gain but excludes acts motivated by a desire to cause physical harm, such as contaminating food with unsafe substances.¹²

In countries that do not adopt a legislative definition for food fraud, the problems raised by fraudulent acts in the food system are addressed through what this report’s authors call a

piecemeal approach. In a piecemeal approach, no law specifically defines or addresses the offense of food fraud. Rather, certain acts that would be considered acts of seafood fraud under a definition-based approach are instead prohibited by a series of existing laws that may have disparate aims and enforcement mechanisms. These may include laws regulating fisheries or aquaculture, imported goods, food safety, and sales of consumer goods. For example, the act of species substitution is a particular instance of seafood fraud that might violate a general consumer protection statute in addition to a mislabeling prohibition in a food safety law. Although neither law aims specifically to prevent food fraud, they both prohibit conduct that would be targeted by a statute defining and prohibiting food fraud.

Both definition-based and piecemeal approaches have advantages and drawbacks.

DEFINITION-BASED APPROACH

Strengths



Defining “food fraud” in legislation has the advantage of establishing the parameters of the problem, identifying the root causes, and developing mechanisms to address the many reasons someone might engage in food fraud. Creating a shared understanding of what actions constitute food fraud can support a more efficient and targeted approach to the issue. Such an approach might include centralizing implementation efforts within one agency, tracking data on violations, and establishing consistent enforcement mechanisms through a dedicated enforcement budget and set of priorities.

Weaknesses



Conversely, using a definition-based approach to food fraud risks separating the problem of food fraud from related policy concerns that might be addressed more effectively together, such as food safety. In the seafood sector specifically, using a definition-based approach to food fraud may miss opportunities to address the drivers of seafood fraud at the fisheries level if the statute’s main approach uses a general food fraud lens. Coordinating to maintain synergies with other areas of policy is possible but carries additional costs. Policymakers addressing food fraud should note the practical considerations related to imposing new legal obligations on the seafood industry in the absence of efforts to harmonize new requirements with those already imposed on the industry by other laws or agencies.



A definition-based approach may also fail to capture activity that technically falls outside the defined parameters of the offense yet remains a prevention priority, such as unintentional or negligent mixing of seafood products. For example, a 2019 study engaging in meta-analysis of seafood price and mislabeling suggests there may be other root causes of misrepresented seafood products¹³ beyond the motive of undue advantage captured in food fraud definitions. Using a definition-based approach, lawmakers would need to define a legal offense separate from food fraud to regulate those activities or refine the definition to incorporate particularly egregious examples.

PIECEMEAL APPROACH

Strengths



A piecemeal approach has its own set of strengths and weaknesses. One key strength is the possibility of quicker and less bureaucratic implementation. A piecemeal approach is less likely to require new legislative acts to address the problem of seafood fraud. It uses existing legal authorities and agency expertise, thereby mitigating the implementation learning curve.

Weaknesses



Weaknesses of the piecemeal approach stem mainly from its lack of enforcement coordination. Seafood fraudsters may face inconsistent penalties or adjudicative processes depending upon which specific law they violate, or which agency brings enforcement actions against them. At a policy level, attention to the overall problem of seafood fraud may be diminished if no single agency has a mandate to address the issue. When each agency that may play a role in preventing food fraud has priorities that lie elsewhere, such as food safety or fisheries conservation, attention to seafood fraud enforcement is likely to receive less attention or emphasis.

The United States, like many countries, takes a piecemeal approach to combating food fraud.¹⁴ Legal prohibitions on the various acts that constitute seafood fraud reside in US food safety law, fisheries law, and consumer protection law, among others.

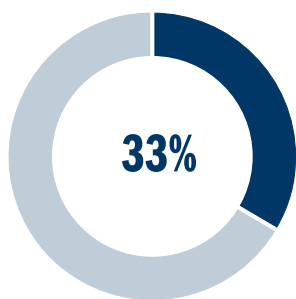
This report will primarily address legal considerations related to using a piecemeal approach. However, as discussed above, this is not the only means by which a government can approach the problem of seafood fraud. Nor are the two approaches mutually exclusive. States can legally define food fraud while continuing to enforce against some acts of seafood fraud under statutes addressing other areas of concern, such as food safety or fisheries management. Ultimately, these choices largely depend on state-specific determinations about how effectively an existing body of laws can respond to seafood fraud violations, the regulatory capacity to enforce those laws, and the magnitude of the problem.



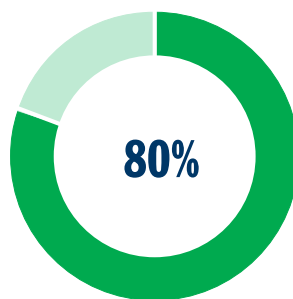
FRAUD IN THE SEAFOOD SUPPLY CHAIN

GLOBAL FISH AND SEAFOOD PRODUCTION TOPS 172 MILLION TONS ANNUALLY, divided nearly evenly between capture production (54 percent) and aquaculture (46 percent).¹⁵ Over one-third of all fish production enters international trade.¹⁶ In some countries, the imported seafood represents a much larger share of total consumption; in the United States, over 80 percent of all seafood comes from international supply chains.¹⁷

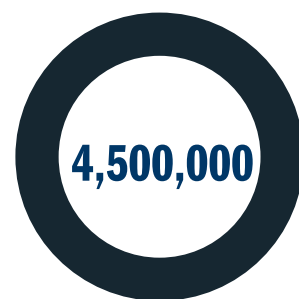
Reliable data documenting the extent of fraud in the seafood sector is difficult to obtain because many instances of fraud remain undetected. However, studies in multiple countries have uncovered high rates of mislabeled species of seafood in various markets.¹⁸ Data from these studies are difficult to compare due to differences in research methods, fish species, and type of market (e.g., restaurant or supermarket), but they show mislabeling rates ranging from 16.5 percent to 75 percent in US studies alone.¹⁹ European studies also showed a range of mislabeling rates, with some as high as those seen in the United States.²⁰ Due to the significant market size of the most common seafood products, even low rates of mislabeling can lead to large quantities of fraudulent seafood in the market.²¹



The amount of total fish production that enters international trade



The percentage of seafood in the US that comes from international supply chains



The approximate number of fishing vessels dispersed across the world



Studies show that in the US alone, between 16 and 75 percent of all seafood is mislabeled.

Seafood fraud implicates many policy concerns, including food safety and public health, consumer trust in the seafood industry and the corresponding regulatory agencies, the livelihood and viability of fishers who act in good faith, a country's international reputation as it relates to the global fishing industry, and ongoing conservation efforts and fishery management.

Among types of food fraud, seafood fraud is distinctive due to its implications for natural resource management. Fishing is one of the primary means by which human activity affects the health of ocean ecosystems.²² Consequently, tracking and managing fishing effort is critical to marine conservation efforts. Instances of seafood fraud that misrepresent catch data undermine attempts to build accurate models of fish stocks, which, in turn, undermines science-based fisheries management policies.

Categories of Seafood Fraud

Although seafood fraud always involves intentional deception for the purpose of gaining undue advantage, the deception can take many forms. Scholars and official sources have developed several different categorization schemes for characterizing and typifying the different forms of seafood fraud.²³ The authors of this report, informed by multiple categorization schemes, group seafood fraud into five categories. These categories were selected to capture different types of consumer deception about seafood attributes, rather than to identify all the specific fraudulent actions that could lead to consumer deception. The first two categories are forms of adulteration: species substitution and undisclosed processing methods. The remaining three categories involve deception related to the product's provenance: fishery fraud, IUU substitution, and ethical claims fraud. Each type of seafood fraud confers an economic gain on the fraudster, either by selling a lower quality product at a higher price²⁴ or by avoiding costs of legitimate production.²⁵

Species substitution is the replacement, in whole or in part, of the species identified on the product label with another species. One example of species substitution would be a whole filet labeled with the name of an incorrect, usually higher value, species. Another example might occur in a processed fish product labeled as one type of fish but including other species in addition to the one identified on the label.

Undisclosed processing methods capture forms of adulteration that do not involve the presence of unlabeled fish species. Instead, this type of fraud includes practices such as overtreating,²⁶ using excessive glaze water in frozen seafood,²⁷ using undeclared additives,²⁸ and short-weighting.²⁹

Fishery fraud refers to types of fraud that obscure a seafood product’s fishery or aquaculture farm of origin. One example would be mislabeling Atlantic salmon as Pacific salmon to obtain a higher price. Advertising farmed fish as “wild caught” is another example of fishery fraud. Fishery fraud also encompasses the practice of transshipping seafood products to obscure their origin, often to avoid duties on imported products. For a detailed discussion of transshipment, see [Box 2](#).

IUU substitution refers to the introduction into the value chain of seafood from illegal, unreported, or unregulated (IUU) fishing. This practice has significant overlap with fishery fraud. However, fishery fraud wrongfully augments the apparent value of otherwise legally obtained catch whereas IUU substitution often obscures prior illegal fishing activity.

Ethical claims fraud is a category that encompasses fraudulent labeling and advertising of claims relevant to consumers. This type of fraud takes advantage of consumers’ willingness to pay a premium for higher standards of sustainability, environmental protection, humane treatment of animals, or worker protections in the supply chain.



BOX 1. ILLEGAL, UNREPORTED AND UNREGULATED FISHING



SAMANTHA DELEO, UNSPLASH

Illegal,³⁰ unreported,³¹ and unregulated³² (IUU) fishing encompasses any fish illegally harvested, including undersized fish, fish caught in excess of quota limits or in areas closed to harvest, fish caught by unlicensed vessels, and fish misreported as a lower-value species.³³

Grouping illegal, unreported, and unregulated fishing into one category (IUU fishing) aims to capture all fishing activity not already captured through the official monitoring and reporting mechanisms that measure fishing activity worldwide. The category of IUU fishing is a useful concept for conservation purposes and for estimating economic activity. All types of IUU fishing introduce uncertainty into calculations of total fishing effort and fishery stock levels and may thereby undermine conservation efforts. However, illegal fishing is the most relevant of the three to concerns about seafood fraud. Nevertheless, because the three concepts are so frequently grouped together by policy makers, this report will generally use the broader term “IUU fishing.”

Although seafood fraud and IUU fishing are distinct offenses, the two concepts link together in several ways. First, some of the same seafood supply chain conditions create opportunities for both seafood fraud and IUU fishing. The complex and opaque supply chains that make fraud possible also obscure the origin of illegally caught fish. Price distinctions based on characteristics that are difficult for consumers to verify likewise enable both fraud and the sale of illegally harvested seafood.

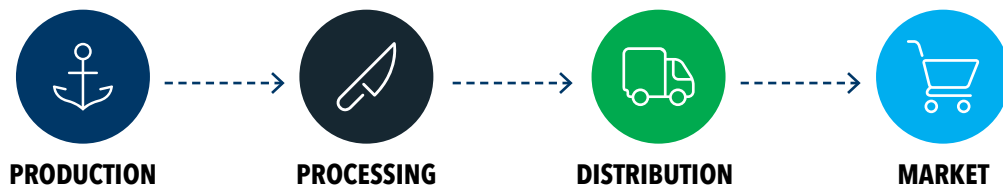
Second, fraud is sometimes employed to hide IUU fishing activity. For example, fraud can occur when seafood products are mixed during transshipment, “laundering” IUU seafood with legally caught product.³⁴

Third, the two issues are often grouped together in efforts to address them, using the same legal authorities or government agencies to tackle both problems.³⁵ For example, in 2014 the United States established a Presidential Task Force on Combating IUU Fishing and Seafood Fraud³⁶—a clear sign of the policy decision to treat the two problems jointly.

Opportunities and Drivers for Fraud Along the Supply Chain

A basic seafood supply chain consists of four key stages: production (capture or harvest), processing, distribution, and market.³⁷ Producers catch or farm fish; processors transform the raw product into any number of frozen, cooked, breaded, or other value-added products; distributors sell those products wholesale; and consumers purchase them at markets that include grocery stores and restaurants.³⁸

KEY STAGES OF A BASIC SEAFOOD SUPPLY CHAIN



Actual seafood supply chains are often more complex.³⁹ Farmed fish supply chains include earlier stages for hatching and raising the fish. The production or processing stage may include transshipment, the practice of aggregating the catch of multiple vessels at sea (see discussion in [Box 2](#)). There may be multiple processors or distributors before seafood gets to market. Adding additional complexity, many seafood supply chains are international in scope. Over one-third of global fish production enters international trade, with over half of seafood exports coming from developing countries.⁴⁰ A seafood supply chain may pass through a country of production, a separate country of processing, and a third for sale. In some cases, even domestically produced seafood is exported to another country for processing and reimported to the producing country.⁴¹ These complex and opaque supply chains give fraudsters multiple opportunities to intervene.

Opportunities and drivers for fraud exist at each stage along the seafood supply chain—production (including transshipment), processing, distribution (including importation), and market transactions. Drivers describe the circumstances that motivate supply chain actors to commit fraud whereas opportunities are the situations enabling them to execute fraudulent activities.



At the **production** stage, multiple drivers and opportunities for seafood fraud can influence fishers' actions. Drivers may include low or declining stocks of high-value species or the desire to obscure illegal fishing activity such as illegal catch methods or fishing in protected areas. Consolidation in fisheries may provide opportunities for fraud to go undetected (see discussion in [Box 3](#)). However, the greatest opportunity for fraud likely arises from difficulties monitoring fishing activity at sea.

Fishing occurs over wide geographic areas with both fishing vessels and their quarry continually moving. The worldwide fishing fleet comprises some 4.5 million vessels⁴² dispersed across the jurisdictions of coastal states and the high seas. Evidence suggests that some vessels disable their automated identification system (AIS) transponders to illegally fish in marine protected areas.⁴³ Transshipment provides additional opportunities for fraud, as mixing catch from multiple vessels can obscure the seafood's origin. This practice is of particular concern when used to mix the catch from IUU fishing with legally caught fish.⁴⁴



At the **processing** stage, supply chain actors face some of the same drivers to commit fraud: low supplies of high-value species and the desire to obscure illegal fishing activity in the supply chain. Processing introduces a new opportunity for fraud by removing morphological traits useful for identifying fish species, making it easier to substitute one product for another.⁴⁵ Consequently, highly processed products are more vulnerable to fraud due to their lack of identifying characteristics.⁴⁶ Like transshipment, processing is a point at which multiple catches and species may be mixed, including laundering illegal or undocumented catch into a legitimate supply chain. Processing locations may also be used to obscure the true origin of a catch, facilitating fishery fraud. Some producers process their catches at ports with limited oversight and then export them as products of that processing country.⁴⁷



The **distribution** stage includes importing seafood to its eventual country of sale as well as domestic distribution and wholesale. Drivers for fraud may include high demand for specific products or market price fluctuations of similar, substitutable products.⁴⁸ Cost avoidance in the form of avoided customs duties on imports is an additional driver for fraud. The key opportunity for fraud remains the complexity of the supply chain, making it difficult for wholesale buyers or regulators to trace a product back to its origins.



At the **market** stage, the product characteristics of seafood provide both opportunities and drivers for committing fraud. Distinctions among fish species are not readily observable to the consumer, particularly in the processed forms in which they often purchase seafood. Commentators note seafood is “a highly traded commodity with a very diverse range of closely related and visually similar species which undergo procedures and processing, reducing or eliminating the morphological traits used for identification.”⁴⁹ Consumers’ difficulty detecting differences between what they intend to purchase and the product they receive creates opportunities for fraud.

Additionally, seafood products command different prices based on characteristics or values that are not readily verifiable by the end consumer (e.g., catch method and geographic origin).⁵⁰ The lure of capturing this market price advantage without incurring the associated costs of compliance is an incentive to commit fraud. Some retailers (e.g., restaurants) may also be motivated by the need to appear to have a consistent supply of certain products even when supply fluctuates.⁵¹

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BOX 2. TRANSSHIPMENT




Transshipment is a practice in which small fishing vessels and vessels fishing far offshore offload their catches to a larger carrier ship while being resupplied with food, water, fuel, crew, and bait.⁵² While this process increases fishing efficiency, it can also obscure the origin of a vessel's catch, decreasing the transparency of the supply chain.⁵³

Transshipment is not illegal per se, but because it occurs in areas with decreased oversight it provides opportunities for illegal actions.⁵⁴ Transshipment may be used to avoid duties and other trade restrictions as well as contribute to the mislabeling of seafood products' country of origin.⁵⁵ Additionally, transshipment has been connected to crimes such as slave labor and drug and weapon trafficking⁵⁶—criminal activity that newly enacted US legislation, the Maritime Security and Fisheries Enforcement Act, aims to address.⁵⁷

Regional Fishery Management Organizations (RFMOs) and flag states—the state in which a vessel is registered—largely regulate transshipment, even though this practice often occurs in regions of questionable jurisdiction.⁵⁸ According to available automatic identification system (AIS) data, 35 percent of all observed transshipment encounters occur on the high seas—where oversight is sparse and lenient—off the coast of West Africa, in the southern Indian Ocean, and in the tropical Pacific, while 65 percent of transshipment encounters take place within nations' exclusive economic zones (EEZs).⁵⁹



TABLE 1. TYPES OF SEAFOOD FRAUD ALONG THE SUPPLY CHAIN⁶⁰

 PRODUCTION	Species substitution	<ul style="list-style-type: none"> • Fishers or aquaculture farmers mislabel species of seafood
	Fishery fraud	<ul style="list-style-type: none"> • Fishers or aquaculture farmers misrepresent the origin of seafood when landing the catch or harvesting farmed species • Falsifying traceability documentation
	IUU substitution	<ul style="list-style-type: none"> • Fishing in areas closed for harvest • Using illegal harvest methods • Using unlicensed vessels • Transshipping to flags of convenience
	Ethical claims fraud	<ul style="list-style-type: none"> • Mislabeling the catch method or type of production
 PROCESSING	Species substitution	<ul style="list-style-type: none"> • Removing morphological traits used to identify species creates an opportunity for fraud
	Undeclared product extension	<ul style="list-style-type: none"> • Using undeclared or banned additives to increase apparent quality • Using technology to misrepresent or artificially increase the perceived weight of seafood products
	Fishery fraud	<ul style="list-style-type: none"> • Mislabeling the origin of fish products • Mixing products of disparate origin or products lacking traceability documentation with traceable products
	IUU substitution	<ul style="list-style-type: none"> • Mixing legally and illegally sourced fish
	Ethical claims fraud	<ul style="list-style-type: none"> • Labeling and advertising with false product claims
 DISTRIBUTION	Species substitution	<ul style="list-style-type: none"> • Mislabeling fish as higher value species, especially under conditions in which retail establishment customers cannot readily ascertain the fish's species
	IUU substitution	<ul style="list-style-type: none"> • Laundering illegal seafood into the supply chain
	Fishery fraud	<ul style="list-style-type: none"> • Mislabeling or advertising seafood as coming from a superior value fishery • Mislabeling seafood to avoid border controls or customs duties
	Ethical claims fraud	<ul style="list-style-type: none"> • Labeling and advertising with false product claims
 MARKET	Species substitution	<ul style="list-style-type: none"> • Mislabeling fish as higher value species, especially under conditions in which consumers cannot readily ascertain the fish's species
	Fishery fraud	<ul style="list-style-type: none"> • Mislabeling or advertising seafood as originating from a fishery, farm, or geographic region with a superior reputation
	Ethical claims fraud	<ul style="list-style-type: none"> • Labeling and advertising seafood with false product claims (e.g., "dolphin-safe," "line caught")

Recognizing that seafood fraud is motivated by circumstantial drivers and enabled by opportunities in the supply chain does not excuse or minimize the wrongful acts that constitute it. However, acknowledging these factors enables policymakers to identify practical prevention measures addressing the root causes.⁶¹



Five mechanisms for preventing food fraud:

- 1 Increasing effort for offenders
- 2 Increasing the risk of detection
- 3 Reducing the rewards of fraud
- 4 Reducing the temptations to commit fraud
- 5 Removing excuses⁶²

Source: Lord et al.

Measures to increase transparency in the supply chain are attempts to increase the effort required for offenders to commit fraud.⁶³ Inspections and product verifications are examples of increasing risk of detection. High penalties reduce the rewards of fraud when perpetrators are caught. Reducing provocations refers to measures that “neutralis[e] organisational/market pressures” so potential fraudsters can profit from legitimate business instead.⁶⁴ Finally, removing excuses might occur through prescriptive rules for supply chain actors or through education about the harms of fraud.⁶⁵

Seafood supply chains are characterized by a lack of transparency, which creates significant opportunities and incentives for fraud. Traceability measures (discussed below) are one approach to incorporating greater transparency into supply chains. They also serve as a primary means of increasing the level of effort required to commit seafood fraud offenses.

Traceability Measures to Reduce Fraud Along the Seafood Value Chain

Traceability has traditionally been considered a public health tool for identifying disease-causing food items in the event of a foodborne illness. However, traceability also plays a role in mitigating fraudulent acts that do not implicate human health. Traceability systems address seafood fraud by minimizing opportunities for fraud in the supply chain.

Traceability systems link information to the physical movement of products through their supply chains.⁶⁶ The Codex Alimentarius Procedural Manual defines traceability (also called product tracing) as “the ability to follow the movement of a food through specified stage(s) of production, processing and distribution.”⁶⁷ Codex further identifies that traceability tools “should be able to identify at any specified stage of the food chain (from production to distribution) from where the food came (one step back) and to where the food went (one step forward), as appropriate to the objectives of the food inspection and certification system.”⁶⁸



Seafood traceability systems comprise multiple components.

- 1 The first component attaches data to logistic units of seafood through an identifier linking the logistic unit with the data. The most widely used identifiers for packaged products are barcodes.⁶⁹ This component ensures products can be individually identified.⁷⁰
- 2 Traceability systems must also maintain records of steps in the supply chain. GS1, a prominent international organization setting standards for traceability, refers to these steps as Critical Tracking Events (CTEs) and identifies eight key CTEs in seafood supply chains:⁷¹
 - initial packing
 - initial sale
 - receiving
 - processing
 - packing
 - aggregation
 - shipping
 - final sale to end consumer⁷²

Each of these steps generates records of transformations or changes that units of the product undergo.⁷³

- 3 Lastly, traceability systems need to allow for data sharing among system users. This component can be especially difficult in complex, international supply chains.⁷⁴ Consequently, interoperability of systems is a key consideration for achieving traceability of seafood products.⁷⁵ In addition to technical interoperability, policymakers should consider the importance of harmonizing traceability requirements across all jurisdictions in the supply chain. Transparency is compromised when traded commodities are subject to inconsistent traceability requirements in different countries.⁷⁶

One key consideration when developing a traceability system is determining how much of the supply chain should be subject to its requirements. In the United States, for example, the law does not require full-chain traceability ([seafood import monitoring program](#)).⁷⁷ However, countries that develop extensive supply chain traceability regulations can mitigate opportunities for fraud due to the increased perceived risk of detection at different points of the supply chain. Practically, these countries will need to consider the costs and feasibility associated with implementation, as well as the extent of the relevant regulatory body's legal authority over the supply chain.

Another key consideration for traceability systems is whether regulators or industry should be responsible for the system. Many seafood businesses have embraced traceability, sometimes due to regulatory requirements but also to “reduce liability through due diligence, protect brand integrity and company reputations, and ensure customers that their supply chains can be trusted.”⁷⁸ Third-party entities also play a role in establishing traceability regimes: in the US, GS1 and the National Fisheries Institute provide the industry with guidance.⁷⁹ Countries considering new regulatory traceability requirements should consider what traceability measures currently exist within the industry, as well as those mandated by other trade partners. (For more specific discussion of regulatory measures for traceability, see [page 27](#).)



LEGAL AND REGULATORY FRAMEWORK FOR PREVENTING, DETECTING, AND ENFORCING AGAINST SEAFOOD FRAUD

AS DISCUSSED ABOVE, the United States does not employ a definition-based approach to addressing the problem of seafood fraud—in other words, no single US law is specifically devoted to the issue. Instead, the US adopts a piecemeal approach through a broad array of laws and regulations to prevent, detect, mitigate, and penalize seafood fraud. The strength of this approach lies in its use of existing legal authorities and enforcement systems. However, existing legal measures are not tailored to the specific problem of seafood fraud. Without significant interagency cooperation and coordination, the mix of agency authorities and policy priorities creates the potential for regulatory gaps.

Policy makers have various tools to coordinate law and policymaking where multiple laws address the same issue. For example, in the US, the executive branch often develops national policies or strategies on certain issues to coordinate planning and implementation among laws and agencies. For seafood fraud, it created a Presidential Task Force on Combating IUU Fishing and Seafood Fraud to pursue a policy of “strengthening coordination and implementation of relevant existing authorities” to tackle seafood fraud.⁸⁰ In 2019, the legislative branch established an interagency working group on IUU fishing and seafood fraud representing 14 federal agencies.⁸¹ In the US, agencies often develop memoranda of understanding to clearly articulate the roles of each agency where laws create conflicting, overlapping, or redundant roles. For other states considering a piecemeal approach that does not rely on a single law administered by a single agency, an interagency approach allows regulators to consider multiple legal angles, while strong and meaningful interagency coordination established by executive order, legislation, or through agency-created agreements can efficiently address the complex nature of seafood fraud.

Key piecemeal legal approaches to seafood fraud can be broadly categorized into three main areas of focus: 1) transparency measures and traceability requirements; 2) food safety regulation; and 3) consumer protection law. Each of these legal approaches offers some promise as an effective means to reduce seafood fraud. To varying degrees, each approach increases effort for perpetrators, raises the risk of detection, or reduces the rewards of fraud.

Overview of US Regulatory Authorities

Because the United States does not define and address seafood fraud as an individual legal issue, its approach to seafood fraud is the result of an overlapping patchwork of laws with each assuming some role in preventing or detecting seafood fraud. This section will introduce the key laws and agencies that address aspects of seafood fraud in the United States.

Magnuson-Stevens Fishery Conservation and Management Act (MSA)

Fisheries regulation, although primarily targeted toward natural resource management, serves a role as part of a legal approach to seafood fraud. Measures to increase transparency in fishing activity for conservation purposes also contribute to transparency in the seafood supply chain.

The Magnuson-Stevens Fishery Conservation and Management Act (MSA) governs US fisheries.⁸² It mandates science-driven conservation management to maintain fisheries resources and the US seafood industry.⁸³ With a focus on preventing overfishing and replenishing overfished stocks, the MSA manages fisheries for both biological and economic sustainability.⁸⁴

The agency primarily tasked with implementing the MSA is the National Marine Fisheries Service (NMFS), an office within the National Oceanic and Atmospheric Administration (NOAA). (NMFS is also known as NOAA Fisheries.) Under the MSA, NMFS is tasked with conserving and managing domestic fisheries resources by implementing “sound conservation and management principles,” supporting the implementation and enforcement of international fishery agreements, establishing Regional Fishery Management Councils (RFMCs), protecting essential fish habitat, and encouraging the development of US fisheries.⁸⁵ NMFS also works alongside internationally established governing entities such as Regional Fisheries Management Organizations (RFMOs) on remote monitoring of fishing activity on the high seas.

The eight RFMCs work with NMFS to create regional fishery management plans including catch limits and region-specific management requirements.⁸⁶ RFMC members represent the commercial and recreational fishing sectors in tandem with environmental, academic, and governmental interests.⁸⁷

Federal Food, Drug, and Cosmetic Act (FDCA)

The Federal Food, Drug, and Cosmetic Act (FDCA) of 1938, as amended, is a set of federal laws authorizing the Food and Drug Administration (FDA) to regulate the safety and wholesomeness of food.⁸⁸ The FDCA addresses two main issues in its regulation of food products: adulteration and misbranding. Both are relevant to the risks associated with seafood fraud.⁸⁹ The FDCA grants FDA regulatory authority related to food safety, consumer protection, and (through the Food Safety Modernization Act, below) traceability. For these reasons, FDA is an important player in all the US legal approaches to seafood fraud.

FDA has discretion to use a variety of enforcement mechanisms. However, due to limited resources and FDA’s primary focus on consumer protection as it relates to public health, the agency typically reserves strong measures, including fines and criminal penalties, for violations that pose serious public health risks.

Food Safety Modernization Act (FSMA)

In 2011, Congress enacted the Food Safety Modernization Act (FSMA) as an amendment to the FFDCA to give FDA “a modern mandate and toolkit to improve the safety of the nation’s food supply.”⁹⁰ FSMA expanded FDA’s purview to include more process-based food safety measures and gave the agency the ability to regulate activities on farms for the first time. The explicit purpose behind FSMA was to prevent foodborne illness through recognition that it presents both a public health concern and a considerable threat to the economic vitality of the food system.⁹¹ Although FSMA’s traceability and prevention measures focus on food safety, they may also prevent and detect instances of seafood fraud.

Federal Trade Commission Act (FTCA)

The Federal Trade Commission Act (FTCA) created the Federal Trade Commission (FTC) and vested it with authority to regulate unfair and deceptive advertising practices.⁹² The FTC is a consumer protection agency. The FTC and FDA share jurisdiction over food product advertising, with FDA regulating labeling and the FTC regulating marketing. The FTC is a key agency in addressing seafood fraud because of its emphasis on consumer deception. For more on the Federal Food, Drug, and Cosmetic Act and the Food Safety Modernization Act, refer to the section discussing the [Food Safety Framework](#).

Key Piecemeal Legal Approaches to Seafood Fraud

The previous section introduced the key laws that provide the scaffolding for these approaches in the US. The subsequent three sections describe how each of the three types of regulatory approaches contributes to seafood fraud prevention and detection, using the United States regulatory framework as an extended example.





Traceability Measures and Transparency Along the Supply Chain

Seafood’s nontransparent supply chain creates many opportunities for fraud. Improving transparency and traceability along the seafood supply chain could manifest in several ways, such as remote monitoring of fishing activity, increased documentation requirements for domestic and imported seafood, and use of newer technologies like blockchain⁹³ and DNA barcoding. Traceability systems are one means to improve supply chain transparency and reduce opportunities for fraud. Industry and third-party certifiers are key innovators in seafood traceability, and their engagement with new technologies (discussed on [page 63](#)) may also influence the evolution of government traceability programs.

The following sections discuss a range of approaches to improving transparency within the seafood supply chain. The first addresses transparency measures in fisheries governance—making visible the fishing locations and levels of fishing effort⁹⁴ at the beginning of the seafood supply chain. The next three approaches represent a set of interrelated measures to ensure traceability and transparency, including improvements to information exchange (between regulators and industry, among domestic regulators, and internationally), traceability requirements for seafood products, and risk management measures. These approaches are discussed in the context of the US regulatory framework yet reflect priorities and concerns common to other states.⁹⁵

Transparency Measures in Fisheries Governance

Fisheries governance in the US focuses on fishery conservation and productivity rather than fraud reduction.⁹⁶ Even so, measures to improve fishery sustainability by emphasizing transparency can help reduce IUU fishing and seafood fraud by making it more difficult to mask a fish’s catch location.⁹⁷ Collecting data on fishing effort and location is useful both for managing fisheries and tracking fraudulent activity.

The primary federal law governing fisheries in the United States is the Magnuson-Stevens Fishery Conservation and Management Act (MSA).⁹⁸ Notably, the MSA does not explicitly address seafood fraud. However, while the overarching purpose of the act is to “conserve and manage the fishery resources found off the coast of the United States,”⁹⁹ NMFS’ regulations implementing the legislative directive give the agency a clear role in detecting and preventing fraudulent activity at sea. In addition, fisheries governance practices can affect the incentives to commit seafood fraud. For example, fishers may employ species substitution and mislabeling to hide noncompliance with the MSA’s overfishing prevention measures.¹⁰⁰

Regional Fishery Management Councils (RFMCs) establish management plans under the MSA. These plans must follow the National Standards for Fishery Conservation and Management¹⁰¹ and include measures to conserve fish stocks and require species-specific documentation.¹⁰² Conservation and management plans are location-specific and require data on fish stocks themselves, as well as details regarding fishing vessels and gear.¹⁰³ However, these practices—management plans, catch-share programs, etc.—can create loopholes for abuse if not implemented in a way that avoids consolidating a fishery or incentivizing mislabeled products (see discussion in [Box 3](#)).¹⁰⁴

RFMCs have the authority¹⁰⁵ and responsibility to ensure the catch-share programs they implement are not contributing to rapid economic, political, and supply chain consolidation such that fraudulent activity is incentivized or normalized.¹⁰⁶ Local-level input from small-scale fishers and sustainable fisheries advocates in the New England region has consistently urged the RFMC to adopt more stringent antitrust and anticonsolidation policies within the catch-share program.¹⁰⁷ Other measures to address the negative impacts of the quota system include community-supported fisheries, cooperative structures, direct-to-retail supply chains, and permit banks.¹⁰⁸

BOX 3: CAN FISHERY CONSERVATION MEASURES CREATE OPPORTUNITIES FOR FRAUD?

Regional Fishery Management Councils have implemented 17 **catch-share** programs since 1990.¹⁰⁹ Although these programs can be effective in meeting conservation goals, they may indirectly create opportunities for seafood fraud by creating incentives for consolidation and vertical integration in fisheries, which can undermine MSA reporting requirements that might otherwise detect seafood fraud.

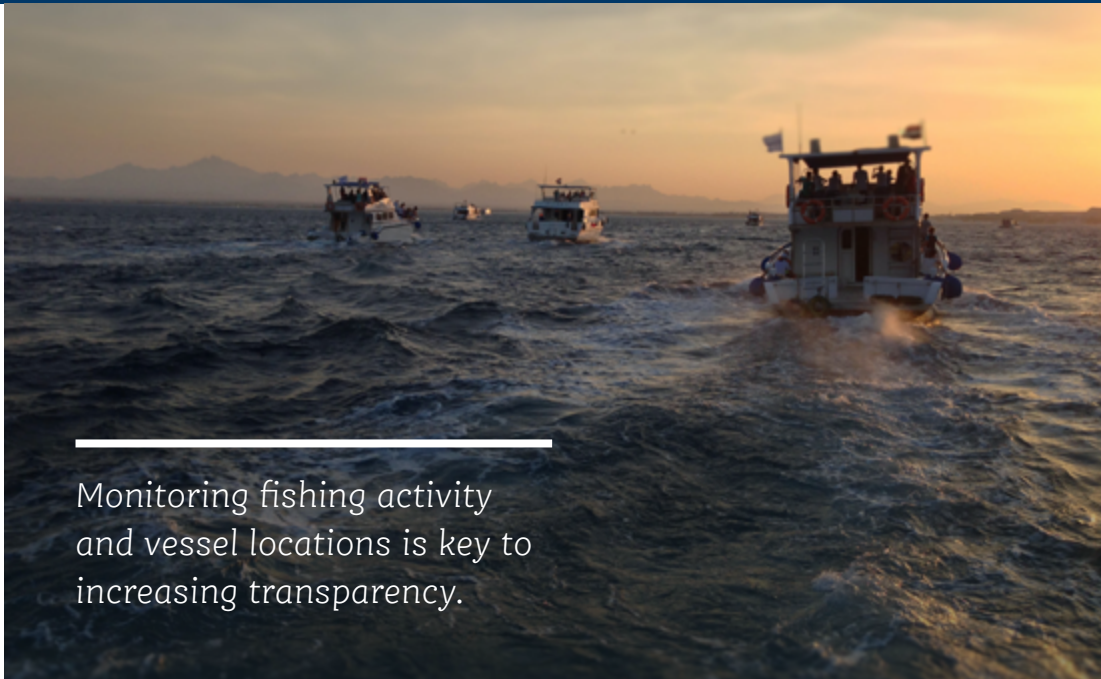
Catch-share programs establish an overall catch limit for a fishery, then divide the total catch amount into shares, giving rights to a certain portion of the overall catch limit to individual fishers, associations, or communities.¹¹⁰ Congress intended the catch-share system to reduce bycatch, extend fishing seasons, and most importantly, ensure that fishers would not surpass annual catch limits.¹¹¹ Catch-share programs have successfully curtailed overfishing, rebuilt fisheries, and improved economic performance.¹¹² Unfortunately, however, those gains have largely been at the expense of smaller fishers. In fact, as observed by Holland et al., these programs have been “implemented with an implicit, if not explicit, goal of reducing excess capacity through consolidation.”¹¹³

Rapid consolidation has occurred in at least 13 of the programs as of 2017, due to catch-share program implementation in combination with vessel or permit buybacks.¹¹⁴ When a catch-share system is established, the shares are divided up among local fishers based on their historical catch.¹¹⁵ This approach results in the largest fishers getting the largest shares.¹¹⁶ While the consolidation of shares increases economic efficiency, it can be detrimental to individual fishers and communities who lose access to fisheries and can prevent beginning fishers

from entering the industry.¹¹⁷ As a result, the industry becomes dominated by a handful of larger, wealthier owners who can then stockpile shares and rent them back to smaller fishers.¹¹⁸ In Alaska, for example, four companies own 77 percent of the rights to fish a single crab species in the Bering Sea crab fishery.¹¹⁹

As consolidation of fishing rights increases, the incentive to integrate vertically increases as well. Vertical integration of the fishery supply chain is concerning because it enables integrated companies to more easily commit fraud. For instance, in a 2017 case in New England, a fisher pleaded guilty to falsifying fish quotas, mislabeling species, tax evasion, and conspiracy related to more than 350,000 kilograms of fish.¹²⁰ The fisher amassed economic and political power in the region for decades, eventually owning over 15 percent of the shares and his own distribution company.¹²¹ NMFS requires both fishing vessels and seafood distributors to report species and weight of catches, among other metrics, to verify the supply chain.¹²² In this case, one company oversaw both the fishing and the distribution aspects of the supply chain in New England, allowing its owner to coordinate efforts among his staff to mislabel species and underreport his fleet’s catches.¹²³

The flipside to concerns of fraud from consolidation is that consolidation can also enable greater traceability in the supply chain because more supply chain activities occur under the control of one company. Provided that the company acts in good faith, simplifying the supply chain through consolidation makes it easier to track all supply chain actors.



Monitoring fishing activity and vessel locations is key to increasing transparency.

CHRIS DAVIS - UNSPASH

At the production stage of the supply chain, monitoring fishing activity and vessel locations is key to increasing transparency. Onboard monitoring of fishing activity can be conducted by independent observers or, increasingly, electronic monitoring equipment such as onboard cameras.¹²⁴ With either method, the monitor can track catch volume and composition, which reduces opportunities for the fisher to make fraudulent catch reports.¹²⁵ Remote monitoring systems such as the Automatic Identification System (AIS) and Vessel Monitoring System (VMS), which track vessel locations, can also be used to discourage and detect IUU fishing and seafood fraud. (For a detailed discussion of how the two systems work, see [Box 6](#).)

Remote monitoring systems collect information on vessel activity from periodic position reports. Regulators can use these reports to ensure that vessels are not fishing in non-permitted or environmentally protected areas.¹²⁶ By increasing transparency for conservation and natural resource management, vessel monitoring can also reduce the opportunity for fishers to engage in fishery substitution or IUU substitution.

The International Maritime Organization (IMO) Convention for the Safety of Life at Sea (SOLAS) requires ships to carry an AIS system sufficient to automatically provide information about the ship to other ships as well as coastal authorities.¹²⁷ Under domestic laws, remote monitoring requirements vary. For instance, in the United States, certain fishing vessels are required to use AIS Class A devices, which comply with the IMO standards,¹²⁸ while Canada exempts all fishing vessels from AIS requirements.¹²⁹ VMS requirements vary internationally and are often implemented by Regional Fisheries Management Organizations (RFMOs).¹³⁰

Data from remote monitoring systems is useful beyond monitoring the activity of individual vessels. Data sets compiled by these systems can be used to better understand global fishing activity.¹³¹ That information, in turn, can inform coordinated approaches to seafood fraud. However, data can be limited by technological difficulties (e.g., low satellite coverage, high vessel density), participation requirements (e.g., vessel size exemptions), or bad faith actors (i.e., fishing vessels that intentionally turn off their AIS transponders). In turn, opportunities for IUU fishing or seafood fraud arise when monitoring and tracking data are not actively collected.¹³²

Information Exchange Measures

The ability to share information among supply chain actors and regulatory bodies is an integral aspect of transparency—but it can be particularly challenging in complex international supply chains. Ports and borders add jurisdictional complexity to the task of maintaining information flow along the full length of the supply chain.

The US seafood import process primarily relies on three agencies, which coordinate to ensure imports are conducted efficiently, and that products are properly documented and meet US food safety standards. Customs and Border Protection (CBP) facilitates imports and exports, focusing on efficient information exchange and intercepting fraudulent shipments. Next, FDA has authority to inspect imports for compliance with US food and drug laws. To ensure and support compliance, NMFS offers a voluntary fee-based service to assist the fishing industry in meeting regulatory requirements.¹³³

The 2006 Security and Accountability for Every Port Act (SAFE Port Act) mandated all agencies requiring documentation for importation and exportation of cargo participate in the International Trade Data System (ITDS) to “eliminate redundant information requirements, to efficiently regulate the flow of commerce, and to effectively enforce laws and regulations related to international trade.”¹³⁴ ITDS allows businesses to submit this required information to agencies electronically through a single point of entry, or “single window.”¹³⁵ The ITDS aims to reduce the administrative burden of managing international trade.¹³⁶

The Automated Commercial Environment (ACE) is the primary import and export processing system for CBP. ACE serves as the “single window” for all international trade data, filings, and communications with relevant US agencies.¹³⁷ A 2014 executive order mandated the creation of the single window system to facilitate a streamlined import-export process by eliminating duplicative agency efforts.¹³⁸ For importers and regulators both, the single window system is designed to facilitate faster, more efficient communication.

Customs and Border Protection, under the authority of the Trade Act of 2002, the Customs Modernization Act of 1993, and the SAFE Port Act, is responsible for “detecting, interdicting, and investigating fraudulent activities intended to avoid the payment of duties, taxes and fees, or activities meant to evade the legal requirements of international traffic and trade.”¹³⁹ CBP works with 46 partner government agencies to implement ITDS, allowing agencies to receive data about shipments more quickly, process cargo more efficiently, and identify unsafe or prohibited cargo.¹⁴⁰

Port State Measures Agreement

International efforts to target IUU fishing through port security culminated in the Agreement on Port State Measures to Prevent, Deter, and Eliminate Illegal, Unreported, and Unregulated Fishing (PSMA).¹⁴¹ PSMA applies to fishing vessels “seeking entry into a port other than those of their own State”¹⁴² and attempts to ensure that no cargo from IUU fishing enters PSMA state ports.¹⁴³ Ideally, denying port entry to vessels carrying illegally harvested fish increases overall IUU fishing operation costs and removes the incentive to participate in this activity.¹⁴⁴



PSMA has increased information-sharing practices among domestic regulatory entities—including CBP, the US Coast Guard (USCG), FDA, and NMFS’ Office of Law Enforcement—ultimately enhancing the United States’ ability to combat IUU fishing.¹⁴⁵ This improved information exchange should also aid the agencies in detecting seafood fraud, particularly in the forms of IUU substitution and fishery substitution. Under PSMA, each foreign-flagged vessel seeking entry into the US is required to submit to the USCG, in advance of the vessel’s arrival, a notice of its intent to enter a US port, which is then relayed to NMFS for a decision on whether to authorize or deny port entry.¹⁴⁶ NMFS can deny use of the port if the vessel is listed as an IUU vessel; the vessel is undocumented “under the laws of another nation”; the fish on board the vessel were taken “in violation of foreign law or in contravention of any RFMO conservation and management measure”; or the flag nation failed to provide information to NMFS about the fish on board, among other information.¹⁴⁷

PSMA’s structure also increases information exchange among PSMA states. It relies upon importing vessels’ flag nations to provide information related to the legality of the catch.¹⁴⁸ If NMFS inspects a shipment, it shares inspection results with the vessel’s flag state for possible follow-up actions.¹⁴⁹ A limitation to this collaborative approach is that it requires the importing state to rely on a foreign state’s certification that the fishing activity on board a foreign vessel was not illegal, unregulated, or unreported. In some cases, the other state may not have the capacity to identify IUU fishing vessels or IUU catches.¹⁵⁰ Ultimately, under this scheme, if the paperwork submitted by the other state (whether it is a member of PSMA or not) meets the statutory criteria for authorization of entry,¹⁵¹ NMFS is obligated to grant entry regardless of whether the information is truthful.

Traceability Measures for Imported Seafood

Traceability systems link information to physical products in the supply chain, record steps in the supply chain, and allow data sharing among system users (see discussion of traceability in Part 3.3). Two of the key design considerations in traceability systems are how much of the supply chain will be subject to the traceability system and who will be responsible for implementation.

The United States developed a traceability program specific to seafood: the Seafood Import Monitoring Program (SIMP). In 2016, NOAA created SIMP through regulations in response to two recommendations of the Presidential Task Force on Combating Illegal, Unreported, and Unregulated Fishing and Seafood Fraud.¹⁵² SIMP was established under an import authority provision of the MSA, a fisheries law.¹⁵³ The bounds of that legislative authority limit the extent of SIMP's traceability systems in two key ways. First, SIMP applies to imported but not domestically produced seafood. However, when catch is harvested in the US and exported for processing, it is subject to SIMP upon reimportation from the processing country.¹⁵⁴ Second, SIMP applies to only part of the supply chain—from production to import—because the MSA does not grant the agency authority over the domestic distribution or marketing stages of the supply chain.

SIMP is a risk-based traceability program that requires (1) permitting, data recording, and recordkeeping, and (2) verifying the supply chain of seafood, from extraction or harvest to point of entry into the US.¹⁵⁵ CBP maintains the data portal for all imports under SIMP.¹⁵⁶ ITDS records data from the point of production to the point of entry into US commerce for fish and fish products known to be associated with IUU fishing or seafood fraud.¹⁵⁷ SIMP is envisioned to cover all fish species, but currently covers only 13 species that have been identified as high risk.¹⁵⁸ SIMP tracks the geographic origin of fish by collecting information on the harvesting entity,¹⁵⁹ the harvest event,¹⁶⁰ and the “importer of record,”¹⁶¹ also called the International Fisheries Trade Permit holder.¹⁶² Importers are responsible for linking each shipment to a harvest event.

This program is an example of a co-regulation approach, in which both private and government actors participate in governance, primarily through information exchange.¹⁶³ Policymakers designed SIMP “to shift the responsibility for preventing the import of IUU-sourced and misrepresented seafood to the supply chain itself.”¹⁶⁴ By collecting data directly from importers, SIMP enforcement relies on a government-to-business data collection framework.¹⁶⁵ By contrast, the EU catch documentation scheme uses a government-to-government approach, gathering enforcement data from the importer's flag state.¹⁶⁶ Each approach involves tradeoffs, including imposing different requirements on businesses that may import products into both markets.

SIMP is intended to be an efficient, flexible, and proactive enforcement tool.¹⁶⁷ Rather than relying on traditional reactive enforcement measures such as inspection programs, SIMP shifts enforcement burdens from government to industry.¹⁶⁸ However, a public-private partnership model still presents challenges. While importers can provide supply chain information efficiently through SIMP, greater efficiency may sacrifice a more holistic approach to fisheries and seafood fraud.¹⁶⁹ Additionally, increasing industry demands may place a greater burden on small producers that lack the infrastructure capabilities of larger producers.

BOX 4. INTERNATIONAL AGREEMENTS: REGIONAL FISHERIES MANAGEMENT ORGANIZATIONS

Regional Fisheries Management Organizations (RFMOs) are additional sources of traceability regulation in seafood.¹⁷⁰ Two RFMOs in which the United States is a member—the Commission for the Conservation of Antarctic Marine Living Resources (CCAMLR)¹⁷¹ and the International Commission for the Conservation of Atlantic Tunas (ICCAT)¹⁷²—operate under catch documentation schemes requiring that fish be traceable from harvest to port of entry.¹⁷³

Penalties for ICCAT violations include administrative penalties¹⁷⁴ and the possibility of forfeiture of fish.¹⁷⁵

CCAMLR requires that all toothfish imported to the US be accompanied by a *Dissostichus* catch document¹⁷⁶ detailing information about the harvest and transshipment procedures.¹⁷⁷ The US statute implementing CCAMLR does not provide criminal penalties for catch documentation scheme violations, but civil administrative penalties go up to \$11,000¹⁷⁸ and catches can be subject to forfeiture.¹⁷⁹ Forfeiture may be a more effective deterrent than administrative penalties because the loss of income can be substantial.¹⁸⁰

SIMP is not designed to detect and prevent all illegal fishing and other fraudulent activity at the port of entry. It is designed to detect missing or defective records. However, if a fisher produces the necessary paperwork for fish caught at the wrong time or with the wrong gear, SIMP would not necessarily identify those violations. In part, this is because importers are not required to be very specific in their documentation. For fish caught in areas beyond national jurisdiction, the importer need only report the general FAO-defined region¹⁸¹ where the fish were caught.¹⁸² Additionally, SIMP allows for bulk identification of fish, meaning that not every fish must be traceable to a particular harvest event.¹⁸³ As a result, harvest information may be too general to be useful in some instances.¹⁸⁴ SIMP also does not require reporting transshipment information,¹⁸⁵ which is known to be a major contributor to IUU fishing.

Additionally, SIMP faces several regulatory implementation challenges. For example, the MSA includes strict data confidentiality requirements to protect proprietary business information,¹⁸⁶ but these confidentiality measures make it difficult to share information among agencies and countries. To combat this challenge, Interpol¹⁸⁷ and enforcement personnel in the US and other countries use an exception that allows information sharing for enforcement purposes.¹⁸⁸

Notably, since SIMP regulation is implemented under the authority of an MSA provision specific to imports, agencies have control only up to the port of entry.¹⁸⁹ After seafood shipments make it through port, opportunities remain for fraud to occur during distribution and at the point of sale. Tracing seafood from port to plate would require legislation providing that authority to FDA as the responsible agency once seafood products are within national borders.

Forfeiture of catches may be a more effective deterrent than administrative penalties, because the loss of income can be substantial.

BOX 5. THE MARITIME SAFE ACT

The Maritime Security and Fisheries Enforcement Act (SAFE Act)¹⁹⁰ is a 2019 statute focused on increasing international cooperation and improving domestic IUU enforcement.¹⁹¹ The Maritime SAFE Act emphasizes coordination among domestic agencies and internationally within priority regions at high risk for IUU fishing activity.¹⁹² The Act establishes an interagency working group on IUU fishing and seafood fraud comprising 20 individuals from 14 different agencies including NOAA, the Department of Defense, the FTC, the Department of Justice, and CBP.¹⁹³ This working group is charged with facilitating and coordinating information-

sharing agreements and supporting the implementation of the Port State Measures Agreement.¹⁹⁴

The Maritime SAFE Act's priorities are combating IUU fishing and human trafficking in connection with seafood production,¹⁹⁵ rather than addressing seafood fraud. However, the measures it promotes—information exchange, traceability, coordination among regulatory bodies—should reduce opportunities for seafood fraud in the supply chain. Because the Act is so recent, implementation data is not yet available to determine how well these co-benefits of an IUU-focused approach will be achieved.

Risk Management Approaches to Transparency in the Food System

Regulators value transparency in seafood products to guarantee food safety, sustainable fisheries management, and consumer trust. Focusing on transparency through food safety regulation enables regulators to identify and remedy fraud before it reaches consumers, protecting them from health hazards they may otherwise be unable to avoid. Similarly, traceability regulations require those in the industry to be transparent, which promotes sustainable fisheries management and prevents repeat fraudulent activity.

The Food and Drug Administration (FDA) is the primary federal agency with authority over food safety, wholesomeness, and labeling in the US. Its authority extends to imported food.¹⁹⁶ FDA personnel, in collaboration with CBP, are on duty at most ports of entry into the United States.¹⁹⁷ Depending on the port, once a shipment has entered, the items may be managed by CBP or they may go to FDA for further inspection per a local FDA/CBP agreement.¹⁹⁸ FDA has authority to examine or sample the product, request “Notice of Import” documentation, detain the product, release the product, or ultimately refuse the product admission.¹⁹⁹

FDA uses **import alerts** to inform their field staff and the public that it has enough evidence to allow Detention Without Physical Examination (DWPE) for products that may be in violation of the FFDCAs.²⁰⁰ Categories of import alerts include those that are country- or area-wide, manufacturer/product specific, shipper specific, or country/worldwide.²⁰¹ The import alerts are also divided by color-coded lists to signify the likelihood of a violation and the reasoning behind the DWPE designation.²⁰² Products on the red list are always subject to DWPE based on the history of that product.²⁰³ Products on the yellow list²⁰⁴ are subject to “intensified surveillance,” while those on the green list²⁰⁵ are exempt from DWPE.²⁰⁶

BOX 6. IMPORT PROCESSES UNDER THE FOOD SAFETY FRAMEWORK

A prior notice of import is required for “all food for humans and other animals” that is intended for “use, storage, or distribution in the United States.”²⁰⁷ Per FDA’s regulations, if the imported food is arriving by water, then prior notice of imported food must be submitted to the agency by the importer “no less than 8 hours before arriving at the port of arrival.”²⁰⁸

If FDA decides to sample a product at a port of entry, the filer or importer receives a “Notice of Sampling.”²⁰⁹ If FDA does not sample a product, it notifies CBP and the filer or importer by issuing a “May Proceed” notice for electronic entries or a “Notice of Release” for paper entries.²¹⁰

If FDA decides to detain a product for further investigation, the agency provides the importer with a “Notice of FDA Action–Detained.”²¹¹ In response, the importer is expected to testify to FDA and propose relabeling or suggest other ways to bring the product into compliance within 10 working days.²¹² If FDA determines that the product is still in violation, or the importer fails to address FDA’s concerns, the agency will submit a “Notice of FDA Action–Refusal of Admission.”²¹³

Notably, FDA may detain products without physical examination when “there exists a history of the importation of violative products, or products that may appear violative, or when other information indicates that future entries may appear violative.”²¹⁴

Once a product has been detained by FDA, the agency must decide whether to release the product (“Notice of Release”) or ultimately refuse the product’s entry into the US (“Notice of FDA Action–Refusal of Admission”).²¹⁵ Typically, when an importer addresses the violations flagged by FDA, the agency may determine that the article can be released and will identify the product as “Originally Detained and Now Released.”²¹⁶ FDA has authority to refuse admission of a product if it is manufactured, processed, or packed under insanitary conditions; forbidden or restricted within the US; adulterated or misbranded under the FFDCA; or missing “notice of import” documentation.²¹⁷ The agency may also refuse admission if the importer does not respond to a detention notice or adequately relabel or recondition the product.²¹⁸



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FDA's import inspection authority is longstanding, but in recent years the agency has pivoted toward traceability as a more proactive risk management approach. FDA's ability to trace food products expanded in 2002, when Congress passed the Public Health Security and Bioterrorism Preparedness Response Act (Bioterrorism Act) to increase FDA's regulatory authority over imported food and protect the food supply against acts of bioterrorism.²¹⁹ Under this expanded authority, FDA developed two relevant regulations that required (1) prior notice of imported food²²⁰ and (2) food facility registration with FDA.²²¹

The Food Safety Modernization Act (FSMA) of 2011 further expanded FDA's authority to enact traceability requirements,²²² in part, by imposing additional requirements on registered food facilities. For example, food facilities must allow FDA to inspect the facility during reasonable times.²²³ Domestic or international²²⁴ fishing vessels that harvest and transport fish as well as those that engage in minimal processing are not required to register as food facilities.²²⁵ However, any fishing vessel that is engaged in processing²²⁶ fish must register as a food facility, making it subject to inspections.²²⁷ While FDA can hold any article from an unregistered foreign facility at the port of entry,²²⁸ fishing vessels exempt from registration requirements are not subject to this authority.

FDA's import inspection authority is longstanding, but in recent years the agency has pivoted toward traceability as a more proactive risk management approach.

In 2020, FDA released a Proposed Rule for Food Traceability which, if promulgated as written, will create new recordkeeping requirements for entities across the food supply chain.²²⁹ FDA proposed this rule pursuant to the Food Safety Modernization Act, which required the agency to both determine which foods should be subject to additional recordkeeping requirements

to protect public health and establish those additional requirements.²³⁰ Additionally, FDA developed a proposed Food Traceability List, which includes a set of foods the agency determined are high risk based on a draft risk ranking model.²³¹ Under the proposed rule, foods included on this list will be subject to the additional recordkeeping requirements to enable FDA to quickly identify and address credible public health threats.²³² FDA intends to finalize and publish the Food Traceability List at the same time it finalizes the Proposed Rule for Food Traceability.²³³

The proposed regulation requires individuals who grow, manufacture, create, process, pack, transport, ship, receive, or hold foods on the Food Traceability List to create and maintain specific records called **Key Data Elements (KDEs)**.²³⁴ KDEs are records that relate to **Critical Tracking Events (CTEs)**, or specific events along the food supply chain including growing, receiving, or shipping (see [traceability discussion](#)).²³⁵ Many types of seafood and food containing seafood ingredients, excluding catfish, are included on the Food Traceability List.²³⁶ Additionally, fishing vessels are included as regulated entities, but receive a partial exemption from some recordkeeping requirements.²³⁷ Fishing vessels would still be required to create or maintain some traceability records such as traceability lot codes, harvest date range, and harvest location for each fishing trip.²³⁸ Because this regulation has not been finalized, it is subject to change and its requirements are not yet enforceable.

Overarchingly, FDA's risk management and traceability measures are directed toward reducing food safety risk rather than detecting fraudulent food items unless the fraud presents a food safety risk. Nevertheless, the traceability infrastructure developed for the food safety regulatory framework may present co-benefits by increasing the level of effort for fraudsters to falsify product information.

Key Takeaways on Transparency and Traceability



Seafood supply chain transparency benefits multiple policy objectives beyond seafood fraud. The legal and regulatory frameworks addressing those objectives—fisheries conservation, port oversight, and food products traceability at a minimum—may create co-benefits for addressing seafood fraud. Policymakers should consider how best to coordinate among these frameworks to ensure their effectiveness at preventing seafood fraud.



Data collection is crucial to transparency, information exchange, traceability systems, and risk management. Whether supply chain data is collected for natural resource management, food safety, or other purposes, regulatory bodies should ensure that the data collection requirements are adequate for detecting and deterring seafood fraud as well. This may require interagency coordination on traceability program design.



Determining who bears responsibility for traceability data and information exchange is a crucial part of implementing transparency measures. Policymakers should consider the roles of domestic agencies, foreign governments, and industry. Different actors within the regulatory system may affect the system's efficiency, accuracy, or legitimacy. Actors also vary in their capacity to undertake extensive data collection. This consideration may be particularly important in considering the relative capacity of fishing companies, in particular smaller entities, and exporting state governments.



Food Safety Framework

Any seafood fraud not deterred or detected through traceability measures may affect consumers. Once seafood has reached the point in the supply chain where it is prepared or held for sale to consumers, efforts to combat fraud must come from food safety and labeling laws, consumer protection laws, or other measures like third-party certifications and verifications. Although food safety regulation does not primarily target fraud, it is the most comprehensive source of regulatory oversight for food products. Using food safety law to address food fraud is worth considering because of its extensive existing regulatory framework and because some instances of food fraud present food safety concerns. This section addresses opportunities to combat seafood fraud through laws and programs focused primarily on food safety.

In the United States, two federal administrative agencies exercise most of the regulatory authority over food safety: the Food and Drug Administration (FDA), housed within the Department of Health and Human Services (HHS), and the United States Department of Agriculture (USDA).²³⁹ USDA's Food Safety Inspection Service (FSIS) oversees safety and labeling of most meat and poultry.²⁴⁰ FDA enforces the safety, hygienic standards, and labeling of most food, except most meat and poultry.²⁴¹

Due to the jurisdictional split of product oversight between the two agencies, FDA regulates approximately 80 percent of the food supply, including most seafood products.²⁴² While specific mandates determine which processes and products both FDA and USDA regulate,²⁴³ the seafood category has considerable overlap. The US Congress identified food safety as a high-risk issue area due, in part, to this system of shared responsibility between FDA and USDA, which increases opportunities for fraud.²⁴⁴

Using food safety law to address food fraud is worth considering because of its extensive existing regulatory framework and because some instances of food fraud present food safety concerns.



FDA can also coordinate with other agencies on specific food safety issues. For example, FDA and the National Oceanic and Atmospheric Administration (NOAA) cooperate to conduct the National Shellfish Sanitation Program (NSSP). The NSSP promotes the sanitation of shellfish in interstate commerce and uniformity of state shellfish programs. These food safety measures provide additional oversight that may also increase risk for potential fraudsters. As a Congressional Research Service report notes, "[s]uch cooperative efforts may act as a further deterrent to fraudulent activities, or improve detection if fraud is occurring."²⁴⁵

Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act (FFDCA) is the primary food safety law in the United States. It prohibits two main categories of activity with respect to food: adulteration and misbranding. Through a recent amendment, the Food Safety Modernization Act (FSMA), the FFDCA also addresses safety-related risk reduction in food production.

Adulteration of Food Product

Adulteration of a food product refers to changes in the product's composition that may make it unwholesome or inferior in quality. Under the FFDCA, adulteration manifests in two main ways. The first is through exposure to or addition of a substance that creates an actual or potential health risk.²⁴⁶ The second form of adulteration involves the intentional addition of a substance to cause the food to appear to be of higher value than it is (**economically motivated adulteration**, or EMA). The FFDCA prohibits both types of adulteration, but this section focuses on adulteration presenting food safety risks. Economically motivated adulteration is discussed in [Consumer Protection](#).

Food Additives

One of the primary mechanisms in the FFDCA to address food safety risks is through the regulation of additives. Two forms of seafood fraud—overtreatment and short-weighting—deal specifically with substances added to seafood. The FFDCA defines a **food additive** as:

“any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use).”²⁴⁷

This provision is intentionally broad to include any substances used in packaging, transport, processing, preparation, and other processes that might either affect or migrate into food. Unlike most requirements in the FFDCA, the Act requires preapproval of food additives, which includes a safety assessment,²⁴⁸ before a manufacturer can introduce them into the food supply.²⁴⁹ Under this approval process, “the burden is on the manufacturer to prove the safety of the use of the substance” and “FDA must review and approve the proposed use before the additive can be used in food.”²⁵⁰ If a food product contains an unapproved food additive, the product can be deemed adulterated by FDA.²⁵¹ Some suggest this process is cumbersome for companies to undergo, as it can take years to obtain approval.²⁵²

However, there are two categories of substances exempted from premarket approval: (1) those that have obtained prior FDA approval; and (2) those that are “generally recognized . . . to be safe under the conditions of [their] intended use.”²⁵³ FDA's most recent regulation pertaining to substances generally recognized as safe (GRAS) created a voluntary reporting system allowing food companies to legally introduce food products containing added substances into interstate commerce after determining the substance has a “general recognition of

safety” without obtaining approval from FDA.²⁵⁴ Although the regulation is explicit in its call for companies to submit petitions for review when using a new substance they find to be GRAS, the process is entirely voluntary. Since GRAS substances are monitored through a voluntary notification system, rather than a legally binding petition system like that for food additives,²⁵⁵ there is an opportunity for unregulated substances to enter the seafood supply chain. If these substances go unreported, FDA may never know they have been introduced into the food supply. Internationally, by contrast, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) publishes standards for the safe use of food additives through the Codex Alimentarius.²⁵⁶ The only food additives included in Codex are those that are produced using defined good manufacturing practices and that present no health risk to consumers at proposed levels.²⁵⁷

Additionally, the GRAS list currently includes substances advocates argue should not be included.²⁵⁸ For example, FDA’s Center for Veterinary Medicine has approved drugs that can be legally administered to fish, which include ordinary substances like calcium chloride and carbon dioxide gas.²⁵⁹ However, recent petitions have called on FDA to eliminate carbon monoxide, which is used as an agent to retain the bright color of meat and fish, from its list of GRAS substances.²⁶⁰ Major US supermarket chains briefly refused to sell carbon monoxide-treated meats out of a concern for “ambiguous” safety information.²⁶¹ Some retailers preemptively sought permission from USDA to include a warning label on carbon monoxide-treated meats.²⁶² Industry producers, however, maintain that there are no scientifically established connections between carbon monoxide-treated meats and foodborne illness.²⁶³ There have also been cases of the addition of sodium polyphosphates to fish, which increases water retention, bulking the weight of the product.²⁶⁴

There have been cases involving the addition of sodium polyphosphates to fish, which increases water retention and bulks the weight of the product.



Food Safety Modernization Act (FSMA)

The Food Safety Modernization Act (FSMA) is a relatively recent addition to the food regulatory landscape. FSMA is an amendment to the FFDCA that aims to prevent foodborne illness through traceability and risk reduction measures. It reflects an evolution in US food safety law from a primarily reactive stance to a preventive approach. Food safety risks are typically unintentional and present public health hazards.²⁶⁵ FSMA addresses both unintentional food safety risks as well as intentional acts with the intent to harm, but does not directly address instances of food fraud where the motivation is solely economic. Therefore, any instances of fraud revealed through the measures required under FSMA become a priority for FDA when they present significant public health threats.

According to FDA, the agency's top priorities are those FSMA regulations that outline the "framework for industry's implementation of preventive controls" and strengthen the agency's ability to monitor and enforce them for domestic and imported food."²⁶⁶ Consequently, FDA identifies seven rules as "foundational," including the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food ("Preventive Controls Rule") and the Mitigation Strategies to Protect Food Against Intentional Adulteration ("Intentional Adulteration Rule"), which are most relevant to the issue of seafood fraud.²⁶⁷ Importantly, FSMA contains some exemptions for seafood processors given the recognition that FDA already required their compliance with the Seafood Hazard Analysis and Critical Control Points Program (HACCP).²⁶⁸

The Food Safety Modernization Act reflects an evolution in US food safety law from a primarily reactive stance to a preventive approach.

Preventive Controls Rule

When the US Congress enacted FSMA, it recognized that FDA had long used the Hazard Analysis and Critical Control Point (HACCP) system, a preventive controls solution used to analyze risks for fish and fishery products, along with other identified high-risk food products. FSMA generally requires entities registered as "food facilities" under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)²⁶⁹ to comply with the Preventive Controls Rule's Hazard Analysis and Risk-Based Preventive Controls (HARPC) program.²⁷⁰ The purposes of HACCP and Current Good Manufacturing Practices are to address "post-process contamination" issues to safeguard against unintentional adulteration, whereas HARPC mandates a set of preventive controls designed to detect risks or threats to the entire food supply chain and develop corrective measures that will prevent both unintentional and economically motivated intentional adulteration.²⁷¹ Consequently, HARPC is viewed as broader in coverage than HACCP. See [Table 2](#) for a comparison between the HARPC and HACCP requirements.

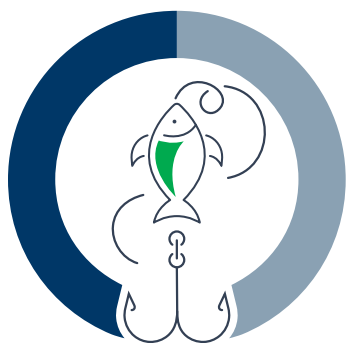
Specifically, FSMA's Preventive Controls Rule mandates implementation and monitoring of risk-based preventive controls, including requiring food facilities to implement a food safety plan based on existing hazard analysis and risk-based preventive controls that apply to seafood processors, among others.²⁷² Fishing vessels are exempt from food facility registration under the

Bioterrorism Act, making them exempt from most requirements under the Preventive Controls Rule unless they engage in processing on the vessel.²⁷³ Seafood processors are exempt from the Hazard Analysis and Risk Based Preventive Controls²⁷⁴ and the Supply Chain²⁷⁵ regulations if the processor is in compliance with the regulations pertaining to HACCP.²⁷⁶ However, seafood processors are required to comply with the general provisions,²⁷⁷ current good manufacturing practices (CGMPs),²⁷⁸ and records²⁷⁹ requirements under the Preventive Controls Rule.

Consequently, for seafood processors seeking to import to the United States, it is important to ensure compliance not only with the seafood HACCP regulations, but also the requirements under FSMA related to CGMPs and recordkeeping. For example, while the seafood HACCP regulations contain their own training requirements for personnel,²⁸⁰ managers must also ensure employees meet the training requirements²⁸¹ included in the Preventive Controls Rule. In nonbinding guidance, FDA advised that the CGMP requirements included in the Preventive Controls Rule generally align with the requirements seafood processors were already required to follow.²⁸² The additional requirements mandated for seafood processors under FSMA related to training, good manufacturing practices, and recordkeeping provide additional safety assurances, but also ensure traceability, which will enable better detection of fraud in the supply chain.

Intentional Adulteration Rule

In addition to the Preventive Controls Rule, FDA created a regulation entitled “Mitigation Strategies to Protect Food Against Intentional Adulteration,” which broadly applies to any domestic or foreign facility required to register as a food facility under the Bioterrorism Act.²⁸³ The stated purpose of the rule is to “protect food from intentional acts of adulteration where there is an intent to cause wide scale public health harm.”²⁸⁴ Its focus is on large companies whose products have the capacity to reach large numbers of people.²⁸⁵



While the rule’s emphasis is on food safety risks, many of the required measures would enable the detection of fraud unrelated to food safety as an ancillary benefit. For example, to comply with the rule, every covered facility²⁸⁶ must develop and implement a food defense plan that includes:²⁸⁷

- a vulnerability assessment, including required explanations, to identify significant vulnerabilities and actionable process steps;²⁸⁸
- mitigation strategies, including required explanations;²⁸⁹
- food defense monitoring procedures;²⁹⁰
- food defense corrective actions procedures;²⁹¹ and
- food defense verification procedures.²⁹²

FDA adopted a HACCP-type approach to intentional adulteration despite recognizing that the hazards presented by food safety and intentional adulteration may be different.²⁹³ Other entities refer to the approach FDA adopted here as a Threat Assessment and Critical Control Point (TACCP) plan. From FDA's perspective, the framework for preventing adulteration, whether it occurs intentionally or not, is the same and requires the same basic components: a hazard analysis to identify potential hazards and appropriate mitigation measures, implementation of the measures, and systematic analysis and assurance that the measures are working.²⁹⁴

Through research and consultation, FDA identified this approach as more effective than an approach targeted at good manufacturing practices, which might simply restrict access to the food facility, to combat the risk associated with an "inside attacker" likely to intentionally adulterate the food at actionable process steps.²⁹⁵ FDA identified inside attackers as those that present the highest risk for intentional adulteration.²⁹⁶ Again, while this rule is targeted at intentional adulteration with the intent to harm the public, FDA cites the organized nature of such attacks, which is comparable to intentional adulteration for the purposes of food fraud in the sense that such acts are unlikely to be committed by someone outside the facility.

The framework mandated under the Intentional Adulteration rule, with its requirements to assess vulnerabilities for specific points, steps, and procedures, enables a facility to identify fraudulent activity even where it is focused solely on economic gain. This approach comports with some of the recommendations based on empirical studies suggesting prevention measures should focus on increasing the barriers by "making it harder to adulterate food products or to hide frauds behind legitimate business practices" through increased transparency requirements and increasing the likelihood of detection through "routine surveillance."²⁹⁷

Hazard Analysis and Critical Control Point Program

In 2009, FDA and NMFS signed a memorandum of understanding to increase information sharing between the two agencies to increase effective enforcement of each agency's seafood importation regulations.²⁹⁸ The NMFS responsibilities under the agreement focused on maintaining a list of "processing establishments or vessels that have voluntarily contracted with NMFS for inspection services," called the List of Approved Establishments.²⁹⁹ In maintaining this list, NMFS agreed to cooperate with FDA by incorporating the HACCP and Current Good Manufacturing Practice regulation standards into NMFS inspection requirements.³⁰⁰ Further, NMFS agreed to refrain from adding or continuing to contract with processing establishments that have current or pending FDA violations.³⁰¹ In broad terms, NMFS agreed to share its inspection information with FDA to promote efficient enforcement.

As discussed above, FSMA permitted ongoing use of HACCP for seafood regulation rather than the mandated HARPC program implemented through the Preventive Controls Rule. FDA's regulations require that every seafood processor³⁰² "shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur."³⁰³ Seafood HACCP plans must be specific to the type of fish and fishery product that is processed to account for specific hazards associated with certain types of processing methods or certain species of fish.³⁰⁴

Traditional HACCP plans require no assessment of hazards associated with food fraud or intentional adulteration. Rather, HACCP is a science-based program focused on unintentional adulteration that presents food safety risks.

FDA requires seafood importers to demonstrate that the seafood has been processed in accordance with HACCP requirements either through an equivalence agreement showing the country's system is the same as or more protective than the US or written verification standards.³⁰⁵ Since the US has no equivalence agreements with other countries, seafood importers comply through written verification, yet the HACCP regulations do not require the importer to visit a seafood processor's facility to ensure they are implementing their HACCP plans.³⁰⁶

While there are similarities between the requirements under each of the programs, there are differences that may impact the detection of seafood fraud. Codex recommends use of a "HACCP-based approach wherever possible to enhance food safety" and many countries require compliance with HACCP principles as a prerequisite to import or sale.³⁰⁷ When developing a HACCP plan, the team conducts a hazard analysis which is focused on hazards "of such significance that they are reasonably likely to cause injury or illness if not effectively controlled" resulting in unintentional adulteration of the food.³⁰⁸ The major difference between a HACCP approach and the approach mandated by FSMA is that the former focuses on significant hazards that have the potential to result in unintentional adulteration of food products, whereas the latter focuses more broadly on overall risk, extending its requirements to a food processor's entire supply chain to include things like naturally occurring adulterants, intentionally introduced contaminants, and biological hazards.³⁰⁹ Significantly, when performing a hazard analysis under HARPC, individuals must consider hazards that can "reasonably occur," including hazards "intentionally introduced for economic gain (if they affect the safety of the food),"³¹⁰ which is not traditionally included in a hazard analysis under HACCP.

FSMA's inclusion of hazards focused on the introduction of a food safety risk due to fraudulent activity was considered a new requirement to traditional HACCP programs that would require specialized expertise, as well as consideration of the "raw material supply chain."³¹¹ However, FDA was clear that compliance with the Preventive Controls Rule required food safety plans to include hazards related to economic gain only insofar as they present a food safety risk.³¹² Traditional HACCP plans require no assessment of hazards associated with food fraud or intentional adulteration. Rather, HACCP is a science-based program focused on unintentional adulteration that presents food safety risks. Consequently, a significant limitation of the use of HACCP standards to minimize seafood fraud is their specific applicability to food safety hazards, as they fail to include risks of economically motivated adulteration unless the risks overlap, such as the addition of a harmful additive used to bulk the weight of a product or change its appearance. Given the breadth of the HARPC requirements and the need to consider intentional adulteration and fraud, regulators could consider HARPC as a regulatory approach in lieu of HACCP if concerned about fraud.

TABLE 2. DIFFERENCES BETWEEN THE HACCP AND HARPC PROGRAMS

HACCP ³¹³	HARPC ³¹⁴
<ul style="list-style-type: none"> ■ Hazard analysis including: <ul style="list-style-type: none"> • Locations where that processor processes fish products and each kind of fish processed³¹⁵ • List the types of food safety hazards reasonably likely to occur³¹⁶ ■ Critical control points (CCPs) including CCPs designed to control food safety hazards introduced in the processing plant and those introduced outside the plant "before, during, and after harvest"³¹⁷ ■ Critical limits ■ Monitoring procedures and frequency of monitoring³¹⁸ ■ Corrective actions ■ Verification procedures and documentation procedures 	<ul style="list-style-type: none"> ■ Hazard analysis ■ Preventive controls, including: <ul style="list-style-type: none"> • Process controls • Food allergen controls • Sanitation controls • Other controls (not described above, but necessary to ensure that a hazard requiring a preventive control will be significantly minimized or prevented) ■ Oversight and management of preventive controls, including: <ul style="list-style-type: none"> • Monitoring • Corrections • Corrective action • Verification ■ Supply chain program ■ Recall plan



Private Sector Initiatives

In addition to compliance with the food safety laws described above, the food industry may also obtain third-party certifications administered and enforced by the private sector. Some of these certifications may be required for entry into specific markets or retail sectors.³¹⁹ For example, in 2008, Walmart became the first US grocery retailer to require all of their private and some of their national brand suppliers to become certified by the Global Food Safety Initiative by demonstrating compliance with one of their recognized standards.³²⁰

The Global Food Safety Initiative (GFSI) is a private sector, industry led initiative developed to increase consumer trust “by improving food safety management practices.” Through a global community of public and private sector contributors with expertise in food safety, GFSI developed a set of requirements that benchmark different “international food safety standards against expert-derived, unifying food safety criteria.”³²¹ GFSI evaluates existing certification programs to verify they meet the benchmarking requirements and then officially recognizes them.³²²

In 2017, GFSI developed a set of requirements specifically focused on food fraud, adding three new elements to its benchmarking requirements that constitute a Vulnerability Assessment and Critical Control Point (VACCP) plan.³²³ In other words, it applies the HACCP principles to a food fraud incident. First, each organization is required to have a documented food fraud vulnerability assessment procedure.³²⁴ Second, the organization must “outline the measures the organization has implemented to mitigate the public health risks from the identified food fraud vulnerabilities.”³²⁵ Finally, the organization’s mitigation plan must be supported by its overall Food Safety Management System, meaning there should be separate assessments for food safety, food fraud, and food defense.³²⁶ In its technical document, GFSI recognized the concern that incorporating assessments for food fraud may interfere with the effectiveness of a food safety HACCP inspection.³²⁷ However, there was general agreement that while the consideration of food fraud in an overall food safety management system may impose additional requirements on auditors, it is beneficial because of the potential for food fraud to impact food safety and overall public health.³²⁸

PLAN TYPE	FOCUSED ON PREVENTING ³²⁹
HACCP	unintentional food adulteration
TACCP	malicious intentional adulteration
VACCP	intentional adulteration broadly

Private sector initiatives do not face the same political obstacles in implementing cross-border food safety requirements. However, because private sector initiatives are not subject to the same political process and public input, their effectiveness may be limited.

Private sector initiatives do not face the same political obstacles in implementing cross-border food safety requirements. However, because private sector initiatives are not subject to the same political process and public input, their effectiveness may be limited.³³⁰ Additionally, private standards are often created in the culture and context of a specific geography resulting in variable reception in different countries.³³¹ Food safety requirements that make sound scientific sense in the importing country may not be feasible, practical, or rational in exporting countries. Consequently, private standards may be more effective when developed using joint investment in infrastructure and information sharing with food-exporting countries.³³² Well-developed private governance structures may increase the marketability of food products from countries that depend on food exports.³³³

Key Takeaways on Food Safety



Food safety laws and regulations can increase transparency and traceability in the food supply chain and aid in the detection of food fraud generally. However, when considering seafood fraud specifically, a preventive controls system like the HARPC program, given its breadth, might be better suited to detect instances of seafood fraud. Unlike HACCP, it requires traceability measures for raw materials. While any traceability and recordkeeping measures have the potential to reduce instances of fraud due to increased surveillance, HARPC appears to be better suited to prevent seafood fraud due to its focus on the broader food supply chain and its increased scope of analysis to include vulnerability assessments to detect hazards from intentional adulteration.



As more companies demand GFSI certification, it is possible the HACCP program, through the incorporation of TACCP and VACCP analyses, may provide additional opportunities to detect seafood fraud. However, if law and policymakers are considering a framework to prevent seafood fraud, they may look to the VACCP and TACCP requirements created by GFSI in addition to the HARPC framework mandated by the Food Safety Modernization Act in the United States.³³⁴



Consumer Protection

Some of the known motivations for seafood fraud exploit consumer priorities and preferences. Mislabeled seafood can undermine a consumer's choice when evaluating market reputation, environmental sustainability, and nutritional or health differences among seafood options.³³⁵ For example, intentionally mislabeling a cheaper variety of seafood as a more expensive variety may deceive a consumer into spending more, thereby increasing profits for the retailer.³³⁶ Consumers may also choose not to purchase some varieties of seafood to avoid ingesting higher levels of heavy metals; mislabeled seafood could have serious unanticipated negative health impacts on these consumers.³³⁷

When it comes to seafood purchasing decisions, consumers have the most interaction with their local retailers.³³⁸ Further, retailers possess more knowledge about their procurement and marketing practices than consumers. Therefore, US consumer protection laws also hold retailers responsible for preventing mislabeled products from being offered for sale.³³⁹ Even if a retailer does not engage in fraudulent mislabeling, negligent and accidental mislabeling may ultimately have the same negative impacts on consumers. To encourage retailer diligence in purchases and marketing, consumer protection statutes hold retailers strictly liable for fraudulently, negligently, and mistakenly mislabeled seafood.³⁴⁰

This section discusses entities charged with consumer protection in the US, including those that exercise authority over some aspect of seafood labeling or advertising: two federal agencies (the Food and Drug Administration and the Federal Trade Commission), state governments, and the private sector.

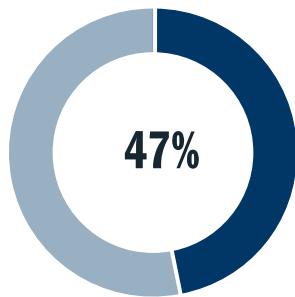
Food and Drug Administration

The primary purpose of the Federal Food, Drug, and Cosmetic Act (FFDCA) is to “safeguard and ‘protect’ consumers from exposure to dangerous products affecting public health and safety.”³⁴¹ However, many provisions in the Act are aimed at preventing consumer confusion and deception for economic reasons. As discussed in the previous section, the FFDCA prohibits adulteration related to safety, as well as adulteration which might deceive consumers. In addition, the misbranding provisions of the Act were included to require manufacturers and food producers to convey truthful, accurate, and uniform information to consumers, enabling them to make informed choices.

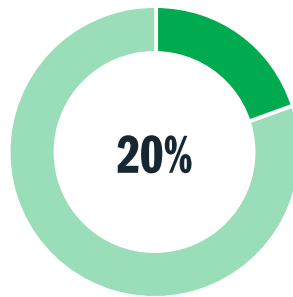
Economically Motivated Adulteration

Although the FFDCA does not use the phrase “economically motivated adulteration,” the Act prohibits the actions that constitute it. Most relevant to the context of seafood fraud, a food can be deemed adulterated when ingredients are substituted; imperfections are hidden; or substances are added to increase the product's weight, appearance, or overall value.³⁴²

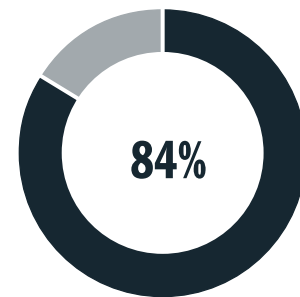
Many seafood adulteration violations relate to the substitution of one fish species for another. For example, a 2019 study surveyed 323 samples from 26 sushi restaurants in California over four years and found that seafood was mislabeled 47 percent of the time and that all samples of halibut and red snapper were mislabeled. A 2011 Consumer Reports investigation sampled



Percent of seafood mislabeled in a sampling of California sushi restaurants (2019 STUDY)



Percent of seafood mislabeled in a sampling of restaurants in NY, NJ, and CT (2011 CONSUMER REPORTS INVESTIGATION)



White tuna samples found to be a species of escolar, which can disrupt human gut functions (2013 STUDY)

190 seafood products from restaurants and retailers in New York, New Jersey, and Connecticut and found that one in five seafood samples were mislabeled.³⁴³ In a 2013 study, 84 percent of the white tuna samples collected were a species of escolar, which can disrupt human gut functions when eaten in excess.³⁴⁴

Most seafood fraud is likely to fall into the category of **economically motivated adulteration (EMA)**, which tends to be a lower enforcement priority for FDA. FDA has no official definition of “economically motivated adulteration” but did create a working definition of that term for a 2009 workshop:

fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production, i.e., for economic gain. EMA includes dilution of products with increased quantities of an already-present substance (e.g., increasing inactive ingredients of a drug with a resulting reduction in strength of the finished product, or watering down of juice) to the extent that such dilution poses a known or possible health risk to consumers, as well as the addition or substitution of substances in order to mask dilution.³⁴⁵

However, since legislators treat the two types of adulteration alike in the FFDCA, FDA addresses health-related and economically motivated adulteration under one statutory mandate. The predictable result is that FDA, as a public health agency, prioritizes addressing forms of adulteration that put public health at risk. In its response to a 2011 report by the Government Accountability Office (GAO),³⁴⁶ FDA countered GAO’s call for agency action on EMA by concluding that this type of adulteration is a “subset of cases within the broader concept of adulteration, and [FDA] believes that a holistic approach toward understanding and addressing adulteration is the best course forward.”³⁴⁷ Because EMA does not typically pose significant health risks, most types of seafood fraud are unlikely to be high enforcement priorities for FDA. However, violations of the FFDCA may be considered consumer deception under state statutes (see discussion on [page 53](#)), which would allow for other enforcement mechanisms to be used against seafood fraud violations.

Another reason FDA has not rigorously engaged in enforcement activities against EMA is that strict enforcement might be overly inclusive. Many ingredients consumers generally consider acceptable in packaged foods, such as color additives or preservatives, might violate a strict interpretation of the FFDCA's prohibition against adding substances to "make [food] appear better or of greater value."³⁴⁸ As a policy matter, FDA may reserve enforcement for only the most egregious violations of this section.

Despite a general lack of enforcement against EMA, FDA has taken steps to detect and deter seafood fraud, given the extent of the problem. To deter EMA by seafood producers, FDA developed a DNA-tracking system that uses DNA sequencing to identify fish species and location of harvest.³⁴⁹ The project, entitled **Fish SCALE**—Seafood Compliance and Labeling Enforcement—started in response to an outbreak of illness in 2007 connected to puffer fish, certain species of which can be toxic to humans.³⁵⁰

FDA developed a Regulatory Fish Encyclopedia (RFE), which is a list of "high resolution images of whole fish and their marketed product forms (e.g. fillets, steaks), as well as other taxonomic, geographic, and relevant tools for species identification."³⁵¹ There are currently 94 DNA sequences listed in the RFE, which FDA intends to update as it develops new fish profiles with this technology. The DNA barcoding identification system is fairly inexpensive for the agency to operate,³⁵² and if monitored regularly, can be very efficient in deterring bad actors in the seafood industry from engaging in adulteration. There are 20 trained analysts within FDA performing species-determination DNA tests nationwide.³⁵³

Misbranding

In addition to economic adulteration, the FFDCA prohibits **misbranding**. Misbranding includes **false or misleading** claims on food, drug, or cosmetic packaging, or any information used to supplement a statement regarding a regulated product.³⁵⁴ Labeling seafood as "wild caught" if it was farmed is an example of seafood misbranding. Food is also misbranded if it violates a standard of identity.

The FFDCA authorizes FDA to establish definitions and standards for food, commonly referred to as **standards of identity**.³⁵⁵ Food is misbranded under the FFDCA:

if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations . . . unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard. . . .³⁵⁶

The US Congress included this section in the Act to ensure product similarity in the marketplace, prevent confusion among consumers, set standards to maintain quality of food products, and fulfill consumer expectations. The Act directs FDA to promulgate rules establishing a standard of identity (or regulatory recipe) for any food it deems necessary and grants it the authority to condemn a food as misbranded if it does not conform to the standard of identity of that food.³⁵⁷ For example, to label a product as "canned Pacific salmon," the manufacturer can only include two additives: salt and "edible salmon oil comparable in color, viscosity, and flavor to the oil which would occur naturally in the species of salmon canned."³⁵⁸ Therefore, if a



manufacturer labels a product “canned Pacific salmon” and it contains any other additive—garlic powder, for example—the product would violate the standard of identity.

FDA has promulgated just nine standards of identity for seafood, some of which only link a common name to its scientific name, and some of which include very specific standards for packing and content requirements. These standards include Pacific whiting, bonito, crabmeat, Greenland turbo, canned oysters, canned Pacific salmon, canned wet pack shrimp, canned tuna, and catfish.³⁵⁹ The standard of identity for canned tuna is eight pages long and includes the scientific names for what is commonly known as tuna, as well as explanations of which species constitute different color designations, and when it is appropriate to label that the product is in vegetable oil versus water.

While some of the nine standards of identity are incredibly specific, they address few of the myriad species of seafood currently sold in the United States. In addition to the standards of identity, FDA also publishes the *Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce*, referred to as the *Seafood List*, which specifies the common name, scientific name, and acceptable market names of about 1,800 fish or shellfish. FDA updates the list every six months.³⁶⁰ While tuna, shrimp, and salmon are the most common seafood products in the United States,³⁶¹ concern remains about classifications of seafood that do not have coherent standards in federal regulations.

FDA also developed *Guidance for Industry: The Seafood List* to assist the seafood industry in using the *Seafood List* by defining categories and terms used in the *Seafood List* and providing general principles for properly naming seafood products.³⁶² This guidance provides specific information for understanding acceptable market names, common names, scientific names,

FDA has promulgated just nine standards of identity for seafood, some of which only link a common name to its scientific name, and some of which include very specific standards for packing and content requirements.

and vernacular names.³⁶³ The guidance outlines six labeling principles FDA uses in evaluating market names,³⁶⁴ which provide FDA's policy, decision-making rationale, and supporting regulations.³⁶⁵

FDA's *Compliance Policy Guide* provides guidance to FDA staff on determining Seafood List naming compliance.³⁶⁶ It specifically states the considerations for acceptable and suitable names, including how other labeling regulations affect Seafood List policies.³⁶⁷ It also includes descriptions of other seafood compliance policy guidelines including the Snapper Guidelines and Use of the Term Caviar.³⁶⁸ Finally, the *Compliance Policy Guide* provides general definitions for regulatory actions and specimen charges, such as misbranding and import refusal.³⁶⁹

Mislabeling a Fish Species Might Violate Other Labeling Requirements

In addition to general prohibitions on misbranding, the FFDCa contains several affirmative labeling requirements. Mislabeling a fish species might lead to a violation of one or more of these requirements for food.

The Food Allergen Consumer Protection Act of 2004, which amended the FFDCa, requires that food producers declare major food allergens on labeling.³⁷⁰ The Act specifies eight categories of major food allergens subject to the labeling requirement, including fish and crustacean shellfish.³⁷¹ For both fish and shellfish, the specific name of the species must be declared on the labeling.³⁷² Declaring the wrong species as an allergen in the food product is a violation of the allergen labeling requirement and thus a misbranding violation.

Mislabeling a fish species may also violate requirements for nutrient content claims. Nutrient content claims are representations about a food product on labels or labeling that characterize nutrient levels in the food (e.g., "high in calcium"). Nutrient content claims are prohibited as misbranding unless made in accordance with FDA regulations.³⁷³ Per FDA guidance, fish products may carry certain limited nutrient content claims related to omega-3 fatty acids.³⁷⁴ However, the levels of omega-3 fatty acids vary widely across fish species and depending on fish diets (i.e., wild versus farmed fish).³⁷⁵ Therefore, a fish incorrectly labeled as a variety with a high omega-3 fatty acid content might also violate requirements for nutrient content claims if the label bears a claim regarding nutrient content that is not correct for the fish species in the package.

Federal Trade Commission

The US Federal Trade Commission (FTC) regulates trade and consumer protection through rulemaking and enforces trade laws and regulations through adjudication.³⁷⁶ Through the Federal Trade Commission Act (FTCA), the FTC has broad authority to regulate trade practices and protect consumers from unfair and deceptive trade practices, such as false advertising and mislabeling.³⁷⁷ The FTC also drafts policy statements,³⁷⁸ industry guides,³⁷⁹ and advisory opinions³⁸⁰ to assist industries in compliance. The FTC does some consumer education, but FTC enforcement generally comes in the form of investigations and prosecution through the FTC's administrative law court.³⁸¹ Investigations may use several tools to secure compliance including civil penalties, injunctions, issuing policy statements, and recommending trade regulation rules.

Environmental marketing claims, including the use of third-party certifications, are expressly regulated by the FTC with a focus on preventing consumer deception.

The FTC may investigate and prosecute companies that engage in deceptive trade practices, including deceptive labeling. Environmental marketing claims, including the use of third-party certifications, are expressly regulated by the FTC with a focus on preventing consumer deception.³⁸² The Environmental Marketing Claim Guides apply to environmental statements on labels, advertisements, promotional materials, and “all other forms of marketing in any medium.”³⁸³ The guides provide general principles, specific guidance, and examples of common environmental claims.³⁸⁴ The FTC may take administrative action against those making environmental marketing claims that are deceptive and do not comply with the guides.

FDA and the FTC share jurisdiction over food product advertising in the United States. FDA regulates labeling, which is broadly defined; the FTC has authority over marketing, including fraudulent, deceptive, and unfair trade practices. The two agencies divide regulatory jurisdiction according to a 1971 Memorandum of Understanding (MOU).³⁸⁵

US State-Level Consumer Protection Measures

In the United States, state attorneys general are the primary enforcement mechanisms for state consumer protection statutes.³⁸⁶ In a consumer protection context, attorneys general represent the interests of their state’s individual consumers. For this reason, attorneys general are in a good position to advocate for comprehensive consumer protection initiatives, both in their state’s legislature and on a national scale. For example, after DNA barcoding revealed widespread fraud in the herbal supplements industry, a bipartisan group of fourteen state attorneys general called on the US Congress to launch a congressional inquiry into herbal supplements.³⁸⁷ Following this pressure, FDA created the Office of Dietary Supplement Programs and began the process of implementing “one of the most significant modernizations of dietary supplement regulation and oversight in more than 25 years.”³⁸⁸ State attorneys general could adopt a similar strategy by using their consumer protection powers to advocate for a comprehensive regulatory response to seafood fraud.

Some US states explicitly allow for individuals to bring consumer protection lawsuits against companies that engage in false, misleading, or deceptive advertising, including mislabeling. California is one US state with very broad consumer protection statutes. The California Unfair Competition Law (UCL) gives consumers the ability to bring lawsuits against companies that engage in unfair, unlawful, and deceptive business acts.³⁸⁹ California consumers were able to use the California UCL to enforce the state’s FFDCA equivalent, the California Sherman Food, Drug, and Cosmetic Law,³⁹⁰ against a salmon producer for misbranding.³⁹¹ The California Sherman Food, Drug, and Cosmetic Law has identical requirements to the federal Nutrition Labeling and Education Act of 1990 and allows California to enforce the same substantive requirements as FDA.³⁹² Using the UCL, consumers claimed that a farmed salmon manufacturer’s undisclosed

use of color additives constituted misbranding under California's FFDCa equivalent because it would have constituted a misbranding violation under the FFDCa, which requires disclosure of artificial coloring.³⁹³

California's Proposition 65 may also be a useful law, especially in conjunction with the UCL, to enforce accurate and transparent seafood labeling. Proposition 65 requires businesses to warn consumers if certain chemicals are present in their products at high enough levels to be dangerous.³⁹⁴ The state maintains a list of chemicals requiring disclosure including some found in seafood like cadmium and mercury.³⁹⁵ Proposition 65 may be another means of enforcing transparent seafood labeling by requiring producers to give accurate statements about the chemical contents of their products.

Key Takeaways on Consumer Protection



Consumer protection laws like those related to food at the federal level in the United States may not be a particularly effective tool for combating seafood fraud given the fact that the FFDCa does not give private citizens the right to sue to enforce the law. Without a private right of action, a consumer's only recourse is to alert the agency and hope the agency makes the violation an enforcement priority. However, given its limited budget and resources, FDA exercises a great deal of discretion in pursuing enforcement actions, taking a risk-based approach by focusing on issues of greatest public health concern. Because economically motivated adulteration does not typically pose significant health risks, most types of seafood fraud are unlikely to be high enforcement priorities for FDA.



Even for consumer protection laws with private rights of action, enforcement is a challenge. When consumers seek to challenge violations of the FFDCa, they do so at the state level in the US, as most states have consumer protection laws, with some being more protective of consumers than others. These cases, however, can be impractical for the average consumer to bring. Typically, the recovery is so minimal that an individual consumer would not challenge a company unless the violation presented significant medical issues or some other damage that would make litigation costs reasonable. Most consumer cases in this field are brought as class action lawsuits, which present a host of procedural challenges and are often not decided on the merits of the case.



Policymakers should consider the enforcement measures and remedies available under consumer protection law when using that avenue to address seafood fraud.



ENFORCEMENT OF SEAFOOD FRAUD PROHIBITIONS

ANY LEGAL MEASURES PROHIBITING SEAFOOD FRAUD or preventing it through risk reduction and traceability measures are most effective when routinely enforced. Key questions for policymakers include who will be responsible for enforcement and what legal mechanisms and resources are available to them. When developing legal measures, there are many elements to consider in determining who should exercise authority and how best to enforce the legal measures cost effectively.

Several legal design choices influence the decision on who may enforce seafood fraud law. Government agencies and law enforcement officers are the typical choices. However, laws can also allow for some measure of private enforcement through private causes of action, collective action, or incentive-based measures encouraging industry self-regulation. These choices implicate questions of who has the information and the resources to deter and detect seafood fraud.

Whether seafood fraud is defined as a crime, an administrative violation, or both, will affect enforcement efforts. Criminal sanctions typically carry higher penalties but also often require higher burdens of proof. From a fraudster's perspective, criminal penalties may be less likely to manifest, but more damaging if they do. In the United States, enforcement decisions are generally left to the discretion of the relevant agency unless the law has clearly mandated some form of implementation or enforcement. Other countries should consider how enforcement decisions are typically made in their local legal and policy context when determining how to address enforcement against seafood fraud.

In the United States, enforcement decisions are generally left to the discretion of the relevant agency unless the law has clearly mandated some form of implementation or enforcement.

Enforcement by Governmental Actors

Enforcement by governmental actors—either a regulatory agency or a branch of law enforcement—is the traditional legal approach. The effectiveness of government enforcement depends on a range of related factors, including the relevant agency’s legal authorities and enforcement tools, capacity, and priorities.

Authority and Enforcement Tools

A government agency must have legal authority to pursue enforcement against the violation of concern. Either the statutory offense of seafood fraud (defined to encompass the elements of intentionality, deception, and undue advantage) must fall within an agency’s enforcement jurisdiction or the acts that constitute seafood fraud (e.g., species substitution) must fall within an agency’s enforcement mandate.

Seafood fraud may fall under the purview of multiple agencies, depending on where in the supply chain the fraud is occurring. If different agencies regulate conduct at those various points, overlaps in mandates or gaps in authority are likely. One means to address this concern is to identify a lead agency responsible for coordinating an interagency strategy addressing seafood fraud.³⁹⁶

The physical extent of an agency’s jurisdiction is also a critical consideration as it may be limited at multiple points along the seafood supply chain. At sea, the United States Coast Guard (USCG) enforces federal laws,³⁹⁷ including fishers’ obligations under fishery management plans. The USCG has authority to board fishing vessels; examine their paperwork, permits and gear; inspect their activities; and in some cases seize catches or vessels.³⁹⁸ Violations of federal law are forwarded to the National Marine Fisheries Service (NMFS) for further enforcement action.³⁹⁹



BOX 7: REMOTE MONITORING OF FISHING ACTIVITY: AIS AND VMS

Remote monitoring systems such as the Automatic Identification System (AIS) and Vessel Monitoring System (VMS) can be used in conjunction with on-the-water patrolling as a way to ensure fisher and vessel safety and to discourage and detect IUU fishing and seafood fraud. Under an AIS system, the vessel's onboard transponder automatically broadcasts a signal once every few seconds with the vessel's identity, location, position, speed, and direction.⁴⁰⁰ This data is publicly available and is monitored by the US Coast Guard.⁴⁰¹ AIS was originally designed as a safety measure for vessels to avoid collisions at sea.⁴⁰² While many countries use AIS for monitoring fishing activity, vessel-specific requirements vary significantly. For instance, in the United States, certain fishing vessels are required to use AIS Class A devices, which comply with International Maritime Organization standards,⁴⁰³ while Canada exempts all its fishing vessels from AIS requirements.⁴⁰⁴

By contrast, VMS is a closed-source tracking system that monitors the location and movement of commercial fishing vessels via satellite-based communications from onboard transceivers.⁴⁰⁵ Domestically, its purpose is to

"monitor compliance, track violators, and provide substantial evidence for prosecution"⁴⁰⁶ for agencies such as NMFS that uphold provisions within fisheries law, the Lacey Act, and other laws protecting marine wildlife and habitats.

In the US, the VMS program currently monitors more than 4,000 vessels, the largest national monitored fleet in the world.⁴⁰⁷ Onboard transceivers send position reports that include vessel identification, time, date, and location, all of which is monitored by NMFS.⁴⁰⁸ Vessels typically send position reports every hour but increase how frequently they report as they approach environmentally sensitive areas.⁴⁰⁹ Position reports are an essential tool to ensure that vessels are not entering environmentally protected areas nor fishing in prohibited areas.⁴¹⁰ By tracking vessel movements, NMFS enforcement officials receive notifications of activity within the exclusive economic zone (EEZ),⁴¹¹ and can use this information to detect IUU fishing and seafood fraud in addition to monitoring compliance with conservation and management plans.

In the US, the Vessel Monitoring System currently monitors more than 4,000 vessels, the largest national monitored fleet in the world.



The Food and Drug Administration (FDA) has enforcement authority over domestic seafood and imported products. FDA has many enforcement tools available. FDA enforcement usually starts with a warning letter to the regulated entity. Warning letters are posted publicly online. They do not create direct legal consequences but can cause reputational damage

and sometimes act as a catalyst for consumer class action lawsuits under state consumer protection laws. FDA can also inspect registered food facilities, although such inspections tend to be infrequent and based on risk analysis.

Because FDA and NMFS have overlapping jurisdiction related to fish and fishery product inspections, the two agencies developed a Memorandum of Understanding (MOU) to develop methods of “cooperation and information sharing.”⁴¹² Specifically, under the MOU, FDA agreed to (1) maintain guidance documents regarding Current Good Manufacturing Practices and HACCP to assist NMFS in identifying violations; (2) notify NMFS of enforcement actions against fish or fishery product establishments; and (3) invite and include NMFS inspectors and personnel in FDA inspections, trainings, and discussions as they relate to fisheries.⁴¹³

FDA can remove food from the marketplace if it violates the Federal Food, Drug, and Cosmetic Act (FFDCA). FDA has the authority to seize and condemn food products that have been adulterated or misbranded, thereby preventing them from entering interstate and international commerce.⁴¹⁴ The agency can issue a mandatory recall if it finds “reasonable probability” of adulteration or misbranding, *after* providing an opportunity for a voluntary recall.⁴¹⁵ FDA can hold food in administrative detention and can order the seizure of food by US marshals or other government employees.⁴¹⁶

FDA can also prevent entities from engaging in food commerce. Withdrawal of facility registration is a new enforcement tool under the Food Safety Modernization Act (FSMA).⁴¹⁷ Through the Department of Justice, FDA can initiate an action for injunctions for violations that are likely to continue or recur.⁴¹⁸ These are often resolved with consent decrees with the regulated entities rather than through a full adjudicative process. FDA can also bar individuals from importing food if they have previously been convicted of a felony relating to food imports.⁴¹⁹

FDA has authority to level civil penalties up to USD 1 million; however, penalties this high are rarely used for food producers. FDA can also pursue criminal prosecution of individuals under the *Park doctrine*⁴²⁰ (also called the *responsible corporate officer doctrine*). However, it is unclear whether that authority extends to issues not related to food safety, like economically motivated adulteration. The FFDCA is a strict liability statute, so the violator’s intent to engage in seafood fraud does not need to be proved.⁴²¹

Capacity and Priorities

When agencies have discretion to prioritize among a broad range of enforcement responsibilities, some violations are likely to receive more enforcement effort than others. Additionally, agency capacity—funding, personnel, and other resources—influences enforcement effectiveness.

FDA has regulatory responsibility for over 80 percent of the nation’s food supply, but the agency’s resources do not match that broad mandate.⁴²² Consequently, FDA exercises a great deal of discretion in pursuing enforcement actions. The agency takes a risk-based approach, focusing on issues of greatest public health concern. Because economically motivated adulteration does not typically pose significant health risks, most types of seafood fraud are unlikely to be high enforcement priorities for FDA. However, violations of the FFDCA may be considered consumer deception under state statutes (see discussion on [page 53](#)), which would allow for other enforcement mechanisms to be used against seafood fraud violations.

FDA and the Federal Trade Commission (FTC) share jurisdiction over food product advertising in the United States (see discussion on [page 52](#)). The FTC enforces the Federal Trade Commission Act (FTCA) through a variety of administrative and legal enforcement mechanisms (see [Table 3](#)). However, its main enforcement tool is litigation, so the FTC is likely to exercise its enforcement discretion by seeking out a few serious offenders and building cases against them, rather than admonishing every minor infraction of the statute. By contrast, FDA uses warning letters as a key enforcement tool. FDA sometimes posts a batch of warning letters to several companies at once to address a particular issue.⁴²³ The agencies can also conduct joint enforcement efforts, such as issuing joint warning letters to indicate an issue’s importance to both agencies. Sending a batch of joint warning letters to seafood companies selling mislabeled products would send a message to the industry that further enforcement actions might follow.

TABLE 3. COMPARISON OF FDA AND FTC ENFORCEMENT MECHANISMS

	FDA	FTC
Administrative Enforcement Mechanisms	<ul style="list-style-type: none"> • Regulatory meetings⁴²⁴ • Warning letters⁴²⁵ • Public notices • Import alerts⁴²⁶ 	<ul style="list-style-type: none"> • Civil investigative demand (CID) • Confidential investigations • Disgorgement • Monetary penalties
Legal Enforcement Mechanisms	<ul style="list-style-type: none"> • Product seizure • Injunction • Civil penalties • Criminal penalties 	<ul style="list-style-type: none"> • Asset freeze • Temporary receivership • Temporary restraining order • Injunction • Civil litigation

In addition to its different jurisdictional mandate, the FTC also takes a somewhat different approach from FDA to misrepresentations about food. Because FDA focuses more heavily on public health than consumer deception, economically motivated adulteration and misbranding without significant public health impacts are not top priorities for the agency. The FTC, by contrast, focuses on consumer deception and is interested in the truth of advertising claims that are material to many customers. For example, the FTC is likely to closely scrutinize weight loss claims about food, which are relevant to many consumers, even though a product with a false claim would be unlikely to have adverse health impacts on consumers. Whereas FDA promulgates extensive regulations about the form of labeling claims (e.g., claims on labels must use appropriate phrasing), the FTC focuses less on the form an advertising claim takes and more on the substantiation behind any claims.⁴²⁷ For seafood fraud to become an FTC priority, the seafood advertising in question would likely need to be untrue and material to a significant number of consumers.

BOX 8. SUBNATIONAL GOVERNMENTAL ENFORCEMENT

Subnational governments in some countries may have enforcement capacity additional to what the national government can provide. In the US, state-level FDCA statutes authorize state officials to enforce violations, rather than relying on FDA to inspect food facilities. FDA's relative lack of resources along with its broad regulatory authority have resulted in the federal agency performing inspections of any individual facility very infrequently. Therefore, US states implementing their own authority to enforce misbranding and adulteration standards may be more effective.⁴²⁸ Although they might create no additional legal requirements for food producers, state-level replicas of the Federal Food, Drug, and Cosmetic Act are

important in ensuring safety in the food system because they provide additional enforcement mechanisms and personnel. For example, New Hampshire state law gives authority to state officials to embargo and condemn misbranded or adulterated food items.⁴²⁹ Similarly, the law in the state of Oregon allows the state to dispose of adulterated, misbranded, unsound, or unsafe food or consumer commodities.⁴³⁰ States can also increase enforcement by creating enforcement bodies specifically targeting seafood fraud. The state of Louisiana's Seafood Safety Task Force, created in 2010, has increased inspection frequency for fish products and tests for contaminants or additives in imported seafood.⁴³¹

Enforcement by Nongovernmental Actors

In addition to enforcement measures undertaken by governmental entities, private enforcement mechanisms can address the issue of seafood fraud. For states with limited resources to fund agency implementation and enforcement, reliance on nongovernmental actors with some degree of governmental oversight to prevent against corruption and malfeasance can be an effective means to deter and identify instances of seafood fraud.

Food Label Certifications

Voluntary certification schemes aimed at promoting sustainable global seafood production through a consistent set of supply chain rules and standards have been touted as a promising complement to traditional modes of public governance, which may have significant regulatory gaps.⁴³² Since regulatory authorities often lack capacity and choose not to prioritize issues of food fraud that do not present a corresponding public health concern, voluntary certification programs administered by actors outside of government provide an additional means of detecting and preventing seafood fraud.

Many of these certifications are reflected on the food label as a means of encouraging consumer purchases in sustainable seafood. As discussed above, in the United States, food product labels are regulated primarily by FDA and USDA. Some of the information presented on a food label is required by law or regulation while other food label claims are voluntary and included primarily for marketing.⁴³³ Some voluntary claims in the US are also defined through regulations—e.g., “good source of ALA”—while others are not. The USDA requires preapproval of many voluntary label claims included on food products, including a demonstration of compliance.⁴³⁴ In addition, some government agencies provide fee-based certification services that allow producers to include the certification on the product label.⁴³⁵ Finally, another category of claims is independently verified through third-party certifiers. Importantly, regardless of whether the claim is overseen by the federal government, all statements on food product labels must comply with the general requirement that they be truthful and not misleading.⁴³⁶

TABLE 4. COMPARISON OF LABEL REQUIREMENTS UNDER USDA AND FDA

US Agency	Label Requirements
United States Department of Agriculture	Product name, inspection mark, establishment number, safe handling requirements, net weight, ingredients, nutrition information, and handling statement.
Food and Drug Administration	Name of the food, net weight, nutrition information, and ingredients.



CHOOSE
THE
BLUE FISH



From 2003 to 2015, seafood certified as sustainable, including both wild caught and farmed fish, grew from 0.5 percent to 14 percent of global production, outpacing the growth of global seafood production.

Most food labeling certification programs are voluntary and administered by industry, the retail sector, independent nongovernmental organizations, or through partnerships between these various groups.⁴³⁷ Ensuring compliance with these programs varies depending on the program. Some rely on self-enforcement by producers whereas others are verified by a membership organization or independent third party.⁴³⁸ While compliance with these certifications is generally not overseen by the federal government in the United States, the USDA's Process Verified Program (PVP) allows producers to submit their standards for consideration to the agency and once USDA grants approval of those standards, it then conducts an audit to ensure the company is following its own standards.⁴³⁹

In the seafood context, some of the main drivers of certifications are food safety, IUU fishing, sustainability, and misleading labeling. In the United States, NMFS provides fee-based certifications that assure regulatory compliance in addition to "seafood production best practices."⁴⁴⁰ Relatedly, some of the most common independently verified seafood claims address sustainable production practices. The Marine Stewardship Council (MSC) is an independent nonprofit that provides certifications focused on the "environmental sustainability of wild capture fisheries" by evaluating individual fisheries to consider the sustainability of the populations being targeted, the impact of their activities on other habitats and species, and the efficacy of their management practices.⁴⁴¹ Similarly, the Aquaculture Stewardship Council is an international, independent nonprofit providing certifications ensuring that farms practice responsible aquaculture by considering "key environmental impacts," protections for workers in the supply chain, and the surrounding communities.⁴⁴²

Researchers estimate that from 2003 to 2015, seafood certified as sustainable, including both wild caught and farmed fish, grew from 0.5 percent to 14 percent of global production, outpacing the growth of global seafood production.⁴⁴³ This growth has largely been attributed to corporate sustainability commitments and increased access to markets rather than consumer preferences or brand distinction.⁴⁴⁴ One of the major challenges associated with food label certifications is their sheer magnitude. According to the Ecolabel Index, a global directory of ecolabels, there are currently 457 different ecolabels across 199 countries representing 25 different industry sectors.⁴⁴⁵ An additional challenge is that ecolabeling certification schemes can further restrict market access for developing countries attempting to navigate a maze of standards for different markets.⁴⁴⁶ Specifically, FAO's *Guidelines for the Ecolabeling of Fish and Fishery Products from Marine Capture Fisheries* recognize that financial and technical assistance, training, and technology transfer may be necessary for developing countries to participate in ecolabeling schemes, and less sophisticated data gathering methods should not preclude certification so long as the fishery can demonstrate good management performance.⁴⁴⁷ For

seafood, FAO recognizes two types of certifications, each of which requires its own assessment: (1) certification of the fishery's conformance with specific standards, and (2) certification of the chain of custody from harvest to market to ensure identification measures along the supply chain are adequate.⁴⁴⁸

FAO has played a significant role in developing consistency through minimum sets of standards, as have the International Social and Environmental Accreditation and Labelling Alliance (ISEAL), the International Organization for Standardization (ISO), the International Trade Centre (ITC), and the Global Sustainable Seafood Initiative (GSSI). Traceability and segregation are key to ensuring compliance with certification schemes. Consequently, many certification schemes have Chain of Custody (CoC) requirements either as a specific part of the system or as an independent standard. For example, a fishery can be certified under the MSC standard, but unless it also pursues CoC certification, it is not able to use the MSC label or even reference its MSC certification to customers. Documenting the CoC requires listing all individuals and entities taking ownership of the product throughout the full supply chain.⁴⁴⁹ Standards for CoC vary depending on the certification scheme in place leaving commentators to question whether CoC requirements provide the necessary levels of supply chain transparency to fulfill their goal.⁴⁵⁰

Given the wide variation in certification schemes—their focus, verification, and auditing procedures, etc.—there have been instances of fraud related to the use of certifications. Consequently, in the United States, consumer protection groups and others have called for increased government oversight, including the use of mandatory labeling to set minimum standards, similar to the USDA's organic certification program, which includes a set of federal standards codified into regulations coupled with enforcement measures.⁴⁵¹

The following section includes other modes of enforcement by private actors in the United States with a description of how they may be used and an explanation of the potential limitations.

Industry Self-Regulation Measures

Due to the complexities of regulating certain industries, self-regulation within the industry may create a more thorough regulatory framework than government regulation alone. Industries have several mechanisms for self-regulation, such as risk assessments and registers, professional codes of ethics, self-regulatory organizations and trade groups, and increased supply chain transparency through improved supplier relations and analytical surveillance.

Risk assessments identify risks and liabilities within a company. Risk registers compile risk information, including that gained from risk assessments. Risk registers serve to inform management and stakeholders of identified risks, the severity of those risks, and measures that have been, or need to be, taken to mitigate those risks. These risk measures increase

Self-regulation within the industry may create a more thorough regulatory framework than government regulation alone.

transparency by keeping key members of the company aware of the severity of their risks and promote taking active steps to decrease risk. This mechanism complements government regulation in the sense that many official consumer protection regulations are reactive, coming into effect after the consumer is harmed; risk assessments and registers are proactive and prevent consumer harms.

Some companies are skeptical or apprehensive about using risk assessments and risk registers due to the sensitive information these measures reveal. Others may not be truthful in their risk assessments out of fear that these documents may be used against them in future litigation. In this case, risks cannot be accurately identified and mitigated, making the assessment ineffective. Similarly, companies may be highly conscious of what information goes into their risk registers and withhold important information. Stakeholders and managers may not be fully aware of the present risks and their severity if risk registers are incomplete.

Many industries have developed **professional codes of conduct or ethics**, which set clear guidelines about acceptable business practices. In 2005, FAO published a *Code of Conduct for Responsible Fisheries*⁴⁵² which includes an *International Plan of Action to Prevent, Deter, and Eliminate Illegal, Unreported and Unregulated Fishing*.⁴⁵³ In this code, governments and states are largely responsible for enforcing the agreement, but the code was drafted considering industry interests. Another example of a fisheries code of ethics is the American Fisheries Society's *Standards of Professional Conduct*.⁴⁵⁴ It is important to note that enforceability presents a significant limitation to the use of professional codes of ethics. An effective code of ethics would require some form of discipline or penalty for a company breaching the code. Without an enforcement mechanism, a code of ethics may set an expected course of conduct, but those in the industry may see no incentive to comply.

Companies may also choose to use **third-party certifications** to assist in risk management, set clear company-wide sustainability goals, and increase brand reliability.⁴⁵⁵ Effective third-party certifications should have clear standards with measurable outcomes, sustainable finances, “transparency in decision making, implementation, and evaluation, and mechanisms for preventing or addressing conflicts of interest,” and “clear policies on claims and labeling that ensure the accuracy of claims being made.”⁴⁵⁶ Through this model of certification, companies assure their compliance with verifiable standards, for which they can be held accountable. The primary limitation is that certifications are only as effective as they are transparent. Without independent oversight, continuous auditing, and periodic updates to ensure alignment with best practices, certifications become meaningless branding tools rather than mechanisms to ensure accountability.

Additional Private Enforcement Mechanisms

Lanham Act⁴⁵⁷

The purpose of the Lanham Act is to protect those competing in the marketplace from unfair competition and false advertising.⁴⁵⁸ The Lanham Act is a federal law in the United States that governs trademarks and service marks, copyrights, false advertising, and unfair competition. Private enforcement of the act is permitted only where the plaintiff alleges and pleads “an injury to a commercial interest in sales or business reputation,”⁴⁵⁹ meaning consumers are

who are deceived into buying a product due to false advertising are unable to enforce the act. However, business competitors can invoke the protections of the Lanham Act even when a company is in compliance with the labeling requirements under the Federal Food, Drug, and Cosmetic Act because the Lanham Act is intended to protect “commercial interests against unfair competition while the FFDCa protects public health and safety.”⁴⁶⁰

Private Enforcement Under Consumer Protection Laws

US state consumer protection laws empower consumers to hold companies liable for fraudulent statements and may cause them to change labeling practices. Many state consumer protection laws borrow heavily from the Lanham Act and established common law. Unlike the Lanham Act, many state consumer protection laws allow individual consumers to bring a lawsuit against a company that makes a false, deceptive, or misleading statement—often called Unfair and Deceptive Acts and Practices (UDAP) laws.⁴⁶¹

UDAP laws cover label claims as well as advertisements. While each US state’s laws differ, there are some general patterns. Importantly, a consumer must actually purchase the deceptive or misleading product.⁴⁶² Further, the untrue, misleading, or deceptive label claims must be a material reason for purchasing the product.⁴⁶³ If a consumer meets the requirements for their state’s UDAP law, they can bring a private claim in court to recover the purchase cost of the product and potentially additional damages.⁴⁶⁴

For seafood products, actionable claims would likely include intentionally mislabeled fish species, representing a certification that the product does not actually have,⁴⁶⁵ and misrepresenting the source of the fish (i.e., wild caught versus farmed fish). For example, Alaska’s UDAP law covers general false and deceptive label claims, but also specifically forbids marketing fish as fresh if the fish has previously been frozen.⁴⁶⁶ Alaska allows defrauded consumers to recover their purchase cost or USD 500, whichever is greater.⁴⁶⁷

Like all litigation, UDAP litigation can be prohibitively expensive, disincentivizing consumers from bringing a suit. Companies also usually have more legal resources than individuals, which may further limit private enforcement access and effectiveness. Additionally, state laws are preempted by federal statutes and regulations. A state court may not be able to hold a company liable for false label statements if the packaging complies with the FFDCa, because some courts have interpreted the FFDCa to preempt state UDAP laws.

California has taken a novel approach to supply chain transparency that has indirectly affected the international seafood trade. The California Transparency in Supply Chains Act (CTSCA) requires large retail sellers and manufacturers doing business in California to disclose to consumers the company’s “efforts to eradicate human trafficking and slavery within their supply chains on their website or, if a company does not have a website, through written disclosures.”⁴⁶⁸ The purpose of this law was to ensure consumers have information on human trafficking and slavery in commercial supply chains and “educate consumers on how to purchase goods produced by companies that responsibly manage their supply chains.”⁴⁶⁹

Covered retailers and manufacturers must disclose information regarding whether their business:

(1) engages in verification of product supply chains to evaluate and address risks of human trafficking and slavery; (2) conducts audits of suppliers to evaluate supplier compliance with company standards for trafficking and slavery in supply chains; (3) requires direct suppliers to certify that materials incorporated into its products comply with laws regarding slavery and human trafficking; (4) maintains internal accountability standards and procedures for employees or contractors who fail to meet company standards regarding slavery and trafficking; and (5) provides company employees and management with training on human trafficking and slavery.⁴⁷⁰



The CTSCA involves specific and in-depth supply chain disclosures which may bring to light other illegal practices in the supply chain. Individual consumers cannot use the CTSCA alone to sue violative companies. However, the California Unfair Competition Law (UCL) allows individuals to sue companies for “any unlawful, unfair or fraudulent business act or practice”⁴⁷¹ which includes violating the CTSCA.⁴⁷²

The CTSCA’s mandatory disclosures of certain acts may disincentivize illegal activity in the supply chain and promote strong industry self-regulation policies. Further, the individual use of the California UCL allows consumers to hold companies accountable without depending on the state’s prosecutorial priorities.

Consumers have used the CTSCA and UCL against several food retailers and manufacturers, including those in the fisheries sector.⁴⁷³ However, these claims have been unsuccessful, revealing the CTSCA and UCL’s limitations. First, the CTSCA does not require covered entities to change their business practices, but rather to disclose a limited amount of information. Similarly, covered companies are required only to disclose the specific information required under the CTSCA. Consumers cannot use the UCL to enforce omissions under the CTSCA unless the omission is a specifically required disclosure.⁴⁷⁴ Consequently, any other supply chain information disclosures are not required.

Consumer Class Action Litigation

Consumer class action lawsuits originated in the United States and are uncommon in other countries with the exception of Canada and some European countries. The purpose of class action litigation is to allow a number of parties to jointly bring a lawsuit where they share common issues governed by legal questions commonly applied to the entire class.⁴⁷⁵ Class actions provide an opportunity for parties to efficiently enforce their rights when it may not be economically feasible to pursue the cause of action individually.⁴⁷⁶

In the context of food labeling and misbranding, consumers have pursued class actions under state-level consumer protection laws challenging the labeling of food products either due to violations of the Federal Food Drug and Cosmetic Act and its implementing regulations or on the basis that the labeling language is misleading even if technically in compliance with

the law.⁴⁷⁷ Many of these cases focus on false labeling claims related to use of the phrase “all natural” on food products with synthetic ingredients or ingredients produced using pesticides, statements about production practices including animal welfare concerns, and misrepresentations related to the product’s origin.⁴⁷⁸ Class actions are relatively difficult and costly as extensive difficulties often arise around the certification of the class.

Workplace Whistleblower Protections

Whistleblower laws protect and empower employees to disclose corruption and illegal activity in the workplace. Whistleblowers can make complaints to government agencies, which then investigate the complaint on behalf of the employee. Several laws in the US protect whistleblowers, and some even reward whistleblowing activity by sharing part of a civil judgement with the whistleblower if the complaint leads to successful prosecution.⁴⁷⁹ For example, the Lacey Act makes it unlawful “to import, export, transport, sell, receive, acquire, or purchase any fish or wildlife or plant taken, possessed, transported, or sold in violation of any” state or federal law, or US treaty.⁴⁸⁰ The Lacey Act also provides that “any person who furnishes information which leads to an arrest, a criminal conviction, civil penalty assessment, or forfeiture of property for any violation of this chapter or any regulation issued hereunder” is entitled to a reward for such information, and reimbursement for costs they have incurred from assisting enforcement.⁴⁸¹

Whistleblowers may also disclose workplace violations to the US Occupational Safety and Health Administration (OSHA), an administration of the Department of Labor that enforces the Occupational Safety and Health Act (OSH Act).⁴⁸² Employees, excluding government employees, have the right to file complaints with OSHA and request an inspection if the employee believes their employer is in violation of the act’s health and safety requirements.⁴⁸³ In addition, the OSH Act protects employees from employer retaliation for exercising their right to report. OSHA may also enforce whistleblower laws relating to environmental compliance and consumer protection.⁴⁸⁴

Through whistleblower protections, employees can hold their employers accountable for violating laws. Employees have more insight and access to their workplace than government agencies, enabling them to supply important information government agencies could not otherwise access.

Strong whistleblower protections may still face practical limitations. Employees may choose for many reasons not to become a whistleblower. Employees may not know of their ability to exercise their disclosure rights or be intimidated or persuaded into not disclosing. Many employees choose to leave their jobs after disclosure and may find it difficult to find new employment.

Several laws in the US protect whistleblowers, and some even reward whistleblowing activity by sharing part of a civil judgment with the whistleblower if the complaint leads to successful prosecution.


Key Takeaways on Enforcement



Policymakers should consider how best to align enforcement authority with favored methods of detection. For example, enforcement that relies on testing or inspection may be most appropriate for a food safety agency that already has the expertise and infrastructure to conduct widespread food testing.



Private actors vary in their access to information and their motivation for enforcing against seafood fraud. Certification schemes provide a means of transparency and traceability but are only as effective as the oversight that accompanies them. Consumer private rights of action create many potential enforcers, but most lack the expertise to detect fraud or the individual level of harm to motivate them to follow through with a lawsuit. Competitor private rights of action put enforcement in the hands of actors with better information and more potential harm from their competitors' wrongdoing. However, competitors with fraud vulnerabilities in their own supply chains may be reluctant to bring forward legal action against fraudsters out of concern over increased scrutiny of the industry. Whistleblowing protections place enforcement decisions in the hands of private actors with the most information about fraudulent practices but they rely on employees knowing their rights and they may not extend to supply chain employees outside the state's jurisdiction.



RECOMMENDATIONS AND CONCLUSION

Seafood fraud is a multifaceted issue requiring a coordinated, intersectional response. As discussed in this report, the United States utilizes a variety of federal and state-level laws and regulations—as well as formal and informal programs, in conjunction with private enforcement mechanisms—to prevent and detect seafood fraud and protect consumers. While this patchwork approach is useful in the sense that dedicated regulatory bodies are informed by expertise in the specific area of the seafood supply chain over which they have jurisdiction, there are also some drawbacks.

Notably, a patchwork approach to regulation over a specific issue area requires tremendous coordination and information sharing among the responsible agencies. Without a single agency leading the effort or responsible for ensuring coordination, agencies can duplicate efforts, or regulatory gaps can occur when one agency is operating under the assumption that another agency is filling the gap. For example, several US agencies have some authority over seafood fraud, but they all have different mandates that make seafood fraud an unlikely enforcement priority.

Traceability measures present promising tools for preventing seafood fraud, but to be fully effective they may need to be implementable “from bait to plate.” The legal authority for the Seafood Import Monitoring Program (SIMP) in the US does not extend that far. Because different agencies in the US regulate different points along the seafood supply chain, a full traceability program may need to involve multiple agencies or grant one agency authority over more of the supply chain.

A preventive controls system like the Hazard Analysis and Risk-Based Preventive Controls (HARPC) program mandated under the Food Safety Modernization Act might be better suited to detect instances of seafood fraud than a traditional HACCP system. While any traceability and recordkeeping measures have the potential to reduce instances of fraud due to increased surveillance, a preventive controls system like HARPC that includes vulnerability assessments to detect intentional adulteration appears to be better suited to prevent seafood fraud.

A consumer protection approach to seafood fraud should consider who can enforce the protections and how. Individual consumer suits may be cost prohibitive and aggregated suits present other procedural difficulties. To effectively deter fraud, regulatory violations need to be either an enforcement priority for the responsible agency or legally and practically enforceable under a citizen suit provision.

An analysis of the US approach to seafood fraud leads to a set of conclusions and recommendations for other states to consider, as follows.

Defining the Legal Meaning of Seafood Fraud

In the US, the five main categories of seafood fraud are all illegal under either fisheries or food law, or both. However, US law does not employ a legal definition of “seafood fraud” or a unified and coordinated means of addressing the problem systematically. While the Food and Drug Administration has the authority to address economically motivated adulteration, it prioritizes enforcement against adulteration presenting significant public health risks. Other states can address these issues by:

- **Developing a legal definition** of food fraud generally, and seafood fraud specifically, to raise the profile and priority level of those types of violations.
- In addition, states that have organic standards or other voluntary certification programs administered by government agencies could **create enforceable standards** for fish and shellfish, providing an additional degree of oversight.

Preventing and Detecting Seafood Fraud

Fishery management plans can aid seafood fraud prevention efforts by increasing transparency, but they can also create incentives for fishery consolidation⁴⁸⁵ or product mislabeling, e.g., to hide noncompliance with the fishery management plan or other conservation measures. In the seafood context, there are significant limits to traceability data due to technological difficulties, inadequate participation requirements, and bad faith actors. Moreover, the Seafood Import Monitoring Program (SIMP) presents a set of limitations that make full traceability difficult. Specifically, SIMP is designed to detect documentation violations, not violations that occur even when paperwork is in order. Relatedly, documentation required under SIMP may not be specific enough for fraud-preventing traceability, e.g., for fish caught in areas beyond national jurisdiction, the importer need only report the general FAO-defined region where the fish were caught.⁴⁸⁶ Additionally, SIMP allows for bulk identification of fish; not all fish have to be traceable to a particular harvest event,⁴⁸⁷ making harvest information too general to be useful in some instances.⁴⁸⁸ SIMP does not require reporting of transshipment information.⁴⁸⁹ SIMP is promulgated under the Magnuson-Stevens Act (MSA), which has strict data confidentiality requirements,⁴⁹⁰ making it difficult to share information among agencies and countries. Finally, SIMP is not a “bait to plate” program: because SIMP is implemented under the authority of an MSA provision specific to imports,⁴⁹¹ agencies have control only up to the port of entry.



To address these issues, states could consider:

- **Requiring fishing vessels to register as food facilities** under a law like the Bioterrorism Act, enabling the responsible agency to inspect them like other registered food facilities.
- **Coordinating efforts among agencies** addressing food fraud and the intelligence and enforcement agencies tasked with addressing the types of maritime crime that often co-occur with seafood fraud, such as illegal fishing, wildlife and drug trafficking, and modern-day slavery.
- **Developing and implementing meaningful whistleblower laws** to allow fishing crew members to safely provide information regarding illegal fishing practices by providing incentives and protections for confidentiality.
- **Requiring seafood producers to incorporate fraud risk and vulnerability assessment** into their food safety assessments.

Strengthening Enforcement

In many ways, meaningful enforcement is related to the authority given to governmental bodies through a definition of seafood fraud as an offense or a specific mandate to address some aspect of fraud along the seafood supply chain. Because the United States employs many different agencies with specific mandates, none of which specifically addresses food fraud, agencies may decide not to prioritize enforcement when the fraud does not present other risks tied to their existing regulatory authority. In addition to developing a legal definition of seafood fraud, states could consider:

- **Designating specific agencies responsible for enforcement** of seafood fraud violations and including a mandate for enforcement removing some of the agency's discretion.
- **Imposing penalties** substantial enough to deter fraud.
- **Administrative and judicial enforcement** to combat IUU fishing and seafood fraud.

Addressing the Complexity of International Supply Chains

Illegal transshipment demands stricter electronic monitoring and documentation of the supply chain. Consequently, for states with multiple agencies and bodies involved, coordination is needed to share information, crosscheck data, and implement stricter regulations regarding vessel participation in Automatic Identification System (AIS) and Vessel Monitoring System (VMS) programs. In addition to interagency coordination, international cooperation is also required for states that rely on other states' certification of fishing on board their flag vessels, which can weaken oversight if the flag state lacks the capacity to identify IUU fishing vessels or IUU catches. To address these issues, states can consider:

- **Increasing remote monitoring of fishing and transshipment activity** on the high seas through cooperative governance, self-regulation, and machine-learning technology.
- **Private supply chain governance** that accounts for speed of change, level of resources, and compatibility with public governance mechanisms with some level of public oversight to inspire confidence and reduce opportunities for fraud.
- **Adopting new technologies** (e.g., blockchain, advances in DNA barcoding).

Endnotes

- 1 John Spink et al., *Global Perspectives on Food Fraud: Results from a WHO Survey of Members of the International Food Safety Authorities Network (INFOSAN)*, NPJ SCIENCE OF FOOD (2019), <https://doi.org/10.1038/s41538-019-0044-x>.
- 2 *E.g.*, species substitution, undisclosed processing methods, some forms of fishery fraud, or ethical claims fraud.
- 3 *E.g.*, IUU substitution or some forms of fishery fraud.
- 4 *See infra*, Section 3.
- 5 Kailin Kroetz, C. Josh Donlan, Cassandra E. Cole, Jessica A. Gephart, & Patrick Lee, *Examining Seafood Fraud Through the Lens of Production and Trade: How Much Mislabeled Seafood Do Consumers Buy?*, RESOURCES FOR THE FUTURE, 5 (2018), <https://media.rff.org/documents/RFF-Rpt-Kroetz-Donlan-et-al-final.pdf>.
- 6 FAO YEARBOOK, FISHERY AND AQUACULTURE STATISTICS 2017, xvii (2019). www.fao.org/fishery/static/Yearbook/YB2017_USBcard/index.htm. These numbers include fish, crustaceans, molluscs, and other aquatic animals.
- 7 *Id.*
- 8 Nat'l Oceanic and Atmospheric Admin., *The Global Picture*, FISHWATCH U.S. SEAFOOD FACTS, <https://www.fishwatch.gov/sustainable-seafood/the-global-picture>.
- 9 Anastasia Telesetsky, *U.S. Seafood Traceability as Food Law and the Future of Marine Fisheries*, 47 ENVTL. L. 765, 770 (2017).
- 10 MICHAEL T. ROBERTS, TEEMU VIINIKAINEN, & CARMEN BULLON, FOOD AND AGRICULTURE ORGANIZATION, INTERNATIONAL AND NATIONAL REGULATORY STRATEGIES TO COUNTER FOOD FRAUD 6 (2022), <https://www.fao.org/3/cb9035en/cb9035en.pdf>.
- 11 *See id.* at 7; FAO, *Food fraud--Intention, detection and management*, Food safety technical toolkit for Asia and the Pacific No. 5, 8 (2021), <https://www.fao.org/3/cb2863en/cb2863en.pdf>.
- 12 *See generally* ROBERTS et al., *supra* note 10.
- 13 C. Josh Donlan & Gloria M. Luque, *Exploring the causes of seafood fraud: A meta-analysis on mislabeling and price*, 100 MARINE POL'Y 258, 262 (2019). Some examples include: avoiding tariffs focused on specific species, needing to have the appearance of a constant supply of certain species when actual supply fluctuates, and unintentional mixing of species similar in appearance.
- 14 Note that the US does have a statutory definition for "economically motivated adulteration" of food, which is a similar concept to food fraud. *See* discussion in Section 4, *infra*.
- 15 FAO YEARBOOK, *supra* note 6. These numbers include fish, crustaceans, molluscs, and other aquatic animals.
- 16 *Id.*
- 17 Nat'l Oceanic and Atmospheric Admin., *The Global Picture*, *supra* note 8.
- 18 Alan Reilly (Consultant for Fisheries and Aquaculture Policy and Resources Division), *Overview of Food Fraud in the Fisheries Sector* 4, U.N. Doc. FIAM/C1165 (2018).
- 19 *Id.*
- 20 *Id.*
- 21 Kroetz et al., *supra* note 5.
- 22 The World Bank, *Oceans: Sector Results Profile*, WBG (Apr. 2, 2014), <https://www.worldbank.org/en/results/2013/04/13/oceans-results-profile> (referring specifically to overfishing).
- 23 *See, e.g.*, Reilly, *supra* note 18 (listing common forms of fish fraud: "species substitution, . . . mislabelling of fish to conceal the geographical origin of illegally harvested species[,] . . . marketing of counterfeit products, . . . undeclared use of food additives[,] . . . illegal use of food additives[,] . . . addition of glaze water[, and] mislabelling of ingredients . . . to bulk up the weight of processed products"); HAROLD F. UPTON, CONG. RES. SERV., RL34124, SEAFOOD FRAUD 1 (2015) ("transshipping products to avoid antidumping and countervailing duties; mislabeling products or substituting one species for another; overtreating products with water-retaining chemicals; and short-weighting products"); U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-258, SEAFOOD FRAUD: FDA PROGRAM CHANGES AND BETTER COLLABORATION AMONG KEY FEDERAL AGENCIES COULD IMPROVE DETECTION AND PREVENTION 8-9 (2009) ("[t]ransshipment to avoid duties[,] . . . [o]ver-treating[,] . . . [s]pecies substitution[,] . . . [s]hort-weighting[, and o]ther mislabeling and misrepresenting"); Michaela Fox, Mike Mitchell, Moira Dean, Christopher Elliott & Katrina Campbell, *The seafood supply chain from a fraudulent perspective*, 10 FOOD SEC. 939, 948 (2018) (identifying the "nine sins of seafood" as species substitution; species adulteration; undeclared product extension; fishery substitution; chain of custody abuse; illegal, unregulated and under reported substitution; catch method fraud; modern day slavery; and animal welfare).
- 24 *E.g.*, species substitution, undisclosed processing methods, some forms of fishery fraud, or ethical claims fraud.
- 25 *E.g.*, IUU substitution or some forms of fishery fraud.
- 26 Overtreatment occurs when seafood products are treated with an excessive amount of chemical to extend the shelf life or improve the appearance of a product to deceive the customer. For example, fish treated with carbon monoxide look fresher but the treatment does not delay spoilage. UPTON, *supra* note 23.
- 27 Some seafood sellers overglaze their products to avoid freezer burn and increase the apparent weight. In 2009, FDA reissued guidance "warning the industry that the net weight of frozen seafood may not include the weight of glazing." *Id.*
- 28 *See, e.g.*, FAO, *Food fraud--Intention, detection and management*, *supra* note 11, at 3 (describing the practice of injecting gel into shrimp to improve their appearance and add weight to the product).
- 29 Short-weighting products involves seafood businesses reporting inaccurately low counts or high net weights. One way that businesses do this is through overglazing. UPTON, *supra* note 23.

- 30 Illegal fishing includes fishing activities in contravention of national laws or regulations, applicable international legal obligations, or conservation and management measures adopted by regional fisheries management organizations that bind the fishing vessel's flag State. FAO, INTERNATIONAL PLAN OF ACTION TO PREVENT, DETER AND ELIMINATE ILLEGAL, UNREPORTED AND UNREGULATED FISHING § 3.1 (2001), <http://www.fao.org/documents/card/en/c/71be21c9-8406-5f66-ac68-1e74604464e7>.
- 31 Unreported fishing includes fishing activities either not reported or misreported to the relevant national authority or regional fisheries management organization. *Id.*
- 32 Unregulated fishing includes fishing activity undertaken where no applicable conservation or management measures are in place, or where the vessel's flag State is not party to the relevant regional fisheries management organization, if the fishing activity is inconsistent with international legal requirements for conserving living marine resources. *Id.*
- 33 Fox et al., *supra* note 23.
- 34 *Id.*
- 35 Office of the Press Secretary, The White House, *Presidential Memorandum -- Comprehensive Framework to Combat Illegal, Unreported, and Unregulated Fishing and Seafood Fraud* (Jun. 17, 2014), <https://obamawhitehouse.archives.gov/the-press-office/2014/06/17/presidential-memorandum-comprehensive-framework-combat-illegal-unreported> (discussing the Presidential Taskforce to address IUU fishing); Maritime Security and Fisheries Enforcement Act (Maritime SAFE Act), S. 1269 116th Cong. (2019).
- 36 Office of the Press Secretary, *supra* note 35.
- 37 See U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 23 (describing a simplified supply chain).
- 38 *Id.*
- 39 See, e.g., Interactive Tuna Supply Chain, Seafood Alliance for Legality and Traceability, last visited Jan. 30, 2022, <https://www.saltraceability.org/tuna-supply-chain/>, for an interactive model of one type of seafood supply chain.
- 40 Francisco Blaha & Kenneth Katafono, *Blockchain Application in Seafood Value Chains*, FAO Fisheries and Aquaculture Circular No. 1207, 3 (2020), <https://doi.org/10.4060/ca8751en>.
- 41 Telesetsky, *supra* note 9. For example, lobster harvested in the U.S. state of Maine may be sent to Canada for processing and then reimported to the U.S. for consumption.
- 42 FAO YEARBOOK, *supra* note 6.
- 43 Konstantina Bereta, Aristides Millios, Konstantinos Chatzikokolakis & Dimitris Zissis, *Monitoring Marine Protected Areas using Data Fusion and AI Techniques*, INFORE, <https://www.cmre.nato.int/msaw-2019-home/msaw2019-papers/1394-msaw2019-bereta-monitoring-marineprotectedareasusingdatafusionandaitechniques/file>.
- 44 Katerina Zimmer, *How seafood's "dark web" obscures fraud, fish laundering, and slavery on the high sea*, THE COUNTER, (Aug. 15, 2017, 11:17 AM), <https://newfoodeconomy.org/seafood-dark-web-fish-fraud-transshipment/>.
- 45 See Fox et al., *supra* note 23.
- 46 See NESTLE, FOOD FRAUD PREVENTION 6 (2016) (describing this phenomenon using the example of apple juices and purees being more vulnerable to fraud than apple pieces).
- 47 Zimmer, *supra* note 44.
- 48 See NESTLE, *supra* note 54 (describing factors that increase a food product's vulnerability to fraud).
- 49 Fox et al., *supra* note 23.
- 50 See *Id.* at 953 (noting that consumers view "wild" fish as preferable to farmed fish and accordingly pay more for them).
- 51 Donlan & Luque, *supra* note 13, at 262 (2019).
- 52 Kristina Boerder, Nathan A. Miller & Boris Worm, *Global hot sports of transshipment of fish catch at sea*, 4 SCI. MAG. 1 (2018), <https://advances.sciencemag.org/content/4/7/eaat7159>.
- 53 *Id.*
- 54 *Id.*
- 55 UPTON, *supra* note 23.
- 56 Boerder et al., *supra* note 45.
- 57 For a discussion of the Maritime SAFE Act, see Box 5.
- 58 Boerder et al., *supra* note 45.
- 59 *Id.*
- 60 Adapted from UPTON, *supra* note 23, at T. 1.
- 61 See Nicholas Lord, Jon Spencer, Jay Albanese & Cecilia Flores Elizondo, *In pursuit of food system integrity: the situational prevention of food fraud enterprise*, 23 EUR. J. CRIM. POLICY RES. 483, 486 (2017) (describing the role of situational prevention theory in moving from understanding the opportunities and circumstances of crime to developing prevention measures).
- 62 *Id.* at 486.
- 63 *Id.*
- 64 *Id.*
- 65 *Id.*
- 66 Jianrong Zhang & Tejas Bhatt, *A Guidance Document on the Best Practices in Food Traceability*, 13 COMPREHENSIVE REV. IN FOOD SCI. AND FOOD SAFETY 2014, 1074, 1075 (2014).
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- 70 Blaha & Katafano, *supra* note 40.
- 71 The actual CTEs for a given product will vary depending on the specific steps in that product's supply chain.
- 72 GS1 Foundation for Fish, Seafood and Aquaculture Traceability Guideline 26-28, Release 1.3 (ratified Feb. 2019), https://www.gs1.org/sites/default/files/docs/traceability/GS1_Foundation_for_Fish_Seafood_Aquaculture_Traceability_Guideline.pdf.
- 73 Blaha & Katafano, *supra* note 40.
- 74 *Id.* "Language and technological barriers have hindered the use of standardized electronic systems for end-to-end traceability within supply chains."
- 75 Charlebois, *supra* note 69, at 1104, 1107.
- 76 *Id.* at 1108.
- 77 Where full-chain traceability does exist, it is often proprietary information. Ganapathiraju Pramod, Katrina Nakamura, Tony J. Pitcher & Leslie Delagran, *Estimates of illegal and unreported fish in seafood imports to the USA*, 48 *MARINE POL'Y* 102, 106 (2014), <https://www.sciencedirect.com/science/article/pii/S0308597X14000918>.
- 78 Sara G. Lewis & Mariah Boyle, *The Expanding Role of Traceability in Seafood: Tools and Key Initiatives*, 82 *J. FOOD SCI.* A13, A16 (2017).
- 79 *See, e.g.*, NAT'L FISHERIES INST., *TRACEABILITY FOR SEAFOOD: U.S. IMPLEMENTATION GUIDE* (2011).
- 80 Office of the Press Secretary, *supra* note 35.
- 81 Maritime SAFE Act, S. 1269, *supra* note 35.
- 82 Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. § 1801 *et seq.* (2017).
- 83 NOAA Fisheries, *Laws & Policies*, <https://www.fisheries.noaa.gov/topic/laws-policies#magnuson-stevens-act> (last visited Sept. 28, 2020).
- 84 *Id.*
- 85 16 U.S.C. § 1801(b).
- 86 16 U.S.C. § 1851; *see also id.* § 1852.
- 87 U.S. Regional Fisheries Management Councils, <http://www.fisherycouncils.org/> (last visited Aug. 31, 2020).
- 88 Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (2014).
- 89 *Id.* at §§ 342, 343.
- 90 Neil D. Fortin, *The Hang-Up with HACCP: The Resistance to Translating Science into Food Safety Law*, 58 *FOOD AND DRUG L. J.*, 565 (2003).
- 91 U.S. Food & Drug Admin., *Food Safety Modernization Act (FSMA)*, FDA (April 09, 2020), <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma>; *see also* 156 Cong. Rec. H8861-01 (daily ed. Dec. 21, 2010) (statement of R. Dingell) ("[FSMA] serves a basic and necessary and admirable purpose. It is going to have the purpose of seeing to it that the American consumer can again have confidence in the safety of their food supply.").
- 92 Federal Trade Commission Act of 1914, 15 U.S.C. § 41 *et seq.*
- 93 *See generally* Blaha & Katafano, *supra* note 40, for an overview of blockchain's potential to improve traceability in seafood value chains.
- 94 "Fishing effort" refers to a measurement of intensity of fishing activity. FAO describes it as "[t]he amount of fishing gear of a specific type used on the fishing grounds over a given unit of time" FAO Coordinating Working Party on Fishery Statistics, *Handbook of Fishery Statistical Standards*, 212 (2004), <https://www.fao.org/3/j4000e/j4000e.pdf>.
- 95 *See, e.g.*, the European Union TRACES program approach (aiming to ensure traceability, information exchange, and risk management). European Commission, *Traces*, https://ec.europa.eu/food/animals/traces_en.
- 96 NOAA Fisheries, *About Us*, <https://www.fisheries.noaa.gov/about-us#>.
- 97 Boerder et al., *supra* note 45, at 8.
- 98 16 U.S.C. § 1801 *et seq.*
- 99 16 U.S.C. § 1801(b)(1).
- 100 *See* Kroetz et al., *supra* note 5 (noting that incentives for mislabeling include "circumventing catch limits on wild-caught stocks" and providing the example of the "Codfather" case in which a fisher mislabeled 300,000 pounds of an overfished species as another species); WARNER ET AL., *OCEANA STUDY REVEALS SEAFOOD FRAUD NATIONWIDE* 4 https://oceana.org/sites/default/files/reports/National_Seafood_Fraud_Testing_Results_FINAL.pdf (noting that mislabeling can be used to "provide cover and profit for illegal . . . seafood," including overfished species). Seafood fraud may also be committed to hide noncompliance with other conservation laws, such as those requiring protection of ocean wildlife. *See, e.g.*, the Marine Mammal Protection Act, 16 U.S.C. § 1361 *et seq.* (prohibiting taking of marine mammals).
- 101 Magnuson-Stevens Act Provisions, 50 C.F.R. § 600.305.
- 102 16 U.S.C. § 1853.
- 103 Section 303 of the MSA requires fishery management plans to "contain a description of the fishery, including, but not limited to, the number of vessels involved, the type and quantity of fishing gear used, the species of fish involved and their location [...] and the nature and extent of foreign fishing and Indian treaty fishing rights, if any." Magnuson-Stevens Act, *supra* note 82, § 1853(a)(2); *See also id.* § 303.
- 104 NOAA, *ENFORCEMENT CONSIDERATIONS FOR NOAA FISHERIES AND NORTH PACIFIC FISHERY MANAGEMENT COUNCIL 7* (2015) ("Fishery regulations that do not allow for a complete accounting of fish from catch to final sale can lead to loopholes that allow illegally-harvested fish to enter the market, either comingled with, or as a substitute for, legal product."); Ben Goldfarb, *The Deliciously Fishy Case of the "Codfather."* *MOTHER JONES* (Mar/Apr 2017),

- <https://www.motherjones.com/environment/2017/03/codfather-carlos-rafael-fish-fraud-catchshares/>.
- 105 16 U.S.C. § 1852 (h).
- 106 Nat'l Oceanic and Atmospheric Admin. Fisheries, *Design and Implementation of Catch Share Programs: Guidance for fishery management councils*, NOAA (May 13, 2019), <https://www.fisheries.noaa.gov/national/laws-and-policies/design-and-implementation-catch-share-programs>.
- 107 See New England Fishery Management Council, *Groundfish Catch Share Program Review: Groundfish Catch Share Comments* (Aug. 19, 2019), <https://s3.amazonaws.com/nefmc.org/All-Catch-Share-Comments-sept-27-2019.pdf>; See also Goldfarb, *supra* note 104.
- 108 Northwest Atlantic Marine Alliance, *Permit Banks, Local Access, and Local Control*, NAMA (May 18, 2012), <http://www.namanet.org/permit-banks-local-access-and-local-control-fishing-rights>.
- 109 Nat'l Oceanic and Atmospheric Admin. Fisheries, *Catch Share Programs by Council Region*, NOAA, <https://www.fisheries.noaa.gov/national/sustainable-fisheries/catch-share-programs-council-region>.
- 110 Nat'l Oceanic and Atmospheric Admin. Fisheries, *Commercial Fishing: Catch Shares*, NOAA, <https://www.fisheries.noaa.gov/insight/catch-shares>.
- 111 *Id.*
- 112 Daniel S. Holland et. al., *Impact of Catch Shares on Diversification of Fishers' Income and Risk*, 114 PROC. NAT'L ACAD. SCI. 9302 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5584416/>.
- 113 *Id.* at 9303.
- 114 *Id.* at 9302.
- 115 Sustainable Fisheries, *Some Facts About Catch Shares* (Oct. 11, 2016), <https://sustainablefisheries-uw.org/some-facts-about-catch-shares/>.
- 116 *Id.*
- 117 Holland, *supra* note 112, at 9302.
- 118 Fisheries Off West Coast States; Pacific Coast Groundfish Fishery Management Plan; Amendments 20 and 21; Trawl Rationalization Program, 75 Fed. Reg. at 78,343, 78,348, 78,371 (Dec. 15, 2010) (addressing the catch share's consolidation effect and negative impact on small business); Goldfarb, *supra* note 104.
- 119 Claire Kelloway, *Catch shares lead to consolidation of Alaskan fisheries*, FERN'S AG, May 28, 2019, https://thefern.org/ag_insider/catch-shares-lead-to-consolidation-of-alaskan-fisheries/.
- 120 *U.S. v. Rafael*, 282 F.Supp.3d 407, at 408 fn. 2 (D. Mass. 2017).
- 121 Goldfarb, *supra* note 104.
- 122 50 C.F.R. § 300.341 (a).
- 123 Antonia Noori Farzan, *The 'Codfather' was a seafood kingpin, until fake Russian mobsters took him down. Now he'll never fish again*, WASH. POST, Aug. 20, 2019, <https://www.washingtonpost.com/nation/2019/08/20/codfather-fishing-russian-mobsters-carlos-rafael/>.
- 124 See Nat'l Oceanic and Atmospheric Admin. Fisheries, *Electronic Monitoring*, NOAA, <https://www.fisheries.noaa.gov/national/fisheries-observers/electronic-monitoring> (describing electronic monitoring systems in U.S. fisheries).
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- 126 Nat'l Oceanic and Atmospheric Admin. Fisheries, *Vessel Monitoring*, NOAA, <https://www.fisheries.noaa.gov/topic/enforcement#vessel-monitoring>.
- 127 Int'l Maritime Org., *AIS transponders*, IMO, <http://www.imo.org/en/OurWork/Safety/Navigation/Pages/AIS.aspx>.
- 128 Navigation Safety Regulations, 33 C.F.R. § 164 *et seq.*, at 164.46 (b)(1).
- 129 Automatic Identification Systems (AISs), SOR/2005-134 (Can.), <https://laws-lois.justice.gc.ca/eng/regulations/sor-2005-134/page-5.html>.
- 130 RFMOs are international bodies made up of multiple countries that "share a practical and/or financial interest in managing and conserving fish stocks in a particular region." RFMOs are established by international agreements or treaties that are typically aimed at regulating fishing for a particular species (e.g., there are tuna-specific RFMOs) in an effort to sustain the global marine ecosystem. Pew, *FAQ: What is a Regional Fishery Management Organization?*, PEW CHARITABLE TRUSTS (Feb. 23, 2012), <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2012/02/23/faq-what-is-a-regional-fishery-management-organization>; FAO, *Regional fisheries management organizations and deep-sea fisheries*, FAO (Aug. 26, 2016), <http://www.fao.org/fishery/topic/166304/en>.
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- 132 Boerder et al., *supra* note 45.
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- 138 *Id.* at 6.
- 139 U.S. CUSTOMS AND BORDER PROTECTION, IMPORTING INTO THE UNITED STATES: A GUIDE FOR OUR COMMERCIAL IMPORTERS 5 (2006), <https://www.cbp.gov/sites/default/files/documents/Importing%20into%20the%20U.S.pdf>.
- 140 U.S. CUSTOMS AND BORDER PROTECTION, INTERNATIONAL TRADE DATA SYSTEM (ITDS) FACT SHEET, https://www.cbp.gov/sites/default/files/documents/itds_capab_2.pdf
- 141 16 U.S.C. § 7401; FAO, No. I-54133 *Agreement On Port State Measures To Prevent, Deter And Eliminate Illegal, Unreported And Unregulated Fishing* (Jan 26, 2017), http://www.fao.org/fileadmin/user_upload/legal/docs/037s-e.pdf.
- 142 *Id.*
- 143 FAO, *The PSMA as a cost-effective tool to combat IUU Fishing*, FAO (Mar. 06, 2019) [hereinafter FAO, *PSMA*], <http://www.fao.org/port-state-measures/resources/detail/en/c/1196980/>.
- 144 The Agreement also focuses on vessels that “engage in supportive activities such as refueling or transshipping fish from IUU fishing vessels at sea.” NOAA Fisheries, *Frequent Questions : Implementing Port State Measures Agreement*, NOAA (Jan. 21, 2020), <https://www.fisheries.noaa.gov/enforcement/frequent-questions-implementing-port-state-measures-agreement>.
- 145 *Id.*
- 146 16 U.S.C. § 7404.
- 147 16 U.S.C. § 7404(c).
- 148 FAO, *PSMA*, *supra* note 143.
- 149 Inspection results may also be shared with coastal states, RFMCs, or other organizations to “report infractions of conservation measures or other evidence of illegal, unreported, or unregulated fishing.” NOAA Fisheries, *supra* note 144.
- 150 FAO offers capacity development assistance for both party and non-party states of PSMA. Assistance includes “legal reviews, operations, strengthening the monitoring control surveillance, [and] market-related measures.” FAO, *Agreement on Port State Measures*, *supra* note 141.
- 151 16 U.S.C. § 7404(b)
- 152 NOAA FISHERIES, COMPLIANCE GUIDE: U.S. SEAFOOD IMPORT MONITORING PROGRAM (2019) [hereinafter NOAA FISHERIES, SIMP COMPLIANCE GUIDE], https://www.iuufishing.noaa.gov/Portals/33/SIMPComplianceGuide_June2019.pdf?ver=2019-05-28-134131-697.
- 153 16 U.S.C. § 1825.
- 154 NOAA FISHERIES, SIMP COMPLIANCE GUIDE *supra* note 152.
- 155 *Id.*
- 156 *Id.*
- 157 The species include: Abalone, Atlantic Cod, Blue Crab (Atlantic), Dolphinfish (Mahi Mahi), Grouper, King Crab (red), Pacific Cod, Red Snapper, Sea Cucumber, Sharks, Shrimp, Swordfish, and Tunas (Albacore, Bigeye, Skipjack, Yellowfin, and Bluefin). *Id.*
- 158 Legislation introduced in 2022 proposes to expand SIMP to cover imports of all seafood and seafood products. United States Innovation and Competition Act of 2021, H.R. 4521, 117th Cong. § 70112 (2022). At the time of this report’s publication, both the House of Representatives and the Senate had passed versions of this bill, but only the House version included the SIMP species expansion.
- 159 Information recorded by CBP includes the name and flag state of harvesting vessel(s); evidence of authorization to fish/farm (i.e., permits, farm registration, or license number); unique vessel identifier (when available); and the type(s) of fishing gear used. NOAA FISHERIES, SIMP COMPLIANCE GUIDE *supra* note 152.
- 160 The harvest event information required includes: the species (pursuant to FAO 3-Alpha Species Codes); landing or offloading date(s); product form(s) at the time of landing or offloading (this includes quantity and weight of product); area(s) of wild-capture or aquaculture harvest (i.e., farm address); point(s) of first landing; and the name of entity(ies) to which the fish was landed or delivered. *Id.*
- 161 Importers must report: name, affiliation, and contact information; valid International Fisheries Trade Permit number; records regarding the chain of custody; information on any transshipment of product; and records on processing, re-processing, and commingling of product. *Id.*
- 162 *Id.* Under SIMP, importing any fish product for human consumption requires an International Fisheries Trade Permit.
- 163 For an in-depth discussion of co-regulation in the context of food fraud, see ROBERTS ET AL., *supra* note 10.

- 164 16 U.S.C. §1801 *et seq.*; Seafood Import Monitoring Program, 81 Fed. Reg. at 88,975, 88,982 (Dec. 09, 2016) (codified at 50 C.F.R. § 300.321), <https://www.federalregister.gov/documents/2016/12/09/2016-29324/magnuson-stevens-fishery-conservation-and-management-act-seafood-import-monitoring-program>.
- 165 16 U.S.C. §1801 *et seq.*
- 166 IUUWatch, *Background to the Regulation*, ENVTL. JUSTICE FOUND., <http://www.iuuwatch.eu/new-background-to-the-iuu-regulation/>.
- 167 *Id.*
- 168 *Id.*
- 169 Ken Coghill and Dennis Woodward, *Political issues of public-private partnerships*, in *THE CHALLENGE OF PUBLIC-PRIVATE PARTNERSHIPS: LEARNING FROM INTERNATIONAL EXPERIENCE* 81, 88 (Graeme Hodge & Carsten Greve, eds., 2005).
- 170 See Alexa Cole; Meggan Engelke-Ros; Jonathan Galatzan, *More than Just Paperwork Violations: Combating IUU Fishing through Enforcement of Seafood Traceability Schemes*, 63 U.S. ATT'YS BULL. 27, 28-29 (2015).
- 171 The U.S. implements CCAMLR requirements under the Antarctic Marine Living Resources Convention Act (AMLR-CA) (16 U.S.C. §§ 2431-2444).
- 172 The U.S. implements ICCAT requirements under the MSA (16 U.S.C. § 1801 *et seq.*) and the Atlantic Tunas Convention Act of 1975 (ATCA) (16 U.S.C. § 971 *et seq.*).
- 173 Cole *et al.*, *supra* note 170.
- 174 16 U.S.C. § 971e.
- 175 16 U.S.C. § 971e(f); *see also* 19 U.S.C. § 1595a(c).
- 176 50 C.F.R. § 300.106(a).
- 177 50 C.F.R. §§ 300.106(b), (c).
- 178 16 U.S.C. §2437.
- 179 16 U.S.C. § 2439(d)(1).
- 180 Cole *et al.*, *supra* note 170.
- 181 There are 20 FAO fishing regions worldwide.
- 182 Seafood Import Monitoring Program, 81 Fed. Reg. 88,975, 88,980; *See also* Telesetsky, *supra* note 9.
- 183 *Id.*; *see also* 16 U.S.C. §1801 *et seq.*
- 184 Telesetsky, *supra* note 9.
- 185 *Id.*
- 186 16 U.S.C. §1881a(b); Monica Medina & Scott Nuzum, *Electronic Reporting and Monitoring in Fisheries: Data Privacy, Security, and Management Challenges and 21st-Century Solutions*, 49 ENVTL. L. REP. NEWS & ANALYSIS 10670, 10687 (2019).
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- 188 16 U.S.C. §1881a(b).
- 189 16 U.S.C. § 1825.
- 190 Maritime SAFE Act, S. 1269, *supra* note 35, at § 3531 *et seq.*
- 191 *Id.* at §§ 3533-3534.
- 192 *Id.*
- 193 *Id.* at § 3551(b).
- 194 *Id.* at § 3551(c).
- 195 *Id.* at §§ 3533, 3561.
- 196 21 U.S.C. § 381; *see also id.* § 801.
- 197 *Id.*; U.S. FOOD AND DRUG ADMIN., *REGULATORY PROCEDURES MANUAL* § 9-1-4 (2017) <https://www.fda.gov/media/71776/download>.
- 198 *Id.* at § 9-7; U.S. CUSTOMS AND BORDER PROTECTION, *IMPORTING INTO THE UNITED STATES*, *supra* note 139.
- 199 *Id.* at § 9-1-4, 9-1-5.
- 200 U.S. Food & Drug Admin., *Actions & Enforcement: Import Alerts*, FDA (May 14, 2019), <https://www.fda.gov/industry/actions-enforcement/import-alerts>.
- 201 *Id.*
- 202 *Id.*
- 203 For example, "a food that previously was shown to contain deadly bacteria that can cause a food-borne illness" would be on the red list. *Id.*
- 204 For example, the FDA can identify foreign facilities that have food safety controls in place to control for a particular toxin which, to ensure the safety of American consumers, need intensified surveillance by the agency before being imported into the United States. *Id.*
- 205 For example, according to the FDA, all soft cheeses from France are subject to DWPE except those from producers that have already received an exemption based on the guidance in the import alert and are thus on the green list. *Id.*
- 206 *Id.*
- 207 21 C.F.R. § 1.277(a).
- 208 21 C.F.R. § 1.279(a)(4).
- 209 U.S. FOOD & DRUG ADMIN., *REGULATORY PROCEDURES MANUAL*, *supra* note 197, at § 9-1-4.
- 210 *Id.*
- 211 *Id.* at § 9-1-5. ("Notices are official documents communicating FDA decisions on entries. The distribution of the notices should be made by FDA, not the filer, to ensure proper notification to the parties involved (i.e., FAX, express pick-up services, postal service, etc.) The key is for FDA to distribute to the responsible firm directly without an intermediary.")
- 212 *Id.*
- 213 *Id.*
- 214 *Id.* at § 9-1-2.
- 215 *Id.* at § 9-1-5.
- 216 *Id.*
- 217 21 U.S.C. § 381(a).
- 218 U.S. FOOD & DRUG ADMIN., *REGULATORY PROCEDURES MANUAL*, *supra* note 197, at § 9-1-5.
- 219 21 U.S.C. §§ 381(m)(1), 381(l)(1). The Bioterrorism Act amended the Federal Food, Drug, and Cosmetic Act (FFDCA). Enacted in response to concerns about the food supply's vulnerability to terrorism, the Bioterrorism Act's traceability measures are aimed at strengthening FDA's response to food supply threats. U.S. Food

- & DRUG ADMIN., CPG SEC 110.300 REGISTRATION OF FOOD FACILITIES UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002: GUIDANCE FOR FDA STAFF (2006), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-110300-registration-food-facilities-under-public-health-security-and-bioterrorism>. "The purpose of registration is to provide FDA with sufficient and reliable information about food and feed facilities. [In conjunction with other sections of the Act,] registration will . . . aid in the detection and quick response to actual or potential threats to the U.S. food supply. Registration information will also help FDA notify firms that may be affected by the actual or potential threat." U.S. FOOD & DRUG ADMIN., CPG SEC 110.300 REGISTRATION OF FOOD FACILITIES UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002: GUIDANCE FOR FDA STAFF (2006), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-110300-registration-food-facilities-under-public-health-security-and-bioterrorism>.
- 220 21 C.F.R. §§ 1.277, 1.279.
- 221 21 C.F.R. § 1.225.
- 222 See generally, FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011); 21 U.S.C. § 350(c) *et seq.*
- 223 21 U.S.C. § 350d(1) (requiring that "any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered" with the agency).
- 224 In 2011, the Food Safety Modernization Act (FSMA) amended the FFDCa to allow the FDA to inspect registered foreign food facilities. 21 U.S.C. § 384c.
- 225 21 C.F.R. § 1.226(f). The food facility registration requirement is aimed at facilities whose primary purpose is manufacturing, processing, packing, or holding food products.
- 226 In this context, "processing" is defined as "handling, storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel." 21 C.F.R. § 1.327(c).
- 227 21 C.F.R. § 1.226(f).
- 228 21 U.S.C. § 381(l)(1).
- 229 Requirements for Additional Traceability Records for Certain Foods, 85 Fed. Reg. 59,984 (Sept. 23, 2020).
- 230 21 U.S.C. § 2223(d).
- 231 FDA, Food Traceability List, <https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list#List>.
- 232 Requirements for Additional Traceability Records for Certain Foods, 85 Fed. Reg. 59,984 (Sept. 23, 2020).
- 233 *Id.*
- 234 *Id.* at 59,992.
- 235 *Id.*
- 236 Requirements for Additional Traceability Records for Certain Foods, 85 Fed. Reg. 59,984, 59,991 (finfish, crustaceans, mollusks, and bivalves).
- 237 *Id.* at 59,984, 59,998 ("Under this partial exemption, activities of fishing vessels such as harvesting, transporting, heading, eviscerating, and freezing fish would generally not be subject to the proposed recordkeeping requirements. Under this exemption, the owner, operator, or agent in charge of a fishing vessel also would not have to keep tracing records on the sale and shipment of food produced through the use of the vessel, except as provided in proposed § 1.1305(j)(2).")
- 238 *Id.* at 59,999-60,000.
- 239 RENÉE JOHNSON, CONG. RES. SERV. RS22600, THE FEDERAL FOOD SAFETY SYSTEM: A PRIMER (2016), <https://fas.org/sgp/crs/misc/RS22600.pdf>.
- 240 *Id.*
- 241 *Id.*
- 242 *Id.* In one anomaly, USDA regulates the production and harvesting of catfish. Food, Conservation, and Energy Act of 2008, Pub. L. No. 110-246, 122 Stat. 1652 (May 22, 2008).
- 243 For example, USDA regulates Country of Origin Labeling (COOL) for seafood in general. Fish and shellfish covered by COOL "include fresh and frozen fillets, steaks, nuggets, and any other flesh from a wild or farm-raised fish or shellfish," but do not include seafood items that are ingredients in a processed food product. USDA Agric. Mktg. Serv., *Country of Origin Labeling (COOL) Frequently Asked Question*, <https://www.ams.usda.gov/rules-regulations/cool/questions-answers-consumers>; 7 C.F.R. § 60.105.
- 244 U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-19-157SP, SUBSTANTIAL EFFORTS NEEDED TO ARCHIVE GREATER PROGRESS ON HIGH-RISK AREAS, 195 (2019), <https://www.gao.gov/assets/700/697245.pdf>. ("For more than four decades, we have reported on the fragmented federal food safety oversight system, which has caused inconsistent oversight, ineffective coordination, and inefficient use of resources.")
- 245 JOHNSON, *supra* note 239.
- 246 21 U.S.C. § 342(a).
- 247 21 U.S.C. § 321(s).
- 248 The FDA recommends the following elements be included in a safety assessment petition for food additive approval: the identity and composition of the additive, proposed use, use level, data establishing the intended effect, full reports of all safety studies, environmental information, quantitative detection methods, consistent information. See U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: QUESTIONS AND ANSWERS ABOUT THE FOOD ADDITIVE OR COLOR ADDITIVE PETITION PROCESS (2011) [hereinafter U.S. FOOD & DRUG ADMIN., FOOD ADDITIVE GUIDANCE FOR INDUSTRY], <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-about-food-additive-or-color-additive-petition-process#answerG>.

- 249 *See id.*
- 250 *Center for Food Safety v. Price*, No. 17-CV-3833 (S.D.N.Y. Sept 12, 2018).
- 251 21 U.S.C.A. § 342 (a-c).
- 252 "The average time between submission until a final rule is published for a direct food additive petition is 24 months and for color additive petitions, the approval process varies significantly." *See* U.S. FOOD & DRUG ADMIN., FOOD ADDITIVE GUIDANCE FOR INDUSTRY, *supra* note 248.
- 253 *Center for Food Safety*, No. 17-CV-3833.
- 254 U.S. Food & Drug Admin., *FDA Issues Final Rule on Food Ingredients that May Be "Generally Recognized as Safe,"* FDA (2016), <https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-final-rule-food-ingredients-may-be-generally-recognized-safe>.
- 255 Laurie J. Beyranevand, *Generally Recognized as Safe?: Analyzing Flaws in the FDA's Approach to GRAS Additives*, 37 VT. L. REV. 887 (2013).
- 256 FAO & WHO, CODEX ALIMENTARIUS INTERNATIONAL FOOD STANDARDS 2–4, at §§ 1.2, 3.1–3.4 (2019), http://www.fao.org/gsfaonline/docs/CXS_192e.pdf.
- 257 *Id.* at § 1.1.
- 258 *See* Food & Water Watch, *Carbon Monoxide: Masking the Truth About Meat?* (2008), https://www.foodandwaterwatch.org/sites/default/files/carbon_monoxide_report_apr_2008.pdf.
- 259 *See* U.S. FOOD & DRUG ADMIN., *Chapter 11: Aquaculture Drugs, in FISH AND FISHERY PRODUCTS HAZARDS AND CONTROLS GUIDANCE 183* (2020), <https://www.fda.gov/media/80297/download>.
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- 262 *Id.*
- 263 Ahmed Al Amin, *FDA Asked to Rescind Use of Carbon Monoxide for Meats*, FOOD NAVIGATOR (Aug. 11, 2005), <https://www.foodnavigator-usa.com/Article/2005/11/17/FDA-asked-to-rescind-use-of-carbon-monoxide-for-meats>.
- 264 Karen Everstine et al., *Economically Motivated Adulteration (EMA) of Food: Common Characteristics of EMA Incidents*, 76 J. OF FOOD PROTECTION 723 (2013), <https://foodprotection.org/doi/pdf/10.4315/0362-028X.JFP-12-399>.
- 265 Spink et al., *supra* note 1.
- 266 Mitigation Strategies to Protect Food Against Intentional Adulteration, 81 Fed. Reg. at 34,165.
- 267 *Id.*
- 268 FDA Safety Modernization Act, Pub. L. No. 111-353; 21 U.S.C. § 350g (j); U.S. FOOD & DRUG ADMIN., SEAFOOD HACCP AND THE FDA FOOD SAFETY MODERNIZATION ACT: GUIDANCE FOR INDUSTRY 3 (2017) [hereinafter U.S. FOOD & DRUG ADMIN., SEAFOOD HACCP GUIDANCE].
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- 271 Safe Food Alliance Team, *What is the Difference Between HACCP and HARPC?*, SAFE FOOD ALLIANCE (Jan. 14, 2019), <https://safefoodalliance.com/haccp/what-is-the-difference-between-the-haccp-and-harpc/>.
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- 273 21 C.F.R. § 117.5 (b), Subpart A; 21 C.F.R. § 123, Subpart A. "Processing" is defined as "handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding" but does not include: "practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel." 21 C.F.R. § 123.3(k)(1)-(2).
- 274 21 C.F.R. § 117, Subpart C.
- 275 21 C.F.R. § 117, Subpart G.
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- 277 21 C.F.R. § 117, Subpart A (includes definitions, exemptions, and requirements related to qualifications and the need to maintain records).
- 278 21 C.F.R. § 117, Subpart B.
- 279 21 C.F.R. § 117, Subpart F.
- 280 21 C.F.R. § 123.10.
- 281 Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must: (1) be a qualified individual as that term is defined in §117.3—*i.e.*, have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties; and (2) receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties. 21 C.F.R. § 117.4(b).
- 282 21 C.F.R. § 110.
- 283 Mitigation Strategies to Protect Food Against Intentional Adulteration, 81 Fed. Reg. at 34,165 (there are limited

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- 284 *Id.*
- 285 U.S. FOOD & DRUG ADMIN., KEY REQUIREMENTS: FSMA FINAL RULE FOR MITIGATION STRATEGIES TO PROTECT FOOD AGAINST INTENTIONAL ADULTERATION (2016), <https://www.fda.gov/media/98085/download>.
- 286 Small businesses and very small businesses are excluded because they are considered low-risk. Mitigation Strategies to Protect Food Against Intentional Adulteration, *supra* note 266, at 34, 167.
- 287 See U.S. FOOD & DRUG ADMIN., DOES THE FINAL RULE ON INTENTIONAL ADULTERATION APPLY TO ME? fig. 2 (2020) (outlining regulatory requirements for food defense plans), <https://www.fda.gov/media/97788/download>.
- 288 21 C.F.R. § 121.130(c).
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- 293 Mitigation Strategies to Protect Food Against Intentional Adulteration, *supra* note 266, at 34, 165.
- 294 *Id.*
- 295 *Id.*
- 296 *Id.*
- 297 Lord et al., *supra* note 61.
- 298 U.S. FOOD & DRUG ADMIN., MOU 225-09-0008, MEMORANDUM OF UNDERSTANDING BETWEEN U.S. DEPARTMENT OF COMMERCE NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION AND U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION (Sept. 16, 2009), <https://www.fda.gov/about-fda/domestic-mous/mou-225-09-0008>.
- 299 *Id.*
- 300 *Id.*
- 301 *Id.*
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- 303 21 C.F.R. § 123.6(b).
- 304 21 C.F.R. § 123.6(b). For example, sulfites may be of particular concern in shrimp; parasites may be of particular concern in fish consumed raw. In addition, a subpart to seafood HACCP regulations establishes the National Shellfish Sanitation Program (NSSP), which is overseen by a coordinated effort of FDA, the Environmental Protection Agency, and NOAA. M.T. ROBERTS, *FOOD LAW IN THE UNITED STATES §3.06[3][e]* (Cambridge University Press 2016).
- 305 U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-17-443, IMPORTED SEAFOOD SAFETY: FDA AND USDA COULD STRENGTHEN EFFORTS TO PREVENT UNSAFE DRUG RESIDUES (2017), <https://www.gao.gov/assets/690/687183.pdf>.
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- 309 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 Fed. Reg. at 56,028. (“Economically motivated adulteration that affects product integrity or quality, for example, but not food safety is out of the scope of this rule.”)
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- 311 Kassy Marsh, *The Need for a Combined HACCP and HARPC Food Safety Plan*, FOOD SAFETY MAGAZINE (Oct./Nov. 2016), <https://www.foodsafetymagazine.com/magazine-archive1/october-november-2016/the-need-for-a-combined-haccp-harpc-food-safety-plan/>.
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- 398 14 U.S.C. § 522. ("The Coast Guard may make inquiries, examinations, inspections, searches, seizures, and arrests upon the high seas and waters over which the US has jurisdiction, for the prevention, detection, and suppression of violations of laws of the US. For such purposes, commissioned, warrant, and petty officers may at any time go on board of any vessel subject to the jurisdiction or to the operation of any law of the US, address inquires to those on board, examine the ship's documents and

- papers, and examine, inspect, and search the vessel, and use all necessary force to compel compliance. When from such inquiries, examination, inspection, or search it appears that a breach of the laws of the US rendering a person liable to arrest or, if escaping to shore, shall be immediately pursued and arrested on shore, or other lawful and appropriate action shall be taken; or, if it shall appear that a breach of the laws of the US has been committed so as to render such vessel, or the merchandise, or any part thereof, on board of, or brought into the US by, such vessel, liable to forfeiture, or so as to render such vessel liable to fine or penalty, and if necessary to secure such fine or penalty, such vessel or such merchandise, or both, shall be seized.”)
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- 421 *See* 21 U.S.C. § 301; 21 U.S.C. § 331.
- 422 *See* Lisa Heinzerling, *Divide and Confound: The Strange Allocation of U.S. Regulatory Authority Over Food*, in *FOOD AND DRUG REGULATION IN AN ERA OF GLOBALIZED MARKETS* (2015) (noting the discrepancy between FDA’s regulatory scope and its funding).
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- 429 N.H. REV. STAT. ANN. § 146:20.
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