



February 22, 2021

Via Federal e-rulemaking portal

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Requirements for Additional Traceability Records for Certain Foods; 85 Fed. Reg. 59984 (Sept. 23, 2020); Dkt. No. FDA-2014-N-0053; RIN: 0910-AI44

Dear Mr. Pendleton:

Oceana, the largest international ocean conservation organization solely focused on protecting the world's oceans, with more than 1.2 million members and supporters in the United States appreciates the opportunity to submit comments regarding the proposed rule. The World Wildlife Fund (WWF) is the world's largest conservation organization, working in over 100 countries for over 60 years, with over 1 million U.S. members welcomes this opportunity to provide comments on the proposed rule. Oceana and WWF work to promote seafood traceability to keep illegally-sourced product of out of the supply chain; to ensure that our seafood is safe, legally caught and honestly labeled. Oceana and WWF support the proposed rule by the Food and Drug Administration (FDA) and recommend that the agency take further measures to improve seafood traceability and keep misbranded and illegally sourced products out of the supply chain including expanding the rule to all seafood products; aligning with other federal seafood programs like the Seafood Import Monitoring Program; requiring electronic recordkeeping and reporting; and providing consumers and seafood buyers with more information at the final point of sale. These measures would ensure that our seafood sold in the United States is safe, legally caught and honestly labeled.

Oceana and WWF recommend that the FDA require all firms in the seafood supply chain to identify and maintain records for all Critical Tracking Events (CTEs) and corresponding Key Data Elements (KDEs). KDEs, such as a unique vessel identifier,¹ are important to

¹ Other KDEs to establish legality may include: acceptable market name and scientific name of the species; date of catch or harvest; specific location in which the fish was caught; method of harvest, including gear type used; the weight or number, as appropriate, of the product for an individual fish or lot; vessel license and registration details,

verify the legality of seafood products, a key measure for both food security and food defense, as well as the chain-of-custody of the seafood. In addition, with respect to seafood, the FDA should align the requirements with the National Oceanic and Atmospheric Administration's ("NOAA") Seafood Import Monitoring Program ("SIMP"), harmonize data collection requirements with best practices, expand the requirements to all seafood products, require electronic recordkeeping, remove the exemption for fishing vessels and pair traceability with expanded consumer labeling.

Oceana and WWF support recommendations that the FDA should require each member of the food supply chain to develop, document, and exercise a product tracing plan, and urge the FDA to implement a policy of standardized electronic recordkeeping for all product tracing data to enable interoperability within and across industries. Electronic records are the easiest and most efficient means of tracking a product through the supply chain, and many companies have already employed this system.

Furthermore, electronic recordkeeping is particularly important for seafood, when real-time electronic data helps law enforcement track shipments of illegally-caught fish or seafood products and prevent them from entering our markets. It also helps businesses know immediately where their shipments came from and when, giving them information about the safety of the product. These are critical data points for retailers, who want to sell safe and legal seafood.

Background

Fish are the most heavily traded food commodity in the world, with intricate supply chains that are often very opaque. Further complicating the path to markets and the reliability of the products sold, is that there is a significant amount of illegal and unreported seafood that is laundered into the supply chain. Global estimates suggest that as much as 31% of the global marine catch is illegally caught or not reported.² Furthermore, NOAA estimates that more than 90% of the seafood consumed in the U.S. is imported.³ Even though a small portion of the fish we import may have been originally caught by U.S. fishermen, there are no systems in place to verify that the products the U.S. exports to third countries for processing are the same products imported back to the U.S.

The complex path that seafood takes from the point it is caught to the point it is sold to a consumer makes it difficult to isolate where in the supply chain the illegally sourced fish may enter. It would be difficult to ascertain that vessels fishing illegally and trans-shipping at sea are meeting appropriate health and safety standards.

Seafood fraud, specifically species substitution, can confound these issues, proving a new identity for illegally sourced product hampering efforts to stop illegal fishing. In a global

including (where available) IMO numbers or other unique vessel identifiers; whether (and where) the seafood was processed in a country other than where it was caught or harvested.

² Agnew D, Pearce J, Pramod G, Peatman T, Watson R, et al. 2009. Estimating the worldwide extent of illegal fishing. PLoS ONE 4(2): e4570. Doi:10.1371/journal.pone.0004570

<http://www.plosone.org/article/info:doi/10.1371/journal.pone.0004570>

³ NOAA. Fisheries of the United States – 2011, p. iv

review of more than 200 seafood fraud investigations found seafood mislabeling on every continent except Antarctica, with 1 in 5 samples mislabeled. These seafood swaps included fish with health advisories sold as safer alternatives; lower cost fish sold as higher cost seafood; imported fish sold as domestic or local seafood; and farmed seafood sold as wild-caught.⁴ This proposed rule requiring traceability would help stop seafood fraud, keep illegally caught fish out of the U.S. market and protect consumers from food safety concerns.

In 2014, President Obama established the Task Force on Combating IUU Fishing and Seafood Fraud (Task Force) via Presidential Memorandum.⁵ The Task Force developed recommendations for the “implementation of a comprehensive framework of integrated programs to combat IUU fishing and seafood fraud.”⁶ The final recommendations and action plan were released in March 2015 which included a recommendation for traceability.⁷ Oceana commented that this program should require traceability through the full supply chain.⁸ In December 2016, NOAA issued the final rule establishing the SIMP which required catch documentation and traceability requirements for 13 types of seafood considered at risk of IUU fishing and seafood fraud.⁹ The traceability requirements only required traceability from the point of catch or the farm to the first entry into US commerce.¹⁰ The final rule stated that FDA

is currently exploring which of its authorities could fill the gap, including regulations that would require designating high risk foods for certain additional recordkeeping under the authority of section 204 of the Food Safety Modernization Act (21 U.S.C. 2223), which addresses enhanced tracking and tracing of food through recordkeeping and was passed by Congress in 2011. Such additional recordkeeping requirements to enhance food safety are expected to facilitate FDA’s ability to track the origin of and prevent the spread of foodborne illness.¹¹

After SIMP was in force, Oceana sampled seafood not covered by SIMP and found 1 in 5 samples mislabeled, demonstrating that a limited approach and the lack of full chain

⁴ Warner, K *et al.* Deceptive Dishes: Seafood Swaps Found Worldwide <https://usa.oceana.org/publications/reports/deceptive-dishes-seafood-swaps-found-worldwide>, Sept. 2016 and references therein.

⁵ Press Release, Office of the Press Secretary, The White House, Presidential Memorandum-Comprehensive Framework to Combat Illegal, Unreported, and Unregulated Fishing and Seafood Fraud (June 17, 2014). <https://obamawhitehouse.archives.gov/the-press-office/2014/06/17/presidential-memorandum-comprehensive-framework-combat-illegal-unreported>.

⁶ *Id.*

⁷ Presidential Task Force on Combating IUU Fishing and Seafood Fraud, *Action Plan for Implementing the Task Force Recommendations* (March 2015), https://www.iuufishing.noaa.gov/Portals/33/noaa_taskforce_report_final.pdf.

⁸ Letter from Beth Lowell, Senior Campaign Director, Oceana, to Mark Wildman, International Fisheries Division, NOAA Fisheries (April 12, 2016), available at <https://beta.regulations.gov/comment/NOAA-NMFS-2015-0122-0086>.

⁹ Magnuson-Stevens Fishery Conservation and Management Act; Seafood Import Monitoring Program, 81 Fed. Reg. 88,975, 88,997 (Dec. 9, 2016).

¹⁰ *Id.* At 88,997-98.

¹¹ *Id.* At 88,978 (internal citations omitted).

traceability was not effective at fixing these problems.¹² To be truly effective, documentation should be required for all seafood and traceability required through the full supply chain, from boat or farm to plate.

As Oceana previously commented, Oceana is supportive of seafood being included in the Food Traceability List (FTL).¹³ Seafood presents multiple risks from microbiological and chemical contamination and allergens. Seafood is the world's most highly traded food commodity; and the global nature of this food supply means U.S. consumers are increasingly being exposed to novel pathogens and allergens.¹⁴ Seafood is also frequently subject to misbranding and species substitution.¹⁵ In a global review of studies on seafood mislabeling, more than half (58%) of the samples identified as substitute species carried a species-specific health risk to consumers, meaning these risks could not be adequately screened or mitigated due to mislabeling including parasites, environmental contaminations and aquaculture drug.¹⁶ These included risks of histamine or scombrototoxin poisoning found in certain tuna-related species; ciguatera, a natural toxin in some reef fish; tetrodotoxin found in certain pufferfish species; and gempylotoxin, a natural toxin found in escolar and oilfish.¹⁷

Seafood species substitution and incomplete labeling frustrate consumer efforts to choose seafood wisely to maximize health benefits and minimize risk. Emerging research on seafood allergens also shows that seafood allergies may be species-specific, meaning that if seafood species were correctly labeled, some allergen-sensitive consumers could enjoy certain seafood species while avoiding those that cause problems.¹⁸ Seafood mislabeling complicates this ability. Requiring actual seafood species scientific or common names on labels would provide greater protections by providing unique species identification. With traceability for seafood, this species-specific information would follow the product through the supply chain and be more readily available to disclose to the consumer.

Since the Food Safety Modernization Act (FSMA) passed by Congress in 2011 and the establishment of the SIMP in 2016, a number of non-governmental organizations, researchers, business leaders and other stakeholders have identified opportunities to harmonize the recordkeeping and reporting requirements with respect to seafood,

¹² Oceana, *Casting a Wider Net: More Action Needed to Stop Seafood Fraud in the United States* (March 2019), <https://usa.oceana.org/publications/reports/casting-wider-net-more-action-needed-stop-seafood-fraud-united-states>

¹³ Letter from Kimberly A. Warner, Ph.D., Senior Scientist, Oceana to Sherri Dennis, U.S. Food and Drug Administration (April 7, 2014), available at <https://www.regulations.gov/document?D=FDA-2014-N-0053-0007>.

¹⁴ Annibarro, B. *et al.* 2007. Involvement of hidden allergens in food allergic reactions. *J Investig Allergol Clin Immunol* 17(3): 168-172

¹⁵ Warner, K. *et al.* 2013. Oceana Study Reveals Seafood Fraud Nationwide. <http://oceana.org/en/news-media/publications/reports/oceana-study-reveals-seafood-fraud-nationwide>, Feb. 2013 and references therein

¹⁶ Warner, K *et al.* Deceptive Dishes: Seafood Swaps Found Worldwide, <https://usa.oceana.org/publications/reports/deceptive-dishes-seafood-swaps-found-worldwide>, Sept. 2016 and references therein.

¹⁷ *Id.*

¹⁸ Carrera, M. *et al.* 2012. Rapid direct detection of the major fish allergen, parvalbumin, by selected MS/MS ion monitoring mass spectrometry *J. Proteomics* 75:3211 – 3220; Tomm, TM *et al.* 2013 Identification of new potential allergens from Nile perch (*Lates niloticus*) and cod (*Gadus morhua*). *J Investig Allergol Clin Immunol* 23(3): 159-167.

including the Global Dialogue for Seafood Traceability (GDST).¹⁹ Due to the seafood being a global commodity, ensuring that the KDEs and CTEs are harmonized across markets²⁰ would allow for streamlined compliance for industry members, regulatory certainty and provide governments and managers with information that is more easily analyzed and assessed across the full supply chain to identify areas of enhanced risk.

FSMA was developed in part, out of a need to protect the food supply against intentional contamination due to sabotage, terrorism, counterfeiting, or other illegal, intentionally harmful means.²¹ This food defense, as well as food safety, is a critical issue for seafood, where elements of organized crime have been implicated in the illegal catch and handling of seafood, and where the supply chains remain opaque. A recent study by the United Nations on transnational organized crime in the fishing industry found that criminal groups are engaged in IUU fishing and that fishing vessels are used for the purpose of smuggling of migrants, illicit traffic in drugs, illicit traffic in weapons, and acts of terrorism.²² This poses challenges for ensuring appropriate measures for food defense and food safety so that seafood is not a potential vehicle for future bioterrorism.

It is thus important to prevent future threats by establishing traceability systems capable of documenting that all wild fish that enter the U.S. market comply with legal and health and safety requirements. Illegally caught seafood escapes from basic management controls; FDA should recognize that illegal fish are unsafe fish. Furthermore, as other markets (e.g., EU) take steps to prevent illegally caught products from entering their domestic markets, the United States should not become a market to which illegal products are diverted because they cannot meet more stringent requirements elsewhere. To effectively address this problem, the United States needs better seafood traceability and enforcement throughout the entire chain of sale, from boat to plate.

Recommendations for Strengthening the Proposed Rule

The proposed rule for traceability of certain foods which includes seafood is welcomed to address food safety, legality and seafood fraud. Our organizations are generally supportive of the rule with some additional recommendations for improvements. Oceana and WWF suggest that the agency also consider requiring all firms in the supply chain to identify and maintain records for all CTEs and corresponding KDEs. In addition, with respect to seafood, the FDA should align the requirements with the Seafood Import Monitoring Program, harmonize data collection requirements with best practices, expand the requirements to all seafood products, require electronic recordkeeping and reporting, remove the exemption

¹⁹ Global Dialogue on Seafood Traceability, *GDST 1.0 Standards and Materials* (Feb. 2020), <https://traceability-dialogue.org/gdst-1-0-materials/>

²⁰EJF *et al.* January 2020. A comparative study of key date elements in import control schemes aimed at tackling illegal, unreported and unregulated fishing in the top three seafood markets: the European Union, the United States and Japan <http://www.iuuwatch.eu/wp-content/uploads/2020/01/CDS-Study-WEB.pdf>

²¹ *See generally* Mitigation Strategies to Protect Food Against Intentional Adulteration, 81 Fed. Reg. 34,165 (July 26, 2016).

²² United Nations Office on Drugs and Crime (UNODC). 2011. Transnational Organized Crime in the Fishing Industry. Vienna. http://www.unodc.org/documents/human-trafficking/Issue_Paper_-_TOC_in_the_Fishing_Industry.pdf

for fishing vessels and pair traceability with expanded consumer labeling. Specifically, the proposed rule should:

1) **Expand the Food Traceability List (FTL) to include all seafood products.**

The FDA issued a federal register notice to solicit comments in 2014 on the draft approach for developing a list of high-risk foods.²³ Oceana submitted comments recommending that all seafood be designated as high-risk and subject to full recordkeeping and traceability requirements.²⁴ Oceana supports the FTL including finfish,

crustaceans, mollusks and bivalves with a few noted additions:

- a) **Expand finfish to include siluriformes:** The FTL does not include siluriformes fish, such as catfish. As noted by FDA, “data for catfish were excluded from the Risk-Ranking Model because siluriformes fish (such as catfish) are primarily regulated by the U.S. Department of Agriculture (USDA).”²⁵ This reluctance to include siluriformes has nothing to do with risk, but with the authority for siluriformes residing at USDA. Basa, swai and other Pangasius family of catfish are frequently found substituted for higher value fish in seafood fraud studies. In a global review of seafood mislabeling studies, pangasius was found to be the most commonly substituted fish worldwide, often for wild-caught, higher value fish.²⁶

By requiring traceability of siluriformes through the supply chain, the risk of misbranding and species substitution would be reduced. The U.S. should take a one government approach to this rule and require traceability for all finfish, regardless of the regulating agency. If the USDA must issue parallel regulations to do so, then FDA should work with USDA to ensure all finfish are subject to full chain traceability requirements.

- b) **Expand “mollusks, bivalves” to include all scallop products:** The FTL includes all mollusk species but does not include the scallop adductor muscle. Oceana strongly recommends that all scallop products be included on the FTL. Scallops are subject to seafood fraud including short weighting due to treatment with food preservatives such as sodium tripolyphosphate. Scallops are susceptible to bacteria such as *Vibrio parahaemolyticus*²⁷ and viruses such as

²³ Designation of High-Risk Food for Tracing; Request for Comments and for Scientific Data and Information, 79 Fed. Reg. 6596 (Feb. 4, 2014).

²⁴ Letter from Kimberly A. Warner, Ph.D., Senior Scientist, Oceana to Sherri Dennis, U.S. Food and Drug Administration (April 7, 2014), available at <https://www.regulations.gov/document?D=FDA-2014-N-0053-0007>.

²⁵ U.S. Food & Drug Administration, *FSMA Proposed Rule for Food Traceability* (2014), <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-food-traceability>.

²⁶ Warner, K *et al.* Deceptive Dishes: Seafood Swaps Found Worldwide, <https://usa.oceana.org/publications/reports/deceptive-dishes-seafood-swaps-found-worldwide>, Sept. 2016 and references therein

²⁷ Center for Disease Control, *Vibrio and Food* (last rev. Dec. 23, 2019) <https://www.cdc.gov/vibrio/food.html>

hepatitis A.²⁸ As a seafood product that is sometimes consumed raw, it is important for it to be included in the traceability list.

2) Align the Food Traceability Rule with the Seafood Import Monitoring Program

While the SIMP and the FDA's traceability proposed rule are promulgated under different authorities and implemented by separate agencies, the U.S. government should take a one government approach to seafood and ensure these programs are not established in silos, that information can be shared where needed to best address risk in supply chain and that the KDEs and CTEs are aligned. Additionally, the CTEs and KDEs should be harmonized across the U.S government and evaluated with respect to international best practices. Harmonizing these CTEs and KDEs would improve regulatory certainty for the seafood industry and allow for more streamlined compliance with U.S regulations and international mandates. Some specific alignments include:

- a) **Traceability Lot Code**-The traceability lot code should be linked with the unique catch or production document identifier required under SIMP. The Unique Document Identifier is provided by the harvester or landing recipient or competent authority under SIMP.
- b) **International Fisheries Trade Permit (IFTP)**-Importers of record who import seafood covered by SIMP must have an IFTP. The FDA should require the IFTP number as a KDE to be tracked once the product enters U.S. commerce.
- c) **IMO Number**-Reporting of the IMO number of vessels that caught or transshipped the product should be required. If a vessel does not have an IMO number, then another Unique Vessel Identifier should be required such as a registration, license number or other documentation, similar to what is required under SIMP.
- d) **Species Identity**-to better align with SIMP, the name of the species in addition to the ASFIS 3 alpha code²⁹ that corresponds with the species should be used. This allows for standardization of name throughout the supply chain.

3) Require Record Keeping for All Critical Tracking Events (CTEs) Throughout the Supply Chain

Key to ensuring the safety and legality of seafood products is ensuring that the KDEs follow the product at each and every step in the supply chain. FDA should ensure that for seafood the CTEs reflect the various ways that fish are moved and need to include the fishing event and any transshipment that may occur. The proposed exemption for fishing vessels defined by the Magnuson-Stevens Fishery Conservation and Management Act in FSMA Section 204(6(c)) in this proposed rule allows for an opening for unsafe and illegal products to enter the supply chain. It is

²⁸ Viray, M., Hofmeister, M., Johnston, D., Krishnasamy, V., Nichols, C., Foster, M., . . . Park, S. (2019). Public health investigation and response to a hepatitis A outbreak from imported scallops consumed raw—Hawaii, 2016. *Epidemiology and Infection*, 147, E28. doi:10.1017/S0950268818002844

²⁹ NOAA, *NMFS Seafood Import Monitoring Program - Species that Require the full set of the SIM Program Records*, <https://www.iuufishing.noaa.gov/Portals/33/SIMP.MandatoryFullMessageSetSpecies.3Alpha%20Codes.pdf>.

critical that the traceability requirement applies to each unique custodian of the product, beginning at the point of catch, and especially as product moves between vessels and custodians before it even reaches land. These are the easiest opportunities for laundering in of unsafe and illegal catches, which may have come from or passed through vessels which are not meeting health and safety phyto-sanitary requirements. The proposed rule could be strengthened by also requiring mass balance reconciliations at every CTE. By accounting for and validating any changes in mass as the product moves through the supply chain, it becomes much more difficult for illegal products to be laundered and mixed in with safe and legal products.

Additionally, a large subset of seafood imports is now required to report the KDEs proposed in this rule as part of the SIMP.³⁰ The FDA rules should conform with these reporting and traceability requirements and will also help to avoid compliance issues that may stem from any confusion caused by this proposed exemption.

Furthermore, for aquaculture products, the key data elements and critical tracking events should also apply further down the supply chain to the feed ingredients for those farmed products. Information on the feed is needed to ensure that other pathogens and bacteria are not introduced at that stage. The FDA requirements can also help to ensure other government requirements are met. A requirement for recordkeeping and traceability for aquaculture feed would also help to ensure that products that may have been created through forced labor or illegal fishing are also not entering the U.S. market, where it is illegal to handle, possess, or sell them.

4) Require Reporting of Information

The KDEs that are recorded for imported seafood should also be reported to regulators. This already is the case, as mentioned, for some seafood imports already as part of the SIMP. The gaps in SIMP, which does not currently apply to all imported seafood, creates an opportunity for mislabeling and seafood fraud to avoid compliance for species that are easy substitutes and look similar in appearance. This clearly creates a health and safety concern as well given the allergies and health problems that may present for consumers who eat something other than what it is claimed to be, because of mislabeling or other seafood fraud.

The architecture for a database for importers to report the information that would be required to record under the FDA proposed rule is already in place as a result of SIMP through the Customs International Trade Database System (ITDS) and automated customs entry (ACE). This makes it technically possible for FDA to require reporting of the recorded information by importers to the FDA, since the KDEs can be submitted through the ITDS and ACE portal, with relative ease. The KDE information, as well as the identity of the custodians of the product, should at a

³⁰NOAA's SIMP applies to 13 species groups, which account for around 40% of US seafood imports. NOAA Fisheries, *Seafood Import Monitoring Program*, <https://www.fisheries.noaa.gov/international/seafood-import-monitoring-program>.

minimum be reported for seafood imports to regulators, ideally through the established SIMP system. In this way then, both FDA and NOAA can access and review the information to ensure compliance.

5) Require use of electronic recordkeeping and communications for traceability

The proposed rule is intended to rapidly and effectively identify recipients of foods covered by the rule to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death. Rapid trace forward and trace backs need electronic recordkeeping and communications. Additional effective audits and verification of products that allow for risk based screening requires electronic reporting to facilitate these efforts.

6) Improve consumer facing product information

The FTL includes foods identified as higher risk of food safety concerns. Consumers have a right to know more about the food they eat, particularly with seafood so they can make more informed decisions on the seafood they purchase. Paired with seafood traceability, seafood consumers should be provided with the specific species of fish they are purchasing, where it was caught, how it was caught and whether it was farm raised.

Oceana and WWF support FDA's proposed rule to improve product tracing and recordkeeping in the seafood supply chain. There is a need to ensure that seafood does not remain subject to a set of standards and controls that are in any way weaker from those applying to other food categories. These requirements, if implemented and standardized throughout the industry, will help ensure that businesses and consumers have better information about where their seafood comes from and give them confidence that the seafood they buy is safe, legal and honestly labeled. We urge the FDA to establish product tracing requirements, such as the KDEs and CTEs, aligned with the requirements for seafood under the SIMP; expand the traceability requirements to all seafood products; require electronic recordkeeping and reporting; and provide consumers with more information about their seafood purchases. Increasing traceability requirements for seafood will help regulators address concerns about the health and safety of seafood products, and also help to prevent products created through illegal fishing and the use of forced labor in production from entering the U.S. market.

Oceana and WWF appreciate the opportunity to provide input and thank you for your time. We will continue to be engaged in this process moving forward.

Sincerely,

Beth Lowell
Deputy Vice President, US Campaigns
Oceana

Roberta Elias
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