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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:

On behalf of our organizations and our millions of members, we are writing to support the Food and Drug Administration's (FDA) proposed rule for traceability for certain foods, including seafood. As groups working to protect the health of our oceans, the environment, workers and public health, we strongly support traceability as an important tool to ensure that the seafood sold in the United States is safe, legally caught, responsibly sourced and honestly labeled. As the FDA finalizes the regulations, we urge the agency to extend the traceability requirements for all seafood; align with the Seafood Import Monitoring Program; ensure tracking and reporting of all critical tracking events and associated key data elements; require electronic recordkeeping and communication; and provide consumers more adequate and accurate information about the origins of their seafood.

Seafood fraud and illegal fishing are significant threats to the health of our oceans. With more than a billion people worldwide depending on seafood for nutritional and economic benefits, responsibly managed fisheries are critical to the health of the oceans and the health of those that depend on them. Illegal, unreported and unregulated (IUU) fishing is a low-risk, high-reward activity, especially on the high seas where a fragmented legal framework and lack of effective enforcement allows it to thrive. It is off the books, ignores domestic and international fisheries laws and amounts to estimated losses of \$25 billion to \$50 billion per year<sup>1</sup>. IUU fishing has been linked to transnational crimes like human trafficking and forced labor. Transparency at sea and traceability of seafood are essential to monitor fishing, identify suspicious activities, eliminate illegal fishing and restore healthy fisheries.

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<sup>1</sup> Sumaila, U. R., Zeller, D., Hood, L., Palomares, M. L. D., Li, Y., & Pauly, D. (2020). Illicit trade in marine fish catch and its effects on ecosystems and people worldwide. *Science advances*, 6(9).

Seafood fraud undermines honest fishermen and businesses that play by the rules, rips off consumers and can even impact our health. Seafood fraud can provide illegally caught fish with a new legal identity, hampering efforts to stop illegal fishing. In a global review of more than 200 seafood fraud investigations from every continent except Antarctica, 1 in 5 samples tested were 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<sup>2</sup>. 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.

Many of the undersigned organizations have advocated for federal actions to address illegal fishing and seafood fraud including supporting the Seafood Import Monitoring Program (SIMP) which was established in 2016. This program requires catch documentation and traceability to the first entry into U.S. commerce for 13 types of imported seafood at risk of illegal fishing and seafood fraud<sup>3</sup>. This was an important first step, but more needs to be done to ensure that our markets are closed to illegally sourced and fraudulent products. 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 traceability was not effectively fixing these problems<sup>4</sup>. 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.

A key takeaway from past federal efforts on combating IUU fishing and seafood fraud<sup>5</sup> is that these issues cannot be effectively addressed by a single government agency, the federal government must take a whole of government approach. As such, the FDA traceability rule should not be developed in a vacuum. The FDA should align key data elements (KDE) and critical tracking events (CTE) (where appropriate) with SIMP. The FDA should also look to international best practices to align and harmonize these KDEs and CTEs across programs. The traceability program should require electronic reporting of information to allow these separate but related systems to share data and information across the federal government

Our organizations recommend that the FDA:

- 1) **Expand the Food Traceability List (FTL) to include all seafood products:** The FTL covers most seafood except for siluriformes (species such as catfish) and scallop adductor muscles. Basa, swai and other Pangasius family of catfish are frequently found as substitutes in seafood fraud studies. Scallops are both a high value fish susceptible to illegal fishing and a mollusk susceptible to food safety concerns. The FTL should be expanded to cover all seafood.
- 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 and ensure these programs are not established in silos, that information

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<sup>2</sup> [www.oceana.org/DeceptiveDishes](http://www.oceana.org/DeceptiveDishes)

<sup>3</sup> <https://www.fisheries.noaa.gov/international/seafood-import-monitoring-program>

<sup>4</sup> <https://usa.oceana.org/publications/reports/casting-wider-net-more-action-needed-stop-seafood-fraud-united-states>

<sup>5</sup> <https://www.fisheries.noaa.gov/international-affairs/us-government-task-force-combating-illegal-unreported-and-unregulated-fishing#background>

can be shared where needed to best address risk in supply chain and that the KDEs and CTEs are aligned

**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 key data elements follow the product at every step in the supply chain. FDA should ensure that for seafood the critical tracking events (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.

**4) Require Reporting of Information**

The key data elements that are recorded for imported seafood should also be reported to regulators. This already is the case, as mentioned, for some seafood imports as part of the NOAA SIMP.

**5) Require 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.

**6) Provide Consumers with More Information About Seafood**

Seafood consumers should be provided with basic information about the seafood they purchase including what specific species of fish it is, where it was caught, how it was caught and whether it was farm raised.

These recommended improvements would allow the proposed rule for traceability to be even more effective with respect to seafood and ensure the U.S. government is taking a one government approach to addressing issues like IUU fishing and seafood fraud that cross multiple agencies and departments.

These recommended actions will protect law-abiding fishermen and seafood businesses that are competing with illegal and fraudulent products; it will give consumers more information about the origins of their seafood; and it will help stop IUU fishing and seafood fraud, which harms the oceans, people's livelihoods, and the food security of coastal communities dependent on sustainable fisheries.

Thank you for your consideration,

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