February 16, 2021

To the Members of the Food and Drug Administration,

Please accept the following comments on behalf of FishWise on the Requirements for Additional Traceability Records for Certain Foods (Docket No. FDA-2014-N-0053).

FishWise suggests the following recommendations to align the FDA's Proposed Traceability Rule with traceability best practices within the seafood industry:

(1) Require Vessel Identification Number(s) at First Receiver CTE for all products produced through the use of a fishing vessel.
(2) Require transshipment KDEs (vessel identification number, vessel name, and transshipment date) to be collected and recorded at First Receiver CTE.
(3) Require date of first frozen KDE for products produced through the use of a fishing vessel at First Receiver CTE.
(4) Include additional language to clarify KDEs required for seafood products produced from aquaculture.
(5) Align KDE definitions and formats as identified by NOAA to improve industry adoption and compliance.
(6) Communicate and share data across U.S. governmental agencies to increase efficiencies in data tracking and risk mitigation.

About FishWise

FishWise supports retail and mid-supply chain companies to leverage traceability practices and technologies for identifying and mitigating a variety of risks linked to seafood production. Our consultative approach stems from 17+ years of experience in seafood supply chain engagement, and our expertise is trusted by human rights and conservation organizations, seafood buyers and suppliers, and government representatives alike. We work directly with companies to improve electronic data collection and traceability for seafood products in alignment with comprehensive policies for environmental sustainability and social responsibility. Our close collaboration with seafood retailers, mid-supply chain companies, and producers to enact measurable changes to companies' seafood sourcing has resulted in a rich body of experiences from which FishWise, our partners, and our colleagues may draw lessons from to advance the field of seafood traceability. We have built trusting relationships with industry, government, and civil society partners and have come to be considered thought leaders on traceability best practice and implementation.

As a result, we know firsthand that the diversity of species, harvest methods, and global supply chains for seafood result in unique food safety risks and traceability challenges for these products as compared to agricultural products - including risks resulting from illegal fishing. Illegal, unreported, and unregulated (IUU) fishing results in catch entering the supply chain without proper accountability, increasing risks of mislabeling seafood and potentially mishandling of the products. End-to-end, electronic, and interoperable traceability is the

industry's best practice, and allows for documenting seafood product's legal origins *and* proper handling.

FishWise's seafood traceability efforts align with the FDA's New Era of Smarter Food Safety Blueprint first core element to support end-to-end traceability with interoperable and electronic systems. We are pleased to see electronic traceability as a requirement under this proposed rule. We recognize the wide breadth of food products under this rule's jurisdiction, and our comments act to provide insight into the nuances of seafood supply chains.

(1) Vessel Identification Number

The proposed definition of "Vessel Identification Number" (§ 1.1310) states that this number can be assigned by the International Maritime Organization (IMO) or by any entity or organization for the purpose of uniquely identifying the vessel. **FishWise agrees with this definition and confirms that the clause to include identification numbers other than IMO numbers is necessary.** Smaller vessels, less than 300 gross tonnage, are not assigned IMO numbers, and therefore this language to extend to other unique vessel identification numbers is important. Our suggestion is to add language describing when an IMO number is required.

(2) Transshipment

Transshipment is a common business practice in seafood supply chains describing the transfer of fish between vessels that can be owned by different entities. Fishing vessels offload catch with a large refrigerated transport vessel (known as "carriers" or "reefers") either at sea or in port. This transaction within seafood supply chains frequently occurs to increase fishing efficiency at sea by reducing the number of trips of fishing vessels back to port to offload catch. For example, tuna species are typically harvested on the high seas, often using distant water fleets, where monitoring and regulatory enforcement are weak. In this case, at-sea transshipment practices allow fishing vessels to spend long periods at sea and avoid in-port compliance or inspection. At-sea transshipment has been associated with higher risk of transporting illegal, unreported, and unregulated (IUU) catch, undermining social well-being of workers, effective fisheries management, and traceability efforts. These carrier vessels physically possess seafood products that can originate from several harvest vessels, maintain the cold storage of the product, and are therefore a key step within seafood supply chains for documenting proper handling and legal origin of a product. Many industry leaders from harvesters through to FishWise's retail partners have published at-sea transshipment policies that require data collection on the occurrence of transshipment. For these reasons, it is critical to require transshipment KDEs (vessel identification number and name) to be collected and recorded at First Receiver CTE.

A vessel participating in at-sea transshipment is considered a fishing vessel according to the definition described in section 3(18) of the Magnuson-Stevens Fishery Conservation and Management Act, and this proposed rule, because these vessels are involved with storage, refrigeration, and transportation of seafood. Although considered a fishing vessel, FishWise

suggests altering the requirements for First Receiver KDEs for products produced from a fishing vessel to include transshipment information. Proposed § 1.1335 states that previous location identifier (proposed § 1.1335(a)) and the name of the transporter who transported the food to the receiver (proposed § 1.1335(h)) will be recorded. In the outlined **First Receiver KDEs of products produced from a fishing vessel, FishWise recommends to include the transshipment vessel identification number as the previous location identifier, name of the vessel as the previous transporter name, and the date of transshipment** (*See KDE Table, Row E, L, M*).

(3) First Frozen

As described above, seafood products can have a long journey prior to reaching the First Receiver whether from a harvest vessel or transshipment vessel. These long periods of time at sea require operators to maintain freshness. Seafood that has not been kept at proper temperatures can cause foodborne illness. Proposed § 1.1330(a) described the KDEs to be collected by the First Receiver KDEs of products other than those produced through the use of a fishing vessel (§ 1.1330(b)) to require information about where/when the food was cooled as well as where/when the food was packed. **FishWise suggests that fishing vessels not be excluded from this First Receiver KDE requirement and require date and time the seafood was first frozen** (*See KDE Table, Row N)*.

(4) Aquaculture

Aquaculture products now make up more than 50% of seafood consumption in the U.S. and issues of traceability and even IUU fishing (of wild-capture feed sources) still exist within those supply chains. Aquaculture produces all three seafood products identified on the FDA's Food Traceability List: finfish, crustaceans, and mollusks. Because of this, there needs to be improved clarification regarding expectations of the First Receivers of seafood produced from aquaculture. Aquaculture is only defined as a harvest activity in this proposed rule, but is also defined as a Farm in Subpart J §1.328. **Clearly state in Subpart S that aquaculture is a farm and therefore requires Growing Area Coordinates (§ 1.1325(a)) as a First Receiver KDE.** FishWise agrees with the use of GPS coordinates to identify pond specific harvest and identify small-scale aquaculture farms. (*See KDE Table, Row O)*

FishWise agrees that the First Receiver of seafood products is the buyer or the first person (other than a fishing vessel or aquaculture farm) who purchases and takes physical possession of a food on the Food Traceability List. We do not propose changing the definition of fishing vessel, but we urge the FDA to allow for the differentiation of harvest and transshipment vessel information if transshipment occurs. We suggest that key data elements (KDEs) that a First Receiver collects include the above recommendations. These recommendations for First Receiver KDEs are summarized in the below table.

	First Receiver KDE	Description
A	Traceability Lot Code	descriptor, often alphanumeric, used to identify a traceability lot and acts as the linking KDE
B	Harvest Date Range	Dates of Capture
C	Harvest Location	Harvest location (NMFS Ocean Geo Code/geographical coordinates)
D	Location description	Name of the fishing vessel that caught the seafood, the country in which the fishing vessel's license, and a point of contact for the fishing vessel ***Suggest collecting: Vessel Flag**
E	Location Identifier	Vessel Identification Number ***Suggest collecting: Transshipment Vessel Identification Number for products that are transshipped *(Recommendation 1)***
F	Entry Number (import)	Importer license number
G	Location identifier and description of receiver	Unique identification code, complete physical address, and key contact business information of the first receiver purchaser
H	Date/time of receiving	Date and time
I	Quantity and Unit of Measure	quantity and unit of measure of the food (*e.g.,* 6 cases, 200 pounds)
J	Traceability product identifier and description	Category Code/Term, Category Name ***Suggest collecting: scientific name *(Recommendation 5)***
K	Reference record types and numbers	Bills of lading (BOL), purchase orders, advance shipping notices (ASNs), work orders, invoices, batch logs, production logs, and receipts
L	Name of the previous transporter	Vessel Name ***Suggest collecting: Transshipment vessel name for products that are transshipped *(Recommendation 1)***
M	***Suggest collecting: Date of Transshipment (*Recommendation 1*)**	If transshipment occurred, date of transshipment.
N	***Suggest collecting: Date/time of first Freezing (*Recommendation 3*)**	Date and time
O	***Suggest collecting: Growing Area Coordinates for products produced from Aquaculture (*Recommendation 4*)**	Pond location (geographical coordinates)

(5) Alignment of KDEs

FishWise is encouraged by the continued momentum to prioritize electronic and end-to-end traceability. We agree that standardized data collection streamline internal records and promote interoperability throughout the supply chain, which can improve verification exercises (§ 1.1315(a)(4)). However, many import requirements already collect a subset of this data from the seafood industry. A review of the information currently collected against the information proposed in this new traceability program might reveal that a good amount of information is already collected. Where KDEs required under this rule overlap with information collected under others (e.g. SIMP, NOAA 370 Form) alignment will improve efficiency and cost effectiveness of compliance.

The Seafood Import Monitoring Program (SIMP) (Docket No. 150507434-6638-02) exists as a traceability program that requires importers to record and provide key data elements from point of harvest to entry into the U.S. market. As the FDA proposed rule intends to collect several pieces of key data elements from seafood products, **FishWise suggests alignment on KDE definitions and formats as identified by NOAA**. For example, we agree that Category Code/Term aligns with ASFIS as expected for SIMP, and we encourage the use of the product's scientific name as the Category Name.

With standardization and alignment of KDE formats, companies can more readily adapt their existing data management systems that are already collating supply chain data, resulting in improved opportunities for data interoperability. **For the KDEs required for seafood produced from a fishing vessel or from aquaculture by FDA Subpart S, FishWise suggests aligning KDE definitions and formats as outlined by NOAA.**

Standardized, open and industry-wide nomenclature is encouraged to prevent confusion and harmonize existing procedures and protocols. Currently, the seafood industry is moving towards standardization of KDEs as outlined in the GDST 1.0 standards[1]. FishWise encourages the seafood industry to align with GDST 1.0 standards, which will help with achieving traceability best practices of electronic, end-to-end, and interoperable systems. In addition to GS1 and the 3-Alpha Seafood Species Code (§ 1.1310(1)), **FishWise recommends the FDA include a reference to GDST's existing standards for relevant information required for seafood in Subpart S**. This will streamline compliance and remain current in industry standards as traceability progresses.

(6) Intragovernmental Coordination

An important component of this recommendation will be standardizing how this new U.S. traceability rule operates along other programs and best practices within the seafood industry. Seafood supply chains are global and complex, resulting in several United States governmental agencies having jurisdiction over seafood products as they enter the country

[1] https://traceability-dialogue.org/gdst-1-0-materials/

for consumption. Improved supply chain transparency and effective traceability practices of products are the foundation of regulations governing seafood products. As these regulations and rules continue to evolve it is necessary to have intragovernmental coordination between agencies (e.g. NOAA, CBP, and FDA). **FishWise urges the FDA to create Memorandums of Understanding to identify compliance barriers and facilitate interagency coordination between governmental agencies implementing documentation and inspection programs for seafood products.**

For example, if the FDA progresses to an automated system of data collection, it will be more efficient if done in alignment with existing government traceability platforms such as the International Trade Data System (ITDS) through the Automated Commercial Environment (ACE) maintained by the CBP. We encourage the FDA to consider what automated verification can be built into these existing electronic systems. When information is requested by several entities, ensuring that data is recorded in one electronic and interoperable platform will help the industry submit the information and allow it to be accessed by the agencies needing to view it.

FishWise thanks the U.S. government for taking leadership on this important topic, allowing for the opportunity to provide input, and for all of its excellent work to date to address food traceability. We believe a holistic, collaborative approach to these issues has the potential to create a strong foundation of transparency and coordination that will allow for aligned information sharing and real change in seafood supply chains.

Please contact FishWise with any additional questions.

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