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February 11, 2021

DOCKET NUMBER: FDA-2014-N-0053

Attn: Brian Pendleton, Senior Policy Advisor, Office of Policy
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Proposed Rule: Requirements for Additional Traceability Records for Certain Foods (Docket # FDA-2014-N-0053)

Dear Mr. Pendleton,

On behalf of the Southern Shrimp Alliance, we are grateful for the opportunity to submit comments on the U.S. Food and Drug Administration's (FDA) proposed rule regarding requirements for additional traceability records for certain foods. See Requirements for Additional Traceability Records for Certain Foods, 85 Fed. Reg. 59,984 (FDA Sept. 23, 2020) (proposed rule). These comments are timely filed in accordance with the FDA's extension of the comment period to February 22, 2021. See Requirements for Additional Traceability Records for Certain Foods; Extension of Comment Period; Reopening of the Comment Period, 85 Fed. Reg. 82,393 (FDA Dec. 18, 2020).

Founded in 2002, the Southern Shrimp Alliance is a non-profit 501(c)(6) industry association comprised of shrimp fishermen, farmers, processors, unloading docks, and associated shoreside businesses in the coastal states of North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Louisiana, and Texas. A thriving U.S. shrimp industry supports thousands of small and medium-sized family-run enterprises throughout the coastal South and is a vital contributor to the economies of dozens of communities in the region. As an organization, the Southern Shrimp Alliance is committed to enhancing the long-term viability of one of the nation's most valuable commercial fisheries and delivering a healthy, wholesome food product to the American public.

The comments offered below regard a few select issues of importance to the membership of the Southern Shrimp Alliance. These comments are, however, by no means exhaustive and the

organization has encouraged industry participants to submit comments directly to the FDA regarding concerns and questions regarding individual business operations. Further, we understand that the agency's obligations pursuant to the June 11, 2019 consent decree in Center for Food Safety v. Azar, Case No. 4:18-cv-06299 (N.D. CA) require the FDA to publish a final rule pursuant to Section 204(d)(1) of the Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (FSMA) by no later than November 7, 2022. Although there is now only a limited time window in which to implement a law enacted a decade ago, the Southern Shrimp Alliance believes that minor modifications to the proposed regulations, as well as concentrated outreach efforts and practical changes to the FDA's reporting system, could significantly improve the new regulatory requirements and encourage compliance over the next nineteen months.

I. The Vessel Exemption & Direct Sales to Consumers

Section 204(d)(6)(C) of the FSMA affords unique rules of application of the law to fishing vessels, as follows:

> (C) FISHING VESSELS.—The requirements under this subsection with respect to a food that is produced through the use of a fishing vessel (as defined in section 3(18) of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1802(18))) shall be limited to the requirements under subparagraph (F) until such time as the food is sold by the owner, operator, or agent in charge of such fishing vessel.

Paragraph (F) of Section 204(d)(6), in turn, limits the extent of the exemption afforded to fishing vessels, as follows:

> (F) RECORDKEEPING REGARDING PREVIOUS SOURCES AND SUBSEQUENT RECIPIENTS.—In the case of a person or food to which a limitation or exemption under subparagraph (C), (D), or (E) applies, if such person, or a person who manufactures, processes, packs, or holds such food, is required to register with the Secretary under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) with respect to the manufacturing, processing, packing, or holding of the applicable food, the Secretary shall require such person to maintain records that identify the immediate previous source of such food and the immediate subsequent recipient of such food.

The FDA's proposed regulations account for FSMA's Section 204(d)(6)(C) and Section 204(d)(6)(F) through 21 C.F.R. § 1.1305(j), which provides that subpart S of the regulations do not apply to the owner, operator, or agent in charge of a fishing vessel. The proposed regulations explain that "activities of fishing vessels such as harvesting, transporting, heading, eviscerating, and freezing fish would generally not be subject to the proposed recordkeeping requirements" and, as such, "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 . . ."[1] However, the proposed regulations further clarify that certain fishing vessels are not encompassed

[1] 85 Fed. Reg. 59,998 (FDA Sept. 23, 2020).

within this exemption, such that any fishing vessel that "is required to register with FDA under section 415 of the [Food, Drug, & Cosmetic (FD&C)] Act with respect to the manufacturing, processing, packing, or holding of the applicable food . . ." would not be covered. Accordingly, any "fishing vessels that must register with FDA because they process fish on the vessel would be required to comply with the existing subpart J traceability recordkeeping requirements in §§ 1.337 and 1.345, even though many such fishing vessels are currently exempt from those requirements under § 1.327(c)," and such records must be kept for two years.[2]

The FDA explains that it has interpreted the FSMA's Section 204(d)(6)(C) as not meaning that traceability requirements are not imposed upon a non-FDA registered fishing vessel once seafood is sold from that vessel:

> Although the phrase "until such time" could be interpreted as meaning that the owner, operator, or agent in charge of the fishing vessel could be subject to requirements relating to the sale of the relevant food, we believe it is appropriate to exempt the owner, operator, or agent in charge of the fishing vessel from all requirements relating to the relevant food (except as specified in proposed § 1.1305(j)(2)).[3]

The Southern Shrimp Alliance agrees with this reasonable interpretation of the statute and believes that the FDA's proposed regulations are consistent with Congressional intent.

As vessels operating in the commercial warmwater shrimp fishery in the coastal South Atlantic and the Gulf of Mexico engage in the heading and/or freezing of shrimp "solely to prepare a fish for holding on board a harvest vessel" (21 C.F.R. § 123.3(k)(2)(ii)), these vessels are not required to register as a facility with the FDA pursuant to 21 U.S.C. § 350d(c)(1). Accordingly, the Southern Shrimp Alliance understands that per the agency's proposed regulations, the owners, operators, or agents in charge of these fishing vessels are exempt from all requirements relating to the relevant food.

Although the Southern Shrimp Alliance believes that the extent of the application of the proposed regulations to fishing vessels that are not required to register with the FDA is clear, we note that the proposed regulations also include an express exemption for farms when food is sold directly to consumers. The proposed language for 21 C.F.R. § 1.1305(b) provides that "[t]his subpart does not apply to a farm with respect to food produced on the farm (including food that is also packaged on the farm) that is sold directly to a consumer by the owner, operator, or agent in charge of the farm." Similarly, fishing vessels that are not required to register with the FDA may also make sales directly to consumers. While food produced by these fishing vessels is exempt from the requirements implemented through the proposed regulations by virtue of the language proposed by 21 C.F.R. § 1.1305(j)(1), the Southern Shrimp Alliance believes that an express exemption for food sold directly to consumers from fishing vessels, mirroring the language of 21 C.F.R. § 1.1305(b) for farms, is appropriate. Section 204(d)(6)(E) of the FSMA authorizes the FDA to "modify the requirements under this subsection with respect to, or exempt a food or a type

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2 *Id.* at 59,999.

3 *Id.*

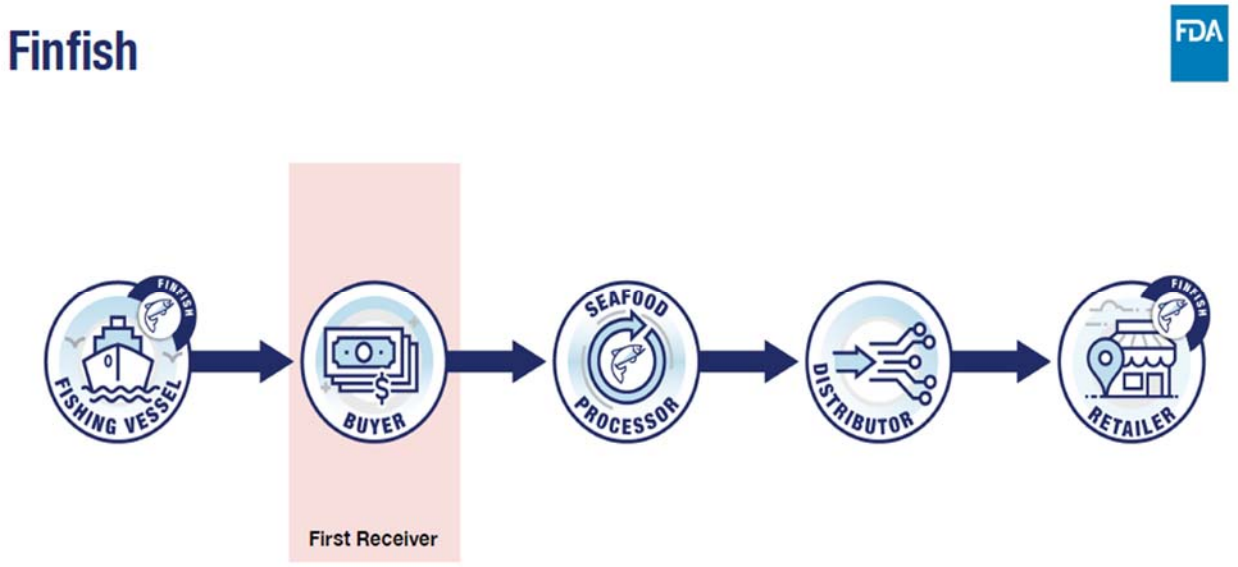
of facility from, the requirements of this subsection (other than the requirements under subparagraph (F), if applicable) if the Secretary determines that product tracing requirements for such food . . . or type of facility is not necessary to protect public health." Here, sales of food from a fishing vessel directly to a consumer is directly analogous to sales of food from a farm directly to a consumer.

Accordingly, we request that the language of 21 C.F.R. § 1.1305(b) be amended to read, as follows:

> (b) *Exemption for farms and fishing vessels when food is sold directly to consumers.* This subpart does not apply to a farm or fishing vessel with respect to food produced on the farm (including food that is also packaged on the farm) or fishing vessel that is sold directly to a consumer by the owner, operator, or agent in charge of the farm or fishing vessel.

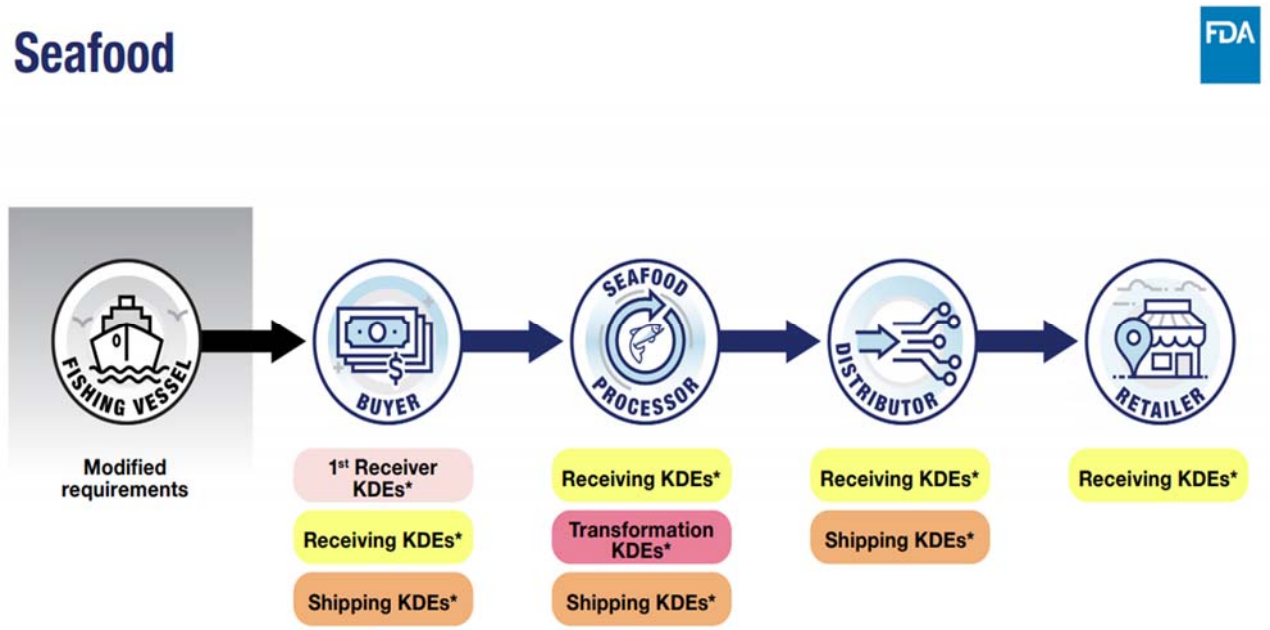
II. The Regulatory Obligations of Unloading Docks and Fish Houses

In its public presentations, the FDA has mapped supply and distribution chains for seafood through graphics such as this one:



As conceived by the proposed regulations, it is the Southern Shrimp Alliance's understanding that obligations to identify critical tracking events (CTEs) and report key data elements (KDEs) associated with these CTEs would initiate with the first receiver of food produced on fishing vessels that are not required to register with the FDA. Pursuant to 21 C.F.R. 1.1330(b), if not already established, the first receiver is asked to establish and assign traceability lot codes to shrimp purchased from a fishing vessel. The first receiver also would be obliged to maintain records, for at least two years after the date of the receipt of the food, that are to be made available to the FDA within 24 hours of any agency request.

As the FDA has described in its public presentations, the first receiver of food produced by a fishing vessel would be required to identify and keep track of first receiver KDEs, receiving KDEs (for receipt of the food), and shipping KDEs (for the shipping of the food to the next link in the supply chain).



Within the shrimp industry, the first receiver of shrimp is generally the unloading dock or fish house.

Hundreds of such family-owned and operated businesses are located throughout the coastline of the southern United States. These businesses are already required to obtain and maintain records regarding the shrimp (and other seafood products) unloaded from fishing vessels in response to other regulatory controls. In order to limit duplication and to ease the implementation of the FDA's new proposed traceability requirements, the Southern Shrimp Alliance requests that the agency work with the National Sea Grant College Program of NOAA to develop outreach compliance programs for unloading docks and fish houses throughout the country. Sea Grant has programs, either located within a university or as a state agency, in each of the eight states wherein the U.S. warmwater shrimp industry operates. Historically, Sea Grant has provided invaluable technical assistance to commercial fishing industries as these industries have attempted to abide by ever-increasing and expanding federal government regulations.

III. Application of Traceability Requirements to Imported Seafood

The proposed regulations, at 21 C.F.R. § 1.1460(b), provide that an article of food may be subject to refusal of admission into the United States pursuant to section 801(a)(4) of the FD&C Act "if it appears that the recordkeeping requirements under section 204 of the [FSMA] (other than the requirements under subsection (f) of that section), including the requirements of this subpart, have not been complied with regarding such article." The Southern Shrimp Alliance

agrees with this proposed regulation and believes that any seafood offered for importation by an importer that cannot meet the traceability requirements of proposed 21 C.F.R. § 1.1330(a)(2) should not be allowed entry into the United States.

As the Southern Shrimp Alliance has investigated shrimp trade fraud, we have repeatedly discovered circumstances wherein a foreign shrimp exporter is simply incapable of identifying the source of shrimp packaged for export. These foreign businesses may purchase shrimp not only from a large number of aquaculture farms and/or fishing vessels in their own country, but may also import substantial quantities of shrimp from other countries to be used as raw material for further processing. This imported shrimp feedstock may, in turn, be commingled with shrimp supplied by domestic sources, eliminating the ability of the food to be traced to its source of harvest.

For example, U.S. Customs and Border Protection (CBP) recently completed an investigation under the Enforce and Protect Act (19 U.S.C. § 1517) of a Vietnamese shrimp processor and exporter in response to allegations that the company was transhipping Indian-origin shrimp to the United States, evading payment of antidumping duties on these goods.[4] CBP found that the company did not have a system in place to trace imported shrimp feedstock through its processing to its sale. Responding to the company's arguments that it met its obligations to track the origins of its seafood under NOAA's Seafood Import Monitoring Program (SIMP), CBP observed:

> SIMP requires traceability back to point of harvest of the shrimp, with records regarding the movement among and between each custodian of the shrimp up to the point of entry into U.S. customs territory. However, the accuracy of Minh Phu's SIMP documents are in question if they are unable to trace imported shrimp that has been processed through its production documents.[5]

Although the company claimed that it could demonstrate its ability to ensure that imported shrimp feedstock was not used for shrimp exported to the United States through its compliance with SIMP, NOAA's audit system does not appear to, in fact, require traceability of imported shrimp back to the source of harvest.

The inability – or unwillingness – of participants in the supply chain for imported seafood to maintain the ability to trace foreign seafood back to its source in a meaningful, accurate manner has been identified by the FDA as a significant threat to the health of American consumers.[6] Cheap, tainted foreign shrimp is routinely traded from one country to another before ultimately being exported to the United States. Indeed, widespread importation of Chinese-origin shrimp into Malaysia for export to the United States is likely responsible for the agency's Import Alert

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[4] *See* Letter from U.S. Customs and Border Protection to MSeafood Corporation and the Ad Hoc Shrimp Trade Enforcement Committee, *Notice of Determination as to Evasion*, EAPA Case Number 7356 (Oct. 13, 2020), public version available at: https://www.cbp.gov/document/guidance/eapa-case-7356-mseafood-corporation-notice-determination-evasion-october-13-2020.

[5] *Id.* at 8.

[6] 85 Fed. Reg. 59,989 (FDA Sept. 23, 2020).

16-136 (*Detention Without Physical Examination of Aquacultured Shrimp and Prawns from Peninsular Malaysia Due to the Presence of Drug Residues from Unapproved Animal Drugs or the Presence of Unsafe Food Additives*).[7]

As the FDA considers adoption of traceability requirements for domestic seafood that allow U.S.-produced food to be linked back to its initial harvest, the agency must ensure that the same requirements attach to the imported products that compete for sales in the U.S. market. The FDA cannot permit the entry of seafood into the U.S. market that fails to meet the same traceability standards imposed on domestically-harvested seafood. As a practical matter, the FDA should create a unique violation code for food entry lines refused at the border pursuant to the agency's authority under 21 C.F.R. § 1.1460(b) as well as a unique ASC ID and charge code that will facilitate the public's ability to monitor the FDA's enforcement of its traceability requirements with regard to imported food included on the Food Traceability List.

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Thank you for any consideration you are able to give to these comments. I am available to address any questions you might have regarding this correspondence.

Sincerely,

John Williams
Executive Director

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[7] *See* Arnold Loh, *Tainted Shrimp Suspected to Be from Transhipments*, The Star (Malaysia) (Jan. 5, 2020), available at: https://www.thestar.com.my/news/nation/2020/01/05/tainted-shrimp-suspected-to-be-from-transhipments; Jason Gale, Lydia Mulvany, and Monte Reel, *How Antibiotic-Tainted Seafood from China Ends Up on Your Table*, Bloomberg Businessweek (Dec. 15, 2016), available at: https://www.bloomberg.com/news/features/2016-12-15/how-antibiotic-tainted-seafood-from-china-ends-up-on-your-table; and Southern Shrimp Alliance, *SSA Asks FDA to Take Additional Action Regarding Shrimp Shipped from Malaysia* (Feb. 2, 2015), available at: https://www.shrimpalliance.com/ssa-asks-fda-to-take-additional-action-regarding-shrimp-shipped-from-malaysia/.