February 22, 2021

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted electronically at www.regulations.gov

RE: Docket No. FDA-2014-N-0053; Requirements for Additional Traceability Records for Certain Foods; 85 *FR* 59984 (September 23, 2020)

Dear Sir/Madam:

National Fisheries Institute (NFI) appreciates this opportunity to submit comments in response to the *Federal Register* notice referenced above regarding Food and Drug Administration's (FDA's) Requirements for Additional Traceability Records for Certain Foods.

NFI is the nation's largest commercial seafood trade association. Now in its eighth decade, NFI today represents the seafood harvesters, vessel owners, processors, distributors, and associated companies that help feed families in the United States and around the world. NFI and its members support and promote sound public policy based on scientific principles.

NFI's members globally source, process and distribute safe and healthy seafood for the enjoyment of the American consumer. Over 25 years ago, NFI supported FDA as the nation's competent authority over seafood with the development and implementation of the "Seafood HACCP Regulation." We continue to support actions by the agency, such as the need for enhanced traceability, which protect the health and well-being of the general public.

Traceability is here to stay. As technology evolves, the supply chain, regulators, and consumers will have information at "their fingertips" to understand the journey of food from origin to finished product to point of sale. We support the agency's forward thinking "Blueprint for a New Era of Smarter Food Safety" as a means to achieve an end goal of a technology-based traceability system. But as NFI's comments on the Blueprint cautioned, further technological and infrastructure advances are needed to make this a reality.[1]

[1] Docket FDA-2019-N-4187-0120

FDA repeatedly mentioned transparency during the public meetings for this proposed rule. Greater transparency and supply chain intelligence is a business benefit and is not necessary for food safety. Because businesses are built on protected sources and relationships, traceability can and must be achieved without full transparency of the supply chain. We urge that the final traceability rule focus on what is essential for tracing product, not on supply chain transparency.

Because of the global nature of the seafood industry, the final rule must address the needs of our trading partners. An international outreach must be adopted to ensure successful implementation.

As a member of the Food and Beverage Issue Alliance (FBIA), we completely support the comments, concerns and suggested remedies provided in the joint comments for this proposed traceability rule.

We concur with the FBIA comments that the final rule be simplified and focused on filling the gaps that are missing from the existing subpart J recordkeeping requirements. This in itself will dramatically improve the ability of industry and agency to achieve more efficient product tracebacks and recalls.

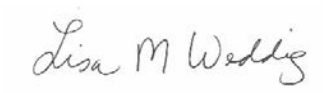
The attached document provides extensive comments on behalf of NFI's members. The document is organized in the following focused areas:

- FSMA Section 204 Legal Authority
- Food Traceability List Determination
- Exemptions for Certain Products
- Exemptions for Certain Facilities
- Specific questions and Need for Concurrence
- Alignment to other Traceability Rules
- Costs to Implement and Recordkeeping
- Implementation of Rule
- Specific Comments about the Proposal
- Appendix A – Seafood Supply Chain Examples
- Appendix B – Review of FDA's Supply Chain Example

NFI appreciates FDA providing the extended public comment period, as this proposed traceability rule is an important step in developing a workable modern approach to strengthen protection of the food supply. However, NFI is disappointed that the industry request for additional time to comment was not granted; especially with the last minute release of supportive materials that included responses to Frequently Asked Questions and a detailed supply chain example. The mere fact that 42 pages are necessary to provide the Supply Chain example showcases the complexity of the proposed rule.

We welcome future dialogue as the agency prepares the final traceability rule and Food Traceability List. Thank you for the opportunity to provide our comments to this major food safety rule.

Sincerely,



Lisa Weddig
Vice President, Regulatory and Technical Affairs

NFI Comments on FDA Proposed Rule
Requirements for Additional Traceability Records for Certain Foods
Docket No. FDA-2014-N-0053

Overstepping legal authority

We appreciate the complexity of food traceability in general and in particular the challenge of effectively implementing Section 204 – Enhancing Tracking and Tracing of Food and Recordkeeping. However, the proposed rule in multiple respects exceeds the legal authority Congress established for FDA via FSMA, burdening seafood companies with requirements that provide no public health benefits and that duplicate the information contained in separate records seafood companies already possess. Specifically:

Section 204(d) provides the authority for these regulations, but the proposed rule violates several of the associated guidelines found in section 204(d)(1)(A)-(M). We note the following:

Subsection (d)(1)(A) restricts recordkeeping requirements to those that *"relate only to information that is reasonably available and appropriate".*
The required KDEs will not be reasonably available when fishing vessels and aquaculture operations and subsequent supply chain steps do not know the final destination of the product, due to global competition within the seafood industry.

Subsection (d)(1)(B) mandates that requirements must "*be science-based".*
FDA's own guidance document – Fish and Fishery Products Hazards and Controls, fourth edition (the Hazards Guide) – does not support the directive to maintain extensive documentation of "originating" for the vast majority of the finfish and crustaceans on the Food Traceability List (FTL). Of the 980 species the Hazards Guide identifies, only 191 have potential hazards associated with the harvest or growing locations. The agency proposes to apply this requirement to over 500 percent of the species its own, longstanding guidance indicates should be covered. That is hardly "science-based."

Subsection (d)(1)(C) prohibits FDA from *[prescribing] specific technologies for the maintenance of records".*
The agency's recommendation for use of master lists to manage certain required KDEs, such as traceability product identifiers and location identifiers, ignores the fact that master lists are relevant only for computerized systems and have no utility for paper-based systems. In addition, due to the large number of data attributes for many of the required KDEs, even simple supply chains, such as presented in the examples provided by the agency, would overwhelm a

paper-based systems.[2] The number and complexity of KDEs, with associated data attributes, required to be gathered, maintained and, in some cases, passed along, will force companies to invest in new digital systems that may not be necessary today. This mandate amounts to a *de facto* FDA requirement that regulated companies convert to digital systems, despite a clear congressional command not to pick one technology over another.

Subsection (d)(1)(D) requires the agency to "*ensure that the public health benefits of imposing additional recordkeeping requirements outweigh the cost of compliance with such requirements".*
As made clear above, with respect to Subsection (d)(1)(B), there is no public health benefit to requiring additional recordkeeping for documenting the "originating" KDEs for the overwhelming majority of the seafood species included on the FTL. NFI cannot fathom how FDA concluded that application of this requirement to virtually all seafood products yields public health benefits that exceed the manifest burdens the requirement imposes. The costs badly outweigh the benefits.

Subsection (d)(1)(E) provides that recordkeeping mandates must "*be scale-appropriate and practicable for facilities of varying sizes … and not require the creation and maintenance of duplicate records where the information is contained in other company records kept in the normal course of business".*
Here, again, FDA ignores existing practices in the seafood industry. FDA and NOAA already requires seafood companies to capture the same or similar KDEs for harvesting and importing – KDEs that the rule as proposed does not accept. Without the flexibility to use different KDEs that provide data comparable to that contained in the acceptable records, companies will be compelled to maintain and report multiple records containing the same or virtually the same information.

Subsection (d)(1)(F) directs FDA to "*minimize the number of different recordkeeping requirements for facilities that handle more than 1 type of food".*
Despite this provision, the proposed rule represents a quantum leap in industry recordkeeping requirements, especially for processors and distributors. Though each entity, in theory, has the flexibility to develop its own internal traceability program, as proposed in §1.1315, in practice the passing forward of KDEs from a shipper to a receiver will create demands for multiple different record formats based on unique business systems. The unavoidable result will be an ever-growing web of differing traceability data requirements.

[2] Comments Specific to the Proposed Rule: Requirements for Additional Traceability Records for Certain Foods: Supply Chain Example

Subsection (d)(1)(G) compels the agency, "*to the extent practicable, not [to] require a facility to change business systems to comply with such requirements".*
The discussion above demonstrates that as a practical matter the proposed rule will force seafood businesses to revise their current systems, with respect to shipping and receiving related documents, in order to capture, maintain, and manage the information. Some companies will have no choice but to incorporate tandem codes – the new Traceability Lot Code and the conventional inventory code – even though these codes capture almost exactly the same information.

Subsection (d)(1)(J) states that recordkeeping requirements must "*be commensurate with the known safety risks of the designated food".*
As mentioned above in connection with Subsection (d)(1)(B), requiring additional recordkeeping for documenting the "originating" KDEs adds no public health benefit *at all* for the majority of the seafood species included on the FTL. Depending on the finished product/package form, many of the seafood species included on the FTL have no known safety risks.[3]

Subsection (d)(1)(K) requires FDA to *"take into account international trade obligations"* in designing recordkeeping requirements under Section 204 of the FSMA.
The majority of the seafood consumed in the United States is globally sourced, and therefore this regulation will have a major impact on our trading partners. As demonstrated in Appendix A, it is common for a seafood "originator" or even the "first receiver" to have no knowledge of the destination or destinations of the finished products. Because of this, the regulation will impose additional recordkeeping requirements on companies with respect to seafood products that will never enter the United States.

Subsection (d)(1)(L) prohibits the agency from requiring *"(i) a full pedigree …, (ii) records of recipients … beyond the immediate subsequent recipient … of such food; or (iii) product tracking to the case level …*
The rule as proposed plainly violates this subsection of the law. The rule will require tracking to the case level, because shipments to the "retail establishment" move not by an entire "traceability lot" but rather by case count. As is the case with so many of the flaws discussed above, only by ignoring the rule's obvious practical effects can FDA argue that the rule stays within guardrails Congress established in Subsection (d)(1)(L). NFI member companies will have no such luxury.

[3] As determined by conducting a hazard analysis based on the agency's recommendations outlined in the Hazards Guide.

The proposed rule appears to violate two other components of Section 204 of FSMA.

First, Section 204(d)(3) stipulates that the agency must take measures to protect trade secrets and confidential information when promulgating the regulations. However, the very nature of some of the regulation's requirements will force disclosure of confidential information to subsequent entities in the supply chain by requiring certain KDEs to be passed forward – not only to the next step in the supply chain, but potentially all the way to the "retail establishment". The proposed rule stipulates that the traceability lot code cannot be assigned for the shipping and receiving CTEs,[4] and therefore the entity performing the final transformation of the product – the company that produces finished product – will assign the final traceability lot code. The proposed requirement to pass forward the location identifier, location description, and point of contact information for the traceability lot code generator[5] will expose confidential supplier/buyer relationships as well as the identities of contract manufacturers for large branded and private labeled products.

Second, Section 204(d)(6)(D) limits the recordkeeping requirements that FDA can impose on commingled raw agricultural commodities to the immediate previous source and the immediate subsequent recipient. However, the proposed rule limits this partial exemption to raw agricultural commodities that are commingled from different farms. This distinction is not provided for in section 204(d)(6)(D) and thus, depending on the specific supply chain in question, will not be available to certain seafood products.

[4] Proposed §1.1320(b)
[5] Proposed §1.1350(a)(4)

Food Traceability List

Section 204 of FSMA requires FDA to designate high-risk foods for which additional recordkeeping requirements are appropriate and necessary to protect the public health. We are challenged to understand why certain seafood species with no inherent food safety hazards or hazards associated with the harvest or growing locations would require additional recordkeeping requirements to protect the public health. Therefore, we do not agree that all finfish, including smoked fish; all crustaceans; and all bivalve mollusks shellfish with the exception of scallop abductor muscle warrant additional traceability records.

For almost 25 years, the production of fish and fishery products sold in the United States has been regulated by FDA's "Seafood HACCP regulation".[6] Processors in the U.S. and around the world have developed HACCP plans necessary to meet these regulatory requirements based on recommendations in the Hazards Guide. Using information from the Hazards Guide to identify potential hazards associated with a multitude of species, both vertebrates and invertebrates,[7] processors are able to assess whether or not there are potential species-related hazards either associated with the species (such as scombrotoxin formation) or with the harvest or aquaculture location. If the potential hazard is determined to be "reasonably likely to occur" control measures are put into place to address these hazards – even those that occur "before, during, and after harvest."[8]

We have no explanation for our members on why certain seafood that have had no identified species-related hazards[9] are now considered by the agency to be so risky that extensive records are now critical to allow traceback to the fishing vessel or the aquaculture farm.

FDA's Model for Risk-Ranking Foods

In reviewing the FDA memorandum, "Designation of the Food Traceability List Using the Risk-Ranking Model for Food Tracing"[10] we have the following observations:

We agree with the concept that for traceability recordkeeping purposes, and when identifying FTL foods, the focus should be on foods contaminated with biological and acute chemical toxins. We also agree that enhanced records are not useful for adverse health effects from chronic exposure to chemical hazards or food allergens.

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[6] Procedures for Safe and Sanitary Processing and Importing of Fish and Fishery Products, 21 CFR 123 (the Seafood HACCP Regulation).

[7] Finfish species are included in Table 3-2, Potential Vertebrate Species-Related Hazards; molluscan shellfish and crustaceans species are included in Table 3-3, Potential Invertebrate Species-Related Hazards.

[8] 21 CFR 123.6(c)(2)(ii)

[9] As described in Tables 3-2 and 3-3 of the Guide.

[10] Reference 17, found at https://www.regulations.gov/document/FDA-2014-N-0053-0061

We do not agree with the statement that "[f]ood items within the same 'commodity' designation generally have similar characteristics, associated hazards, and production and supply-chain practices and conditions."[11] Grouping all finfish together as a commodity on the FTL implies that all have the same known safety risks requiring extensive recordkeeping back to the point of origin. That is not the case, nor is it science based.

We appreciate being able to study and review the commodity-hazard pair rankings for the FTL foods. However we do not understand why the rankings for the foods which are not on the FTL have not been provided for public review. For example, there seem to be several notable absences from the FTL of foods, such as onions and products made from nuts or seeds, which have been implicated in several multi-state foodborne illness outbreaks.[12] Providing the scoring outcomes for all of the commodity-hazard pairing for the 200 commodities, 47 commodity categories and 100 hazards would provide for more transparency and understanding of the establishment of the FTL and could "forewarn" future additions to the FTL.

While we don't agree that essentially all seafood species commercially marketed in the US belong on the FTL, the remainder of our comments are based on the list as currently proposed. These comments should not be viewed as an endorsement of the proposed FTL.

Clarifying language to the FTL

For a rule of this magnitude, the scope of the foods that are on the FTL must be crystal clear. The agency has determined that the "proposed traceability recordkeeping requirements would apply not only to foods specifically appearing on the FTL, but also to foods that contain foods on the list as ingredients".[13] We appreciate that the agency tried to provide clarity to several of the items on the list as provided in the memo of January 12, 2021, Food Traceability List for "Requirements for Additional Traceability Records for Certain Foods" Proposed Rule – Clarified Language. But even with the addition of "(fresh)" to several items the concept of a FTL as an ingredient is still not clear.

We have considered value-added seafood products to be FTL foods because seafood is an ingredient and seafood is on the FTL. Likewise, if the product includes other FTL foods as ingredients, records will need to be maintained for the receiving and transformation of those ingredients as well. Using a frozen salmon fillet with herbed butter product, as an example, demonstrates the confusion that must be clarified. The processor purchases salmon fillets and

[11] Reference 17, page 3
[12] As an example, the agency provides an example of a soy nut butter recall which would have been facilitated and expedited with improved traceability documentation; however soy nut butters are expressly excluded from the FTL. (85 FR at 59989).
[13] 85 FR at 59991-59992

frozen herbed butter to assemble the final product. Salmon is on the FTL as a finfish. Herbed butter appears to be an FTL because fresh herbs are ingredients in the frozen herbed butter. But is this correct? Obviously the various herbs in the butter started as "fresh" but were transformed into frozen herbed butter prior to being purchased by the salmon product processors. When does the need to keep shipping, receiving, and transformation records for the herbs stop because one could understand that the fresh herbs are an ingredient all the way through to the final frozen salmon product?

Understanding when FTL foods stop being FTL foods will be a key factor in successfully implementing the provisions of a final rule. The seafood supply chain is diverse and global. Communicating new regulations to our global trading partners often falls to the importers working with their suppliers.

Exemptions for Certain Products

Section 204 of FSMA requires FDA to establish a system that improves the capacity for tracking and tracing foods to prevent or mitigate foodborne illness outbreaks and to address credible threats of serious adverse health consequences or death. Criteria that the public health benefits of imposing additional recordkeeping requirements outweigh the cost of compliance (section 204(d)(1)(D) and (E)) determines that product tracing requirements is not necessary to protect the public health. Section 204(d)(6)(E) specifically allows FDA to foods if it is determined that product tracing requirements for such food (such as bulk or comingled ingredient that are intended to be processed to destroy pathogens) is not necessary to protect the public health.

There are several categories of seafood products which meet these provisions and therefore should be exempted from any such new recordkeeping requirements. While we recognize that the agency is proposing provisions for petitioning to request modified requirements, exemptions, or waivers from the rule, we feel that it is important for certain products to be exempted through the rulemaking to ensure consistent implementation of the final rule and to avoid misunderstanding of what products are and are not required to comply throughout the supply chain.

When identifying categories of products that warrant being exempted from subpart S records, we started by reviewing the purpose of the proposed enhanced recordkeeping requirements. The main purpose, as we understand, is to assist the agency to rapidly identify the food and source of the food responsible for foodborne illness outbreaks. There are certainly ancillary benefits which we support such as providing a roadmap for the development of an internal traceability program, but that is not the Section 204 mandate. So the main criteria that we looked at was how does requiring a series of records linking back to the fishing vessel or aquaculture producer facilitate this main purpose. In addition, exempting certain FTL seafood products from subpart S records does in no way suggest that they should also be exempted from the existing subpart J records.

Low-Acid and Acidified Canned Seafood products (LACF/AF) must be exempted from additional recordkeeping requirements for the following reasons:

1) FDA is proposing that the additional recordkeeping requirements for food subjected to a kill step would stop at the kill step (proposed §1.1310). While clarification of what constitutes a kill step remains to be provided (see separate section of comments), there can be no question that

the thermal process delivered to LACF/AF constitutes a kill step which "significantly minimizes pathogens in a food".[14] Therefore, additional records after the kill step would not be required.

2) LACF/AF regulations already require that all products be marked with a permanent identifying code that identifies the establishment, product packed, year, day and period packed. This provides the agency with the necessary information to directly contact the manufacturer or distributor if necessary.[15]

3) LACF/AF regulations already require that manufacturers of LACF/AF maintain records of the initial distribution of the finished product for the sole purpose of enabling a recall if necessary.[16]

4) LACF/AF regulations already require that manufactures keep production records for 3 years, a period of time which is longer than 2 years as proposed in 1.1455(c).[17]

5) The thermal process delivered to LACF/AF seafood products is comparable to that received by certain produce and shell eggs which the agency is proposing at 1.1305(d) to be exempted from the recordkeeping rule. These foods specifically include produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, provided the conditions set forth in 112.2(b) are met, and shell eggs when all eggs produced at the particular farm receive a treatment in accordance with 118.1(a)(2). While we realize that the comparable Seafood HACCP regulation does not have a mechanism to identify products that are destined for canning, this should not preclude an exemption. Food safety concerns will continue to be addressed with the Seafood HACCP regulation, unlike the exempted produce and eggs which are also exempted from their respective safety rules. If it is simply a matter of having the "mechanism" to identify products that are destined for canning, a provision can be added to subpart S.

6) FDA's Seafood HACCP regulation requires that the primary processor implement controls for the natural toxins that may be associated with the species. These CCP monitoring records provide the agency with information necessary to trace back to the source if warranted.

7) FDA's Seafood HACCP regulation requires extensive time/temperature controls and monitoring to minimize the risk of scombrotoxin formation. Canned tuna, the most commonly

[14] 21 CFR 113.3(e) provides the definition of "Commercial sterility" and 21 CFR 114.3(e) provides the definition of a "Scheduled process" both which address rendering the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution

[15] 113.60(c) and 114.80(b)

[16] 113.100(f) and 114.100(d)

[17] 113.100(g) and 114.100(e)

consumed canned seafood item, has an excellent food safety history as documented in other's comments.[18]

Pasteurized crabmeat must be exempted from additional recordkeeping requirements for the following reasons:

1) FDA is proposing that the additional recordkeeping requirements for food subjected to a kill step would stop at the kill step (proposed §1.1310). The thermal process delivered to pasteurized crabmeat products constitutes a kill step which "significantly minimizes pathogens in a food". Therefore, additional records after the kill step would not be required.

2) The Seafood HACCP regulation already requires that manufactures keep production records for 2 years, which is comparable to the 2 years proposed in 1.1455(c).[19]

3) The thermal process delivered to pasteurized crabmeat is comparable to that received by certain produce and shell eggs which the agency is proposing at 1.1305(d) to be exempted from the recordkeeping rule.

4) Pasteurized crabmeat undergoes two "kill steps" during the production process. The initial processing step steams or boils the crabs to facilitate meat removal from the shell. The second is the actual pasteurization process once the crabmeat is sealed in the package. Either of these steps would meet the proposed definition of a kill step, thus eliminating the need to keep any additional subpart S records.

5) FDA's Seafood HACCP regulation requires that the primary processor implement controls for the natural toxins that may be associated with the species. Table 3-3 of the Hazards Guide does not identify any potential natural toxin hazards for eviscerated crabs. Crabs are cooked, eviscerated and removed from the shell prior to the pasteurization process. Therefore, there is no risk to public health needing records to trace back to point of harvest.

Surimi seafood products must be exempted from additional recordkeeping requirements for the following reasons:

1) FDA is proposing that the additional recordkeeping requirements for food subjected to a kill step would stop at the kill step (proposed §1.1310). The thermal process delivered to surimi analogue products constitutes a kill step which "significantly minimizes pathogens in a food". Therefore, additional records after the kill step would not be required.

[18] As seen at https://www.regulations.gov/document?D=FDA-2014-N-0053-0215
[19] 123.9(b)(1)

2) The Seafood HACCP regulation already requires that manufactures keep production records for 2 years, which is comparable to the 2 years proposed in 1.1455(c).[20]

3) The thermal process delivered to surimi analogue products is comparable to that received by certain produce and shell eggs which the agency is proposing at 1.1305(d) to be exempted from the recordkeeping rule.

4) Surimi analogue finished products undergo two "kill steps" during the production process. The initial processing step is applied to the formation of the product. The second is a pasteurization process once the surimi analogue is sealed in the package. Either of these steps would meet the proposed definition of a kill step, thus eliminating the need to keep any additional subpart S records.

4) FDA's Seafood HACCP regulation requires that the primary processor implement controls for the natural toxins that may be associated with the species. Table 3-2 of the Hazards Guide does not identify any potential natural toxin hazards for the species of finfish used in the production of surimi. Therefore there is no risk to public health needing records to trace back to point of harvest.

Seafood species that are rarely consumed raw must be exempted from additional recordkeeping requirements for the following reasons:

Proposed section 1.1305 (e) would allow for the exemption for produce that is rarely consumed raw as listed in 112.2(a)(1).[21] These produce are exempted from the Part 112 – Standards for the Growing, Harvesting, Packing, and Holding of Product for Human Consumption – because, as we understand, any microbial contamination resulting from growing, harvest and packing would not impact public health because the these products are cooked prior to consumption.[22] The same can be declared for many seafood species. While it is well recognized that certain species are consumed raw, there are many that are not. Crustacean shellfish such as crab, lobster, and crawfish are very rarely consumed raw, and in fact, unless sold live, are cooked prior to sale. There are also finfish species that are rarely consumed raw such as pollock, cod, haddock etc. Public health will not be further protected by requiring additional recordkeeping for these seafood species very rarely consumed raw. If further input is needed to establish the

[20] 123.9 (b)(1)

[21] §112.2(a)(1) lists the following produce that is rarely consumed raw: Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

[22] Important to note that the exempted produce could still become contaminated through growing, harvest and packing, however cooking by the consumer would minimize the risk.

list of seafood species which are rarely consumed raw, FDA could open up a comment period specifically to receive stakeholder comments on such a list. This would be comparable to establishing the list of produce rarely consumed raw in part 112.

Seafood species with no inherent food safety risks (as identified in Tables 3-2 and 3-3 of the Guide) must be exempted from additional recordkeeping requirements for the following reasons:

FDA's Seafood Hazards Guide provides an assessment of potential food safety hazards, both microbial and chemical associated with 748 species of finfish and 236 species of crustaceans and molluscan shellfish. Depending on the hazard, these may be associated with the harvest or growing location. The lists contain those hazards which FDA would expect to see addressed in the hazard analysis, and if reasonably likely to occur, the HACCP plan. Of the five hazard categories catalogued in the Hazards Guide, only natural toxins and scombrotoxin are assessed in the model to determine the Food Traceability List.[23] Without potential hazards associated with the harvest or growing location, these species must not be subjected to the enhanced recordkeeping requirements, which would track back to the point of harvest. Public health is not protected with the requirement of extensive recordkeeping of the source of these species.

Molluscan shellfish regulated under the National Shellfish Sanitation Program (NSSP)must be exempted from additional recordkeeping requirements for the following reasons

For many years the harvesting and selling of molluscan shellfish have been regulated by individual state authorities. The NSSP provides science-based model ordinances which allow for uniform laws and regulations to support interstate shipments. Product traceability is a key control to allow for tracing product back to harvest location in case of illness for product recall purposes and to prevent further harvesting from implicated growing areas. An enhanced recordkeeping program which discloses the harvest location and date, type and quantity of shellfish, and harvest information are already captured and maintained; end customer/consumer packaging identifies processing plant information linked through the Interstate Certified Shellfish Shippers List (ISSCL). Additional subpart S records, as proposed, will not enhance the public health protection steps already adhered to by the molluscan shellfish industry, therefore molluscan shellfish regulated under the NSSP should be exempted from additional subpart S records which would duplicate current practices.

[23] Environmental chemicals and aquaculture drugs would pose "chronic" issues and are not assessed in the model.

Partial Exemptions for Certain Facilities

Section 204(d)(6)(E) of FSMA specifically allows FDA to modify or exempt the requirements for additional recordkeeping for a type of facility when it is determined that additional records are not necessary to protect public health. Therefore we are dismayed at the cavalier dismissal of the relationship between third-party cold storage facilities and importers.[24]

Third-party cold storage facilities are an integral part of the seafood distribution chain and play an important role in the movement and storage of product for clients who do not have the facilities to do so. It is typical for seafood importers buying seafood products from overseas to store the product at a third-party cold storage facility near the port of landing until the product can be moved to its next destination. The importer maintains ownership of the product and is responsible for the records, including the records of origin, entry, transportation, and subsequent sale. In some instances, some or all of the importer's inventory in a third-party cold storage unit can be sold (transfer in ownership) to another entity without leaving the facility or even leaving that individual storage unit. In that instance, the buying entity would then maintain the records for the product it purchases. Each company owning the seafood product has the ability to request removal of the product in various quantities at the time it is ordered by one or more buyers. The important point is that the product moves in or out of the facility at the direction of the owner, not the third-party storage facility.

Third-party cold storage operators have expressed that the current "one step forward, one step back" system of recordkeeping enables them to quickly and accurately provide traceability information during a recall; the ability to do so has been confirmed during mock recall drills.

The agency has indicated that the third-party storage facility could "enter into agreements with individuals or firms to create and keep the records required under this rule on their behalf."[25] As we have stated elsewhere in this document, the proposed rule itself does not provide any indication that this is even an option.

Current recordkeeping functions are aligned with the concept that the company owning the product at each juncture in the supply chain has the vested interest in maintaining the required records, not the facility providing the holding services.[26]

We strongly urge FDA to work with the third-party storage industries to develop a workable regulatory option to proposed §1.1315 to accommodate this unique relationship between third-party storage facilities and their clients. Doing so will ensure that this "deferral" of recordkeeping responsibility is done in a consistent manner and that each party in the

[24] See 85 FR at 60000-60001
[25] See 85 FR at 60004
[26] We note that this arrangement is similar in concept to the relationship between the farm and contract harvesters, packers and coolers.

"agreement" will understand their role in maintaining subpart S records. This will continue to provide for a traceability recordkeeping program which is achievable, recognizes current industry practices, is be protective of public health, and meets the intent of section 204 of FSMA.

Specific questions and need for concurrence

While reviewing the proposed rule, NFI members noted several common questions for which we are seeking clarity. Our concerns (or lack thereof), comments and questions throughout this document are based on our understanding and interpretations of the following issues:

GENERAL PROVISIONS

1.1305 What foods and persons are exempt from this subpart?

1.1305(a)(3) *Certain other originators of food*. We understand that fishers and aquaculture operators would be considered "certain other originators of food" and therefore would be exempted from the regulations if they have an average annual monetary value of food sold of no more than $25,000 during the previous 3-year period (as proposed in 1.1305(a)(3)). Does the agency concur with this interpretation? Guidance will need to be developed to explain how this number is calculated – especially since the majority of "originators" of seafood are based in other countries.

1.1305(f) *Partial exemption of commingled raw agricultural commodities*. Section 204 (c)(6)(D) limits the extent of recordkeeping requirements for commingled raw agricultural commodities to the immediate previous source and the immediate subsequent recipient of the RAC. We believe that seafood, either wild-captured or farmed, is a raw agricultural commodity[27] and therefore would be eligible for this partial exemption when commingled, even though the agency only recognizes shell eggs as the only commingled RAC on the current proposed food Traceability List (see page 59997). We are concerned that the proposal did not recognize that farmed and wild-captured seafood is often being commingled from multiple sources prior to processing. Once the commingled RAC is processed[28] it would lose this partial exemption, and subpart S recordkeeping could be applied as necessary to protect public health. Therefore it is our interpretation that first receivers of commingled RACs that are seafood products on the Food Traceability List would not need to capture any of the KDEs as proposed in §1.1330 or §1.1335 other than the immediate previous source of the commingled RAC. Does the agency concur with this interpretation? And if not, why not.

1.1305(j) *Partial exemption for food produced through the use of fishing vessels*. Section 204(2)(d)(6)(C) limits the extent of recordkeeping requirements to the foods harvested by fishing vessels to the immediate previous source and the immediate subsequent recipient of

[27] FDCA 201(r) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

[28] FDCA 201(gg) The term "processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

the food if the vessel is required to be registered in accordance with subpart H. We interpret this proposed partial exemption to include the product that is produced by factory trawlers or at-sea processing vessels that both harvest and process the fish as these vessels are required to register with the FDA and are considered processing facilities. Does the agency concur that factory trawlers/at-sea processing vessels that both harvest and process fish would receive a partial exemption for the products produced by these vessels?

One addition that we suggest the agency consider is that fishing vessels that are also registered food facilities have the option to fulfil the proposed recordkeeping requirements of the first receiver if so desired since often they are in the best position to capture the proposed first receiver KDEs. For vertically integrated companies the product may remain in their control from harvest, through both primary and secondary processing with the end food service or retail distribution point being the first point of transfer in ownership.

1.1305(l) *Exemption for nonprofit food establishments*. We understand that this exemption applies only to the nonprofit food establishment and not to persons shipping FTL foods to the nonprofit establishment. Therefore the shipper of such foods would still need to keep records of the shipping KDEs. But since the nonprofit food establishment is exempted from the proposed subpart S regulations, there would be no purpose for the shipper to send forward the shipping KDEs since these would serve no purpose. Does the agency concur that shippers of FTL foods going to a nonprofit food establishment would not be required to send forward the shipping KDEs?

1.1310 What definitions apply to this subpart?

Fishing vessel. The agency is proposing the definition of a fishing vessel to be "any vessel, boat, ship, or other craft which is used for, equipped to be used for, or of a type which is normally used for fishing or aiding or assisting one or more vessels at sea in the performance of any activity relating to fishing, including, but not .limited to, preparation, supply, storage, refrigeration, transportation, or processing." We have no objection to this definition since it has been established as the definition of a fishing vessel in section 3(18) of the Magnuson-Stevens Fishery Conservation and Management Act. While we agree with this definition, we want to ensure that our interpretation of the definition of fishing vessel does include vessels that collect fish such as tender vessels, carrier vessels, or mother ships and therefore would receive the partial exemption as proposed in 1.1305(j). Does the agency concur that the definition of fishing vessels includes tender vessels or mother ships?

Kill Step. (60001) As proposed, a kill step means processing that significantly minimizes pathogens in a food. We agree that "kill step" needs to be defined because of the proposed special requirements for foods which are subjected to a kill step (proposed §1.1355). However

the proposed definition does not provide the clarity needed to understand when subpart S records no longer need to be kept and sent for the shipping CTE. In addition, for products with multiple cooking steps, which step is the kill step? For example, steaming crabs in order to facilitate the picking of crabmeat is a kill step. Does this step end the need for subpart S records or are transformation KDEs still required when producing the final pasteurized crabmeat? Likewise, pre-cooking raw tuna prior to the final canning step; which one is the kill step? Is post-harvest processing of molluscan shellfish a kill step? Since there are many questions on what constitutes a kill step, the agency must provide further clarification. Otherwise, there will be inconsistent application of the definition and continued questions about whether or not subpart S records are required for subsequent CTEs in the supply chain.

Retail food establishment. As proposed, a retail food establishment means an establishment that sells food products directly to consumers, as its primary function. Included in the proposed definition are additional clarifying statements that indicate that grocery stores, convenience stores, vending machine locations, and certain farm-operated businesses are considered retail food establishments. It is our understanding that retail food establishments would also include online food retailers, restaurants, and meal kit delivery companies as stated on page 60003. If the agency concurs that retail food establishments also include online food retailers, restaurants, and meal kit delivery companies, than we suggest that these business types be listed in the regulatory definition for retail food establishment.

Transformation. As proposed, transformation means an event that involves changing a food on the Food Traceability List, its package, and/or its label, … such as by combining ingredients or processing a food (e.g., by cutting, cooking, commingling, repacking, or repackaging). We interpret this to mean that multiple traceability lot codes of a food traceability list food ingredient would be "transformed" into a single "grandlot" food traceability code after combining the multiple lots. This form of "commingling" is common practice in the seafood industry. Does the agency concur? In addition, the same should be true for multiple traceability lot codes of the same packaged food traceability list food. Multiple traceability lot codes of the packaged food would be "transformed" by combining (AKA commingling) the multiple traceability lot codes of finished goods into a single new traceability lot code. Does the agency concur? In both examples provided, the traceability of the products is still maintained because the various traceability lot codes will be linked to the new code through the transformation records.

Vessel Identification Number. As proposed, the vessel identification number means the number assigned to a fishing vessel by the International Maritime Organization, or by any entity or organization, for the purpose of uniquely identifying the vessel. We interpret this definition to allow for identification numbers other than those assigned by the International Maritime Organization. Does the agency concur?

RECORDS OF GROWING, RECEIVING, TRANSFORMING, CREATING, AND SHIPPING FOOD

1.1325 What records must I keep when I grow a food on the Food Traceability List?

The agency has not defined "growing", but from language on page 60007 growing appears to be strictly associated with fruits and vegetables and sprouts. Therefore, we interpret that the records requirement proposed in 1.1325 would not apply to fish and other seafood raised in aquaculture operations, specifically the requirement to maintain a linkage between the traceability lot code and the growing area coordinates. Does the agency concur?

Alignment to other Traceability Rules and Programs

There is no doubt that the traceability of certain seafood supply chains is challenging. That is why NFI has worked with technology providers to explore how technology can facilitate implementation of a comprehensive seafood traceability system. Even prior to the passage of FSMA, NFI anticipated that FDA would incorporate certain seafood products into any additional traceability requirements. NFI and members worked with GS1 US to develop an implementation guide for applying traceability standards for the seafood supply chain. More recently we conducted a pilot test of IBM's Food Trust blockchain platform to demonstrate traceability for two seafood products: wild caught mahi and farmed raised shrimp.

What adds to the traceability challenge is the need to meet the demands of multiple regulations (in the U.S. and elsewhere), voluntary third-party certification schemes, and customer requests; each provides traceability, but with different end goals. These competing endgames force seafood suppliers to capture the same or similar information in different formats, records, and technology transfer systems. We implore the agency to finalize a traceability regulation that is truly flexible enough to allow companies to realistically utilize the information that they are currently capturing. For example, NOAA's Seafood Import Monitoring Program allows the reporting of the harvests from multiple small boats as one commingled event. This level of tracing and recordkeeping should be acceptable for this rule. Also, many of the proposed KDEs and associated data attributes are currently maintained in other government (even FDA's) records.

When reviewing the multiple requests and regulations for seafood traceability, it is important to understand the purpose of these programs. Is it to provide chain of custody for a certification program? Or to tell the story of the heritage of a product? Or is it to provide data for fisheries management? Or is it to prove the legal harvest? Or is it to satisfy international treaties? Or is it to protect public health by facilitating foodborne illness outbreak investigations and product recalls? All of these goals have value, but each may require slightly different CTEs and KDEs. NFI's members fully support the need for enhanced traceability recordkeeping to benefit public health when warranted – there is no argument. We do question the need to trace back to the harvest or farm for the vast majority of the seafood species consumed in the United States. Just because that need is important for other regulations and programs, that does not mean that FDA has to require the same. Finally we trust that the agency will continue to focus on what is needed for food safety reasons as well as what has been mandated in section 204 of FSMA. Just because something is currently being done by some, does not mean it has to be included in this regulation.

That being said, we found that the proposed rule does not align with other federal traceability requirements in existence for certain seafood species, so it creates confusion within the seafood industry and unnecessary duplication of records. Multiple layers of regulatory requirements

already exist for many seafood species, so inclusion of new KDEs is cumbersome, expensive and unnecessary. As robust traceability requirements exist for many species, exemption from or modification of the rule where data elements overlap must be considered.

Exemptions or alignment of this rule to these other food or seafood traceability rules will be necessary to minimize duplication of recordkeeping requirements:

- National Shellfish Sanitation Program[29]
- FDA Food Facility Registration[30]
- FDA Prior Notice[31]
- Importer Security Filing (10 + 2) US Customs Border Protection[32]
- NOAA's Seafood Import Monitoring Program[33]
- NOAA Tuna Tracking and Verification Program (TTVP) - Dolphin Safe[34]
- NOAA Atlantic Highly Migratory Species (HMS) International Trade Program[35]
- NOAA NMFS Antarctic Marine Living Resource Program (AMLRP)[36]

Existing FDA databases, such as those maintained to support the Food Facility Registration and the Prior Notice and import entry processes, have some of the same information that is being proposed as subpart S records. FDA should explore how to utilize this existing, industry-provided information rather than requiring the supply chain to report duplicate information.

For example, the Prior Notice requirements, including many similar KDEs, provide a good example of data that FDA currently maintains, as demonstrated in the following chart.

Prior Notice Data Element	**Comparable subpart S KDE as Proposed**
Entry type and CBP identifier	Import Entry Number
Identification for each article of food in the shipment, including FDA product code; common product name or market name; estimated quantity; and lot, code number or other identifier	Traceability Product Description Quantity of Product Traceability Lot Code Traceability Product Identifier
If the food is in its natural state: the name of the grower and location	Originator Location Description

[29] https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp
[30] Subpart H, 21 CFR 1.225 – 1.245
[31] Subpart I, 21 CFR 1.276 – 1.285
[32] 19 CFR Parts 4, 12, 18 et al.
[33] 50 CFR Part 300 also 15 CFR 902 and 50 CFR Part 600
[34] 50 CFR Part 216, subpart H
[35] 50 CFR 300 and 635
[36] 50 CFR 300 Subpart G

If the food is no longer in its natural state: manufacturer's name, address, country or registration number or a the reason why no registration number	Transformation/Creation Location Description
Shipper's name and full address	Shipper Location Description
Name and full address of importer, owner and consignee, unless imported for transshipment	Receiver Location Description (if takes possession)

In addition, FDA should consider how to collaborate with other government agencies such as NOAA National Marine Fisheries Service who already hold domestic vessel identification and fishing permits information, plus have federally collected harvest information reported by the Seafood Dealer (First Receiver) in their fishery management reporting databases. Comparable systems exist with our fishery trading partners around the world.

In addition, the seafood industry has successfully traced product for many third parties like Marine Stewardship Council and GFSI-recognized food safety schemes for multiple years. If a facility is under a recognized GFSI audit that includes traceability (like Best Aquaculture Practices), an exemption should apply.

We acknowledge that the proposed rule allows firms to use existing records to fulfill these new requirements. That may be achievable for the records that must be maintained within a facility. But companies will also have to compile a record of the KDEs that are being sent for each shipment of FTL foods; everyone in the supply chain, with the exception of the retail establishment, is a shipper. Our concern is that this regulation will not bring all the current traceability systems together but will rather create more differences as Receivers in the supply chain start to demand that they receive subpart S data in different formats (*e.g.*, some by email, some by advanced ship notices, some through their own unique data portal, etc.). Therefore, the more seafood products that can be exempted from the subpart S requirements will lessen the overall recordkeeping burden of this regulation.

Costs to Implement and Recordkeeping Burden

The costs for industry to meet the requirements of the proposed rule are severely underestimated by FDA. There will be both a significant time and cost burden on companies to prepare for and to comply with the recordkeeping requirements.

FDA estimated the following average recordkeeping burden:[37]

- A one-time set up of traceability program records – 33.3 hours (1,000 records at 2 minutes each)
- Annual total time for:
    - Maintaining traceability program records – 4.2 hours (1,000 records at 15 seconds each)
    - Grower – 33.3 hours (1,000 records at 2 minutes each)
    - First receiver – 33.3 hours (1,000 records at 2 minutes each)
    - Receiver – 4.2 hours (1,000 records at 15 seconds each)
    - Transformer – 33.3 hours (1,000 records at 2 minutes each)
    - Shipper (distribution centers) – 402 hours (48,333 records at 30 seconds each)
    - Shipper (other) – 146 hours (1,000 records at 3.5 minutes each)

NFI feels that the agency neglected to account for the annual recordkeeping burden for Receivers who are distribution centers. Logically, if a distribution center ships over 48,000 FTL food items annually, they will be receiving more than 1,000 items.

In addition, FDA's estimate for the recordkeeping burden for the shipper does not account for the time that will be necessary to disclose, or send, as it is referred to in the proposed rule, the required KDEs to each receiver. We do not agree that the time to satisfy this recordkeeping requirement would be minimal. While the information is required to be maintained, it must be obtained from existing records and formatted into an acceptable mode of submission to the receiver. This will, at a minimum, double the time that has been estimated for the shipper's recordkeeping burden since keeping the data and disclosing the data are two separate actions.

The time burdens in recordkeeping are too low throughout the "Requirements for Additional Traceability Records for Certain Foods" report (Analysis Report)[38] for several elements, including:

[37] Tables 9 and 11 at 85 FR 60025-60027

[38] "Requirements for Additional Traceability Records for Certain Foods" Docket No. FDA 2014-N-0053, Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis and Unfunded Mandates Reform Act Analysis, published by the Economics Staff, Office of Economics and Analysis, Office of Policy, Legislation, and International Affairs, Office of the Commissioner, Food and Drug Administration, Department of Health and Human Services

- The time spent reading and comprehending,
- Costs to purchase the hardware, develop the software, and implement the system for recordkeeping,
- Developing procedures for implementation,
- Training time for employees for new processes,
- Updating existing forms and master files already in existence,
- The number of lots for which to enter the data, and
- Time involved in day-to-day data entry.

FDA's estimates of 3.3 hours for the time burden in reading and understanding the rule, and implementing the recordkeeping portion, as outlined in Table 9 on p. 60025, are too low, according to input received from members. Reading and understanding the supplemental examples posted by the agency on February 12, by itself, would take an estimated 4-6 hours for an average person employed at a company involved in the supply chain. This estimate should be considered as well when evaluating the time burden. The total time burden should be increased to at a minimum of 10 hours which would roughly triple the employee costs.

NFI received several comments from member companies regarding their concerns about the time and costs involved in implementing these systems. Some specific areas of concern are noted below:

A large food distribution company expressed that the "high" numbers noted in Table 31 in the Analysis Report for recurring recordkeeping costs were too low. Assuming .01 hours (less than one minute) for each record (the high number in the table was .006 hours) is a truer estimate, simply adjusting the time needed to establish and maintain records and the time needed to send records would increase the costs by 67 percent. This would take the average annual shipping cost from under $1 billion to over $1.6 billion.

The Analysis Report noted the capital investment required by companies to meet the requirements and NFI members have also expressed a concern about these costs.

Throughout the Analysis Report, the recordkeeping costs of different events are noted. The time noted to record a transaction in the "high" column is .05 hours, meaning 3 minutes. NFI members have suggested that 5 minutes to type each transaction is a more reasonable estimate. Increasing the time per entry from 3 to 5 minutes would increase costs by 67 percent.

Considering also that some data entry points contain more than one piece of information (*e.g.*, the name field also includes the telephone number and email address), the estimates are lower than practical. NFI members have noted that if the computer systems in the chain of custody don't pass on the information, then all of the required KDEs and associated data attributes will need to be manually rekeyed for every Receiving CTE.

Some members have noted that reprogramming software to include additional data fields to accommodate the additional recordkeeping burden would involve a high cost (unknown at this time, but certainly expensive).

Additionally, industry has estimated that annually training employees on the requirements will take 5 hours of each employee's time. This annual training has not been accounted for in the Analysis Report. We do not agree with the agency's assumption that firms will not face additional costs for ongoing training. An annual review, commonly required by auditors, would need to be conducted, all adding to costs. The resources needed to develop and train employees far exceeds $500, based on FDA's assumptions that a subject matter expert may be required to train staff or to develop an internal training program.

Seafood businesses note that counting a shipment as one traceability lot is not an accurate measure. Most shipments contain multiple lots because of breakdowns into different sizes (*e.g.,* cutting seafood into 4, 6 and 8 ounce sizes) means multiple lots for inventory. These multiple lots would require multiple data entries for the same shipment, thus increasing costs. When a raw product is transformed, it may become multiple products therefore multiplying the number of records.

Every business will need to modify existing systems and records to meet new requirements. FDA is requesting new information be created and that would need to be maintained. The cost to implement assumptions are too low as capital investments, reprogramming costs, manpower, and training are more extensive due to the complexity of the proposed rule. Even something seemingly straightforward such as adding a second code to a transaction in order to accommodate the new Traceability Lot Code requirement will require modifications to existing systems.

FDA has taken a strong step forward in attempting to standardize the required traceability KDEs, but without a standardized data format for digitalization for computers to recognize the information (harmonization) the information will not be understandable. It is costly to industry for small players to digitize and for large players to reprogram. Each entity at the next step in the supply chain may request the information in different formats, due to their internal systems, so manpower and infrastructure costs will escalate down the supply chain with the heaviest burden in the middle.

New Recordkeeping Burdens

The agency has proposed that existing records can be utilized to meet the subpart S recordkeeping requirements and that all required information does not need to be maintained in one set of records.[39] This we appreciate. However, there are two records which will need to be added to the records portfolio for the majority of the firms impacted by this proposed rule.

[39] Proposed §1.1455(e)

Those are the electronic sortable spreadsheet and the disclosure of KDEs that must be sent to the receiver for each shipment of FTL foods.

The seafood industry requests a spreadsheet template be provided to help expedite the development of the spreadsheet by companies. Having a standard template will benefit FDA as well as it will allow easier combining of multiple spreadsheets from numerous entities We do not feel that 24 hours to generate this spreadsheet is a sufficient lead time, depending on the product and time period of the request. It will particularly be challenging for foreign facilities which can lose up to 12 hours, due to time zone changes. To comply with the 24 hour window, companies will be forced into upgrading record management systems in order to create the spreadsheet, even though the associated records which would supply the necessary KDEs for the spreadsheet could be made available in the 24 hours.

As mentioned earlier, the recordkeeping requirements for the shipper are twofold: 1) to keep and 2) to send the applicable KDEs for each shipment of FLT foods. These are two separate functions. All companies will need to invest in updating their current recordkeeping practices to generate their documentation to support the send requirement. A single shipper will have multiple customers. It is unrealistic to expect that each customer ("receiver") will accept this data in the same format. This will force the shippers to adapt to a multitude of record requests.

Implementation of Rule

NFI supports the need to improve traceability recordkeeping throughout the supply chain to improve the ability to rapidly identify and trace foods through the supply chain that may be causing illness. Faster outbreak investigations and more efficient product recalls are essential priorities to minimize the impact of foodborne illness.

Due to the complexity of this proposed rule, NFI recommends taking a step-wise approach to minimizing the major gaps in recordkeeping in existing Subpart J in the least burdensome way possible. This approach would involve first focusing implementation on the area's most lacking in proper recordkeeping procedures. As highlighted by FDA on page 59990, among the most significant gaps in the subpart J recordkeeping requirements are:

Lack of coverage of all sectors involved in food production, distribution, and sale (*e.g.,* exemptions for farms and restaurants).
Lack of uniform data collection (*e.g.,* regarding the source of food ingredients used in each lot of finished product; the requirement to record a lot code or other identifier only ''to the extent this information exists'' (see §§ 1.337(a)(4) and 1.345(a)(4)); and
Inability to link incoming with outgoing product within a firm and from one point in the supply chain to the next …

The vast majority of seafood consumed in the United States (approximately 90 percent) comes from foreign sources, and U.S. seafood companies source from a number of countries. The global seafood chain is vast and complex. For example, seafood can be caught on a vessel flagged to one country, sent to another country for processing or substantial transformation, and then shipped to the United States where it may be further processed. Seafood harvested from a land-based aquaculture operation in one country can be sent to another for processing and then sent to the United States. The scenarios involved may be simple or they can be complex and involve many steps.

NFI recommends beginning implementation of a final rule with a narrow focus and moving to a phased approach, much like the pharmaceutical industry was allowed under the Drug Quality and Security Act (DQSA).[40]

NFI members felt that the proposed implementation period is inadequate as from the seafood industry's experience:

More than two years will be necessary for the initial implementation phase due to software development, training needs, and translation of materials to other languages due to the global nature of the seafood industry; and

[40] https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-dscsa-implementation-plan

New foods added to the FTL should have a comparable implementation period to that provided for during the initial implementation provided for in a final rule.

Outreach during implementation is essential due to companies being in different phases of implementation for traceability recordkeeping due to various factors, including customer demand, compliance with trading partners, and other regulations. Other countries have required and implemented their own traceability requirements. These parallel, but different, traceability recordkeeping procedures will likely not fully meet the final requirements enforced by FDA. An existing traceability program is not the same as a traceability program that meets specific FDA requirements. As NFI learned with implementation of the Seafood HACCP regulation, a regulation based on HACCP principles may not always be the same as traditional CODEX or NACMCF HACCP. To avoid confusion, training for the entire industry, both in the US and abroad, must convey the expectations of FDA for this new traceability regulation. Any lack of understanding within the industry needs to be addressed prior to an emergency since that will be the critical test of the regulation.

Specific Comments about the Proposal

For the majority of the seafood on the FTL, we do not agree that requiring additional records of the point of origin is necessary to facilitate foodborne illness outbreak investigations. Our comments below are not an endorsement of requiring such records for those products. In addition, as previously stated, we support major revisions to the proposed requirements. We offer the following comments on specific aspects of the proposed rule if the agency intends to continue with the rule as proposed.

General Provisions

§ 1.1300 Who is subject to this subpart?
While the Congressional mandate for the additional traceability records applies only to persons who manufacture, process, pack, or hold foods that appear on the Food Traceability List, we feel that the role of persons who own the food, but do not engage in manufacturing, processing, packing or holding needs to be defined in a more specific manner in the rule.

§ 1.1305 What foods and persons are exempt from this subpart?
(a) *Exemptions for small originators* – (3) *Certain other originators of food.* Guidance will need to be developed to explain how the annual monetary value of food sold during the precious 3-year period of no more than $25,000 (on a rolling basis). This guidance must include consideration of small originators in other countries whose income is not based on the U.S. dollar. [1.1305(a)(3).

(d) *Inapplicability to foods that receive certain types of processing*. Our view on seafood products which receive certain types of processing and therefore must be exempted from subpart S records requirements is provided elsewhere in this document.

(e) *Exemption for produce that is rarely consumed raw.* Our view on seafood products which are rarely consumed raw and therefore must be exempted from subpart S records requirements is provided elsewhere in this document.

(f) *Partial exemption of commingled raw agricultural commodities*. Our view on the applicability of this partial exemption to commingled raw finfish, crustacean and molluscan shellfish is provided elsewhere in this document.

(j) *Partial exemption for food produced through the use of fishing vessels*. Our view on the partial exemption for food sourced from fishing vessels is provided elsewhere in this document.

§ 1.1310 What definitions apply to this subpart?

The creation of new terminology is confusing when the definitions proposed by FDA are not intuitive to even a food industry veteran. NFI encourages FDA to use standard industry terminology to avoid an additional layer of confusion in understanding and implementing these new requirements. For example, common industry language is "Ship To" and "Shipped From" rather than "Location Identifier".

Category – While we don't disagree with the proposed definition, we don't understand the traceability utility of using a classification scheme to categorize a food product, especially since a person can develop their own classification scheme. ***Farm*** – NFI finds that the rule is very "produce-centric" with respect to the language describing the requirements for the farm. The vast majority (roughly 90 percent) of seafood consumed in the United States is globally sourced. Correspondingly, the vast majority of farmed (aquaculture grown) seafood consumed in the United States is raised and processed in other countries. Therefore, the provisions of a final rule for farms must be understood by aquaculture operations around the world.

The proposed rule refers to §1.328 to define "farm" when used in this rule. We encourage the final rule to include the actual language from §1.328, rather than by reference, so it is apparent that "farm" includes the "raising of animals (including seafood)."[41]

As discussed elsewhere, the majority of the seafood species on the FTL have no identified species-related hazards which would necessitate the additional subpart S records to trace back to the farm or ancillary farm activities such as harvesting or packing.[42] Therefore, there will be little utility in capturing extensive KDEs related to harvesting, packing and specific GPS coordinates for the aquaculture operation.

Aquaculture farms differ from many of the exemption scenarios described in the proposed rule because direct from the farm to consumer sales are rare in the United States. Most sales of farmed seafood would move from the farm to a processor and then into the supply chain. Therefore, NFI did not focus on the various farm exemptions.

First Receiver – As the regulations are proposed, the first receiver is critical to maintaining the information necessary to link the FTL food to the point of origin; therefore there can be no misunderstanding of which person (as defined in the rule) is the first receiver.[43] For example, when are fish obtained from a fishing vessel actually "purchased"? For vertically integrated

[41] As stated in 21 CFR §1.328

[42] In this case we are referring to the microbiological and chemical toxin hazards as addressed by the Risk-Ranking model utilized to establish the FTL. Seafood HACCP CCPs and associated records address control of other contaminants.

[43] As previously stated, we do not believe that it is always necessary to require these extensive recordkeeping of the originator of certain seafood products.

businesses, we have been considering that to mean "ownership" as shown in Appendix A, but that might not be how the agency is viewing the "purchasing" transaction.

Identifying the person who is the First Receiver will be particularly difficult for seafood product because these products will move through multiple hands at the early stage of the supply chain where physical possession occurs, but not ownership. While this may appear to be similar to the harvest, cooling and packing activities that take place on a produce farm, for seafood these contracted[44] activities do not occur on the fishing vessel or aquaculture farm but rather after leaving these "locations". Specific examples include fishing tenders, brokers, auction houses and third-party cold storage facilities.

Within the global seafood supply chain, the First Receiver, as proposed, may be several steps removed from the harvest and as product moves through supply chains, obtaining the KDEs from the aquaculture farm or fishing vessel become more challenging. This is particularly true when the product "originator" does not know that the United States will be the final destination of the product. Specific examples of the complexity of the seafood supply chain are provided in Appendix A.

NFI requests FDA allow flexibility in determining who the First Receiver is within the specific supply chain to identify the best person that has the information on where the product originated.

Fishing vessel – Our view on the definition of a fishing vessel is provided elsewhere in this document.

Food Traceability List – The classification of foods that contain specifically listed foods as ingredients as needing additional traceability records needs specific parameters as discussed elsewhere in these comments.

Growing area coordinates – Since we understand "growing" applies only to produce, but "harvest" can apply to taking of fish and other seafood in aquaculture operations this definition might be confusing. It will be important to emphasis that growing area coordinates applies for where the food was both grown **and** harvested.

Harvest – Comments on the harvesting definition are incorporated in our comments on the definition for Farm.

Holding – Does this definition include the holding of live animals such as lobsters in a lobster pound?

Kill step – Our view on the "kill step" is elsewhere in these comments.

[44] Contracted is used loosely here to refer to activities that are conducted on behalf of the product owner

Location description and Location identifier – The distinction between location descriptor and location identifier is very confusing to understand as many organizations currently do not assign an "identifier." And since each entity will be assigning the identifier, a single facility will have as many identifiers as they have customers. Therefore it is difficult to understand the necessity of a location identifier to facilitate foodborne illness investigations when a single facility will be identified in multiple ways. The location identifier should be an optional KDE.

We also find it very confusing to refer to the fishing vessel as a "location" because this creates an arbitrary distinction between what is the "description" and what is the "identifier" – a distinction which doesn't currently exist. For the fishing vessel, "location description" should be any of the applicable data attributes being proposed: vessel identification number, license number, name of the vessel, or the country in which the fishing vessel is licensed. The fishing vessel "location identifier" should be an optional, unique identification code that an entity assigns to the vessel. In addition, the fishing vessel is the only location description that requires a Point of Contact. Is there a reason why the vessel is being singled out for this requirement?

Packing – Please recognize that within the seafood industry "packing" means putting the food in the final package.

Physical location name – NFI finds this definition confusing regarding how it differs from location description? It seems like this is a duplication of data.

Point of contact – Because of employee turnover and allowable time off for vacations or illness, we do not think it is practical that the point of contact be a specifically named individual and their associated contact information. The Traceability Lot Code Generator may be a clerical person who may not be the best company point of contact, so flexibility should be given to companies in determining the best means of contact.

Reference record – While the examples of documents is not meant to be an exhaustive list, we suggest that "movement documents" be added to the list of types of reference records.

Retail food establishment – Our view on the definition of a retail food establishment is provided elsewhere in this document.

Traceability lot – This definition is confusing because it related to when the traceability lot code can be assigned. But the traceability lot is also shipped and received.

Traceability lot code generator – While we understand that a "person" means an individual, partnership, corporation, or association, this definition is confusing as it implies that it is a specific person who assigns a traceability lot code to a product, especially since in some cases lot numbers are automatically generated and assigned by the computer system.

Traceability product description – This definition is very prescriptive and requires information that may not be relevant for all foods on the FTL. Also the distinction between single-

ingredient and multi-ingredient products is not relevant for seafood products. For example, shrimp with no added ingredients would be required to have a "trade description" that includes a "commodity" and "variety"; shrimp with added salt, sodium tripolyphosphate and sodium bisulfite would be required to have a "Product name".

Transformation – Our view on commingling as a transformation event is provided elsewhere in this document.

Vessel identification number – Our view on the vessel identification number is provided elsewhere in this document.

TRACEABILITY PROGRAM RECORDS

§ 1.1315 What traceability program records must I have for foods on the Food Traceability List that I manufacture, process, pack, or hold? In principle, we have no issues with establishing a Traceability Program which describes the traceability records, how records are linked, or the system for assigning traceability lot codes. Documenting this information would help to establish the consistent application of a company's traceability program and would facilitate the agency's review of records in case of a recall or foodborne illness investigation. In addition, documented traceability processes commonly exist for seafood due to third party traceability programs requirements. However, while we see the usefulness in having a master list of all the FTL foods shipped from the facility as proposed in §1.1315(a)(2) we don't understand how this is essential for facilitating foodborne illness investigations; especially since all shippers will be required to maintain and send the KDEs associated with FTL foods. It is unrealistic for entities that only receive and ship to establish this master list because they must rely on information provided by the previous shipper.

We also note with interest the concept presented on pages 60001 and 60004 that persons subject to these requirements may enter into agreements with others to create and keep the subpart S records on their behalf. As previously discussed, this will be a viable option for entities which only hold product, but who have no ownership. However, it is not clear in the proposed regulatory language that this is even an option. This option must be clearly stated in the final rule, not just discussed in the Federal Register notice.

§ 1.1320 When must I establish and assign traceability lot codes to foods on the Food Traceability List? NFI agrees that a traceability lot code is to be established and assigned when a FTL food is originated, transformed, or created, as this aligns with current industry practices. However, not allowing the traceability lot code to be changed when receiving a product will require a major disruption in how businesses currently establish lot codes and manage

inventories, as it is not standard industry practice to use another entity's lot code when receiving an ingredient or product into inventory. While the Frequently Asked Questions about the Food Traceability Proposed Rule document posted on the agency's website[45] did clarify that firms could assign a code separate from the traceability lot code provided that the traceability lot code was maintained and linked to the KDEs, this needs to be clearly stated in the final rule if it remains prohibited to change the traceability lot code when receiving and shipping FTL foods.

RECORDS OF GROWING, RECEIVING, TRANSFORMING, CREATING, AND SHIPPING FOOD

As a general comment, we find the order of the requirements in this section to be confusing and difficult to navigate because they do not follow the logical flow of product in the supply chain; product is always shipped before it is received. The requirements for shipping from a farm (or any other originator) are in the last section – this should be at the beginning of the list because it is the first step in the supply chain after originating. We recommend the following order:

- What records must I keep and send when I originate a food on the FTL?
    - to include the records for growing
    - to include both the keep and send records for shipping from the originator (farm and fishing vessel)
- What records must I keep when I am the first receiver …?
- What records must I keep when I receive …?
- What records must I keep when I transform …?
- What records must I keep when I create …?
- What records must I keep and send when I ship …?

Key Data Elements need to be reduced and simplified

NFI recommends that the required KDEs, and associated data attributes for each of the CTEs be reduced and simplified to only those that are necessary to assist with product tracing to rapidly prevent and mitigate food borne illness outbreaks. While a Location Identifier is desirable to have and will facilitate the establishment of a technology-based traceability system, is it truly necessary? If these identifiers were made optional rather than required, would the agency's ability to review CTE records and sort data in the electronic sortable spreadsheet be hampered? As we understand the proposal, unlike the Traceability Lot Code, the identifiers do not have to remain unchanged; each Person in the supply chain establishes these identifiers for their own Traceability Program. In addition, the KDEs for Category Name, Category Code, and

[45] Found at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-food-traceability

Commodity/Variety may not be applicable to all foods on the FTL. Like the Location Identifier, these may be desirable, but are they essential to help identify the previous or subsequent product or source?

NFI does not believe that the Import Entry Number is an essential KDE necessary for subpart S purposes for three reasons. First, the import entry number is only maintained in records by the importer and, unless the importer also hold the product is not covered by this proposed regulation. Second, this information is readily available to the agency through Prior Notice submission and is linked to relevant information as discussed in a previous section. Third, the Import Entry Number is not readily found on shipment documents (BOL).

Table 5 - Example of Data Attributes for Traceability Product Descriptions and Traceability Product Identifiers, found on page 60004 of the Federal Register notice, is a perfect example of the redundancy of the information required under the proposed rule. For the Bluefin Tuna example, the Commodity and Variety data attributes repeat the Category Name. Duplicating information adds another layer of unnecessary recordkeeping. The Category Code demonstrated for the Bluefin Tuna example is from the United Nations Food and Agriculture Organization's Aquatic Sciences and Fisheries Information Systems (ASFIS). ASFIS codes are not commonly used by the US seafood industry to describe seafood species and only recently came into use for a handful of species under the NOAA Seafood Import Monitoring Program. Because the Category Code ("BFT") and the Category Name ("Blue Fin Tuna") provide the same information in two different formats, there is no reason to require both, and by doing so adds another layer of unnecessary recordkeeping. In addition, Table 5 demonstrates that the Trade Description Commodity and Variety requirements do not conform to the seafood industry's practices. Bluefin Tuna would typically be described by Product/Species Name (as based on the FDA Seafood List[46] and appearing on the product label) and Product Form, for example, "Loin". Because the agency does not consider the Scientific Name (*i.e.,* Latin name) to be an acceptable market name[47], many firms do not maintain this information.

§ 1.1325 What records must I keep when I grow a food on the Food Traceability List?
Please confirm that records of growing area coordinates only apply to farms which grow produce and not to aquaculture operations.

[46] Found at https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=SeafoodList
[47] FDA's Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce, found at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-seafood-list

§ 1.1330 What records must I keep when I am the first receiver of a food on the Food Traceability List? NFI recommends the following:

- any location identifier be an optional KDE.
- the KDEs for harvesting ((a)(2) and packing ((a)(4)) be qualified with "as applicable" because, these steps may not apply to aquaculture seafood or be necessary for ensuring the public health for traceability purposes.
- the KDEs for the first receiver of a seafood product from a fishing vessel be listed as separate items (e.g. (b)(1), (b)(2), etc.) to make the requirement easier to understand.

In addition, the harvest location for the fishing vessel trip must recognize options other than the National Marine Fisheries Service Ocean Geographic Code or geographical coordinates. There are other geographical identifiers commonly used in the industry such as FAO Fishing zones[48] or approved harvest (growing) areas used under the NSSP as NSSP already requires an area identifier code that is maintained by each state[49]. This distinction must be made in the final rule language to allow for flexibility and minimize the number of new data elements that firms would need to maintain.

§ 1.1335 What records must I keep when I receive a food on the Food Traceability List? NFI recommends the following:

- any location identifier be an optional KDE.
- the import entry number be an optional KDE.
- the time of receipt be an optional or "as applicable" KDE.
- the location identifier (optional), description and point of contact of the traceability lot code generator be maintained only if provided by the shipper (see comments on §1.1350 below).
- for fishing vessels, the location description (name of vessel, licensing country, point of contact) and location identifier (vessel identification number or license number) be required only if there are hazards associated with the harvest location.

§ 1.1340 What records must I keep when I transform a food on the Food Traceability List? NFI recommends the following:

- any location identifier be an optional KDE.

[48] http://www.fao.org/cwp-on-fishery-statistics/handbook/general-concepts/fishing-areas-for-statistical-purposes/en/
[49] Chapter IV Shellstock Growing Area: National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish: 2017 Revision

§ 1.1345 What records must I keep when I create a food on the Food Traceability List? NFI recommends the following:

- the location identifier be an optional KDE.

§ 1.1350 What records must I keep and send when I ship a food on the Food Traceability List? NFI recommends the following:

- any location identifier be an optional KDE.
- the import entry number be an optional KDE.
- the time of shipping be an optional or "as applicable" KDE.

NFI strongly objects to requiring the shipper to send information about the traceability lot code generator to the immediate subsequent recipient. Because FDA has proposed that traceability lot codes cannot be assigned for shipping and receiving, the same traceability lot code and associated generator information has the potential of being passed along through many steps in the supply chain, thus exposing confidential supplier/buyer relationships. One option to avoid disclosing this confidential information would be to have a KDE for the shipper to declare "Yes" or "No" if their location is the same as the traceability lot code generator. Subsequently, the Receiver would document whether or not the shipper is also the traceability lot code generator. This option will still allow the agency to rapidly identify where the product was created or transformed while still maintaining the confidential supplier/buyer relationships.

The manner in which proposed §1.1350 is organized is very confusing, so clarification will be needed on what passes forward for KDEs versus what is being linked in the records the company holds and which specific KDEs are then further passed along to the next step. In the final rule guidance, we request the KDEs for each CTE be provided in a simplified one to two page format that specifically lists what is kept at each CTE and what is sent on to the next CTE; this would be a valuable reference sheet for companies to follow when establishing the Traceability Program Records.

RECORDS MAINTENANCE AND AVAILABILITY

§ 1.1455 How must records required by this subpart be maintained?
Because of the global nature of the seafood industry, there are concerns with being able to provide records within 24 hours of request, not because the records will be difficult to retrieve but rather due to time differences. For overseas companies the difference in time zones will impact this ability, especially if the request is made during non-working hours.

The biggest challenge with meeting the 24 hour request is not with retrieving the records but rather with generating the electronic sortable spreadsheet. An agency provided template will facilitate creating this record.

Appendix A

Supply Chain Scenarios

When reviewing the proposed regulation with NFI members, various seafood supply chains were discussed to gain a better understanding of the full impact of a traceability regulation. These examples are provided in this appendix along with an assessment of the first receiver location based on the proposed criteria of ownership and possession.

Finfish Supply Chain with Independent Auction House

Step	CTE	Who Owns	Who Has Possession
Vessel catches fish	Harvest/Originator	Boat Owner	Boat Owner
Gut at sea, put on ice or freeze	Hold/Pack	Boat Owner	Boat Owner
Off load to Auction House	Receive	Boat Owner	Auction House
Display Auction Holding	Hold	Boat Owner	Auction House
Processor Buys	Ship (Processor Picks up)	Ownership goes from Boat Owner to Processor but Auction House passes Boat Owner information to Buyer	Auction House
Processor moves fish to their facility (usually on company owned truck, so transport record may be a movement document vs Bill of Lading)	First Receiver	Processor	Processor
Processor transforms into fillets	Transform Hold	Processor	Processor
Processor sells to Retail or Food service Customer	Ship to Distribution center	Retailer or Foodservice Distributor	Retailer or Foodservice Distributor
Distribution Center	Receive/Hold/ Ship	Retailer or Foodservice Distributor	Retailer or Foodservice Distributor
DC Send to Store or Restaurant	Receive	Retailer or Restaurant	Retailer or Restaurant

Small Vessel Harvest **Product: Mahi**

Step	**CTE**	**Who Owns**	**Who has Possession**
Harvesting (1-5 fish a day)	Harvest/Originator	Fisherman	Fisherman
Off load directly on beach	Commingle First Receiver?	Local Buyer/ Aggregator	Local Buyer/ Aggregator
Transport to Processor	Ship/Commingle	Processor or Local Buyer	Aggregator
Processing	Receive (Better place for First Receiver) Transform Hold	Processor	Processor
Sold by Processor or Agent to US Importer	Ship	Processor	Processor
Shipment to US	In Transit	Processor	Container Ship or Plane
Transfer to Cold storage	Receive/ Hold/ Ship	Importer	3rd Party Cold Storage or Importer owned Cold Storage
Transfer to 3rd Party Cold Storage	Receive/Hold/Ship	Importer	3rd Party Cold Storage
Importer sells to Food Service Distributor	Ship	Food Service Distributor	In transit
Transfer to Distribution Center	Receive/Hold/ Ship	Food Service Distributor	Food Service Distributor
DC Transfer to Restaurant	Receive	Restaurant	Restaurant

Small Vessel Harvest **Product: Frozen Tuna Loins**

Step	CTE	Who Owns	Who has Possession
Harvesting hand line (1-5 fish a day	Harvest/Originator	Fisherman	Fisherman
Gut at sea, package and put on ice	Hold/ Pack	Fisherman	Fisherman
Off-loading tuna to village, goes to buyer. Buyer will minimally process (section and trim), then pay fisher based on weight.	First Receiver? Transform? Commingle (grand-lot) Ship	Some buyers are independent (own) or Collector tied to processor (don't own)	Buyer or Collector
3rd Party Cold storage	Receive/Hold/ Ship	Buyer or Processor	Cold Storage
Pre-processor turn trimmed, headed & gutted into loins	Receive, Transform, Ship (Better place to capture and manage KDEs required for First Receiver)	Processor	Processor
Finished good processor turns into final products. (Indonesia, Vietnam)	Receive, Transform, Ship	Processor	Processor
Importing	In transit	Importer	In transit – container ship
Shipping to 3rd party storage	Receive/Hold/Ship	Importer	Cold Storage
Shipping to distribution center	Receive/Hold/Ship	Food service Distributor	Food Service Distributor
Shipping to restaurant	Receive	Restaurant	Restaurant

Complex International Supply Chain **Decision made to sell to US is step 12**

Step	CTE	Owns	Has Possession
Russian vessel catches fish	Harvest/ Originator	Boat Owner	Boat Owner
Head and Gut at sea, put on ice	Originator	Boat Owner	Boat Owner
off load to Russian Processor who freezes H&G fish into larger blocks for shipment	First Receiver?	Packer Not considered a Transformation event but lot code assigned	Packer - This transaction is in Russia; the collection of US required KDEs may not occur.
Broker ships to Busan Korea Cold Storage	Holding	some brokers are independent (own) some brokers tied to processor (don't own)	Cold Storage
Broker sells to Chinese Processor	Ship	Processor	Cold Storage
Chinese processor moves frozen H&G blocks to Chinese facility	Receive	Processor	Processor - best place to collect and maintain First receiver KDEs on origin
Chinese processor transforms Fish H&G Block to skinless boneless block	Transform	Processor - traceability Lot code assigned	Processor
Chinese plant works with Broker to sell product	Hold	some brokers are independent (own) some brokers tied to processor (don't own)	At Processor or cold storage
Broker ships to EU Cold storage	Ships	May not own	Cold storage
Broker sells to EU Processor	Receives	May not own and takes commission only	Cold Storage
EU Processor converts to Fish Sticks	Transforms	Yes - new Lot traceability code assigned	Yes - best place to collect and maintain KDEs on fish block transformation
EU Processor sells to US Importer	Ship	Importer	Cold storage - Importer never takes possession, has information about the EU Processor
Holds in Cold Storage upon arrival in US	Receive	Importer	Cold storage
US Importer sells to Foodservice distributor	Ship	Food Service Distributor	
US Distributor sells to Restaurant	Receive	Restaurant	Restaurant

Value Added Supply Chain Product: Breaded Fish

Step	CTE	Owns	Has Possession
Russian vessel catches fish	Harvest/Originator	Boat Owner	Boat Owner
Head and Gut (H&G) at sea, frozen into blocks/bag	Originator	Boat Owner	Boat Owner
Ships to Busan Korea Cold Storage or could stay within Russia	Ship	Broker some brokers are independent (own), some brokers tied to boat owner (don't own)	As this is a transaction in Russia the collection of US required KDEs may not occur
Cold Storage	Receives/Holds/Ships	Broker/Packer or Boat Owner	Cold Storage
Broker sells to Asian Processor	n/a	Processor #1	In transit
Asian processor moves frozen H&G blocks to their facility	First Receiver Often not the same as harvest country	Processor #1	Processor #1- better place to collect and maintain KDEs on origin
Asian processor transforms into Fish Block or fillets	Transform	Processor #1	Processor #1
Asian plant sells to Importer	Ship	Importer	Processor #1
Importer ships to US Cold Storage	In transit	Importer	In transit
Importer sells to US Processor	Receive	Importer or Processor #2	Transfer of product and ownership may occur after Quality Inspection
US Processor converts to Fish Sticks	Transforms/Ships	Processor #2 new Lot traceability code assigned	Processor #2 - best place to collect and maintain KDEs
US Processor stores in 3rd Party cold storage	Receives	Processor #2	Cold storage
US Processor sells to Retail customer	Shipper	Retailer	May go to a 3rd Party consolidator warehouse or directly to Retailer's DC
Retailer sends to Store	Receiver	Retailer	Retailer

Vertically Integrated Company (where is first receiver?) Product: Breaded Fish

Step	CTE	Owns	Has Possession
US vessel catches fish	Harvest/Originator	Boat Owner (company or individual)	Boat Owner
Fish held in chilled holding tank	Hold	Boat Owner	Boat Owner or Tender Operator
Fillet at sea (factory trawler)	Transform	Boat Owner	Boat Owner
Pack and Freeze into fish blocks at sea (factory trawler)	Transform	Boat Owner	Boat Owner
Hold on fishing vessel	Hold (Cold Storage)	Boat Owner	Boat Owner
Off load to tramper in Alaska	Ship from Boat/Tramper Receives	Boat Owner	Tramper
Truck Transport from Tramper to Processor in Seattle area	Transfer to new Transportation	Boat Owner	Trucker
Processor Receives	Receive	Boat Owner	Boat Owner
US Processor converts to Fish Sticks	Transform Ship	Boat Owner	Processing Facility (Boat Owner owns the Processing Facility)
US Processor sends to 3rd Party Cold storage	Receive	Boat Owner	3rd Party Cold Storage
US Processor sells to Retail customer and ships	Ship	Boat Owner	Cold storage to Retailer
Retail Distribution Center receives	First Receiver? /Ship	Retailer	Retailer
US Retailer sends to Store	Receive	Retailer	Retailer

Simple Aquaculture Supply Chain For farms that also process, where is the First Receiver?

Step	**CTE**	**Owns**	**Has Possession**
Harvester takes fish from pond	Harvest/Originator	Aquaculture farm (company owned)	Aquaculture Farm
Fish held in chilled holding tank alive during transport	Transport	Aquaculture Farm	Aquaculture farm
Processor Receives	Receiver	Aquaculture farm	Aquaculture farm
Processor converts to Fillets	Transforms Ship	Aquaculture farm	Processing Facility (Farm owns the Processing Facility)
Aquaculture company sells to US Importer	Transport	Importer	Airplane or Container ship
Importer ships to US 3rd Party Cold storage (or can direct ship to end customer upon arrival to US)	Receive	Importer	3rd Party Cold Storage
US Importer sells to Retail customer	Ship	Importer	Goes directly from Cold storage to Retailer
Retail Distribution Center receives	First Receiver? /Ship	Retailer	Retailer
US Retailer sends to Store	Receive	Retailer	Retailer

Commingled Live Animals **Product: Live Lobster**

Step	CTE	Owns	Has Possession
Vessel catches lobster	Harvest/Originator	Boat Owner	Boat Owner
Packs into Live storage crate for transit	Pack, Ship	Boat Owner	Boat Owner
Off load to Private Wharf or Wharf Co-op	First Receiver Stored in Crates in ocean off end of wharf for 12-24 hours	Private Wharf or Co-op	Wharf or Co-op
Sold to Seafood Dealer (Distributor)	Transport	Seafood Dealer	Seafood Dealer
Hold in large tank with recirculating water (*i.e.*, Lobster Pound)	Receive Commingled Packs, and Ship	Seafood Dealer	Seafood Dealer
Seafood Dealer sells to Food Service Distributor or Direct to Restaurant	Receive Commingled Ship	Food Service Distributor or Restaurant or Retailer	Food Service Distributor or Restaurant or Retailer
Restaurant or Retailer Lobster is always cooked prior to consumption	Receive, Commingled	Restaurant or Retailer	Restaurant or Retailer

Complex Aquaculture Scenario Product: Shrimp

A harvest aggregator will collect fish from 5-10 farms (farmed imports) and commingle after documenting the weight harvested

Step	CTE	Owns	Has Possession
Harvests shrimp from aquaculture pond	Harvest/Originator	Aquaculture Farmer	Farm Team Broker or Processor
Weigh and Some size grading may be done at harvest site	First Receiver?	Broker or Processor Farm Team	Farm Team
Transport to pre-processing site	Commingling from multiple farms may occur	Broker or Processor Farm Team	Farm Team
Pre Process - peeling	Receive /Transform/ Ship	Broker or Processor Farm Team	Broker or Processor Farm Team
Optional Step: Product sold via Auction by Buyer if not already owned by Processor	Receive/ Hold/Ship	If Broker owned may go through an Auction	Auction First receiver KDEs passed from broker via a movement document through auction house
Processor Receives pre - processed shrimp	Receive - better place to manage KDEs if destined for USA	Processor	Processor
Processor - deveins/freezes (IQF)	Transforms (note: not considered substantial transformation by US CBP	Processor	Processing Facility(s) Some steps may be May be outsourced
Processor sorts IQF Shrimp by size -	Commingles (grand lot). May hold IQF in Bulk as Work in Progress to fill specific orders later	Processor	Processor
Processor packages	Transforms	Processor	Processor
Sells to US Importer	Ships	Processor	In transit to port
Import	n/a	Importer	Container ship
US Importer sends to 3rd Party Cold storage	n/a	Importer	Truck
Cold Storage	Receive/Hold	Importer	Cold Storage
US Importer sells directly to Food service customer	Ships	Importer	In transit
Distribution Center receives	Receiver/ Hold /Ship	Food service	Food Service
Delivers to Restaurant	Receive	Restaurant	Restaurant

Appendix C

Review of FDA's Supply Chain Example

NFI appreciates FDA providing the Proposed Rule: Requirements for Additional Traceability Records for Certain Foods: Supply Chain Example released on February 12, 2021. This detailed example showcases the complexity of the rule and calls attention to the extensive amount of manpower and computer system updating companies will need to undertake.

NFI believes FDA has grossly underestimated the work involved to manage the amount of KDEs required in the proposed rule and the burden this will place on small and medium size businesses throughout the supply chain. The need for reliance on electronic (digital) transactions is shown throughout the Supply Chain Example.

NFI's would like to point out FDA has made several assumptions in putting together this Supply Chain Example:

1. Some of the KDEs records will be managed and sent electronically (digital) vs paper. *In reality many small business transactions are still paper based.*
2. Bills of Lading (BOL) are easily revised to add the new fields for the newly created KDEs plus all the other required information. *Traceability Product description required elements (category code or term, category name and trade description) alone are too long for most BOL print fields forcing companies into having a Product Master File or spreadsheet*.
3. Accuracy in reporting the time of shipment and receiving time. *In reality, (this) will be hand written*
4. KDEs will be in English or easily understood as the information passes along the supply chain. *With global supply chains, products pass through multiple countries that speak different languages.*
5. There are no additional costs to a business to bring existing master files up to data or for revising the "New Item set up" procedure within the company. *A major burden will be placed on Processors and Distributors, due to the number of items stocked, plus shipping and receiving transactions that occur on a daily basis. Distributors will need to add multiple new data fields to their current systems just to identify foods and ingredients found on the FTL.*
6. The FDA example assumes a certain level of computer technology capability already exists: *Advanced Ship Notice and Proof of Delivery Notices are not common in the seafood industry.*
   NFI discovered this was an unexpected road block with the major retailer's distribution center when conducting the NFI blockchain pilot.
7. Skilled Labor is readily available. *FDA is not accounting for the skilled manpower needed to reconfigure existing documents and internal company systems. Records will also need*

constant upkeep. For example: business names and locations often change due to relocations, mergers and acquisitions.

The Seafood Industry has extensive experience in conducting global traceability exercises and undergoes frequent government (NOAA) and third party audits (MSC, BAP). Document linkage is commonly done by matching up a common set of numbers to link one step back/one step forward. The excessive number of KDEs being required makes the proposed rule cumbersome and are unnecessary.