



February 22, 2021

Submitted electrically via www.regulations.gov

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

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

Dear Sir or Madam,

The Alaska Seafood Marketing Institute (ASMI), on behalf of the Alaska seafood industry, appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) "Requirements for Additional Traceability Records for Certain Foods" (Food Traceability Proposed Rule). ASMI commends the effort of the Food and Drug Administration (FDA) to simplify the process of identifying the sources of foodborne illness and enabling more rapid and accurate mitigation should the need arise. We appreciate the work that was done in the Rule's design as well as the spirit in which this design was carried out. We provide our comments to help inform the conversion of these intentions into practical, science-based policy that will both protect the health of Americans and eliminate redundant or contradicting regulatory impositions on American seafood producers who already adhere closely to strict safety measures guided by the FDA.

ASMI is a partnership between the State of Alaska and the Alaska seafood industry representing over 60,000 Alaskan harvesters, processors, and businesses that take pride in providing nutritious, wild, natural, and sustainable seafood to consumers worldwide. Alaska naturally produces more seafood than any other part of the United States, and for decades has sustainably managed this renewable resource with rigorous science to maintain healthy ecosystems.

Decades ago, the FDA developed Guidance for the Industry: Fish and Fisheries Products Hazards and Controls Guidance, and maintains this Seafood Hazard Guide by updating the hazards and controls based on science and technology. The 4th edition of the Seafood Hazard Guide was released in April 2011 and new updates were released in March 2020. The Seafood Hazard Guide includes hazards that are species specific as well as process-related hazards and controls for these hazards. The FDA Seafood Hazard Guide has provided industry with a demonstrated tool that has tangibly reduced the risks associated with seafood food safety hazards.

In addition, the FDA conducts seafood HACCP inspections under the domestic Seafood Products Compliance Program (CP7303.842) and the Imported Seafood Products Compliance Program (CP 7303.844), and conducts periodic evaluations of the FDA's inspections (including State



Contract work). The FDA also provides detailed reviews to the industry and public on the Seafood industry's implementation of the Seafood HACCP Regulation and industry's work to continue to increase the margin of safety of Seafood Products that U.S. consumers already enjoy and to reduce illnesses that do occur to the lowest possible levels.

ASMI provides the following comments on the FDA's Food Traceability Proposed Rule:

Comment #1:

A fundamental aspect of Seafood HACCP (Hazard Analysis and Critical Control Point) training and the development of Seafood HACCP Plans is the determination of species-related hazards. As we have reviewed this draft proposal and discussed the language with the Alaska seafood industry members we represent, many have wondered why finfish are generalized on the Food Traceability List (FTL) when there are different hazards associated with different types of finfish. ASMI agrees that there are specific finfish with hazards such as scombroid and ciguatoxin forming species. However, these hazards are already identified in FDA's Seafood HACCP Guidance Document. ASMI recommends that the proposed FTL list that currently includes all finfish should not conflict with FDA's Seafood Guidance document that FDA and industry utilize under the Seafood HACCP Regulation.

Comment #2

The Seafood HACCP Regulation addresses seafood products that are consumed raw, though the majority of seafood is cooked prior to consumption. ASMI requests that the FDA provide for exemptions for seafood that is rarely consumed raw, like what you previously provided for produce that is rarely consumed raw under the proposed language 1.1305(e). For example, crustaceans such as shrimp, crab, lobster, and crayfish are rarely consumed raw. ASMI also questions why they are included on the FTL list when again the Seafood Hazard Guidance Document addresses environmental and harvest location hazards.

Comment #3:

Seafood may also be commingled at times and yet FDA has not provided for language to exempt or partially exempt seafood products like what has been proposed for commingled raw agricultural commodities under 1.1305(f). For example, commingled seafood may be processed for value added products such as fish sticks and fish burgers. ASMI asks FDA to reconsider this proposed language as well.

Comment #4:

ASMI asks that FDA reconsider having Mollusks, bivalves included on the FTL. The Model National Shellfish Sanitation Program (NSSP) requires harvest tag documentation to note exact locations of the product origin for shell stock throughout the distribution chain in addition to being regulated under the Seafood HACCP Regulation, 21 CFR Part 123. Again, we view this inclusion as a conflict to current FDA Seafood HACCP Regulation and model programs that already exist.

Comment #5:

Most Seafood recalls that are not related to species related hazards are processing related hazards. Seafood products that have processing related recalls should not be subject to tracing



the fish product back to the harvest location. This is cumbersome and unnecessarily adds to industry's recall efforts, wasting time for both industry and the public health officials conducting recall activities.

Comment #6:

The seafood industry is not only regulated under the FDA Seafood HACCP Regulation and model NSSP, but many also operate under Third-Party Auditing Programs that require documented traceability systems be in place. ASMI asks FDA to consider the role of Third-Party Auditing Programs such as BRCG and SQF which are part of the Global Food Safety Initiative (GFSI). ASMI suggests that operations under Third-Party Programs be exempted from this Rule.

Comment #7:

The definition of "first receiver" is not clear. In many seafood harvest situations, boat tenders are used, and they are an extension of the fishing vessel that is exempted. Under the Food Traceability Proposed Rule as written however, this is not clear. Additional questions on "over the dock transfers" have been asked by Alaska industry members and ASMI asks that FDA clarify your definition.

Comment #8:

The proposed language has a definition of "kill step" that appears to conflict with other FDA regulations. Under Seafood HACCP and the cGMP, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (PCHF) the term 'kill step' is not used. Critical Control Points (CCPs) under Seafood HACCP and Preventive Controls (PCs) under the PCHF rule 21 CFR Part 117 are the terms used. Foods processed under the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers Regulation, 21 CFR Part 113, should be clearly exempt due to the "kill step" for microbial concerns and the records and documentation that are already required under that regulation. Under the proposed rule as written, it is unclear as to when and where the "kill step" would apply. It is concerning to us that new terminology is being proposed that can cause confusion and conflict with current FDA regulations.

Comment #9

ASMI has discussed the proposed language on the traceability lot code with stakeholders. This new proposed language is still confusing and there are many concerns that the traceability lot codes will be burdensome if FDA is not specific as to what they expect for such code information. It has been suggested that the FDA should consider utilizing either the Bioterrorism (BT) registration number as part of the traceability system or the FEI numbering system. FDA already has operations registered with FDA under the BT registration requirements and many operations have been assigned a FEI number. In fact, for exports of U.S. seafood products, the FEI number is utilized routinely by both industry, FDA, and the National Marine Fisheries Services for export certificates to China and the European Union. International plants that export to the U.S. must also register under the BT requirements which now includes a DUNS number and is unique to a company facility. ASMI suggests that FDA reconsider alternatives and utilize systems that are already in place.



Comment #10

ASMI has reviewed the information provided under this proposed rule for the Paperwork Reduction Act of 1995 and based on feedback from Alaska industry members, FDA has underestimated the time involved as well as the cost to implementation of industry to meet the proposed Traceability rule. Here are a few examples:

1. Under Third-Party Auditing Programs that members are currently involved in a documented Traceability System is required that includes training. Some have indicated that they have a minimum of 8 to 10 hours of training per employee which does not include annual retraining, verification and any travel costs associated with training on their Traceability System.
2. There will be a need to hire people to create and maintain a database system for electronic recordkeeping, even if it can be an excel spreadsheet that is searchable by FDA upon request. This is because it is not clear just what is needed for the spreadsheet.

Comment #11:

It has been suggested by Alaska seafood industry members that FDA should consider a pilot study on long and/or more complicated supply chains to better understand what FDA should require under this proposed rule and prior to implementation of any final rule. ASMI would be willing to work with FDA on such a pilot study related to seafood products.

The Alaska Seafood industry generally, and ASMI specifically, remain proud of the constructive and collaborative relationship that has been forged with the FDA and that has established a regulatory framework that has protected both industry and seafood consumers alike for many years.

In the event of a foodborne illness event, traceability to the cause is of paramount importance and we believe the Food Traceability Proposed Rule as written is primarily designed to expedite that process. However, ASMI feels that in service of that end, much of the content of the Food Traceability Proposed Rule as written has been generalized, and would leave the seafood-specific considerations that the FDA has helped to build in a state of diminished clarity, adding process and layers of documentation that increase costs and do not enhance the safety protections in place.

Adapting the proposed regulations with the changes and recommendations suggested by ASMI on behalf of the Alaska seafood industry, will enable the continued availability of top quality Alaska seafood to the public at the most affordable prices possible while improving our ability to respond rapidly and appropriately to any incident that may arise, however unlikely. ASMI once again thanks the FDA for the opportunity to provide comment.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Woodrow".

Jeremy Woodrow
Executive Director