National Fisheries Institute Template: Supply Chain Partner Notification Letter

(v.4 August 30, 2023)

Please cut and paste the below text on to your company letter. Modify as needed for your business, including the Food Traceability List examples provided in paragraph one.

**Date:**

**Subject:** New FDA Food Traceability Rule

Dear Supply Chain Partner,

This letter is to notify you of the new U.S. Food and Drug Administration (FDA) regulation required under the Food Safety Modernization Act (FSMA) Section 204. Per the regulation published in [21 CFR Part Subpart S. Requirements for Additional Traceability Records for Certain Foods](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-1/subpart-S?toc=1) entities in the global supply chain who manufacture, process, pack and/or hold (store) foods on the [FDA’s Food Traceability List](https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list) (FTL) destined for the United States market must maintain additional traceability records for those foods. FDA’s FTL list encompasses many foods, including fresh and frozen finfish, crustacean shellfish, molluscan shellfish, and smoked finfish, plus any food that contains these species in raw form. This rule is designed to facilitate faster identification and rapid removal of potentially contaminated food from distribution in the United States market, resulting in fewer foodborne illnesses and deaths.

Per the FDA, entities subject to compliance with this regulation include farms (aquaculture ponds and net pens, etc.), first receivers from a fishing vessel, manufacturers, exporters, shippers, receivers, retail food establishments, restaurants, and any other operations that manufacture, process, pack and/or hold (store) foods that are listed on the FTL.

FDA requires full compliance with 21 CFR Part 1 Subpart S, Additional Traceability Records for Certain Foods by **January 20, 2026.**

At a minimum the new regulation requires each entity to:

* Confirm which of the entities’ products are included in the FTL;
* Develop, maintain, and implement a written Food Traceability Plan;
	+ Define the Traceability Lot Code system that entities will apply to the food products identified on the FTL;
* Maintain and, in some situations, pass records containing the Key Data Elements (KDEs) for each Critical Tracking Events (CTE) identified;
* Share traceability records and KDE information via a Sortable Spreadsheet with the FDA within 24 hours of an official request or within some reasonable time to which the FDA agrees.

National Fisheries Institute Template: Supply Chain Partner Notification Letter

(v.4 August 30, 2023)

Please cut and paste the below text on to your company letter. Modify as needed for your business, including the Food Traceability List examples provided in paragraph one.

Upon review of the complete rule, if your organization determines any of your processes or products may be exempt from this rule, please provide written justification as to how this determination was made. A written agreement letter may be required.

Please note any existing Third-Party Certifications your operation may currently hold will not be recognized as compliance with 21 CFR Part 1 Subpart S. As a supply chain partner, it is critical that you demonstrate a continued commitment to a food safety culture and compliance with

regulations in your organization. Please reference the links attached to learn and familiarize yourself and your company with this rule.

Sincerely,

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Support Information**

* [21 CFR Part Subpart S. Additional Traceability Records for Certain Foods](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-1/subpart-S?toc=1)
* FDA FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods: [FSMA Final Rule](https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods?utm_medium=email&utm_source=govdelivery)
* [Frequently Asked Questions: FSMA Food Traceability Rule | FDA](https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma-food-traceability-rule)
* [FDA’s Food Traceability List](https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list)
* Institute of Food Technologists (IFT) - FSMA 204 explainer videos: [Global Food Traceability Center FSMA Resources (ift.org)](https://info.ift.org/global-food-traceability-center-fsma-resources)
* [Global Dialogue on Seafood Traceability](https://traceability-dialogue.org/gdst-standards-and-materials/) (GDST) Standards and Explanatory Materials for digital, interoperable traceability implementation.
* [GS1 US FSMA 204 Readiness Checklist](https://protect-us.mimecast.com/s/GNubCER6nBHMXXKCQ2mnf)