GLOBAL DIALOGUE on Seafood Traceability

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Re: Docket No. FDA-2014-N-0053: Requirements for Additional Traceability Records for Certain Foods

Dear Mr. Pendleton:

The Global Dialogue on Seafood Traceability (GDST) is a voluntary, pre-competitive seafood industry platform that brings together over eighty companies from around the world and across the seafood supply chain from fishers and aquaculture farmers through to retailers.[1] GDST members include companies of all sizes, and represent combined seafood sales of over USD $35 billion per year, much of which is imported to the US. In March 2020, the GDST promulgated the first-ever voluntary global standards for seafood traceability: GDST 1.0. These standards represent a leap forward for the seafood industry, and are perhaps the most advanced voluntary global traceability standards yet to be adopted by a major sector of the fresh food economy. The principal goals of the GDST standards are (i) to enable digital interoperability of traceability systems, (ii) to set a common baseline for the kinds of information to be routinely associated with seafood products, and (iii) to enable rapid verification of authoritative traceability data. The overarching objective of the GDST is to support responsible sourcing practices aimed at eliminating illegally produced seafood from all markets while advancing environmental and social sustainability.

The GDST strongly supports the Food and Drug Administration (FDA)'s efforts to enhance and standardize food traceability through this rulemaking. Although principally motivated by the need to eliminate trade in illegally harvested seafood, the GDST standards were drafted with the broad benefits of traceability for public health, trade facilitation, and efficiency in mind, among others.

The GDST broadly supports the requirements and regulatory structure laid out in this proposed rule. The emphasis in the proposed rule on event-based traceability through the alignment of Key Data Elements (KDEs), Critical Tracking Events (CTEs), and batch/lot unique identification of logistical units rests on the same fundamental approach to food traceability that underlies the GDST standards--indeed, the GDST employs essentially the same KDE/CTE concepts and batch-lot approach. Similarly, the GDST is fully aligned with the FDA's strong encouragement of digitized traceability systems, both within and between enterprises along the supply chain. We further appreciate that the proposed regulation allows for the use of industry standards such as ours to address the needs and use cases of companies working in particular food industry sub-sectors.

Notwithstanding our broad support for the proposed rule, we wish to offer several comments and requests for clarification that we hope the FDA will consider in developing a final rule. Our inputs reflect the fact that seafood is the most highly traded food commodity on earth,[2] originates from an extremely diffuse global production base, and reaches markets through some of the most complex

[1] These comments were drafted by the Steering Committee of the GDST on behalf of the GDST membership. All GDST members had an opportunity to provide inputs into these comments and to review them before submission. A list of most GDST member companies and associations is attached at the end of this letter; GDST members who indicated a preference not to be associated with these comments are not included in this list.

[2] "Trade and Fisheries: Key Issues for the World Trade Organization" (https://www.wto.org/english/res_e/reser_e/ersd201003_e.htm)

and diverse supply chains of any international commodity. Moreover, current traceability practices are extremely mixed across the seafood industry, with some highly advanced and sophisticated actors being offset by a large number for whom traceability in general, and digital traceability in particular, remains underdeveloped. These multiple challenges were not reflected in the simple supply chain models used by the FDA to conceptualize and explain the structure of the proposed rule.

The GDST was created to assist the thousands of companies confronting the challenges to traceability specific to the seafood sector. Our comments and requests for clarification are intended to reinforce the strong synergies we see between the GDST standards and the proposed rule, and to help the FDA maximize the final rule's effectiveness while avoiding unnecessary frictions.

1. To support compliance, the final rule should encourage flexibility through standardized digital interoperability to the greatest extent practicable.

The proposed rule emphasizes the need for careful creation, organization, and maintenance of records to allow tracking of products through traceability lot numbers (*§ 1.1325 - § 1.1350*). We fully support this, but note that the proposed rule risks appearing to introduce unnecessary rigidities to achieve these goals. The GDST standards focus on enabling digital interoperability as the key to comprehensive event-based traceability (including effective trace-backs) without imposing a "one size fits all" solution. The final rule should be clarified explicitly to recognize the need for flexibility in implementation and to encourage compliance through the use of industry standards that support interoperability among diverse systems in the creation, maintenance, and exchange of digital traceability data records.

2. The final rule should clarify the requirements concerning lot codes.

Some ambiguity in the language of the proposed rule has raised concerns among a number of GDST member companies regarding the proposed requirements for allocation, maintenance, and traceability of lot codes. Many companies maintain clearly defined lot coding structures with specific interpretations such as item number, purchase order number, etc., and there is strong concern that § 1.1320 of the rule may be interpreted as disallowing companies from assigning their own batch lot identifiers to products in their custody and/or requiring them to use or maintain the batch lot identifier(s) used by upstream actors. For example, this interpretation might require a company to manage its own inventory or generate multiple products from the same source material while retaining the lot identifiers and lot codes of its upstream customers rather than its own lot identification system, or it might require a company several tiers downstream from an aggregation event to receive and maintain records of all of the lot codes associated with the inputs to the aggregated product. Such a requirement would be unhelpful and an impose an extraordinary burden--and in some cases be practically impossible--to achieve compliance with reasonable adjustments to current business systems and practices. This rigitidy could also hamper GDST's standardization efforts.

We do not believe that this is the FDA's intention, nor do we think such an interpretation is needed to achieve the objectives of the proposed rule. Our understanding of the proposed language, which we urge the FDA to make explicit in the final rule, is as follows:

- That the traceability lot code requirements are, in essence, outcome-based, data retrieval requirements rather than standards specifying how, where, or by whom traceability information must be stored and transferred. As outcome-based data retrieval expectations, the lot code requirements can be fulfilled by providing to the FDA, in the format and time frame requested, the relevant item codes, lot codes, and associated information for which a company is responsible, regardless of how (or where) that information is managed within a company's internal systems or through its relations with third party service providers or supply chain partners.
- That companies can (and indeed must) create or assign new logistical unit codes (e.g. lot codes, license numbers) when appropriate CTEs require doing so (such as during storing and warehousing), so long as the company maintains and can produce digitally within 24 hours information necessary to link a given logistical unit code with the traceability lot codes of all product used as inputs to the CTEs.
- That companies remain free to employ their own batch lot identification systems regardless of CTE types for such purposes as inventory control, product identification, sales transactions, or other operational needs, so long as their handling of product and identifiers maintains both physical batch and traceability lot code integrity, and they are able to link identifiers used in their operational systems with traceability lot codes to allow reproduction of the lot code information in digital form within 24 hours of the FDA's request.
- That companies are not responsible for recording (or reporting) lot codes previously associated with inputs to products they receive (i.e., prior to transformation events performed by previous product custodians resulting in the lot codes associated with the products so received), so long as all of the products received have appropriate lot codes and companies can report (digitally within 24 hours) such lot codes along with the required information about the "persons" from which the products and lot codes were received. In other words, companies are not required to maintain records prior to the immediate past CTE of their responsibility. Reconstruction of product pedigree in the event of a food safety emergency will be achieved through collaboration with FDA investigators.

3. The final rule should clearly accommodate different "data sharing architectures" within supply chains, including architectures that do not allow all actors to have access to full product pedigrees.

The GDST fully supports the FDA's goal of speeding tracebacks through streamlined use of digitally shared traceability lot codes--indeed the GDST interoperability standards are designed to enable this kind of rapid and direct verification of traceability data. We believe that companies achieving best traceability practices in concert with their supply chain partners will in many cases either possess or have ready digital access to details about upstream CTEs beyond what is required for basic compliance with the proposed rule (including, for example, direct access to pre-transformation traceability lot codes and associated data). The GDST standards fully enable and strongly encourage data collection practices that go further than the proposed rule with regard to the digital sharing of information generated at upstream CTEs. However, the GDST has also recognized that multiple data sharing practices (or "architectures") are currently in use in the seafood industry, some of which explicitly (and sometimes for reasons considered "business

critical") eschew sharing of all product pedigree information with all supply chain actors. The GDST's approach to interoperability through standardized CTEs/KDEs and through data standards conducive to digital linking is a robust means of achieving the outcome-based results mandated by the proposed rule and of driving best practices while respecting the diversity of data sharing architectures necessary to the current business realities of the seafood sector.

4. The final rule should clarify the application of the exemption for fishing vessels.

The proposed rule functionally reiterates the exemption for fishing vessels defined by the Magnuson-Stevens Fishery Conservation and Management Act in FSMA Section 204(6(c)) however the *de facto* enforcement responsibilities on first receivers could be read as functionally nullifying this exemption. To avoid this, our interpretation of this language is that FDA will not require a traceability lot code to be associated with fishing events by fishers themselves, but that a traceability lot code associated with fishing events may still need to be assigned by the first receiver. First receivers are used to assigning lot codes, but may not have associated these with KDEs from the preceding fishing event (such as those required by the US Seafood Import Monitoring Program). The GDST standards strongly encourage the assignment of lot codes to fishing events by fishers, but our own implementation guidelines recognize that achieving this will not be possible in many contexts for at least the next several years. We urge FDA to clarify the final rule to state that there is no exemption from the requirement of a lot code for fishing events, there is only an exemption of that lot code being assigned by fishers, while also encouraging the best practice of lot code assignment at the vessel level when and if appropriate. Further examples of how first receivers may navigate complying with traceability lot code allocation would also be appreciated.

5. The final rule should clarify the application of the "kill step" exemption for seafood.

Similarly, the kill step exemption arises from FSMA Section 204 but functionally cannot fully apply to seafood because process control 'kill' steps to mitigate microbial hazards do not address certain seafood-associated toxins, an identified risk that FDA captured in the risk ranking model used to create the Food Traceability List. Additionally, parties receiving product subsequent to kill steps need to be aware of the previous kill step's documentation at the lot code level of specificity, so this exemption is partial at best. Accordingly, the functional application of the kill-step exemption needs to be clarified for seafood products.

6. Require Vessel Flag rather than other less-used registration factors.

This proposed rule includes a KDE for the country to which the vessel is registered. This is not a data element used by other traceability programs such as the US Seafood Import Monitoring Program (or GDST). For the benefits of harmonization and utility, we propose that this KDE be changed to the vessel flag state. This change will not affect the quality of tracebacks by FDA.

7. Expectations for due diligence of US importers must be limited and clear.

While GDST fully embraces the goals of increased information flow and accountability within seafood supply chains, we are concerned that the proposed rule could be interpreted to require companies--and in particular seafood importers in the United States--to ensure that their supply chains are fully in compliance with this regulation, including as a condition of importation. We suggest that FDA clearly state in the regulatory text that no individual party is responsible for

assessing the compliance of, or providing information originating with, other parties beyond the scope of what the rule specifically requires of the individual party. Moreover, the rule should clarify whether FDA is asserting the authority to conduct spot checks or require completion of tracebacks as a condition for import. If, contrary to GDST's advice, such responsibilities for upstream supply chain compliance are intended to be created, then we believe additional exemptions or phase-in periods should be discussed prior to finalization of the rule.

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In conclusion, GDST would like to repeat its fundamental support for the proposed rule, and our appreciation of the potential synergies between the rule and the GDST standards. We are all looking to drive change in the direction of rapid, effective, and verifiable digitally-based traceability. We look forward to continued engagement with FDA on the development of this regulation, and thank you again for your efforts.

Sincerely,

David K. Schorr
Co-Chair, GDST Steering Committee

Attachment – List of GDST Member Companies and Associations*

GDST Steering Committee Members

AP2HI
Culinary Collaborations LLC
Institute of Food Technologists
Labeyrie Fine Foods
Metro AG
New England Seafood International
Orca Bay
Sainsbury's Supermarkets Ltd
Thai Union
The Fishin' Company
VASEP
Whole Foods
WWF

Other GDST Members

178 Degrees
A. Espersens A/S
Afritex Ventures
Ahold Delhaize
Ajinomoto Co., Inc
ALDI North Group
ALDI South Group
Anova Food LLC
Aquaco, LLC
Asian Alliance International Company
Austral Fisheries Pty Ltd
Beaver Street Fisheries, Inc.
Bolton Food
Bomar (Bogatama Marinusa)
Bumble Bee Foods
Charoen Pokphand Foods Limited (CPF)
China Aquatic Products Processing and Marketing Alliance
Citra Mina
Co-op UK
Eciens
Envisible
Euclid Fish Company
Fortune International (Fortune Fish and Gourmet)
General Tuna Corporation (Century Pacific Group)
Hilton Seafood UK
Hong Kong Exhibition Centre
IBERCONSA (Grupo Ibérica de Congelados, S.A.)
Iberostar Hotels and Resorts
Inland Seafood
Intercity Packers Meat & Seafood
International Pole and Line Foundation
Ipswich Shellfish Group
Japanese Consumers' Co-operative Union (JCCU)
JJ McDonnell & Co
Karoo Catch
LDH (La Doria) Ltd.
LIDL Stiftung & Co. KG
Luen Thai Fishing Venture
Mt Cook Alpine Salmon Ltd.
Nissui
North Atlantic Inc
Nueva Pescanova
Pesca Azteca SA de CV
PT Bumi Menara Internusa (BMI)
PT Segara Makmur Indonesia
Salties
Santa Monica Seafood
Sea Delight
Seacore Seafood Inc.
Seafresh
Seattle Fish Company
Silver Coast Foods LLP

* GDST members who indicated a preference not to be associated with these comments are not included in this list.

Socsksargen Federation of Fishing and Allied Industries, Inc.
Southeast Asian Packaging and Canning
Stavis Seafoods
Sunwoo Corporation
Sysco Corp
Target
Taylor Shellfish
Tesco
Thai Frozen Foods Association
Thai Tuna Industry Association
The Tuna Store
Tri Marine
Unibond Seafood International Limited
Vietnam Tuna Association
Wegmans
Wm Morrison Supermarkets plc (Morrisons)
Woolworths Group
World Tuna Purse Seine Organization
Young's Seafood