

A public-private partnership to advance a shared vision for enhanced food traceability

August 2024

This Membership Prospectus details the structure and membership terms of the Partnership for Food Traceability (PFT), a public-private partnership and independent, sector-neutral forum for stakeholders—industry, regulators, and their technology vendors—to jointly define a shared comprehensive vision for enhanced food traceability.

PFT was developed collaboratively by stakeholders throughout the supply chain. The organization provides an overarching vision for food traceability, enabling implementation of compliant traceability systems. Section 204 of the Food Safety Modernization Act (FSMA) and FDA's associated <u>Final Rule</u> require enhanced traceability and recordkeeping requirements for organizations that manufacture, process, pack, or hold <u>certain foods</u> on FDA's food traceability list (FTL). While the Final Rule does not require electronic traceability, it aligns with and is supported by FDA's New Era of Smarter Food Safety initiative, which aims to harness technology and data to advance food safety and traceability. In parallel, food companies increasingly require electronic traceability as a commercial requirement. Collectively, these requirements have created tremendous momentum toward electronic traceability and simultaneously highlighted the complexities and cross-sector interdependencies that must be overcome to achieve that goal.

All stakeholders are encouraged to participate in PFT. A diversity of members—diverse industries, sectors, company sizes, business models—is needed to define a comprehensive vision for traceability that truly works for everyone.

PFT will officially begin its substantive work on October 1, 2024. This prospectus will help you evaluate membership in PFT. For questions or additional information, email Laura Brown at Laura.Brown@leavittpartners.com or visit www.PFTraceability.org.

To apply for PFT membership or request additional information, please complete the Stakeholder Interest Form at <u>www.PFTraceability.org</u>.

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# **Membership Prospectus**

The Partnership for Food Traceability (PFT) is an independent, sector-neutral nonprofit public-private partnership developing a shared, overarching vision for food traceability across the supply chain, allowing for streamlined implementation of compliant traceability systems. PFT's membership includes producers (including growers and harvesters), manufacturers and processors, distributors (including packagers, wholesalers, holders, and shippers), retailers and grocers, and restaurants across diverse commodities (including produce, seafood, cheese, packaged, and prepared food). Membership includes industry members, trade associations, technology vendors, and technical experts. Together, members are working to establish a comprehensive vision for enhanced food traceability in the U.S.

The ability to exchange, gather, and use traceability data among supply chain partners is essential to the effective and efficient implementation of enhanced food traceability. This will require a level of **cooperation, coordination, and interconnection** not present in the supply chain today, and PFT is designed to meet that need.

PFT will deliver tremendous value to the industry in multiple ways. It will provide:

- A decision-making mechanism for critical questions of how traceability should be implemented.
- A forum for technical implementation discussions between industry and FDA.
- A common vision for traceability across sectors, industries, associations, and consortia.
- A **consistent set of business and functional requirements** for traceability that provides clarity to solution providers and ensures solutions meet business needs.
- An organized **public-private plan** for how the industry will **migrate** to enhanced traceability.

It is important to note PFT will not displace existing work groups and consortia nor the important work they do; rather, PFT aims to bring the work of those distinct groups together into one comprehensive vision for traceability. For additional information, visit <u>www.PFTraceability.org</u>.

#### What is the purpose of the public-private partnership?

PFT will establish an intentional, sector-inclusive implementation plan to advance a shared vision for traceability and will provide certainty and longevity that benefits the effective, efficient implementation of enhanced food traceability. It will provide **clear rules for engagement** between sectors within the supply chain, which, understandably, have independent interests in how traceability is implemented.

The primary objective is to facilitate implementation of compliant traceability programs and the adoption of **interoperable electronic traceability** systems for FTL foods throughout the United States *while maintaining the flexibility to accommodate and support alternate and non-electronic methods for small businesses*. An interoperable framework will support all foods, allowing individual companies to determine their level of adoption beyond FTL foods as they and their commercial partners desire.

PFT's work is not dependent on any one specific technical vision for how interoperability should be achieved. The specific technical vision to be advanced by PFT will be determined by PFT members using its decision-making mechanisms that promote balance and equitability. The partnership will recognize and incorporate existing technical standards that enable interoperability throughout the supply chain but will not independently develop technical standards.

The partnership will also function as a repository for industry-defined requirements, best practices, frameworks, and traceability pilots. The goal is to create transparency, alignment, consistency, and

harmonization of practices and requirements for traceability implementation throughout the supply chain while maintaining individual business flexibility and autonomy within those harmonized frameworks. The defined requirements will enable compliance with FSMA 204 and the associated Final Rule, among other traceability initiatives.

Regulators also play an essential role in both helping to define requirements for food traceability and as a recipient of food traceability information. FDA has formally agreed to collaborate with industry through the Public-Private Partnership as a forum in which industry can work together, with FDA's technical assistance and advisement, to coordinate food traceability approaches across diverse supply chain sectors and help to effectively remove potentially contaminated products from the market more rapidly. Engagement and collaboration with state and local regulators and public health authorities is also expected.

#### What will PFT do?

PFT is a sector-neutral forum where all stakeholders can come together with an equal voice to advance enhanced traceability. PFT will:

**Define open-source consensus business requirements and functional requirements for food traceability.** PFT's specific technical vision will be determined through decision-making mechanisms that promote balance, sector-neutrality, and equitability. PFT will leverage and incorporate existing work from the various sectors of the food industry to the maximum extent practical. PFT strives not to compete with or duplicate existing and ongoing efforts, but rather to create one comprehensive overarching framework to bring this sector-based work together.

**Coordinate pilots and share pilot learnings to advance electronic traceability.** PFT will provide a forum to (i) consolidate learnings from private and public pilots, (ii) identify the need for, and support the coordination and planning of, new pilots, and (iii) promote industry-regulator interactions through pilot activity. PFT will not actively seek to operate technical pilots, but it will be positioned to do so in the event that there is a gap not filled by other stakeholders.

**Provide a forum for the sharing of common practices in setting supplier requirements for data sharing.** Through a dedicated work group, PFT will strive to ensure its consensus business and functional requirements build on, and limit disruption to, supplier requirements. Each company will remain free to establish its own customer and supplier requirements, but PFT will promote more consistent and interoperable requirements by providing a forum for the discussion and identification of promising practices.

#### Who can participate in the public-private partnership?

#### **General Members**

Full, **voting membership** in PFT (and therefore decision-making and voting authority) is reserved for industry members and their trade associations. As the organizations with primary compliance responsibilities under FSMA 204, these organizations are the primary decision-making members. PFT membership is a corporate membership, and each General Member will represent one vote, but an unlimited number of employees may engage in PFT.

General Membership categories:

 Industry Members – entities that manufacture, process, pack, or hold foods (as defined in the Federal Food, Drug, and Cosmetic Act). Industry members will designate their most relevant "Sector Category" upon joining, which include:

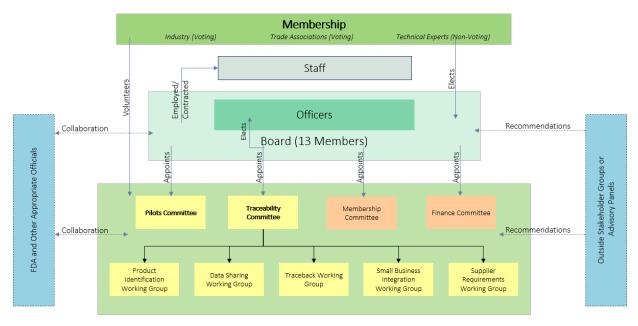
- a. **Producers** (including growers, harvesters, and fishers),
- b. Manufacturers and processors,
- c. Distributors (including packagers, wholesalers, holders, and shippers),
- d. Retailers and grocers, and
- e. Restaurants.
- (ii) Association Members trade associations, societies, and similar membership organizations, the membership of which consists primarily of industry members.

#### **Technical Expert Members**

**Non-voting membership** is extended to technology providers, vendors, service providers, and other technical experts, such as consultants and law firms. It is recognized that these organizations are valuable and necessary for successful implementation of enhanced food traceability. For example, technology solution providers have deep expertise in the systems necessary to achieve interoperability and are essential to implementation. PFT membership is a corporate membership, but an unlimited number of employees may engage in PFT. Technical Expert Members have the right to participate in committees and work group meetings but do not have the right to vote on PFT decisions, as that power is reserved to those with FSMA compliance obligations.

#### How is the organization structured?

PFT is an independent, nonprofit organization. Its structure is generally depicted below:



#### **Board Members**

PFT will be governed by a 13-member Board of Directors, which is elected by the General Membership and is responsible for the executive management of the organization. PFT will rely heavily on committee activity to carry out the substantive work of the organization.

The Board of Directors will serve in an executive function, managing the operational and business aspects of the organization, as well as the strategic direction of the organization. The 13 Board seats will be held by individuals serving staggered two-year terms in their capacity as an employee/contractor of a specific Industry Member or Association Member (*i.e.*, if the elected individual leaves his/her organization, the individual would not retain the seat). Board seats are allocated as follows:

- Two representatives of each of the following sector categories:
  - Producer/Grower/Harvester (industry or association)
  - Manufacturer/Processor (industry or association)
  - Distributor/Packager/Holder/Wholesaler/Shipper (industry or association)
  - Retailer/Grocer (industry or association)
  - Restaurant (industry or association)
- Three At-Large Board Members:
  - $\circ$   $\,$  No more than two at-large Board Members can be from the same sector

Board Member selection and election will occur as follows:

- Sector Board Members: Members from each sector will vote for the Board representatives for their respective sector (*i.e.*, Producer members vote for Producer Board members, Restaurant members vote for Restaurant Board members, etc.).
- **At-Large Board Members**: The three At-Large Board members will be elected by a vote of the full General Membership (*i.e.*, General Members across all sectors vote for all At-Large Board members).

In addition to member nominations/self-nominations, a Nominating Committee drawn from current Board members will strive to ensure the Board represents a balance of industry and associations, a diversity of company sizes, and at least the following commodities at all times:

- Produce
- Seafood
- Shell Eggs
- Cheese
- Nut Butters
- Deli Salads

#### Committees

Committees are where substantive discussions will take place and will be where General Members and Technical Expert Members can all participate in framing the traceability efforts of PFT. Committees are open to all Members. Technical Expert Members may also participate in the Traceability Committee and the Pilots Committee, including all associated Working Groups.

Upon launch, the following committees will be established:

- **Traceability Committee:** The Traceability Committee is where substantive discussions and definition of PFT's shared vision for traceability will take place. The primary charge of the Traceability Committee is to develop and document comprehensive, consensus business requirements and functional requirements for electronic traceability. The work of the Traceability Committee will be supported and expedited through the use of Work Groups, including:
  - The Product Identification WG will analyze and make recommendations to the Traceability Committee on methods and optimal standards for the application of the Traceability Lot Code, including identifier application (*e.g.*, assessment of linear vs. 2D Datamatrix vs. QR Code vs. RFID).
  - The Data Sharing WG will analyze and make recommendations to the Traceability
    Committee on methods and optimal standards for the capture and exchange of Key Data
    Elements. This work will build upon existing standards and frameworks to promote

consensus on both KDE definition (*e.g.*, Should the TLC Source Reference be identified by GLN, DUNS, LEI, name and address?) and methods of B2B data exchange (*e.g.*, ASNs vs. EPCIS vs. portal access vs. mixed methods).

- The Traceback WG will develop and propose to the Traceability Committee traceback use cases and data access requirements, as well as processes and methods for executing tracebacks.
- The Small Business Integration WG will inform the Traceability Committee on small business needs, including necessary accommodation to achieve interoperability with small businesses and how small businesses reliant on paper methods can efficiently interact with electronics methods.
- The Supplier Requirements WG will provide a forum for the sharing of common practices in setting supplier requirements for data sharing and develop recommendations to the Traceability Committee on how business and functional requirements can be structured to build on, and limit disruption to, supplier requirements.
- Pilots Committee: Serves as a coordination point for industry pilots that support the advancement of electronic traceability. The Pilots Committee will work closely with the Traceability Committee to ensure its work supports the development of consensus business and functional requirements. The primary focus of the Pilots Committee will be (i) consolidating learnings from pilots, and (ii) supporting the coordination of new pilots to avoid duplication and support of consensus. The Pilots Committee will not seek to develop and operate pilots but will be positioned to do so in the event there is a gap that cannot be filled by other stakeholders.
- **Finance Committee:** Responsible for the financial planning of PFT, including development of a proposed annual budget and membership dues table for Board consideration and approval.
- **Membership Committee:** Responsible for the development, recruitment, and retention of PFT Members. The Membership Committee will develop the application for membership, as well as policies and procedures surrounding membership.

#### How do FDA and other state and local officials engage with PFT?

A vital aspect of the public-private partnership is engagement with regulators, including FDA and state and local officials. FDA and other officials will have formal, non-voting participation in all full membership meetings as well as committees and work groups (other than the Finance Committee). They will serve as technical advisors to provide perspectives on regulations, guidance documents, policies, and practices. Both industry and public officials will be expected to share information to learn from each other.

The PFT Board will hold quarterly meetings with FDA and other officials. These meetings will focus on the structure and function of the organization, rather than on the substantive technical work of committees.

Due to the nature of the public-private partnership, PFT will not take or advocate for policy positions. In addition, FDA and other officials will not participate in any financial or legal functions nor any decisions relating to PFT.

#### How are PFT decisions made?

All substantive work to define the collective vision for traceability takes place through the PFT committees and the work groups within them. PFT committees generally operate by consensus. Prior to publication, all final requirements, specifications, and other substantive documentation must be

approved by the General Membership.<sup>1</sup> The decision-making process is critical to ensure all PFT decisions and documentation are broadly supported and reflect a cross-sector, cross-industry viewpoint. To that end, all documentation must be approved by both (i) a two-thirds majority of the overall General Membership, and (ii) a simple majority of the General Members within each of the five individual sectors.

#### What is the cost of membership in PFT?

During the first year of operation, the governance body will be fully funded by membership dues. The long-term funding model may include other funding streams, such as certification programs or external programs. However, the substantive output of PFT will be open source.

Membership dues are tiered based on company size to limit barriers to entry for smaller businesses. Members may exclude non-food revenue for purposes of determining their applicable tier.

	Annual Membership Dues Rates						
	Producer / Grower / Harvester / Seafood	Manufacturer / Processor	Distributor / Packager / Holder / Wholesaler / Shipper	Retail / Grocer	Restaurant	Association	Technical Expert
Tier 1	\$12,000	\$20,000	\$20,000	\$20,000	\$20,000	\$500	\$7,500
Tier 2	\$6,000	\$12,000	\$12,000	\$12,000	\$12,000		
Tier 3	\$1,000	\$2,000	\$2,000	\$2,000	\$2,000		
Small Business	\$250	\$250	\$250	\$250	\$250	\$250	\$2,500

	Tier Definitions (by revenue)						
	Producer / Grower / Harvester / Seafood	Manufacturer / Processor	Distributor / Packager / Holder / Wholesaler / Shipper	Retail / Grocer	Restaurant	Association	Technical Expert
Tier 1	>\$100m	>\$1b	>\$1b	>\$1b	>\$1b	10+ Employees	10+ Employees
Tier 2	\$10m- 100m	\$100m-1b	\$100m-1b	\$100m-1b	\$100m-1b		
Tier 3	<\$10m	<\$100m	<\$100m	\$50- \$100m	\$50-\$100m		
Small Business	<100 Employees	<100 Employees	<100 Employees	<\$50m	<\$50m	<10 Employees	<10 Employees

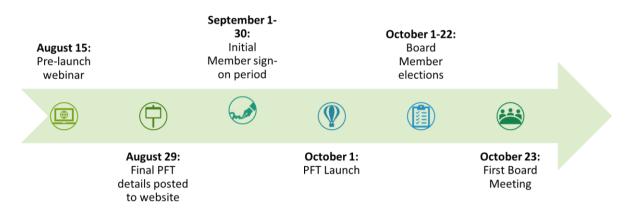
<sup>&</sup>lt;sup>1</sup> General Members have the right to approve substantive documents that have a significant impact on traceability. Documentation that does not have a significant impact on traceability, such as technical clarifications or updates necessary to align with referenced standards, can be made by approval of the Board alone.

Initial membership dues will cover the period from commencement of membership through December 31, 2025. Subsequent membership periods will be calendar year periods.

The budget supported by these dues rates is detailed in Appendix A.

#### Launch Timeline

PFT will begin its substantive work October 1, 2024.<sup>2</sup> Initial member sign-on will occur during the month of September. This requires a commitment to join PFT by filling out the membership application. Members will continue to be admitted after September and applications will be reviewed as they are received. Initial Board Member elections will be held from October 1–22, with the initial meeting to be held October 23.



<sup>&</sup>lt;sup>2</sup> Organizers reserve the right to delay the official start date if a critical mass of representative members have not committed to membership by that date. Organizational commitments to join will not go into effect until PFT launches.

# Appendix

### Appendix A

### Draft Budget

The membership dues structure was developed to provide sufficient funding for the following budget:

Draft Budg	et			
	Year 1	Notes & Assumptions		
Staff \$700,0		For Year 1, this assumes an Executive Director at \$300k and two s at \$200k each (fully loaded). These could be direct hires or outsourced FTEs.		
Consultants/SMEs	\$200,000	This will fund issue-specific technical experts to support development of a framework for interoperability and includes their travel.		
Accounting	\$25,000	This assumes payroll support from any consultant that provides the staffing.		
Legal	\$75,000	Review of SOPs and documents, antitrust advice, general corporate support, etc., but does not contemplate legal counsel in every meeting.		
Facilities/Equipment	\$50,000	Office space, technology, and equipment, recognizing much of this is offloaded if staff are outsourced.		
PR and Communications	\$75,000	Website, marketing materials, educational materials, etc.		
Recruiting/education/ membership services	\$75,000	Membership recruitment and general industry educational activities.		
Travel	\$30,000	12 trips at \$2500 per trip, assuming approximately 6-8 industry functions and 2-4 site visits.		
Meetings	\$100,000	Cost of space and support for membership and committee meetings, assuming such is not provided by outsourced staff.		
Insurance	\$25,000	General business liability and D&O insurance.		
Total Budget	\$1,355,000			