

# **Toward an FDA-FSMA Compliant Supply Chain Consortium—the Commercial and Strategic Role of Foreign Trade Zones**

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An international alliance of forward-looking companies dedicated to providing consumers with natural health products of superior quality, benefit and reliability.



A grayscale background image of a laboratory setting. In the foreground, several test tubes are arranged in a grid. A glass pipette is positioned over one of the test tubes, with a single drop of liquid about to fall. In the background, there are more laboratory equipment, including a beaker and a container with a label that reads "COFFEE BEAN".

# **Fragmented Supply Chains, Source Dependence, Industry Interdependence**

# Broken Chain of Custody

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- The dietary supplement industry is reliant on brokers for sourcing ingredients.
- Brokers may retest and reissue COAs — sometimes legitimate, sometimes not.
- Breaks in the chain of custody sever linkage back to the original manufacturer's COA, which raises the risk of adulteration and contamination.
- This weakens authenticity (provenance), traceability, and audit readiness.
- Regulatory consequence: FDA-FSMA/FSVP compliance undermined; liability increases.

# China Dependence

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- U.S. supply heavily reliant on Chinese production of critical nutrients and precursors.
- Tariffs, reciprocal measures, and trade volatility amplify costs and uncertainty.
- Concentration risk: limited diversification of suppliers increases vulnerability.
- Strategic concern: nutrition security intersects with public health, trade, and national security.

# Critical Nutrient Interdependence

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- Vitamins, amino acids, minerals, and key precursors/starting materials are foundational inputs.
- These ingredients span dietary supplements, infant formula, animal feed, and fortified foods.
- Industry interdependence: shortages or disruptions ripple across multiple sectors.
- Testing, quality standards, and customs (HTS) classifications vary — creating compliance complexity.



## Background and Consortium Partners

# Why Now

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- Policy momentum — supply chain resilience and onshoring prioritized by U.S. government.
- Industry inflection point — COVID disruptions and tariff escalations revealed structural weaknesses.
- Regulatory window — FSMA/FSVP creating need to systematize compliance.
- A consortium can shape the supply chain proactively.

# Building a Network of Partners

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- UNPA's five-year U.S. Commerce (International Trade Administration) Market Development Cooperator Program (MDCP) — focused on export/import trade standards, compliance, and addressing bilateral trade deficit with China.
- Cross-sector reach — engagement with animal feed, pet food, and medical food industries to address shared vulnerabilities in critical nutrient supply chains.
- Global partnerships — MOUs with the China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE), the China Nutrition & Health Food Association (CNHFA), and other industry stakeholders.
- Aligning partners in a consortium to pilot FTZ-based models for testing, custody, and tariff management.





## Success Story

Food and Beverage

China

# FREE TRADE ZONE STRATEGY EXPANDS U.S. EXPORTS

## Exports of Supplements to China: \$9.3M and Growing

Jiangxi Province Foreign Affairs Official inspects U.S. products at the Nanchang Free Trade Zone (FTZ). The United Natural Products Alliance (UNPA) is helping U.S. dietary supplement companies expand exports to China through partnerships with FTZs, e-commerce accelerators, and US. Contract manufacturers and brands. In three years, this strategy has supported \$9.3 million in U.S. export sales to China.

## Navigating Regulatory Complexity and Trade Barriers

Access to China's \$23 billion nutrition and health products market involves navigating a range of regulatory requirements. The most significant is the "Blue Hat" registration, which certifies that products meet stringent quality and safety standards. While this registration is designed to protect consumers, it has created a trade barrier for foreign firms seeking market access. Other markets have similar registration requirements that often create barriers to entry for foreign companies.

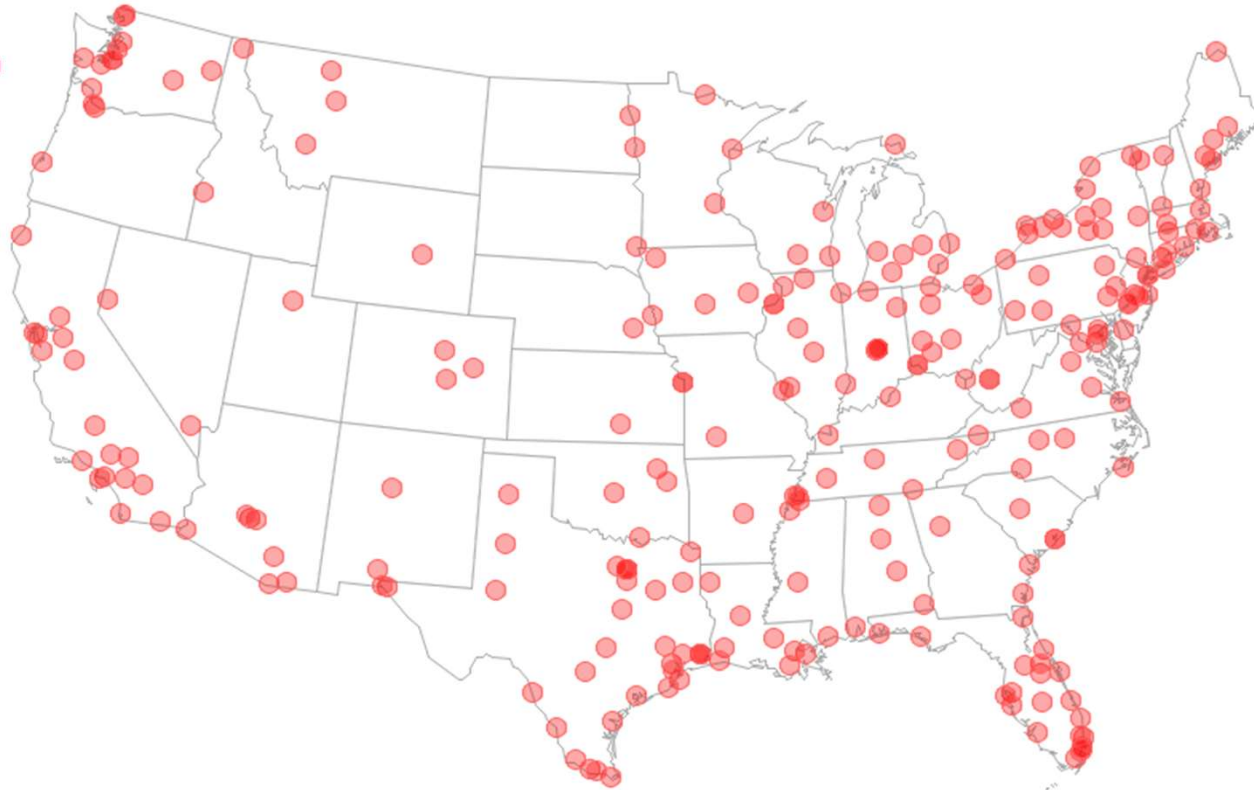
UNPA is working to develop a complementary compliance pathway by integrating distributed ledger technology (DLT) within FTZ environments. This innovation aims to enhance supply chain transparency and product traceability, helping U.S. companies meet or exceed regulatory expectations—including those similar to those of Blue Hat—while supporting mutually recognized standards and fostering greater cross-border trust.





## **Foreign Trade Zones Use Cases:** Exploring FTZs as a foundation for compliance, custody, and tariff flexibility

## 256 U.S. Foreign-Trade Zones



8 additional zones in AK, HI, and PR not shown



## Top 25 States by Type of FTZ Activity

### Warehouse/Distribution Activity

### Production Activity

Merchandise Received		Exports		Merchandise Received		Exports	
Rank	State/ Territory	Rank	State/ Territory	Rank	State/ Territory	Rank	State/ Territory
1	California	1	Texas	1	Texas	1	Texas
2	Illinois	2	South Carolina	2	Louisiana	2	Louisiana
3	Texas	3	Florida	3	California	3	Alabama
4	Louisiana	4	Louisiana	4	Alabama	4	California
5	Tennessee	5	Tennessee	5	Indiana	5	Puerto Rico
6	South Carolina	6	California	6	South Carolina	6	Indiana
7	Pennsylvania	7	New Mexico	7	Illinois	7	Mississippi
8	New York	8	Pennsylvania	8	Kentucky	8	South Carolina
9	Georgia	9	Ohio	9	Mississippi	9	Tennessee
10	Arizona	10	Indiana	10	Puerto Rico	10	Florida
11	Florida	11	Arizona	11	Tennessee	11	Kentucky
12	Ohio	12	New Jersey	12	Ohio	12	Connecticut
13	North Carolina	13	Washington	13	Arizona	13	West Virginia
14	New Jersey	14	Illinois	14	Washington	14	Arizona
15	Maryland	15	Mississippi	15	Colorado	15	Georgia
16	Puerto Rico	16	Alaska	16	Pennsylvania	16	New Jersey
17	Washington	17	Puerto Rico	17	Florida	17	Oregon
18	Kentucky	18	Georgia	18	Delaware	18	Wisconsin
19	Indiana	19	Maryland	19	Nevada	19	Pennsylvania
20	New Mexico	20	Massachusetts	20	New Jersey	20	Virginia
21	Nevada	21	Nevada	21	Wisconsin	21	Missouri
22	Kansas	22	Michigan	22	Maryland	22	Illinois
23	Mississippi	23	Hawaii	23	Georgia	23	Ohio
24	Alaska	24	Iowa	24	Hawaii	24	Nebraska
25	Michigan	25	Idaho	25	Nebraska	25	Washington

Source: U.S. FTZ Board report to Congress

Source: U.S. FTZ Board report to Congress



# FTZ Basics

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- FTZs are U.S.-based sites under CBP supervision.
- Key tools: duty deferral, duty elimination on re-exports, weekly entry to reduce Merchandise Processing Fee, and inverted tariff potential (NPF election).
- Direct importer requirement: FTZ use requires a U.S. company to import directly from the foreign source, reducing reliance on opaque broker layers and helping strengthen FSMA/FSVP compliance.
- FDA oversight continues: FSMA/FSVP requirements must be satisfied before release into U.S. commerce; FDA maintains authority to inspect/test goods while in the FTZ.
- Relevance: FTZs can serve as structured checkpoints to embed testing, custody, and documentation protocols.

# Use Case A — Re-Export

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- Ingredient batches admitted into the FTZ under controlled conditions.
- Testing and documentation completed before release or use in production.
- Portion of the batch re-exported duty-free (in finished product); remainder released into U.S. commerce.
- Benefit: strengthens chain of custody through direct supplier relationships, prevents breaks in COA custody, and aligns with FSMA/FSVP.
- Tariff effect: duties avoided on re-exports; MPF costs reduced through weekly entry.

# Use Case B — Inverted Tariff

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- Multiple inputs admitted and processed inside the FTZ.
- The manufacturer elects Non-Privileged Foreign (NPF) status — meaning the duty is assessed on the finished product when it enters U.S. commerce.
- If the finished good carries a lower duty rate than its inputs, the manufacturer pays duty at the lower finished-good rate — reducing overall tariff liability (the ‘inverted tariff’ benefit).
- Exports leave duty-free; only the portion released into U.S. commerce is dutiable.
- Compliance benefit: batch-level testing links raw material inputs to finished lots, strengthening traceability and recall readiness.
- Tariff effect: inverted tariff treatment can significantly reduce effective duty exposure on U.S.-consumed goods.

# Conclusions

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- Supply chain risks are escalating — fragmented custody, China dependence, tariff volatility, and rising compliance demands.
- UNPA and partners are laying the groundwork — trade-standards focus, cross-sector engagement, and global MOUs.
- Foreign-Trade Zones (FTZs) offer a structured platform — combining tariff tools with a point of control for custody, testing, and FSMA/FSVP documentation.
- A consortium model can align industry stakeholders — to pilot FTZ-based solutions, strengthen compliance, and build resilience.



# Conclusions

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- Liability exposure management — stronger supplier knowledge, testing, security, and compliance reduces risk of civil litigation, consumer complaints, and regulatory enforcement.
- Cost control — cutting broker layers, streamlining testing, and preventing out-of-spec lots reduces downtime and improves margins.
- Financial management — FTZs improve cash flow through deferred duties, eliminate duties on re-exports, and lower effective rates via tariff inversion (duty applied to finished goods rather than inputs).
- Direct purchase model — lowers costs and improves supply assurance by reducing dependency on intermediaries.

# Conclusions

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- Brand distinction — supply-chain management becomes a differentiator; companies can tell a story of resilience and transparency.
- Industry precedent — autos, oil, and other high-import/export sectors already use FTZ frameworks.
- Utah advantage — a mix of young brands, established companies, and co-manufacturers makes Utah an ideal pilot environment.

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# Thank you

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