Temperature Sensitive Cargo: Infrastructure & Clearance Procedure Reform

Global Logistics Solution

Import and Export

Airport, Seaport, LCS & ICDs

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Foreword

The Central Board of Indirect Taxes and Customs (CBIC), vide Office Memorandum dated 22.01.2025 issued under F. No. 450/07/2025-Cus IV, has constituted a Committee to examine the infrastructure and procedural requirements for the examination of temperature-sensitive cargo at ICDs and CFSs, and to formulate an appropriate policy for the same.

Since, I have been appointed as Chairman of the Committee, it gives me great satisfaction to present this Report on Temperature Sensitive Cargo: Challenges, Gaps, and the Way Forward. The efficient handling of temperature-sensitive and time-critical consignments is an essential component of modern international trade. As global supply chains evolve and the volume of specialised cargo continues to rise, Customs administrations are required not only to facilitate legitimate trade but also to safeguard the integrity, safety, and quality of such consignments.

This report is an outcome of a comprehensive study undertaken in consultation with the Trade and Industry, the Importers & Exporters, Custodians, Shipping Lines, Customs Brokers, Ref Cargo Warehouse owners and departmental officers to examine the existing ecosystem for the management of temperature-sensitive cargo at our ports, airports, and cargo terminals. It highlights critical gaps in infrastructure, storage and handling practices, training and capacity-building, as well as inconsistencies in the adoption of international standards. These gaps, if not addressed, have the potential to impede the seamless movement of essential commodities including pharmaceuticals, perishables, and high-value specialised goods which are vital to both domestic supply chains and India's global trade commitments.

The study also puts forth pragmatic and forward-looking recommendations designed to strengthen our processes, streamline inter-agency coordination, and align our logistics environment with global best practices. Implementing these measures will not only enhance trade facilitation but also reinforce India's position as a reliable and efficient partner in international commerce.

I would like to acknowledge the invaluable contributions of the officers and experts who collaborated in the preparation of this report. Their insights, dedication, and domain expertise have been instrumental in shaping the depth and quality of this document. I place on record my appreciation for Sh. Anupam Prakash, JS (Customs); Sh. Hardeep Batra, Commissioner (Mumbai ACC); Sh. A Manimaran, Commissioner (Export), Chennai; Sh. Atul Singh, ADC, Customs Policy Wing: Sh. Kshitendra Verma, ADC (IDC PPG); Sh. Nitin Gupta, DC (ICD PPG); Smt. Shikhadeep Kaur Randhawa, DD (DGGI, HQ); Smt. Pritee Chaudhary (IRS), FSSAI; Sh. Rollin John, Director, Pharmexcil; Sh. Dushyant Mulani, Director, Khimji Poonja Freight Forwarders Pvt. Ltd; Sh. Amit kamat, Chairman, FFFAI; Dr. Rammohan M K, Director, MPEDA; Sh. Prashant Waghmare, DGM, APEDA; Shri Rakesh Malik, DGM (Cargo), AAI Cargo Logistics and Allied Services Co. Limited; Sh. Sarfaraz Khan, President Operations, Snowman Logistics; Sh. Prakash Veer Tyagi, SGM, Gateway Distriparks Limited: Shri Rama Krishna S, MD, M/s Balaji Marine Pvt. Ltd; Sh. Sandeep Kumar Rai, SIO (DGGI, HQ), Sh. Sudesh Gautam, IO (DGGI, HQ); Sh. Lokesh, Inspector (Customs) and the entire team whose efforts made this study possible.

I believe that this report will serve as an important source of progressive reforms for for policymakers, industry stakeholders, and frontline officers, and will provide a strong foundation for temperature-sensitive cargo supply-chain. Together, through sustained coordination and commitment, we can build a robust, responsive and world-class framework.

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(Chairman: Committee on Infrastructure and procedural reform in Import and Export of Temperature Sensitive Cargo)

Executive Summary

The global trade of temperature-sensitive cargo has experienced substantial growth, driven by increasing consumer demand of fresh produce, dairy, meat, seafood, and pharmaceuticals. This expansion necessitates a robust framework for ensuring stringent quality norms and safety standards during the transboundary movement of these perishable goods. Customs Ports (Airports, Sea Ports, ICDs/CFSs, Land Customs Stations) serve as a critical junctures in this supply chain, where efficient clearance processes, specialized infrastructure, and compliance protocols are required to be maintained.

This report outlines a comprehensive framework for the handling of temperature-sensitive cargo at Customs Ports, detailing the roles of various regulatory bodies, specific inspection parameters, quality assurance mechanism, and the professional capabilities required for effective logistics and compliance management. It emphasizes the critical need for temperature-controlled system, appropriate examination processes and dedicated zones, advanced non-intrusive machinery, and seamless digital integration with customs and partner government agencies (PGAs). The analysis reveals a dual imperative: to facilitate trade efficiently while simultaneously safeguarding public health. Current challenges, including fragmented regulatory frameworks, infrastructure gaps across the agency involved in operations, and the complexities of aligning with diverse international standards, are thoroughly examined and solutions are incorporated in the report. Recommendations focus on strategic investments in cold chain infrastructure, advanced technologies like IoT and blockchain technology for enhanced traceability, continuous capacity building, and fostering greater inter-agency collaboration to ensure the integrity and timely clearance of perishable goods.

CHAPTER -1

1. Introduction:

The Criticality of Temperature-Sensitive Cargo for the Customs and the PGAs Clearance

1.1 The global trade of temperature-sensitive cargo, encompassing a diverse range of products from fresh produce and dairy to meat, seafood, and pharmaceuticals & medical devices, has expanded significantly over recent decades. This escalating demand inherently requires the implementation of stringent quality standards and safety norms keeping in mind the sensitivity of the cargo, throughout the international and domestic supply chain, particularly during the transboundary movement of these perishable goods for both export and import. The inherent fragility and limited shelf life of such commodities underscore the critical need for specialized infrastructure and streamlined customs procedures on account of key logistical hubs and compliance methodology. Since temperature sensitive commodities are largely time sensitive (having short life) also, we need to simplify the processes of permission granting, clearance etc. of imported and export cargo so that the dwell time may be reduced. We further need to work on port Infrastructure modernisation, efficient logistic supports and technology based integration across the ports, logistic sectors and PGAs.

1.2 This document therefore, encapsulates a detailed discussion on the challenges faced, and the frameworks outlining the essential infrastructure, inspection/ examination parameters, compliance protocols, and best practices necessary for the effective handling of import and export of temperature-sensitive and perishable cargo. ***The core objective is to precisely define the necessary ecosystems, handling processes, regulatory compliance, logistic support mechanisms, and a suitable framework for infrastructure and handling dynamics.*** This comprehensive approach aims to optimize the Customs clearance process at Customs Sea Ports, Airports, ICDs and Land Customs Stations, thereby ensuring efficiency and maintaining product integrity.

1.3 The management of temperature-sensitive cargo presents a dual imperatives: (1) facilitating the trade efficiently, and simultaneously (2) safeguarding the public health. The increasing demand for perishables necessitates meeting strict quality and safety standards, which is fundamentally about protecting consumer trust and well-being. At the same time, the objective of this report explicitly demands the

efficient customs processes, highlighting achievement of a robust economic goal. The real challenge lies in expediting the trade facilitation, without compromising safety and quality of the temperature sensitive cargo. Inefficiencies in inspection or handling can directly lead to product spoilage, economic losses, and potential health risks. **Therefore, any proposed solutions must serve this dual purpose, optimizing trade flow while enhancing the rigor and effectiveness of safety and quality scrutiny**. This necessitates the deployment of smart systems, advanced infrastructure, and highly trained personnel, moving beyond simple manual checks or merely faster, less thorough processes.

1.4 The key objectives of this report include:

- Providing an overview of the international trade, and challenges,
- The regulatory bodies and compliance requirements.
- Detailing the inspection parameters for perishable items.
- Outlining quality standards and compliance protocols.
- Assessing the professional ability required to maintain logistics, quality, and compliance.
- Proposing a framework for suitable infrastructure and handling dynamics related to Customs, Custodian, and Logistics operations.

CHAPTER - 2

Emerging Imports & Exports Trends of Temperature Sensitive Goods

1 The Emerging Trends of import and export of Temperature Sensitive Cargo in India:

With the steady and robust growth of Indian economy, the consumption and trade pattern of the temperature and time sensitive cargo have been changed drastically. Country has been experiencing significant transformation, driven by **rising demands of fresh fruits, vegetables, meats, seafoods, pharmaceuticals etc., rapid urbanization and need of modern logistics infrastructure.** The temperature sensitive goods are not merely viewed as the commodities, but vital elements for **nutrition, livelihoods, culture, and health security**.

Nowadays, the growth of the perishable and time-sensitive cargo matters more because they provides nutritional security and public health. Therefore, a reliable supply chain is crucial for addressing the challenges on account of product integrity and durability of the cargos. A massive portion of Indian population is employed in agriculture, dairy, fisheries, and horticulture. India is experiencing a fast growing trends in manufacturing and export of pharmaceutical products. Therefore, efficient and safe movement of these goods and extending reach to the international market may boost financial supports to the small-scale entrepreneurs and farm economy of India. As the festivity of Indian cuisines are expanded in India and abroad, the export and import demand of such goods in India and abroad is rising exponentially. It is also a fact that a stable and efficient logistics framework not only reduces the wastages and deterioration of perishable cargo and stabilizes supply chain, but it also controls the volatility of price of the essential food items, and supports the modern urban lifestyle enabling the availability of year-round, pan-India supplies.

The emerging consumption and growth pattern of temperature sensitive cargo across the world and in India due to rapid urbanization, shifting demand from staple cereals diet to a more diverse and protein-rich diet (horticulture, dairy, meat etc.) growth of organized retail like super markets, hypermarkets etc. and e-commerce marketplace like BigBasket, Blinkit, Swiggy, Instamart etc. have raised the requirements of fast clearances and quality adherence. Health and wellness awareness especially post COVID-19 period has also heightened focus on immunity-boosting foods like fresh fruits, vegetables and quality dairy products.

Further, government has also introduced several policies like Operation Greens (to stabilize the supply of tomatoes, onions and potatoes), Kisan Rail (dedicated trains for perishables), and Pradhan Mantri Kisan SAMPADA Yojana (for creating integrated cold chain infrastructure) for boosting efforts of achieving the objectives.

2. Sector Specific Trends:

i. Fruits & Vegetables (Horticulture)

India is the second-largest producer of fruits and vegetables. Consumption is shifting from seasonal to year-round availability. Demand for exotic vegetables (like broccoli, zucchini) and fruits (like avocados, kiwi) is rising in urban centres. This sector is experiencing the highest wastage ratio in domestic supply, which is approximately 15% to 25% because of poor infrastructure. Growth is driven by the expansion of cold storage, pack-houses, and the adoption of reefer trucks.

ii. Dairy Products

India is the largest producer of milk with a 24% share of the global production. However, its contribution to the global dairy trade remains low at 0.25% only due to high domestic consumption. However, while liquid milk consumption is stable, there is massive growth in value-added products like yogurt, probiotic drinks, cheese, paneer, and ice-cream. Growth trend of dairy product is stable and high. The cold chain for dairy is one of the necessity. Growth is fuelled by branded products from companies like Amul, Mother Dairy, and new health-focused brands. Import of the dairy product has increasing trends, which is growing at the rate of 13.57% during FY 2024-25.

iii. Meat & Marine Foods

Poultry (chicken) is the dominant and fastest-growing segment in meat. Seafood consumption is rising, with a growing preference for frozen, filleted, and ready-to-cook products. High growth has been seen, especially in exports. India is a major exporter of buffalo meat and shrimp. The domestic market is also growing, requiring sophisticated cold chains, including deep-freeze facilities for seafood.

iv. Flowers and Plants

Use of flowers in India is no longer limited to festivals. There is a growing demand of cut flowers (roses, gerberas, oriental lilies, orchids and carnations

etc.) for decorative purposes, gifting, and events managements. Demand for indoor ornamental plants has also surged. This is one of the most time-sensitive cargoes. It relies heavily on air freight and specialized cold chains to maintain freshness. The floriculture export market is significant.

v. **Bakery Products**

Bakery products market is shift from local traditional bakeries to packaged bread, buns, cakes, and pastries. Demand for healthier options (whole wheat, multigrain, sugar-free) is rising. Growth trend of bakery products is moderate to high. While some bakery items have a longer shelf life, fresh and artisan products require efficient logistics to reach stores quickly.

vi. **Pharmaceuticals (Cold Chain)**

India is emerging as the "Pharmacy of the World." Domestic consumption of vaccines, biologics, insulin, and specialty drugs is also increasing rapidly. The growth trend is extremely high. This is the most critical and value-intensive segment. It demands an unbroken "cold chain" with precise temperature control (2°C to 8°C, or -20°C). Growth is driven by increased healthcare spending and the complexity of new medicines.

The consumption of perishable and time-sensitive cargo in India is on a strong, irreversible growth trajectory. It reflects the nation's economic development, changing consumer preferences, and a growing emphasis on health and convenience. The importance of these goods is paramount to daily life, from sustenance to wellness.

The future growth of this sector however, is critically dependent on continued investment in and modernization of the integrated cold chain infrastructure. Success in this area will not only fuel economic growth but also ensure nutritional security, health care, reduction in wastages, and improvement in the quality of life for every Indian.

3. Port wise Growth Trends in Import of Temp. Sensitive Cargo:

The analysis of the import and export data of the Temperature Sensitive cargo obtained from the ADVAIT System and from the Ports are produced below with the growth trends. The growth in the aggregate value of the imported temperature-sensitive cargo from 2023-24 to 24-25 is almost 27.4% i.e. from Rs. 85396.57 Cr. to Rs. 108789.64 Cr. whereas the overall growth of imports during this period is

6.24%. Port-wise import growth of the temperature-sensitive cargo at 15 major ports are tabulated below:

Sl. No.	Port	Name of the Port	Sum of Value (In Cr.) 2023-24 (Actual)	Sum of Value (in Cr.) 2024-25 (Actual)	YoY Growth (23-24 to 24-25)
1	**INNSA1**	**Nhava Sheva**	27283.8	33720.5	**23.6%**
2	**INBOM4**	**Bombay Air Cargo**	10725.4	13377.6	**24.7%**
3	**INMAA1**	**Chennai Sea**	9815.9	13000.1	**32.4%**
4	**INTUT1**	**Tuticorin Sea PORT**	7589.7	8183.5	**7.8%**
5	**INCCU1**	**Kolkata Sea**	4939.5	6914.0	**40.0%**
6	**INMUN1**	**Mundra Port**	3437.3	6166.6	**79.4%**
7	**INIXY1**	**Kandla**	731.2	5819.9	**695.9%**
8	**INNML1**	**Mangalore Sea**	4603.6	5077.2	**10.3%**
9	**INATRB**	**Amritsar Attari Road LCD**	3429.8	3538.9	**3.2%**
10	**INDEL4**	**Delhi Air Cargo**	1637.0	1819.6	**11.2%**
11	**INVTZ1**	**Vizag Sea PORT**	1304.3	1450.0	**11.2%**
12	**INHYD4**	**Hyderabad Air Cargo**	1166.0	1238.0	**6.2%**
13	**INHZA1**	**HAZIRA PORT**	1842.5	1021.2	**-44.6%**
14	**INPTPB**	**Petrapole Bengal LCS**	407.9	961.4	**135.7%**
15	**INBOM1**	**Bombay Sea**	617.9	662.1	**7.2%**
		TOTAL	**79531.7**	**102950.5**	**29.45%**

Very high growth in import of perishable and temperature sensitive cargo in 2024-25 is marked at major ports like Mudra, Kandla, Nhava Sheva, Bombay Air Cargo, Chennai Sea, Petrapole and Tuticorin Sea Port contributing significantly in absolute value terms, as well as in percentage growth from 695% to 23%. However, Hazira Port is showing a negative contraction in import growth.

4. Commodity-wise Growth Trends in Import of Temperature Sensitive Cargo:

Value in Rs. Cr.

SL No.	HSN GROUP	HSN GROUP DESCRIPTION	2023-24 (Annual)	2024-25 (Annual)	YoY Growth (23-24 to 24-25)	Apr-Aug 2025 (5-Month)
1	**0201-0208**	**MEAT & POULTRY**	15.9	42.9	**169.59%**	**42.1**
2	**0301-0308**	**SEAFOOD**	330.3	265.1	**-19.76%**	**202.8**
3	**0401-0406**	**DAIRY PRODUCTS**	34031.0	38649.2	**13.57%**	**22977.0**
4	**0601-0604**	**FLOWER & PLANTS**	18534.4	21684.5	**17.00%**	**10224.6**
5	**0701-0714**	**VEGETABLES**	672.5	847.5	**26.01%**	**394.0**
6	**0801-0814**	**FRUITS**	326.2	571.4	**75.20%**	**229.6**
7	**1905**	**BAKERY PRODUCTS**	1403.8	1856.0	**32.21%**	**736.1**
8	**3002-3006**	**PHARMACEUTICALS**	30082.5	44873.0	**49.17%**	**6147.3**
		Grand Total	**85396.6**	**108789.6**	**27.39%**	**40953.6**

The data in above table shows that the growths in all the sectors are not equally consistent. In 2024–25 where growth in import of meat and poultry is marked at the rate of 169.59%, fruits at the rate of 75.20%, pharmaceuticals at the rate of 49.17%, bakery products at the rate of 32.21%, and vegetable at the rate of 26.01% the other sectors like dairy, flowers and plants etc. are showing a medium range of growth from 17% to 13%. However, the import of Seafood has a drastic decline by -19.76% in 2024-25.

From the above data, it may also be derived that the import of pharmaceutical products are the highest amongst the temperature sensitive cargo which alone constitute CIF value of Rs. 44873 Cr. out of total import of Rs. 1,08,789.6 Cr. in the FY 2024-25. The dairy products with a total import of CIF value Rs. 38649.2 Cr. is the second largest import and flower and plants are the third largest import product under this segment having CIF value of Rs. 21684.5 Cr. These 3 product segments have achieved annual growth of 49.17%, 13.57% and 17% in FY 2024-25.

The data of top 20 ports where import of temperature sensitive cargo are taking place pre-dominantly are given in the below table. Nhava Sheva sea port, Bombay Air Cargo, Chennai Sea Port, Tuticorin Sea Port, Mangalore Sea Port, Kolkata Sea Port and Amritsar Attari Road LCS are the prominent 8 ports where 87% of the import of temperature sensitive cargos are taking place. Nhava Sheva is pre-dominantly catering to the import of fruits, vegetables, dairy products and pharmaceuticals, Bombay Air Cargo - pharmaceuticals, Chennai sea port – vegetables and fruits, Tuticorin – fruits and vegetables, Mangalore – fruits, Kolkata

– vegetables, Mundra – vegetables and fruits, Amritsar (Attari) – fruits, Delhi Air Cargo – Pharmaceuticals, Vizag, Chennai Air and Petrapole etc. – Seafood.

2023-24 TO 2025-26 (UPTO AUG 2025) : PORT WISE HSN WISE IMPORT VALUE DATA (VALUE IN CRORES)											
SN	**PORT CODE**	**PORT NAME**	**0201-0208 MEAT & POULTRY**	**0301-0308 SEAFOOD**	**0401-0406 DAIRY PRODUCTS**	**0601-0604 FLOWER & PLANTS**	**0701-0714 VEGETABLES**	**0801-0814 FRUITS**	**1905 BAKERY PRODUCTS**	**3002-3006 PHARMACEUTICALS**	**GRAND TOTAL**
1	**INNSA1**	**NHAVA SHEVA**	79.57	482.77	729.47	154.52	23,358.92	39,795.60	848.47	8,275.93	**73,725.25**
2	**INBOM4**	**Bombay Air Cargo**	11.77	57.27	5.42	116.38	7.92	282.60	7.84	29,768.36	**30,257.56**
3	**INMAA1**	**Chennai Sea**	1.51	175.56	17.87	119.69	23,058.74	1,998.40	339.22	745.28	**26,456.28**
4	**INTUT1**	**Tuticorin Sea PORT**	-	57.35	-	0.82	4,129.32	17,600.38	1.74	0.00	**21,789.62**
5	**INNML1**	**Mangalore Sea**	-	2.99	-	-	15.59	13,422.74	-	-	**13,441.32**
6	**INCCU1**	**Kolkata Sea**	-	862.36	0.93	1.22	10,684.09	1,205.57	163.21	18.84	**12,936.22**
7	**INMUN1**	**Mundra Port**	-	31.14	5.72	0.51	6,934.37	4,036.57	34.22	21.08	**11,063.61**
8	**INATRB**	**Amritsar Attari Road LCD**	-	-	-	-	498.06	6,579.00	-	-	**7,077.05**
9	**INIXY1**	**Kandla**	-	-	-	-	6,520.78	39.32	-	-	**6,560.10**
10	**INDEL4**	**Delhi Air Cargo**	0.99	38.66	0.35	101.51	13.00	301.85	2.04	3,806.45	**4,264.86**
11	**INVTZ1**	**Vizag Sea PORT**	0.55	126.08	-	-	129.94	3,575.85	1.38	-	**3,833.80**
12	**INHYD4**	**Hyderabad Air Cargo**	-	0.83	0.01	-	0.01	2.77	0.01	3,062.55	**3,066.17**
13	**INHZA1**	**HAZIRA PORT**	-	1.20	-	-	3,025.80	2.81	-	-	**3,029.81**
14	**INPTPB**	**Petrapole Bengal LCS**	-	616.58	-	0.15	-	1,419.53	-	-	**2,036.26**
15	**INMAA4**	**Chennai Air Cargo**	-	423.09	-	72.86	0.25	7.60	0.14	1,122.50	**1,626.44**
16	**INBDM6**	**PANCHI GUJARA SONEPAT ICD**	-	-	-	436.10	16.14	1,080.52	4.75	7.70	**1,545.22**
17	**INCOK1**	**Cochin Sea**	1.73	88.85	3.46	0.03	45.27	1,351.39	8.83	3.96	**1,503.54**
18	**INBLR4**	**Bangalore Air Cargo**	0.07	11.21	0.05	43.93	0.79	13.42	0.35	1,350.23	**1,420.07**
19	**INBOM1**	**Bombay Sea**	-	-	-	-	1,279.85	-	0.10	-	**1,279.95**
20	**INENR1**	**Ennore**	-	13.71	1.29	57.05	3.62	900.98	-	29.51	**1,006.15**
		TOTAL	**96.20**	**2,989.65**	**764.56**	**1,104.78**	**79,722.48**	**93,616.90**	**1,412.32**	**48,212.39**	**2,27,919.28**

INNSA1 (Nhava Sheva, JNPT) is the single largest gateway, handling the highest share of temperature sensitive cargo across multiple categories such as fruits, vegetables, dairy, bakery, and meat, making it the undisputed leader. The trend analysis highlights the following:

- Pharmaceuticals (3002–3006) are mostly concentrated in air cargo hubs, led by INBOM4 (Mumbai Air Cargo, 61.7%), INDEL4 (Delhi) (7.9%) and INHYD4 (Hyderabad) (6.4%) with an exception of Nhava Sheva (17.2%)
- Fruits (0801–0814) and Vegetables (0701 - 0714) dominate total import value. Fruits are mainly routed through INNSA1 (Nhava Sheva, 42.5%), followed by INTUT1 (Tuticorin, 18.8%) and INNML1 (Mangalore, 14.3%), while Vegetables are concentrated at INNSA1 (29.3%), INMAA1 (Chennai Sea, 28.9%), and Kolkata Sea Port INCCU1 (13.4%).
- Several ports are highly specialized, with over 90% of their trade concentrated in one category. For instance, INBOM4 (Mumbai Air Cargo) is dominated by pharmaceuticals, INNML1 (Mangalore Sea) by fruits, INPTPB (Petrapole Bengal) by fruits and seafood, and INHYD4 (Hyderabad Air Cargo) again by pharmaceuticals.

The overall port performances are also specified in the below table which reveals the concentration of import of temperature sensitive cargo (almost 84%) at major top 10 ports.

Rank	**Port Code**	**Port Name**	**Total Value (in Crores)**	**% of Total**	**Key HSN Specialties**
1	INNSA1	JNPT (Nhava Sheva)	73725.254	32.35%	Fruits, Vegetables, Dairy, Bakery, Meat
2	INBOM4	Mumbai Air Cargo	30257.563	13.28%	Pharmaceuticals (98% of value)
3	INMAA1	Chennai Sea	26456.285	11.61%	Vegetables (87%), Fruits
4	INTUT1	Tuticorin Sea Port	21789.616	9.56%	Fruits (81%), Vegetables
5	INNML1	Mangalore Sea	13441.321	5.90%	Fruits (99%)
6	INCCU1	Kolkata Sea	12936.224	5.68%	Seafood, Vegetables, Bakery
7	INATRB	Attari Road LCS	7077.054	3.11%	Vegetables (93%)
8	INMUN1	Mundra Port	11063.608	4.85%	Vegetables (63%), Fruits
9	INDEL4	Delhi Air Cargo	4264.856	1.87%	Pharmaceuticals (89%)
10	INPTPB	Petrapole Bengal LCS	2036.263	0.89%	Seafood (30%), Fruits

The commodity wise port analysis shows the concentration patterns, with the imports funneled through a few dominant gateways depending on the products. Pharmaceuticals are mostly handled by air cargo hubs, led by Mumbai Air Cargo, with additional support from Delhi and Hyderabad, while sea ports play only a marginal role except JNPT (17.2%). Fruits, the largest import category, are heavily routed via Nhava Sheva (42.5%), followed by Tuticorin (18.8%) and Mangalore (14.34%), indicating coastal ports' dominance. Vegetables, the second-largest category, show a similar trend with Nhava Sheva (29.3%) and Chennai (28.9%) leading, supported by Kolkata (13.4%) and Mundra (8.7%), reflecting a balanced mix of west, east, and south gateways.

In contrast, seafood imports are more geographically distributed towards Kolkata (28.8%), and Petrapole (20.6%) being key contributors to the eastern coastal and border trade points. Imports of dairy products are almost concentrated at Nhava Sheva (95.4%), whereas, the imports of plants are majorly from Panchi Gujara Sonipat ICD (39.5%), Nhava Sheva (14%), Chennai (10.8%) and Bombay Air Cargo (10.5%). Cut flowers are mostly imported through Airport Mumbai and Delhi, whereas, Meat & Poultry imports are mostly via Nhava Sheva. The bakery products again reflect strong concentration at Nhava Sheva (60.1%), followed by Chennai (24%) and Kolkata (11.6%).

Therefore, Nhava Sheva (JNPT) appears to be the backbone of time sensitive cargo imports, leading in imports of fruits, vegetables, dairy, bakery, and meat. The major Air Cargos i.e. Mumbai, Delhi and Hyderabad are dominating in high value time-sensitive pharmaceutical products, making them critical for India's medical supply chain. Their specialization also shows high dependency on a single sector.

Further, Tuticorin, Mangalore, and Vizag are niche leaders in fruits and vegetables imports, catering to the southern region's demand. Kolkata and Petrapole dominate seafood imports, because of eastern coastal and cross-border trade with Bangladesh. Cochin and Bangalore Air Cargos are limited to Agro-based trade.

5. Export Growth Trend

The overall export of temperature sensitive perishable cargo has grown up from Rs. 2,54,440.70 Cr. to Rs. 3,27,474.55 Cr. in the FY 2024-25 marking an appreciable growth of 28.7%, which is 1% better in reference to import growth of temperature sensitive perishable cargo and almost 201% higher than the imports of temperature sensitive cargo in value terms.

To understand the dynamics of the export of the temperature sensitive cargo, the port-wise growth trend at 15 major ports in 2024-25 is discussed below:

COMPARATIVE ANALYSIS OF EXPORT GROWTH PORTS-WISE (Value in Rs. CRORES)							
SN	**Port**	**PORT NAME**	**VALUE (In Cr.) 2023-24 (Actual)**	**VALUE (In Cr.) 2024-25 (Actual)**	**YoY Growth (23-24 - 24-25)**	**VALUE (In Cr.) 2025-26 (5-Month)**	**Grand Total**
1	INNSA1	Nhava Sheva	62674.584	71287.46	**13.70%**	31316.14	165278.2
2	INBOM4	Bombay Air Cargo	23594.94	23719.6	**0.50%**	10053.38	57367.91
3	INVTZ1	Vizag Sea PORT	16075.521	17498.8	**8.90%**	7953.878	41528.2
4	INSNF6	Hyderabad ICD	15123.38	16961.01	**12.20%**	7583.798	39668.18
5	INHYD4	Hyderabad Air Cargo	12307.271	16586.01	**34.80%**	5271.794	34165.07
6	INMUN1	Mundra Port	12769.82	15535.79	**21.70%**	6669.705	34975.32
7	INVTZ6	ICD Tumb Vizag SEZ/EPZ	0	11819.08		2488.102	14307.18
8	INDEL4	Delhi Air Cargo	8460.619	9739.235	**15.10%**	4125.296	22325.15
9	INCOK1	Cochin Sea	7467.451	7302.041	**-2.20%**	3143.467	17912.96
10	INMAA1	Chennai Sea	8035.632	7234.132	**-10.00%**	3370.075	18639.84
11	INZIP6	Zydus Infrastructure Mundra Port	0	7139.323		2687.117	9826.44
12	INAPL6	Dadri-ACPL CFS	8049.783	7083.055	**-12.00%**	3070.482	18203.32
13	INGLY6	Gulbarga	0	6059.969		3899.702	9959.67
14	INENR1	Ennore	3142.449	5328.291	**69.60%**	3055.366	11526.11
15	INCCU1	Kolkata Sea	5045.82	5327.394	**5.60%**	2949.724	13322.94
		TOTAL	**177701.45**	**223293.8**	**25.70%**	**94688.29**	**495683.5**

The comparative performance of major ports over the last two fiscal year and the current year-to-date (YTD) reveals a significant shifts in trade dynamics and regional competitiveness. Nhava Sheva port (INNSA1) continues to dominate the volumes of the export contributing almost 31% of total export FOB value in the FY 2024-25, registering a growth of 13.70% over FY 2023-24.

Bombay Air Cargo (INBOM4) is the second largest port in cumulative trade value, though the growth of export through this port is marked at 0.5%, indicating a plateau in air cargo throughput. Vizag Sea Port and Hyderabad ICD are closely

handling the cargo of FOB value of Rs 4,152.82 Crores and Rs 3,966.81 Crores respectively with stable growth of 8.90% and 12.20% respectively.

The export of temperature sensitive cargo from Ennore Port, has surged up from Rs 3142.44 Cr. in 2023–24 to Rs 5328.29 Cr. in 2024–25, showing remarkable growth of 69.6%. Hyderabad Air Cargo is another port showing robust growth of 34.8%. This reflects the rising demand for time-sensitive and high-value shipments, possibly driven by pharmaceutical exports. Following ports however, are showing negative growth in export of the temperature sensitive cargo:

- Dadri-ACPL CFS dropped by 12.0%, from Rs 8049.78 Cr. to Rs 7083.05 Cr. Chennai Sea is the another port showing negative growth of − 10.0%, falling from Rs 8035.63 Crores to Rs 7234.13 Crores in 2024-25.
- Cochin Sea has registered a **− 2.2% dip**, indicating marginal loss of throughput.

The are some newly emerging contributors, who are showing a promising growth trend in export and import in 2025-26. Zydus Infrastructure Mundra Port (INZIP6) recorded Rs 2687.12 Crores in just five months. Gulbarga ICD posted Rs 3899.7 Cr., indicating strong regional cargo movement. **SEZ/EPZ Tumb (INVTZ6)** in Vishakhapatnam, is emerging as a new hub for export of temperature sensitive cargo recoding a total export of Rs 2488.1 Crores, in FY 2024-25.

6. Commodity-wise Export Growth Trend in Temperature Sensitive Cargo

The table below is showing the product segment-wise growth trend of temperature Sensitive Cargo in India:

Value in Rs. Cr.

HSN GROUP	HSN GROUP DESCRIPTION	2023-24	2024-25	YoY Growth (23-24 to 24-25)	Apr-Aug 2025 (5-Month)	Grand Total
0201–0208	**Meat**	31,642.74	35,166.15	11.13%	15,433.60	**82,242.49**
0301–0308	**Seafood**	50,118.70	53,170.00	6.09%	23,723.25	**1,27,011.96**
0401–0406	**Dairy**	2,232.93	4,172.48	86.86%	1,609.70	**8,015.12**
0601–0604	**Live plants**	693.75	746.83	7.65%	337.27	**1,777.86**
0701–0714	**Fresh/chilled vegetables**	16,078.08	18,785.48	16.84%	8,188.24	**43,051.80**
0801–0814	**Fresh fruits**	13,294.31	14,450.37	8.70%	5,561.03	**33,305.71**
1905	**Bakery**	4,304.08	5,274.98	22.56%	2,504.74	**12,083.81**

	Products					
3002–3006	**Medicinal products**	1,36,076.10	1,95,708.25	43.82%	87,688.63	**4,19,472.98**
Grand Total		**2,54,440.71**	**3,27,474.55**	**28.70%**	**1,45,046.45**	**7,26,961.71**

Among the top-performing product categories, Medicinal products (HSN 3002–3006) have emerged as the largest contributor, with a total exports reaching to Rs. **4,19,472.98** Cr. adding a remarkable growth of 43.82% over FY 2023-24. Dairy products (HSN 0401–0406) however have registered the highest growth rate at 86.86%, nearly doubling in FOB value, while bakery products (HSN 1905) and **Fresh/chilled vegetables** (HSN 0701–0714) have followed the gains of 22.56% and 16.84%, respectively. Meat and poultry (HSN 0201–0208) maintained steady growth at 11.13%, and Fresh fruits exports (HSN 0801–0814) rose by 8.7%. Seafood (HSN 0301–0308), despite being the second-largest category by value, has shown a modest growth of 6.09%. Overall, the data reflects a healthy diversification in India's export basket, with rising global demand for Pharmaceuticals, Seafood, processed foods, and high-value perishables. The early figures from FY 2025–26 suggest that India is well-positioned to surpass previous records, driven by improved logistics, cold chain infrastructure, and expanding market access.

7. Port-wise product category concentration of export

India's export performance across 212 ports has shown robust growth in time-sensitive product categories. Projecting two and half years of data from 2023 to 2025, it appears that pharmaceuticals (HSN 3002–3006) with FOB value of Rs 4,19,472.98 Cr. stand at the top and the Seafood (HSN 0301–0308) with FOB value of Rs 1,27,011.9 Cr. comes at the second position. The figures of 20 ports are given below:

(2023-24 to Aug 2025), Value In Crores

2023-24 TO 2025-26 (UPTO AUG 2025) : PORT WISE HSN WISE EXPORT VALUE DATA (VALUE IN CRORES)											
SN	**PORT CODE**	**PORT NAME**	**0201-0208 MEAT & POULTRY**	**0301-0308 SEAFOOD**	**0401-0406 DAIRY PRODUCTS**	**0601-0604 FLOWER & PLANTS**	**0701-0714 VEGETABLES**	**0801-0814 FRUITS**	**1905 BAKERY PRODUCTS**	**3002-3006 PHARMACEUTICALS**	**GRAND TOTAL**
1	**INNSA1**	**NHAVA SHEVA**	21,147.34	12,786.45	2,119.49	34.47	10,308.91	11,152.20	3,012.10	1,04,717.22	**1,65,278.18**

2	**INBOM4**	**Bombay Air Cargo**	511.39	450.61	10.69	489.55	721.74	1,068.53	3.01	54,112.39	**57,367.91**
3	**INVTZ1**	**Vizag Sea PORT**	1,470.91	38,065.64	0.34	1.19	0.56	633.17	0.03	1,356.37	**41,528.20**
4	**INSNF6**	**Hyderabad**	-	4.57	5.92	20.75	73.82	6.56	1,252.50	38,304.06	**39,668.18**
5	**INMUN1**	**Mundra Port**	0.003	4,773.88	857.81	7.09	8,353.96	596.56	916.07	19,469.94	**34,975.32**
6	**INHYD4**	**Hyderabad Air Cargo**	0.72	250.34	0.48	3.30	29.75	154.03	0.59	33,725.87	**34,165.07**
7	**INDEL4**	**Delhi Air Cargo**	1,694.62	2.18	19.88	15.26	79.83	28.17	5.43	20,479.78	**22,325.15**
8	**INMAA1**	**Chennai Sea**	1,060.63	10,549.81	364.63	55.84	1,215.45	657.10	295.36	4,441.02	**18,639.84**
9	**INAPL6**	**Dadri-ACPL CFS**	17,264.59	-	191.35	-	1.61	18.62	31.93	695.22	**18,203.32**
10	**INCOK1**	**Cochin Sea**	37.94	12,451.23	412.72	8.00	501.74	3,858.38	225.32	417.64	**17,912.96**
11	**INVTZ6**	**ICD Tumb**	-	-	-	10.84	-	1.64	-	14,294.71	**14,307.18**
12	**INCCU1**	**Kolkata Sea**	261.57	12,292.54	8.31	262.01	103.03	29.50	338.26	27.72	**13,322.94**
13	**INCPL6**	**Dadri-CGML**	7,828.21	-	186.92	0.02	225.09	4.84	333.94	3,050.88	**11,629.90**
14	**INENR1**	**Ennore**	56.89	6,644.11	10.20	51.20	219.47	230.06	184.80	4,129.39	**11,526.11**
15	**INTUT1**	**Tuticorin Sea PORT**	74.95	6,446.04	79.54	197.33	1,758.56	2,318.28	181.38	256.09	**11,312.17**
16	**INWFD6**	**Bangalore ICD**	-	0.03	86.33	0.44	493.02	93.93	83.40	10,467.77	**11,224.92**
17	**INPAV1**	**Pipavav (Victor) Port**	-	8,355.29	1.09	0.00	2,438.03	42.49	9.38	9.21	**10,855.49**
18	**INGLY6**	**Gulbarga**	-	-	-	-	-	-	-	9,959.67	**9,959.67**
19	**INZIP6**	**Zydus Infrastructure Mundra Port**	-	-	-	-	-	-	-	9,826.44	**9,826.44**
20	**INBLR4**	**Banglore Air Cargo**	-	6.61	0.18	221.92	262.08	200.12	3.33	8,911.43	**9,605.66**

		TOTAL	**51,409.77**	**1,13,079.31**	**4,355.86**	**1,379.20**	**26,786.65**	**21,094.18**	**6,876.84**	**3,38,652.81**	**5,63,634.61**

The highest contribution of temperature sensitive cargo export is of Nhava Sheva port with major export of Pharmaceutical products. Further, exports of Pharmaceutical products are concentrated at Hyderabad ICD (FOB of Rs. 38,304.06 crores), and Hyderabad Air Cargo (FOB of Rs. 33,725.86 Cr.). Seafood (HSN 0301–0308) the second-largest category are mostly exported from Vizag Sea Port (Rs. 38,065.63 Cr.), Cochin Sea (Rs. 12,451.22 Cr.), and Chennai Sea (Rs. 10,549.81 Cr.). Meat & poultry (HSN 0201–0208) exports primarily are from Dadri-ACPL CFS (Rs. 17,264.58 crores) and Nhava Sheva (Rs. 21,147.34 Cr.).

Vegetables (HSN 0701–0714) and fruits (HSN 0801–0814) export are primarily from Pipavav Port, Tuticorin, and Bangalore ICD. While dairy products, bakery items, and flower & plants are exported from Delhi Air Cargo, Dadri-CGML, and Kolkata Sea.

Emerging contributors like Gulbarga (FOB value of Rs. 99,59.67 Cr.) and Zydus Infrastructure Mundra Port (FOB Value of Rs. 98,26.44 Cr.) are adding significant pharmaceutical exports, despite limited category diversity. The table below is showing top performing ports for different products groups of temperature sensitive cargo:

HSN Group	**Description**	**Top Port Name**	**Export Value (₹ Crores)**
0201–0208	Meat & Poultry	NHAVA SHEVA	21,147.34
0301–0308	Seafood	Vizag Sea Port	38,065.63
0401–0406	Dairy Products	NHAVA SHEVA	2,119.49
0601–0604	Flower & Plants	Bombay Air Cargo	489.55
0701–0714	Vegetables	NHAVA SHEVA	10,308.91
0801–0814	Fruits	NHAVA SHEVA	11,152.2
1905	Bakery Products	NHAVA SHEVA	3,012.1
3002–3006	Pharmaceuticals	NHAVA SHEVA	1,04,717.22

CHAPTER-3

The Temperature Sensitive Cargo: Classification and Regulatory Framework

1 Introduction:

The temperature sensitive cargos are primarily either consumable goods or are health care substances. These items also have short life. Therefore, its exports and imports are heavily regulated by the national and international agencies with respect to their quality, product integrity and food safety etc. Customs, PGAs and other stakeholders are therefore, expected to understand the delicate nature of the products and its short self-life with a view to maintain appropriate ecosystem and fast-track the clearance system.

2 Classification of Perishable Items based on Shelf Life and storage temperature:

Proper classification of perishable goods and knowledge of their shelf life are fundamental to ensuring that each category of temperature-sensitive items are subjected to the correct inspection, handling, storage, and documentation requirements during import and export. In India, perishables are broadly categorized based on their biological nature, inherent shelf life, and sensitivity to environmental conditions.

The following table illustrates common categories of perishable goods, their typical shelf life, and requisite storage conditions:

Product Category	Examples of Products	Shelf Life	Storage Temperature Requirement
1	2	3	4
Fruits & Vegetables	Mangoes, bananas, onions, potatoes, tomato, cabbage, peas etc.	14–60 days	5 to -15°C, high humidity
Dairy Products	Milk, cheese, butter etc.	12–40 days	2 to –6°C, cold chain mandatory
Meat & Poultry	Chicken, lamb, beef etc.	30-60 days	2 to -4°C, vacuum packed
Seafood	Shrimp, fish, crab, lobsters, prawns, crayfish, oysters, squids, clams, scallops etc.	40-90 days	0 to –30°C, IQF or frozen blocks
Flowers & Plants	Roses, tulips, orchids etc.	3–12 days	2 to –5°C, humidity controlled

Product Category	Examples of Products	Shelf Life	Storage Temperature Requirement
1	2	3	4
Pharmaceuticals (Cold Chain)/Medical products	Vaccines, insulin, temperature-sensitive drugs	Varies	-2 to -20°C, uninterrupted cold chain
Bakery Products	Pastries, cakes, dough, chocolates etc.	2–14 days	4 to –8°C, dry & chilled storage

The classification of the temperature sensitive cargos are based on several critical criteria which includes:

a. **Temperature Sensitivity:** This refers to their dependency on a cold chain and their specific threshold temperatures, beyond which degradation accelerates.
b. **Respiration Rate:** Goods with high respiration rates, such as leafy vegetables, tend to degrade much faster.
c. **Moisture Content:** Items with high moisture content, like cucumbers, require stricter humidity control to prevent spoilage.
d. **Decay Potential:** This measures the time until spoilage if the item is left unrefrigerated.
e. **Pathogen Growth Risk:** This assesses the susceptibility of items to microbial spoilage, with seafood being a prime example.

In addition, each product is required maintain certain health parameters which are specified below:

1. **Fruits and vegetables:** Fruits and Vegetables should be firmed in size and uniformity. It should not have spoilage, bruises or rot. The pesticide residue limits are prescribed. The product shouldn't have crossed the limit of maximum pesticide residue and should be correctly matured (neither over-ripped nor immature for consumption.

2. **Dairy Products:** The microbial limits total plate count, coliforms, pathogens like listeria and salmonella etc. should not be more than the prescribed limits. Temperature and packaging norms should be maintained properly. Self-life must be specified at the packaging.

3. **Meat and Poultry:** Veterinary Health Certificate is mandatory. Testing for e-coli, salmonella etc. and vacuum sealed packaging are must. Similarly, uninterrupted temperature control is required.

4. **Seafoods:** Organoleptic evaluation (smell, texture, colour), Heavy metal testing (Mercury, Lead, Arsenic), Histamine levels testing (especially in tuna, mackerel), hygiene and temperature control.

5. **Flowers and Plants:** Should be free from pests and disease, Phytosanitary certificate required, No signs of fungal infection, Moisture-retaining packaging recommended, cold chain is must.

6. **Pharmaceuticals:** Temperature logs from packaging to arrival. Stability data for customs, Visual inspection of vials, blister packs, Shelf life and batch validation.

3. International Regulatory Framework

There are several international regulatory frameworks for monitoring the export and imports of the temperature sensitive cargo. Different countries or the group of countries have their regulatory framework to protect the product integrity and public health. The key International Regulatory Bodies and their roles in Customs Clearance are given below:

3.1 Codex Alimentarius (CA):

The Codex Alimentarius is a Latin word for "Food Code". The Codex Alimentarius therefore, is a collection of internationally recognized standards, guidelines, and codes of practice established by the Food and Agriculture Organization (FAO) and World Health Organisation (WHO) of UN, which serves as a global reference for food, food production, food labelling, and food safety. It covers critical aspects such as maximum residue limits (MRLs), microbiological standards, labelling requirements, approved additives, and permissible contaminants. Codex Alimentarius is established by an intergovernmental organization which is called the Commission of which there are 189 members. This organisation primarily establishes international food standards for approved food additives, providing maximum levels in foods; maximum limits for contaminants and toxins; maximum residue limits for pesticides and for veterinary drugs used in veterinary animals; and establishing hygiene and technological function practice codes. Though, the CA doesn't have regulatory authority, and the Codex Alimentarius therefore, is a reference guide, but several nations have adopted the principles of the code in their own regulations and WTO has introduced them for application of sanitary and

phytosanitary measures or the member countries. Following are the basic parameters worth discussing here:

a. **Food Labeling**: The Codex Alimentarius provides guidelines on packaging and labelling of the foods and nutrition labelling, so as to prevent the false advertising and promote food safety. To prevent adulteration and fraud, it is necessary to specify the ingredients listings, date of manufacturing and packaging, expiry date, direction to maintain temperature and other ecosystem requirements for keeping intact the product integrity.

b. **Food Additives**: The food grade chemicals and other substances added to food for preserving flavours or enhancing taste, appearance, other sensory qualities etc. such as vinegar, salt, smoke, sugar, bacon, sweets, and wines. Presently many other food additives natural and artificial are introduced. In Europe, many additives are designated with E numbers and in US with GRAS. For examples the E number range 100-199 are used for food grade colours, E number 200-299 are used for Preservatives like - sorbates, benzoates, sulphites, phenols, nitrates, acetates etc. E number 300-399 for Antioxidants and Acidity Regulators like ascorbates (Vitamin C), Tocopherol (Vitamin E), Lactates etc. and similarly for thickener, pH regulator, Antibiotic, Glazing agents etc. Similarly, US Generally Recognized as Safe (GRAS) is the framework in which only those chemical or substances are added to foods which are considered safe by experts and under the conditions of its intended use.

   Food additives can be divided into several groups. Some of the examples are – acidity regulators, anticaking agents, antifoaming agents, antioxidants such as vitamin C, bulking agents such as starch, colouring agents, emulsifiers, flavouring agents etc.

c. **Contaminations**: Contamination is the presence of a constituent, impurity or some other undesirable elements present in the food products that renders something unsuitable, unfit or harmful for the physical body or natural environment. It may be chemical contamination, which may or may not have reactive or catalyst property, which may render toxin, poison or pollutant depending on the type of molecules. Environmental Contaminations – whim may harm at large level of human health, environments or organisms. Agricultural Contaminations – genetically modified organisms especially when they come in contact

with organic agriculture. It may result in the decertification of a farm. The Food, Beverage and Pharmaceutical Contamination is another form in which harmful intrusions such as the presence of toxins or pathogens in food or pharmaceutical drugs are found. Radioactive Contamination takes place when radioactive substances are appeared on surfaces or within solids, liquids, or gases including human body, which may give rise to injury of public health.

d. **Pesticides and Veterinary Chemical Residues in Food:** Pesticides are the substances that are used to control pests. They may be herbicides, insecticides, nematicides, fungicides and many others. Most of the pesticides are used for plant protection products or crop protection products which protects plants from weeds, fungi or insects. Generally pesticides are chemical or biological agents such as virus, bacterium or fungus, that deters, incapacitates, kills or otherwise discourages pests.

Sl. No.	Type of pesticide	Target pest group
1	Algicides or algaecides	Algae
2	Avicides	Birds
3	Bactericides	Bacteria
4	Fungicides	Fungi and oomycetes
5	Herbicides	Plant
6	Insecticides	Insects
7	Lampricides	Lampreys
8	Miticides or Acaricides	Mites
9	Molluscicides	Snails
10	Nematicides	Nematodes
11	Rodenticides	Rodents
12	Slimicides	Algae, Bacteria, Fungi, Slime Molds
13	Virucides	Viruses

e. Risk Assessment and Food Hygiene: Risk Assessment procedures for determining the safety of foods derived from biotechnology (DNA modified plants, DNA modified micro-organisms, allergens) and Food

Hygiene especially industries or food handling establishments and guidelines for the uses of the Hazard Analysis and Critical Control Point or HACCP system.

India has aligned the standards with the **Codex Alimentarius** which offers significant advantages, including hassle free customs clearances, less damages due to delay, enhanced market access for its products, a strong basis for dispute resolution in international trade, improved consumer protection by ensuring food meets global safety levels, and greater regulatory consistency across various Indian ministries and agencies such as FSSAI, APEDA, and EIC.

Despite, challenges are still persisting on account of lack of trained workforce, fragmented regulatory bodies and poor infrastructure, both at the ports and testing agencies level.

3.2 EU Regulatory Harmonization:

The European Union maintains a highly stringent and harmonized set of food safety regulations, enforced uniformly across all member states under the overarching General Food Law (Regulation EC No. 178/2002). Exporters of perishables to the EU must meet mandatory requirements such as end-to-end traceability, adherence to the Hazard Analysis and Critical Control Points (HACCP) food safety protocol, strict compliance with EU MRLs, precise packaging and labelling, and often, third-party certification from recognized bodies.

The EU Regulatory Harmonization derives basic principles from the General Food Law (Regulation EC No. 178/2002, which constitutes the foundation in the food sector of a high level of protection of the public health and interest of consumers and at the same time of the functioning of the internal market. The analysis of hazards and critical points in the system of production and distribution of food products is regulated by technical rules derived from the Hazard Analysis and Critical Control point (HACCP).

Under this regulation, there are obligations for producers and distributors of the food products to maintain the quality and product integrity, complying with the predetermined safety requirements, including risk analysis, precautionary principles, protection of consumer interest, transparency in the development of food law, consumer information, safety obligations for food business operators. This regulation also establishes the procedures for the European Safety Authority, and other procedures related to food emergency situation etc.

To provide a robust framework of regulations aiming to ensure the safety and quality of food products throughout the food supply chain, EU has developed a robust framework of regulations, which include Regulation (EC) No. 178/2002 which is known as General Food Law which sets out general principles as detailed above. Regulation No. (EC) No. 852/2004 which deals with the hygiene of foodstuffs, which lays down specific hygiene rules for food businesses, covering areas such as premises, equipment, personnel hygiene, and food safety management systems. Regulation (EC) No 853/2004, which establishes specific hygiene rules for food of animal origin, including requirements for slaughterhouses, processing plants, and food handling practices and Regulation (EC) No 854/2004, which provides for official controls on products of animal origin intended for human consumption, conducted by competent authorities to verify compliance with EU food safety standards.

To safeguard global food safety, the EU has been participating in the Codex Alimentarius Commissioner, led by the UN Food and Agriculture Organization and the World Health Organization. The compliance is crucial because it is the cornerstone of the consumer trust, business success and thriving food ecosystem. Safeguarding public health is the fundamental principle of the regulations. However, it also opens up the opportunities to access a bigger market protecting consumer health and fostering trust based food supply chain. Traceability system is a key aspect of compliance, which allow swift identification and removal of any potential food safety hazards, minimizing risks and ensuring consumer confidence.

Compliance also fosters a positive brand image and reputation and provide legal protection. Compliance demonstrates a company's dedication and quality repute with customers' loyalty. It also fosters a framework for responsible food production practices. Like responsible waste management and reduced use of harmful chemicals etc. encourage sustainable growth. Non-compliance on the other hand may lead to severe consequences like legal implications, fines, penalties and criminal prosecution for serious violations. It may also be subject to recall of product, leading to financial losses and damage to brand reputation, trade barriers, preventing business from accessing EU markets and international trade opportunities.

Indian agencies such as APEDA, EIC/EIA, and FSSAI actively work towards harmonizing national standards with EU requirements. However, these agencies are still working in silos and there is less coordination with the Customs. Following are the special features of Codex aligned EU Regulatory Harmonization:

Port-Centric Testing & Certification

- Establish ISO17025 accredited labs at major ports and airports.

- Introduce pre-export certification schemes recognized by EU/US authorities.
- Enable risk-based rapid-response labs for perishable consignments with a 12-hour turnaround.

Digital Traceability

- Deploy QR-based farm-to-fork traceability for seafood, spices, rice, and organics.
- Expand blockchain pilots with DGFT & Customs for secure, tamper-proof supply chain data.
- Integrate IoT temperature loggers linked to ICEGATE for real-time monitoring.

Capacity Building

- Conduct training programs for MSMEs on Codex, EU, and USFDA standards.
- Promote adoption of Global Food Safety Initiative recognised (GFSI-recognized) certifications, British Retail Consortium (BRC), Safe Quality Food (SQF), International Featured Standards (IFS), and Global Good Agricultural Practice GlobalG.A.P).
- Enable online and remote certification access for smaller exporters.

Import Controls

- Strengthen port-based inspections aligned with Codex standards.
- Permit imports only from countries or facilities compliant with Codex/EU/USFDA norms.
- Introduce risk-based testing protocols for priority imports.

Public-Private Partnerships (PPP)

- Collaborate with export councils, industry associations, and private labs.
- Develop cold-chain and digital traceability infrastructure jointly.
- Incentivize private participation in perishable cargo handling.

Perishable & Time-Sensitive Cargo Special Measures

- Introduce Perishable Cargo Green Corridors at ports and airports for clearance within 6–8 hours.
- Ensure 24x7 Customs and FSSAI clearance at major hubs.
- Mandate temperature-controlled storage and priority lab testing for high-risk commodities.

3.3 US FDA Compliance:

The United States Food and Drug Administration (US FDA) regulates the import of food products, including perishables, through a comprehensive framework designed to ensure food safety, quality, and traceability. The Food Safety Modernization Act (FSMA), enacted in 2011, marked a significant shift in the U.S. food safety system from a reactive to a preventive approach.

Key pillars of FSMA that directly impact Indian exporters include the Foreign Supplier Verification Program (FSVP), which mandates U.S. importers to verify that their foreign suppliers produce food with the same level of public health protection as domestically required, effectively making FDA standards a pre-export requirement for Indian suppliers.

Common reasons for detention or refusal of Indian shipments include pesticide residues exceeding U.S. MRLs, microbial contamination (e.g., Listeria, Salmonella, E. coli), misbranding or mislabelling, and packaging deficiencies such as the use of unapproved materials or failure in temperature control.

Indian authorities like EIC/EIA, APEDA, and MPEDA provide crucial support to exporters in meeting these stringent U.S. compliance requirements. If the Indian customs effectively verify these parameters at the port and coordinate with other authorities on real time basis, the issue of rejection of export consignment would significantly reduce. This calls for better training, infrastructure and coordination of customs with different other organisations.

The relevant portion of US Food and Drug Administration (US FDA) is given below:

i. Drug Manufacturing Inspections Overview

This compliance program outlines the FDA's approach to conducting drug manufacturing inspections to ensure compliance with CGMP requirements.

- Inspections are categorized into full and abbreviated options based on the establishment's compliance history.
- Full inspections typically cover at least four systems, including the quality system, while abbreviated inspections cover at least two.
- The program incorporates ICH guidelines for quality risk management and pharmaceutical quality systems.

ii. Compliance Program Implementation Details

The program aims to ensure drug establishments consistently produce quality products and minimize consumer exposure to adulterated drugs.

- Inspections, investigations, and sample analyses are conducted to identify quality issues.
- The program emphasizes a risk-based approach to inspection planning and execution.
- Establishments are evaluated on their compliance with CGMP requirements and the effectiveness of their quality systems.

iii. Inspectional Coverage and System Evaluation

The program focuses on evaluating multiple systems within drug manufacturing establishments to assess compliance.

- Inspections cover six key systems: Quality, Facilities and Equipment, Materials, Production, Packaging and Labeling, and Laboratory Control.
- Each system's effectiveness is assessed to ensure overall compliance with CGMP regulations.
- The quality system is mandatory for all inspections, ensuring management oversight of CGMP operations.

iv. Risk-Based Inspection Planning Strategy

The FDA employs a risk-based approach to determine the depth and focus of inspections.

- Inspection planning considers the establishment's compliance history, manufacturing technology, and product characteristics.
- The program allows for the use of remote regulatory assessments to supplement traditional inspections.
- Inspections may be conducted during visits for other compliance programs to maximize efficiency.

v. Summary of Inspection Findings and Updates

Inspection findings are used to update compliance profiles and inform regulatory decisions.

- Findings from inspections are documented and used to assess the establishment's overall compliance status.
- The program aims to ensure that all profile classes are updated based on inspection outcomes.

- Special attention is given to products with unique challenges, such as low-dose or combination products.

vi. Compliance Program for Drug Establishments

This compliance program outlines the inspection strategies and requirements for drug manufacturing establishments to ensure adherence to current good manufacturing practices (CGMP).

- Inspections should be planned flexibly based on the size and complexity of drug establishments.
- Observations of CGMP deficiencies must relate to specific regulatory requirements.
- API and PET drug inspections follow distinct compliance programs (7356.002F for APIs and 7356.002P for PETs).
- Guidance documents cannot justify inspectional observations; only statutory requirements can.
- Form FDA 483 should contain specific and significant observations organized by defined systems.

vii. Quality System Inspection Requirements

The quality system encompasses policies and procedures that ensure drug quality and compliance with CGMP.

- The quality system should include effective management oversight and support for the quality unit.
- Key components include quality risk management, product reviews, complaint investigations, and change management.
- Inspections assess the quality unit's responsibilities and the effectiveness of quality practices.
- Advanced quality practices may indicate a mature quality system, leading to more flexible regulatory oversight.

viii. Packaging and Labeling System Inspection

The packaging and labelling system ensures that drug products are correctly packaged and labelled.

- Adequate procedures for the acceptance and control of packaging materials must be in place.

- Labeling operations should prevent mislabelling and ensure proper documentation.
- Validation of packaging processes is required to maintain compliance.
- Inspections should verify adherence to labelling requirements and control systems.

ix. Sampling Procedures During Inspections

Sampling is crucial for identifying CGMP deficiencies during inspections.

- Physical samples should correlate with observed control deficiencies.
- Samples of products with significant therapeutic importance should be prioritized.
- Documentary samples may be collected when they better illustrate deficiencies.
- The presence of significant CGMP problems can be supported by sample analysis.

x. Reporting and Follow-Up Actions

This section describes the reporting process for inspection findings and follow-up actions.

- Critical conditions observed during inspections may prompt immediate discussions for regulatory action.
- Inspection reports must detail systems covered and adverse findings.
- Corrective actions proposed by establishments must be monitored collaboratively.
- Regulatory actions may include recalls, testing programs, or modifications to operations.

3.4 US Food Safety Modernization Act (FSMA)

FSMA is the Food Safety Management Act of US whereas the FSMS is a company specific **risk-based Food Safety Management System** designed to prevent, eliminate, or control food safety hazards. The FSMA is enacted to ensure continuous monitoring and improvement of food handling and processing practices in line with global and local regulatory requirements.

The Food Safety Modernization Act, (FSMA) emphasises on improving capacity to prevent food safety problems, improving capacity to detect and respond to the

food safety problems, improving the safety of imported goods etc. The capacity improvement on food safety problems leverages the hazard analysis and risk-based preventive controls, provides standards for product safety, strategies for protection against international adulteration, national agriculture and food defense strategy, food safety and sanitary policy for transportation and logistics management, food allergy and anaphylaxis control, port shopping, alcohol related policies etc.

The policy on detection and respond to food safety problems constitutes the inspection resources for domestic and foreign facilities, and ports management, laboratory accreditation, integrated consortium of laboratory networks, tracking and tracing of food and recordkeeping, surveillance, mandatory recall, detention of food, decontamination and disposal standards, training and capacity building etc.

The policy related to safety of Imported foods incorporates foreign supplier verification, voluntary qualified importer program, authority to require import certification for foods, prior notice of imported food shipments, building capacity of foreign government with respect to food safety, inspection of foreign food facilities, accreditation of third-party auditors, foreign offices of the foods and drug administration, treatment with smuggled foods, etc.

In addition, the Food Safety Modernization Act, (FSMA) also deals with the funding for food safety, budgetary effects, compliance with international agreements etc. Following are the components of the FSMA:

Component	**Details**
Food Safety Policy	A written commitment by top management toward ensuring food safety.
Hazard Control Plan	Integration of **HACCP** and **PRPs (Pre-Requisite Programs)**.
Documentation & Records	Maintenance of SOPs, checklists, logs, and traceability reports.
Monitoring Mechanisms	Regular checks on temperature, contamination risks, and personal hygiene.
Corrective Actions	Defined steps in case of non-conformance or deviation.
Internal Audits	Periodic reviews of processes to ensure compliance and continual improvement.

The Standards followed under FSMS are prescribed below:

Standard	Scope
ISO 22000	Global FSMS standard integrating HACCP and ISO 9001 principles.
FSSC 22000	GFSI-recognized FSMS for food manufacturers and exporters.
BRCGS Food Safety	Widely used by UK/EU retailers; includes supplier audits.
IFS Food	Focuses on food safety and quality of processes and products.
SQF (Safe Quality Food)	Common in US and Asia-Pacific; retailer-driven standard.

The contents of FSMS in reference to Indian Regulatory Framework

- Mandated by **FSSAI** for all food business operators.
- Large exporters must demonstrate FSMS through:
    - **Third-party audits**
    - **FSMS Plan submission**
    - **Corrective action documentation**
- Inspections by **EIC (Export Inspection Council)** and **APEDA** often require FSMS as proof of food safety commitment.

The FSMS improves compliance with global regulatory bodies and reduces the risk of rejection at importing countries. It builds customer confidence and traceability. Enabling faster customer clearance with the help of pre-certification process the Food Safety Management System governance system to protect and prevent public health effectively. However, the FSMS may further improve its efficiency by implementing appropriate data logging, and integrating the suppliers and third-party control system.

3.5 HACCP AND QUALITY CONTROL FRAMEWORK

The **Hazard Analysis and Critical Control Points (HACCP)** framework is a globally recognized system designed to ensure food safety from production to consumption. For perishable goods, this framework is critical to prevent contamination, spoilage, and regulatory non-compliance during import and export.

HACCP framework is a preventive approach that focuses on identifying, evaluating, and controlling hazards that are significant for food safety. It shifts the focus from end-product testing to proactive control of processes.

a. **The 7 Principles:** The HACCP framework has 7 principles which are described in the tale below:

Principle	Description
1. Conduct Hazard Analysis	Identify potential biological, chemical, and physical hazards in the food chain.
2. Determine Critical Control Points (CCPs)	Identify points where control is essential to prevent or eliminate hazards.
3. Establish Critical Limits	Define acceptable safety thresholds for each CCP (e.g., temperature, pH, time).
4. Monitor CCPs	Set up methods to monitor each CCP regularly.
5. Establish Corrective Actions	Define steps to take when critical limits are breached.
6. Verification Procedures	Ensure the HACCP system is working effectively (e.g., audits, tests).
7. Record-Keeping & Documentation	Maintain documentation for traceability and audits.

b. **Application in perishable Goods Trade:** The are certain pre-requisite conditions which require to be followed. A gist of the conditions are described below:

Sl. No.	Stage	HACCP Application Example
1	**Pre-Harvest**	Water used for irrigation is tested for microbes.
2	**Harvesting**	Use of sanitized tools and gloves.
3	**Storage (Cold Chain)**	Temperature at -18°C for frozen products is monitored and logged.
4	**Transportation**	Vehicles are cleaned, pre-cooled, and validated.
5	**Port/Customs Inspection**	Sample-based inspection at entry points.
6	**Processing/Packaging**	Metal detectors, allergen control, and label verification.

c. HACCP in Indian Export Framework

- The HACCP is Mandatory for Exports of:

- Marine products (MPEDA requirement)
- Processed fruits and vegetables
- Dairy and meat products (EIC certification)

- Implemented under FSSAI's FSMS Guidelines
- Exporters must maintain HACCP documentation and undergo regular audits by third-party agencies or Export Inspection Council (EIC).

d. Integration with Quality Control System:

HACCP is capable to integrate with many broader Quality Management Systems (QMS). Some of the important and standard quality control system which are compatible to integrate with HACCP are given below:

System	Integration
ISO 22000	Combines HACCP with QMS principles.
BRCGS	Includes HACCP, food safety, and supplier audits.
IFS Food	Focuses on process safety and compliance, especially for EU trade.
FSSC 22000	Combines ISO 22000 with sector-specific standards.

e. Challenges in Implementation of HACCP Framework

- Small exporters often lack trained food safety professionals.
- Record-keeping and documentation is not consistent.
- Difficulty in verifying cold chain integrity through third-party logistics.

f. The Best Practices for Exporters:

- Appoint a trained HACCP Team Leader**.**
- Conduct **annual reviews** and **mock recalls**.
- Use digital **temperature loggers** and **monitoring dashboards**.
- Maintain **supplier audit records** and **material traceability**.

3.6 International Plant Protection Convention (IPPC):

IPPC is a 1951 multilateral treaty overseen by the United Nation Food and Agriculture Organization that aims to secure coordinated, effective action to prevent and to control the introduction and spread of Pests of Plants and plant products. The Convention extends beyond the protection of cultivated plants to the protection of natural flora and plant products. It also takes into

consideration both direct and indirect damage by pests, so it includes weeds. IPPC promulgates International Standards for Phytosanitary Measures (ISPMs).

The convention created a governing body consisting of each party, known as the Commission on phytosanitary Measures, which oversees the implementation of convention. As of August, 2017, the convention has 183 parties, being 180 United Nations Members States and the Cook Islands, Niue and EU. The convention protocols and the conditions are recognised by World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures.

- The IPPC provides guidelines for the regulation of plant health and ensures that countries harmonize their plant health regulations to prevent the spread of plant pests and diseases.
- International Standards for Phytosanitary Measures (ISPMs) are standards adopted by the Commission on Phytosanitary Measures (CPM), which is the governing body of the International Plant Protection Convention (IPPC). The first International Standard for Phytosanitary Measures (ISPM) was adopted in 1993.
- As of March 2025, there are 46 adopted ISPMs (ISPM 30 being revoked), 34 Diagnostic Protocols (DPs), 43 Phytosanitary Treatments (PTs) (PT 1, PT 2 and PT 3 being revoked) and 1 Commodity Standard (CS). These international standards:

    a) Protect sustainable agriculture and enhance global food security
    b) Protect the environment, forests and biodiversity
    c) Facilitate economic and trade development

The several International Standards for Phytosanitary Measures (ISPMs) are adopted by the IPPC. A few amongst them are given below:

- English: International standards for phytosanitary measures - ISSN 2521-7232 (Online)
- French: Normes internationales pour les mesures phytosanitaires - ISSN 2521-7275 (Online)
- Spanish: Normas internacionales aprobadas sobre medidas fitosanitarias - ISSN 2521-7283 (Online)
- Chinese: Guójì zhíwù jiǎnyì cuòshī biāozhǔn - ISSN 2521-7291 (Online)

- Arabic: Al-Maʿāyīr al-duwaliyyaẗ li-tadābīr al-ṣ iḥḥaẗ al-nabātiyyaẗ - ISSN 2521-7305 (Online)
- Russian: Meždunarodnye standarty po fitosanitarnym meram 2522-1698 (Online)

The Commission on Phytosanitary Measures of the IPPC has defined in short the aim of IPPC which are produced in following bullet points.

- Protec farmers from economically devastating pest and diseases outbreaks,
- Protec the environment from the loss of species diversity,
- Protect ecosystems from the loss of viability and function as a result of pest invasions,
- Protect industries and consumers from the costs of pest control or eradication,
- Facilitate trade through international standards that regulate the safe movements of plants and plant products,
- Protect livelihoods and food security by preventing the entry and spread of new pests or plant into a country.

3.7 World Organization for Animal Health (WOAH):

The WOAH sets international standards for animal health, ensuring that countries manage animal diseases effectively and reduce the risks of zoonotic diseases.

The WOAH works to improve animal health and welfare worldwide. They do this in several ways. The Organisation monitors the emergence of animal diseases in terrestrial and aquatic animals, either domestic or wild, so they can act before the situation imperils animal health and welfare, public health, or livelihoods. By collecting, analysing, and disseminating veterinary scientific information, through standards, global initiatives, and publications, WOAH collaborates with a wide network of people and has a thorough knowledge base and pool of informative resources. The Organisation also ensures that its Members have the tools and capacity to equip their Veterinary Services and respond to the threats of animal diseases

The WOAH ensures transparency in the global animal diseases situation. The well-structured policies, increased resources to support members, strengthened partnerships and the notification and monitoring of global diseases and shared

information via the organisation's health information system, help us in maintaining a better heath prospects for the animals.

Timely dissemination of information is crucial to contain outbreaks. The world Animal Health Information Database Interface provides access to all data held within WOAH's World animal Health Information System. This interface provides access to immediate notifications on animal disease events, allowing the organisation's members to share follow-up reports in response to exceptional disease events in their countries or territories.

3.8 World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) Agreement:

The World Trade Organization's (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) establishes international rules for food safety and animal and plant health standards. Its purpose is to ensure that member countries' health and safety regulations are scientifically based and not used as disguised protectionist trade barriers.

Key provisions and requirements:

The SPS Agreement balances a government's right to protect its population, animals, and plants with its obligation to avoid unnecessary restrictions on international trade. The core tenets include:

i. **Scientific basis**: All SPS measures must be based on scientific principles and must not be maintained without sufficient scientific evidence. Provisional measures are allowed if evidence is insufficient, but they must be reviewed within a reasonable timeframe.

ii. **Harmonization**: Members are encouraged to base their national measures on international standards developed by specific organizations.

   - **Food safety**: Codex Alimentarius Commission.
   - **Animal health**: World Organisation for Animal Health (WOAH, formerly OIE).
   - **Plant health**: International Plant Protection Convention (IPPC).

iii. **Equivalence**: An importing country must accept the SPS measures of an exporting country as equivalent if the exporting country can demonstrate that its measures achieve the same level of health protection.

iv. **Risk assessment**: Countries must conduct scientific risk assessments to determine their appropriate level of health protection. These assessments must consider available scientific evidence and relevant methods.

v. **Regionalization**: Members must recognize the concepts of pest- or disease-free areas, even if they cover only part of a country or multiple countries.

vi. **Transparency**: Governments are required to notify the WTO of any changes to their SPS measures that could significantly affect trade. They must also establish national "Enquiry Points" to respond to information requests from other members.

vii. **Technical assistance**: Developed countries should provide technical and financial assistance to developing countries to help them implement the agreement.

viii. **Dispute settlement**: If a member believes that another country's SPS measure is unwarranted and consultations fail, the matter can be brought to the WTO's Dispute Settlement Bo

4. Product Specific Compliance and Protocol

International standards and protocols for import and export of temperature sensitive cargos are derived to ensure safety, quality, fairness, and efficiency in the global market. They are primarily governed by frameworks set by the World Trade Organization (WTO), particularly **Sanitary and Phytosanitary (SPS)** and **Technical Barriers to Trade (TBT)** Agreements, which mandate that national/international regulations should be reliable, science-based, transparent, and non-discriminatory. These frameworks are implemented through specialized international bodies:

a) **For Food Safety (e.g., fruits, vegetables, meat, seafood):** The **Codex Alimentarius Commission** sets standards for contaminants, pesticide residues, and hygiene.

b) **For Plant Health (e.g., plants, flowers, wood):** The **International Plant Protection Convention (IPPC)** governs phytosanitary measures to prevent pest spread.

c) **For Animal Health (e.g., live animals, meat):** The **World Organisation for Animal Health (WOAH)** sets health standards to manage disease risks.

d) **For Product Quality & Safety:** The **International Organization for Standardization (ISO)** develops thousands of voluntary standards for quality, safety, and efficiency.

Key common protocols across sectors include certification (e.g., Phytosanitary, Veterinary, or Certificate of Origin), conformity assessment to ensure products meet standards, and accurate labeling and packaging.

For sensitive goods like pharmaceuticals and perishable foods, stringent protocols like **Good Manufacturing Practices (GMP)**, **cold chain management**, and **track-and-trace serialization** are critical.

Adherence to these standards is essential for market access, minimizing trade disputes, and protecting consumers and the environment worldwide.

Here, we are discussing the standards and protocols derived internationally for specific sectors and commodities under following 4 categories:

Sector	Description	HSN
Sector 1	Meat, poultry and sea foods	0201-0206, 0301-0306 and 0401 - 0406
Sector 2	Plants, flowers, vegetables and fruits	0601-0604, 0701-0714, 0801-0814
Sector 3	Bakery products	1905
Sector 4	Pharmaceuticals	3001-3006

4.1 Sector-1: International Standards and Protocols for import and export of Meat, Poultry and Seafoods:

The international trade of meat, poultry, and seafood is governed by a combination of global agreements, international standards, and region-specific protocols (such as those in the EU, US, GCC, China, and Japan). At the foundation lies the WTO-SPS Agreement (Sanitary and Phytosanitary Measures), which requires that food

safety and animal/plant health regulations in trade be based on scientific risk assessments. Complementing this, the Codex Alimentarius, developed jointly by the FAO and WHO, provides universally accepted food safety and hygiene standards, including microbiological limits, contaminants, and additives, that are frequently referenced in WTO dispute resolutions.

In parallel, the World Organisation for Animal Health (OIE) has prescribed international health standards for import and export of animals, offering guidance on disease-free status, certification, and traceability.

The Food Safety Management Systems, such as HACCP, ISO 22000, BRC, and IFS, which are widely mandated to manage risks from production to distribution (ISO, 2018) are in centre. Certification and documentation are also critical, including veterinary or health certificates, catch certificates for wild-caught seafood to prevent illegal, unreported, and unregulated (IUU) fishing, and Halal or Kosher certifications where required by importing countries (FAO, 2022).
Packaging and labelling standards must comply with destination-country regulations, covering lot numbers, country of origin, storage conditions, and processing dates (Codex Alimentarius, 2023). Maintaining cold chain integrity is another essential requirement, with continuous monitoring of transport temperatures to preserve product safety and quality (FAO/WHO, 2021). Finally, sustainability and traceability certifications such as MSC (Marine Stewardship Council), ASC (Aquaculture Stewardship Council), and Global G.A.P. are increasingly demanded by global buyers, reflecting the growing emphasis on responsible sourcing and transparent supply chains (MSC, 2024; ASC, 2024; Global G.A.P., 2023).

a. Meat & Poultry (HSN 0201–0210)

i. **Key Protocols:**

- Compliance with the Veterinary Health Certificates of the Exporting Country in confirmation with the provisions of the importing country.
- **Slaughtering facilities** must follow HACCP (Hazard Analysis and Critical Control Points), Good Manufacturing Practices (GMP), and Good Hygiene Practices (GHP).
- Testing for **pathogens** (Salmonella, E. coli O157:H7, Campylobacter, Listeria monocytogenes).
- Residue monitoring for **antibiotics, hormones, pesticides, heavy metals**.

- **Animal welfare standards** during slaughter (as per OIE).

ii. Regional Protocols:

- **EU:** Strict compliance with **Regulation (EC) 853/2004** and **Official Controls Regulation (EU) 2017/625**.
- **USDA-FSIS:** Equivalence determination for foreign establishments; mandatory HACCP.
- **GCC countries:** Require **Halal certification** under approved Islamic boards.

Few key technical and procedural standards for meat and poultry trade, with some illustrative examples.

Domain	**Key Requirements / Protocols**
Veterinary health certification	Exporting countries must issue a **veterinary (health) certificate** attesting that the meat/poultry complies with disease and residue standards of the importing country.
Disease-free status/zoning/ regionalization	Certain diseases may restrict trade; OIE provides **risk categories** (negligible, controlled, undetermined) and conditions for trade from regions.
Slaughter & processing standards / food safety systems	Facilities must use Hazard Analysis & Critical Control Points (HACCP), Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP). Pathogen testing (e.g. Salmonella, E. coli) is standard.
Residue and contaminant limits	Monitoring for antibiotics, hormones, pesticides, heavy metals (lead, cadmium, etc.). The importing country often specifies maximum residue limits (MRLs).
Animal welfare	Transport, handling, stunning, slaughter must meet acceptable animal welfare standards. Many markets or private buyers demand compliance with OIE welfare codes or equivalent standards.
Inspection and certification systems	National inspection agencies must have robust systems to inspect, certify, and regulate export establishments. Equivalence agreements between countries allow reliance on each other's inspection systems.
Traceability / labelling / packaging	Each lot must be traceable to the origin (farm, slaughterhouse). Labels must comply with origin, lot, production date, expiry, handling instructions.

b. Seafood (HSN 0301–0308)

i. **Key Protocols:**

- Compliance with **HACCP for seafood** (mandatory for US, EU, Japan).
- Monitoring of **biotoxins, histamine, heavy metals (mercury, cadmium), veterinary drug residues**.
- Certification of **disease-free aquaculture zones** (e.g., free from White Spot Syndrome Virus, EMS, etc.).
- Implementation of **traceability systems** from harvest to export.
- **Temperature controls** (frozen products at –18°C or below; chilled products at 0–4°C).

ii. **Regional Protocols:**

- **EU:** Regulation (EC) 854/2004 and 2073/2005 (microbiological criteria).
- **US FDA:** Seafood HACCP (21 CFR 123).
- **China:** Requires registration of foreign seafood traders with GACC (General Administration of Customs China).
- **Japan:** Ministry of Health, Labour and Welfare (MHLW) oversees strict monitoring for residues and contaminants.

Further, Seafood has its own additional concerns (toxins, parasites, aquaculture diseases, temperature control). Below are the main standard categories.

Domain	Key Requirements / Protocols
Codex Code of Practice for Fish and Fishery Products	A globally accepted code giving best practices for handling, processing, storage, and transport to ensure safety.
Seafood HACCP	Many importing countries require seafood processors to implement HACCP systems (identifying hazards, critical control points).
Monitoring toxins, biotoxins, histamine	For species susceptible to histamine (scombroid fish), or shellfish toxins (e.g. paralytic shellfish toxin), routine testing is required.
Residue / contaminant testing	Heavy metals (like mercury, cadmium), chemical residues, antibiotics in aquaculture.
Health / export certification	Traders must obtain health certificates for seafood exports, often issued by national seafood inspection authorities (e.g. NOAA in the U.S.).

Temperature / cold chain control	Frozen fish must be held at ≤ –18 °C, chilled fish 0–4 °C (or per regulatory spec). Traceability through cold chain is essential.

4.2 Sector-2: Standards and Protocols for import and Export of Flowers, Plants, Vegetable and Fruits:

The international trade of vegetables, fruits, plants, and flowers operates within a structured global framework, designed to facilitate market access while safeguarding human, animal, and plant health. This system is anchored by the World Trade Organization's **Sanitary and Phytosanitary (SPS) Agreement**, which mandates that national health measures must be science-based, transparent, and non-discriminatory. A core principle of this agreement is the use of international standards to harmonize regulations across borders.

These international standards are primarily set by two key bodies. For all **food safety** aspects, including pesticide residues, contaminants, and microbiological hazards, the benchmarks are established by the **Codex Alimentarius Commission** (FAO/WHO).

Simultaneously, for **plant health (phytosanitary)** measures aimed at controlling the cross-border spread of pests, the governing authority is the **International Plant Protection Convention (IPPC)**, which publishes detailed International Standards for Phytosanitary Measures (ISPMs).

To successfully implement this framework, importers/exporters must adhere to the sequence of common international requirements, which begin at the production stage. This includes implementing **residue monitoring** programs to ensure compliance with Codex-defined Maximum Residue Limits (MRLs) and often involves meeting voluntary **sustainability standards** (e.g., GLOBAL G.A.P., Organic) demanded by many buyers. Other compliances like **packaging and labelling standards**, indicating the details such as botanical name, origin, and treatment history are important. The critical pre-shipment step is obtaining an official **Phytosanitary Certificate** from the national plant protection authority, certifying the consignment is pest-free. Finally, for the entire logistics chain, maintaining unbroken **cold chain integrity** is paramount to preserve the quality and safety of these perishable products until they reach the end consumer.

a. **Vegetables and Fruits:**

- **Key Protocols:**
    - Must meet **Maximum Residue Limits** (**MRLs)** of Pesticides (Codex or importing country's stricter levels, e.g., EU).
    - **Phytosanitary Certificates** issued by National Plant Protection Organizations (NPPOs).
    - Inspection for pests and diseases (fruit flies, fungi, bacteria).
    - Cold treatment or irradiation required for some fruits to control pests.
    - Compliance with **Good Agricultural Practices (GAP)** – e.g., GLOBALG.A.P. certification.
- **Regional Protocols:**
    - **EU:** Plant health regulation (EU) 2016/2031; pesticide limits (Regulation EC 396/2005).
    - **US:** USDA-APHIS requires phytosanitary certification, pest treatment, and FDA inspection.
    - **Japan:** MAFF quarantine inspection for pests.
    - **GCC:** Halal-compliant packaging and strict MRL checks.

b. **Plants and Flowers:**

- **Key Protocols:**
    - Must be accompanied by **phytosanitary certificates**.
    - Inspections for **quarantine pests** (e.g., nematodes, fungi, viruses).
    - Requirements for **soil-free plants** (soil can carry pests).
    - Quarantine treatment methods: fumigation, hot water treatment, irradiation.
    - Restrictions on importing endangered species (CITES-listed ornamental plants).
- **Regional Protocols:**
    - **EU:** Strict plant passport system under Regulation (EU) 2016/2031.
    - **US:** USDA-APHIS Plant Protection and Quarantine (PPQ) program.
    - **Japan & Korea:** Quarantine inspection at entry ports.
    - **Middle East:** NPPO-based certification + adherence to local pest risk analysis.

4.3 Sector-3: Standards and Protocols for Import and Export of Bakery Products:

The international trade of bakery products is governed by a combination of WTO rules, Codex Alimentarius standards, and region-specific regulations.

Under the World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) Agreement, all food safety measures must be science-based, transparent, and non-discriminatory. Countries are allowed to impose restrictions to protect human health, but such measures must be justified.

The primary international standards for food safety are set by the Codex Alimentarius Commission (CAC), established by the FAO and WHO. The CAC provides a comprehensive set of international food standards that cover all aspects of food safety, including pesticide residues, contaminants, and microbiological hazards, ensuring that bakery products meet globally recognized benchmarks for quality and safety. Relevant standards for bakery products include:

- **Codex Stan 243-2003**: General Standard for Bakery Products
- **Codex Stan 192-1995**: Food Labeling
- **Codex Guidelines on Food Additives** Covers **ingredients, labeling, hygiene, and food safety**.

Regional regulations further govern the trade of bakery products in specific markets. In the European Union (EU), bakery products are regulated under Regulation (EC) No 178/2002, known as the General Food Law, along with specific regulations tailored to bakery goods.

In the United States, the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) oversee bakery products under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Code of Federal Regulations.

Similarly, in the Gulf Cooperation Council (GCC) countries, bakery and confectionery products must comply with the Gulf Standards Organization (GSO) standards, ensuring product safety, quality, and proper labelling.

2. Key International Standards for Bakery Products

Area	Standard / Requirement	Description
Ingredients	Codex Alimentarius	Permitted additives, preservatives, sweeteners, and emulsifiers.

Microbiological Safety	CAC/ISO 22000	Limits on pathogens like Salmonella, Bacillus cereus, molds, and yeast.
Allergens	Codex Stan 1-1985	Mandatory labelling of allergens: wheat, gluten, milk, nuts, soy, eggs.
Labeling	Codex Stan 1-1985 & local laws	Product name, ingredients, net weight, expiration date, storage instructions, nutrition facts.
Packaging	ISO 9001 / ISO 22000	Must protect against contamination, moisture, and spoilage during transport.
Shelf Life & Storage	HACCP / Codex Guidelines	Guidelines for temperature, humidity, and packaging to maintain quality.

Health and Safety Protocols

i. **HACCP (Hazard Analysis & Critical Control Points)**

a. Mandatory for most exports to EU, US, and GCC.

b. Focus on **contamination prevention, critical limits, monitoring, and corrective actions**.

ii. **ISO 22000 / FSSC 22000**

a. Food safety management systems widely recognized for international trade.

iii. **Residue & Contaminant Testing**

- Testing for **pesticides, heavy metals, and mycotoxins**.
- Some countries require **certificate of analysis (CoA)**.

4.4 Sector-4: Standards and Protocols for import and Export of Pharmaceuticals:

The international trade of pharmaceuticals is subject to stringent and multi-layered regulation due to its direct impact on human health and life. The foundational framework is provided by the World Trade Organization, whose **Sanitary and Phytosanitary (SPS) Agreement** ensures that health protection measures are science-based and non-discriminatory, while the **Technical Barriers to Trade (TBT) Agreement** governs technical regulations concerning quality standards, labelling, and packaging.

Operating within this framework, the **World Health Organization (WHO)** plays a critical role in establishing global guidelines for Good Manufacturing Practices (GMP) and quality control, further ensuring the safety of medicines through its Prequalification of Medicines Programme.

Complementing these standards and frameworks, the **International Council for Harmonization (ICH)** also play pivotal role in harmonizing scientific and technical requirements across major regions like the European Union, the United States, and Japan, thereby streamlining the development and registration of safe, effective, and high-quality pharmaceuticals for international markets.

2. Key International Standards

Area	Standard / Guideline	Description	Reference
Regulatory Framework	WTO SPS & TBT Agreements	Ensures all regulations are science-based, transparent, and non-discriminatory while allowing health protection measures.	WTO SPS Agreement
Good Manufacturing Practices (GMP)	WHO GMP, ICH Q7, EU GMP, US cGMP	Ensures pharmaceutical manufacturing is consistent, controlled, and meets quality standards.	WHO GMP
Quality Control	ISO 9001, ISO 13485	Covers testing, validation, and documentation of pharmaceutical products.	ISO9001 Standards
Clinical Trials & Safety	ICH E6(R3)	Guidelines for Good Clinical Practice to ensure safety, efficacy, and ethical compliance.	ICH Guidelines
Packaging & Labeling	EU Directive 2001/83/EC, FDA CFR Title 21	Requirements for tamper-proof packaging, labelling, and traceability.	EMA Guidelines
Pharmacovigilance	ICH E2, WHO Guidelines	Monitoring adverse drug reactions post-marketing.	WHO Pharmacovigilance

Regional Regulations - EU	EMA Directive 2001/83/EC	Strict requirements for GMP compliance, clinical trial approvals, and pharmacovigilance.	EMA
Regional Regulations - USA	FDA FFDCA & 21 CFR Parts 210–211	Ensures safety, labelling compliance, and approval before import/export.	FDA Pharmaceutical Regulations
Regional Regulations - GCC	GSO Pharmaceutical Standards	Requires GMP certification, registration, and Arabic labelling.	GSO Standards
Transport & Distribution	IATA Good Distribution Practices (GDP)	Guidelines for cold chain logistics, tamper-proof packaging	

3. Regional Regulations

1. **European Union (EU)**
    - Regulated by the European Medicines Agency (EMA) under **Directive 2001/83/EC**.
    - Emphasis on GMP compliance, clinical trial approvals, and pharmacovigilance in view of EMA.
2. **United States (FDA)**
    - Regulated under **Federal Food, Drug, and Cosmetic Act (FFDCA)** and **21 CFR Parts 210–211** for GMP.
    - FDA ensures safety, labelling compliance, and approval before import/export. Ref. FDA Pharmaceutical Regulations.)
3. **Gulf Cooperation Council (GCC)**
    - Compliance with Gulf Standard Organization (GSO) guidelines for pharmaceutical products.
    - Requires GMP certification, registration, and labelling in Arabic.

4. Health and Safety Protocols

- **GMP Certification** is mandatory for international trade.
- **Batch Testing and Quality Control** for contaminants, potency, and sterility.
- **Cold Chain Management** for temperature-sensitive drugs.

- **Pharmacovigilance Reporting** for exported medicines.

4.5 Key CCODEX Standards relevant to Perishables:

Codex Code	Coverage
CXS 193-1995	General standard for contaminants and toxins in food
CXS 234-1999	Recommended microbiological criteria for food
CXS 1-1985	General labelling of pre-packaged foods
CXS 198-1995	Pesticide residue limits
CXS 79-1981	Hygiene code for meat, fish, dairy, and fresh produce

4.6 Key EU Food Safety Regulations:

Regulation	Description
EC No. 178/2002	Lays down general principles and requirements of food law, establishing the **European Food Safety Authority (EFSA)**.
Regulation EC No. 852/2004	Covers food hygiene practices across the supply chain.
Regulation EC No. 853/2004	Specific hygiene rules for food of animal origin.
Regulation EC No. 396/2005	Sets **Maximum Residue Limits (MRLs)** for pesticides.
Regulation EC No. 1333/2008	Governs the use of food additives.

4.7 Key US Regulatory Frameworks:

Regulation	Key Provisions
FSMA (2011)	Introduces **Preventive Controls**, **Foreign Supplier Verification Program (FSVP)**, and **Sanitary Transportation Rule**.
21 CFR Part 1	Regulations on registration of food facilities and prior notice of

Regulation	Key Provisions
	imported food.
Bioterrorism Act (2002)	Requires prior notice and recordkeeping of food shipments.
FDA Import Alerts	Allows automatic detention of goods violating FDA standards.

5. The Best Practices of the Regulatory Frameworks

To appreciate the impacts of these Regulatory Frameworks, we need to find out the processes and protocols which have brought transformative changes in the world trade of temperature sensitive cargo. Some of the important processes are described below:

5.1 The Track and Trace Framework

The Track and Trace Framework is very crucial in food safety and international trade management. The US Temperature Sensitive Cargo and Drugs Track and Trace system and EU-wide Traceability system are the paradigms for a better control and management system of temperature sensitive cargo.

Track and Trace Framework mandates that manufacturers, re-packagers, wholesale distributors or dispensers of any product using an electronic system may track and trace the ***location, legitimacy, and history of a product*** at the package level. The electronic system enables the trading partners and the enforcement agencies to rapidly trace the location and history of the product. By placing a patchwork/ instrument on the packing/container, a signalling system establishes nationwide network for tracking.

The supply chain actors including enforcement agency may verify the suspected product by determining availability of the Product Identifier (PI) affixed upon the packages by manufacturer or re-packager. The PI may include the standardized numerical identifier (SNI), lot number and expiration date of the product or any other information as the enforcement agency required.

Technical features:

i. **Unique identifiers (UIs)**

- Every unit packet of the product is marked with a unique identifier, for the tracking and recording of the product's movement throughout the supply chain, from the manufacturer to the last economic operator before the retail outlet.
- The relevant economic operators involved in the manufacturing, trading of the product are required to record the movement of these packets throughout the supply chain and transmit the related information to the system.
- An independent entity ("ID issuer platform") is appointed for maintaining system, generating and issuing the UIs and capturing subsequent data received during movement of the product.
- The data associated with each such products, including where it was manufactured, shipped, and stored etc., is linked to its unique identifier (using blockchain). For this purpose a specific dynamic update system (like dynamic QR Code/dynamic barcode) enabled with a *link content update system*, *track and traceability, and risk based interdiction* etc. are used.

ii. **Independent data storage**

- The UIs data and the product movement related data from every operator, handling the product, are transmitted to the independent platform handling platform with blockchain.
- The independent data processing, storage and management system protects the data integrity from manipulation by any industry/supplier.
- The data is made accessible to the enforcement agencies and the supplier of commodities depending upon the policy and uses.
- MISs and artificial intelligence based analytics, risk based inspection strategy and tracking and traceability of product are provided by the system.

iii. **Security features system**

- The system requires that each unit packet of product carries a security feature that includes at least five types of authentication elements.
- These elements are a mix of overt, covert, and semi-covert technologies.
- The independent third party, who manages the platform, provides at least one of these security elements (thread) with a view to ensure the system identifier product integrity.
- These security features enable authorities to verify the authenticity of products, history of product, quality and legitimacy of the product.

iv. **Data management and access**

- The system is based on an international standard, fostering innovation and interoperability.
- It provides authorities with unprecedented, real-time visibility over the entire product supply chain.
- Data is managed in a way that allows for validation and control at every step of the supply chain.
- The high-quality, structured data collected online helps enforcement authorities identify illegal sales activities and other irregularities.

v. **Actors and infrastructure**

- The system involved a large-scale technical rollout, including registration for over half a million economic operators and over a million facilities.
- Information Technology provider maintains various sets of technology and components, such as scanners, cloud-based reporting solutions, blockchain to handle the entire process.
- Appropriate training and annual audit of the performance required to ensure the continued integrity of the system.

5.2 Quality Grading Systems

Quality grading is an **essential component of the inspection process** for perishable goods at the port. It standardizes product expectations, ensures consistency, and supports regulatory compliance. Grading systems are typically based on physical characteristics, maturity, defect levels, and overall product condition.

The purpose of quality grading is multi-faceted: it ensures uniform product classification across markets thereby reducing classification issues, enhances marketability (as higher-grade products command better pricing), supports documentation and inspection needs for regulatory compliance, based on risk assessment.

Indian Grading System (AGMARK) In India, the AGMARK certification, administered by the Directorate of Marketing and Inspection (DMI) under the Ministry of Agriculture, governs quality grading. Grades range from Grade I (superior quality, defect-free) to Grade II (good quality with minor acceptable defects), Grade III (average quality, usable but lower shelf life), and "Below Standard" for products failing minimum quality norms. This system applies to various products, including fruits, vegetables, spices, dairy, and cereals.

International Grading Standards International grading standards vary by region. The USA (USDA) uses grades like Extra Fancy, Fancy, No. 1, and No. 2. The

EU (UNECE) employs Extra Class, Class I, and Class II. Codex Alimentarius provides product-specific descriptors, while the Middle East (Gulf Standards Org - GSO) uses custom country-specific classifications.

Packaging and labelling must reflect the assigned grade, with grade-marked stickers or printed labels matching the invoice, inspection certificate, and import/export documentation. This will help in better understanding of the products and faster clearances at the port. Training port manpower with FSSAI and APEDA grading standards, integrating grading with cold chain logistics, and adopting blockchain-based traceability for high-value perishables is a desirable factor.

5.3 Maintain Product Integrity in Extreme Climates

The frigid and very high temperatures can damage temperature-sensitive shipments. To ensure the integrity of shipment in extreme climates, temperature-controlled shipping and storage are essential; these controls ensure that products will never get exposed to too hot or too cold temperature. This is the purpose of cold chain logistics: ensuring that shipments are always being transported or stored in temperature-controlled environments, especially under the acceptable temperature range.

In most of the circumstances, the space where shipment is to be transferred must be pre-cooled (or pre-heated). Additionally, steps are taken to ensure that goods are transferred quickly from area to another area avoiding unacceptable temperature deviations.

Further, temperature monitoring devices come in several forms, including data loggers, wireless sensors, probe thermometer, strip chart recorder etc. These sensors transmit data via Wi-Fi, LoRaWAN, or other protocols and the data is then displayed via real-time monitoring software. The data logger provides the history of supply chain and the duration for which the expected temperature range was not met, so as to examine whether the authenticity of the product integrity is maintained or not. Further, temperature sensors and alarm system are also installed for sensing and alarming the irregularity in maintaining ambient temperature of shipment.

5.4 Effective Packaging and Storage Solutions:

The packaging of the shipment of temperature-sensitive goods are specific and appropriate to the nature of product. Packaging may include:

- Cooling agents/Thermal barrier Solutions
- Absorbent materials
- Leak-proof bags or boxes
- Insulation

- Biotech materials
- Passive Packaging Systems with gel-packs or other coolants
- Cryogenic materials
- Hybrid materials.

Ideally, businesses should opt for reusable packaging. Temperature-sensitive shipments are necessarily more expensive than their non-temperature-sensitive counterparts. Each product has unique feature and that is why they need very specific packaging.

5.5 Regulatory Compliance and Quality Control:

Meeting the regulatory benchmarks is not sufficient, the product owner should be able to prove that the product is meeting the benchmarks and the supplier is able to produce the documentary evidences of such quality control (like temperature data loggers, packing standards etc.). Sometimes the regulatory standards of a state or province may be contradictory to national standards, which creates a labyrinth of complex situation to navigate.

Therefore, it is very essential to understand and meet the standards of packaging, transportation, storage, temperature control etc. for every jurisdiction.

5.6 World Health Organization (WHO)

Safe storage and distribution of time and temperature-sensitive pharmaceutical products (TTSPPs). Following are the best practices:

- **Port of entry handling:** Recommends that TTSPPs be imported through specialized ports to minimize time spent on the tarmac or dock, with immediate transfer to a temperature-controlled environment.
- **Customs clearance:** Encourages pre-clearance or the use of customs agents with expertise in handling pharmaceuticals to avoid delays that could cause temperature excursions.
- **Warehouse design:** Stipulates that storage facilities should be purpose-built or adapted for TTSPPs, with features like climate control, backup power, and dedicated quarantine areas for compromised products.
- **Continuous monitoring:** Requires the use of calibrated continuous temperature and humidity monitoring systems with alarm functions to alert personnel of any excursions.

5.7 International Air Transport Association (IATA)

Emphasis on safe and compliant air transport for temperature-controlled air freight, especially pharmaceuticals. The best practices are given below:

- **Temperature Control Regulations (TCR):** Provides step-by-step guidance on packaging, labelling, and documentation to meet mandatory regulations.
- **Dedicated label:** Mandates the "Time and Temperature Sensitive Label" to ensure cargo is handled correctly by all parties in the supply chain.
- **Auditing and certification:** Developed the Center of Excellence for Independent Validators in Pharmaceutical Logistics (CEIV Pharma) to audit and certify supply chain partners who exceed baseline regulations.
- **Risk mitigation:** Compiles scientific data from airlines to develop standards that mitigate the risk of damage and product loss.

5.8 U.S. Food and Drug Administration (FDA)

Emphasis is on ensuring the safety and efficacy of pharmaceuticals and the safety of foods that are time/temperature-controlled for safety (TCS). The best practices are as under:

- **Temperature controls:** Requires food facilities to implement temperature controls as part of a written food safety plan under the Food Safety Modernization Act (FSMA).
- **Electronic records:** Under 21 CFR Part 11, temperature monitoring systems for pharmaceuticals must use secure electronic records with validated audit trails.
- **Safe temperature zones:** Establishes specific temperature limits for different products, such as 2°C to 8°C for many vaccines and a "Temperature Danger Zone" (41°F–135°F) for food.
- **Proper handling procedures:** Specifies cooling methods for food, such as using shallow pans or ice water baths, to minimize time in the danger zone.

- **Risk-based inspection and recall**: US FDA has implemented inspection system basis the risks and also risk based recalling of consignments breaching the standards.
- **Track and Trace system:** Track and Trace System transmit and store data pertaining to supply chain of the product and ensure product integrity.

5.9 European Union (EU) Good Distribution Practice (GDP)

- **Emphasis:** Quality assurance throughout the distribution process for medicinal products.
- **Best Practices:**
    - **Quality system:** Requires a comprehensive, documented, and implemented quality system that includes risk management, training, and handling procedures.
    - **Temperature mapping:** Mandates that storage areas be temperature-mapped under representative conditions, including seasonal variations, to confirm temperature homogeneity.
    - **Validated equipment:** Specifies the use of validated equipment, including temperature-controlled containers and vehicles, for transporting temperature-sensitive products.
    - **Documentation:** Requires full traceability of products and temperature records to be available for review by a Qualified Person (QP), who is responsible for certifying materials.

5.10 Cross-cutting best practices

Beyond the regulations of specific bodies, several practices are consistently emphasized across all major systems:

- **Thorough risk assessment:** Evaluating the supply chain to identify and control critical points and potential hazards, from origin to final destination.

- **Validation and qualification:** Prequalifying shipping containers and other equipment under standard, highly-controlled conditions, and then validating the entire process under simulated or actual transport conditions.
- **Advanced packaging and monitoring:** Using both active (refrigeration units) and passive (insulation, gel packs, dry ice) systems, paired with real-time temperature tracking via IoT sensors and data loggers.
- **Personnel training:** Ensuring all staff involved in handling temperature-sensitive goods are specifically trained on cold chain requirements and proper procedures.
- **Clear documentation:** Maintaining accurate, accessible records of transport, monitoring, and any temperature excursions to ensure traceability and compliance.
- **Contingency planning:** Having robust plans in place for power outages, equipment failures, or other supply chain disruptions to protect product integrity.

CHAPTER – 4

Clearance Process of Import and Export goods in India Stringent Norms, Product Integrity and Quality Management,

1. Customs Clearance Process:

The perishable cargos are shipped through freight forwarded declaring the details of shipment along with the handling conditions needed for perishable cargo. They also provide the copy of the permits etc. obtained from the govt. agencies enforcing particular regulations in which the commodity is covered in addition to the marking, labelling and documents etc.

The carrier of the cargo (shipping lines/airlines etc.) examine and communicate the discrepancies if any that can impact the load, safety of the crew, aircraft, ship etc. or health of the employees. They also ensure the time line of the delivery of goods at destination port, suitable space allotted to the perishable cargo, prioritisation of cargo offload and handing over to custodian etc. They also check whether shipper has handed over appropriate permits, necessary documents and have ensured that all the security measures including the customs procedures have been met.

1.1 Import:

Import of the temperature sensitive cargo takes place through Airports, Sea Ports, ICDs/CFSs and Land Customs Stations. Import through ICDs/CFSs engages additional processes and stakeholders and takes more time in transit from gateway port to the destination port, it poses more challenges for imports of temperature sensitive cargo. The carrier of cargo (airlines/shipping lines or vehicle in-charge) files IGM/Import Report in which details of the goods, supplier, importer, port of loading and port of destination etc. are contained.

Where goods are destined to ICDs/CFSs from the ports or are imported by other country through Indian Ports, Customs allow transhipment/transit under appropriate transhipment bond/transit bond and clearance process takes place at the port of destination or in the other country as the case may be.

Once goods are arrived at the port of clearance, and IGM (Cargo Manifest) is filed online, the importers have the option to clear the goods for home consumption after payment of the duties leviable or to clear them for warehousing without

immediate discharge of the duties leviable in terms of the warehousing provisions under the Customs Act. For clearance of the goods, every importer is required to file in terms of the Section 46 an entry (which is called Bill of Entry) for home consumption or warehousing on EDI System, along with the documents. The list of such documents required in different types of the imports are given below:

- Invoice
- Packing list
- Bill of Lading or Delivery Order/Airway Bill
- GATT declaration form duly filled in
- Importers/CHA's declaration
- Licenses/permits/certificates, wherever necessary
- Letter of Credit/Bank Draft/wherever necessary
- Insurance document
- Import license
- Industrial License, if required
- Test report in case of chemicals, wherever applicable
- Ad hoc exemption order, wherever applicable
- DEEC Book/DEPB
- Catalogue, Technical write up, Literature in case of machineries, spares or chemicals as may be applicable
- Separately split up value of spares, components machineries
- Certificate of Origin, if preferential rate of duty is claimed
- No Commission declaration etc.

In the self-assessment process, the Bills of Entry after filling, are processed by the ICES system and then RMS system picks up the file and assesses the risk and the Regulatory Compliance requirements. The BE having no risk are assessed by the system for payment of duty and OOC. The Risky BEs are diverted to assessment and examination etc. with the instruction to examine inter-alia the compliance of the CCRs.

Simultaneously, ICES also selects the BE and forwarded to the PGA for testing/permission. The BE pertaining to Temperature Sensitive cargos are transmitted to the concern PGAs like food item to FSSAI, Fruits, Plant etc. to Plant Quarantine department, Pharmaceutical to ADC etc. On receipt of such test reports/permission and after examination/assessment of the consignment as the case may be, the importers are required to make payment and OOC is given for clearance.

The temperature sensitive cargo are mostly consumable goods and therefore, there are stringent norms related to product integrity, quality assurance and compliance requirements. Therefore, they are mandatorily required testing and certification, whether they are fit for human consumption, have permissible limit of chemicals,

pesticides etc. used in their production. To fast track clearance, Direct Port Delivery, Auto-OOC, RMS facilitation system etc. are functional in EDI System of Customs.

1.2 Export:

For clearance of export goods, the export or his agents have to undertake a registration in EDI System. The exporters obtain PAN based Business Identification Number(BIN) from the Directorate General of Foreign Trade prior to filing of shipping bill for clearance of export goods. Under the EDI System, PAN based BIN is received by the Customs System from the DGFT online. The exporters are also required to register authorised foreign exchange dealer code (through which export proceeds are expected to be realised) and open a current account in the designated bank for credit of any drawback incentive.

Whenever a new Airline, Shipping Line, Steamer Agent, port or airport comes into operation, they are required to be registered into the Customs EDI System. All the exporters intending to export under the export promotion scheme need to get their licences/DEEC book etc. registered at the Customs Station. For such registration, original documents are required.

Processing of Shipping Bill-Non-EDI start with filing of the SB under self-declaration process along with other relevant documents and permissions/certification, if any. RMS process the documents filed by the exporter and assigns the risks and Compulsory Compliance Requirements. The export in addition to declaring all the facts of export clearly, also selects the scheme under which SB is filed like free SB, DBK SB, Advance Authorisation SB etc. The Export Goods are brought to the port and registration of the goods arrived at the port is completed. Once, the shipping bill is passed by the Export Department, the exporter or his agent present the goods to the shed appraiser (export) in docks for examination, if required. The shed appraiser may mark the document to a Custom officer (usually an examiner) for examining the goods. The examination is carried out under the supervision of the shed appraiser (export). If the description and other particulars of the goods are found to be as declared, the shed appraiser gives a 'let export' order, after which the exporter may contact the preventive superintendent for supervising the loading of goods on to the vessel/aircraft.

In case any discrepancy is found, they may mark the shipping bill back to export appraising group with their observations as well as sample of goods, if needed. The export department re-considers the case and decide whether export can be

allowed, or amendment in description, value etc. is required before export and whether any other action is required to be taken under the Customs Act, 1962 for mis-declaration of description of value etc.

For export items which are subject to export cess, the TR-6 challans for cess is generated by EDI System once SB is processed from groups and clearance is likely to be given. Online payment system is available at EDI.

Where, there are permission to export certain limited quantity of goods, the quota allocation label is required to be pasted on the export invoice. The allocation number of AEPC is to be entered in the system at the time of shipping bill entry. The query status and query reply etc. are also online at EDI System.

In case where misdeclaration is found and goods are found to be liable for confiscation (after investigation/testing of the representative samples/market enquiry etc.), the competent officer adjudicate the case following the principles of natural justice and impose fine and penalty if offences are proved. The export goods once redeemed in lieu of payment of redemption fine, the same may either be sent back to town or may be allowed for export.

Once Let Export Order (LEO) is given by the competent authority, the goods are handed over to the steamer agent/airlines/ICD Custodian as the case may be for loading of the goods and export. The in charge of vessel/train/aircraft after loading of the export goods file an Export General Manifest incorporating the details of all the goods being export through the vessel/aircraft/train/truck etc.

Once export is made successfully, and train summery/EGM etc. are filed by the in charge of vessel/aircraft/career, the SB is moved to the DBK/Licence queue for disbursement of the export incentives/IGST refund etc.

2. Partner Govt. Agencies (PGAs):

The Customs Clearance Process of the imports and Exports of the temperature sensitive cargo are managed with the help of several Departments/Authorities in India. There are several regulatory provisions to manage the quality, product integrity and standards of the products imported from outside and exported from India to other countries. Though, most of those regulatory frameworks are aligned with the norms prescribed by international agencies like World Health Organization (WHO), UN Food and Agriculture Organization (FAO) etc., the requirements of the domestic industries and the law of the land has also been taken care of. There are several Agencies

empowered to regulate and maintain the stringent norms of the temperature sensitive cargos on their imports and export. A combination of national and international regulations are framed to govern the imports and exports of such cargos in India. Key regulatory bodies are given below:
UN Food and Agriculture Organization and the World Health Organization

i. The Food Safety and Standards Authority of India (FSSAI)
ii. The Directorate General of Foreign Trade (DGFT)
iii. The Plant Quarantine Management System (PQMS)
iv. The Agricultural and Processed Food Products Export Development Authority (APEDA)
v. Merin product Export Development Authority (MPEDA)
vi. Export Promotion Councils (EPC)
vii. National Dairy Development Board (NDDB)

The regulatory framework for imports and exports of the temperature sensitive cargo are derived from indigenous sources as well as from the international regulations. A gist of such regulatory provisions are given below:

2.1 Food Safety and Standard Authority of India

The Food Safety and Standards Act, 2006: This Act consolidates the laws relating to food and to establish the Food Safety and Standards Authority of India for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, etc. to ensure availability of safe and wholesome food for human consumption and for matters connected therewith or incidental thereto.

a. The basic responsibility of the FSSAI is to lays down standards for food articles, covering aspects like microbiological, chemical, physical, and nutritional content;

b. It issues Food Business Licenses to the companies ensuring the compliances with safety norms,

c. FSSAI administers strictly the regulations on food packaging and labelling including mandatory declaration of ingredients, nutritional information and health claims to inform consumers.

d. FSSAI regulates the import of foods item into India through safety and quality checks at ports, through online import clearance system.

e. It mandates the testing norms and process, and ensures that the testing is done through accredited laboratories so as to ensure accurate and reliable results.

f. Another important role of FSSAI is to enforce with the help of State Food Safety Authorities the provisions of the Act, through inspections and penalties for non-compliance.

The regulation on Food Products Standards and Food Additives is primarily responsible for ensuring standards of food products whereas majority of food products used in the day-to-day life are covered therein.

However, there are specialized regulations which take care of standards for special verticals such as Alcohol, Nutraceuticals, Infant Nutrition, Organic Food, Fortified Food, Vegan Food and Ayurveda Aahara. (List-I). The products which are not defined in Standards falls under Proprietary Food Products which are covered vide Clause 2.12 of the Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011.

All these food products whether standard or proprietary, together they fall under various categories from category 1-18 under Appendix-A of the regulation. There are specific set of regulations which are equally applicable to every Standard and Proprietary product with respect to safety norms such as regulation on Prohibition and Restriction, regulations on Contaminants and Toxins and Appendix-B to Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011. These are considered as vertical parameters. (List-II). In addition to the horizontal and vertical parameters labelling, packaging and acclaims are important in nature for importation of food products. These regulations directly address to the need of an informed consumer. (List-III). In total, there are 22 regulations and one Rule issued under Food Safety and Standards Act 2006 and a set of rules i.e., The Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011. Put together they create a concept eco-system for Food Safety and Standards of food.

A risk-based approach to food import clearance is a globally preferred method that focuses inspection resources on products with the highest potential for harm, instead of the less efficient 100% checks of all shipments. The decision to inspect a

consignment is based on a risk profile that considers factors such as the product type, country of origin, importer's compliance history, and port of entry. High-risk consignments are subjected to more rigorous inspection, in comparison to the low-risk goods. The other Regulations governed by the FSSAI are given below:

List-I

i. Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011 • Food Safety and Standards (Alcoholic Beverages) Regulation, 2018
ii. Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016
iii. Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020
iv. Food Safety and Standards (Organic Food) Regulation, 2017
v. Food Safety and Standards (Fortification of Food) Regulation, 2018
vi. Food Safety and Standards (Vegan Foods) Regulations, 2022
vii. Food Safety and Standards (Ayurveda Aahara) Regulations, 2022

List II

i. Food Safety and Standards (Prohibition and Restriction of Sales) Regulation, 2011
ii. Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011
iii. Appendix B Microbial Requirements under Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011

List III

i. Food Safety and Standards (Advertising and Claims) Regulation, 2018
ii. Food Safety and Standards (Labelling and Display) Regulations, 2020
iii. Food Safety and Standards (Packaging) Regulation, 2018

2.2 CITES

The Convention on international Trade in Endangered Species of Wild Fauna and Flora (CITES) is a forum which regulates international trade of wild animal and plant species, including their parts and products, through a series of permits and

certificates. Shipping of live plants and animals takes additional rules and regulations to ensure their safe transports.

2.3 The Directorate General of Foreign Trade (DGFT):

The Directorate General of Foreign Trade (DGFT) regulates perishable cargo by setting import/export policies, issuing necessary licenses for restricted items, and establishing procedures to ensure compliance with international standards and to prevent the spread of pests or diseases. While the DGFT is the primary body for policy and licensing, it also works with other agencies, like customs, to oversee the actual movement of goods and to enforce regulations concerning the quality and safety of perishables. Major role of DGFT are specified below:

b) Policy formulation:

The DGFT develops and implements the Foreign Trade Policy, which includes provisions for regulating the import and export of various goods, including perishables.

c) Licensing and authorization:

DGFT issues licenses, authorisations, and registrations required for importing or exporting certain goods, including those that are restricted or prohibited. This is crucial for perishables to ensure they meet quality standards and do not pose a health risk.

d) Compliance and enforcement:

The DGFT ensures that all export and import activities comply with national and international trade regulations and standards.

e) Issue Export Licenses for Restricted Items

Under the Export Policy, items classified as restricted can be exported with a license issued by DGFT. Exporters can apply for these licenses online through the DGFT's website.

2.4 The Plant Quarantine Management System:

Plant quarantine Management System facilitates Importers to apply online for Import Permit, Import Release Order and Exporters to apply online for Phyto-sanitary Certificate. Automation of background workflow processes has resulted in speedy processing of these applications saving time and workload. The Import (Plant Quarantine Order) and Exports (Export inspection and certification

procedure) are the regulatory frameworks which provides has made the reference to these documents easy for Importers and Exporters.

The regulatory framework for plant quarantine in India is primarily governed by the Destructive Insects & Pests Act, 1914 and the Plant Quarantine (Regulation of Import into India) Order, 2003. This system aims to prevent the introduction and spread of pests that could harm India's agriculture and environment by regulating the import and export of plants and plant products. Key aspects include pest risk analysis, import/export inspection, issuing phytosanitary certificates, and domestic quarantine measures. The above regulatory measures are regulated by the Directorate of Plant Protection, Quarantine and Storage (DPPQS).

The Key functions of the PPQ are pest risk analysis (PRA), Import Inspection and Certification, Export Inspection and Certification, Domestic Quarantine, and post-entry Quarantine. The Indian Plant Quarantine activities particularly, the export certification are aligned with International Plant Protection Convention (IPPC) and World Trade Organisation's Sanitary and Phytosanitary (SPS) Agreement.

2.5 Animal Quarantine:

The regulatory framework for animal quarantine in India is primarily governed by the Livestock Importation Act of 1898 and its amendments. The Animal Quarantine and Certification Services (AQCS), functioning under the Department of Animal Husbandry, Dairying & Fisheries (DAHDF), is the key authority for implementing these regulations for both import and export.

Primary legislation and amendments

- **Livestock Importation Act, 1898:** This central law forms the foundation for regulating the import of livestock and livestock products to prevent the entry of infectious and contagious animal diseases into India.
- **Livestock Importation (Amendment) Act, 2001:** This amendment brought livestock products, such as meat, milk, semen, and embryos, under the purview of the original act, giving the central government the power to regulate, restrict, or prohibit their import.

- **Notifications and Orders:** The central government frequently issues notifications under the Act to update the specific regulations, including procedures for importing particular animals and products.

Key agencies and permissions

- **Animal Quarantine and Certification Services (AQCS):** The AQCS is responsible for enforcing the laws and issuing the necessary permits and certificates. It has stations at major airports and seaports in cities like Delhi, Mumbai, Kolkata, Chennai, Hyderabad, and Bengaluru.
- **Sanitary Import Permit (SIP):** For most livestock products, a Sanitary Import Permit (SIP) from the DAHDF is mandatory and is granted based on an import risk analysis.
- **No Objection Certificate (NOC):** An NOC from the AQCS is required for the import and export of live animals and is issued in advance of shipping.

The functions of animal quarantine in India cover both imports and exports to protect national animal and human health and facilitate international trade.

Import functions

- **Preventing exotic diseases:** This is the primary objective of animal quarantine. It serves as India's "defense force" against the ingress of dangerous animal diseases like anthrax and glanders through the import of livestock, products, and microorganisms.
- **Risk analysis:** Before issuing permits, AQCS authorities conduct a detailed import risk analysis based on scientific principles and the disease status of the exporting country. This helps determine if the import poses a threat to India's animal and human populations.
- **Inspection and testing**: At the port of entry, AQCS officials inspect consignments and take samples for testing in designated laboratories, such as the National Institute of High Security Animal Disease (NIHSAD) in Bhopal, to ensure they are disease-free.
- **Quarantine detention**: Imported live animals are held for a prescribed observation and testing period at a government quarantine station. This is

a critical step for detecting pathogens that may not be apparent at first glance.

- **Handling infected consignments**: If any imported livestock or products are found to be infected or pose a threat, the AQCS has the authority to order their deportation, re-export, or destruction at the importer's expense.
- **Regulation enforcement**: AQCS works with Customs authorities to ensure that all livestock and products are referred for quarantine clearance and that the regulations are effectively implemented.

Export functions

- **International certification**: AQCS provides internationally recognized certification services for Indian livestock and livestock products. This is essential for meeting the health requirements of importing countries and adhering to global standards set by organizations like the World Organisation for Animal Health (OIE).
- **Pre-shipment control**: For exports, AQCS carries out pre-shipment quality control. Officials conduct physical examinations and quarantine observations to ensure animals are healthy and fit for travel.
- **Meeting importer requirements**: The export certification process is tailored to meet the specific health protocols and requirements of the destination country, which can include particular tests, vaccinations, or treatments.
- **Export facility registration**: AQCS also inspects and registers plants and mills that export animal by-products to ensure they meet the required international standards.

2.6 The Agricultural and Processed Food Products Export Development Authority (APEDA)

The apex body of the Agricultural and Processed Food Products Export Development Authority (APEDA) is involved in regulating the export of agricultural and processed food products since last three decades. The majority of the functions of the organization comes from the power specified under Section 10 of the APEDA Act 1986.

There are other functions which flow from the foreign trade policy from time to time. In addition Government has also given responsibilities to discharge various other requirements of regulations.

The following functions has been assigned to the authority as per Section 10 of the APEDA Act 1986.

i. Development of industries relating to the scheduled products for export by way of providing financial assistance or otherwise for undertaking surveys and feasibility studies, participation in equity capital through joint ventures and other reliefs and subsidy schemes;

ii. Registration of persons as exporters of the scheduled products on payment of such fees as may be prescribed;

iii. Fixing of standards and specifications for the scheduled products for the purpose of exports;

iv. Carrying out inspection of meat and meat products in slaughter houses, processing plants, storage premises, conveyances or other places where such products are kept or handled for the purpose of ensuring the quality of such products;

v. Improving of packaging of the Scheduled products;

vi. Improving of marketing of the Scheduled products outside India;

vii. Promotion of export oriented production and development of the Scheduled products;

viii. Collection of statistics from the owners of factories or establishments engaged in the production, processing, packaging, marketing or export of the scheduled products or from such other persons as may be prescribed on any matter relating to the scheduled products and publication of the statistics so collected or of any portions thereof or extracts there from;

Further, following functions have been assigned to the authority as per section 10 A of the APEDA Act. 1986:

Without prejudice to any law for the time being in force, it shall be the duty of the Authority to undertake, by such measures as may be prescribed by the

Central government for registration and protection of the Intellectual Property rights in respect of Special products in India or Outside India.

Some functions are also assigned to the authority under Foreign Trade Policy (FTP) which are specified below:

i. Registration of contract for export of Basmati Rice. (Sl. No. 57 Chapter 10 of Schedule 2 of ITC (HS)

ii. Registration of contract for import of Sugar. (ITC (HS) Import Policy 2017 for Chapter 17).

iii. Registration of contract for export of organic pulses (Notification No 03/ 2015-2020 dated 19th April 2017)

iv. Issuance of Certificate of Exports for export of Peanut and Peanut Products. (Notification No. 28 (RE 2012)/2009-2014 dated 3rd January, 2013)

v. Allocation of TRQ for export of raw sugar to USA. Conditions for export of sugar to USA under TRQ (DGFT Notification No 3/2015-2020 dated April 20, 2015.).

vi. APEDA has been identified as the secretariat for the National Programme for Organic and it performs the lead role for promotion of export of organically grown agro-products. (Public Notice No 19(RE-2001)/1997-2002 dated 11.6.2001). APEDA serves as secretariat to National Steering Committee, National Accreditation Body and APEDA does the accreditation of the Certification Bodies.

vii. DGFT vide Public Notice No.24/2015-20 dated 1.9.2017 has authorized APEDA to issue GSP Certificate and Non Preferential Certificate of Origin under Appendix-2C and 2E of FTP 2015-2020. APEDA is also authorized to issue Certificate of Origin (COO) for Asia Pacific Trade Agreement (APTA) and SAARC Preferential Trade Agreement (SAPTA).

viii. The National Programme for Organic Production (NPOP) is being implemented by the Ministry of Commerce & Industry for exports under the Foreign Trade Development Regulations (FTDR) Act since October 2001. APEDA functions as the Secretariat for implementation of the NPOP (NPOP chapter 2, clause 2.3 (d).

Other functions assigned by Government APEDA has been entrusted with the following additional responsibly apart from the mandate given to the organization:

i. SPS notifications : DoC vide their letter No. 14/6/2009-TPD dated 28th April 2009, has entrusted APEDA the task of dealing with SPS notifications relating to all agriculture commodities for various countries. The major tasks entrusted were to download the SPS notifications, to disseminate the identified SPS Notifications, English translation of original notification, to examine the comments received from the stakeholders and prepare a comprehensive response from Indian side, list out the possible trade restrictive issues which need to be raised and submission of a quarterly report to DOC.

ii. Non-Tariff Barriers (NTB): APEDA address following Non-Tariff Barriers (NTB) including SPS to get market access for all agri products.

2.7 Marine product Export Development Authority (MPEDA)

The Marine Products Export Development Authority (MPEDA) was set up by the MPEDA Act, 1972 by the Parliament. The erstwhile Marine Products Export Promotion Council established by the Government of India in September, 1961 was converged into MPEDA on 24th August, 1972. The Marine Products Export Development Authority under the Ministry of Commerce and Industry is a statutory body entrusted with the primary task of promotion of export of marine products.

The headquarters of MPEDA is in Kochi, Kerala headed by the Chairman. MPEDA has been serving the Marine Products Export sector for the past 50 years. In order to reach out to the exporters in different parts of the Country, MPEDA has set up 18 – Regional/Sub Regional Divisions/Desk offices at Veraval, Porbandar, Valsad, Mumbai, Mangalore, Nagapatinam, Kochi, Tuticorin, Chennai, Vijayawada, Hyderabad, Bhimavaram, Visakhapatnam, Bhubaneswar, Kolkata, Guwahati, Kawarathi & Port Blair.

MPEDA has Trade Promotion offices at New Delhi, Tokyo and New York. MPEDA has set up five full-fledged Quality Control Laboratories, at Kochi (Kerala), Nellore & Bhimavaram (Andhra Pradesh), Bhubaneshwar (Odisha) and Porbandar (Gujarat). In addition, fifteen ELISA Screening Laboratories set up by MPEDA in the maritime states.

The MPEDA Act, 1972, assigns the following functions to the Authority:

i. It shall be the duty of the Authority to promote, by such measures as it thinks fit, the development under the control of the Central Government of the marine products industry with special reference to exports.

ii. Without prejudice to the generality of the provisions of sub-section (1), the measures referred to therein may provide for:

a. Developing and regulating off-shore and deep-sea fishing and undertaking measures for the conservation and management of off-shore and deep-sea fisheries;

b. Registering fishing vessels, processing plants or storage premises for marine products and conveyances used for the transport of marine products;

c. Fixing of standards and specifications for marine products for purposes of export;

d. Rendering of financial or other assistance to owners of fishing vessels engaged in off-shore and deep-sea fishing and owners of processing plants or storage premises for marine products and conveyances used for the transport of marine products, and acting as an agency for such relief and subsidy schemes as may be entrusted to the Authority;

e. Carrying out inspection of marine products in any fishing vessel, processing plant, storage premises, conveyance or other places where such products are kept or handled, for the purpose of ensuring the quality of such products;

f. Regulating the export of marine products;

g. Improving the marketing of marine products outside India;

h. Registering of exporters of marine products on payment of such fees as may be prescribed;

i. Collecting statistics from persons engaged in the catching of fish or other marine products, owners of processing plants or storage premises for marine products, or conveyances used for the transport

of marine products, exporters of such products and such other persons as may be prescribed on any matter relating to the marine products industry and the publishing of statistics so collected, or portions thereof or extracts there from;

j. Training in various aspects of the marine products industry; and

2.8 National Dairy Development Board (NDDB)

National Dairy Development Board was constituted under National Dairy Development Board Act, 1987. The NDDB is one of the main channelizing agency for the export and import of dairy products and milch animals. It facilitates the import and export of dairy products by developing the domestic dairy sector's infrastructure, improving product quality to meet international standards, and advising producer-owned institutions on marketing and branding. For imports, its role involves managing the import of essential dairy commodities and milch animals as needed, often to bridge supply gaps.

Role in export

- **Infrastructure and quality:**

  The NDDB focuses on building a robust domestic dairy industry, which is a prerequisite for exports. This includes supporting milk cooperatives and modernizing processing and marketing infrastructure.

- **Quality assurance:**

  It assists in developing quality standards and ensures products meet export requirements, which is crucial for competing in the international market.

- **Market development:**
  The NDDB advises producer-owned institutions on marketing and branding, helping them improve their business operations and capture a larger market share, including export markets.

Role in import

- **Channelizing agency:**

  The NDDB is the designated agency for managing the import of dairy products and milch animals into India.

- **Bridging supply gaps:**

  It imports products and animals when there is a domestic supply deficit, ensuring the availability of necessary commodities.

- **Policy support:**
  It uses its market intelligence and analysis to provide insights for policy decisions related to dairy imports

2.9 Central Drugs Standard Control Organization/ADC For pharmaceutical products

To ensure the safety and efficacy of the drugs being exported from India or importer into India, the role of Additional Drug Controller (ADC) is very crucial. The Additional Drug Controller is a regulatory authority under the Central Drugs Standard Control Organization, under the regulatory framework governed by the following legislation:

- **Drugs and Cosmetics Act, 1940:** The foundational law that regulates the import, manufacture, distribution, and sale of drugs and cosmetics.
- **Drugs and Cosmetics Rules, 1945:** Provides the specific rules for implementing the Act.
- **Narcotics and Psychotropic Substances Act, 1985:** Controls the import and export of controlled substances.

The primary function of the Additional Drugs Controller in respect to the import and export of pharmaceutical products is to examine and issue No-Objection Certificate (NOC) in case the drugs imported or being exported are maintaining the efficacy of the drugs law. This is mandatory for any entity wishing to import or export pharmaceutical products.

Import functions:

1. **Ensuring the propriety of formulation contents etc:** ADCs examine the documents pertaining to the formulation, use and contents of the pharmaceutical products, in relation to the permissible limits of the contents in India and ensures that the drugs are imported in compliance of Drugs law prevailing in India.
2. **Sample analysis:** ADCs draw samples from imported drug consignments to send to government laboratories for testing. If a sample from a specific batch has already been tested and approved, samples are not required for subsequent imports of the same batch.

3. **Dual-use items:** They grant NOCs for "dual-use" items, which have both pharmaceutical and industrial applications. However, simpler procedures exist for importers who declare the items are not pharmaceutical-grade or intended for medicinal use.
4. **Personal use permits:** ADCs grant permission for the import of small quantities of drugs for personal use.

Export functions

- **Issuing the NOC:** The ADC grants an NOC for each specific pharmaceutical consignment to be exported. This certificate is valid for six months.
- **Enforcing compliance:** The ADC ensures that exported drugs meet the standards of the Drugs and Cosmetics Act.
- **Record-keeping:** ADCs maintain data on imports and exports and forward monthly and quarterly reports to senior officials at CDSCO.
- **Coordination with customs:** They work with customs authorities to verify export shipping bills and manage the clearance process.
- **Handling special cases:** For exports of unapproved or banned drugs, the manufacturer must obtain an export-specific NOC from the CDSCO's zonal or sub-zonal offices. The manufacturer must provide a valid export order and prove that no part of the consignment will be sold domestically.

3 Pre-Shipment Inspection of Export Consignment:

APEDA (Agricultural and Processed Food Products Export Development Authority, Marine Products Export Development Authority, Export Inspection Agency or NDDB Certified labs, Animal Quarantine and Certification Services, Spices Board of India, etc. are the Pre-Shipment Agencies who do the pre-shipment exports goods inspection and certification.

The export/import cycle of perishable goods, designed to ensure that products meet the importing country's regulatory, safety, and quality standards before they leave the country of origin. Some countries mandate PSI by independent approved agencies before cargo loading or stuffing. The primary objectives of PSI include preventing rejection at destination ports due to non-compliance, certifying quality, safety, and packaging conformity, minimizing risks of product spoilage or

deterioration in transit, ensuring traceability and documentation completeness, and fulfilling mandatory requirements of the importing/exporting country.

Mandatory Pre-Shipment Inspection is done by the specific agencies are authorized for PSI across different product categories:

Product Category	Authorized Inspection Agency
Fresh Fruits & Vegetables	APEDA (Agricultural and Processed Food Products Export Development Authority)
Marine Products	MPEDA (Marine Products Export Development Authority)
Dairy Products	EIA (Export Inspection Agency) or NDDB-certified labs
Meat & Poultry	AQCS (Animal Quarantine & Certification Services)
Spices	Spices Board of India
Veterinary Doctor	Raw and frozen Meat except Cow meat.

These bodies operate under their respective ministries or the Directorate General of Foreign Trade (DGFT).

Key activities during PSI involve visual inspection for defects, sampling and laboratory tests for microbiological, chemical, and pesticide levels, packaging and label review for compliance, cold chain verification using temperature loggers, and seal verification under customs or QA agency supervision. PSI is typically conducted 24–72 hours before dispatch, with most certificates valid for 7–14 days depending on the product and import country. To enable speedy Customs clearance, a valid Pre-Shipment Certificate from an approved agency, incorporating all required details, is essential. The certifying agencies shall involve Customs officials at certain stages of PSI so that real time monitoring and data flow prevails and the consignment does not take much of a clearance time. The custodians can be guided to facilitate PSI activities by creating dedicated inspection area for the agencies at the port itself.

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Chapter – 5

Compliance Paradigms: Inspection, Examination and Testing

The temperature sensitive commodities are mostly consumables and therefore, the quality, product integrity, packing materials, contamination limit, restricted chemical limits etc. become more important to upkeep with all the stringent norms and parameters. Therefore, testing, examination, inspection etc. becomes important at pre-clearance level. Any breach in product integrity or quality standards may have serious health issue for the public at large. Therefore, this chapter is dedicated on basics of the examination, testing etc.

1. Risk based Interdiction:

To extend trade facilitation, minimise dwell time in customs clearance and optimize resource allocation risk-based interdiction in customs is strategized based on the data analytics, general intelligence, profiling and risk assessment. The high risk cargos are identified for inspection, examination and testing. This approach allows customs and other partner government agencies to efficiently maintain compliance management of temperature sensitive cargo without creating much ado to the processes and stringent norms.

Since high-risk shipments are targeted, the enforcement agencies cope up with handling the threats of non-compliance, smuggling, trafficking and national security with optimum number of resources. Simultaneously, low risk and compliant shipments are cleared faster without delay, saving their quality and product integrity. Departments get opportunity to focus more on illicit goods crossing the boarders. Data driven automated processes of selecting high risk consignment reduces the potential arbitrary and corrupt practices.

Risk-based interdiction replaces the outdated practice of physically inspecting every shipment with a more targeted and effective approach. The process relies on these key components:

- **Data collection and analysis**: Customs and other govt. agencies gather and analyse extensive data from customs declarations, intelligence reports, and trade patterns to find anomalies and indications of suspicious behaviour.
- **Risk criteria and profiling**: Customs defines a set of selectivity criteria to determine risk levels for different shipments. Examples of criteria include:

- **Commodity type:** Certain items, such as pharmaceuticals, chemicals, or electronics, may be considered higher risk.
- **Country of origin or transit**: Goods coming from or through high-risk countries may be subject to closer scrutiny.
- **Importer/Exporter Profile and history**: The track record of the exporter or importer, including past violations, can affect their risk profile.
- **Documentation errors**: Incomplete or inaccurate paperwork can be a red flag for further examination.
- **Customs Broker Profile**: Some customs brokers are also known for undertaking non-compliance and corrupt practices.

Using the data, system may calculate the risk and score on the basis of predefined algorithms set forth under the risk rules for selection of suitable non-compliant consignments. The Compulsory Compliance Requirements (CCRs) under RMS system are also derived through the above mention processes.

The policy and administrative wing of Customs and PGAs decides the treatment of the low-risk, medium-risk and high-risk consignments. The low-risk consignments are facilitated through green channel, medium-risk shipments may undergo document verification and physical inspection etc. and high-risk consignments are flagged for intensive assessment, examination and testing etc.

2. Sampling Techniques for Perishables:

Sampling is a critical step in the quality inspection process for both imports and exports of perishable goods. Accurate and standardized sampling ensures a representative quality evaluation, aids in regulatory compliance, and minimizes rejection risks at the border.

The primary objective of sampling is to ensure that the lot meets regulatory and quality specifications, detect the presence of contaminants, spoilage, or non-compliance, validate claims regarding grading, freshness, or processing, and provide a defensible sample for laboratory analysis or dispute resolution.

Effective sampling adheres to several core principles:

- **Representativeness:** Samples must accurately reflect the entire batch or consignment.

- **Randomization:** Statistically valid methods should be used for random selection to avoid bias.
- **Quantity:** The amount/quantity sample should be enough to test the required parameters.
- **Integrity:** The chain of custody must be maintained and contamination prevented by properly sealing the samples.
- **Documentation:** Comprehensive records are essential, including sample source, time, temperature, lot number, and handler identity.
- **Timeliness:** The delay between sampling and analysis should be minimized to preserve sample integrity.

Various tools are employed for proper sampling, including sampling spoons, corers, knives, sterile swabs, scoops, polyethylene/sterile sample bags, cool boxes, gel packs for transport, digital sampling labels, and tamper-proof seals.

Challenges in sampling are also important aspect to handle. Some common problems face in sampling are given below:

a. Lack of skilled samplers,
b. Inadequate documentations,
c. Temperature abuse during transit, and
d. Disputes over sample validity,

These challenges can be mitigated through training and certification programs of the customs, adequate infrastructure, digital sampling apps, insulated transport and storage by the custodians and transporters, and adherence to standardized protocols. Samples should be kept at the same temp and quality controls for maintaining the integrity of the testing.

3. Packaging and Labelling Norms

Proper packaging and labelling are paramount for preserving the quality, safety, and regulatory compliance of perishable goods throughout their import and export journey. These elements serve to protect against physical damage, microbial contamination, and temperature variations, while also enabling traceability and regulatory checks.

Packaging Standards for Perishable Goods: Recommended packaging types vary by product category to ensure optimal protection:

Product Category	Recommended Packaging Type	Purpose
Fruits & Vegetables	Corrugated fibreboard boxes, ventilated crates	Air circulation, shock resistance
Seafood	Insulated boxes with gel packs/ice bricks	Temperature maintenance, hygiene
Meat & Poultry	Vacuum-sealed plastic pouches, EPS boxes	Extend shelf life, prevent leakage
Dairy Products	Food-grade plastic containers, Tetra packs	Microbial protection, spillage control
Frozen Goods	Rigid containers, shrink wrap with cold gels	Integrity under freezing conditions

Labelling Guidelines for International Trade: Labels for perishable goods must be clear and durable, and it should comply with standards set by FSSAI, Codex, and WTO. Accurate information and proper packaging will facilitate the custom officials for faster examination and clearance. Further, the officials must be aware of the special packaging requirements of such cargo and must ensure proper care while examination.

Cold Chain Compatibility: Packaging must actively support temperature control throughout all transit stages. This involves the use of thermal insulation (e.g., foil linings, ice gel packs), ensuring containers are stackable and can withstand condensation during thawing, and confirming that materials are non-toxic and compliant with food-grade standards (e.g., BIS IS: 10146 for polyethylene).

Common Non-Compliance Issues: Non-compliance issues, such as incomplete or illegible labels, absence of expiry/manufacture dates, use of banned packaging materials, or poor sealing, can lead to customs clearance delays, rejection or recall of goods, unnecessary examinations and testing, regulatory penalties, spoilage of cargo, re-export costs, and increased microbial load or spillage.

4. Compliance Landscape to be looked by the Customs

We have studied about the examinations and certifications being one of the most important aspect in perishable cargo clearance. However, it is important to understand the various parameters and regulatory compliances based on which such examinations are conducted. We need to understand the regulatory framework governing the import/export of temperature sensitive cargo. The effective management of temperature-sensitive cargo at ICDs is underpinned by a

complex regulatory framework involving multiple government agencies (PGAs). These bodies collectively ensure that perishable goods meet national and international standards for safety, quality, and trade compliance. The recent trade agreements with various countries like UAE, Australia and the ongoing trade negotiations with the USA necessitates strict compliances with the international standards of safety.

Common checkpoints at the port

Checkpoint	**Purpose**
Document Verification	Match shipping documents with declared product and origin
Seal Integrity Check	Confirm no tampering has occurred during transit
Random Sampling	Test for microbial load, pesticides, heavy metals, additives
Temperature Check	Verify cold chain was maintained with loggers or thermometers
Labelling& Barcode Validation	Ensure compliance with destination market labelling standards

The clearance process for perishable cargo involves a **"many-to-one"** relationship, where numerous distinct regulatory bodies (PGAs) interact with Customs. While digital integration with Customs systems has been implemented for several of these agencies, the sheer volume of individual touchpoints and the sequential nature of approvals can create significant bottlenecks. E.g. for the import of medicines, NOC is required from Drug Controller. After such approval, if there is doubt in its fitness for human consumption, the goods are sent for testing in FSSAI.

Thus, this sequential approval creates unnecessary delays and will impact the quality of the goods. Further, even if one PGA's system experiences a delay, or if manual intervention is required for specific conditions, the entire consignment clearance can be held up. This complexity means that achieving true efficiency requires more than just digital integration; it demands deep process harmonization and potentially a unified decision-making authority or highly synchronized parallel workflows for perishables, rather than a series of sequential approvals.

The current setup, despite its digital advancements, often involves sequential handoffs that add considerable time, which is particularly detrimental for temperature-sensitive goods. Integrating ICEGATE with the PGA's system (like FSSAI) will considerably reduce the manual process time. Also, parallel approvals/testing/NOC from various agencies can be initiated in the system itself, so as to reduce the TAT for customs clearances.

A critical, and often unaddressed, infrastructure gap exists within the PGAs' own operations. For example, both FSSAI and AQCS explicitly mandate that "goods are kept at suitable temperature and the examination are conducted in a temperature controlled environment, the samples are drawn and forwarded under temperature controlled containers and FSSAI keeps the samples and test them in a similar eco system". This is not merely a general cold chain requirement for the cargo's movement and safety, but a specific, mandated design of inter-operability process within the PGAs' domain for examination, sampling, and testing. If the PGAs themselves lack the necessary temperature-controlled environment for these critical steps, the integrity of the sample and the overall quality of the goods can be compromised, regardless of how well the cargo was maintained prior to arrival at the CFS/ICD.

This highlights the imperative for **investment not only in general cold storage at ICDs but, more specifically, in dedicated temperature-controlled examination zones within the ICDs for use by Customs and PGAs.** Furthermore, it underscores the need for temperature-controlled sample transport and adequately equipped laboratory facilities for the PGAs to ensure the validity and reliability of their tests. This is a crucial, yet often overlooked, infrastructure component that directly impacts the reliability and speed of clearance. Major ports can also have a dedicated and trained staff for coordinating with the PGAs along with proper handling of the cargo. Responsibilities must be fixed for any lapses.

5. Role of PGAs in Inspection and Pre-Shipment Inspection Requirements:

PGAs play an important role in the inspection of goods by conducting the testing of goods and certifying the quality based on the established standards. It also ensured proper labelling has been mentioned in the packages.

Pre-shipment inspection (PSI) is a crucial stage in the export/import cycle of perishable goods, designed to ensure that products meet the importing country's regulatory, safety, and quality standards before they leave the country of origin.

Some countries mandate PSI by independent approved agencies before cargo loading or stuffing. The primary objectives of PSI include preventing rejection at destination ports due to non-compliance, certifying quality, safety, and packaging conformity, minimizing risks of product spoilage or deterioration in transit, ensuring traceability and documentation completeness, and fulfilling mandatory requirements of the importing/exporting country.

Mandatory Pre-Shipment Inspection Agencies: Specific agencies are authorized for PSI across different product categories:

Product Category	Authorized Inspection Agency
Fresh Fruits & Vegetables	APEDA (Agricultural and Processed Food Products Export Development Authority)
Marine Products	MPEDA (Marine Products Export Development Authority)
Dairy Products	EIA (Export Inspection Agency) or NDDB-certified labs
Meat & Poultry	AQCS (Animal Quarantine & Certification Services)
Spices	Spices Board of India

These bodies operate under their respective ministries or the Directorate General of Foreign Trade (DGFT).

Key activities during PSI involve visual inspection for defects, sampling and laboratory tests for microbiological, chemical, and pesticide levels, packaging and label review for compliance, cold chain verification using temperature loggers, and seal verification under customs or QA agency supervision. PSI is typically conducted 24–72 hours before dispatch, with most certificates valid for 7–14 days depending on the product and import country. To enable speedy Customs clearance, a valid Pre-Shipment Certificate from an approved agency, incorporating all required details, is essential. The certifying agencies shall involve Customs officials at certain stages of PSI so that real time monitoring and data flow prevails and the consignment does not take much of a clearance time. The custodians can be guided to facilitate PSI activities by creating dedicated inspection area for the agencies at the port itself.

6. Inspection/Examination Parameters for Perishable Items by the Customs

Inspection and examination forms a major part in clearance of perishable cargo at ports. Majority of delays and damage to the cargo occurs during the examination

process of the customs. It is therefore necessary to have a robust, standardised and streamlined procedure for temperature sensitive cargo.

6.1 Port Inspection Procedures:

Port inspections represent the final checkpoint for perishable goods before their entry (for imports) or exit (for exports) from a country. These inspections are vital to ensure that only safe, compliant, and quality-assured goods are permitted to pass through ports.

The primary objectives of port inspection include preventing the entry or exit of contaminated or substandard perishables, verifying documentation and product integrity, protecting national food safety and biosecurity, and enforcing compliance with regulations from FSSAI, Plant Quarantine (PQ), Customs, other Partner Government Agencies, and international norms. Several key authorities are involved in port inspections:

- **FSSAI Port Officers:** Responsible for food safety clearance, sampling, and coordinating laboratory tests.
- **Customs Department:** Handles clearance after documentation review, duty payment, and physical inspections.
- **Animal & Plant Quarantine:** Conducts inspections specifically for meat, dairy, fruits, and vegetables.
- **Port Health Officer (PHO):** Performs health inspections, particularly for seafood, dairy, and packaged food.
- **EIA or MPEDA (for exports):** Provides final quality and compliance certification for exported goods.

Common checkpoints at the port include document verification (matching shipping documents with declared product and origin), seal integrity checks (confirming no tampering), random sampling (testing for microbial load, pesticides, heavy metals, additives), temperature checks (verifying cold chain maintenance), and labelling & barcode validation (ensuring compliance with destination market standards).

Required documents at the port include the Bill of Entry (for imports), Shipping Bill (for exports), Health Certificate, Phytosanitary Certificate, Invoice & Packing List, FSSAI Import License, Test Reports from Accredited Labs, and Pre-Shipment Inspection Certificate.

Sampling protocols adhere to specific norms, with sample size determined by FSSAI Manual or Codex Guidelines, typical lab testing time averaging 72 hours (with urgent options), and results valid only for that specific lot/shipment. Clearance outcomes can be a "Pass" (product cleared), "Conditional Clearance" (allowed under supervision or requiring remedial action), or "Rejection" (goods detained, destroyed, or re-exported). The final decision for clearance, destruction, or re-export of perishable goods rests with Customs, contingent on the fulfilment of applicable compliance protocols.

Effective and efficient inspection of sensitive cargo involves better knowledge of the cargo, good quality testing tools, efficient sampling techniques and better decision making. Various factors which make the inspection process of the customs efficient while handling temperature sensitive cargo are discussed below.

6.2 Key Inspection Parameters and testing tools:

When handling the import and export of perishable goods, several endorsements are necessary, including the modality to examine temperature sensitive goods for legal compliance, inspection to ensure their condition, temperature safety, and the quality of goods within appropriate ecosystems. Inspections are conducted based on standardized parameters that may vary depending on the specific commodity within the perishable category.

6.3 General Inspection Parameters for Perishables:

The following table outlines common inspection parameters and their descriptions:

Inspection Parameter	Description
Visual Quality	Checks for spoilage, bruising, colour, cuts, mould, decay.
Temperature	Core product and container temperature, must align with storage norms.
Packaging Integrity	Packaging must be undamaged, sealed, and meet material regulations.
Labelling Compliance	Product name, net weight, expiry date, storage instruction, origin country.
Odour Check	No sour or foul smell (especially in dairy, seafood, meat).
Pest Infestation	No signs of insects, larvae, or contamination.

6.4 Testing Methods and Tools:

Various methods and tools are employed for accurate inspection:

Method	Usage
Infrared Thermometer	For surface temperature check.
Data Loggers	Monitor temperature during transit.
Gas Chromatography (GC)	Used for pesticide and contaminant detection.
PCR Tests	Detect pathogens like E. coli, Salmonella.
Moisture Meters	For dry perishables like nuts, spices.
Visual + Organoleptic Test	Used for flowers, fruits, seafood (colour, texture, odour).

Proficiency of the customs officials in these general inspection parameters and testing methods/tools is essential for the proper examination of perishable goods, which in turn will facilitate speedy clearance by Customs at ports. Regular training of the officials and thematic audits will help in better handling of the reefer cargo at the ports. RMS instructions may be specifically created keeping in mind the specific requirement of such sensitive cargo.

6.5 Microbiological Parameters:

Microbiological safety is one of the most critical aspects of quality inspection for perishable goods, as microbial contamination can lead to foodborne illnesses, spoilage, and trade rejections. The evaluation of microbiological parameters is essential during both import and export to comply with domestic and international food safety standards. Common Microbiological contaminants in perishables are as below:

Contaminant	Associated Risk	Commonly Found In
SALMONELLA SPP.	Food poisoning, Diarrhea, fever	Poultry, meat, eggs, seafood
LISTERIA MONOCYTOGENES	Severe illness, especially in pregnant women	Ready-to-eat foods, dairy, seafood
ESCHERICHIA COLI (E. COLI)	Gastroenteritis, kidney damage	Beef, leafy greens, raw milk

Contaminant	Associated Risk	Commonly Found In
CLOSTRIDIUM BOTULINUM	Botulism (fatal in severe cases)	Canned foods, smoked fish
STAPHYLOCOCCUS AUREUS	Toxin-induced vomiting, cramps	Processed foods, dairy, bakery
YEASTS AND MOLDS	Spoilage, toxin production (mycotoxins)	Fruits, vegetables, cereals

6.6 Standards and permissible limits:

Authorities such as FSSAI (India), Codex Alimentarius, EU regulations, and the US FDA have prescribed limits for various microbiological contaminants based on product category. These are evaluated through batch-wise or lot-wise sampling during inspections.

Example – FSSAI Microbiological Standards:

Product Category	Microorganism	Limit (CFU/g or mL)
Milk and Dairy	E. COLI	Not Detected in 1g
Meat Products	SALMONELLA SPP.	Absent in 25g
Fruits & Veg	Total Plate Count	$\leq 10^4$ CFU/g
Ready-to-Eat	LISTERIA MONOCYTOGENES	Absent in 25g

7. Sampling and Testing Methods:

- **Swab Sampling:** Used for surface testing of carcasses or processed foods.
- **Liquid Samples:** For dairy, juices, and seafood.
- **Enrichment Culture:** To isolate slow-growing pathogens like *LISTERIA*.
- **PCR Testing:** Rapid, accurate detection of microbial DNA.
- **ELISA Kits:** Used for specific toxin detection.

7.1 Compliance Requirements:

i. Exports:

a) Primarily exporters required to obtain and submit the microbiological test certificates from NABL/FSSAI-accredited labs.
b) Export Inspection Agencies (EIA) often verify the results

c) Certain countries (e.g., Japan, EU) require zero-tolerance levels for specific organisms.

ii. Imports:

a) Based on risk-analysis the Import documents are selected and transmitted online to the PGAs. The PGAs authorities demand test reports wherever required, especially in high-risk items like seafood, meat, and dairy.
b) Samples are collected or forwarded by/to the Agencies' accredited/notified labs for testing.

8 Chemical Residue Monitoring:

Chemical residue is trace amount of chemicals that remain in food from various sources, including agricultural pesticides, veterinary drugs, environmental contaminants, and process contaminants. While these residues often pose health risks, regulatory bodies set Maximum Residue Levels (MRLs) to ensure food safety by keeping residues below established thresholds. Chemical residue monitoring is vital to ensure the safety and quality of perishable goods. Residues from pesticides, veterinary drugs, processing aids, and cleaning agents can accumulate in food products if not properly managed, leading to health risks and non-compliance with international trade regulations.

8.1 Sources of chemical residues

- **Pesticides:** Residues from ***herbicides, insecticides, and fungicides*** used during crop growth can remain on fruits, cereals and vegetables.
- **Veterinary drugs:** Residues can be found in meat, poultry, milk, seafoods, dairy and eggs from the animals treated with medicines or fed contaminated feed.
- **Environmental contaminants:** Industrial activities, pollution, and even natural sources can lead to contaminants like heavy metals (e.g., lead, mercury) or dioxins entering the food chain through soil, water, and air.
- **Process contaminants:** Chemicals can be unintentionally formed during food processing or cooking, such as acrylamide in starchy foods cooked at high temperatures.
- **Food contact materials:** Residues from packaging, cleaning agents, or equipment can migrate into food products.

- **Heavy metals (e.g., lead, cadmium, arsenic)** due to contaminated soil or water.

8.2 The Health Risks of the Chemicals Residues:

Chemical residues in food, vegetables, and animal products can lead to a range of health risks, from acute issues like allergies, nausea, and skin irritation to chronic conditions such as cancer, reproductive harm, and neurological damage. Long-term exposure to pesticides, heavy metals like lead and arsenic, antibiotics, and other contaminants can be especially concerning, affecting development, the immune system, and organ function.

- **Acute toxicity**: Symptoms like nausea, vomiting, headaches, or convulsions from high levels of exposure.
- **Chronic exposure**: Can lead to cancer, hormonal disruption, reproductive issues, and developmental problems.
- **Allergic reactions**: Triggered by trace chemicals in sensitive individuals, skin irritation, rashes, or more severe allergic responses may be seen.
- **Gastrointestinal issues:** Nausea, vomiting, and Diarrhea etc. are the common symptoms.
- **Neurological symptoms:** Dizziness, headaches, and in severe cases, blindness or death.
- **Irritation:** Stinging eyes and throat irritation.

Long term effect of such chemical residues may be fatal to the public health. Sometimes it may have a catastrophic impact of cancer due to exposure to various chemicals including some pesticides, disinfection by-products and heavy metals. Some chemical residues may cause neurological and developmental problems because of the neurotoxicity and damages of nervous system.

The chemical residues even affects our reproductive ability causing defects, reduced fertility and adverse pregnancy outcomes etc. our endocrine system (hormonal balances) are disrupted due to these chemical residues and immune system may be affected adversely. The chemical residue may increase chances of diabetes, cardiovascular diseases and non-communicable diseases. It created antibiotic resistance and disturbs the response of our natural defence system of body.

8.3 Global Regulatory Limits of Chemical Residues:

The authorities of different countries and the global agencies like World Agriculture Organisation, World Health Organisation etc. have fixed the Maximum Residue Limits (MRLs) for the chemical residues in foods.

Pesticide residue management is one of the most critical aspects of food safety compliance, especially for perishable agricultural commodities. International trade is significantly impacted by Maximum Residue Limits (MRLs), which are legally permissible limits set for pesticide residues in food products. This section explores pesticide monitoring, compliance requirements, analytical techniques, and mitigation strategies.

Pesticide residues refer to the trace levels of chemicals that remain on or in fruits, vegetables, and other crops after the application of agricultural pesticides. The common pesticide categories include:

a) Insecticides (e.g., Chlorpyrifos, Imidacloprid)
b) Fungicides (e.g., Carbendazim, Mancozeb)
c) Herbicides (e.g., Glyphosate)
d) Nematicides and growth regulators

Some of the important parameters of chemical residues fixed by international organizations in compliance of Codex Alimentarius Guidelines are given below:

Compound Common Name	**Chemical Abstracts Service (CAS) #**	**Residue to which the maximum residue level applies**	**Food**	**Maximum Residue Level (mg/kg)**
1,3-Dichloropropene	542-75-6	1,3-Dichloropropene,sumofisomers	Fruits Vegetables	0.01(*) 0.01(*)
1-Methylcyclopropene	07-04-3100	Ethylene receptor bound 1-methylcyclopropene	Fruits Vegetables	0.01 0.01
Acibenzolar-s-methyl	135158-54-2	*Sum of:* Acibenzolar-s-methyl and Acibenzolar acid (CGA210007) *Expressedas*:Acibenzolar-s-methyl	Kiwifruit	0.02(*)
Amprolium	121-25-5	Amprolium	EggsPoultry meat	4 0.5
Bromoxynil	1689-84-5	Bromoxynil	Cerealgrains	0.01(*)
Chlormequat	7003-89-6	Chlormequatcation	Barley Oats Wheat	1 5

				1
Clopyralid	1702-17-6	Clopyralid	Beetroot	4
Cyazofamid	120116-88-3	Cyazofamid	Potatoes Onions	0.01(*) 0.01(*)
Cymoxanil	57966-95-7	Cymoxanil	Garlic Onions Peas Potatoes	0.05(*) 0.05(*) 0.05(*) 0.05(*)
Dicofol	115-32-2	*Sum of: o,p'* -Dicofol isomer and *p,p'* -Dicofol isomer	Fruits Vegetables	3 3
Diflubenzuron	385-00-2	2,6-diflurobenzoicacid	Mushrooms	1
Diphenylamine	122-39-4	Diphenylamine	Apples	10
Dithiocarbamates (exceptpropineb)		Total dithiocarbamates, determinedas CS2, evolved during acid digestion and expressed as mg CS2/kg (MRLs apply to total residues from the use of anyoreachofthegroupsof dithiocarbamates alone or in combination, excluding propineb)	Fruits Vegetables	7 7
Fenamidone	161326-34-7	*Sum of*: Fenamidone and its desmethylthio metabolites	Onions Potatoes	0.05(*) 0.05(*)
Fenitrothion	122-14-5	Fenitrothion	Cerealgrains	0.5
Flufenacet	142459-58-3	*Sum of:* Flufenacet, flufenacet sulfonic acid, flufenacet thioglycolate sulfoxide and flufenacet oxalate *Expressedas:*Flufenacet	Barley Potatoes Wheat	0.05(*) 0.01(*) 0.05(*)
Fluoxastrobin	361377-29-9	*Sum of:* Fluoxastrobin and fluoxastrobin isomers *Expressedas:*Fluoxastrobin	Cerealgrains	0.01(*)
Fluroxypyr	69377-81-7	Fluroxypyr	Apples Onions	0.02(*) 0.05
Fluthiacet-methyl	117337-19-6	Fluthiacet-methyl	Maize	0.01(*)

Forchlorfenuron	68157-60-8	Forchlorfenuron	Apples	0.01(*)
Formetanate hydrochloride	23422-53-9	Formetanatefreebase	Onions	0.2
Fuberidazole	3878-19-1	Fuberidazole	Barley Oats Wheat	0.05(*) 0.05(*) 0.05(*)
Halosulfuron-methyl	100784-20-1	Halosulfuron-methyl	Maize	0.01(*)
Imazapyr	81334-34-1	Imazapyr	Maize	0.05(*)
Iodosulfuron-methyl- sodium	144550-36-7	Iodosulfuron-methyl	Cerealgrains	0.01(*)
Iprovalicarb	140923-17-7	Iprovalicarb	Onions Potatoes	0.05(*) 0.05(*)
Isoproturon	34123-59-6	Isoproturon	Cerealgrains	0.01(*)
Kasugamycin	19408-46-9	Kasugamycin	Kiwifruit	0.01(*)
Kresoxim-methyl	143390-89-0	Kresoxim-methyl	Apples Barley Wheat	0.01(*) 0.05(*) 0.05(*)
MCPA	94-74-6	MCPA	Cerealgrains	0.02(*)
MCPB	94-81-5	MCPB	Cerealgrains	0.02(*)
Mecoprop and/or Mecoprop-P	93-65-2and/or 16484-77-8	Mecoprop(sumofisomers). *Expressedas:*Mecoprop-P	Cerealgrains	0.05(*)
Mepiquatchloride	24307-26-4	Mepiquat	Cerealgrains	2
Mesotrione	104206-82-8	Mesotrione	Maize	0.01(*)
Metamitron	41394-05-2	Metamitron	Apples Pears	0.01(*) 0.01(*)
Methiocarb	2032-65-7	Methiocarb	Cerealgrains	0.05(*)
Nicosulfuron	111991-09-4	Nicosulfuron	Maize	0.01(*)
Paclobutrazol	76738-62-0	Paclobutrazol	Avocados Stonefruits	0.01(*) 0.01(*)
Paraquat	4685-14-7	Paraquatcation	Fruits Vegetables	0.05(*) 0.05(*)

Pinoxaden	243973-20-8	*Sum of:* Pinoxaden and its M2 metabolite: (8- (2,6-diethyl-4-methyl-phenyl)-tetrahydro-9H-pyrazolo[1,2-d][1,4,5]oxadiazepine-7,9-dione *Expressedas:*Pinoxaden	Cerealgrains	0.01(*)
Propazine	139-40-2	Propazine	Carrots Parsnips	0.05(*) 0.05(*)
Propineb	12071-83-9	Total dithiocarbamates, determined as CS2, evolved during acid digestion and expressed as mg CS2/kg	Onions	0.5
Pyrethrins	8003-34-7	Total pyrethrins, calculated as the sum of pyrethrins I and II, cinerins I and II and jasmolins I and II, determined after calibration with the World Standard pyrethrum extract.	Fruits Vegetables	1 1
Spinosad	168316-95-8	*Sumof:*SpinosynAandspinosynD	Citrus fruits	0.05
Tepraloxydim	149979-4-9	*Sum of:* Tepraloxydim and metabolites converted to 3-(tetrahydro-pyran-4-yl)-glutaric acid and 3-hydroxy-3-(tetrahydro-pyran-4-yl)- glutaric acid *Expressedas:*Tepraloxydim	Onions	0.1*
Terbufos	13071-79-9	*Sum of:* Terbufos, its oxygen analogue, and theirsulfoxidesandsulfones *Expressedas:*Terbufos	Cerealgrains	0.01(*)
Triallate	2303-17-5	Triallate	Barley Peas Wheat	0.05(*) 0.05(*) 0.05(*)
Uniconazole-P	83657-17-4	Uniconazole-P - sum of isomers, expressed as Uniconazole-P	Avocados	0.5

8.4. Important issues pertaining to testing

Since rejection, blacklisting, abandonment of consignments etc. are common in the export and import of Temperature sensitive cargo, and it has harsh health consequences too, due care is required while performing testing of the same.

Sampling and Analytical techniques must include the multi-residue methods, which entails simultaneous detection of multiple pesticide or drugs use, quicker technology driven testing techniques, and atomic absorption spectroscopy (AAS) for heavy metal analysis etc. Similarly High-Performance Liquid Chromatography (HPLC) for detecting drug residues and preservatives tec are also required.

The export of any temperature sensitive cargo needs certificates of analysis with MRL data for clearance. Most of the countries have their specific chemical clearance based on their local standards and maximum residue limits parameters, which is required to be adhered with by the exporters.

8.5 Monitoring and Testing Techniques:

There are several testing techniques which are accepted and prescribed at international level. A few amongst them are given below:

a. LC-MS/MS (Liquid Chromatography – Mass Spectrometry): This is one of the gold standard for multi-residue analysis.

b. GC-MS/MS (Gas Chromatography): Effective for volatile pesticides testing.

c. QuEChErS Method: Widely used sample preparation method for multiple pesticides testing.

d. Rapid Test Kits: Used for initial screening at port or field level.

Additives and preservatives play a key role in extending the shelf life and maintaining the safety and appearance of perishable goods. However, their use is strictly regulated by food authorities to prevent health hazards. This section outlines the various types of food additives and preservatives, their allowable limits, regulatory guidelines, and inspection protocols.

- **Additives**: Substances added to food to enhance its flavour, appearance, texture, or shelf-life. For example - Emulsifiers, stabilizers, anti-caking agents, colorants.

- **Preservatives**: Chemicals added to inhibit microbial growth and spoilage. For example - Sodium benzoate, sorbic acid, nitrates, sulphites.

8.6 Categories of Additives and their Limits

Additive Type	Common Additives	FSSAI Permitted Limit	Codex Limit (Typical)
Preservatives	Sodium Benzoate	200 ppm	250 ppm
	Sorbic Acid	1000 ppm	1000 ppm
Antioxidants	Ascorbic Acid (Vitamin C)	GMP*	GMP
Sweeteners	Aspartame	40 mg/kg (ADI)	40 mg/kg
Coloring Agents	Tartrazine, Sunset Yellow	100 ppm	100 ppm
Emulsifiers	Lecithin, Mono-glycerides	GMP	GMP

Food inspection agencies test both imported and exported consignments for additive and preservative levels, especially when dealing with processed or semi-processed perishables (e.g., cut fruits, juices, dairy, and seafood).

Commonly used testing methods:

- **HPLC (High Performance Liquid Chromatography)**
- **Spectrophotometry**
- **Titration methods** for sulphites and nitrates

Testing is generally done by:

- **NABL-accredited labs in India**
- **Third-party international labs** for export-bound goods

9. Phytosanitary and Sanitary Protocols:

Phytosanitary and sanitary protocols are critical in ensuring the safety and health of perishable goods during international trade. These protocols are designed to prevent the spread of plant pests, diseases, and contaminants in food products, which could affect the environment, economy, and public health. This section explores the importance of these protocols, their requirements, and the procedures followed for their implementation.

Phytosanitary protocols focus on preventing the introduction and spread of harmful plant pests and diseases through international trade, particularly in perishable goods such as fruits, vegetables, and seeds. Sanitary protocols, on the other hand, are primarily concerned with ensuring that animal-based products, such as meat, dairy, and seafood, are free from contaminants that could impact human health. These protocols are enforced through a set of international standards and regulations, most notably those established by the **World Trade Organization (WTO)** and **Codex Alimentarius**.

9.1 Importance of Phytosanitary and Sanitary Protocols:

1. **Public Health Protection:** The primary aim of these protocols is to safeguard consumers from potential health risks associated with contaminated food products. By preventing the importation of harmful pathogens, toxins, and residues, these protocols protect public health.
2. **Biodiversity Preservation:** Phytosanitary protocols are designed to protect ecosystems from the introduction of invasive plant species or pests that could harm agricultural production and biodiversity.
3. **International Trade Facilitation:** Compliant goods are more likely to meet international trade standards, making it easier for exporters to access global markets. Non-compliant goods may be rejected at borders, leading to financial losses and trade disruptions.
4. **Economic Stability:** These protocols help prevent the spread of plant and animal diseases that could disrupt local agriculture and affect the global food supply chain, thus stabilizing prices and ensuring sustainable food production.
5. **Phytosanitary Certificate**: Exporters must obtain a phytosanitary certificate from the competent authority in the exporting country. This certificate confirms that the goods are free from harmful plant pests and diseases.

9.2 Phytosanitary and Sanitary Inspection Procedures:

The inspection procedures for phytosanitary and sanitary protocols vary based on the type of product being traded. However, common steps include:

1. **Inspection at Point of Origin:** Exporters must provide documentation to show that their products comply with the relevant phytosanitary or sanitary

standards. This typically involves obtaining certificates from the relevant authorities in the country of origin.

2. **Inspection at Point of Entry:** Upon arrival in the importing country, consignments are often subject to random or routine inspections to verify compliance. This includes visual inspection, sampling, laboratory testing, and the review of certification documents.

3. **Rejection and Re-exportation:** If products are found to be non-compliant with phytosanitary or sanitary requirements, they may be rejected, destroyed, or re-exported. In such cases, the exporter may bear the cost of the non-compliance.
4. **Contingency Measures:** If pests, diseases, or contaminants are found, immediate action must be taken to mitigate the risk. This may include treatment, quarantine, or destruction of the affected goods.

CHAPTER – 6

Infrastructure and Vendor Quality Assessment

1. Infrastructure:

Infrastructure refers to the systems, facilities, and resources that enable an organization to function efficiently. In the present context dealing with the handling of import and export of time and temperature-sensitive perishable cargo, a robust and well-developed cold chain infrastructure is essential to maintain product integrity throughout the entire logistics process.

Efficient handling must be ensured right from the point of origin (exporter's premises) to the final delivery destination (importer's facility). This comprehensive approach not only safeguards the quality and safety of perishable goods but also ensures compliance with international standards and minimizes losses arising from temperature deviations.

2. Details of available Infrastructure at various ICDs/CFS:

Reports from various ports have been obtained to assess the availability of necessary infrastructure and related facilities. The compiled findings from these reports are presented as under:

Custom location code	**Membership Association**	**Does Port/CFS/ICD/ Air Cargo Terminal at your location have adequate facilities for storage and customs clearance of temperature-controlled cargo?**	**When the export consignment/export is selected for examination, does your Custodian poses the facilities to maintain the cold chain temperature when selected for "open and examination" of export cargo?**	**Have you experienced any instances of export or import cargo being spoilt or damaged due to temperature variation due to non-availability of cold chain facilities**	**For Pharma grade products, does your Custodian possesses sterile and separate chamber to handle such sensitive cargo?**	**Does your Custodian posses adequate number of working plug points to handle the temperature sensitive reefer containers etc**	**Does the custodian provide gel packs/dry ice for such cargo?**
INAMD4	Ahmedabad Custom Brokers' Association	Infrastructure and facilities are available but not adequate, need to increase capacity	Yes	Yes	No	Yes	No

INSBI6	Ahmedabad Custom Brokers' Association	No infrastructure or facilities	No	No	No	No	No
INSAU6	Ahmedabad Custom Brokers' Association	No infrastructure or facilities	No	No	No	No	No
OTHER	Association of Custom House Agents Thiruvanthapuram	No infrastructure or facilities	No	Yes	No	No	No
INBOM4	Brihnamumbai Custom Brokers Association	Infrastructure and facilities are available but not adequate, need to increase capacity	Yes	No	No	No	No
INNSA1	Brihnamumbai Custom Brokers Association	No infrastructure or facilities	No	No	No	Yes	No
INCCU4	Calcutta Customs House Agents Association	Yes adequate infrastructure and facilities are available and being utilized	Yes	No	No	No	No
INCCU1	Calcutta Customs House Agents Association	Infrastructure and facilities are available but not adequate, need to increase capacity	No	No	No	Yes	No
INMAA1	Chennai Customs House Agents Association	Yes adequate infrastructure and facilities are available and being utilized	Yes	No	Yes	Yes	No
INCOK1	Cochin Customs Brokers' Association	Yes adequate infrastructure and facilities are available and being utilized	Yes	Yes	Yes	Yes	No
OTHER	Goa Custom Brokers Association	No infrastructure or facilities	No	No	No	Yes	No
INIDR4	Indore Customs House Agents Association	No infrastructure or facilities	No	No	No	Yes	No
INIXY1	Kandla Custom Brokers Association	Infrastructure and facilities exist but not functional/not operationalized	No	No	No	Yes	Yes

INLDH6	Ludhiana Customs House Agents Association	Infrastructure and facilities are available but not adequate, need to increase capacity	No	No	No	Yes	No
INNML1	Mangalore Customs House Agents Association	No infrastructure or facilities	No	No	No	Yes	No
INKPK6	Nagpur Customs House Agents Association	No infrastructure or facilities	No	No	No	Yes	No
OTHER	Nashik Customs House Agents Association	Infrastructure and facilities are available but only partially functional on random days	Yes	No	No	Yes	No
INAPL6	Noida Custom Brokers Association	Infrastructure and facilities are available but not adequate, need to increase capacity	Yes	No	No	Yes	Yes
INPRT1	Odisha Customs Brokers' Association	No infrastructure or facilities	No	No	No	No	No
OTHER	Odisha Customs Brokers' Association	No infrastructure or facilities	No	Yes	No	No	No
INPAV1	Pipavav Custom Brokers Association	No infrastructure or facilities	No	No	No	No	No
OTHER	Pune Customs House Agents Association	Infrastructure and facilities are available but not adequate, need to increase capacity	No	No	No	Yes	No

The above table makes it evident that most of the ICDs/CFS are lacking requisite infrastructure for proper handling of time sensitive cargo.

3. Infrastructure and Handling Dynamics to be maintained by Custodians

An effective framework for handling temperature-sensitive cargo at ICDs/CFS requires specialized infrastructure and dynamic processes that integrate Customs,

Custodian, and Logistics operations. This ensures product integrity and efficient clearance.

From the above table, it is evident that, most of the ports have not proper facility to maintain integrity of temperature sensitive cargo.

The requisite facilities / infrastructure for temperature and cold chain management and requisite equipment and tools for efficient handling of perishable cargo are discussed as under:

a. Temperature and Cold Chain Management

Cold chain integrity is paramount for preserving the safety, quality and shelf life of temperature-sensitive products. Maintaining the correct temperature from the source through the port to the final destination is a fundamental regulatory and operational mandate.

The importance of the cold chain in perishables is multifaceted. It prevents microbial growth and spoilage, maintains nutritional and sensory quality, ensures regulatory compliance with bodies like FSSAI, EU, US FDA and Codex, and significantly reduces financial losses due to spoilage or rejection.

Key Components of Cold Chain management at the ports: The cold chain comprises several interconnected components:

- **Refrigerated Transport:** Includes reefer trucks and containers equipped with temperature monitoring systems to ensure consistent temperatures during transit. These trucks/containers need to be plugged in for all the time so as to maintain the optimum temperature.
- **Cold Storage Facilities at or near port:** Warehouses designed with multiple temperature zones to accommodate diverse perishable goods must be present in or near the ICDs/CFS for temporary storage of goods and preserve its quality.
- **Real-Time Monitoring Devices:** Temperature loggers and GPS-integrated sensors must be present in examination areas, warehouses and containers which will provide continuous monitoring, allowing immediate detection of deviations.
- **Power Backup Systems:** DG sets and solar backups must be present at the ports which are vital to ensure uninterrupted power supply to refrigeration units, preventing temperature excursions during outages.

ICDs/ CFS should ensure using calibrated thermometers/data loggers with GPS, installing alarms for deviations, maintaining digital/manual temperature logs, conducting periodic audits, and training staff on proper handling during loading/unloading. Emerging technologies like IoT-based sensors, blockchain integration for traceability, smart packaging with time-temperature indicators, and mobile apps for compliance tracking are maximizing efficiency and speeding up clearances.

Having a robust infrastructure of Cold chain in or near ICDs and CFS will have multi-faceted benefits. Dedicated exam areas for such cargo can be created with temperature and dust control environment. A mandatory condition requirement of cold storage may be created while approving new ICDs.

4. Inspection Equipment and Tools

Efficient inspection of perishable goods during import and export hinges on the use of advanced, accurate, and calibrated equipment. These tools are crucial for ensuring accurate assessment of compliance parameters, reducing human error, facilitating faster decision-making, and maintaining standardized quality checks across different locations. ICDs/CFS should ensure that they possess calibrated and updated tools and equipment to ensure efficient handling of sensitive cargo.

Common Equipment Used The following table outlines common inspection equipment, their purpose, and typical users:

Equipment	Purpose	Used By
Thermometer (Digital/Infrared)	Measures surface or core temperature of products	Customs, FSSAI, Cold Chain Operators
Moisture Meter	Assesses moisture content in grains, fruits, etc.	Laboratory Technicians
pH Meter	Checks acidity/alkalinity of foods and beverages	Food Inspectors, Labs
Refractometer	Measures sugar content (Brix level) in fruits, juices	Horticulture Departments, Exporters
Colorimeter	Assesses color quality against grading standards	Lab Technicians
Metal Detector	Detects physical contaminants like metal pieces	Plant Inspectors

Equipment	Purpose	Used By
Gas Chromatography (GC-MS)	Detects chemical residues, pesticides	Accredited Labs
High-Performance Liquid Chromatography (HPLC)	Identifies chemical composition and additives	FSSAI, NABL Labs
Microbiological Testing Kits	Identifies microbial contamination	Food Safety Labs
UV Spectrophotometer	Measures absorbance for qualitative analysis	Laboratory Use

Ports with high perishable volumes often have on-site cold storage temperature monitoring systems, quick test kits for pesticide residues, barcode scanners for traceability, infrared cameras for thermal assessments, and calibrated weighing scales. All equipment at ports must undergo **regular calibration** as per ISO/IEC 17025 guidelines, with certificates maintained and preventive maintenance schedules to reduce errors and downtime. Digital tools like handheld tablets with inspection checklists, IoT sensors, mobile apps for officers, and portable lab units enhance efficiency. Future developments include AI-integrated inspection systems, blockchain tools linking test results, and drone-based warehouse inspection. ICDs/CFSs should have advanced, accurate, and calibrated equipment for quick examination and testing.

5. Impact of Delays on the Quality of Perishables

Delays in the transportation, handling, or processing and clearances of perishable goods have significant implications for their quality, safety, and shelf life. These consequences affect both product integrity and the financial viability of shipments.

Types of Delays and Their Causes: Delays can occur at any supply chain stage. Transport delays stem from customs clearance, poor handling of goods at the port, adverse weather, or mechanical failures. Handling delays arise from port congestion, insufficient labour, or operational inefficiencies. Documentation delays are caused by inaccurate paperwork or extended regulatory reviews.

Consequences of Delays:

- **Temperature Abuse:** Even minor delays can lead to temperature excursions, accelerating spoilage and reducing shelf life.

- **Microbial Growth:** Delays increase exposure to temperature fluctuations, boosting bacterial, mold, and pathogen growth, leading to foodborne illnesses or rejection.
- **Quality Deterioration:** Colour, texture, taste, and nutritional value degrade rapidly. Fruits may bruise, dairy may sour.
- **Loss of Nutritional Value:** Prolonged delays, especially in warmer temperatures, reduce nutritional content (e.g., Vitamin C).
- **Financial Implications:** Include waste costs, penalties from regulators/customers, and loss of business reputation due to damaged client relationships.

6. Vendor Quality Assessment in Import and Export of Time-Sensitive Cargo in India

Vendor Quality Assessment (VQA) plays a pivotal role in ensuring the integrity, safety, and timely delivery of **time-sensitive cargo** such as pharmaceuticals, vaccines, perishable food products, floriculture, and other temperature-controlled commodities. In the Indian context, where climatic diversity and infrastructural variation exist across ports and airports, systematic vendor evaluation becomes crucial to maintain the **cold chain integrity** and **compliance with international quality standards**.

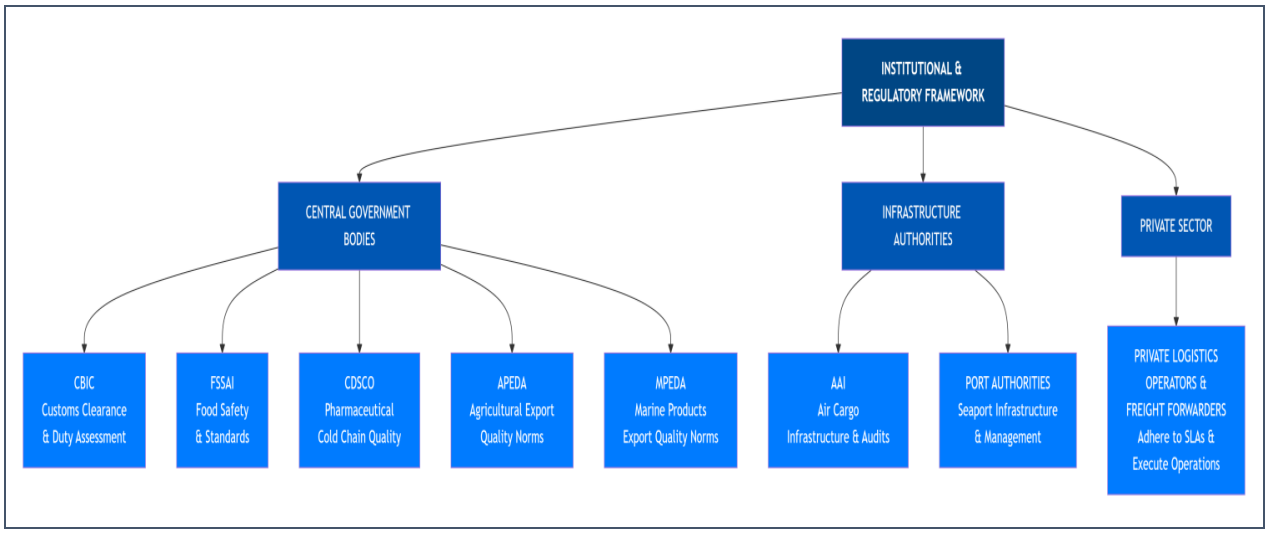
6.1 Objectives of Vendor Quality Assessment

- **Ensure Compliance:** Verify that vendors handling time-sensitive cargo comply with domestic and international standards such as GDP (Good Distribution Practices), GHP (Good Handling Practices), HACCP, and ISO 9001/22000.
- **Maintain Cargo Integrity:** Prevent temperature deviations, contamination, or delays that could compromise product quality.
- **Risk Mitigation:** Identify potential risks in the supply chain such as unreliable logistics partners or inadequate cold storage and implement corrective actions.
- **Continuous Improvement:** Promote data-driven performance evaluation and feedback mechanisms for vendors.

6.2 Institutional and Regulatory Framework

- **Central Board of Indirect Taxes and Customs (CBIC):** Oversees customs clearance efficiency and infrastructure standards at ports/airports.

- **Agricultural and Processed Food Products Export Development Authority (APEDA):** Sets quality norms for perishable agricultural exports.
- **Marine Products Export Development Authority (MPEDA):** Sets quality norms for main products exports
- **Central Drugs Standard Control Organisation (CDSCO):** Regulates pharmaceutical cold chain quality during import/export.
- **Food Safety and Standards Authority of India (FSSAI):** Regulates and oversee all food license-related work
- **Airports Authority of India (AAI) / Port Authorities:** Responsible for infrastructure audits and vendor approvals at air cargo complexes and seaports.
- **Private Logistics Operators & Freight Forwarders:** Must adhere to SLAs (Service Level Agreements).



6.3. Challenges in the Indian Context

India faces several challenges in implementing a uniform and effective Vendor Quality Assessment framework for time-sensitive cargo. One major issue is the **non-uniformity of cold chain infrastructure** across ports, airports, and Inland Container Depots (ICDs), which leads to inconsistencies in temperature maintenance during storage and transit. There is also **limited real-time monitoring and temperature tracking**, particularly during hinterland transportation, which increases the risk of product deterioration. Moreover, **varying levels of awareness and inadequate training among handling staff** often result in deviations from standard procedures. Another concern is the **lack of consistent audit practices and vendor rating mechanisms** across different

regions, leading to uneven quality assurance. Additionally, many smaller logistics operators still rely heavily on **manual record-keeping systems**, making traceability and data accuracy a challenge.

6.4. Standards and Improvement Roadmap

To address these challenges, several best practices can be implemented. The **adoption of standardized Vendor Quality Assessment (VQA) templates** aligned with global benchmarks such as **IATA CEIV Pharma** and **WHO GDP** can help harmonize evaluation procedures. The **integration of IoT-based tracking systems** is essential for real-time monitoring of temperature and cargo conditions. Establishing a **National Vendor Quality Database** would enable importers and exporters to identify pre-qualified logistics partners, ensuring reliability and accountability. Regular **third-party audits and benchmarking with leading global logistics hubs** can further strengthen quality standards. Additionally, **capacity-building and training programs** for handlers and transporters in temperature-sensitive logistics would enhance operational efficiency and reduce the risk of non-compliance.

Thus, a robust Vendor Quality Assessment framework is indispensable for maintaining the integrity of India's time-sensitive import and export cargo chain. By integrating advanced technology, enforcing regulatory compliance, and adopting performance-based vendor management practices, India can ensure global competitiveness, reliability, and quality in the handling of perishable and pharmaceutical logistics

7. Commodity Specific Quality Grading Systems and Infra Requirement:

Quality grading is an **essential component of the inspection process** for perishable goods at the port. It standardizes product expectations, ensures consistency, and supports regulatory compliance. Grading systems are typically based on physical characteristics, maturity, defect levels, and overall product condition.

The purpose of quality grading is multi-faceted: it ensures uniform product classification across markets thereby reducing classification issues, enhances marketability (as higher-grade products command better pricing), supports documentation and inspection needs for regulatory compliance, based on risk assessment.

Indian Grading System (AGMARK) In India, the AGMARK certification, administered by the Directorate of Marketing and Inspection (DMI) under the Ministry of Agriculture, governs quality grading. Grades range from Grade I (superior quality, defect-free) to Grade II (good quality with minor acceptable defects), Grade III (average quality, usable but lower shelf life), and "Below Standard" for products failing minimum quality norms. This system applies to various products, including fruits, vegetables, spices, dairy, and cereals.

International Grading Standards International grading standards vary by region. The USA (USDA) uses grades like Extra Fancy, Fancy, No. 1, and No. 2. The EU (UNECE) employs Extra Class, Class I, and Class II. Codex Alimentarius provides product-specific descriptors, while the Middle East (Gulf Standards Org - GSO) uses custom country-specific classifications.

Packaging and labelling must reflect the assigned grade, with grade-marked stickers or printed labels matching the invoice, inspection certificate, and import/export documentation. This will help in better understanding of the products and faster clearances at the port. Training port manpower with FSSAI and APEDA grading standards, integrating grading with cold chain logistics, and adopting blockchain-based traceability for high-value perishables is a desirable factor.

a. Meat, Poultry (HSN 0201–0210) and Seafoods (HSN 0301–0308):

Food Safety Management Systems, such as HACCP, ISO 22000, BRC, and IFS, which are widely mandated to manage risks from production to distribution (ISO, 2018). Certification and documentation are also critical, including veterinary or health certificates, catch certificates for wild-caught seafood to prevent illegal, unreported, and unregulated (IUU) fishing, and Halal or Kosher certifications where required by importing countries (FAO, 2022).

Export commodity must comply with importing country's veterinary health certificates. Slaughtering facilities must follow HACCP (Hazard Analysis and Critical Control Points) Good Manufacturing Practices (GMP) and Goo Hygiene Practices (GHP). Testing for Pathogens (especially Salmonella, E. coli O157:H7, Campylobacter, Listeria Monocytogenes etc.) Testing facility of chemical residue (antibiotics, hormones, pesticides, heavy metals etc.) and Animal Welfare Standards during slaughters (as per OIE).

For Regional Protocols it requires to maintain strict compliance with Regulation (EC) 853/2004 and Official Control Regulation (EU) 2017/625. GCC Countries

requirement i.e. Facility of Halal Certification under approved Islamic Boards is required to be maintained.

Few key technical and procedural requirements for Seafoods international trade, are given below:

- Compliance with **HACCP for seafood** (mandatory for US, EU, Japan).
- Monitoring of **biotoxins, histamine, heavy metals (mercury, cadmium), veterinary drug residues**.
- Certification of **disease-free aquaculture zones** (e.g., free from White Spot Syndrome Virus, EMS, etc.).
- Implementation of **traceability systems** from harvest to export.
- **Temperature controls** (frozen products at –18°C or below; chilled products at 0–4°C).

iii. **Regional Protocols:**

- **EU:** Regulation (EC) 854/2004 and 2073/2005 (microbiological criteria).
- **US FDA:** Seafood HACCP (21 CFR 123).
- **China:** Requires registration of foreign seafood traders with GACC (General Administration of Customs China).
- **Japan:** Ministry of Health, Labour and Welfare (MHLW) oversees strict monitoring for residues and contaminants.

Further, Seafood has its own additional concerns (toxins, parasites, aquaculture diseases, temperature control). Therefore, maintaining proper hygiene and temperature control etc. remains absolute necessity. The infra handling, product processing, storage and transport paradigms are to be maintain as per the Codex Code of Practices. Processing also requires to maintain HACCP norms and routine testing especially for species susceptible to histamine. Heavy metals, residue and contamination testing are must. Therefore, appropriate cold-chain with high degree of chillers and accredited labs are the necessities.

b. Fruits, Plants, Flowers and Vegetables"

The international trade of vegetables, fruits, plants, and flowers operates within a structured global framework, designed to facilitate market access while safeguarding human, animal, and plant health. This system is anchored by the World Trade Organization's **Sanitary and Phytosanitary (SPS) Agreement**,

which mandates that national health measures must be science-based, transparent, and non-discriminatory. A core principle of this agreement is the use of international standards to harmonize regulations across borders.

Therefore, benchmarking and food safety standards of infrastructures are prescribed as per Codex Alimentarius Commissioner recommendation. Simultaneously, the plant health (phytosanitary) measures are to be taken as per the International Plant Protection Convention (IPPC). The import and export of fruits, plants, vegetables and flowers therefore, are required to be adhered with the *residue monitoring, sustainability standards, packaging and accurate labelling, phytosanitary certification and cold-chain integrity.*

The phytosanitary Certificates are issued by the National Plant Protection Organizations (NPPOs), the cold treatment or irradiation is required for some fruits to control pests, EU Plant health Regulation 2016/2031, pesticide limits regulation EC 396/2005, USDA-APHIS requirement of treatment and inspections, Japan MAFF quarantine inspection for pests, GCC Halala compliant packaging and strict MRL checks etc. are the regional key protocols.

c. Bakery Products:

The international trade of bakery products are governed by a combination of WTO Rules, Codex Alimentarius standards and region-specific regulations. Sanitary and Phytosanitary (SPS) restrictions to protect human health, are predominantly maintained by the exporting countries.

To avoid contamination, risks of pests and microbial growth etc. and to maintain globally recognized benchmarks of the product quality/integrity; appropriate infrastructure and temperature control, monitoring are very essential. The relevant standards for bakery products include:

- **Codex Stan 243-2003**: General Standard for Bakery Products
- **Codex Stan 192-1995**: Food Labeling
- **Codex Guidelines on Food Additives** Covers **ingredients, labeling, hygiene, and food safety**.

In the European Union (EU), the bakery products are regulated under Regulation (EC) No 178/2002, known as the General Food Law, along with specific regulations tailored to bakery goods. Any export of bakery product to EU countries, it requires to maintain the standards and benchmarks specified under it. In the United States, the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) oversee bakery products under the Federal Food, Drug, and

Cosmetic Act (FFDCA) and the Code of Federal Regulations. Similarly, in the Gulf Cooperation Council (GCC) countries, bakery and confectionery products must comply with the Gulf Standards Organization (GSO) standards, ensuring product safety, quality, and proper labeling.

Therefore, while maintaining infra and vendor quality for Bakery products, we need to following the following Key International Standards:

Area	Standard / Requirement	Description
Ingredients	Codex Alimentarius	Permitted additives, preservatives, sweeteners, and emulsifiers.
Microbiological Safety	CAC/ISO 22000	Limits on **pathogens** like Salmonella, Bacillus cereus, molds, and yeast.
Allergens	Codex Stan 1-1985	Mandatory **labeling of allergens**: wheat, gluten, milk, nuts, soy, eggs.
Labeling	Codex Stan 1-1985 & local laws	Product name, ingredients, net weight, expiration date, storage instructions, nutrition facts.
Packaging	ISO 9001 / ISO 22000	Must protect against contamination, moisture, and spoilage during transport.
Shelf Life & Storage	HACCP / Codex Guidelines	Guidelines for **temperature, humidity, and packaging** to maintain quality.

Despite, vendors are required to maintain following health and safety protocols for bakery products:

B. HACCP (Hazard Analysis & Critical Control Points)

- Mandatory for most exports to EU, US, and GCC.
- Focus on **contamination prevention, critical limits, monitoring, and corrective actions**.

C. ISO 22000 / FSSC 22000

- Food safety management systems widely recognized for international trade.

D. Residue & Contaminant Testing

- Testing for **pesticides, heavy metals, and mycotoxins**.
- Some countries require **certificate of analysis (CoA)**.

CHAPTER - 7

CHALLENGES

The import and export of perishable goods such as fresh foods, flowers, and pharmaceuticals poses several challenges due to their sensitivity, short shelf-life, and strict handling requirements.

In Indian context, to accurately assess the challenges, import and export data analysis of time sensitive perishable goods was done. The challenges and bottlenecks derived from the data are given below:

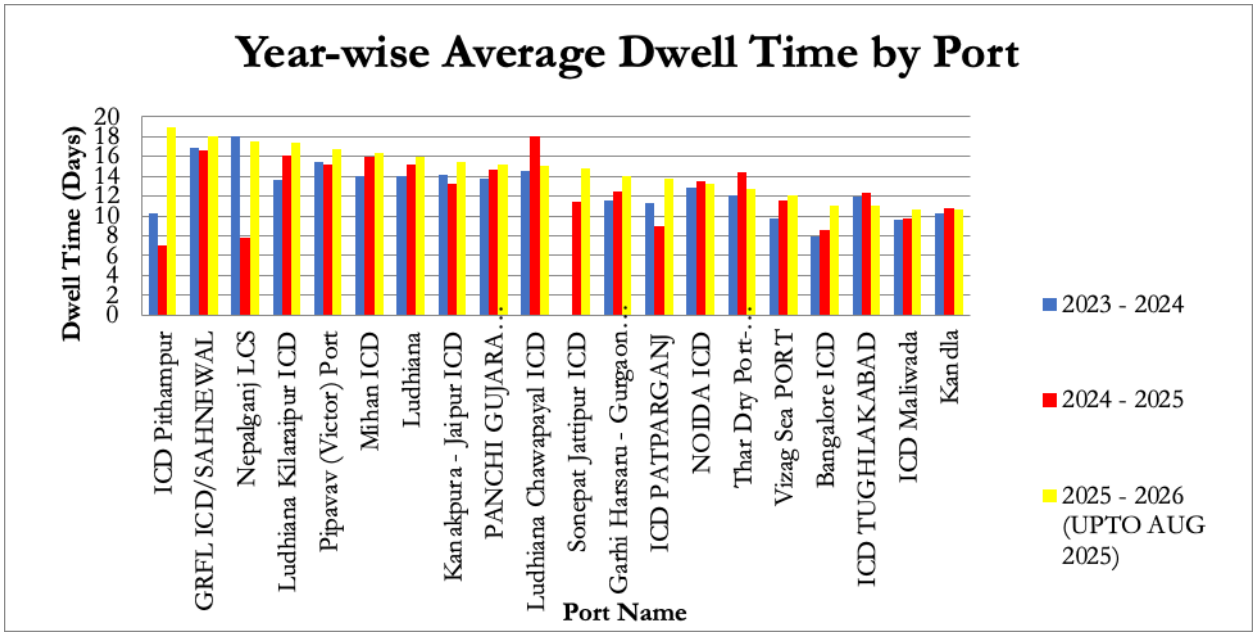
1. Imports: Excessive Dwell Time:

A sample data extracted from ICES shows that the time taken in clearance of the temperature sensitive import cargo through the sea ports, ICDs and Land Customs Stations are 10 to 20 days, which is absolutely inappreciable in view of the short-life of the perishable cargos. This fact may be derived from the table given below:

IMPORT: AVERAGE DWELL TIME

IMPORTS: Average of Dwell Time from arrival of goods to OOC (in no. of days)							
SN	**PORT CODE**	**PORT NAME**	**2023 to 2024**	**2024 to 2025**	**% GROWTH FROM 2023-24 TO 2024-25**	**2025 - 2026 (UPTO AUG 2025)**	**OVERALL AVERAGE**
1	ININD6	ICD Pithampur	10.3	7	-31.71%	19	11.6
2	INSGF6	GRFL ICD/Sahnewal	16.9	16.6	-1.37%	18	17
3	INNGRB	Nepalganj LCS	18	7.8	-56.94%	17.5	12.8
4	INQRH6	Ludhiana Kilaraipur ICD	13.6	16.1	18.14%	17.4	15.3
5	INKPK6	Mihan ICD	14	16	14.29%	16.3	15.8
6	INLDH6	Ludhiana	14	15.2	8.48%	15.9	14.9
7	INKKU6	Kanakpura - Jaipur ICD	14.2	13.2	-6.65%	15.4	14.2
8	INBDM6	PANCHI GUJARA SONEPAT ICD	13.7	14.7	7.37%	15.2	14.4

9	INCPR6	Ludhiana Chawapayal ICD	14.6	18	23.43%	15	15.4
10	INDWN6	Sonepat Jattipur ICD		11.4		14.8	12.5
11	INGHR6	Garhi Harsaru - Gurgaon ICD	11.5	12.5	8.70%	14	12.7
12	INPPG6	ICD Patparganj	11.3	9	-20.35%	13.7	11.7
13	INDER6	NOIDA ICD	12.8	13.5	5.32%	13.3	13.3
14	INSAU6	Thar Dry Port-Ahmedabad ICD	12.1	14.4	18.99%	12.7	13.1
15	INWFD6	Bangalore ICD	7.9	8.6	8.40%	11.1	9
16	INTKD6	ICD Tughlakabad	12	12.4	3.85%	11	11.9
17	INMWA6	ICD Maliwada	9.6	9.7	1.12%	10.7	10



Across the 17 ICDs, the average dwell time ranges from 9.0 to 17.0 days, reflecting mixed performance trends. While some locations have shown improvement in clearance speed, several others continue to face rising delays. This variation indicates operational and procedural bottlenecks that are emerging as a key challenge to trade facilitation and logistics efficiency.

The increase in dwell time leads higher logistics and storage costs, port conisation and delayed cargo movement. It disrupts supply chain efficiency, undermines the competitiveness, and adversely impacts the ease of doing business. Extended clearance periods also erode the gains achieved through digitalization and trade

process reforms. Moreover, prolonged dwell times compromises product integrity and operational reliability, particularly for temperature-sensitive goods resulting in product deterioration, packaging damage, and reduced shelf life. Addressing this challenge requires enhanced coordination among port authorities, customs, and logistics operators to ensure faster, more predictable cargo clearance.

Ports with Rising Dwell Time (Efficiency Decline)

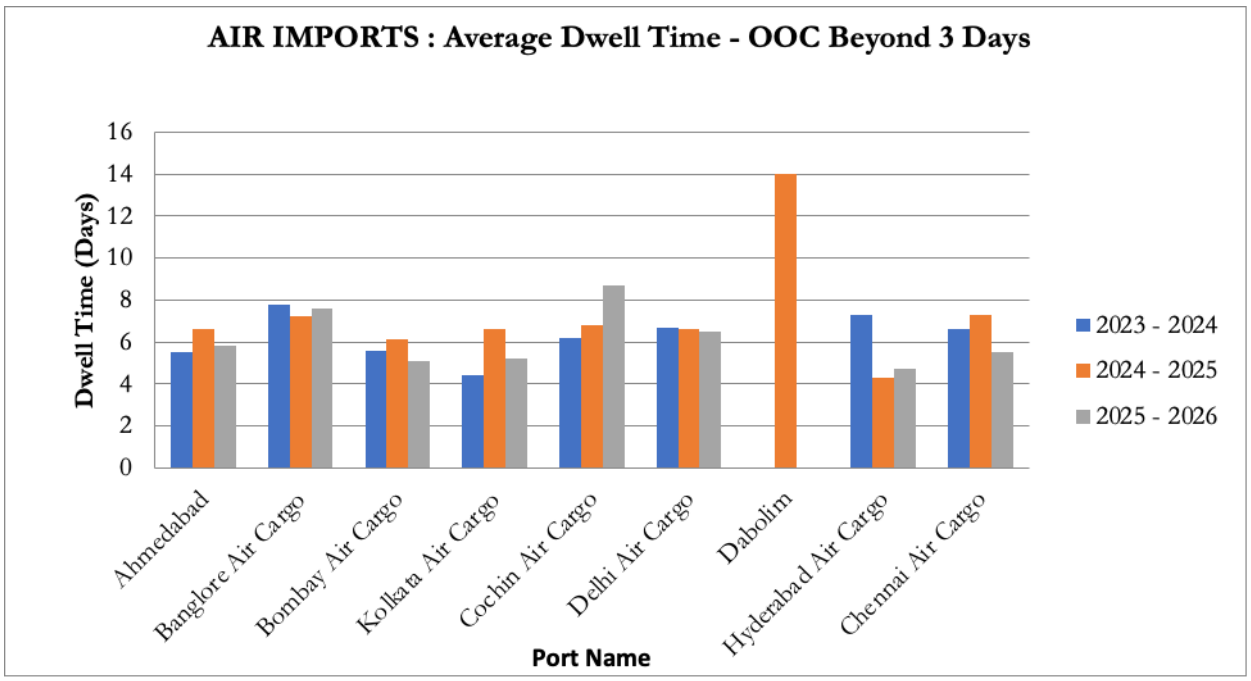
Port Name	FY 2023–24	FY 2024–25	% Change	Insight
Ludhiana Chawapayal ICD	14.6	18	23.43%	Highest increase in dwell time YoY
Thar Dry Port – Ahmedabad	12.1	14.4	18.99%	Notable rise in delay
Ludhiana Kilaraipur ICD	13.6	16.1	18.14%	Consistent increase in dwell time
Mihan ICD	14	16	14.29%	Rising delays despite infrastructure upgrades

These ports require attention to streamline customs, logistics, and terminal operations to reverse the upward trend in dwell time. Similarly, we may see that the dwell time of the temperature sensitive cargo clearance from the Airports are also not appreciable. Major ports are taking 5 to 10 days in clearance of such perishable cargo.

IMPORTS through Airports: Average of Dwell Time - OOC Beyond 3 days.

IMPORTS through Air: Average of Dwell Time - OOC Beyond 3 Days						
PORT CODE	PORT NAME	2023 - 2024	2024 - 2025	% GROWTH FROM 2023-24 TO 2024-25	2025 - 2026	OVERALL AVERAGE
INAMD4	Ahmedabad	5.5	6.6	19.74%	5.8	5.9
INBLR4	Banglore Air Cargo	7.8	7.2	-7.96%	7.6	7.5
INBOM4	Bombay Air Cargo	5.6	6.1	10.14%	5.1	5.6
INCCU4	Kolkata Air Cargo	4.4	6.6	48.72%	5.2	5.5
INCOK4	Cochin Air Cargo	6.2	6.8	8.54%	8.7	6.9
INDEL4	Delhi Air Cargo	6.7	6.6	-0.63%	6.5	6.6
INGOI4	Dabolim		14			14

INHYD4	Hyderabad Air Cargo	7.3	4.3	-40.60%	4.7	5.4
INMAA4	Chennai Air Cargo	6.6	7.3	10.55%	5.5	6.6
	OVERALL AVERAGE	6.3	6.6	4.25%	5.9	6.3



Dwell time beyond three days reflects delays in customs clearance and cargo release. Across nine major air cargo terminals, the overall average dwell time stands at 6.3 days, with mixed trends in performance. While some airports have improved efficiency, others show rising delays, impacting supply chain responsiveness.

Airports with Rising Dwell Time (Efficiency Decline)

Airport	FY 2023–24	FY 2024–25	% Change	FY 2025–26	Insight
Kolkata (INCCU4)	4.4	6.6	48.72%	5.2	Sharp increase in FY 2024–25; partial recovery underway
Cochin (INCOK4)	6.2	6.8	8.54%	8.7	Rising delays; highest dwell time in current year
Chennai (INMAA4)	6.6	7.3	10.55%	5.5	Recovered in FY 2025–26 but still above average
Ahmedabad (INAMD4)	5.5	6.6	19.74%	5.8	Moderate increase; needs monitoring

These 4 airports experienced rising delays in FY 2024–25, with Cochin showing the most concerning trend due to continued increase in FY 2025–26.

SEA IMPORTS: Average of Dwell Time: OOC Beyond 5 days

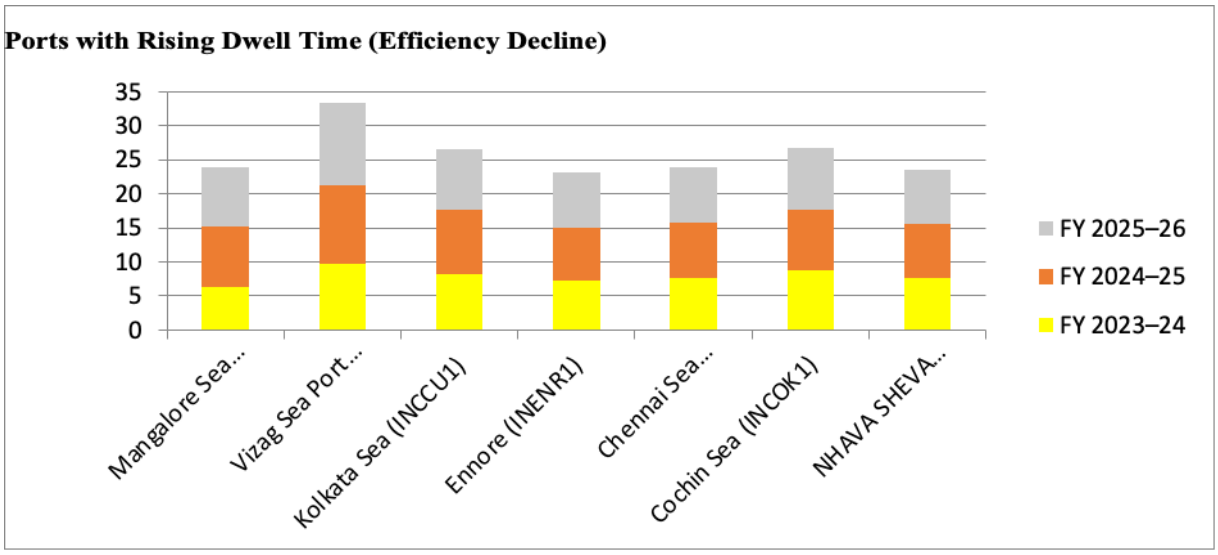
SEA IMPORTS: Average of Dwell Time: OOC Beyond 5 days						
PORT CODE	**PORT NAME**	**2023 - 2024**	**2024 - 2025**	**% GROWTH FROM 2023-24 TO 2024-25**	**2025 - 2026**	**OVERALL AVERAGE**
INBOM1	Bombay Sea		5.9			5.9
INCCU1	Kolkata Sea	8.2	9.5	16.61%	8.8	8.9
INCOK1	Cochin Sea	8.8	8.9	1.00%	9.1	8.9
INENR1	Ennore	7.2	7.8	7.08%	8.2	7.7
INGGV1	Gangavaram Port		10.6			10.6
INHZA1	HAZIRA PORT	9	7.4	-17.96%	9.4	8.6
INIXY1	Kandla	18	10.8	-39.75%	10.6	12.8
INJGD1	Jaigad	6		-100.00%		6
INKAK1	Kakinada		13			13
INKAT1	Kattupalli Port, ENNORE	11.2	7.5	-33.09%	6.2	7.8
INKRI1	Krishnapatnam	18		-100.00%		18
INMAA1	Chennai Sea	7.6	8.1	5.77%	8.1	7.9
INMUN1	Mundra Port	9.6	9.2	-4.62%	10.4	9.7
INNML1	Mangalore Sea	6.4	8.7	35.84%	8.7	7.9
INNSA1	NHAVA SHEVA	7.7	7.8	0.64%	8	7.8
INPAV1	Pipavav (Victor) Port	15.4	15.2	-1.26%	16.7	15.8
INTTS1	Kidderpore LCS	13		-100.00%		13
INTUT1	Tuticorin Sea PORT	10.3	8.9	-13.36%	10	9.7
INVTZ1	Vizag Sea PORT	9.7	11.5	19.11%	12.1	11.2

Dwell time beyond five days indicates delays in customs clearance and cargo release at sea ports. Across 19 major ports, the overall average dwell time ranges from 5.9 to 15.8 days, with mixed trends in operational efficiency. While some ports have improved clearance speed, others show rising delays, impacting supply chain fluidity and cost.

Ports with Rising Dwell Time (Efficiency Decline)

Port Name	FY 2023–24	FY 2024–25	% Change	FY 2025–26	Insight
Mangalore Sea (INNML1)	6.4	8.7	35.84%	8.7	Sharp rise in dwell time; sustained delays

Vizag Sea Port (INVTZ1)	9.7	11.5	19.11%	12.1	Consistent increase; needs operational review
Kolkata Sea (INCCU1)	8.2	9.5	16.61%	8.8	Moderate rise; partial recovery underway
Ennore (INENR1)	7.2	7.8	7.08%	8.2	Gradual increase in dwell time
Chennai Sea (INMAA1)	7.6	8.1	5.77%	8.1	Stable but slightly rising delays
Cochin Sea (INCOK1)	8.8	8.9	1.00%	9.1	Marginal increase; consistently high dwell time
NHAVA SHEVA (INNSA1)	7.7	7.8	0.64%	8	Stable performance with minor increase



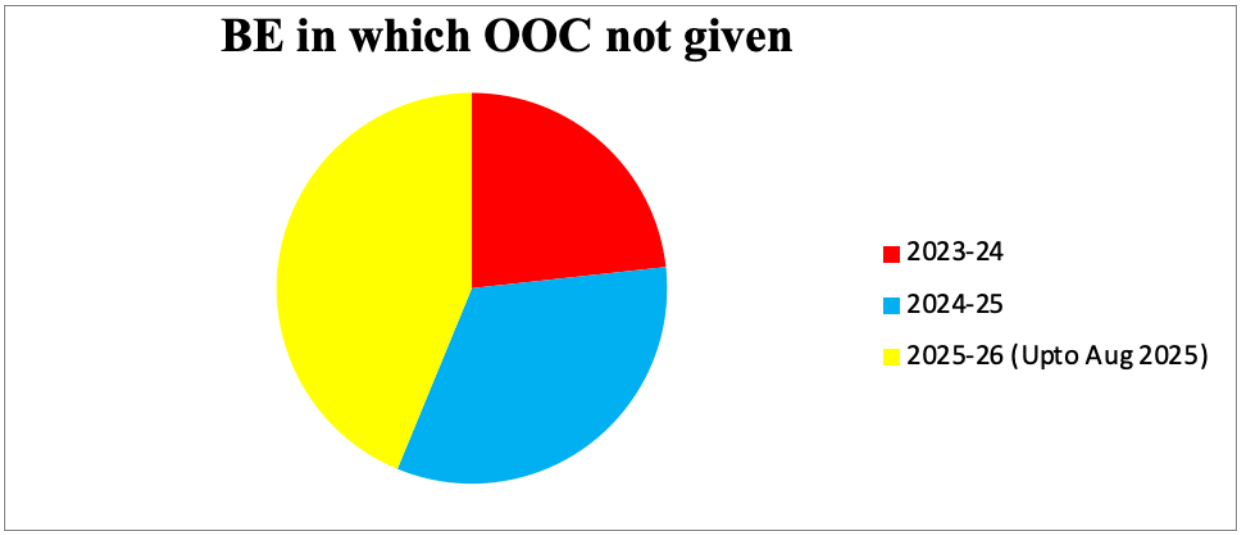
2. Relinquishment of the Title of Import Consignments:

It has also been observed from the ICES data that OOC of many consignments of Import of Perishable (Temperature Sensitive) Cargo are not given either because of non-compliance or because importers disown the consignment because of unprecedented time taken in clearance. The scenario may be perceived through following data at all India level:

Details of the Bills of Entry in which OOC not given

Number of BEs in which OOC not given at 55 Ports including Sea/air/ICDs				
TOTAL PORTS	**2023 - 2024**	**2024 - 2025**	**2025 - 2026**	**Grand Total**

TOTAL 55 PORTS	516	731	971	2218



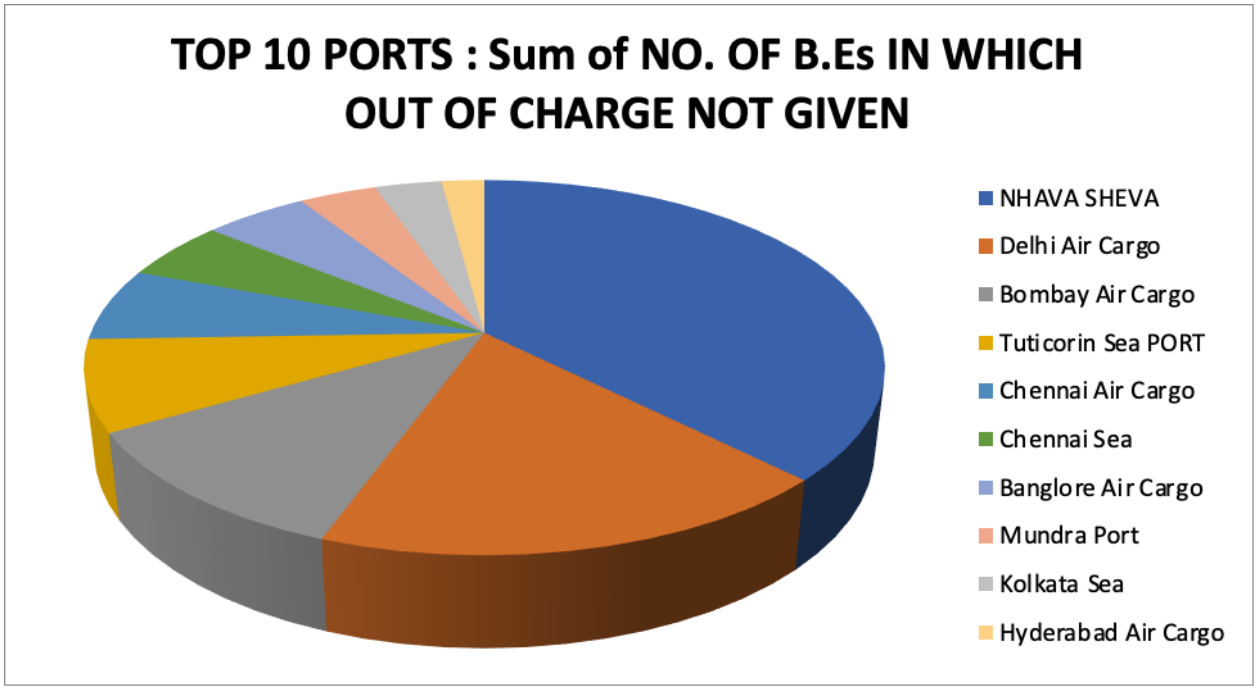
The data reveals a significant and accelerating challenge across Indian ports regarding the number of Bills of Entry where temperature sensitive consignments are not cleared because either importer disowned the consignment or due to serious non-compliance issue. The overall trend shows 88% increase in this metric over two years, rising from 516 in FY 2023-24 to 971 in FY 2025-26. This indicates growing delays in the customs clearance process, leading to potential supply chain bottlenecks, increased demurrage costs for importers, reduced efficiency at ports as well as product deterioration, damaged packaging, and reduced shelf life.

The data specified in below table shows the number consignments year-wise at top 10 ports, in which temperature sensitive goods were imported but clearance of the goods didn't take place. One can derive easily, that the non-clearance of the goods due to compromising quality, product integrity or non-compliance etc. are very high. Not only the ratio of non-clearance of other goods is lower than the ratio of non-clearance of temperature sensitive cargo, but the reasons are also different. The non-clearance of other goods are mostly related to serious offences.

Ports-wise No. of BEs (at top 10 ports) in which OOC not given:

TOP 10 PORTS : Sum of NO. OF B.Es IN WHICH OUT OF CHARGE NOT GIVEN						
S N	**PORT CODE**	**PORT NAME**	**2023-24**	**2024-25**	**2025-26**	**TOTAL**

1	**INNSA1**	**NHAVA SHEVA**	134	167	407	708
2	**INDEL4**	**Delhi Air Cargo**	90	110	140	340
3	**INBOM4**	**Bombay Air Cargo**	71	72	66	209
4	**INTUT1**	**Tuticorin Sea PORT**	32	30	86	148
5	**INMAA4**	**Chennai Air Cargo**	30	46	43	119
6	**INMAA1**	**Chennai Sea**	25	43	29	97
7	**INBLR4**	**Banglore Air Cargo**	27	34	34	95
8	**INMUN1**	**Mundra Port**	12	16	43	71
9	**INCCU1**	**Kolkata Sea**	3	57	1	61
10	**INHYD4**	**Hyderabad Air Cargo**	16	17	6	39
		TOTAL	**440**	**592**	**855**	**1887**



The data on Bills of Entry where "Out of Charge" (OOC) was not granted reveals a bottleneck in customs clearance process, concentrated heavily in a few key ports. The total pendency across these top 10 ports stands at **1,887 cases**, indicating widespread delays that directly impact supply chain efficiency and importer costs.

The situation is most critical at Nhava Sheva Sea **Port (INNSA1)**, which is by far the worst-performing hub. It alone accounts for **708 cases,** or **37.5%** of the entire pendency from the top 10 ports.

Following Nhava Sheva, **Delhi Air Cargo (INDEL4)** presents a persistent, high-volume problem with **340 (18%) pending cases**. It has consistently been the second-largest source of delays, showing steady year-on-year growth. Similarly, **Bombay Air Cargo (INBOM4)** maintains a stubbornly high backlog of **209 cases (11.1%)** , though its numbers have recently plateaued.

While major air cargo ports are seen struggled, several sea ports are now seeing growth in pendency. **Tuticorin Sea Port (INTUT1)** saw a 187% year-on-year jump in 2025-26, while **Mundra Port (INMUN1)** experienced a 169% increase in the same period.

Amid these concerning trends, **Kolkata Sea Port (INCCU1)** stands out as a notable exception and a potential success story. After a spike from 03 to 57 cases from 2023-24 to 2024-25, it successfully reduced its pendency to 01 cases in 2025-26, demonstrating that improvement is achievable with targeted intervention.

In summary, the overall customs clearance environment is deteriorating, with total pendency growing in the recent years. The crisis is acutely concentrated at Nhava Sheva but is simultaneously spreading to other major and mid-sized ports, demanding urgent, port-specific solutions to address this mounting challenge to trade efficiency.

3. Concentration of the Imports of Temperature Sensitive Cargo at some major Ports

The import of temperature sensitive cargos are mostly concentrated in major cities right now. The overall performance of ports in comparison to total value of imports of temperature sensitive cargo shows concentration of the imports at major ports only.

List of top 10 ports with Major Commodities account for a staggering 84% of the total Import value (of top 20 ports)

Rank	Port Code	Port Name	Total Value (in Crores)	% of Total	Key HSN Specialties
1	INNSA1	JNPT (Nhava Sheva)	73725.254	**32.35%**	Fruits, Vegetables, Dairy, Bakery,

					Meat
2	INBOM4	Mumbai Air Cargo	30257.563	**13.28%**	Pharmaceuticals (98% of value)
3	INMAA1	Chennai Sea	26456.285	**11.61%**	Vegetables (87%), Fruits
4	INTUT1	Tuticorin Sea Port	21789.616	**9.56%**	Fruits (81%), Vegetables
5	INNML1	Mangalore Sea	13441.321	**5.90%**	Fruits (99%)
6	INCCU1	Kolkata Sea	12936.224	**5.68%**	Seafood, Vegetables, Bakery
7	INATRB	Attari Road LCS	7077.054	**3.11%**	Vegetables (93%)
8	INMUN1	Mundra Port	11063.608	**4.85%**	Vegetables (63%), Fruits
9	INDEL4	Delhi Air Cargo	4264.856	**1.87%**	Pharmaceuticals (89%)
10	INPTPB	Petrapole Bengal LCS	2036.263	**0.89%**	Seafood (30%), Fruits

The HSN-wise port analysis shows clear concentration patterns, with imports funneled through a few dominant gateways depending on the product. Pharmaceuticals are mostly handled by air cargo hubs, led by Mumbai Air Cargo, with additional support from Delhi and Hyderabad, while sea ports play only a marginal role except JNPT (17.2%). Fruits, the largest import category, are heavily routed via Nhava Sheva (42.5%), followed by Tuticorin (18.8%) and Mangalore (14.34%), indicating coastal ports' dominance. Vegetables, the second-largest category, show a similar trend with Nhava Sheva (29.3%) and Chennai (28.9%) leading, supported by Kolkata (13.4%) and Mundra (8.7%).

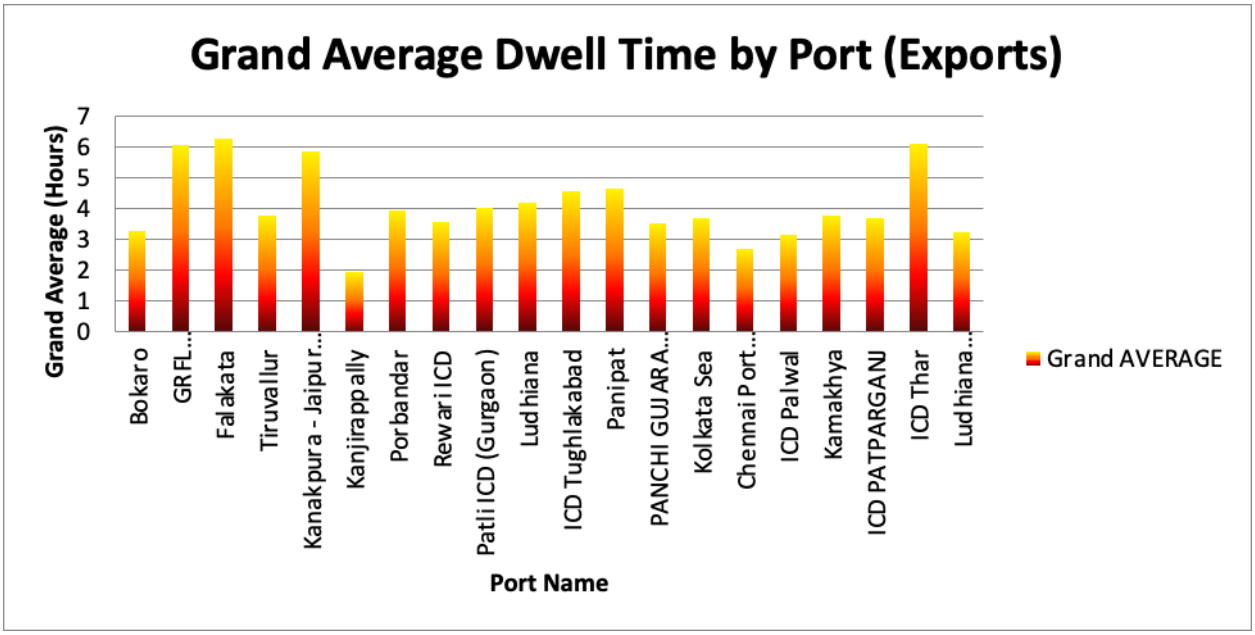
The concentration of specific categories of time-sensitive commodities at certain ports results in supply chain congestion, putting additional pressure on the clearance process. This also indicates that some ports have developed specialization in handling particular types of goods due to the availability of suitable infrastructure and related facilities.

4. EXPORTS: Excessive Dwell Time

4.1 Average Dwell Time Analysis (From Goods Arrival to LEO)

The average dwell time in Export at different ports are quite appreciable. We may see from the following data that the average dwell time at ICDs/ports are from 2 hours to 5 hours, which is quite goods.

TOP 20 PORTS: AVERAGE DWELL TIME ANALYSIS (FROM ARRIVAL OF GOODS TO LEO IN HOURS)						
SN	**PORT CODE**	**PORT NAME**	**2023 - 2024**	**2024 - 2025**	**2025 - 2026**	**Grand AVERAGE**
1	INBOA6	Bokaro	1.6	1.56	17	3.28
2	INSGF6	GRFL ICD/SAHNEWAL	7.48	3.99	7.05	6.05
3	INFLT6	Falakata			6.27	6.27
4	INTRV4	Tiruvallur	2.52	3.51	5.73	3.76
5	INKKU6	Kanakpura - Jaipur ICD	7.02	5.37	5.48	5.88
6	INKGJB	Kanjirappally		0.79	5.38	1.94
7	INPRT1	Porbandar		3.25	5.29	3.93
8	INPKR6	Rewari ICD	1.84	3.82	4.59	3.58
9	INPTL6	Patli ICD (Gurgaon)	4.45	3.49	4.45	4.01
10	INLDH6	Ludhiana	3.78	4.57	4.29	4.18
11	INTKD6	ICD Tughlakabad	4.95	4.47	4.29	4.59
12	INPJN6	Panipat		5.21	4.2	4.64
13	INBDM6	PANCHI GUJARA SONEPAT ICD	3.08	3.51	4.03	3.54
14	INCCU1	Kolkata Sea	4.35	2.92	3.97	3.71
15	INMAA6	Chennai Port (CITPL/CCTPL/Thiruvottiyur)		0.1	3.97	2.68
16	INPWL6	ICD Palwal	3.45	2.24	3.95	3.16
17	INKMAB	Kamakhya			3.78	3.78
18	INPPG6	ICD PATPARGANJ	3.41	3.96	3.66	3.71
19	INTHA6	ICD Thar	9.01	6.15	3.65	6.13
20	INCPR6	Ludhiana Chawapayal ICD	2.74	3.56	3.5	3.24



Dwell time from arrival to LEO (Let Export Order) is a critical metric for assessing port efficiency and customs responsiveness. Across 20 locations, the grand average dwell time ranges from 1.94 to 6.27 hours.

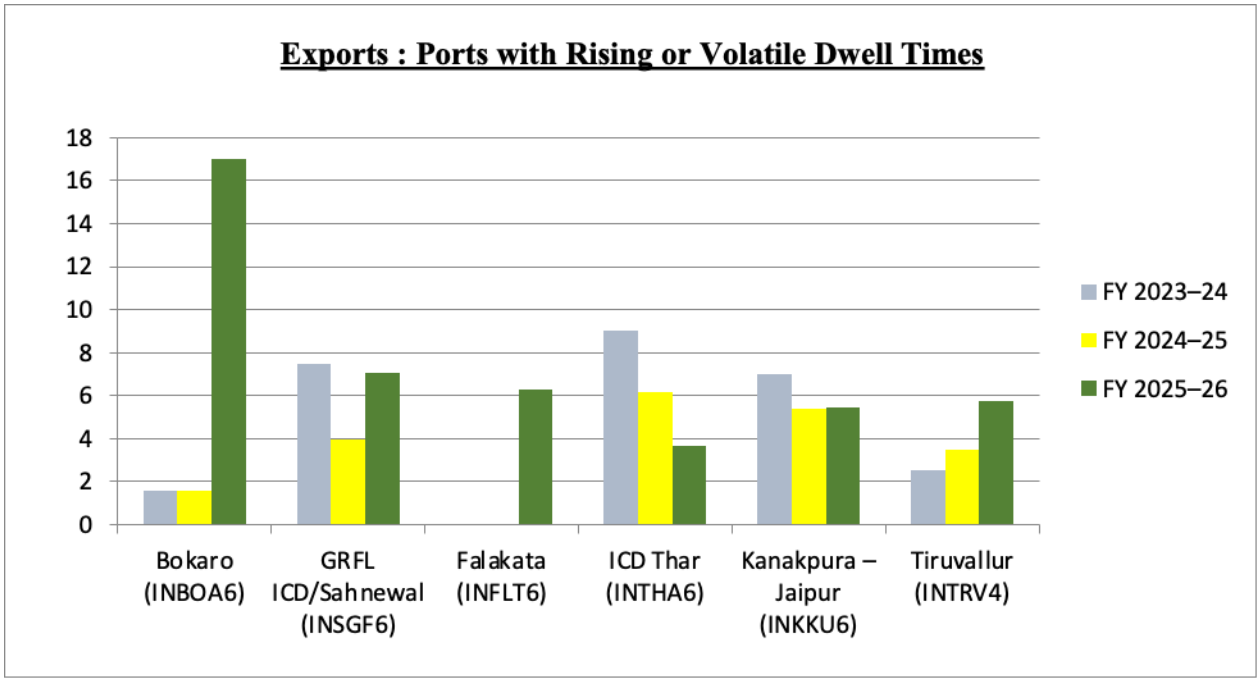
The rise in export dwell time has emerged as a significant challenge affecting trade efficiency and supply chain reliability. Longer clearance durations at ports and ICDs lead to missed shipping schedules, higher inventory and logistics costs, and reduced global competitiveness of Indian exports. This delay also offsets the progress made through digitalization and trade facilitation initiatives.

Extended dwell periods also compromise the quality and integrity of export consignments, particularly temperature-sensitive and perishable goods. Prolonged storage or improper handling may lead to product degradation, reduced shelf life, and non-compliance with international quality standards. Persistent delays at certain ports highlight the need for streamlined coordination among customs, port authorities, and logistics operators to ensure time-bound cargo movement and enhance India's export efficiency.

Exports: Ports with Rising or Volatile Dwell Times (In hours)

Port Name	FY 2023–24	FY 2024–25	FY 2025–26	Grand Avg	Insight
Bokaro (INBOA6)	1.6	1.56	17	3.28	Extreme spike in FY 2025–26; needs urgent review

GRFL ICD/Sahnewal (INSGF6)	7.48	3.99	7.05	6.05	Fluctuating performance; inconsistent clearance speed
Falakata (INFLT6)	—	—	6.27	6.27	Initial data shows high dwell time
ICD Thar (INTHA6)	9.01	6.15	3.65	6.13	Improving trend; still above average
Kanakpura – Jaipur (INKKU6)	7.02	5.37	5.48	5.88	Gradual improvement; still elevated
Tiruvallur (INTRV4)	2.52	3.51	5.73	3.76	Rising dwell time; needs monitoring



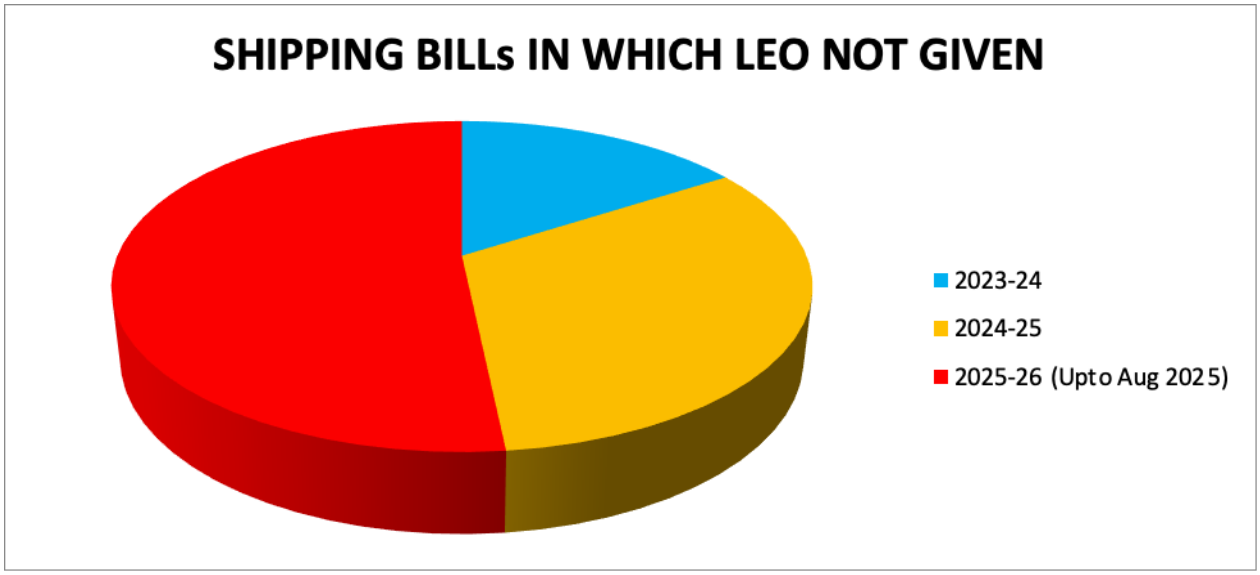
These ports show either rising delays or inconsistent performance.

4.2 SB in which Let Export Order not given:

However, it has been noticed that quite a large number of export consignments are not cleared and LEO not given at different ports. The following table shows the number of SBs which were not cleared and LEO not given in FY 2023-24, 2024-2025 and 2025-26. The reasons behind non-clearance of the SBs are mostly cancelation of order, delay in obtaining suitable permissions or the non-compliance of the norms and stands required by the country of destination.

SHIPPING BILLS, IN WHICH, LEO NOT GIVEN

Sum of NO. OF SBs IN WHICH LEO NOT GIVEN				
PORT	**2023 - 2024**	**2024 - 2025**	**2025 - 2026**	**Grand Total**
TOTAL 152 PORTS	2330	4742	7560	14632



The analysis of Shipping Bills (SBs) in which Let Export Order (LEO) was not issued across 152 Indian ports reveals a concerning upward trend in export clearance delays. In the fiscal year 2023–2024, there were 2,330 such cases, which more than doubled to 4,742 in 2024–2025, and surged further to 7,560 in 2025–2026, culminating in a grand total of 14,632 instances.

Thus, reducing dwell time for import and export clearances remains a major challenge for port and logistics operations. Despite various trade facilitation measures, delays in documentation, coordination gaps among stakeholders, and limited infrastructure capacity continue to hinder faster cargo movement. Achieving consistent reduction in dwell time is essential to enhance supply chain efficiency, improve cargo quality, and strengthen India's global trade competitiveness.

4.3 Port wise commodity wise analysis:

Below is the table showing port-wise top commodities based on export value (in crores) from FY 2023–24 to FY 2025–26 (up to August 2025). Each port is listed with its highest-performing HSN category:

Port-Wise Top Export Commodities

Port Name	Top Commodity (HSN Group)	Description	Export Value (IN Crores)
NHAVA SHEVA	3002–3006	Pharmaceuticals	1,04,717.22
Bombay Air Cargo	3002–3006	Pharmaceuticals	54,112.39
Vizag Sea Port	0301–0308	Seafood	38,065.63
Hyderabad ICD	3002–3006	Pharmaceuticals	38,304.06
Mundra Port	3002–3006	Pharmaceuticals	19,469.94
Hyderabad Air Cargo	3002–3006	Pharmaceuticals	33,725.87
Delhi Air Cargo	3002–3006	Pharmaceuticals	20,479.78
Chennai Sea	0301–0308	Seafood	10,549.81
Dadri-ACPL CFS	0201–0208	Meat & Poultry	17,264.59
Cochin Sea	0301–0308	Seafood	12,451.23
ICD Tumb	3002–3006	Pharmaceuticals	14,294.71
Kolkata Sea	0301–0308	Seafood	12,292.54
Dadri-CGML	0201–0208	Meat & Poultry	7,828.21
Ennore	0301–0308	Seafood	6,644.11
Tuticorin Sea Port	0301–0308	Seafood	6,446.04
Bangalore ICD	3002–3006	Pharmaceuticals	10,467.77
Pipavav (Victor) Port	0301–0308	Seafood	8,355.29
Gulbarga	3002–3006	Pharmaceuticals	9,959.67
Zydus Infra Mundra Port	3002–3006	Pharmaceuticals	9,826.44
Bangalore Air Cargo	3002–3006	Pharmaceuticals	8,911.43

The above table make it evident that Pharmaceuticals are the top export at 12 of the 20 ports, especially air cargo and inland container depots near manufacturing centres (e.g., Bombay, Delhi, Hyderabad). Major sea ports on the eastern and southern coasts (e.g., Vizag, Cochin, Chennai) are dominated by seafood exports, leveraging proximity to fishing zones.

Specialized Export Hubs: Inland depots excel in meat exports, while new specialized ports and SEZs are emerging as significant hubs exclusively for pharmaceuticals.

High Specialization, Low Diversification: Most ports are dominated by a single commodity category, showing a regionally segmented export ecosystem where infrastructure and location directly determine the primary export.

5. The challenges derived from the reports received from various Trade Associations and Customs Zones

Given the perishable nature of the cargo, it is essential for all stakeholders to ensure that the clearance process is both fast and seamless. This report focuses on an empirical study of the challenges faced by different stakeholders, along with the measures required to address these issues and accelerate the clearance process.

To support this analysis, inputs have been sought from various trade associations. A summary of their submissions, highlighting the key issues they encounter, is presented below:

5.1 Ekram Husain, Vice President, VAFA, Fresh Vegetables And Fruits Exporters Association: vide his email dated 19.09.2025 has forwarded their concerns as under:

Key Issues at Air Customs (Mumbai)

1. Manual Shipping Bill Filing: In case of server downtime, exporters are unable to obtain Shipping Bill numbers. As a result, shipments are delayed and airlines charge heavy no-show penalties. We request that manual Shipping Bill filing be permitted during system failures to avoid cargo losses.

2. ICEGATE System Issues: Shipping bills often do not reflect on ICEGATE in a timely manner despite multiple follow-ups and Helpdesk tickets. Exporters are penalized for EGM error corrections, even when the issue lies at the system's end. Customs sometimes demand hard copy e-BRC submissions as E-BRC data is not linked with DGFT.

3. Product Classification Issues: Lack of clear guidelines for new customs officers often leads to confusion between APEDA products and Spice Board products (e.g., fresh haldi, amba haldi). This causes unnecessary delays in shipments

4. Perishable Cargo Handling: Back-to-town process for perishable shipments offloaded by airlines should be fast-tracked. Acceptance of perishable cargo should be defined as minimum D-4 hours, with a clear notification issued. In case of flight cancellations where custodians change (APEDA to CSC or vice versa), back-to-town clearance should not be required for the same shipment.

5. Bank & Drawback Issues: Customs require NOC from previous banks (via email and hard copy) to change IFSC codes for drawback purposes.

Many banks do not easily issue NOCs, leading to delays. We request that new AD code registration itself be sufficient without mandatory NOCs from previous banks.

Key Issues at Seaports (Mumbai)

1. Clearance Facility: No clearance is available at night. For perishables, clearance should be 24×7.
2. Infrastructure Bottlenecks: Shortage of plug-in points for reefer containers. No separate lane for perishable cargo; trailers get stuck with general cargo leading to temperature abuse and shut-outs. Long waiting times (sometimes 12+ hours) cause generators to fail, resulting in product spoilage.
3. Inspection Issues: Containers carrying perishable products are often opened in uncontrolled conditions during inspection, damaging quality. Inspection facilities should ensure controlled temperatures.
4. Documentation Delays: Hard copy submission of documents is still required. Allowing scanned documents will significantly speed up the process.
5. Traffic Jams at Ports: Regular congestion causes further delays in perishable cargo movement.

5.2 **Sh. Rollins John, Director, PHARMEXCIL**, vide email dated 15.09.2025 has forwarded report on the matter as under:

- Goods imported for Re-Export should have Green Channel Clearance without any hindrance of Local procedures. The Import Shipments for Re-Export should have blanket approval of Physical Bond Waiver and once Bill of Entry, Out of Charge done, goods should be allowed for Carting at the desired Export CFS / Airport. The process needs to eliminate lengthy procedures to obtain approval from Desk to Desk. This will not only reduce the time but also reduce the Cost for the Shipment and will encourage Exim trade to get more Cross-Country business
- Requested for issuance of a clear guidance note or checklist related to merchant export of pharmaceuticals, nutraceuticals, food supplements, and medical devices. Merchant exporters generally purchase goods from the open market for onward export and are

therefore not in a position to provide a Certificate of Analysis (CoA) or manufacturing license. In such cases, they should be allowed to rely upon valid GST purchase invoices and corresponding purchase orders as sufficient documentation. Further, we would like to add that Pharma products have a declaration on their labels of their contents with manufacturing license details. This declaration helps ADC officer to derive the technicalities of the product and hence should suffice for granting NOC.

- Companies exporting to Pakistan have stated that there has been an update from many of the agents in Pakistan indicating that the Government of Pakistan has approved the acceptance of shipments originating from India. Additionally, airlines such as Thai Airways, Turkish Airlines, and Gulf Air are reportedly accepting cargo bound for Pakistan. However, there seems to be alack of clarity both at Air Cargo as well as Indian Ports as exporters have stated that custom officers have dissuaded companies from exports.

5.3 Report shared by Customs Mumbai Zone-III

The Customs Mumbai Zone III has forwarded a detailed note made on Pharma Sector covering current stay of play, available infra across the ports, gaps identified and way forward. The challenges faced by the stakeholders as mentioned in the reports are as under:

Challenges Faced By Stakeholders in the Smooth Movement Of Export Cargo:

1. **Space Constraints:**
   In major air cargo terminals, space limitations pose a significant challenge. Warehouses often operate using only a portion of the total available area, resulting in frequent congestion and long queues of vehicles waiting at the offloading docks.

2. **Inadequate Manpower**
   Most warehouses are functioning with sub-optimal staff strength. The shortage of manpower, coupled with limited storage space, leads to increased turnaround times for cargo offloading and processing.

3. **Detention and Demurrage Charges**

Warehouse charges commence once the vehicle is positioned at the offloading dock. Due to the combined issues of space and manpower constraints, delays in cargo offloading and the subsequent clearance process often occur, leading to substantial detention and demurrage charges for exporters.

4. Delays in Cargo Arrival Report (CARR) Generation

The Cargo Arrival Report is generated only after cargo has been carted into the warehouse. However, frequent system outages and unreliable internet connectivity often delay CARR generation. These delays contribute significantly to increased detention and demurrage costs.

5. Lack of Stacking Plans from Airlines

For efficient cargo handling, warehouse operators require proper stacking plans from airlines to align with dispatch schedules. In many cases, airlines fail to provide these plans, resulting in haphazard cargo placement. This not only hampers smooth cargo movement but also affects optimal utilization of warehouse space.

6. Thermal Packaging Requirements of Foreign Clients

Certain foreign clients, especially in the pharmaceutical sector, mandate that thermal packaging remain intact upon receipt of goods. During the customs examination process, such packaging is often opened, leading to damage. This results in consignment rejections at the destination and causes financial losses for the exporter.

7. Examination, Sampling and Testing of Pharmaceutical Export Cargo

During the examination of pharmaceutical cargo, Customs systems occasionally generate instructions mandating physical examination of the consignment or the withdrawal of samples for compositional analysis. While such measures are important for regulatory compliance, several critical challenges arise in their practical implementation, particularly with respect to maintaining the integrity of sensitive pharmaceutical products.

i. Absence of Temperature-Controlled Sampling Facilities

Currently, there is no dedicated temperature-controlled facility for the withdrawal of samples within the Air Cargo Complex or associated

examination zones. This presents a significant risk, especially for bulk pharmaceutical active ingredients (APIs) and temperature-sensitive formulations. In the absence of a controlled environment following challenges are faced:

- Sampling often takes place in open or ambient conditions, exposing the entire consignment or the opened package to unregulated temperatures and humidity levels.
- This exposure can lead to chemical or physical degradation of the cargo, particularly in the case of hygroscopic or thermolabile substances.
- Even if only a portion of the product is sampled, breach of the packaging compromises the overall sterility, stability, or shelf-life of the remaining consignment.
- As a result, there is a high risk that international buyers may reject the shipment, citing non-compliance with product integrity standards, which can cause significant financial losses for the exporter.

ii. Limitations in Sample Testing by DYCC Laboratories.

Once samples are withdrawn, they are typically forwarded to DYCC for compositional testing. However, several issues have been repeatedly encountered in this process:

- Non-availability of Specific Testing Equipment: DYCC laboratories have, on multiple occasions, reported their inability to test certain pharmaceutical compounds due to the lack of appropriate analytical instruments or standard reference materials.
- Quality Degradation of Samples During Transit: The transportation of samples without a cold chain or other protective measures often leads to the deterioration of sample quality. This is especially critical for products requiring specific storage conditions (e.g., 2–8°C or below -20°C).
- As a result, the test results may not accurately reflect the true composition or quality of the original consignment, potentially leading to false negatives or misinterpretation of the product's compliance status.
- In cases where a valid analysis cannot be performed, the entire consignment may be held back or rejected, causing further delays and operational inefficiencies.

iii. Consequences and Implications

a) Operational Delays: Extended hold times due to re-sampling, re-testing, or lack of clear test outcomes cause avoidable delays in export clearance.

b) Commercial Losses: Exporters may face contractual penalties, loss of buyer confidence, and even blacklisting if product quality is compromised or delivery timelines are breached.

c) Regulatory Risk: Repeated instances of cargo deterioration due to inadequate sampling protocols may lead to non-compliance with international regulatory requirements (e.g., EUGMP, USFDA), affecting India's global export credibility in pharmaceuticals.

Moving perishable cargo/time sensitive commodities are like running a relay race. The cargo is the baton, and every stage like farmer, transporter, Customs, cold storage, airline or shipping line, and finally the buyer is like a runner. Each one has to do their part quickly and hand it over smoothly to the next. If even one person is late, careless, or drops the baton, the whole chain breaks and the goods may spoil or get delayed.

6. Key Operational and Regulatory Challenges

The recommendations of various stakeholders have been examined, and, also, an empirical study based on data from the DG System and its analysis was conducted. The study indicates that the movement of time-sensitive cargo, from pre-arrival preparation to final delivery faces distinct challenges that can affect quality, shelf life, and commercial value.

These challenges can be broadly categorized into three sequential phases. A clear understanding of these phases is essential for stakeholders to develop faster, safer, and more efficient supply chains.

Phase	Challenge Area	Description / Problem	Impact
Phase 1: Pre-Arrival & Regulatory Complexity	**Multi-Agency Regulatory Tangles**	Importers must comply with multiple authorities (Customs, FSSAI, Plant/Animal Quarantine, CDSCO), each having distinct	Conflicting requirements, extended clearance time, and confusion among stakeholders.

		documentation and timelines. Lack of coordination causes duplication and delays.	
	Complex and Frequently Changing Rules	Frequent amendments to food safety norms, Maximum Residue Limits (MRLs), and import restrictions due to disease outbreaks create compliance uncertainty.	Shipments compliant earlier may get rejected later, leading to financial losses.
	Documentation Chain Delays	Certificates often move through multiple attestation levels (exporter → local authority → Indian Embassy → importer).	Paperwork not ready at arrival, causing immediate storage costs and clearance delays.
Phase 2: Clearance & Handling Bottlenecks	**Slow and Manual Clearance Processes**	Despite digital systems, physical verification, manual stamping, and non-prioritization of perishables persist.	Delays on tarmac or in warehouses shorten product shelf life and increase costs.
	Prolonged Lab Testing and Approval Times	FSSAI and other agencies require sample testing; overloaded labs delay results.	Perishable cargo may deteriorate before results are received, causing loss of product and value.
	Gaps in Cold-Chain Infrastructure	Insufficient reefer plug points, inadequate cold storage at airports/ports, and slow transfer to warehouses expose cargo to ambient temperatures.	Temperature excursions lead to spoilage of food and reduced efficacy of pharmaceuticals.
Phase 3: Post-Clearance	**Limited Logistics Capacity**	Shortage of specialized reefer containers and high cost of	Increases transportation time and cost; affects trade

Logistics & Systemic Weaknesses		temperature-controlled airfreight.	competitiveness.
	Weak Traceability and Human Errors	Lack of end-to-end digital tracking and reliance on manual handling.	Higher risk of mislabeling, contamination, or misplaced consignments; difficult to trace accountability.

7 Commodity-Specific Challenges:

Category	Major Challenges	Key Issues / Impacts
1. Meat	Regulatory complexity, contamination risk, cold-chain dependence, lab delays	Multiple clearances (FSSAI, Animal Quarantine, Customs); strict disease checks (avian flu, swine fever); requires continuous refrigeration; testing delays reduce shelf life.
2. Seafood	Regulatory overlaps, perishability, poor cold-chain, testing bottlenecks	FSSAI and Animal Quarantine approvals; temperature fluctuations cause spoilage; limited reefer zones; microbiological testing takes days.
3. Dairy	Strict safety standards, short shelf life, documentation delays	FSSAI norms for bacterial count and pasteurization; refrigeration crucial; multiple attestations delay clearance.
4. Plants	Quarantine inspections, complex paperwork, handling sensitivity	Requires phytosanitary certificates and import permits; fragile cargo; temperature/humidity variation causes loss.

5. Vegetables	High perishability, pesticide compliance, weak cold-chain	Needs rapid clearance; Plant Quarantine & FSSAI checks delay movement; inadequate refrigerated last-mile delivery.
6. Fruits	Temperature sensitivity, clearance delays, special storage needs	Heat exposure accelerates ripening/spoilage; multiple agency approvals; limited controlled atmosphere facilities.
7. Bakery Products	Short shelf life, certification needs, refrigeration dependency	FSSAI certification for additives and safety; quick clearance required to maintain freshness; prone to spoilage if storage delayed.
8. Pharmaceuticals	Strict regulatory control, temperature sensitivity, traceability & lab delays	Requires CDSCO, Customs, and FSSAI (for nutraceuticals) approvals; vaccines and biologics need cold-chain; human or data errors cause rejection; testing delays affect timely delivery.

8. National Center For Cold-Chain Development (NCCD) Report On Present Cold-Chain Infrastructure And Gap

(A) Airports

Major airports like **Delhi, Mumbai, Bengaluru, and Hyderabad** have developed dedicated **Perishable Cargo Centres** equipped with temperature-controlled chambers ranging from **–18°C to +25°C.**

- **Delhi Air Cargo Logistics Centre (DIAL)** handles over **150,000 metric tonnes** of perishable goods annually through a modern cold chain terminal.
- **Mumbai** and **Chennai airports** have integrated cold storage systems for **seafood, meat, and pharmaceutical exports**.

Source: Airports Authority of India – Cargo Infrastructure

(B) SEAPORTS

At the seaports, infrastructure development remains **uneven**.

- **Major ports like JNPT, Cochin, and Kandla have reefer plug points and dedicated cold storage warehouses.**
- **However, several mid-tier ports still lack integrated temperature-controlled zones, efficient cargo segregation, and fast-track customs clearance for perishables.**

Source: JNPT Annual Report 2023–24

(C) ICDS AND CFSS

Many Inland Container Depots (ICDs) and Container Freight Stations (CFSs) are now adopting refrigerated storage. However, their distribution is unequal, especially across northern and eastern India, where real-time tracking systems and adequate reefer connections are still missing.

- As per **Energy Transition In Cold Chain Infrastructure Report (NCCD)**, the number of packhouses remains relatively low compared to cold storage facilities. Fewer than 250 integrated packhouses existed as of 2015. Maharashtra leads in this aspect of infrastructure and accounts for approximately 70% of the nation's packhouse facilities. Cold storage constitutes the most extensive cold chain infrastructure. Uttar Pradesh has the highest concentration due to its substantial agricultural yield, making it the largest state in terms of agriculture and horticulture output (MoAFW, Horticulture Statistics at a Glance, 2021). As of May 2024, India has 8,698 cold storage facilities of various types. These facilities provide a total capacity of 395 lakh metric tonne (NCCD, Cold Storage Infrastructure as of May 2024, 2024). States like West Bengal and Gujarat also play key roles, underscoring the significant reach and importance of cold storage capacity across the nation. Ripening chambers, crucial for climacteric fruits like bananas and mangoes. Their number has gradually increased, reaching 812 in 2015. Andhra, Maharashtra, and Karnataka dominate this segment. These states are major banana producing regions. This targeted growth reflects that authorities have made concerted efforts to enhance ripening infrastructure where it is most needed. Refrigerated transport remains underutilised, as highlighted by NCCD in their 2015 gap assessment report. Refrigerated transport is essential for maintaining the cold chain. As of 2015, approximately 9,000 reefer vehicles were in operation, primarily observed near urban and semi-urban regions, with an 85% infrastructure gap (NCCD, All India Cold-chain Infrastructure Capacity (Assessment of Status & Gap), 2015). These vehicles predominantly serve export-oriented perishables and industries that require stringent temperature controls, such as dairy and processed

foods. Refrigerated transport thus plays an integral role in India's cold supply chain.

Source:
https://nccd.gov.in/uploads/ET_in_cold_chain_sector_in_India_v8_3bfe3b8148.pdf

- As per the Report in the matter "Requirement and Availability of Cold-Chain for Fruits and Vegetables in the Country" published by Institute of Economic Growth, Delhi University Enclave, North Campus, New Delhi- 110 007, the following table based upon the existing and required infrastructure was discussed:

Component	Requirement	Existing Infrastructure	Gap (2 – 3)	% Share of Gap to Required ((4/2) × 100)
Integrated Pack Houses (in numbers)	70,080	249	69,831	**99.60%**
Reefer Trucks (in numbers)	61,826	9,000	52,826	**85.40%**
Cold Stores				
• Bulk (Mn tons)	34.16	31.82	2.34	**6.80%**
• Hubs (Mn tons)	0.94	3.23	–2.29 *(surplus)*	—
Total Cold Storage Capacity (Mn tons)	35.1	31.82 + 3.23 = 35.05	0.05	**≈0.1%**
Ripening Chambers (in numbers)	9,131	812	8,319	**91.10%**

Source: Ministry of Food Processing Industry (MOFPI) Annual Report 2018-19

The above Table presents the capacity requirement for each of the infrastructural component of cold-chain separately, using the demand-side projections along with the supply-side estimates of the baseline survey conducted by the NHB (NABCONS-NCCD, 2015). It estimates a gap of 3.2 million tons, amounting to

9.3 % in the installed capacity of cold storage-bulk and cold storage- hub taken together. This data are widely circulated in the media and other places to argue that there is a near saturation in the cold storage capacity in the country (For e.g. Nuthalapati et al.,2017). However, the reality is different. Much of the installed capacity is concentrated in few hubs in north-western states and western states in the country. Few states like UP, West Bengal, Punjab and Gujarat together have more than 70% of all the cold storage installed capacity, while several states have negligent levels of installed capacity. Therefore, the macro-scenario constructed at the all India level by NABCONS-NCCD does not reflect the ground level realities, where there is large unmet needs for both farmgate and market hub cold storages. The major limitation of the cold storage capacity at present is that the market hub cold storages do not constitute only 3% of the available cold storage capacity. As is now well documented by NCCD and several other experts in the sector, cold storages close to market are also required like at the farmgate. Traditionally, most cold storages in the country are at the production site and the market hub ones have been coming in the last decade only.

https://desagri.gov.in/wp-content/uploads/2024/03/2021-22-Requirement-and-Availability-of-Cold-Chain-for-Fruits-and-Vegetables-in-the-Country.pdf

- As per All India Cold Chain Infrastructure Report 2015, India's cold-chain infrastructure remains inadequate to meet the growing demand for efficient handling of time-sensitive and perishable commodities. As per the data recorded on **31 March 2014**, the country had created **31.82 million metric tonnes (MMT)** of cold storage capacity against a requirement of **35.10 MMT**, resulting in a **current gap of 3.28 MMT** in cold storage space (Bulk and Hub).

Significant deficits are also observed in other critical cold-chain components such as pack-houses, reefer vehicles, and ripening chambers. The shortage of integrated pack-houses and refrigerated transport facilities severely limits the ability to maintain temperature integrity throughout the logistics chain, thereby contributing to higher **dwell times** for import and export clearance of perishable cargo.

According to a **baseline survey conducted by the National Horticulture Board (NHB) in December 2014**, approximately **5,367 cold stores** with a capacity of **26.85 MMT** were operational. Based on this data, the total national gap in cold storage capacity can be assessed at **8.25 MMT**. However, it is also noted that several non-functional cold stores could be upgraded and modernised rather than replaced by new infrastructure, which would optimize investment and improve efficiency.

Type of Infrastructure	Infrastructure Requirement (A)	Infrastructure Created (B)	All India Gap (A–B)
Pack-House	70,080 Nos.	249 Nos.	69,831 Nos.
Cold Storage (Bulk)	34,164,411 MT	31,823,700 MT	3,276,962 MT
Cold Storage (Hub)	936,251 MT	—	—
Reefer Vehicles	61,826 Nos.	9,000 Nos.	52,826 Nos.
Ripening Chambers	9,131 Nos.	812 Nos.	8,319 Nos.

Source:
https://nccd.gov.in/uploads/All_India_Cold_Chain_Infrastructure_2015_5da1279baa.pdf

The above data and reports suggest that ndia's cold chain infrastructure, though expanding, is unevenly distributed and functionally limited. The lack of **integrated packhouses, reefer vehicles, and market-hub storages** directly affects **temperature control, clearance efficiency, and dwell time** for perishable goods.

9 Dis-Integration in the Regulatory Framework of India in comparison to EU and USA:

9.1 EU basic features:

ii) European Union (EU): The regulatory framework is quite integrated, standard, harmonised and technology driven.

iii) The oversight is centralized under the European Commission and the European Medicines Agency (EMA).

iv) The EU good distribution practice (GDP) Guidelines (Directive 2013/01) mandates strict controls on storage, transport, and documentation of Temperature Sensitive cargo.

v) The Union Customs of Union Customs Code (UCC) of EU ensures uniform and expedited customs procedures across member states.

vi) The advance systems like EDI, IOT Monitoring and IATA CEIV Pharma-Certified Hubs, Enhanced real-time traceability and quality assurance etc. make the export and import of temperature sensitive cargo easier and fault free.

vii) The cross boarder movement of perishable cargo and temperature sensitive cargo is very smooth.

9.2 United States (USA) – Strong Regulatory Oversight and Enforcement

i. The U.S. follows a federal, risk-based regulatory model with strict quality and enforcement standards across multiple agencies.
ii. The **FDA** regulates pharmaceutical and biological shipments under **21 CFR Parts 203, 205, and 211**, while the **USDA** oversees perishable food trade under the **Perishable Agricultural Commodities Act (PACA)**.
iii. **Customs and Border Protection (CBP)** coordinates with these agencies to ensure smooth clearance of temperature-controlled goods.
iv. The U.S. enforces rigorous **Good Distribution Practices (GDP)**, cold-chain validation, and real-time digital monitoring, with many logistics providers certified under **IATA CEIV Pharma** or **ISO 13485/9001**.
v. The **Automated Commercial Environment (ACE)** system integrates customs, FDA, and USDA processes, enabling faster pre-clearance.
vi. The U.S. framework is compliance-driven, technologically advanced, and focused on maintaining cargo integrity while reducing dwell time.**3. India – Developing and Partially Integrated Framework**

9.3 India – Evolving but Fragmented Framework

India's regulatory system for time-sensitive cargo is developing but remains fragmented, with overlapping responsibilities among multiple agencies and limited digital integration. Key regulators include **CBIC** (customs procedures), **FSSAI** (food safety), **CDSCO** (pharmaceuticals and biologicals), **APEDA/MPEDA** (agricultural and marine exports), and **Plant & Animal Quarantine** departments. While India has adopted **GDP**, **GHP**, and **HACCP** standards, enforcement and cold-chain infrastructure vary widely across ports and airports. Only a few major airports like **Delhi, Mumbai, Hyderabad, and Bengaluru** hold **IATA CEIV Pharma** certification. Customs modernization under **ICEGATE** and initiatives like the **National Logistics Policy (2022)** aim to enhance digital integration, yet interoperability between agencies remains limited. Real-time temperature monitoring is still emerging outside metro hubs. Overall, India's framework shows strong intent but faces challenges in uniform implementation, infrastructure, and coordination, leading to inconsistencies and higher dwell times.

9.4 Comparative Table

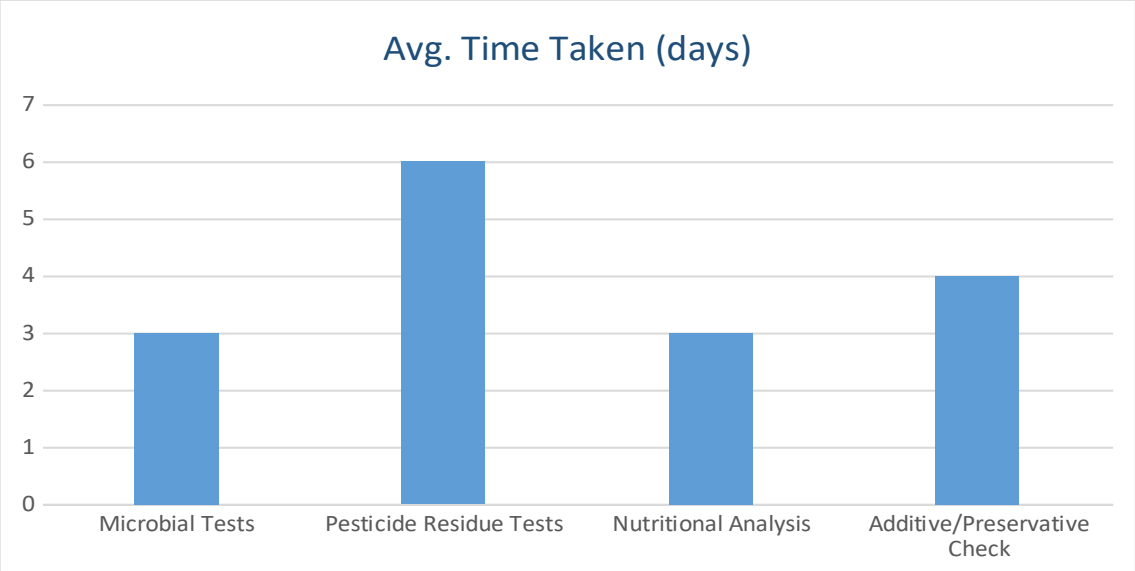
Parameter	EU	USA	India

Parameter	EU	USA	India
Regulatory Integration	Fully integrated (EU-wide)	Centralized under federal agencies	Fragmented among multiple agencies
GDP / GSP Enforcement	Mandatory and harmonized	Strictly enforced	Adopted but inconsistently applied
Customs & Border Coordination	Union Customs Code (UCC) – seamless	ACE system – integrated clearance	ICEGATE – improving but limited linkage
Traceability & Monitoring	Real-time digital systems	IoT & validated cold chains	Limited to major ports/airports
Vendor Qualification	Centralized certifications (CEIV, GDP)	Strict vendor audits	Varies regionally
Dwell Time Efficiency	Very low	Low	Moderate to high

10. Testing Time and Challenges in Lab Testing

Laboratory testing by PGAs is an indispensable component of the inspection process for perishable goods, providing crucial data for clearance decisions. However, the time required for testing and various associated challenges can significantly impact the efficiency of the supply chain.

Turnaround Times for Testing The typical duration for different types of lab tests varies:



Laboratory results serve as the final decision criterion for accepting or rejecting a shipment, supporting traceability and audit trails for food safety recalls, and can be used to challenge rejections if samples were improperly handled. The establishment of multi-purpose testing labs within ICDs/CFSs, potentially operating under a model similar to FSSAI where provisional NOCs are issued based on preliminary positive findings, could significantly expedite the clearance process.

Common Challenges in Lab Testing Several issues commonly arise in lab testing, along with their suggested remedies:

Issue	Remedy
Delay in test results	Build capacity and introduce legal contract/mandate with NABL accredited labs.
Sample degradation in transit	Use insulated containers and temperature tracking.
Discrepancy in test interpretations	• Clear & Standardised parameters for conformity. • Cross-verification with a second lab (if needed).
Non-availability of test facility	Refer to central FSSAI-recognized labs or EIC support.

To summarize, India's perishable export–import ecosystem, which includes Indian Customs, Various ICDs/ CFS, Transporters, Cold storages, warehouses, faces unique challenges that can impede quality inspection, compliance, and smooth trade, as detailed below:

A. **Infrastructure Gaps:** India's perishables facing shortages on various account including many small farms lacking pre coolers and refrigerated transport. Port congestion, insufficient reefer plug points and limited cold storage facilities at ports, particularly specific ICDs/CFSs for reefer containers, lead to delays, temperature excursions, and spoilage risks. **Power Failures & Equipment Malfunctions** including electricity outages or refrigeration failures risk compromises cargo integrity.
B. **Fragmented Regulatory Framework:** Multiple agencies (FSSAI, APEDA, EIC, PQIS, AQCS, Customs) with overlapping jurisdictions create coordination gaps especially at the clearances at ports. Further, there is no

clear and single framework on commodity class-wise sample size and standard test parameters.

C. **Limited Testing Capacity:** NABL-accredited labs are concentrated in metros, leaving remote production areas underserved. High sample volumes and limited manpower cause Turnaround Time (TAT) delays that can exceed the shelf life of some perishables. Further, there is no legal mandate for CUSTOMS to accept NABL accredited lab reports for most of the commodities. Further, there is no mandate for ICD/CFS custodians to provide dedicated areas for setting up of these labs.

D. **Skill and Awareness Deficit:** There is a shortage of trained inspectors and auditors at the ports. Small and Medium Enterprises (SMEs) often lack resources for ISO/HACCP/FSSC accreditations, leading to low adoption of quality systems. The workers at the CFS/ICDs are ill-trained for port operations and handling sensitive cargo.

E. **Traceability & Technology Adoption:** Specific requirement of perishable cargo is not maintained because no marking of such cargo is available at the system. Many ports still rely on manual records from the importer/exporter, leading to errors. Limited usage of new technology and latest tools results in poor real-time monitoring.

F. **Market & Policy Challenges:** Unpredictable seasonal variability (monsoon, heat waves) strains cold chain capacity and affects product quality.

G. **Lack of Real-time Monitoring**: Absence of IoT-enabled temperature tracking systems hampers compliance and monitoring.

Addressing these challenges requires boosting investment in last-mile refrigeration and port cold storage, streamlining regulatory coordination through a single-window approach, expanding lab networks, upskilling the customs workforce, accelerating digitalization, and enhancing "Brand India" through rigorous quality checks.

7. Case Studies

Real-world examples of perishable goods being either rejected or cleared provide valuable insights into the critical nature of compliance with food safety and regulatory standards. These case studies highlight common pitfalls and successful strategies, while also shedding light on broader challenges within the Indian context.

Case studies offer practical demonstrations of compliance successes and failures in the perishable goods trade.

- **Case Study: Seafood Import from Vietnam:** This section details a real-world scenario of importing frozen shrimp from Vietnam to India, highlighting critical inspection parameters, documentation, FSSAI compliance, and challenges in ensuring food safety for imported seafood.

  An Indian seafood distributor imported frozen Black Tiger Shrimp from a Vietnamese aquaculture company to Chennai Port via refrigerated containers. Import compliance required FSSAI Import Clearance, a Sanitary Import Permit (SIP) from DADF, a Veterinary Certificate from Vietnam, container temperature records, and a Certificate of Origin. The inspection procedure at the port involved arrival and Bill of Entry submission, visual inspection of packaging/labeling, seal verification, random sampling under FSSAI, lab testing for microbiological and chemical parameters, and awaiting lab clearance before dispatch to cold storage. Laboratory testing confirmed parameters like Salmonella spp. (Not Detected), Histamine Level (24 ppm vs. < 100 ppm), Cadmium Content (0.03 mg/kg vs. < 0.1 mg/kg), and Antibiotic Residue (Not Detected). Packaging and labeling checkpoints confirmed compliance for product name, net weight, country of origin, storage instructions, and date of catch/processing. Issues encountered included delays in temperature log submission (resolved by extracting data from the reefer chip), minor label misalignment (rectified at a bonded warehouse), and lab testing backlog (followed up for clearance in 4 working days). The consignment cleared after 6 working days, with cold chain integrity maintained and no adverse health/compliance issues reported.

- **Case Study: Successful Export of Mangoes to EU:** This case study illustrates the end-to-end inspection, documentation, and quality control procedures for exporting fresh mangoes from India to the European Union, demonstrating the integration of compliance, inspection, and laboratory processes.

  An Indian agri-exporter shipped Alphonso mangoes to a German distributor. Key requirements included EU MRL compliance, a Phytosanitary Certificate from PQIS, Hot Water Treatment (HWT) for fruit fly control, Pre-Shipment Inspection (PSI) by an APEDA-recognized agency, and traceability documentation. The inspection process involved

farm-level grading, pre-harvest pesticide usage logs, HWT at an APEDA-approved facility, sampling and lab testing (residues, sugar, firmness), packaging and labeling per EU norms, PSI by APEDA, Phytosanitary Certificate issuance, Customs clearance, and cold chain shipment via air cargo. Laboratory testing confirmed parameters like Carbendazim residue (0.01 ppm vs. EU ≤ 0.1 ppm) and Brix level (18.5 vs. >17). Challenges included short lab report timelines, export delays due to missing harvest dates, and language translation for German customs. The outcome was smooth EU customs clearance, excellent quality feedback, and repeat orders, underscoring the importance of strict date coding alignment with EU standards. **Case Study: Rejection of Seafood at US Port:** Frozen shrimp from Kerala was rejected at a US port due to Salmonella detection, absence of a HACCP plan or sanitation logs, and incomplete DS-2031 certificates. The shipment was returned, the company faced an import alert, and the US importer terminated the contract. This highlighted the strict US FDA microbiological and documentation norms, the mandatory nature of HACCP, and the value of third-party audits. Custom formations should strictly adhere to the inspection norms while allowing exports, in order to prevent such events.

- **Case Study: Dairy Products to Middle East:** This case study presents the export of processed dairy products (ghee and paneer) from India to the UAE, highlighting inspection, regulatory checkpoints, export documentation, and challenges in maintaining quality and compliance with Gulf food safety standards.

- An Indian dairy cooperative exported vacuum-packed paneer and ghee to a UAE distributor at Jebel Ali Port. Export compliance required FSSAI License, APEDA Registration, Health Certificate from EIC, Halal Certification, and dual-language ingredients declaration/labeling. Packaging and labeling protocols ensured compliance for product name, nutritional information, storage conditions, best before date, and exporter details. Inspection and pre-shipment testing confirmed microbial load (TVC), fat content, moisture content, absence of foreign matter, and heavy metals within limits, aligning with Gulf Food Code and Codex standards. Cold chain and logistics measures included data loggers for paneer containers, pre-testing reefer efficiency, insulated boxes for ghee, and pre-dispatch inspection by EIA. Issues like initial delay in Halal certification, paneer pouch leakage, and label alignment were addressed through pre-verified

bodies, re-packing, and batch correction. The shipment cleared UAE Customs within 5 working days, with no cold chain breach and positive feedback on quality and labeling.

Common patterns in rejections include chemical/microbial contamination, incomplete documentation, temperature deviations, labelling/packaging errors, non-compliance with MRLs or additives, and lack of traceability. Recommendations from these cases include using accredited labs, maintaining country-specific compliance, digital checklists, trained staff at customs port, implementing digital documentation and seamless data flow through ICEGATE, investing in internal QA/QC systems of the customs, and training export customs staff on changing regulations.

8. Impact of Delays on Perishables

Delays in the transportation, handling, or processing and clearances of perishable goods have significant implications for their quality, safety, and shelf life. These consequences affect both product integrity and the financial viability of shipments.

Types of Delays and Their Causes: Delays can occur at any supply chain stage. Transport delays stem from customs clearance, poor handling of goods at the port, adverse weather, or mechanical failures. Handling delays arise from port congestion, insufficient labour, or operational inefficiencies. Documentation delays are caused by inaccurate paperwork or extended regulatory reviews.

Consequences of Delays:

- **Temperature Abuse:** Even minor delays can lead to temperature excursions, accelerating spoilage and reducing shelf life.
- **Microbial Growth:** Delays increase exposure to temperature fluctuations, boosting bacterial, mold, and pathogen growth, leading to foodborne illnesses or rejection.
- **Quality Deterioration:** Colour, texture, taste, and nutritional value degrade rapidly. Fruits may bruise, dairy may sour.
- **Loss of Nutritional Value:** Prolonged delays, especially in warmer temperatures, reduce nutritional content (e.g., Vitamin C).

- **Financial Implications:** Include waste costs, penalties from regulators/customers, and loss of business reputation due to damaged client relationships.

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CHAPTER 8

RECOMMENDATIONS

1. Infrastructure:

As we have seen in the discussions undertaken in different chapters of this report, unlike import and export of other commodities, the temperature sensitive goods have very short self-life, and are require end to end temperature control, specific process of inspection or examination. The reports received from different sources including FFFAI, reveals that many ports/airports/ICDs/CFSs are lacking crucial infrastructure for handling temperature sensitive shipments. Several incidences of deterioration of the quality and product integrity have been experienced at different ports due to infrastructure deficiency or the other problems in clearance.

We may understand this paradigms through the facts that several Ports/ICDs like ICD Sabarmati (Ahmedabad), ICD Sanand, Thiruvananthapuram port, Dabolim Airport and Panaji sea port, Goa, Air Cargo Indore, Kandla Seaport, ICD Ludhiana and ICD Nagpur, Pipavav and Paradip, Dhamra and Gopalpur port in Orisha have either no infrastructure for the temperature sensitive cargo or have inadequate infra, which hampers seriously the export and import of temperature sensitive shipments to and from India.

Similarly, many ports like air cargo Ahmedabad, Thiruvananthapuram, Cochin, Paradip, many ICDs have experienced deterioration of the quality of temperature sensitive cargo because of poor infrastructure and insensitive approach towards handling and timely clearance of the consignments.

There are serious lacking on account of temperature controlled ecosystem at several port for examination/inspection of the temperature sensitive goods like almost all the ICDs, Nhava Sheva port, Kolkata port, Goa, Kandla ports etc. have no facilities to examine/inspect the goods in temperature controlled environment. Similarly, all the ICDs, and Sea Ports (except Cochin and Chennai), including some air cargos like Ahmedabad, Kolkata and Indore have no sterile and separate chamber for handling pharmaceutical cargo. Even working plug points for Reefer cargos are not available at many ports and ICDs/CFSs and Sea Ports.

Normally, such goods are imported in reefer Containers/Trucks through Sea Ports/ICD/CFS or Land Routs. However, they are imported or exported in Unit

Load Device (ULD) by air, which is a small container with little amenities. The reefer containers are backed by power in ships or on train carrying from gateway ports to ICDs/CFSs. The temperature of normal ULDs is not controlled.

However, there are specific temperature-controlled air cargo containers like the ULD provided by Envirotainer, which are used for import/export of temperature sensitive cargos especially pharmaceuticals. Such containers have capability to maintain temperature from -20 to 20 degrees Celsius with the help of power or dry ice. This ULD may be used extensively for import and export of temperature sensitive shipments, which provides cold-chain logistics and ensures product integrity.

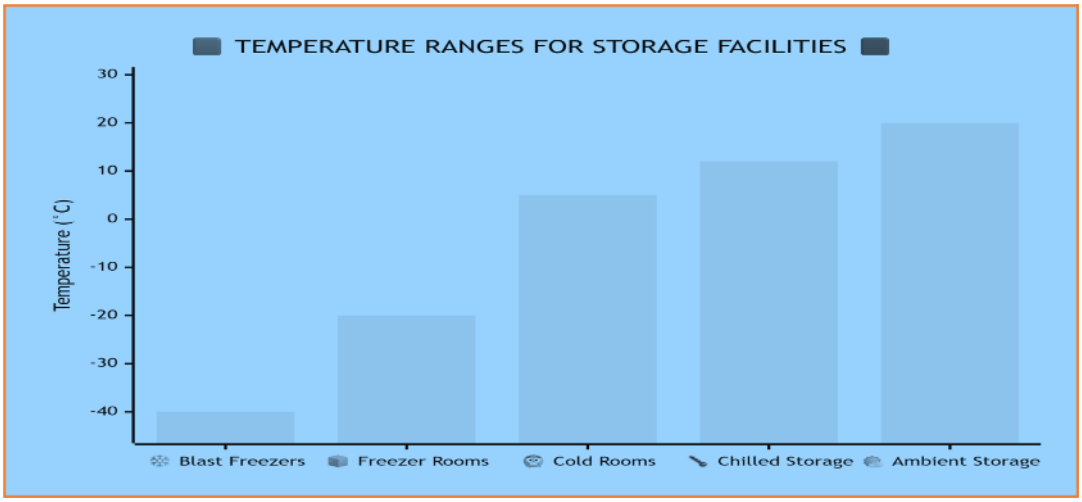
On offloading of the reefer containers from the ship/train, the supply chain managers or port manager require to put the refer containers on power backup immediately. Similarly, the ULDs of perishable cargos are required to be kept in temperature controlled environment. Some Ports/CFSs/ICDs have either no plug in facilities and some airports also have no sufficient temperature controlled warehouses. Therefore, it is essential to equip the Ports/CFSs/ICDs with required infrastructures.

1.1 Basic Port Infra Requirements:

A. Temperature-Controlled Storage Facilities

Proper storage is the backbone of cold chain management. It ensures that perishable cargo remains within the required temperature range during storage and handling. The key components include:

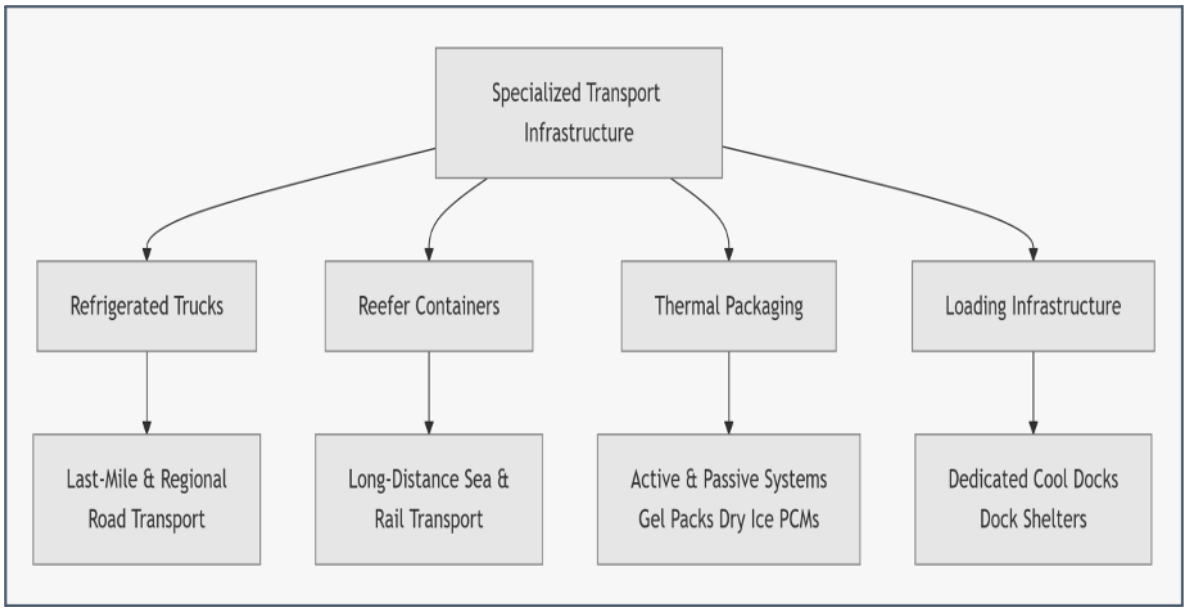
- **Cold Rooms/Refrigerated Warehouses** (2°C–8°C) for general perishables.
- **Freezer Rooms** (−20°C or below) for frozen goods.
- **Chilled Storage Areas** (8°C–15°C) for specific products.
- **Ambient Temperature-Controlled Areas** (15°C–25°C) for temperature-stable goods.
- **Blast Freezers / Quick-Freezing Units** for rapid temperature reduction.



B. Specialized Transport Infrastructure

Safe transportation is critical for ensuring that temperature-sensitive cargo remains within permissible limits throughout transit. This requires:

- **Refrigerated Trucks / Reefers** with real-time temperature tracking.
- **Reefer Containers** for sea and rail movement.
- **Active and Passive Thermal Packaging Systems** (gel packs, dry ice, PCM packs).
- **Thermal Blankets / Insulated Pallet Covers.**
- **Dedicated Cool Chain Loading Bays / Dock Shelters.**

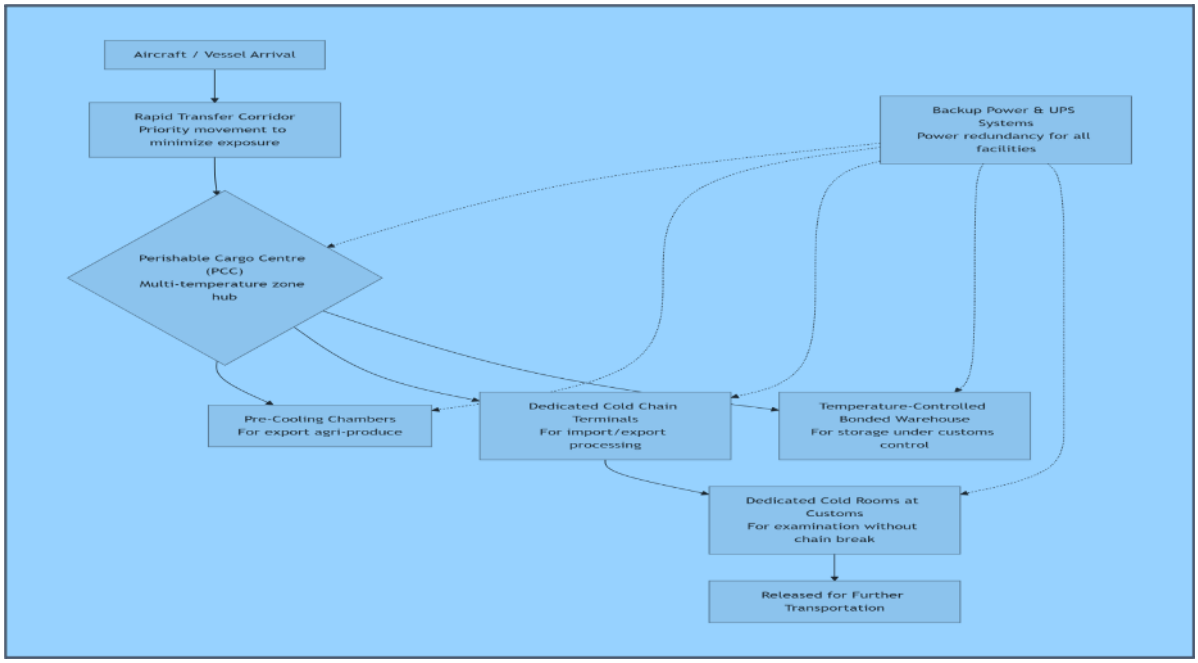


C. Airport / Port / ICD / CFS Infrastructure

Efficient handling at gateways and terminals is crucial for time- and temperature-sensitive cargo. The required facilities include:

- **Dedicated Cold Chain Terminals** for imports and exports.
- **Perishable Cargo Centres (PCCs)** with multiple temperature zones.
- **Pre-Cooling Chambers** for export commodities like agricultural produce.
- **Temperature-Controlled Bonded Warehouses.**
- **Dedicated Cold Rooms** at customs examination areas.
- **Rapid Transfer Corridors** from aircraft or vessel to cold storage.
- **Backup Power and UPS Systems** for uninterrupted cooling.
- **Automation of controlling and regulation of the system**

Temperature Sensitive Cargo Flow Design in temperature-controlled ecosystem

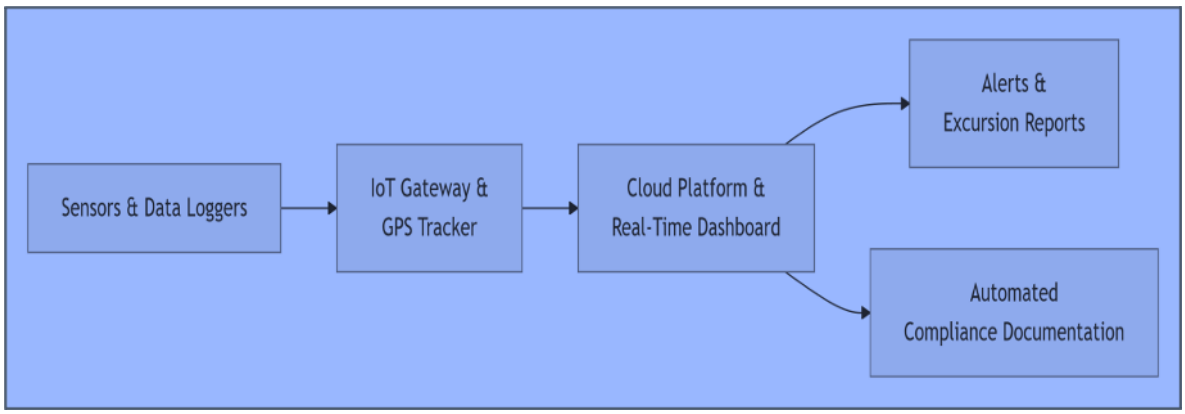


D. Monitoring, Calibration, and Data Systems

Continuous temperature monitoring and calibration are essential to maintain product integrity and regulatory compliance. The key systems include:

- **Calibrated Thermometers and Data Loggers** (USB / Wi-Fi / Bluetooth).

- **IoT-Based Sensors** for temperature and humidity with GPS tracking.
- **Real-Time Monitoring Dashboards** for alerts and deviations.
- **Automatic Temperature Recording and Archival Systems.**
- **Alarm Systems** for temperature excursions.
- **Calibration Facilities** or contracts for periodic accuracy checks.



E. Supporting Utilities and Redundancy

To ensure operational continuity, robust utilities and backup systems are essential. These include:

- 24×7 Power Backup **(DG sets, UPS, solar).**
- Proper Insulation and HVAC Systems.
- Dehumidifiers / Humidity Control Units.
- Fire Detection and Suppression Systems **suitable for cold environments.**
- Backup Cooling Units to prevent losses during equipment failure.

F. Handling and Packaging Infrastructure

Proper handling and packaging facilities are vital to maintain hygiene and prevent thermal shocks. The essential elements are:

- Cold-Compatible Material Handling Equipment **(forklifts, pallet jacks).**
- Insulated Loading and Unloading Docks.
- Temperature-Controlled Packaging Areas.
- Clean Rooms / Hygienic Zones **(especially for pharma and food cargo).**

- Labeling and Barcoding Systems for traceability and compliance.

G. Quality Assurance and Compliance Infrastructure

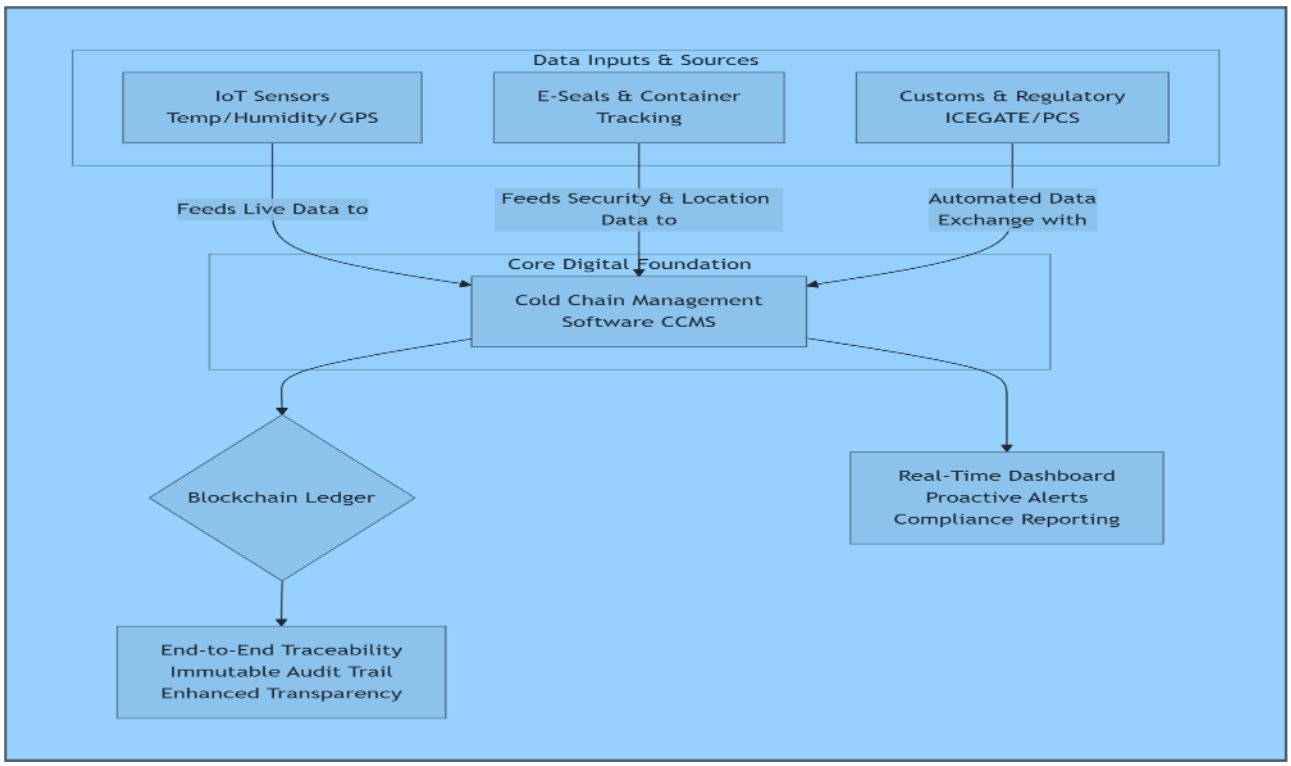
Quality assurance ensures that cargo meets regulatory and safety standards. Necessary facilities include:

- Standard Operating Procedures (SOPs) **and** Training Facilities **for cold chain handling.**
- QA/QC Laboratories **for testing, especially for food and pharmaceutical goods.**
- Quarantine Areas **for non-compliant cargo.**
- Temperature Mapping and Validation Reports **for audits.**
- Documentation and Audit Trail Systems for regulatory compliance.

H. Digital and Traceability Infrastructure

Digital integration enhances transparency, accountability, and coordination across the supply chain. Key systems include:

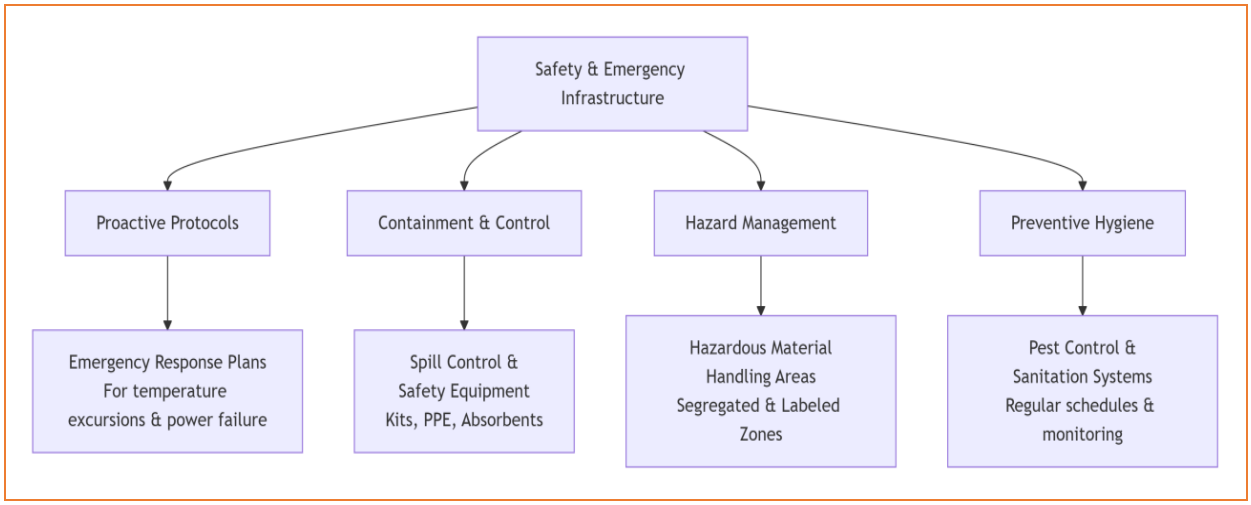
- Cold Chain Management Software (CCMS).
- Blockchain Integration **for end-to-end traceability.**
- E-Sealing and GPS-Enabled Container Tracking Systems.
- Integration with Customs ICEGATE / Port Community Systems



I. Safety and Emergency Responses:

Safety mechanisms are crucial to prevent damage or contamination in case of deviations or emergencies. Important components are:

- Emergency Response Plans **for temperature excursions.**
- Hazardous Material Handling Areas **(for sensitive chemicals).**
- Spill Control and Safety Equipment.
- Pest Control and Sanitation Systems.



Component	Primary Function	Key Features & Actions
Emergency Response Plans	To provide a predefined, actionable framework for responding to incidents that threaten cargo integrity.	**For Temperature Excursions:** Immediate steps to isolate affected cargo, investigate root cause, and implement corrective actions.
		For Power Failure: Protocols for switching to backup generators and prioritizing critical storage.
		Clear Communication Trees: Defining who to contact and when.
		Documented Drills: Regular training and simulation exercises.
Hazardous Material Handling Areas	To safely segregate and manage sensitive, dangerous, or high-risk perishable goods (e.g., chemicals, certain pharmaceuticals).	**Dedicated, Segregated Zones:** Clearly marked and access-controlled.
		Specialized Ventilation & Containment: To prevent cross-contamination.
		Compliant Labeling: As per international and national safety standards.

		Trained Personnel: Staff specifically trained in handling hazardous materials.
Spill Control and Safety Equipment	To enable immediate containment and clean-up of spills, preventing accidents, contamination, and environmental damage.	**Spill Kits:** Readily available, stocked with absorbents, neutralizing agents, and PPE.
		Personal Protective Equipment (PPE): Gloves, goggles, aprons, and boots for staff.
		Eye Wash Stations & First Aid Kits: Easily accessible in strategic locations.
		Clear Signage: Indicating the location of safety equipment.
Pest Control and Sanitation Systems	To maintain a hygienic environment and prevent infestation, which is critical for perishable and pharmaceutical cargo.	**Regular & Documented Pest Control:** Schedules for fumigation and trapping.
		Sanitation SOPs: Standard procedures for cleaning and disinfecting storage areas and equipment.
		Waste Management: Proper disposal systems for organic and packaging waste.
		Preventive Design: Sealed gaps, air curtains, and rodent-proofing to deter pests.

J. Institutional and Coordination Infrastructure

Effective coordination and institutional support are key to smooth operations. The required mechanisms include:

- Coordination with Airlines, Shipping Lines, and CHAs.
- MoUs with Temperature-Controlled Logistics Providers.
- Regulatory Interface Units **(FSSAI, CDSCO, PQ, AQ, etc.).**
- Training and Certification Centres for cold chain staff.

1.2 Delivery of the Cargo in temperature sensitive Container:

The Airport authorities/Custodians often deliver the temperature sensitive goods without temperature controlled ULDs/reefer containers. And the importers take them to their temperature controlled vehicles for carrying to their premises. In case the period during which the goods suffers uncontrolled temperature is prolonged the product quality and integrity deteriorated, even the goods may be contaminated

during that period. Though, abundant precaution have been maintained at major ports, but still some challenges are found prevalent which requires appropriate resolutions:

- **Temperature excursions**: Uncontrolled temperature changes happen during loading, unloading, or transit, which degrade product quality and safety.
- **Infrastructure gaps**: As seen under Chapter-7, some ports/airports/LCSs are lacking reliable power supply system and cold storage facilities/ refrigerated vehicles etc. We need to improve temperature controlled warehouses, power-supplies to the reefer containers etc.
- **Imperfect monitoring system of the Cold-storage**: Even the cold storage available with the custodians have manual maintenance system, which cause deterioration of the quality of products because of lack of the awareness of the persons operating temperature control.
- **High operational costs**: Maintaining temperature-controlled logistics is energy-intensive and requires specialized equipment, leading to higher operational costs.
- **Human Error**: Inadequate training or improper handling during any stage of the process can compromise the integrity of the cold chain.

1.3 Automated temperature monitoring and Control system:

Many a time, the quality and integrity of temperature sensitive consignments are compromised because of human errors in monitoring of the temperature control system. Therefore, an automated temperature monitoring and control system is required to be installed in the cold-chain supply warehoused of temperature sensitive cargos.

Real-time monitoring and alarming system monitors the exact temperature for particular commodity and the humidity level also so as to maintain sanctity of the process. Alarms are shared by the system on emails, SMS, alarm towers, relay to alarm service and voice calls etc. Data loggers is also supplemented by the alarm system for keeping records of the time and temperature breaches.

Such automated temperature monitoring system is not only scalable and reliable but also eliminate the redundant process of frequent human access to the environment. The redundant recording process is also run parallel to control system for simplified validation. On-site calibration ensures accurate temperature and humidity maintenance without any error.

Therefore, automating temperature control may ensure continuous support and reach out of the temperature sensitive products from the origin to consumers without any compromise, breach or contamination.

1.4 Inter-operability

The temperature sensitive shipments of import and export are required to be given uninterrupted temperature control system throughout the supply chain. Therefore, all the stake holders – including shipping lines, airlines, carriers, transporters, terminals, ICD/CFSs custodians, transporters from port to importers'/exporters' premises etc. must have temperature control ecosystem.

In addition, they have advance technology supported monitoring system of the temperature and appropriate power pack with train/vehicles and power back up with cold-chain of warehouse for support during the load-shedding. Such inter-operability support should be 24x7 basis without compromising the quality of the services.

1.5 Seamless Integration of cold-chain facilities:

A seamless end-to-end advance technology driven integrated temperature-controlled warehouses and cold-storage units at every major transit points including farms, ports, airports, and distribution hubs are required to be developed and maintained with state of art infrastructure frameworks. This facility should feature:

a. Separate storage for incompatible consignments, such as ethylene-producing fruits etc. to prevent pre-matured spoilage.
b. Different temperature zones (chiller, frozen, deep frozen etc.) to accommodate diverse cargo needs.
c. State of the art pre-cooling units to lower the temperature of fresh produce immediately after harvest.

1.6 The dedicated and specialized transport vehicles:

There are many ports who doesn't have dedicated and specialized transport vehicles. Refrigerated trucks (reefers), refrigerated air cargo containers (Envirotainers) and insulated railway wagons are must to enable maintaining specific temperature and humidity support system.

Further, handling time of transferring the consignments from one mode of transport to another are to be minimized for reducing the time cargo spends outside a temperature-controlled environment. This be achieved through efficient layout and automated processes.

1.7 Data Logger:

Temperature and Humidity Data logger is the electronic device, designed to monitor, record and store the data with the help of various sensors throughout the journey of a temperature sensitive shipment. The pharmaceutical products, dairy, blood banks, vaccines and other temperature sensitive cargos require recording of the temperature in which the product was supplied, cleared and reached to the ultimate consumer passing through several stakeholders and their temperature controlled environments.

It is a compact, portable and capable of measuring parameters such as temperature, humidity, pressure, voltage, current etc. and keeping records of the entire journey. After the shipment, the data is downloaded for analysis to identify any temperature excursions and ensure product quality and safety. The temperature and humidity datalogger used in the monitoring of temperature sensitive cargo have following main features:

- **Recording:** A temperature sensor records the ambient temperature at predetermined intervals throughout the journey.
- **Storage:** The device stores this data internally in its memory. Some devices also monitor humidity and other factors.
- **Data download:** Once the shipment is complete, the data is downloaded to a computer for analysis. This can be done via USB or, for more advanced models, through wireless transmission like Bluetooth or cellular networks.
- **Alerts:** Some loggers provide real-time or immediate post-shipment alerts via SMS, email, or a mobile app if a temperature threshold is breached.

Datalogger is required for regulatory compliance also. Temperature data logger meets the specific demand of the temperature sensitive cargo industry standards and metrics to ensure quality control and provide a valid record of the shipment's conditions. Downloaded data can be used to identify the issues, validate processes, and improve the cold chain functioning by identifying problematic routs or storage conditions.

1.8 24x7 operations:

Since most of the temperature sensitive cargos have limited self-life, 24x7 operation of temperature monitoring, transportation and clearance processes are must. Round-the-clock customs and PGAs clearance process and handling operations ensuring uninterrupted movement etc. would be supportive to such commodities.

1.9 Dedicated Facilities:

In the entire supply chain, and clearance, pre-inspection processes, there is a need to maintain dedicated facilities fully equipped with the cold-chain services, monitoring and transportation system to avoid contamination. It shall also avoid across-exposure with non-food cargo.

1.10 Track and Traceability:

Tracking and Traceability is a paramount necessity for import and export of the temperature sensitive shipments. In US, track and traceability framework is driven by industry-specific regulations like FDA's Drug Supply Chain Security Act (DSCSA) and Food Safety Modernization Act (FSMA) etc.

In India also we should have specific regulatory provisions mandating unique identification and tracking-tracing system for the products like pharmaceuticals, certain foods etc. throughout the supply chain to ensure authenticity, patient safety and faster response to recalls. The key components of Track and Trace system are product identifiers, electronic verification and detailed record-keeping at critical steps. The key design of the framework are given below:

a) **Serialization and Product Identifiers:** Products must have unique identifiers, often in a 2D data matrix code, that include the product's national code serial number, and expiration date etc.

b) **Electronic Tracking and Verification:** Manufacturers and supply chain partners are required to test electronic connections to exchange traceability data. Verification systems must be in place to check if a product's identifier matches the information assigned by the manufacturer or re-packager.

c) **Critical Tracking Events (CTEs):** The manufacturers/re-packagers are required to maintain critical events data tracking (Key Data Elements) of specific critical tracking events. These events may include harvesting, initial packing, shipping, receiving etc. along with temperature loggers' data related to duration of prescribed temperature of humidity breach, if any.

d) **Record-keeping and Reporting:** The companies are required to maintain records and upon request, provide them to the Authority and consumer. These data may be processed and analysed by the product tracing system.

e) **Technology and Data Exchange:** The framework relies on technology like QR codes, RFID, and blockchain to capture data and create a transparent, immutable record of a product's journey.

The track and traceability system helps preventing counterfeiting of drugs and improves the ability to respond quickly to foodborne outbreaks or product recalls. It enhances safety of public health and increase supply chain visibility. Trust improvement among the consumers and stakeholders is ensured through verifiable trail of product provenance. Compliance adherence to the regulatory frameworks which are mandatory for companies and operators etc. are also taken care of.

1.11 Integrated Labs and the technical staffing at major Ports

It has been seen that testing and reporting are the major hurdles in fast clearance of the temperature sensitive cargo. Joint examination, instant sampling and testing at the port itself shall reduce the timing of sending representative samples to the labs and coordinating with more than one PGA agencies.

1.12 Sustainability

Operating a sustainable cold-chain is increasingly important for maintaining the product integrity and quality. But minimizing environmental impact and reducing

wastes etc. are also equally important. Therefore, the infrastructure required to be maintained by different stakeholders should have following attributes:

- **Energy efficiency:** Implementing energy-efficient refrigeration systems and using renewable energy sources, like solar power, for cold storage facilities and transport can reduce operational costs and carbon footprint.
- **Eco-friendly refrigerants:** Transitioning away from refrigerants with high Global Warming Potential (GWP) to more environmentally friendly alternatives is a key sustainability goal.
- **Sustainable packaging:** Using reusable, recyclable, and biodegradable packaging materials reduces waste and meets growing consumer demand for sustainable practices.
- **Route optimization:** Using AI and logistics software to find the most efficient transportation routes reduces fuel consumption and emissions.

2. Clearance Process Re-engineering:

There are multiple Govt./Private Agencies administering the clearance processes of import and export of temperature sensitive cargo. The regulatory frameworks, norms and parameter for import and export of the temp. sensitive cargo are also very stringent. Testing time of such shipments are usually longer than any normal commodity. Therefore, we need to re-engineer the processes and design of clearance of such products, so that the time taken in testing, permission and clearance etc. may be minimized.

For this purpose, we may adopt the best practices adopted in developed country in the aegis of The World Customs Organization (WCO), the World Health Organization (WHO) Good Distribution Practices (GDP), and the International Air Transport Association (IATA) Perishable Cargo Regulations (PCR), focus on an approach that is fast, predictable, and compliant with strict temperature requirements.

Here are the key international best practices, categorized for clarity:

A. Pre-arrival and Single Window Integration

The core goal is to complete all necessary checks and approvals **before the cargo physically arrives** or while it is in transit.

a. **True Single Window:** A single, fully integrated electronic platform for the trader to submit all required documentation (Customs Declaration, Health/Sanitary Certificates, Import Licenses) once. This eliminates siloed, sequential agency processing. Impact of this would be the immediate reduction in dwell time of administrative permissions and clearance. It may ensures all the agencies (Customs, Food, Drug, Quarantine etc.) to view and process the same data simultaneously.

b. **Special flag for Temperature Sensitive Cargo:** Declaration documents BE and SB must have special flag for the temperature Sensitive shipment so as to enable different stake holders to treat such cargo special. Such flag may enable the career or custodians to make special arrangement and meet the standard parameters required for such cargos.

c. **Multiple PGAs dynamics:** Sometimes it requires to take permission from more than one PGAs. A standard process design to obtain such permissions simultaneously should be must to minimise the dwell time.

d. **Mandatory Pre-Filing:** Pre-filing (advance declaration) facility is already implemented in India. Pre-arrival document processing etc. are also introduced. It enables Customs and PGAs to conduct **risk assessment, document validation, and even grant conditional pre-clearance** while the cargo is airborne or in transit. In India, RMS facilitated consignments are almost cleared for OOC/LEO on arrival of the goods. Advance declaration therefore, is already implemented.

e. **Inter-Agency Service Level Standards (SLA):** Often the PGAs, who are primarily the Govt. agencies and their accredited labs perform the testing and permission related works. Therefore, implementing Service Level Standards (SLA) for quicker and errorfree actions, would be much appreciable, though without any penal provisions. The concern over non-adhering or failing to meet the SLA's deadline may be a reason to raising the alerts to the senior management of related department for improving upon dwell time. Formal agreements (MoUs) between Customs and PGAs defining **maximum processing times** for critical steps (e.g., 2 hours for document check, 4 hours for inspection slot

allocation) shall help in reducing the clearance timing. It shall also create predictability and accountability, forcing agencies to prioritize cold chain shipments to meet strict deadlines.

f. **Compliance of WCO Revised Kyoto Convention (RKC) Guidelines:** Adherence to RKC principles for maximising the use of technology, simplifying the procedures, and provision for release prior to final determination of duties/taxes and finalisation of permission/test reports etc. may be implemented specifically in clearance of temperature sensitive shipments. The legal frameworks are required to be modified and the different departments/agencies engaged in clearance process are required to maintain appropriate technical and procedural quality to meet the expectations.

B. Dedicated Infra and Handling Approach:

The physical processes must safeguard product integrity above all the other works. Infrastructure dedicated to temperature sensitive cargo is must. Following are the recommendation on this account.

a. **Dedicated Green Lanes/Cold Corridors:** Notifying the goods as temperature sensitive/time sensitive shipment and establishing dedicated, clearly demarcated lanes and areas for cold chain cargo at airports, sea ports, ICDs/CFSs and LCSs, with **24x7 staffing and operation** by both Customs and PGAs support the quick clearance process. **Eliminates queuing** with general cargo and ensuring immediate attention upon offloading, putting under temperature control environment etc. and treated those consignments as urgent shall help in achieving the objectives.

b. **Integrated Temperature-Controlled Facilities:** Providing on-site, bonded cold storage and inspection zones directly adjacent to the tarmac/dock, with power supply for reefer containers/ULDs (Unit Load Devices) is must. Facilities should meet the WHO GDP (Goods Distribution Practices) standards which ensures the integrity of pharmaceuticals from manufacturers to the end. These standards are related to quality management system, personnel and premises related standards, training, storage and handling, transportation, documentation, and specialised procedures etc. Preventing temperature excursions which is the single biggest cause of product loss and rejection during the

clearance process, is must. It also handles the counterfeiting and international trade, removing the barriers and making the product more competitive in international market.

c. **Joint and Co-located Inspection:** When it requires to have physical inspection or sampling of the shipment, it must be performed once by a single joint team from all relevant agencies, in a coordinated manner, under dedicated, temperature-controlled inspection zone. Sequential handling and multiple movements must be avoided to safeguard the product quality and maintaining uninterrupted cold chain.

C. Risk and Compliance-based Facilitation:

Leveraging Technology and compliance history to minimize intervention.

a. **Advance Integrated Risk Management System:** Implementing an automated Risk Management System (RMS) that uses shared data and rules from all PGAs and Customs is useful for fast clearance of temperature sensitive cargo. The system automatically assigns a risk score upon pre-filing. Maximum facilitation for low-risk cargo (e.g., automatically granting "green channel" clearance), allowing officers to focus on high-risk shipments only can be implemented easily.

b. **Authorized Economic Operator (AEO) Priority:** Granting AEO certified cold chain operators (importers, forwarders, carriers) the highest level of facilitation, including minimal to zero physical checks and immediate release upon arrival. Incentivizes the trade community to invest in security and compliance, rewarding reliable partners with speed.

c. **Real-Time Data (IoT) Acceptance:** The enforcement agencies (Customs, PGAs etc.) are required to provide real-time temperature and location data from compliant IoT sensors and data loggers (e.g., as per IATA PCR). This may provide proactive assurance of cargo integrity, reducing the need for physical checks to verify condition.

E. Sampling and Lab Testing:

Sampling and testing is the major source of delay. It must be fast-tracked.

a. **Fast-Tracked Lab Procedures:** Establish **24/7 priority lab testing** for perishable and pharmaceutical samples, with Service Level Agreements (SLAs) for results often within 2-6 hours.

b. **Release Pending Analysis (RPA):** Allow the cargo to be released to the importer's bonded cold storage facility after sampling, under Customs control, while waiting for the lab results. This prevents the cargo from dwelling at the port for days.

c. **Acceptance of Third-Party/Accredited Lab Reports:** Customs/PGAs should recognize test reports from internationally accredited laboratories in the country of export or at the time of shipment, reducing the need for redundant local testing.

F. Optimisation of Physical Intervention/Inspection:

The most import part of recommendation is to optimise the physical intervention/inspection of the shipments. Even in case, it is necessary, it must be aligned with continuous temperature control. Following points are necessary for the physical intervention/examination:

a. **Trust-based Risk Mitigation:** A trust based process design that mitigates the risk of contamination, residue limits, and other parameters is to be built. Accreditation, pre-shipment inspection, stringent compliance norms etc. may help in minimizing interventions and checks.

b. **Minimise Physical Intervention:** Physical examination of the temperature sensitive cargo should be rare. Scanning of the containers, risk analysis, pre-authentication, accreditation, profiling of the exporter and importers etc. are the criteria to be used to minimise the physical intervention.

c. **Joint inspection and Sampling**: Where it is unavoidable, instead of sequential inspection/examination by multiple agencies, implement a single, co-located inspection point and a joint inspection team involving all relevant PGAs and Customs. This prevents multiple unlading/lading events.

d. **Dedicated Cold Chain Corridor/Terminal:** Designate specific port/airport/ICD/CFS terminal supported by customs and PGA staffing and dedicated temperature-controlled handling and storage facilities (e.g., Reefer plugs, cold rooms) for temperature sensitive cargo are must. This prevents temperature excursions during handling.

e. **Fast-track Sampling and Lab Testing:** Establish 24/7 priority laboratory testing for temperature-sensitive samples e.g., pharmaceuticals, perishables etc. using accredited govt./private or third-

party labs under PGA supervision to increase testing capacity and speed. Implement

f. **Direct Port Delivery (DPD) and auto-OOC for Temperature Sensitive cargo**: Where, examination/assessment are avoidable, and samples are either not to be taken or have already taken, the cargo can be moved to a bonded warehouse/importer's facility under Customs control while waiting for test results, minimizing the port dwell time.

G. Enhanced Stakeholders Collaboration:

Improving communication and compliance across the supply chain, following steps are important:

a. **Memorandum of Understanding (MoUs):** All the PGAs are required to sensitise the need of fast-tracking clearance and 24x7 services. Round the clock presence of the officials of PGAs at the port/airport/ICDs/CFSs and minimising permission time so that the entire clearance process may be completed within 24 hours of arrival of the consignment would help in making the process agile.

b. **Trusted Trader Programs (AEO Status)**: Offer enhanced Authorized Economic Operator (AEO) or similar status to reliable importers and logistics providers that specialize in cold chain. These companies benefit from further reduced inspections and faster processing times.

c. **Training and Specialization**: Conduct specialized training for Customs officers, PGA inspectors, and cargo handlers on the unique requirements, handling protocols, and documentation for various temperature-sensitive goods (e.g., pharmaceuticals, specific perishables).

These re-engineered processes move the regulatory burden from physical inspection at the border to digital pre-clearance and a risk-based approach, directly addressing the time-critical nature of temperature-sensitive cargo.

3. Technology and Monitoring:

Advance and modern technology driven by artificial intelligence, internet of things and block-chain etc. is required to maintain a reliable temperature control system for import and export of the temperature sensitive cargo. Such technology may support the supply chain in following manners:

- **Uninterrupted support:** Temperature sensitive shipments can't sustain quality and product integrity if temperature and humidity prescribed for keeping them safe are not maintained. Therefore, it becomes necessary to provide uninterrupted support to save them from contamination and deterioration.
- **Real-time tracking and monitoring:** Integrated IoT sensors and data loggers should continuously track location, temperature, and humidity. These sensors can trigger instant alerts if conditions deviate, allowing for immediate corrective action.
- **Predictive analytics:** Using data analytics and AI can help optimize transportation routes, forecast demand, and predict potential disruptions before they occur, improving operational efficiency.
- **Blockchain for traceability:** Blockchain technology creates a secure and transparent record of a shipment's journey. This increases accountability, enhances traceability from farm to table, and helps in regulatory compliance and food safety recalls.
- **Digitalization and automation:** Paperless, tech-driven customs and logistics systems reduce delays. Automated processes for sorting, packaging, and inventory management increase speed and reduce human error.
- **Smart packaging:** Innovations like smart packaging with integrated sensors and Modified Atmosphere Packaging (MAP) can extend shelf life and provide more information about the cargo's condition.

Such technology may also enable us with fast track customs clearance system by simplifying risk-based digitalized clearance system. It may help us harmonizing documentation by implementing a standard framework like electronic air way bill/bill of lading, and minimizing procedural delays. It may also help in collaborating inter-agency activities and interfaces and leverage 24x7 operation.

3.1 Real-time monitoring technologies:

Real-time monitoring technologies are transforming the tracking and management of perishable goods throughout the supply chain. By providing continuous visibility into environmental conditions, these systems prevent spoilage, ensure compliance, and enable rapid responses to deviations. Some of these technologies are described below:

- **IoT-Based Sensor Networks** These networks deploy wireless sensors in storage rooms, reefers, and containers to measure conditions like temperature and humidity at set intervals. GPS trackers provide location data and enable geo-fencing alerts. Accelerometers and shock sensors detect rough handling, triggering alerts for potential product damage.
- **Data Loggers and Gateways** Data loggers record temperature, humidity, light exposure, and shock events. Gateway hubs aggregate sensor data via Bluetooth/ WAN and upload it to the cloud. Battery packs ensure uninterrupted power for weeks in transit.
- **Cloud Platforms & Dashboards** Real-time dashboards visualize key metrics, historical trends, and alarm statuses, offering customizable views for logistics managers, quality teams, and customers. Data analytics and reporting automatically generate compliance reports for FSSAI, Customs, and importers, and perform trend analysis to identify cold-chain weak points.
- **Alerts, Notifications & Automated Actions** Threshold alerts (SMS, email, mobile push) are triggered when readings exceed set limits (e.g., >4°C for dairy). Automated responses can trigger backup generators or notify staff. Escalation protocols ensure multi-level alerts if issues remain unacknowledged.

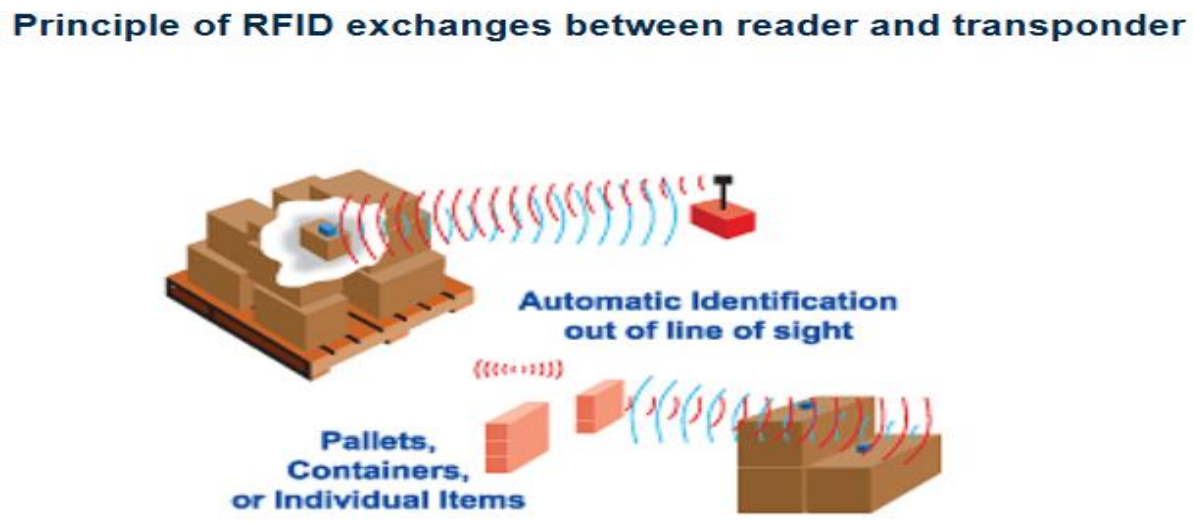
3.2 Blockchain for Track and Traceability

Blockchain technology offers an immutable, decentralized ledger that is ideal for enhancing traceability in the perishable goods supply chain. By recording every transaction or event—from farm harvest to final delivery—on a tamperproof ledger, stakeholders can ensure transparency, trust, and rapid response to quality or safety issues.

What Is Blockchain Traceability? It involves a decentralized ledger where each participant (farmer, packer, transporter, regulator) runs a node that records transactions in real time. Once data (e.g., temperature logs, inspection results) is written, it cannot be altered without consensus, ensuring immutable records. Smart contracts, which are self-executing codes, enforce compliance and automate actions based on predefined rules (e.g., "if temperature >4°C for >30min, trigger alert").

Key Components A blockchain consists of blocks (batches of transactions), a chain (cryptographically linking blocks), nodes (participant's copy of the ledger), and smart contracts (self-executing code).

Benefits for Perishable Goods Blockchain offers end-to-end visibility, allowing all stakeholders to view real-time status (temperature, location, inspection outcomes). It enables faster recall management by instantly identifying and isolating affected batches. It enhances trust among buyers and custom officials, reducing disputes and document fraud. Furthermore, it simplifies regulatory compliance by providing automated proof of compliance (e.g., immutable lab certificates) for customs and FSSAI audits.



3.3 Digital Inspection Checklists

Digital inspection checklists are technology-driven tools that standardize, streamline, and digitize the inspection process of perishable goods during import and export. Replacing traditional paper-based checklists, these tools enhance data accuracy, enable real-time reporting, and improve regulatory compliance.

What Are Digital Checklists? They are mobile or web-based forms used by inspectors, QA professionals, or port officials to record observations, measurements, and compliance parameters using smartphones, tablets, or laptops.

Example: Checklist for Frozen Seafood Import The following table illustrates a sample digital checklist for frozen seafood import:

Parameter	Compliant? (Y/N)	Notes / Photo
Outer packaging intact	Y	
Labelling matches CoA	Y	

Parameter	Compliant? (Y/N)	Notes / Photo
Temperature below -18°C	N	Temp = -15°C, flagged
Date of production visible	Y	
Ice crystals present	Y	[Photo Attached]

Benefits of digital checklist include improved accuracy, real-time reporting, a robust audit trail, sustainability (reduced paper), and customizability for various commodities. Tools range from custom Excel + Power Apps to third-party tools like iAuditor. Implementation involves defining commodity-specific parameters, selecting a platform, training inspectors, and continuous monitoring. Best practices include standardizing templates, including geo-tagging, enabling multi-language support, and periodic auditing of digital records.

3.4 Single Window Integration at ICEGATE platform

Integration of inspection workflows with digital government portals like ICEGATE (Indian Customs Electronic Gateway) is crucial for streamlining import/export clearance processes for perishable goods. This integration facilitates a seamless exchange of data between logistics companies, regulatory bodies (FSSAI, Customs), and stakeholders across the supply chain.

ICEGATE is the official portal of the Indian Customs Department, providing electronic filing services for Bills of Entry (Import), Shipping Bills (Export), Customs Duty Payments, Document Tracking, Importer/Exporter Code (IEC) linkage, and the Risk Management System (RMS).

Why Integration Matters for Perishables: Perishable goods demand faster clearance, real-time visibility, and regulated inspections. Manual processes lead to delays and spoilage risks. Integration enables automated submission of inspection reports, pre-validation of FSSAI licenses, reduction in paperwork duplication, and enhanced tracking of temperature and shelf life.

An electronic online message exchange between the Food Safety and Standards Authority of India (FSSAI) and the Department of Plant Protection, Quarantine and Storage (PQIS) with the Customs has started. Similar arrangements can be made with other PGAs to fast track the clearance process.

Common Points of Integration: Integration occurs across various systems:

System	Integration Purpose	Data Flow
FSSAI /PQ/AQ	Validate food business license & inspection type	ICEGATE ↔ FSSAI
EDI Customs	Sync Bill of Entry, Shipping Bill	Exporter ↔ ICEGATE
DGFT Portal	Match with Authorised Exporter License	DGFT ↔ ICEGATE
e-SANCHIT	Upload and share docs digitally	Exporter ↔ ICEGATE
PCS 1x (Port Community System)	Synchronize port-side processes	ICEGATE ↔ Port Systems
Food Safety and Standards Authority of India	End to end to and fro integration	ICEGATE ↔ FSSAI Portal
Drugs and Cosmetic under Central Standard Control Organisation (CDSCO)	Requires end to end integration	ICEGATE ↔ CDSCO Platform
Ministry of Environment, Forest and Climate Change	Requires end to end integration	ICEGATE ↔ Ministry's portal

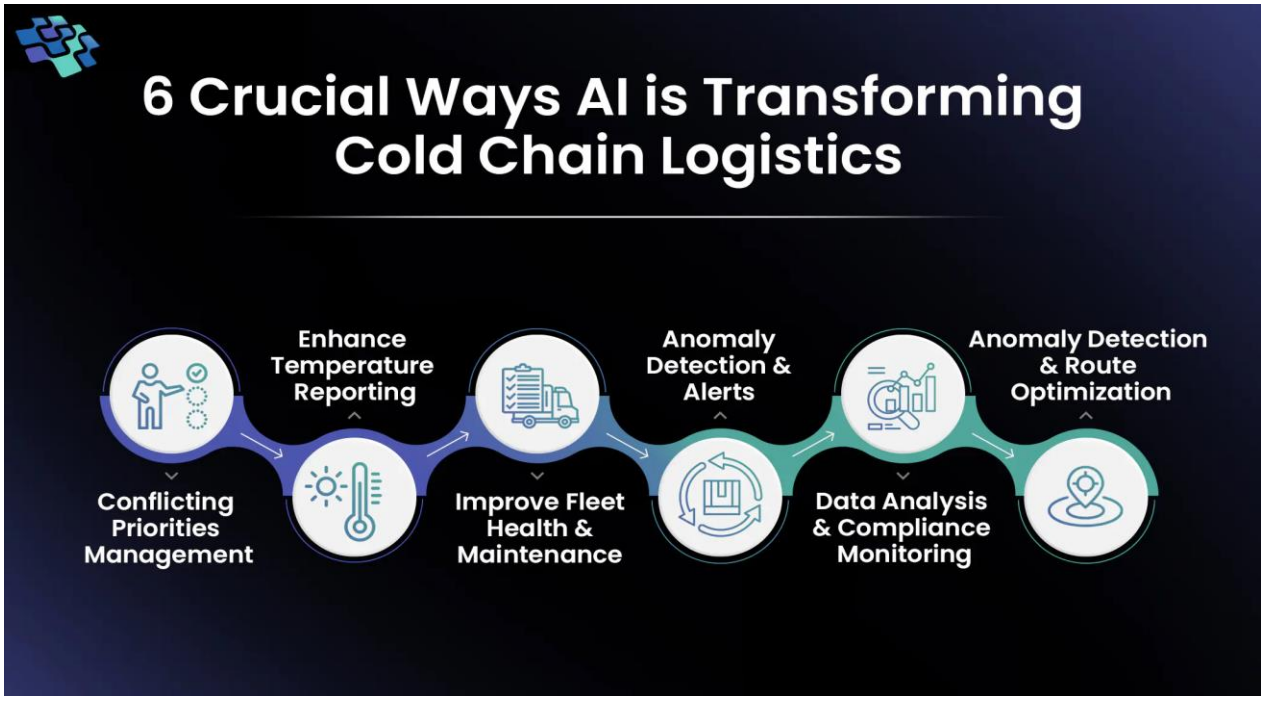
A sample integration flow for fresh fruit imports involves the importer uploading the Bill of Entry on ICEGATE, the FSSAI module auto-checking the license, the inspection agency uploading a digital checklist, and Customs providing e-clearance. Benefits include reduced inspection time, increased transparency, regulatory alignment, predictive risk profiling, and paperless compliance. Technologies involved include ICEGATE APIs, digital signatures, blockchain (in trials), and cloud ERP systems. Challenges like legacy ERP incompatibility, data security, low MSME awareness, and manual upload dependency are mitigated through middleware, secure APIs, government workshops, and auto-sync. Best practices include automating data uploads, cross-checking codes, aligning classifications, and testing environments. ICDs/CFSs should have dedicated temperature-controlled examination zones to maintain goods' temperature during Customs examination.

3.5 Artificial Intelligence (AI) and Machine Learning:

Use of AI tools is must to predict the risk factors of the goods and importers/exporters. It can be used to optimize warehouse functioning and inventory management, and forecast risks by analysing vast data from weather

patterns, transport logs, and historical trends. AI and machine vision improve inspection speed and accuracy, detecting defects or contamination more efficiently and can be of great help during physical examinations.

There are 6 crucial ways, AI is transforming cold-chain logistics:



Source: Nextgen Invent
https://nextgeninvent.com/blogs/artificial-intelligence-transforming-cold-chain-logistics/

i. Conflicting Priorities Management:

AI assists carriers in handling unforeseen disruptions resulted from operational choices. Optimizing truck routes for instance, can lead to more effective operations. However, because trailer doors must be opened more frequently, more efficient routing may lead to increased thermal abuse for reefer carriers. AI in such situation helps technologically. For example, the two-way reefer controls and predictive data analysis assist carriers to make the necessary corrections before an issue arises.

AI can assist carriers in understanding and effectively navigating the shifting landscape as expansion, complexity, and regulations change. AI therefore, assists us in resolving unforeseen conflicts of priorities.

ii. Enhancing Temperature Reporting:

Not only are manual temperature checks inefficient, but they can also be manipulated by deliberate deception or human error. Frequent entry and exit of human resources also cause several negative effect to the ecosystem including bacterial/viral infections etc. Artificial intelligence in conjunction with specialized sensors and Internet of Things (IoT) devices eliminates those issues and provides carriers and other stakeholders with real-time visibility by continuously monitoring the temperature of reefer trailers/warehouse, even in separate compartments inside a single trailer/warehouse. In addition to giving carriers/logistics more reliable and consistent temperature data, AI is also cost effective on account of manpower deployment.

The AI can have product-specific algorithms to check the anomalies and fluctuations in temperature. AI can predict when a problem might occur and notify staff members in advance so they can take the necessary action by sending out automatic alerts. Real-time temperature data is compared with pre-set thresholds or anticipated temperature patterns to achieve this.

iii. Improve Fleet Health and Maintenance

In addition to temperature monitoring, AI enhances predictive maintenance through advanced analytics. By examining historical data from vehicle and equipment components, AI systems can identify patterns and anomalies that signal potential failures. These systems leverage machine learning algorithms to forecast when specific parts are likely to fail, allowing for timely preventive repairs. This proactive approach reduces the risk of unexpected breakdowns and operational downtime, extending the lifespan of equipment.

By implementing such AI-driven predictive maintenance strategies, organizations can optimize their maintenance schedules, reduce repair costs, and improve overall operational efficiency.

iv. Anomaly Detection and Alerts

AI algorithms can effectively detect temperature anomalies by analysing real-time temperature data against predefined thresholds and expected trends. These advanced systems identify potential issues such as temperature excursions, equipment malfunctions, or unauthorized door openings. AI can quickly flag deviations that may compromise product integrity.

When an anomaly is detected, the system generates automated notifications to alert the relevant personnel, enabling swift action to mitigate risks. AI-driven monitoring safeguards product quality and maintains the integrity of sensitive environments.

v. Compliance Monitoring:

Artificial intelligence can analyse vast amounts of temperature data gathered from several reefers and produce useful insights. In addition to generating thorough reports for quality assurance, compliance audits, and strategic decision-making, it can spot trends and evaluate regulatory compliance.

AI can help make sure that cold chain logistics regulations and rules are followed. Artificial intelligence systems can evaluate compliance levels and provide detailed reports for auditing purposes by evaluating temperature data and comparing it with required temperature ranges or industry standards.

vi. Route Optimization:

AI-powered systems enable businesses and their customers to effectively track route progress, ensure temperature compliance, and manage exceptions in real-time. By leveraging advanced analytical technology and machine learning algorithms, AI enabled system provides actionable insights that enhance visibility throughout the supply chain. Businesses can monitor critical parameters, such as temperature fluctuations and delivery timelines, facilitating prompt decision-making. It also simplify the regulatory adherence, reduce risk or errors and improve overall operational efficiency.

4. Training and Capacity Building

Training and capacity building for handling temperature-sensitive cargo are essential for maintaining product integrity (especially for pharmaceuticals and food), ensuring regulatory compliance, and minimizing financial losses. Specialized programs cover **regulations, risk management, packaging technologies, and monitoring systems**.

Specialized training programs: All personnel, from handlers to freight forwarders, must receive training on regulations, packaging requirements, temperature management, and the specific needs of various perishable goods. The International Air Transport Association (IATA) offers specific certification programs, such as CEIV Fresh, to set global standards for handling temperature

sensitive cargo. Global Cold Chain Alliance (GCCA) also provide specialised training program. The main aspects covered under capacity building initiatives are given below:

- **Regulatory Environment:** Adherence to national and international standards and guidelines, such as Good Distribution Practices (GDP), Hazard Analysis and Critical Control Points (HACCP), WHO guidelines, and specific IATA Perishable Cargo Regulations (PCR) and Temperature Control Regulations (TCR).
- **Handling Procedures:** Specific protocols for storing, accepting, and handling time- and temperature-sensitive shipments, including proper loading/unloading and minimizing exposure to ambient conditions.
- **Temperature Management:** Understanding required temperature ranges (e.g., 2°C to 8°C for refrigerated, -20°C for frozen, -80°C for ultra-cold) and managing temperature excursions.
- **Packaging Technologies:** Training on packaging technology is necessary so as to make the persons understand the selection and use of appropriate insulated containers, phase change materials (PCMs), gel packs, and dry ice to maintain temperature stability during transit.
- **Monitoring and Tracking:** Use of real-time temperature monitoring devices, IoT-enabled sensors, data loggers, and GPS tracking to provide continuous visibility and immediate alerts for deviations.
- **Risk Management and Contingency Planning:** Identifying potential critical control points and risks in the supply chain (e.g., customs delays, equipment failure) and developing effective contingency and corrective action plans (CAPAs).
- **Documentation and Audits:** Maintaining comprehensive records of storage conditions, monitoring data, and corrective actions for quality assurance and regulatory compliance purposes.
- **Equipment Operation:** Proper operation and maintenance of refrigeration units and other temperature-controlled equipment, including calibration and backup systems.

Basically, the objective to achieve through capacity building initiatives in the cold-chain sectors involved a combination of strategies, that covers the following:

- **Skill Development:** Implementing specialized training programs to enhance technical expertise in operating and maintaining cold chain equipment and processes.
- **Infrastructure Investment:** Developing standardized cold storage facilities, temperature-controlled vehicles, and advanced warehousing with backup power systems.
- **Technology Integration:** Adopting innovative technologies like AI-driven route optimization, blockchain for traceability, and automated climate control systems.
- **Certifications:** Pursuing industry certifications like IATA's Center of Excellence for Independent Validators in Pharmaceutical Logistics (CEIV Pharma) to ensure compliance with global standards.
- **Collaboration:** Fostering partnerships among government agencies, logistics providers, and manufacturers to share best practices and address common challenges.
- **Continuous upgrade:** Given the rapid pace of technological change and evolving regulations, staff must receive ongoing training to stay up-to-date with best practices.

5. Vendor Quality Assurance (VQA)

Ensuring integrity of temperature sensitive product and compliance management in import and export ecosystem helps in timely clearance and hindrance free movement of the goods. Therefore, the key components, strategies and tools used to monitor and enhance vendor performance, especially in the context of regulatory and quality inspection requirements.

The objectives behind Vendor Quality Assurance are to ensure consistent product quality across batches, minimize risk of shipment rejection due to non-compliance, improve traceability and accountability, foster long-term strategic partnerships with reliable vendors.

viii) Key Elements of the VQA Program

Component	Description
Vendor Pre-Qualification	Initial screening based on certifications (FSSAI license, ISO, HACCP)
Regular Audits	Scheduled and surprise inspections at vendor facilities
Quality Scorecards	Scoring system based on compliance, timeliness, and rejection rate
Product Specifications	Detailed specs on moisture, texture, colour, microbiological limits, etc.
Corrective Action Plans	Timely resolution of NCs (non-conformities) detected during inspection
Training Support	Capacity building initiatives for vendor teams

For example – the VQA may be maintained in the import of dry dates, kiwi etc.

ii. Importer/Exporter Selection and Evaluation Criteria:

Parameter	Weightage (%)	Description
Regulatory Compliance	25%	Valid licenses, previous audit history
Product Quality	30%	Conformity to technical specs and lab test results
Operational Capacity	15%	Cold chain readiness, volume handling capability
Past Performance	20%	Rejection rate, shipment delays, documentation errors
Financial & Ethical Standing	10%	Credit history, ethical trade practices

Where, quality score is higher (85 and above) average rejection is below 1.2%, product quality score is above 95% and regulatory compliance is above 90%, the Vendor shall be treated as reliable.

To mitigate the risk, and plan the checks, annual audit and random sampling etc. may be done in low risk category. In medium risk category biannual audit, batch-wise sampling and in high risk category monthly audit, 100% inspection etc. are required. An exporter implementing a cloud-based VQA system with geo-tagging may reduce rejection rates and examination/inspection drastically and enhance performance consistency.

Such Vendors may be inspected/audited by govt. agencies (customs/FSSAI) etc. to ensure the regulatory compliances so as to reduce the inspection frequency in green category vendors. Joint audit with 3rd party certifiers may help quality assurance.

6. Integrated Regulatory Framework

India does not have a single, integrated regulatory framework that covers all aspects of the import and export of temperature-sensitive cargo. Instead, it relies on a **combination of regulations** from various government bodies and adherence to international standards. Key aspects of the regulatory landscape are given below:

- **Multiple Agencies:** The import/export process involves several agencies, including the Directorate General of Foreign Trade (DGFT), the Central Board of Indirect Taxes and Customs (CBIC), the Food Safety and Standards Authority of India (FSSAI) for food items, and other product-specific bodies.
- **Foreign Trade Policy (FTP):** The DGFT formulates the overarching Foreign Trade Policy, which provides general guidelines for all imports and exports, including licensing requirements like goods under free, restricted, and prohibited category.
- **Customs Procedures:** The CBIC has introduced reforms to streamline air cargo and customs clearance for time-sensitive products, including the digitization of transhipment applications and the abolishment of certain permit fees to minimize delays. However, there are lots many improvements are still required to be done for faster clearance management.
- **Infrastructure and Private Certification:** While government regulations set the baseline, the actual handling and infrastructure often rely on international best practices and certifications. Many cargo terminals at major airports (like Delhi and Mumbai) have achieved IATA CEIV Pharma

certification (Center of Excellence for Independent Validators in Pharmaceutical Handling and Logistics) to ensure compliance with global standards for temperature-sensitive pharmaceuticals. However, many sea ports, airports and ICDs are yet to achieve such infra-standards.

- **National Logistics Policy (NLP):** The government is working towards a more seamless system through initiatives like the National Logistics Policy, Gati-Shakti, which aims to cut across silos and integrate policies of different ministries for efficient movement of goods, including the development of multi-modal logistics parks with temperature-controlled facilities.
- **Product-Specific Regulations:** Specific categories of goods are subject to additional regulations. For example, the import of seeds is regulated under the Plant Quarantine Order.

In essence, while the Indian government is working on integrating and streamlining logistics, particularly for time-sensitive goods like pharmaceuticals and perishables, the current system involves navigating multiple regulatory requirements and relying on specialized, often privately-run, certified facilities to ensure product integrity throughout the supply chain.

Keeping in my the fast-track clearance system along with maintaining all the stringent norms, it requires to integrate the Regulatory Frameworks. A single, integrated regulatory approach essentially can ensure speedy clearance of perishable goods while safeguarding product integrity. India already has implemented these regulatory framework in bits and pieces with the help of different agencies like FSSAI, APEDA, MPEDA, DGFT, PQI, AQI, Drugs Controller etc. but such disintegrated structure is not suitable for quick and collaborated decision making.

It requires to have a *National Centre for Cold-chain Development (NCCD)* for all the infrastructure and technological excellence, and a single interface of *Customs Single Window (SWIFT) system* where all decisions including lab-testing, reporting, permissions and certification etc. are undertaken at a single point of contact. This would also resolve the problems of overlapping procedures and fragmented testing and permission giving interfaces.

A consolidated regulatory structure, adopting global best practices, and investing in rapid, high-technology testing will reduce dwell time at ports and protect public health. The framework may be segregated in following three segments:

(i) A single, comprehensive, unified legislation that consolidates existing national laws and aligns with global best practices:

A unified law would bring together food safety rules, pharmaceutical standards, quarantine requirements, licensing conditions, and cold-chain standards into one harmonized framework. This consolidation would streamline decision-making, eliminate overlapping inspections, and establish uniform timelines and procedures for clearance.

The unified law for perishable imports and exports should integrate all relevant Indian regulations (FSSAI, DGFT, Quarantine, Pharmaceutical, MPEDA, APEDA etc.) and consolidate all based on the global best practices like IATA TCR, HACCP, ISO 22000, GMP, Codex Alimentarius, US FDA Compliance and FSMA, International Plant Protection Convention, World Organization for Animal Health (WOAH), Sanitary and Phytosanitary (SPS) Agreement etc. It would enable single-window clearance, standardize cold-chain infrastructure and operational procedures, and ensure vendor and lab compliance with accredited rapid testing and e-reporting.

(ii) True Single-window framework (one regulation + common portal).

A True Single-Window Framework would enable all permissions, inspections, verifications, and clearances related to the import and export of perishable goods to be processed through one integrated digital platform. Instead of multiple agencies acting independently at their own platforms, this system would consolidate the requirements of FSSAI, Customs, DGFT, Plant & Animal Quarantine, EIC, and other stakeholders at a single regulatory platform from where all the decisions may be taken in fast-track mode. Through this framework, stakeholders can submit documents and certificates once and can receive coordinated, risk-based decisions, and obtain legally binding clearances efficiently.

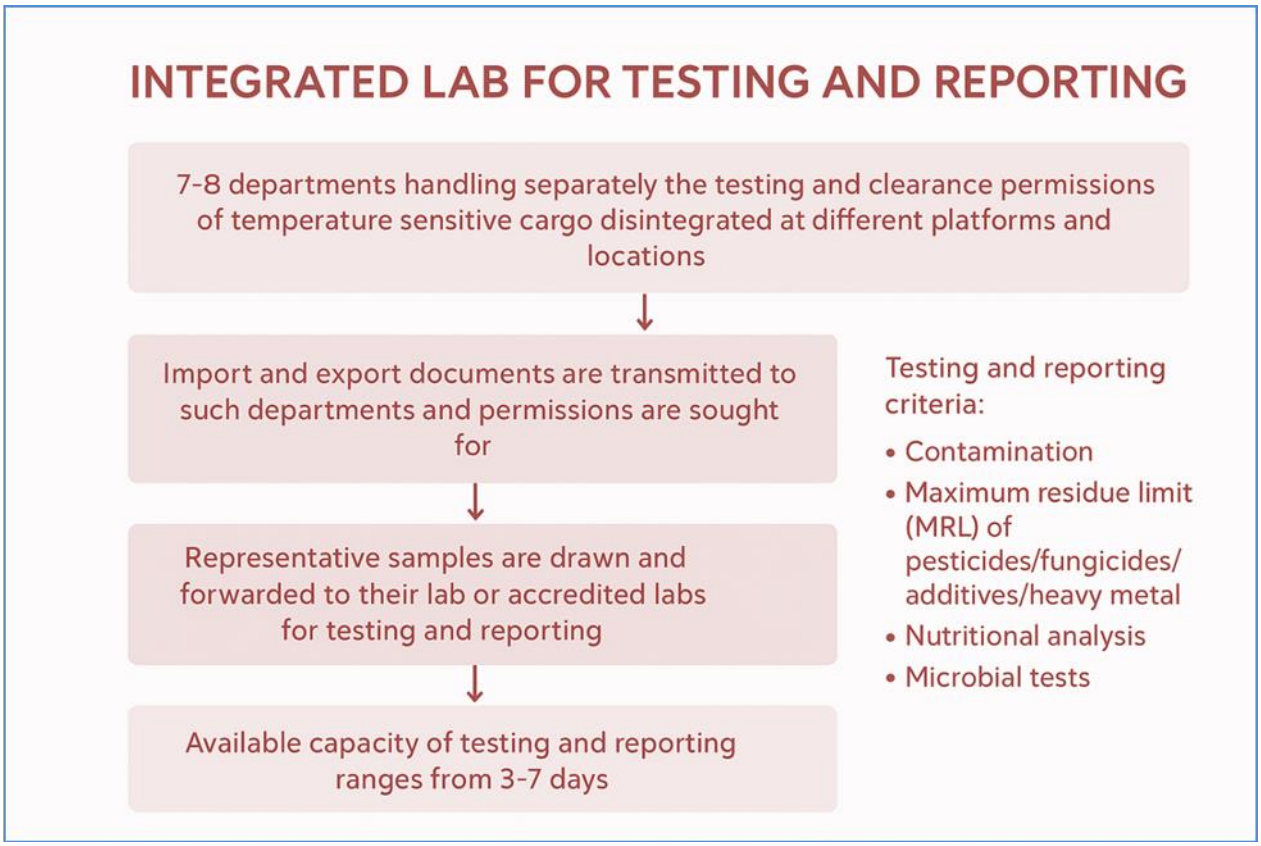
(iii) Centralized, High-tech Laboratory:

A **centralized, high-tech laboratory** should be established at all major ports to handle **all types of testing** for perishable imports and exports, including microbiological, chemical, and cold-chain integrity tests. The lab would provide **rapid, reliable, and comprehensive results** under one roof, minimizing delays, ensuring product integrity, and supporting regulatory compliance. Lab results must integrate with SWIFT/FICS,

support e-reporting, and be prioritized for perishable consignments to meet tight shelf-life windows.

7: Integrated Lab for testing and reporting

Presently, there are 7-8 departments handling separately the testing and clearance permissions of temperature sensitive cargo disintegrated at different platforms and locations. The import and export documents are transmitted to such departments and permissions are sought for. Representative Samples are drawn and forwarded to their lab or accredited labs for testing and reporting. The available capacity of testing and reporting of different criteria of the temperature sensitive cargo e.g. contaminations, Maximum residue limit (MRL) of pesticides/fungicides/additives/heavy metal, nutritional analysis, microbial test etc. are ranging from 3 days to 7 days, that resulted ultimately in minimum 8-10 days time to obtain test reports/permission which is exorbitantly high keeping in view the short shelf life of temperature sensitive cargo.



7.2 Further, integration related technical challenges and absence of Service Level Agreements (SLA) also causes inordinate delay in furnishing test reports/permission for clearance of goods and ultimately increases dwell time of the clearance. Keeping in view, the disintegration and management challenges across the ecosystem, it is recommended to establish integrated lab at the ports accredited by all concerned department and manned by CRCL, along with technological advancement, so as to, reduce drastically the testing time and furnish test reports/permission within one-two days so as to enable reduction of dwell time of clearing import/export cargo. Duration of testing/permission may be reduced by evolving new testing technology and method, simulation of the data and accreditation process.

7.3. A robust framework guideline for testing, reporting, review and audits, and their integration with the eco-system developed by PGAs may be introduced. The size of the labs and technical manpower may be divided in three categories i.e. small, medium and large based on size of port and workload. These labs should provide one stop solution for all types of testing of all types of products and shall provide immediate results, based on which the custom officials can make immediate decision on the clearances.

7.4. Accreditation of Laboratories/ Integrated labs at port for one point solution: Accredited laboratories play a pivotal role in the quality assurance and regulatory compliance of perishable goods during import and export. These testing facilities are certified by national and international accreditation bodies (such as NABL or ISO/IEC 17025) to perform specific inspections or analytical tests with a recognized standard of quality and accuracy. Increased lab presence near ports, reducing testing costs by involving private players and increased competition, faster report generation will enhance the whole process of clearance. A small integrated lab can be present at various designated ports which provide testing of majority of items and majority of parameters. An integrated lab can also coordinate with different PGAs in a unified manner.

8. Recommendation for Pharmaceutical Sectors received from Mumbai Customs Zone III:

Customs Mumbai Zone III has forwarded their detailed report made on Pharma Sector covering current stay of play, available infra across the ports, gaps identified and way forward. The recommendations made by them to expedite the entire process and remove the bottlenecks are as under:

PROBABLE SOLUTIONS FOR CHALLENGES FACED BY STAKEHOLDERS IN THE SMOOTH MOVEMENT OF EXPORT CARGO

The challenges faced by stakeholders in the smooth movement of export cargo were discussed with relevant stakeholders, and the following solutions have been proposed in consultation with them to ensure smoother movement of export cargo.

A: SPACE CONSTRAINTS AT AIR CARGO TERMINALS

Challenges:

i. Limited usable space despite larger total area.
ii. Congestion and long queues at offloading docks.

Solutions:

i. **Slot-Based Scheduling System:** Implement a time-slot booking system for cargo drop-offs to avoid peak-hour congestion.
ii. **Vertical Storage Systems:** Use vertical racking and automated storage/retrieval systems (ASRS) to maximize space.
iii. **Real-Time Yard Management System:** Deploy IoT-enabled yard management systems to track truck movement and optimize dock allocation.
iv. **Temporary Storage Partnerships:** Leverage offsite temporary storage facilities near airports during peak periods (through Public-Private Partnerships or third-party logistics providers).

B: INADEQUATE MANPOWER

Challenges:

i. Understaffed warehouses leading to delays.

Solutions:

i. **Contractual/Outsourced Labour Pools:** Maintain a pool of on-call or third-party labour that can be mobilized during peak loads.
ii. **Process Automation:** Introduce conveyor systems, barcode/RFID scanners, and cargo handling robots to reduce dependency on manual labour.
iii. **Incentivized Staffing Models:** Use performance-based incentives to attract and retain skilled cargo handlers.
iv. **Training Programs:** Implement skill development programs in collaboration with government schemes (e.g., Skill India) to upskill existing staff.

C: DETENTION AND DEMURRAGE CHARGES

Challenges:

i. Delays in cargo offloading lead to costly charges.

Solutions:

i. **Digital Queue Management System:** Enable exporters to track queue status and dock availability in real time via mobile apps or portals.

ii. **Buffer Zone for Pre-Gate Processing:** Create pre-gate holding areas where documentation and cargo checks can be pre-processed before entering terminal docks.

iii. **Service-Level Agreements (SLAs):** Establish SLAs between warehouse operators and exporters for maximum turnaround time and penalties for delays.

iv. **Negotiated Grace Periods:** Collaborate with authorities to extend free time or waive demurrage in case of infrastructure-related delays.

D: DELAY IN ARRIVAL REPORT (CARR) GENERATION

Challenges:

i. Unreliable internet and system outages delay critical documentation.

Solutions:

i. **Redundant Connectivity Solutions:** Equip terminals with backup internet sources (e.g., mobile broadband, satellite). **Offline CARR Entry Option:** Develop systems that allow offline CARR data entry with automatic syncing once connectivity is restored.

iii. **System Performance Monitoring:** Use monitoring tools and SLAs with IT service providers to ensure 99.9% uptime.

iv. **Standardized Digital Systems Across Stakeholders:** Adopt common digital platforms (like ICEGATE, NIC systems) integrated with exporter, custodian, and customs systems with timestamped movement of CARR requests.

E: LACK OF STACKING PLANS FROM AIRLINES

Challenges:

i. Poor coordination results in inefficient cargo placement.

Solutions:

i. **Mandatory Pre-Shipment Stacking Plans:** Introduce regulations requiring airlines to submit stacking plans at least 24 hours in advance.

ii. **Digital Sharing Platform:** Create a shared online dashboard for airlines and warehouses to upload/download stacking data.

iii. **Penalty for Non-Compliance:** Impose penalties or handling

delays on airlines that fail to provide stacking instructions on time.
iv. **AI-Based Auto-Stowage Suggestions:** Implement AI tools in warehouses to optimize stacking layout based on cargo type, priority, and airline data.

F: THERMAL PACKAGING REQUIREMENTS OF FOREIGN CLIENTS

Challenges:

i. Customs inspections damage temperature-sensitive packaging, leading to consignment rejections.

Solutions:

i. **X-Ray Scanning in Place of Manual Inspection:** Use advanced scanning equipment (e.g., dual-view X-rays) to reduce the need for physical unpacking.
ii. **Sealed Inspection Rooms with Client-Specified Protocols:** Develop customs-certified cold inspection zones where packaging can be opened and resealed under controlled conditions.
iii. **Pre-Customs Inspection with Digital Imaging:** Allow digital image submissions (from exporters or freight forwarders) to customs to reduce physical examination frequency.
iv. **Stakeholder MoUs on Thermal Packaging:** Sign agreements between exporters, customs, and clients on handling SOPs for thermally packed goods.

G: EXAMINATION, SAMPLING, AND TESTING OF PHARMACEUTICAL EXPORT CARGO

Challenges:

i. Absence of temperature-controlled sampling facilities.
ii. Limitations in sample testing by DYCC laboratories.

Solutions:

1. **Establishment of Temperature-Controlled Sampling Zones:**
   - Dedicated cold rooms or controlled environment chambers should be established within examination areas for the sampling of pharmaceutical cargo.
   - These zones must be validated to maintain the required storage conditions (e.g., 2–8°C, 15–25°C) and be equipped with appropriate tools for safe sample withdrawal.
2. **Strengthening Laboratory Infrastructure:**

- DYCC laboratories must be upgraded with necessary analytical instruments, reference standards, and qualified personnel to handle the full range of pharmaceutical samples.
- A periodic review and gap analysis should be conducted to ensure capability alignment with current export product profiles.

3. **Cold-Chain Logistics for Sample Transport:**
   - Samples destined for external laboratories should be transported using validated cold-chain mechanisms to preserve their integrity.
   - Tracking and monitoring systems (e.g., data loggers) should be employed during transit to ensure compliance with required conditions.
4. **Alternative Approaches to Sampling:**
   - Where possible, risk-based examination protocols may be adopted in consultation with the ADC and Customs, including:
     - Acceptance of manufacturer-issued Certificate of Analysis (CoA)
     - Use of sealed reference samples from production batches
     - Sampling at manufacturing premises under regulatory oversight

H. REQUIRED INFRASTRUCTURE AND PROCESSES BY INDIAN PHARMA EXPORTERS AND TRADE

i. Dedicated entry and exit of temperature-controlled vehicles.

ii. Truck docks with non-sterile offloading areas maintained at +15 to +25°C, along with areas maintained at +2 to +8°C.

iii. Indian air exporters shall be given self-sealing permission similar to ocean exporters so ULDs can be built at the shipper's factory or warehouse for optimum handling.

iv. Permission to allow airlines' ULDs (containers and pallets) to be taken outside the cargo complex to the shipper's factory/warehouse for loading.

v. Active shipping unit costs to be controlled to make it more cost-effective for SMEs and MSMEs in the pharma industry.

vi. Shipments from shippers holding AEO Tier 2 or Tier 3 status should not be marked for open examination, and their shipping bills should be processed under the Risk Management System (RMS) to minimize cargo handling and exposure.

vii. Shipments of shippers or IATA-accredited agents who are AEO certified should not be marked for open examination.

viii. Similar to Nhava Sheva, scanners should be installed at gates to scan temperature-controlled cargo, so post-clearance re-screening is not required.

ix. Screening machines should be large and wide enough to scan entire ULDs once built; the number of machines should be increased to expedite screening.

x. Screening machines should also be installed in +2 to +8°C zones to avoid transferring customs-cleared cargo to +15 to +25°C zones.

xi. Animal Quarantine and Wildlife PGAs are not present within air cargo terminals, causing delays; samples must be handled in temperature-controlled zones to maintain integrity.

xii. All terminal operators should provide real-time data from data loggers and have necessary equipment and infrastructure.

xiii. Many terminals currently have +2 to +8°C cold zones only after screening; prior handling in +15 to +25°C zones causes temperature excursions.

xiv. Compulsory usage of cooling equipment to maintain temperature levels when moving ULDs from warehouses to airside.

v. Airlines should prioritize loading temperature-controlled cargo in bulk without leaving shipments on the tarmac for more than 10 minutes; shipments should be picked up separately from general cargo.

xvi. Offloaded temperature-controlled shipments must be stored immediately at their respective temperatures.

xvii. Separate sterile areas should be provided at all cargo terminals for examination of pharma shipments.

xviii. Roller beds to be installed across temperature-controlled warehouses from truck docks for smooth ULD movement.

xix. Airlines should have temperature-controlled designated areas in aircraft and at transit hubs.

xx. On-site availability of vendors dealing in gel packs and dry ice should be mandatory at all cargo terminals.

xxi. Government should promote more temperature-controlled packaging companies to reduce packaging costs.

xxii. Increased warehouse capacity is needed for timely offloading, customs clearance, and handover; current +2 to +8°C capacity is insufficient at many terminals.

xxiii. Many terminals lack sufficient truck dock areas, causing delays in the clearance chain.

I: TARGETED TIMELINE FOR CLEARANCE AND HANDOVER OF TEMPERATURE-CONTROLLED PHARMACEUTICAL EXPORTS

Objective: Customs clearance and handover should be within **4–8 hours** of arrival, instead of the standard 12-hour free period.

Key Requirements for Expedited Handover:

1. **Immediate Transfer Post-Clearance:** Shipments must be promptly moved to airline's designated temperature-controlled loading area.
2. **Continuous Temperature Monitoring:** Real-time temperature data to be shared with airlines for traceability.
3. **Pre-Scheduled Loading:** Assign shipments to specific flights to minimize tarmac exposure.

Essential Factors for Achieving Timeline:

- **24/7 Operations:** Round-the-clock functioning of customs, terminal operators, ground handlers, and airlines.
- **Collaborative Digital Infrastructure:** Integrated digital systems across stakeholders.
- **Strategic Location:** Dedicated temperature-controlled zones close to tarmac.
- **Regulatory Compliance:** Adherence to IATA Temperature Control Regulations (TCR) and Time & Temperature Sensitive (TTSP) labeling.
- **Defined Operational Buffer Time**: The system should incorporate short, clearly defined buffer windows (e.g., 2–4 hours) between

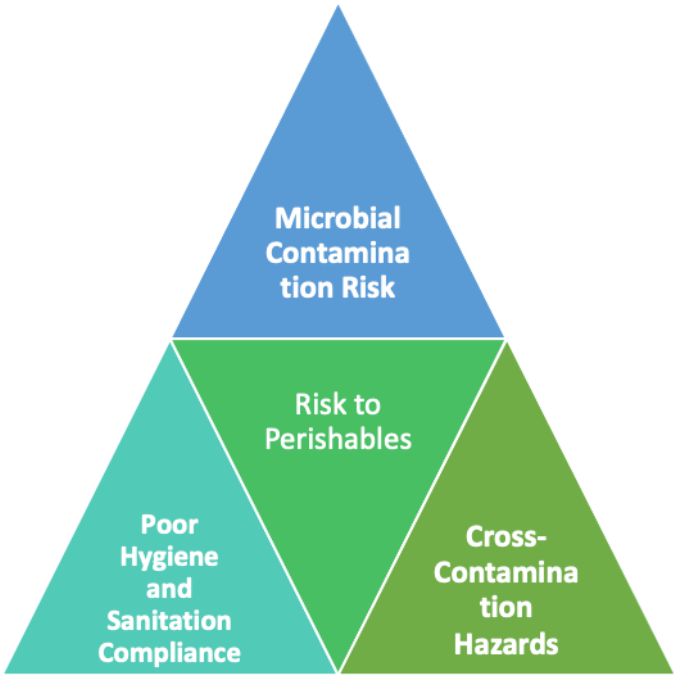
critical process steps. This approach ensures better control and minimizes temperature risk during transitions.

9. Health Related Issues and Recommendations:

Perishable cargo and the personnel handling it pose interconnected health risks to each other. Perishables such as meat, seafood, fresh produce, dairy, and pharmaceuticals can expose workers to harmful bacteria, allergens, chemical residues, and gases released from spoiled goods, while cold working environments may cause physical stress or injury. At the same time, the health and hygiene of personnel directly influence the safety and integrity of the cargo. Illness, poor personal hygiene, open wounds, respiratory droplets, or mishandling can introduce pathogens, physical contaminants, or temperature deviations that accelerate spoilage, reduce shelf life, or compromise compliance with food and pharma safety standards.

9.1 RISK/VULNERABILITIES OF PERISHABLE GOODS:

Perishable cargo such as fresh fruits, vegetables, dairy, meat, seafood, pharmaceuticals, and biologics is extremely sensitive to contamination, temperature variations, and improper handling. When personnel involved in cargo operations are sick, unfit, or lack proper hygiene, it directly threatens product safety, shelf life, and regulatory compliance. Ensuring the health of workers is therefore a critical quality-control requirement across the cold chain.



a) **Microbial Contamination Risk:** Unhealthy workers can transmit bacteria, viruses, or pathogens through coughing, sneezing, open wounds, or unclean hands. This leads to microbial contamination, faster spoilage, reduced shelf life, and potential foodborne illness risks for end consumers.
b) **Poor Hygiene and Sanitation Compliance:** Sick or fatigued personnel are more likely to lapse in hygiene practices such as handwashing, sanitizing workstations, or using proper PPE. These lapses increase the possibility of contaminating sensitive food and pharmaceutical cargo.
c) **Cross-Contamination Hazards:** Unhealthy workers can unknowingly contaminate cargo through respiratory droplets, sweat, improper glove use, or unclean clothing. Cross-contamination is particularly critical for ready-to-eat foods, meat, dairy, and pharmaceutical products requiring strict GMP/HACCP compliance.

9.2 RECOMMENDATIONS TO PREVENT RISKS TO PERISHABLE CARGO

a. Implement Fitness-to-Work Screening

Conduct daily health checks (temperature, symptoms, visible illness), Restrict sick employees from handling perishable cargo and assign them to non-contact tasks and create a clear "fit-for-duty" policy aligned with food safety and pharma guidelines.

b. Strengthen Hygiene and Sanitation Standards

Enforce strict handwashing and sanitization protocols before and during handling, provide mandatory PPE: gloves, masks, hairnets, sanitized uniforms and Introduce regular cleaning schedules for workstations, tools, trolleys, and cold-room surfaces.

c. Train Workers on Health, Cleanliness, and SOP Compliance

Conduct structured training on personal hygiene, food safety, and contamination risks, refresh training periodically to ensure high awareness, especially for new staff and Include modules on handling dry ice, pharma vials, and fragile food items.

d. Improve Workplace Layout & Infrastructure

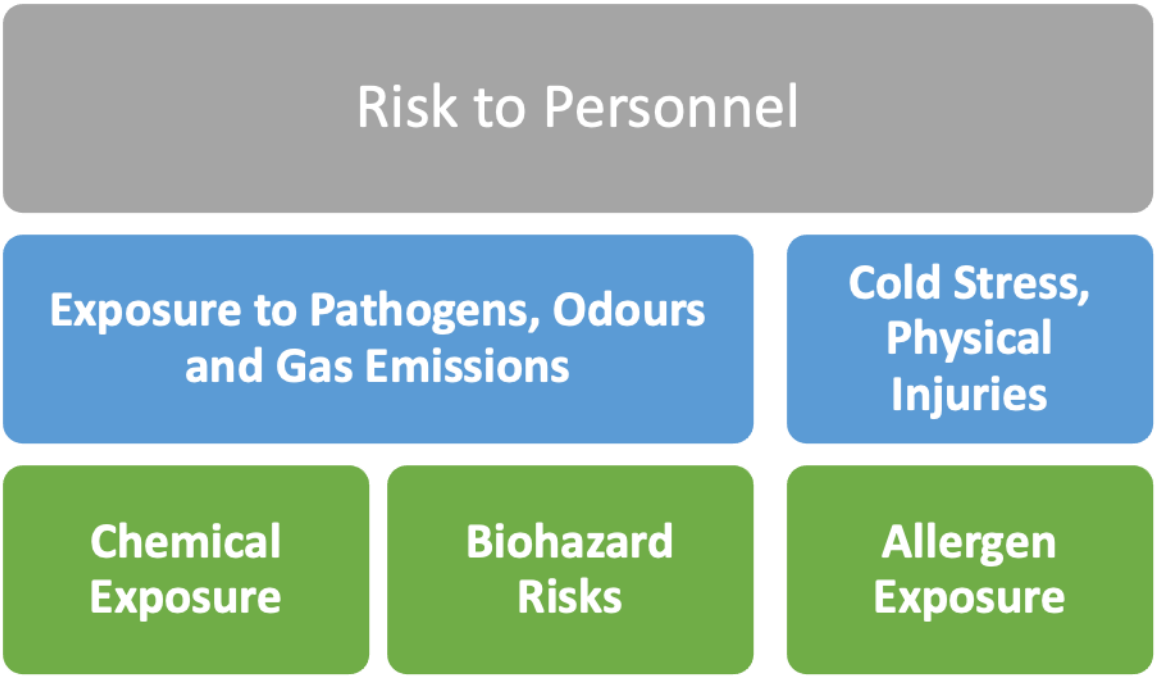
Install handwashing stations near all entry points to cold rooms and handling areas, Ensure proper ventilation to reduce microbial buildup and control humidity, and use physical barriers or enclosed handling zones for high-risk cargo (e.g., meat, seafood, vaccines).

e. Automation and Technology Deployment

Deploy barcode scanners, conveyors, and automated pallet movers to reduce manual handling, Use real-time temperature monitoring systems to minimize human error and introduce touchless logs for hygiene tracking and inventory recording.

9.3 RISK TO PERSONNEL HANDLING THE CARGO

Personnel handling perishable cargo such as meat, seafood, dairy, fruits, vegetables, frozen foods, and pharmaceutical/biological products are exposed to several health hazards arising from contamination, extreme temperatures, chemicals, and physical handling conditions.



a) **Exposure to Pathogens:** Perishables like meat, seafood, and dairy may carry bacteria (Salmonella, Listeria, E. coli), mould, or viruses, which can cause skin infections, respiratory issues, or foodborne illnesses in workers.

b) **Cold Stress:** Working in cold rooms and reefer zones (0°C to –20°C) can lead to hypothermia, frostbite, numbness, muscle stiffness, fatigue, and reduced alertness, increasing the likelihood of accidents.
c) **Chemical Exposure:** Dry ice, refrigerants, and strong cleaning agents can cause CO_2 build-up, dizziness, suffocation, respiratory irritation, or skin burns from cryogenic contact.
d) **Physical Injuries:** Rapid and repetitive handling of heavy or frozen items can cause back injuries, strains, cuts, and slips due to wet or icy floors, along with forklift or pallet jack accidents.
e) **Allergen Exposure:** Items like seafood, nuts, or dairy may trigger allergic reactions, including skin rashes, respiratory distress, or even severe anaphylaxis in sensitive workers.
f) **Odours and Gas Emissions:** Spoiled perishables can release ammonia, sulphur compounds, and organic vapours that may cause headaches, nausea, breathing difficulties, or throat irritation.
g) **Biohazard Risks (Pharma/Biomed):** Handling vaccines, biologics, or lab samples can expose workers to biological agents, needle-stick injuries, or contamination from damaged packaging.

9.4 RECOMMENDATIONS TO REDUCE HEALTH RISKS FOR PERSONNEL HANDLING PERISHABLE CARGO

- **Strengthen Hygiene Practices:** Enforce mandatory handwashing, sanitization, and use of PPE such as gloves, masks, aprons, and hairnets to prevent microbial exposure from raw perishables.
- **Control Cold Exposure:** Provide insulated thermal PPE, limit time spent in cold rooms through shift rotation, create warm rest areas, and train workers to recognize early symptoms of cold stress.
- **Improve Ventilation & Environmental Monitoring:** Maintain proper airflow in cold rooms, install CO_2 or gas detectors where dry ice is used, and ensure regular calibration of ventilation systems to prevent chemical or gas build-up.
- **Safe Chemical Handling:** Train workers in safe use of dry ice, refrigerants, and disinfectants; supply chemical-resistant gloves and face protection; and ensure safe storage and handling protocols are followed.
- **Enhance Ergonomics & Reduce Physical Strain:** Use trolleys, pallet jacks, conveyors, and other mechanical aids; train personnel in safe lifting techniques; ensure anti-slip flooring and adequate lighting to minimize physical injuries.

- **Prevent Allergen Exposure:** Clearly label allergen-prone cargo (e.g., seafood, nuts, dairy), segregate such items, and issue protective gloves and clothing to workers with known sensitivities.
- **Strengthen Biohazard Controls for Pharma Cargo:** Use sealed, leakproof containers for vaccines and biologics; train staff in GMP/GDP and biohazard handling; and ensure availability of spill kits and emergency procedures.
- **Regular Health and Safety Training:** Conduct periodic training on workplace hygiene, cold-chain risks, chemical safety, equipment handling, and emergency response.
- **Promote Reporting and Health Monitoring:** Encourage workers to report symptoms or injuries early, conduct routine health checks, and maintain a "fit-for-duty" screening process to ensure only healthy personnel handle sensitive perishables.

10. Regulatory Audit for Infra and Vendor Management:

A regulatory audit is a systematic examination carried out to verify whether an organization, its infrastructure, and its service providers comply with all applicable laws, regulations, guidelines, and standards related to the handling, storage, transportation, import, and export of perishable cargo (such as food, pharmaceuticals, fresh produce, meat, seafood, flowers, etc.). For perishable cargo, a regulatory audit may ensures that the following objectives are fulfilled:

i. The end to end cold chain management structure and functioning,
ii. The standards as defined under different frameworks for Food safety, product integrity, and quality standards etc. are met,
iii. Vendors handling the product comply with regulatory bodies such as FSSAI, Customs, DGFT, Plant/Animal Quarantine, IATA, etc.,
iv. Operational practices align with required SOPs, certifications, and industry best practices,

A regulatory audit should be done for all entities involved in handling, storing, transporting, or processing perishable cargo to ensure they meet the required regulatory and quality standards. This includes:

A: Internal Operations:

The organization's own facilities, processes, cold-chain infrastructure, and documentation systems.

B: External Vendors / Service Providers:

- Cold storage facilities
- Transporters (reefer trucks, refrigerated vans, airlines, shipping lines)
- Cargo terminal operators at airports/seaports
- Freight forwarders and Customs House Agents (CHAs)
- Packaging and repacking service providers
- Testing laboratories
- Calibration and equipment maintenance vendors
- Phytosanitary/fumigation service providers

C: Supply Chain Partners:

- Contract warehouses
- Third-party logistics (3PL) providers
- Temperature-controlled distribution centers

2. Recommended Key Areas to be Covered in Regulatory Audit

A regulatory audit for perishable cargo ensures that all infrastructure, processes, and vendors involved in import and export operations comply with food safety, customs, and cold-chain regulations. The audit focuses on verifying that temperature-sensitive products are handled under controlled conditions, proper documentation and licenses are maintained, vendors meet compliance standards, and staff are trained to manage perishable goods safely and efficiently.

a. Infrastructure Compliance

Ensures the availability of suitable cold-storage facilities (chillers, freezers, reefers), temperature-controlled zones, hygienic conditions, sanitation controls, and calibrated monitoring equipment.

b. Temperature Control & Monitoring

Covers real-time or continuous temperature logging, validated refrigerated vehicles/containers, management of temperature excursions, and maintenance of calibration and equipment servicing records.

c. Documentation & Regulatory Records

Focuses on compliance with import/export licensing (IEC, FSSAI), health and phytosanitary certificates, customs documentation (BoE, SB, AWB), record-keeping for traceability, and recall preparedness.

d. Vendor Qualification & Management

Evaluates vendor approval processes, SLAs defining compliance expectations, periodic vendor audits, non-conformance tracking, corrective actions, and monitoring KPIs such as delays or temperature deviations.

e. Operational Practices

Reviews handling procedures including unloading, sampling, storage, and packaging, adherence to FIFO/FEFO, segregation of rejected or damaged cargo, and hygiene/PPE practices at all stages.

f. Training & Competency

Checks whether personnel are trained in cold-chain handling, regulatory requirements, documentation, and quality control, along with competency assessments for staff involved in logistics and warehousing.

11. Incentives for High-Investment Cold-Chain Vendors

There is a heavy investment in developing and maintaining the cold-chain infrastructure such as refrigerated storage, reefer vehicles, advanced monitoring systems, tack and traceability, high-tech testing labs etc. which are critical to

ensuring the product integrity of perishable cargo. To encourage such investments, and development of cold-chain infrastructure for supporting such a fast growing trends of the import and export of perishable/temperature sensitive cargo, the government may offer:

i. **Financial incentives:** Capital subsidies, tax breaks or low-interest loans for high-value cold-chain assets.
ii. **Regulatory benefits:** Priority clearance, simplified compliance for certified high-investment vendors.
iii. **Recognition & Certification:** Special accreditation or "approved vendor" status that enhances business credibility.
iv. **Public-Private Partnerships (PPP):** Support for building shared infrastructure, technology upgrades, or integrated logistics hubs.

Providing incentives to vendors making high investments in cold-chain infrastructure encourages the modernization and expansion of storage and transport facilities, ensuring that perishable goods are handled under optimal conditions. This not only reduces product loss, spoilage, and wastage but also strengthens the overall supply chain, making it more resilient and reliable. Additionally, such investments support faster import and export clearance by maintaining product integrity and enabling compliance with regulatory standards, ultimately benefiting both the industry and consumers.

12. Accreditation and Trust based clearance system:

a. Enhanced AEO accreditation in Import & Export of Temperature Sensitive cargo: Enhanced Authorized Economic Operator (AEO) accreditation plays a critical role in ensuring the safe, efficient, and compliant movement of temperature-sensitive cargo in international trade. By extending higher-level AEO benefits such as expedited clearances, reduced examination, priority processing, and greater facilitation at ports and airports stakeholders handling perishable, pharmaceutical, and other temperature-controlled goods can significantly minimize dwell time and maintain product integrity. Enhanced AEO status also promotes stronger supply-chain security, improved traceability, and adherence to globally accepted standards for cold-chain management.

b. Accreditation of Compliance and Document Management: It is imperative for the Stakeholders to recognize that while compliance with regulations is essential, meticulous documentation is the cornerstone of efficient trade. Stakeholders must possess a standard framework of the compliance protocols specific to temperature-

sensitive cargo for both export and import. Filing a complete and accurate set of documents is critical for facilitating speedy customs clearance processes. Documents can be stored and shared using cloud computing and advance submission of documents to various agencies will reduce dwell time. Further, a central single mandate is to be devised incorporating commodity-class-wise procedures of handling of goods, sampling (selection, size, sealing, handling of samples, storage), standardised test parameters with specific conformity rules and rejection management is to be introduced. Further, Preliminary Testing Parameters must be devised for each commodity-class which leads to Provisional 'Pass' or 'Fail' result for AEO clients or Manufacturers which have impeccable track record in compliance. These can be integrated with Risk based Inspection system leading for much faster clearance of goods. Special and separately marked Bill of entry/Shipping bills may be created for perishable cargo. Specific codes for BE of perishable cargo can be made and the system will automatically push such BE in priority handling.

c. Accredited ICDs and CFSs for Temperature-Sensitive Cargo: A nomination program should be introduced for ports ensuring that dedicated and adequate infrastructure for Temperature-Sensitive Cargo is made available at such ports. Such Inland Container Depots (ICDs) and Container Freight Stations (CFSs) must be equipped with dedicated temperature-controlled examination zones. These zones should feature real-time temperature monitoring capabilities and robust, dedicated power backup systems to prevent contamination or degradation of goods during examination. Additionally, segregated storage areas, tailored to the specific temperature requirements of different types of perishable goods, are vital for maintaining product integrity. They must be equipped with mandatory labs/desks for PGAs or their third-party accredited labs which will enable sampling, testing and management of rejected goods.

d. Accreditation of supplier and exporter: Accrediting suppliers and exporters who handle temperature-sensitive cargo helps ensure that goods are stored, packed, and transported under the right temperature conditions during import and export. This accreditation confirms that these businesses have proper cold-storage facilities, reliable temperature-control systems, suitable packaging, and correct handling practices. When suppliers and exporters meet these standards, it reduces the chances of the goods getting spoiled, helps avoid delays at borders, and makes the entire process smoother and safer. It also improves traceability, increases trust among authorities and trade partners, and ensures that temperature-controlled products reach their destination in good condition.

e. Third-Party Process Audits for maintaining Accreditation: Third-party agencies and audits are crucial for maintaining objectivity, credibility, and transparency in the inspection of perishable goods during international trade. These independent bodies help bridge the trust gap between exporters, importers, and the customs by certifying product compliance with international and domestic standards. Key agencies include SGS India (food safety, hygiene audits, lab testing), Intertek (residue testing, compliance certification), Bureau Veritas (supply chain audits, food-grade packaging testing), TUV SUD (HACCP, FSMS certification), and QCI/NABCB Bodies (inspection and audit accreditation). CBIC can partner with these agencies and develop an integrated programme of testing and report sharing for faster clearances of temperature sensitive cargo.

f. Third-Party Audits: Audits include pre-shipment audits (batch-wise verification of product safety), facility hygiene audits (quarterly/annual checks of vendor facilities), traceability audits (on-demand/random confirmation of origin), and compliance audits (annual checks against import country's legal norms). These agencies should integrate with regulatory authorities like Customs, FSSAI, APEDA and EIC, and may submit reports directly to ICEGATE and customs systems.

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F. No. 450/07/2025-Cus IV
Government of India
Ministry of Finance
Department of Revenue
Central Board of Indirect Taxes and Customs
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Room No. 229A, North Block,
New Delhi, Dated 22.01.2025

OFFICE MEMORANDUM

Subject: Constitution of Committee for examining the requirements of infrastructure and procedure for examination of temperature sensitive cargo at ICD/ CFS - reg.

CBIC is in receipt of representations regarding provisioning of appropriate warehouse infrastructure and procedural requirements for examination of temperature sensitive cargo like pharma, vegetables, fish and meat etc. so that their quality is not affected.

2. In this regard, a committee chaired by Commissioner, ICD Patparganj, Delhi has been constituted by the Board for formulating a suitable policy, comprised of the following members:

i. A Commissioner from Chennai Sea Port
ii. A Commissioner from Mumbai Air Cargo Complex
iii. One officer not below the rank of Deputy Secretary from Ministry of Ports, Shipping and Waterways
iv. An officer not below the rank of Deputy Secretary from Ministry of Civil Aviation
v. A representative from Container corporation of India (CONCOR)
vi. A representative from Federation of Freight Forwarders Associations in India (FFFAI)
vii. A representative from Agricultural & Processed Food Products Export Development Authority (APEDA)
viii. A representative from Marine Products Export Development Authority (MPEDA)
ix. A representative from Pharmaceuticals Export Promotion Council of India (PHARMEXCIL)

3. The terms of reference of the committee are as follows –

i. identification of various classes of temperate sensitive cargo
ii. study the adequacy of warehouse infrastructure provided by CCSPs where temperature controlled examination can be conducted for various goods
iii. Enhancing efficiency through non-instrusive inspection and processes to be adopted by all the stakeholders
iv. any other aspect relevant in this matter

4. The Committee may submit its report **latest by 01.03.2025.**

Sanjeet Kumar

(Sanjeet Kumar)
Under Secretary (Cus IV)
Customs Policy Wing, CBIC
Email: uscus4.dor@gov.in
Tele: 011-23095557

To,

i. Sh.R. Lakshmanan, Joint Secretary (Ports,PPP, Sagarmala & Estt-I), Ministry of Ports, Shipping and Waterways, with a request to nominate one officer not below the rank of Deputy Secretary handling matters related to major port terminals, preferably JNPT, Nhava Sheva

ii. Ms Rubina Ali, Joint Secretary, Ministry of Civil Aviation, with a request to nominate one officer not below the rank of Deputy Secretary handling matters related to Air Cargo

iii. Commissioner, ICD Patparganj, New Delhi

iv. Chief Commissioner, Chennai Customs Zone, with request to nominate a Commissioner from Chennai Sea Port

v. Chief Commissioner, Mumbai Zone III, with request to nominate a Commissioner from Mumbai ACC

vi. Sh Sanjay Swarup, Chairman, Container Corporation of India, with a request to nominate one member for the committee

vii. Shri Abhishek Dev, IAS, Chairman, APEDA, New Delhi, with a request to nominate one officer not below the rank of Deputy Secretary

viii. Shri. Dodda Venkata Swamy, IAS, Chairman, MPEDA, Cochin, with a request to nominate one officer not below the rank of Deputy Secretary

ix. Shri Namit Joshi, Chairman, Pharmaceuticals Export Promotion Council of India, with a request to nominate one member for the committee

x. Sh Dushyant Mulani, Chairman, FFFAI, with a request to nominate one member for the committee

Thank You