IATA Time & Temperature Task Force Update & PCR Chapter 17 Regulations

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Chair, IATA Time & Temperature Task Force
Update Topics

- From Guidance to Regulations
- Proliferation of Products & Service
- Time & Temperature Task Force (TTF)
- TTF Realignment
- Major Changes to Chapter 17
- Time & Temperature Handling Label
- FAQ
- Meeting Chapter 17 Requirements
- Label adoption
- IATA World Cargo Symposium
Perishable Cargo Regulations

Air Transport Logistics for Time & Temperature-Sensitive Healthcare Products
(Chapter 17)
9th Edition IATA Perishable Cargo Regulations

Air Transport Logistics for Time & Temperature-Sensitive Healthcare Products

(Chapter 17)

Effective July 1, 2009
Perishable Cargo Regulations

- In 2007 guidance became regulation
- Binding to its 230 Member Airlines
- Healthcare industry continues to work with IATA to implement improvements
How We got Here

- Airlines Form a Time & Temperature Task Force Dedicated to Healthcare Products
  - Improve air freight logistics for highly regulated healthcare freight
  - 60% of the total time a package travels by air is spent at the airport
  - As much as 54% of temperature excursions of healthcare freight occurs while in possession of the airlines
March 2005

Airlines offering tailored products to the Healthcare Sector

- AF/KLM
- CONTINENTAL
- CARGO LUX
- LUFTHANSA
- NIPPON CARGO
- SINGAPORE
- VARILOG (Before bankruptcy)
March 2010
+25 Airlines offering tailored products to the Healthcare Sector

- AER LINGUS
- AEROMEXICO
- AF/KLM
- ALITALIA
- AMERICAN AIRLINES
- AIR CANADA
- ALITALIA
- AUSTRIAN
- BRITISH AIRWAYS
- CATHAY PACIFIC
- CARGO LUX
- CONTINENTAL
- CZECH AIRLINES
- DELTA
- EMIRATES
- KENYA AIRWAYS
- KOREAN AIR
- LUFTHANSA
- JAL
- NIPPON CARGO
- SAS
- SINGAPORE
- SWISS
- QATAR
- UNITED
Logistics Providers

- Global Freight Forwarders Are Responding with Offerings for Healthcare Sector
  - DB Shenker
  - FedEx Custom Critical
  - Kuehne + Nagel
  - LifeConEx
  - Panalpina
  - UPS Healthcare Solutions
  - World Courier
IATA Time & Temperature Task Force 2008-2010

- Dominique Coultier
  Air France / KLM
- Shirley-Ann Feld
  Sanofi-Aventis
- Mary Foster
  Catalent Pharma Solutions
- Donald Harrison
  United Airlines Cargo Services
- Franco Nanna
  CargoLux
- Kevin O’Donnell
  Chair, TTTF
  ThermoSafe Brands

- Aynur Rasulova-Rzepa
  Co-chair, Emirates Cargo
- Hany Ahmed Ragab
  Egypt Air
- Mark Mohr
  Continental Air Cargo
- Nicolas Walzik
  Lufthansa Air Cargo
- Tony Wright
  Excelsius, UK
- Francis Yuen
  Cathay Pacific

- Shirley-Ann Feld
  Sanofi-Aventis
- Mary Foster
  Catalent Pharma Solutions
- Donald Harrison
  United Airlines Cargo Services
TTTF Directive

“Develop minimum standards for the air transport and handling of time and temperature-sensitive healthcare freight.”

- Gregg Pittlekow,
  Chair, Live Animals & Perishables Board, IATA
TTTF Realignment, April 2010

IATA Time & Temperature Task Force
(Airline Members Only)

TTTF Advisory Body
(Organization Representation)

TTTF Care Team
(Subject Matter Experts)
TTTF Advisory Body

- Consists of 5 individuals representing international or regional organizations
  - NGO’s
  - Industry Associations
  - Regulatory bodies
  - Standards organizations
TTTF Care Team

- Consists of 5 subject matter experts from industry
  - Logistics
  - Drug manufacturing
  - Active / Passive Packaging Systems
  - Freight forwarding
  - Training
TTTF Realignment, April 2010

Chair, Time & Temperature Task Force

Time & Temperature Task Force
(Airlines)

TTTF Advisory Body
(Organizations)

TTTF Care Team
(Industry Subject Matter Experts)
2010-2012 IATA TTTF

Airline Members

- Dominique Coultier, AF / KLM
- Donald Harrison, United Airlines
- Trevor Howard, Air Canada
- Mark Mohr, Continental Airlines
- Franco Nanna, Cargolux
- Hany Ahmed Ragab, Egypt Air
- Aynur Rasulova-Rzepa, Vice-chair, Emirates
- Nicolas Walzik, Lufthansa
- Francis Yuen, Cathay Pacific

Advisory Panel

- Shirley-Ann Feld, Sanofi-Aventis & PLF & PCCIG Europe
- Mary Foster, Ph.D., Catalent & United States Pharmacopeia
- Ian Holloway, Medicines & Healthcare products Regulatory Agency (UK)
- Dr. Umit Kartoglu, World Health Organization
- Kevin O’Donnell, Chair, Tegrant Corp., ThermoSafe Brands

Care Team

- Chris Fore, Envirotainer
- Karl Kussow, FedEx Custom Critical
- Christopher Matney, IND Airport Authority
- David Ulrich, Abbott Global Pharmaceuticals
- Tony Wright, Excelsius Consultancy
Major Changes to the 9th Edition of IATA PCR, Chapter 17

- Quality Management Systems requirements (including exception management)
- Shipper, forwarder, ground handlers/transportation service provider, consignee, and air carrier processes and responsibilities
- Regulatory expectations driving specific handling requirements
- Product storage/handling temperature ranges
- Critical control points
- Storage and warehousing requirements (including temperature mapping)
- Training expectations
- Introduction of a new Handling Label usage requirement (effective July 1, 2010)
Time & Temperature Handling Label

- **Label Requirements:**
  - Must meet a multitude of handling and operational requirements
  - Must meet shippers multiple needs
  - Classify as a “perishable” other than flora and fauna
  - But not a healthcare product
  - Shape and color must be unique
  - Simple, universally understood pictorial
  - Must be approved by IATA LAPB
TTTF Recommends Label to LAPB

- Based on input from:
  - PDA-PCCIG label workgroup
  - USP label workgroup
  - Feedback from stakeholders
Originally Approved April, 2009
Revised October, 2009

- ICAO and US DOT insisted on a change of orientation (45°) so as not to be mistaken for a DG label
Revised October, 2009
IATA Handling Label

- High visibility to handlers 4” x 4”
- Must be used in conjunction with QMS between shipper and TSP
- Unique to healthcare but does not allude to contents
- Conveys transportation (external handling) temperatures
- Label typically added by shipper
- Optional temperature range designation area if included on AWB and Quality Agreement. Otherwise handling temperatures assumed to be +15 to +25C
- Area for carrier operations information
- Sunset date, July 1, 2010
17.10.5

“As of the 10th Edition of the Perishable Cargo Regulations manual, effective July 1, 2010, all time- and temperature-sensitive healthcare product shipments should be labeled with the standard IATA ‘Time and Temperature Sensitive’ label.”
IATA PCR Chapter 17

- 17.10.6

“Unless otherwise specified in a contractual agreement, it is the responsibility of the shipper to apply the Time and Temperature Sensitive Healthcare Product Label to the outerrmost visible means of containment to be shipped.

“The label when used, must be affixed to at least 1 side panel of each individual outer shipping package.”
17.10.6

(c) “In all cases, the Celsius scale and the text must be in English unless otherwise required by the State of origin. In such cases, an English translation must also be provided with both languages given equal prominence.”
FAQ

- Is the label mandatory?
  – No

- Does IATA supply the label?
  – No

- Where can I get the label?
  – Specs at iata.org
  – www.coolerheadsblog.com/blog
Meeting Chapter 17 Requirements

- Take control
- Focus on control points and minimize hand-offs
- Adopt a Quality Management System between parties
- Implement performance metrics at critical points
- Incorporate the TTS Handling label
- Keep communication open
Thank You!

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What is the industry doing to help meet the demand for active containers? What are the packaging/logistics alternatives?
I’ve heard conflicting information regarding the use of new Time & Temperature Sensitive handling label. Is it mandatory? Can I use it to ship other perishables such as key lime pie?
What are the weakest links in the temperature controlled supply chain?
Who is responsible for maintaining the cold chain?