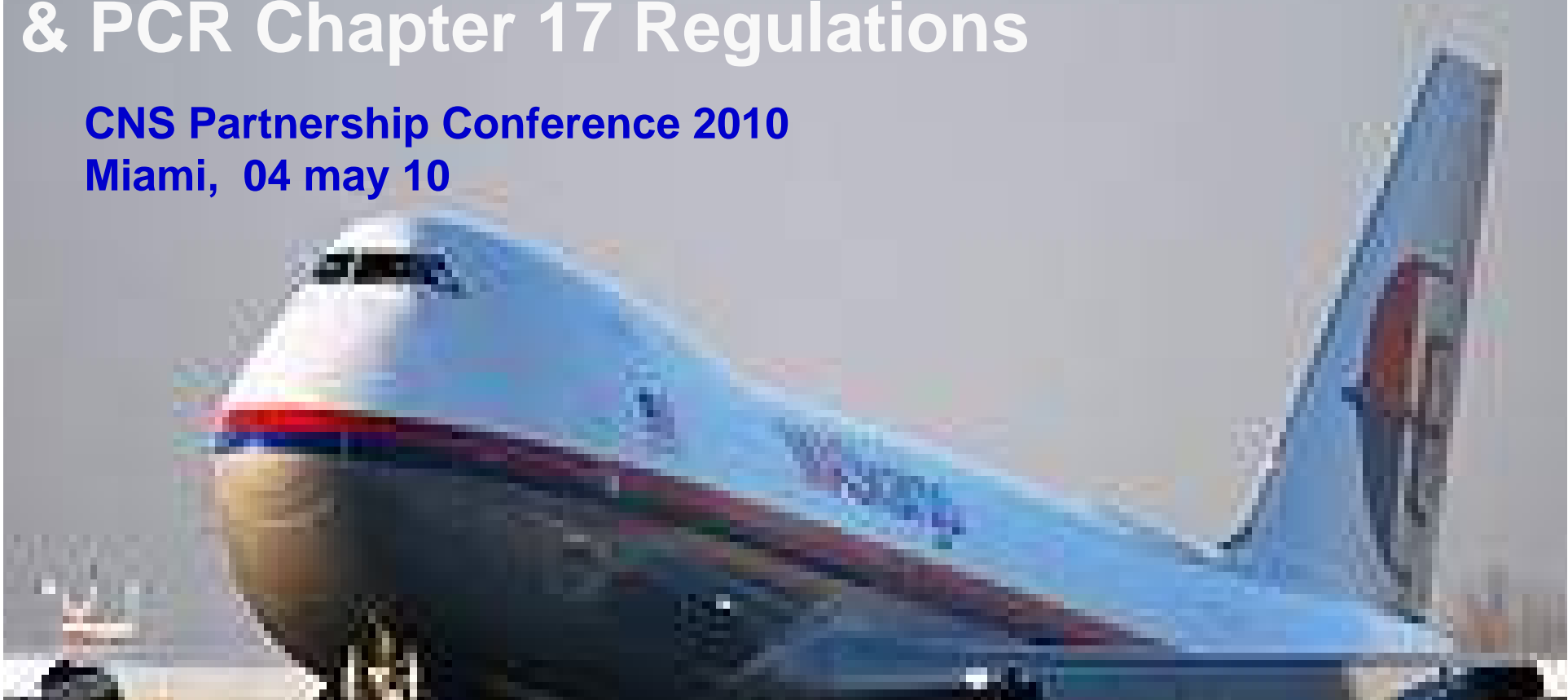


IATA Time & Temperature Task Force Update & PCR Chapter 17 Regulations

CNS Partnership Conference 2010

Miami, 04 may 10



Kevin O'Donnell

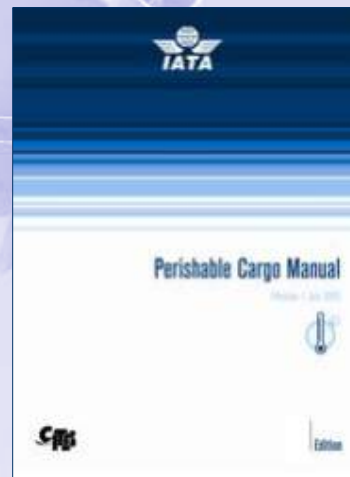
**Director & Chief Technical Advisor, ThermoSafe
Chair, IATA Time & Temperature Task Force**

Update Topics

- **From Guidance to Regulations**
- **Proliferation of Products & Service**
- **Time & Temperature Task Force (TTTF)**
- **TTTF 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
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, Emerates Cargo
- **Hany Ahmed Ragab**
Egypt Air
- **Mark Mohr**
Continental Air Cargo
- **Nicolas Walzik**
Lufthansa Air Cargo
- **Tony Wright**
Excelsius, UK
- **Francis Yuen**
Cathay Pacific



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

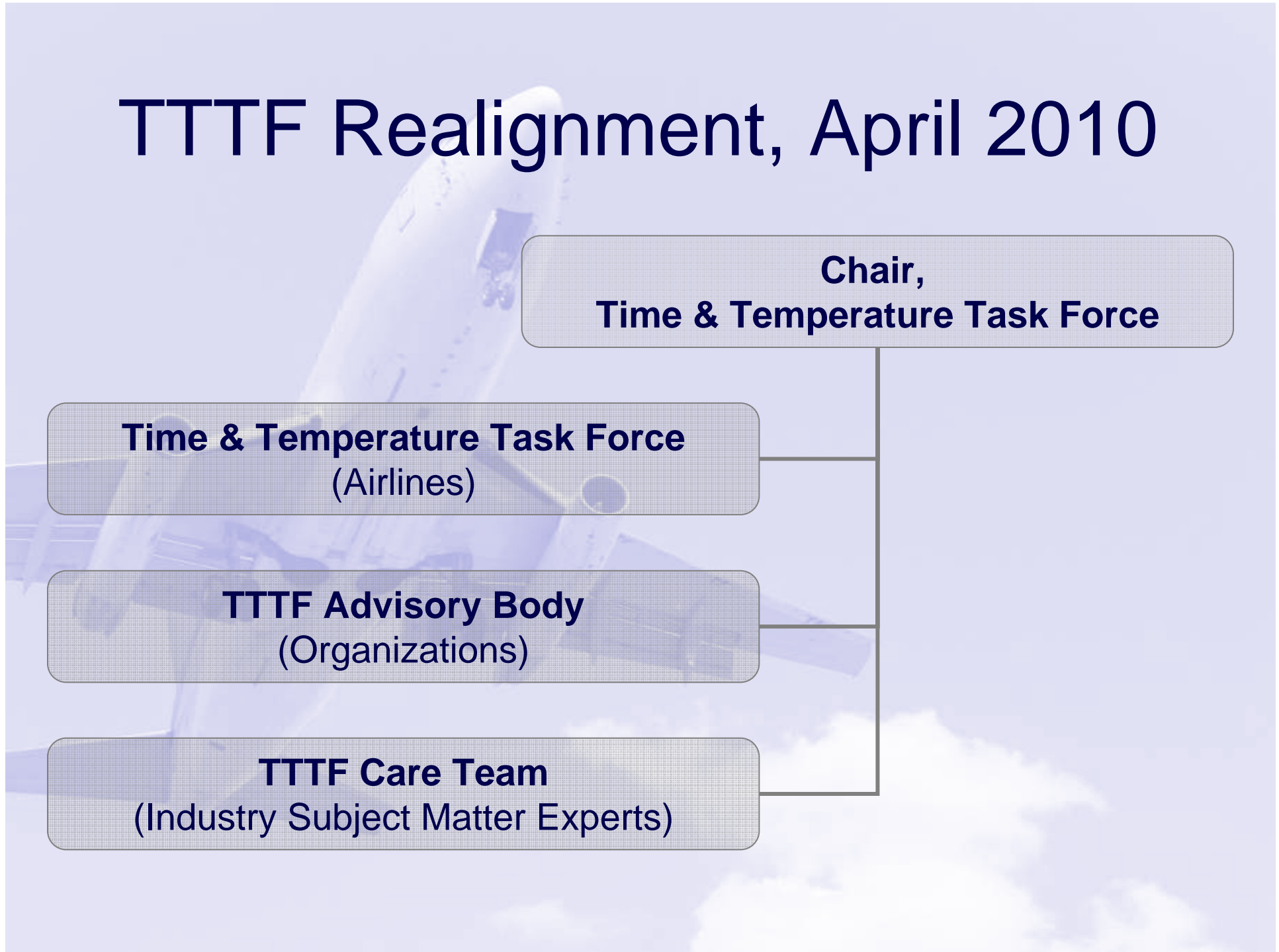
TTTF Realignment, April 2010

**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

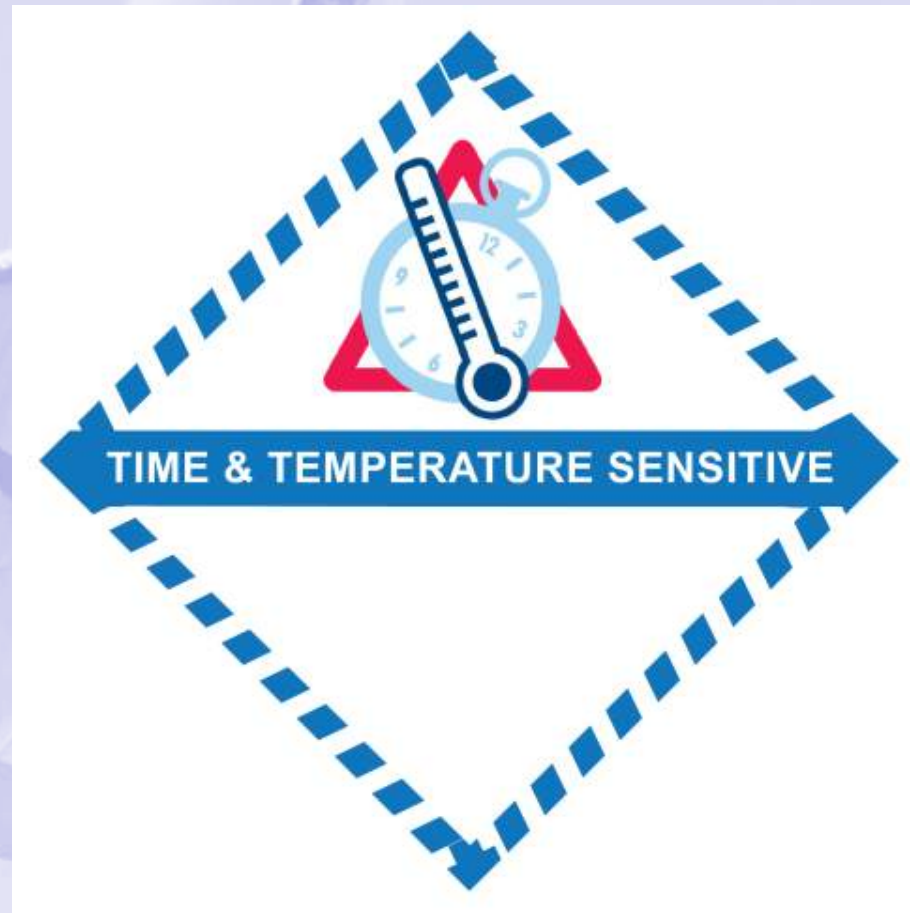
- **Label Requirements:**

- **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

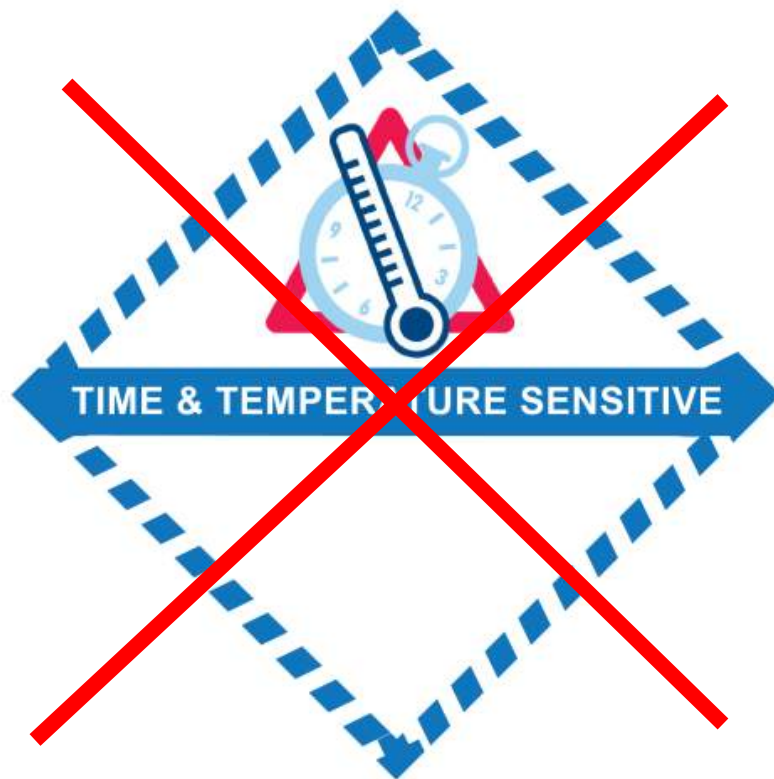
- **Based on input from:**
 - **PDA-PCCIG label workgroup**
 - **USP label workgroup**
 - **Feedback from stakeholders**

Originally Approved April, 2009

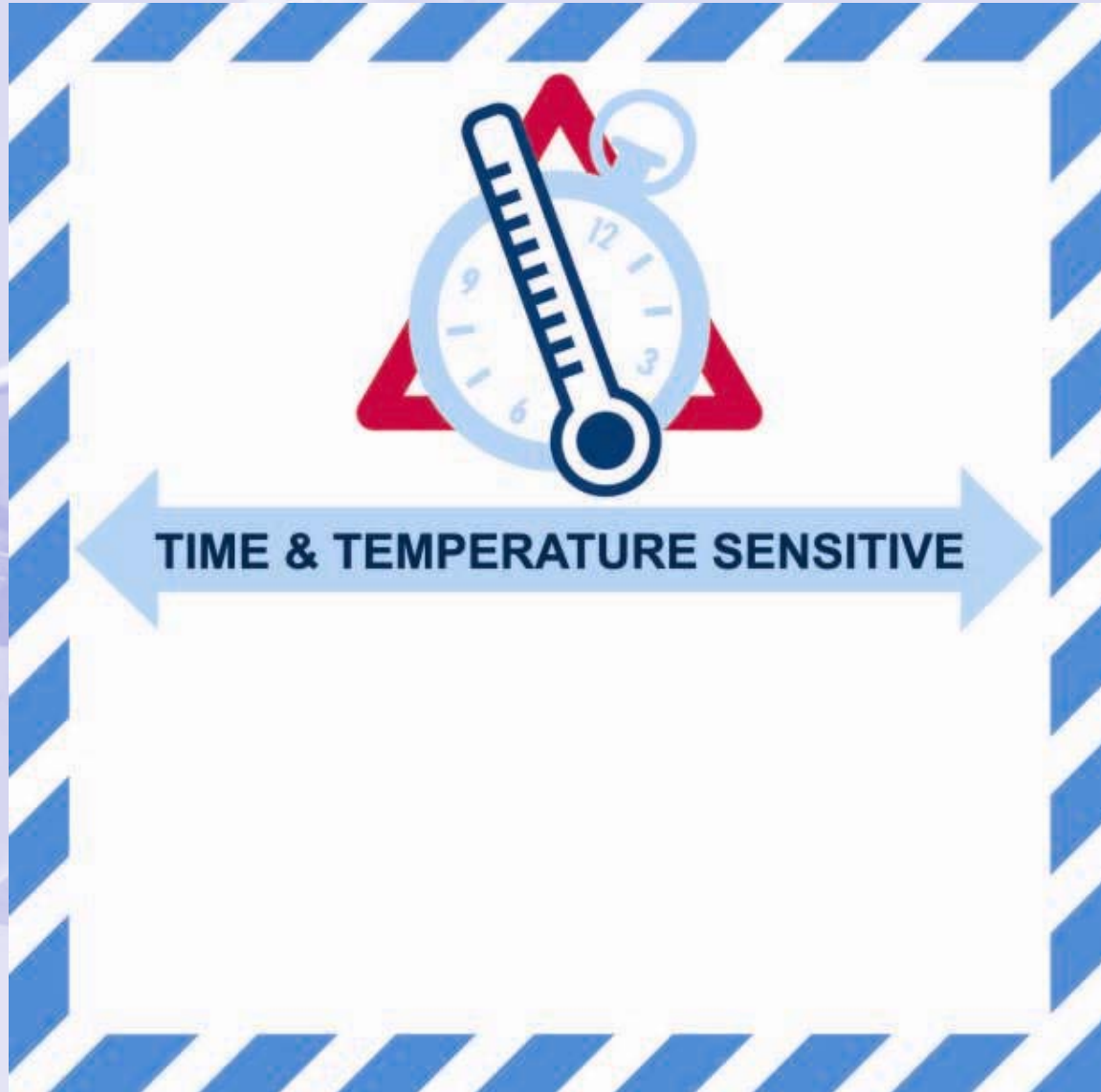


Revised October, 2009

- ICAO and US DOT insisted on a change of orientation (45°) so as not to be mistaken for a DG label

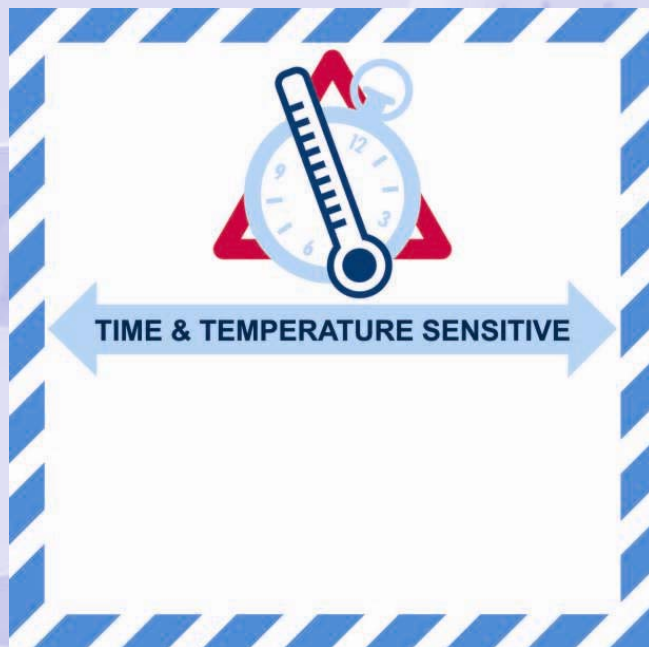


Revised October, 2009



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



IATA PCR Chapter 17

- **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 **outermost 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.”

IATA PCR Chapter 17



- **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!

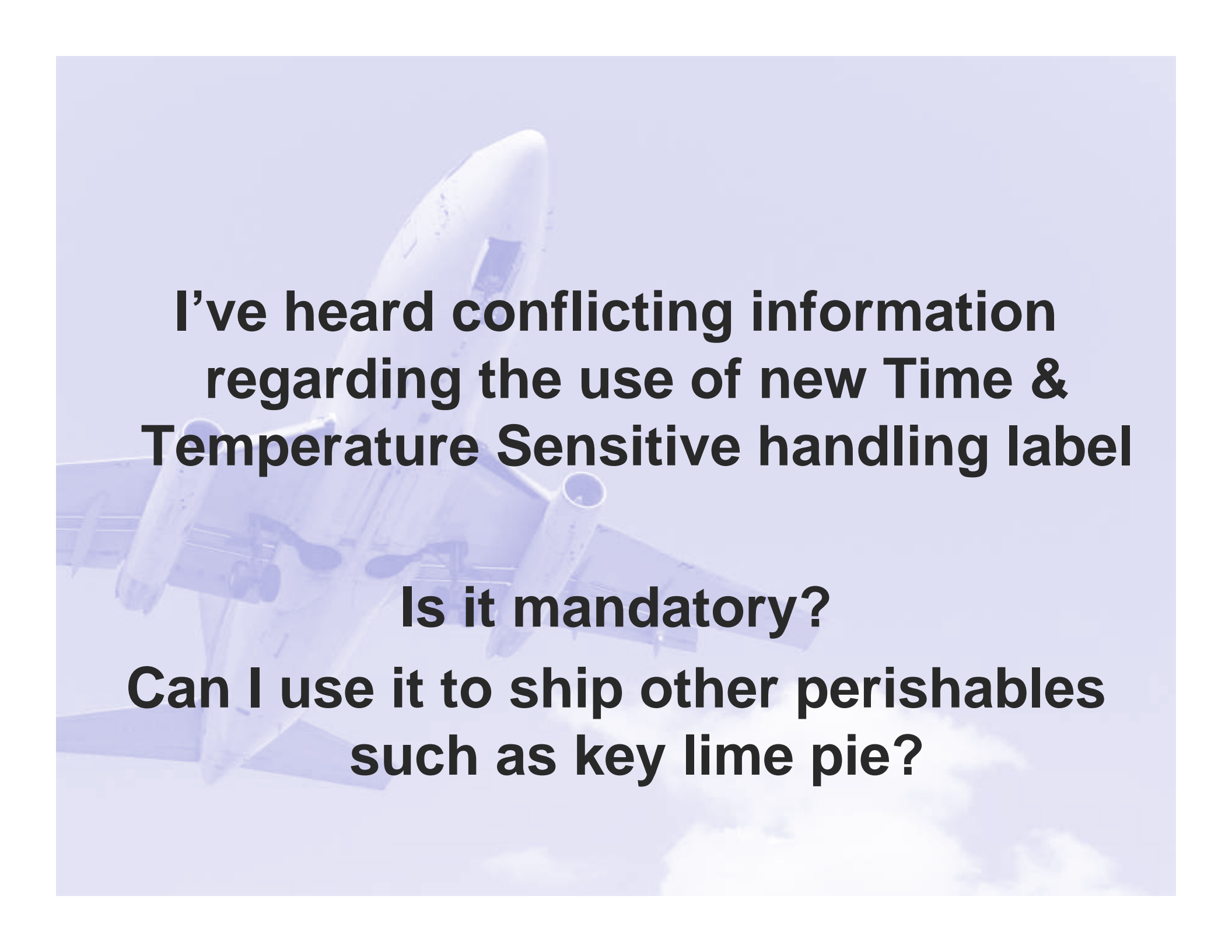
k

Kevin O'Donnell
kevin.o'donnell@tegrant.com
847-632-9649

www.coolerheadsblog.com



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?**

A large commercial airplane is shown from a low-angle perspective, flying upwards and to the right. The aircraft is white with two engines mounted on the wings. The background is a clear blue sky with some white clouds near the bottom. The entire image has a light blue tint.

What are the weakest links in the temperature controlled supply chain?

A large commercial airplane is shown from a low-angle perspective, flying upwards and to the right against a bright blue sky with scattered white clouds. The aircraft is white with dark accents on the engines and landing gear. The text is overlaid in the center of the image.

**Who is responsible for maintaining
the cold chain?**