

Practical and Value Generating Approach to IATA Chapter 17
7th Edition of the Perishable Cargo Regulations

-- David Y. Bang

With much anticipation and efforts by those who work daily with perishable cargo, the International Air Transport Association (IATA) has added a chapter to the 7th Edition of the Perishable Cargo Regulations effective July 1, 2007. The 23 page Chapter 17 is dedicated to air transportation for temperature-sensitive healthcare products. Truly, this is an accomplishment worth noting, since this is the first time a whole chapter dedicated to this segment. Personally, I am looking forward to seeing future outcomes from this first step effort by the industry.

Now if you are like me, I am fanatic about taking information in and extracting practical values out. After getting a hold of chapter 17, I analyzed and cross-referenced much of the regulations and implied practices with my company's own data, written processes and service offering maintenance with over +23 airlines and their ground handlers, +60 airports, all sizes and types of packaging, +150 unique trade lanes, +250 live fully compliant SOPs, touching different climate zones and moving via different aircraft types. Taking longer than, I initially thought, but found it was gratifying, in the sense where my true passion has officially been validated; validated enough to write this article. I hope you will be find value to use parts of this article to transparently evaluate where you with your perishable cargo and put together a practical and value generating plan to comply with Chapter 17 that also has references to PDA Technical Report 39.

This short editorial will quickly walk you through the purpose and contents of this newly issued chapter, then point out what and how you should utilize the given information to apply to your supply chain practically. At the end, you will find a short check list for you to evaluate your current temperature-sensitive transportation chain with some recommended actions to be taken. "Status quo" is a risky place to be at in today's business world. If regulations are getting tighter and over 9 out of 10 new FDA approved products are highly sensitive to temperatures, we as an industry need to work to build a sustainable temperature-controlled transportation solution.

The Purpose and the Contents of the Chapter 17

(Continued from previous page)

The chapter states, “The purpose of this chapter is **to provide information on the factors that affect temperature-sensitive healthcare products and to indicate critical control points in the air transport logistics that can impact these sensitive products and to provide best practices conforming to regulatory agencies requirements.**”

To quickly dive in to what information the chapter provides on the factors that affect temperature-sensitive healthcare products, starts at section 17.2 Global Regulatory Requirements and Maintaining Product Quality and stretches all the way to 17.6 Expectations for Shipping Pharmaceutical Products.

17.2 Global Regulatory Requirements and Maintaining Product Quality section gives a very general overview of those regulatory bodies such as the World Health Organisation (WHO), The International Committee on Harmonization (ICH), and the US Food and Drug Administration (FDA) and their emphasized and publicized expectations regarding temperature control during transport and storage. This section also gives a brief background on product stability studies, i.e. Good Manufacturing Practices (GMP), and Good Storage Practices (GSP).

Section 17.3 Good Trade and Distribution Practices (GTDP) for Pharmaceutical Starting Materials opens by stating how the quality of pharmaceutical starting materials can be compromised by lack of “adequate” control of all activities going through GMP, GSP and GTDP. Now, my practical sense kicks in here. Depending on your knowledge, depth, scope within the industry your opinion of what is adequate and what is not, can vary. I at this point am not sure if section 17.3 could truly address the vagueness of the word “adequate”, due to the complexity of the issue. But on a whole, I would be interested to see how future editions evolve.

Section 17.4 Cold Chain Management also begins with, “Loss of quality is a cumulative process whereby every little break adds up”. The implication by IATA makes a valid part that everybody is involved in the cold chain. Problems don’t just lie with manufacturers, freight forwarders, or airlines, each party should be responsible for their own area and custody. Cold chain management of vaccines is briefly discussed; it highlights how even a small temperature excursion can negatively affect the overall product. *17.4.3 Correct*

(Continued from previous page)

Storage Conditions section touches on the implications of temperature extremes (low and high), and also how direct sun lights affects the efficacy of products.

Section 17.5 Air Transport Logistics Overview gives pretty quick lesson for those unfamiliar with air transport. It discusses the characteristics of legacy carriers, integrators, all cargo carriers, and charters as it pertains to temperature-sensitive air transport. It briefly illustrates service level dynamics between shipper, forwarder, and airlines.

Section 17.6 Expectations for Shipping Pharmaceutical Products list the following expectations:

- All pharmaceutical manufacturers are required by Regulatory agencies to provide evidence that the product safety, identity, potency, purity, and integrity will be maintained at varying storage conditions.
- Testing and qualifying container and pack out configuration
- Proper action in case of delays
- Developing and managing SOP
- Transport instructions from the forwarder to the carrier
- Pre-condition procedures

The second half of the chapter devotes itself to critical control points in air transport logistics that can impact sensitive products and also provides best practices for conforming to regulatory agencies' requirements, starting from *17.7 Active Packaging Systems* to *17.12 Additional Shipper Considerations*.

17.7 Active Packaging Systems sections gives overview of the technology use, and is accompanied by a few illustrations of the active systems, currently available, and brief loading and handling instructions. Of course, these packaging manufacturers have much more detailed handling instructions and equipment specifications on their website and/or published manuals, which become critical especially in risk analysis and contingency planning.

(Continued from previous page)

17.8 *Passive Packaging Systems* discusses base technology behind Passive Packaging, disposable containers, reusable or durable containers, gel packs, and phase change materials; generically it touches on handling procedures.

17.9 is dedicated to *Package Labeling*. This particular section concludes that there is no industry standard labeling for handling of temperature sensitive medicinal packages in transport. Which can worsen the situation when well intended individuals misread applied labels. This relates back to proper handling procedures with each party, ensuring that simple carelessness does not ruin products in transport.

17.10 *Storage Temperatures as Defined by the U.S. Pharmacopeia* consists of a reference to the USP 29 and general notices and definitions.

17.11 *Standard Operating Procedures (SOP's) and service agreements* list the headings of SOPs between Freight Forwarder and Carrier as well as Shipper and Freight Forwarder. While "adequate", I found it missing some of the operational contents, descriptions, operational impacts and as well as change management and continuous improvement methodologies.

17.12 *Additional Shipper Considerations* concludes the last part of this chapter briefly goes over barometric pressure, radio frequency, and x-rays.

Chapter 17 also features two helpful appendices. *The first appendix* gives a useful table of ventilation, heating and cooling capability of Airbus and Boeing aircraft while *the second appendix* generally states design requirements for thermal, insulated and refrigerated containers by referring to the current edition of the *IATA ULD Technical Manual*.

What and how you should utilize the information given to actually implement in your supply chain... Well, you'd better before any regulatory agent forces you to do so!

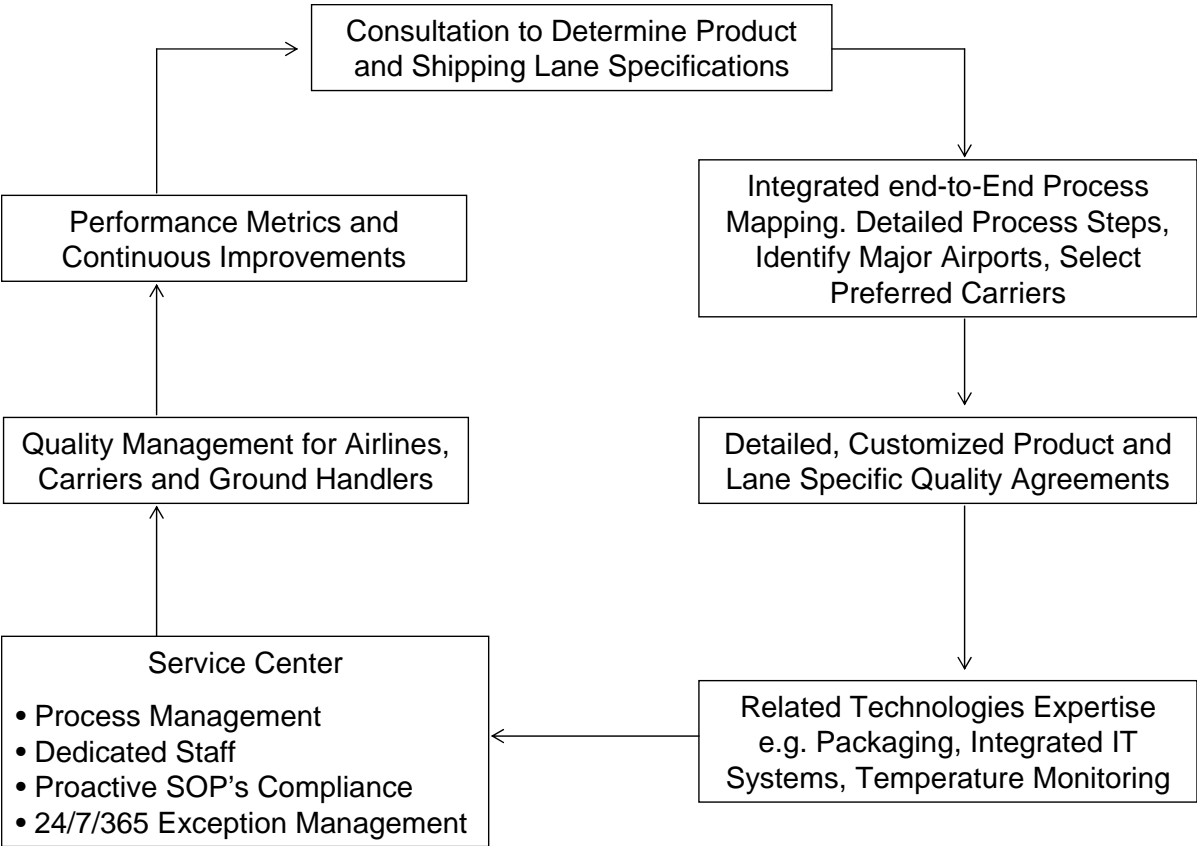
I hope the journey of condensing 23 pages of Chapter 17 into a few brief pages was ok with you. Now, I hope you say "I got it!" And if not, I hope you will ask, "David, what would you recommend me to do?"

(Continued from previous page)

Technically, this IATA Chapter is to be a binding guidance and expected to be adhered to by IATA airline members. However, I see still a couple of editions to go for us to see this Chapter come to the similar level of other IATA regulations like dangerous goods handling. Since this has now been published, I am sure regulatory bodies will start referring to the implied regulation in this chapter when they inquire and inspect your air transportation of pharmaceuticals. Similarly, PDA's Technical Report 39 and USP 1079 are often referenced by these same regulatory inspectors.

Section 17.2 Global Regulatory Requirements and Maintaining Product Quality to 17.6 Expectations for Shipping Pharmaceutical Products are meant to be informational and setting the precedent for implied regulation to come. More of the action-oriented information comes from *17.7 Active Packaging Systems to 17.11 Standard Operating Procedures (SOP's) and service agreements*. However, from practical and yet compliance perspectives, having demonstrably robust SOPs and service agreements in place with solid change management and deviation detection mechanisms (which the chapter does not cover) for all your temperature sensitive products can make your supply chain far more than just compliant to IATA's Chapter 17 in the 7th Edition of the Perishable Cargo Regulations, but holding your temperature-sensitive supply chain to a much higher standard of excellence. These SOPs should be thorough, covering all aspects with more detail than what's described in this chapter. These documents should be live and active with direct links to various parties in the cold chain, who are performing and essentially assuming responsibility for certain roles of the cold chain; where responsibilities are clear and assigned with process management, contingency planning, and robust continuous improvements exist for all shipments.

(Continued from previous page)



Where to start?

First, take a deep breath I have thrown a lot at you in a relatively short amount of time. Recognizing that each person may start at various points in their understanding of the abovementioned topics, I've put together a simple self-evaluation check list that can be helpful for you to assess your situation. Of course, this list should be customized for various cases of your cold chains with further details and variables.

(Continued from previous page)

Check	Task
	Incorporate IATA Chapter 17 of 7 th Edition of the Perishable Cargo Regulations into your department’s training log.
	If you have done so already, train your personnel and log it properly.
	List all products, packaging types, origins and destinations, carriers, and forwarders
	Check if there are consistent and regulatory compliant SOPs that have the headings described in section 17.11 (at the minimum ensure solid change management is in place).
	All deviations to those SOPs should be documented with complete root causes and investigation reports for all your shipments. You should be readily able to identify if any of your shipments are <i>NOT</i> compliant to the SOPs in near-real time and historically.
	There should be a continuous improvement program in place. If you do experience deviations from the implemented SOP, procedures need to be installed to correct them and the root cause. You will need to monitor the progress, and document them properly.

About David Y. Bang

David Y. Bang is CEO of LifeConEx, LLC (www.lifeconex.com), a joint venture between DHL Global Forwarding (www.dhl.com), the world’s largest air and ocean freight forwarder and part of Deutsche Post World Net (www.dpwn.com), and Lufthansa Cargo (<http://www.lufthansacargo.com>) the leading airfreight cargo company on the international market. LifeConEx is the only industry-specific provider of integrated end-to-end temperature controlled transportation solutions for the Life Sciences Industry.

Prior to his current role, David, a founding member of the JV, served as Sr. VP Business Development and Implementation leading the establishment of LifeConEx’s proprietary virtually integrated and regulatory compliant end-to-end process and customer solution designs for temperature controlled transportation and its unique IT platforms. Being with DHL for the last 9 years specializing in strategic global account acquisitions and implementations, David has been deeply involved with DHL’s Life Sciences & Healthcare development over the last 6 years successfully managing a global strategic team acquiring and implementing multiple global customer contracts generating double digit growth for the Life Sciences & Healthcare sector of DHL. His teams methodologically engineered large life sciences customers’ global transportation network implementation and post implementation process to ensure the customer

(Continued from previous page)

base sustainability, providing customers with transparent and process driven implementation and IT solutions resulting overall cost reduction and performance improvement.

About LifeConEx

LifeConEx is the only industry-specific provider of integrated end-to-end temperature controlled transportation solutions for the life sciences industry ensuring that highly sensitive products are delivered at the right place, at the right time, and in the right condition. A global provider of end-to-end qualified transportation services worldwide, designed to protect the integrity and quality of the products posting fewer delays, less cycle time, less temperature deviations, less damage, and far fewer claims than typically experienced by shippers. LifeConEx offers regulatory compliant process mapping, customized quality agreements, comprehensive 24/7 process and quality control, and technical consulting. Strategically LifeConEx looks to integrate new practices and more efficient ways of managing temperature-sensitive products, by providing overall value in regard to time and productivity. LifeConEx boosts various temperature controlled supply chains with greater control, reduction of risk, and elevation of ROI.