

The Active Cold Chain

Donald Harrison, Global Partner Manager - Americas

Miami, 9/14/2011

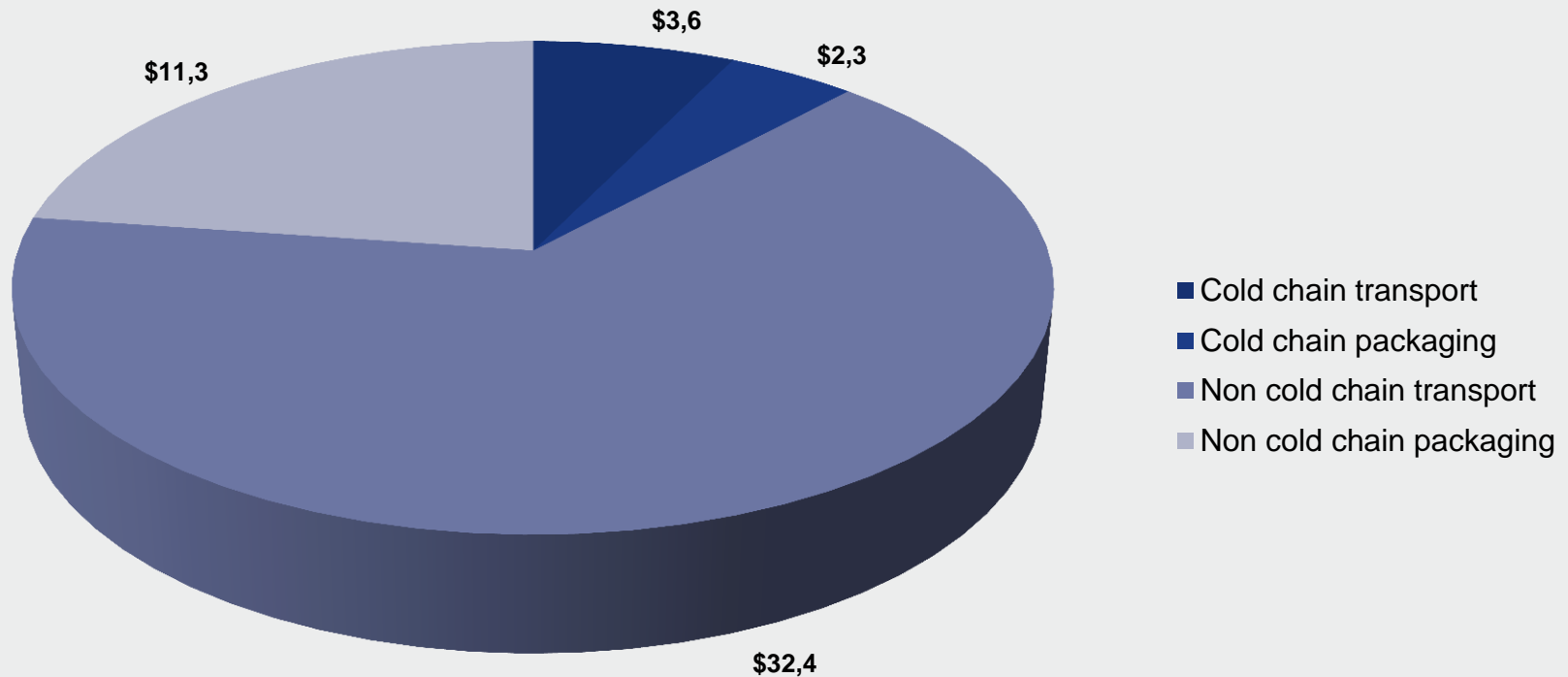


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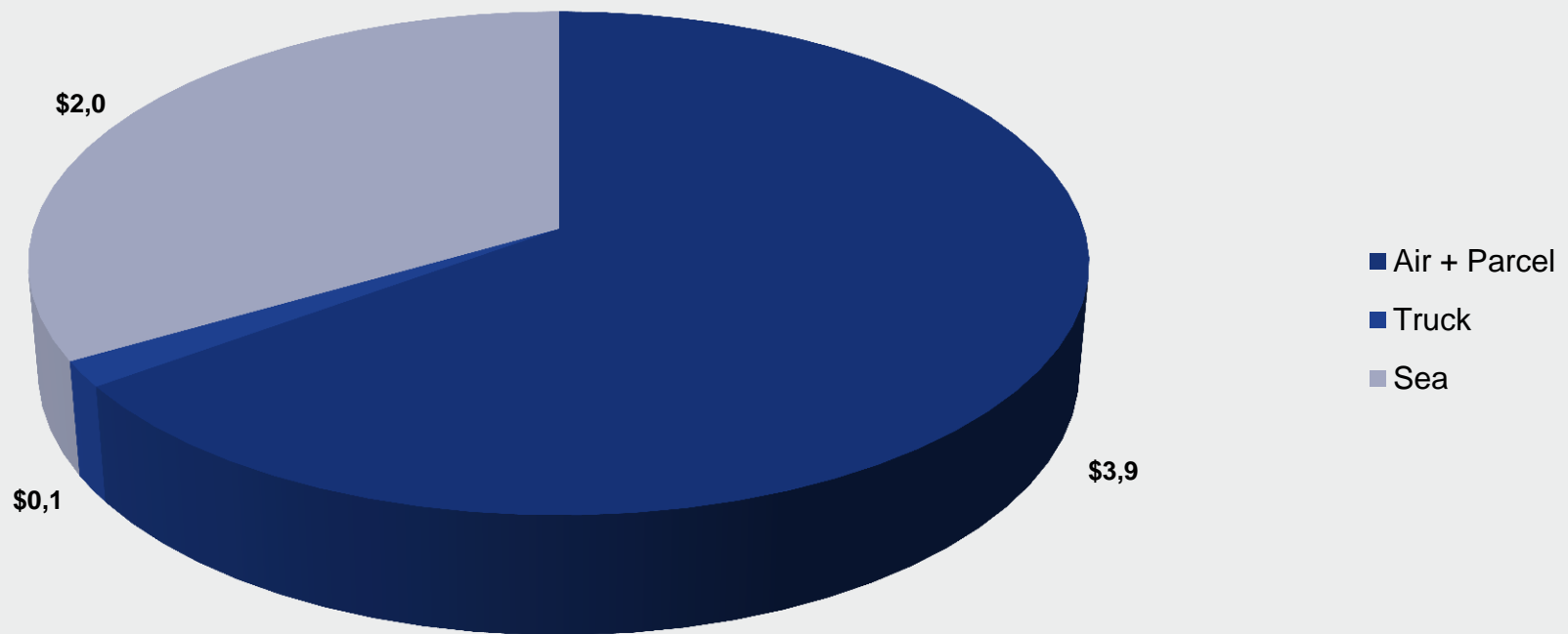
Total cold-chain logistics spend 2009

Nearly \$6 billion was spent on cold-chain logistics in 2009, in a global biopharma logistics market of nearly \$50 billion



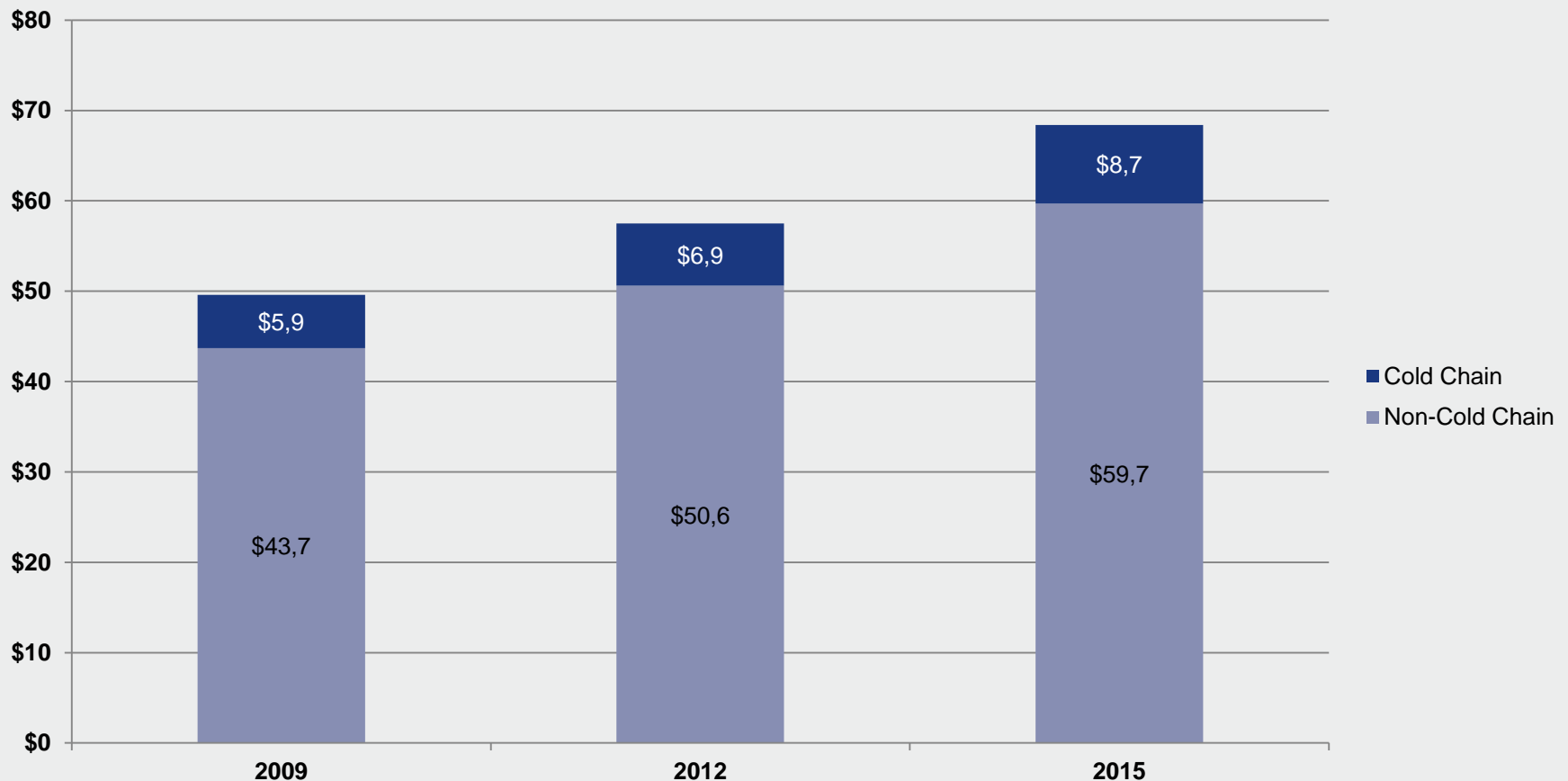
Cold-chain logistics spend by mode 2009

Most cold-chain logistics spending in 2009 was in air and parcel transport



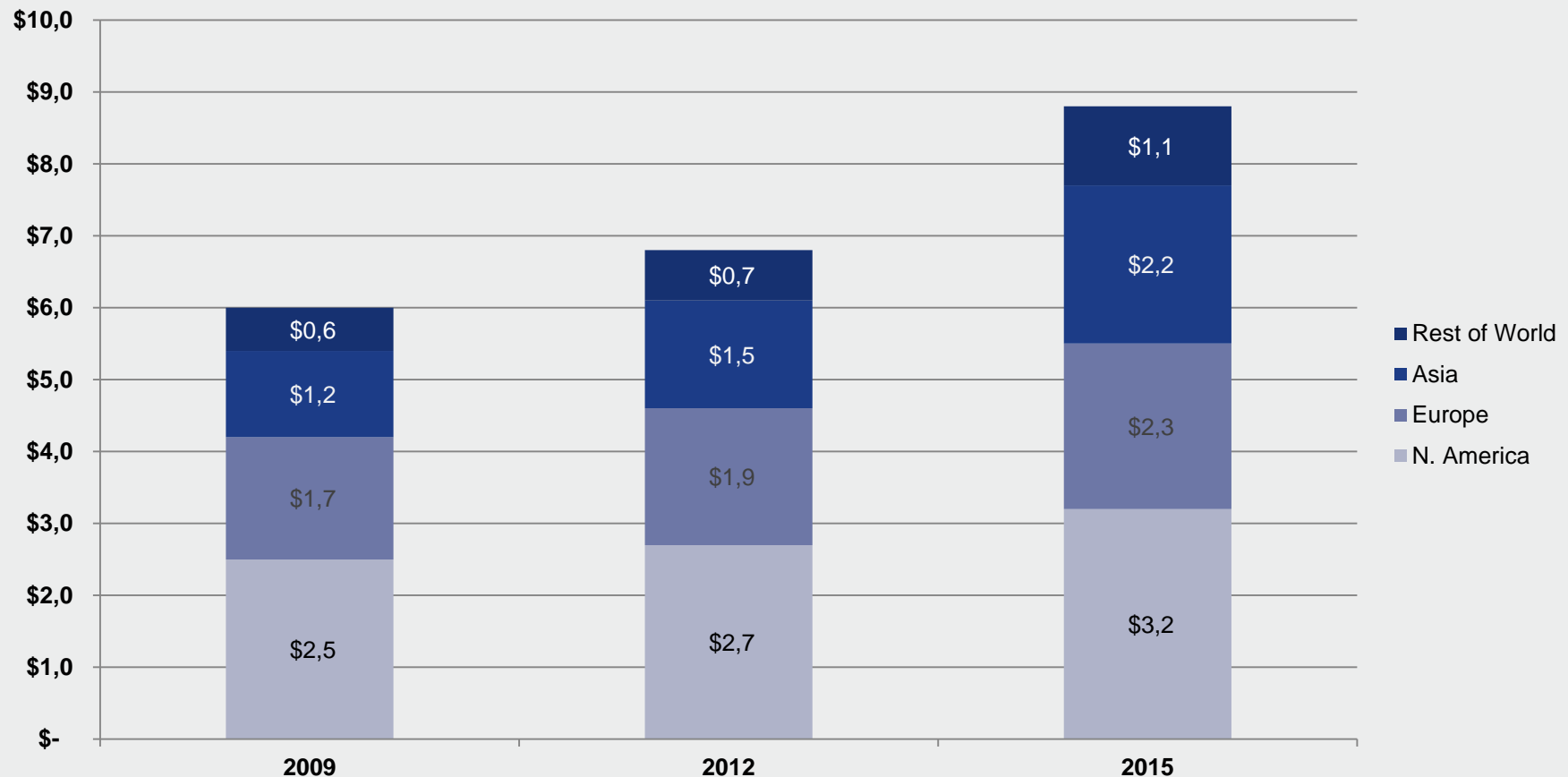
Global cold-chain logistics spend by 2015

Global cold-chain logistics spending will expand from \$5.9 billion in 2009 to \$8.7 billion by 2015



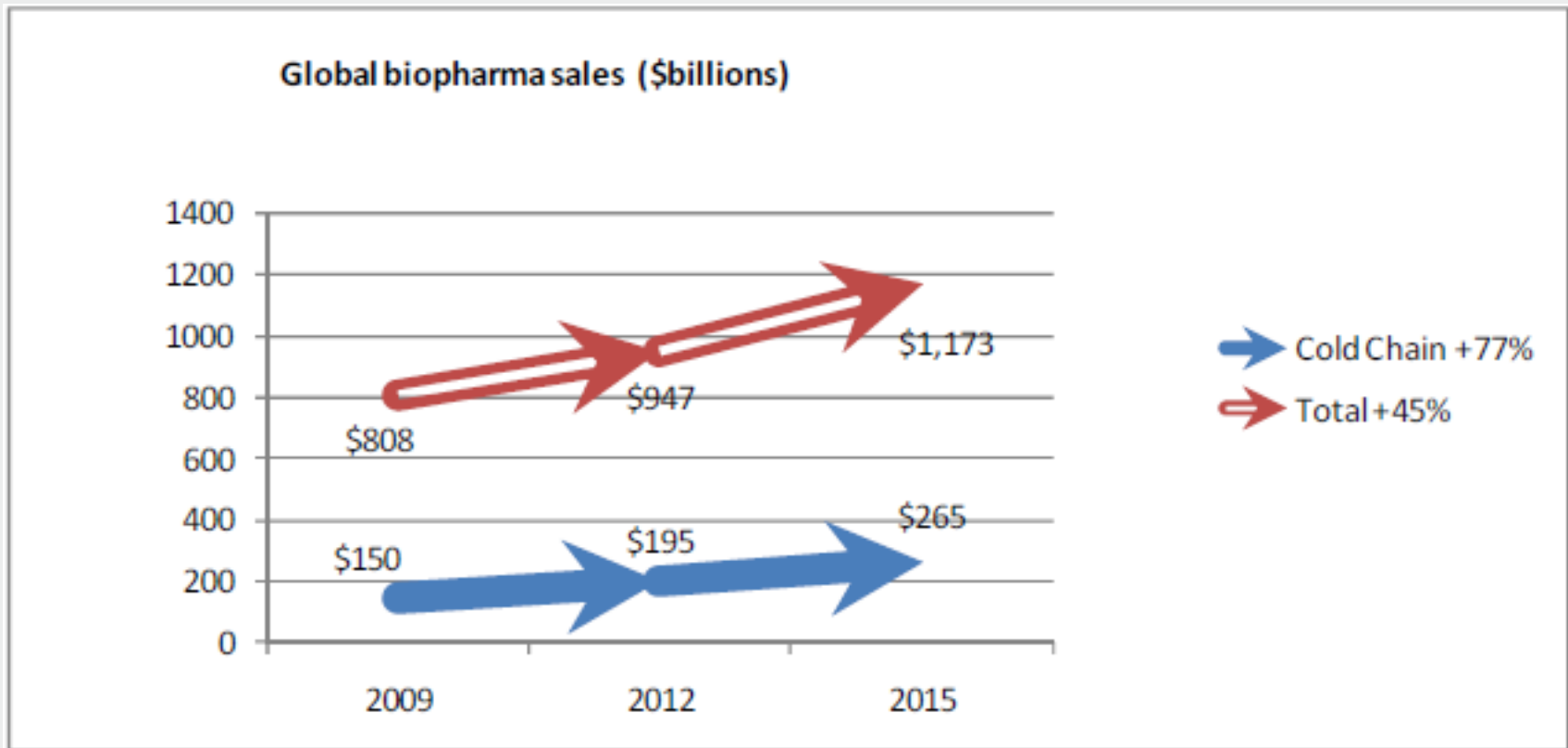
Regional cold-chain logistics spend by 2015

Growth in cold-chain spending will be faster in Asia and LATAM than in N. America and Europe



Cold-Chain drugs and biologicals sales

Cold-chain drugs and biologics sales growth will outpace industry growth through 2015

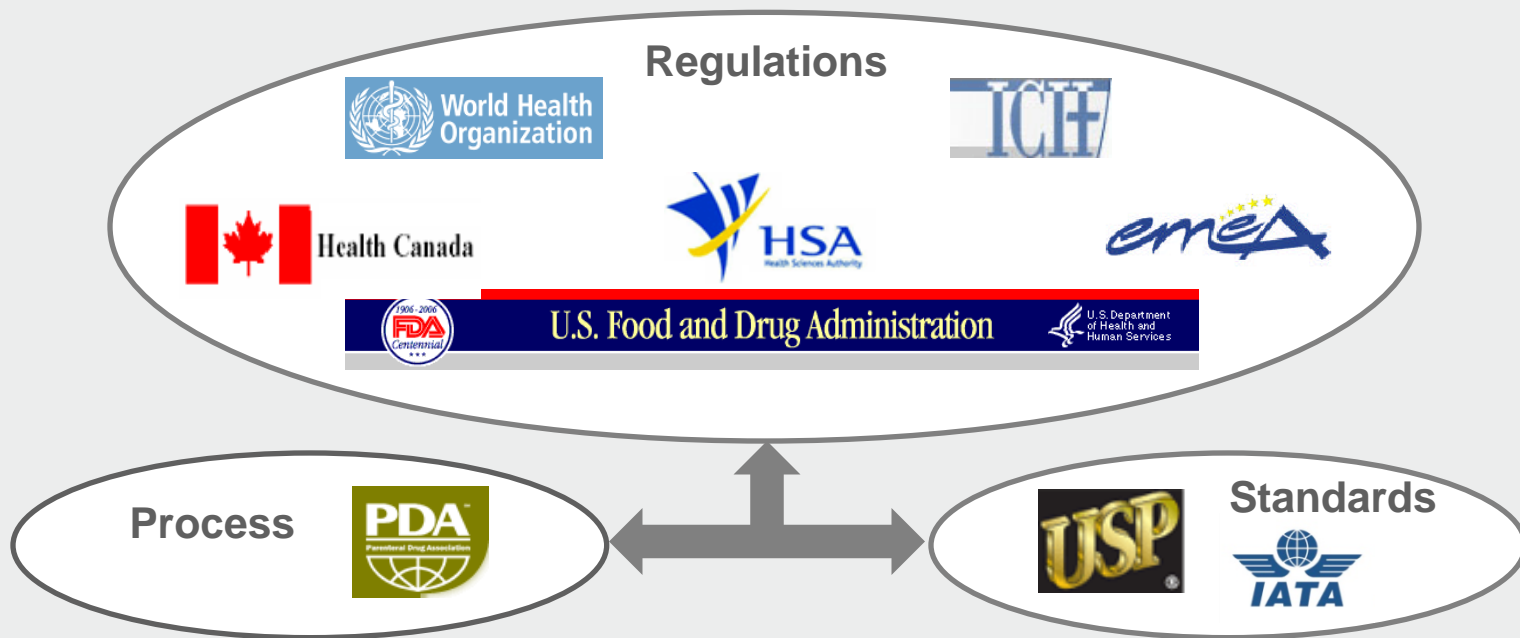


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Good distribution practices

From GMP to Global Supply Chain



- GDPs have become stand alone documents
- Over 35 global GDPs- all are harmonized, some have specifics
- Holistic quality systems includes manufacturing & commercial distribution

Good distribution practices

Newly released GDP documents

World Health Organization

- WHO Technical Report Series, No.961,
- Model guidance for the storage and transport of time and temperature sensitive pharmaceutical products
- May 2011

Health Canada

- Health Canada's recently revised GUI-0069
- Guidelines for Temperature Control of Drug Products during Storage and Transportation
- May 2011

International Society for Pharmaceutical Engineering (ISPE)

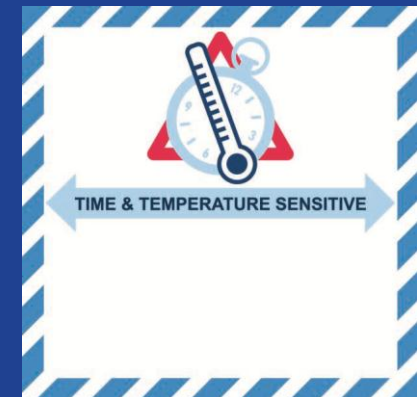
- Good Practice Guide: Cold Chain Management
- May 2011

Good distribution practices

IATA Time & Temperature Label for Healthcare Products

- Effective July 1, 2012, the Label will become mandatory
- Label typically added by shipper
- Must be used with a SLA between shipper and transport service provider
- Unique to healthcare but does not allude to contents
- Conveys external handling temperatures
- Optional temperature range designation area
(or assumed to be +15 to +25C)

“Unless otherwise specified in a contractual agreement, it is the responsibility of the shipper to apply the Time and Temperature Sensitive label for Healthcare Products to the outermost visible means of containment (e.g. package, overpack, ULD, etc) to be shipped.” (PCR 17 10.6.1)



Security mandates and active containers

Changes from the TSA and other security entities have prompted us to create guidance for handling of cold-chain cargo



Put product boxes in an over pack (largest piece level) to expedite screening



Container / dry ice bunker door is sealed with tamper-evident technology



Tamper evident tape should not interfere with the functionality of the container



If removing cargo from a ULD, perform screening under controlled time and temperature conditions

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Envirotainer product portfolio

The RAPe2 expands the fleet of electrical heating and compressor cooling containers to offer a large volume container

Dry ice cooling

CLD t2



RKN t2



Electrical heating and compressor cooling

RKN e1



RAP e2

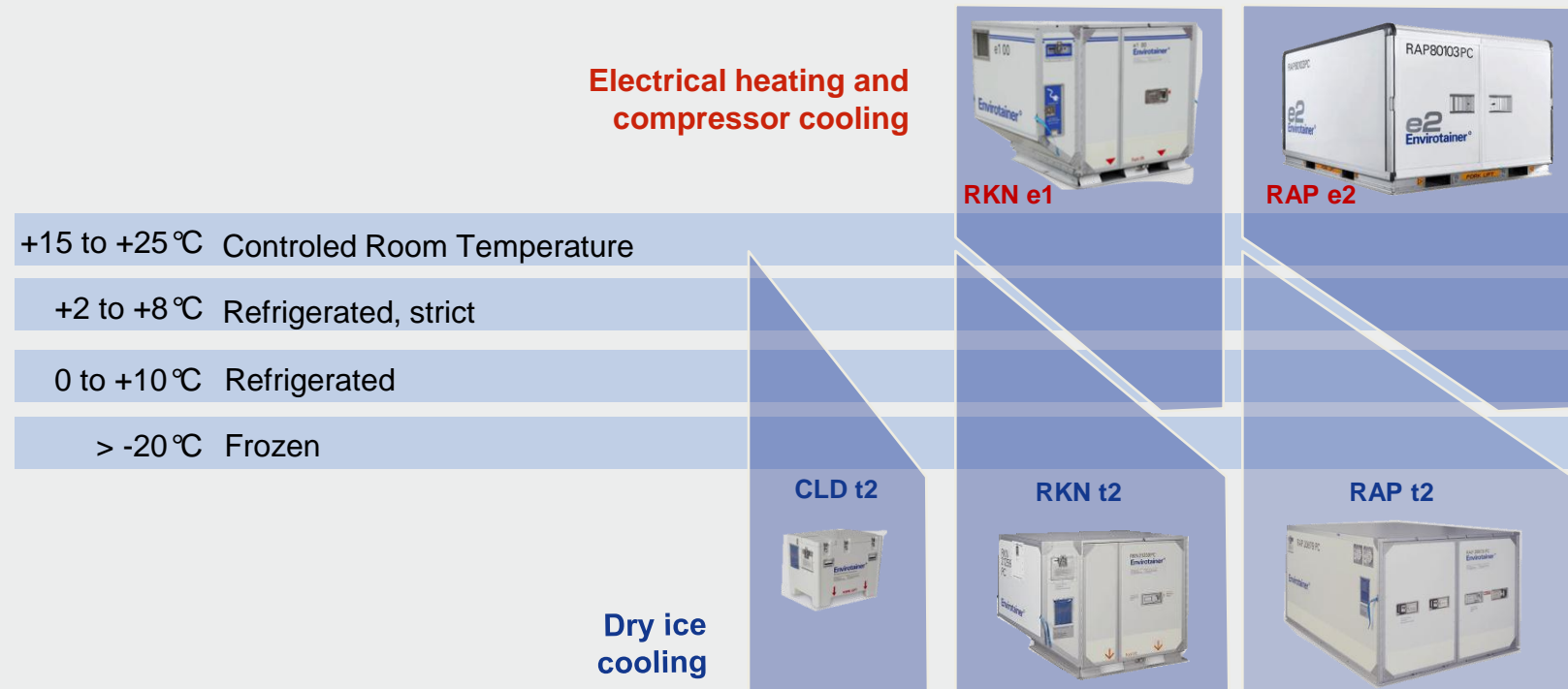


RAP t2



Envirotainer product portfolio

Different products for different temperature requirements
 – RAP e2 closes the gap for strict 2-8°C and CRT high volume shipments



New container shell material

Composite materials offer better insulation and more structural stability resulting in an over all better performance and lower costs

Facts about composite material

Insulation properties improved by up to 100%

- possibility to build 3D structures
- increased autonomy of the system
- better protection from extreme hot and cold conditions
- less energy needed for heating and/or cooling
- increased reliability of the cold chain



Higher structural stability of the container

- container is more vibration and shock resistant
- container structure is stronger
- container is more durable



Less damages and simpler to repair

- higher availability
- reduced repair cost

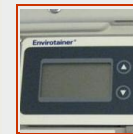


RAPe2 ease of handling

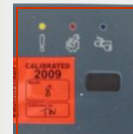
Designed improvements based on 5 years of experience with Envirotainer's RKN e1



Ease of handling



Known interface to set the temperature



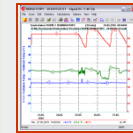
Smart alert system enabling corrective actions if necessary



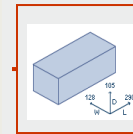
One energy source for all functions of the container



Everything on board cable and adapters for 80% of the world



Data recording option for full shipment transparency

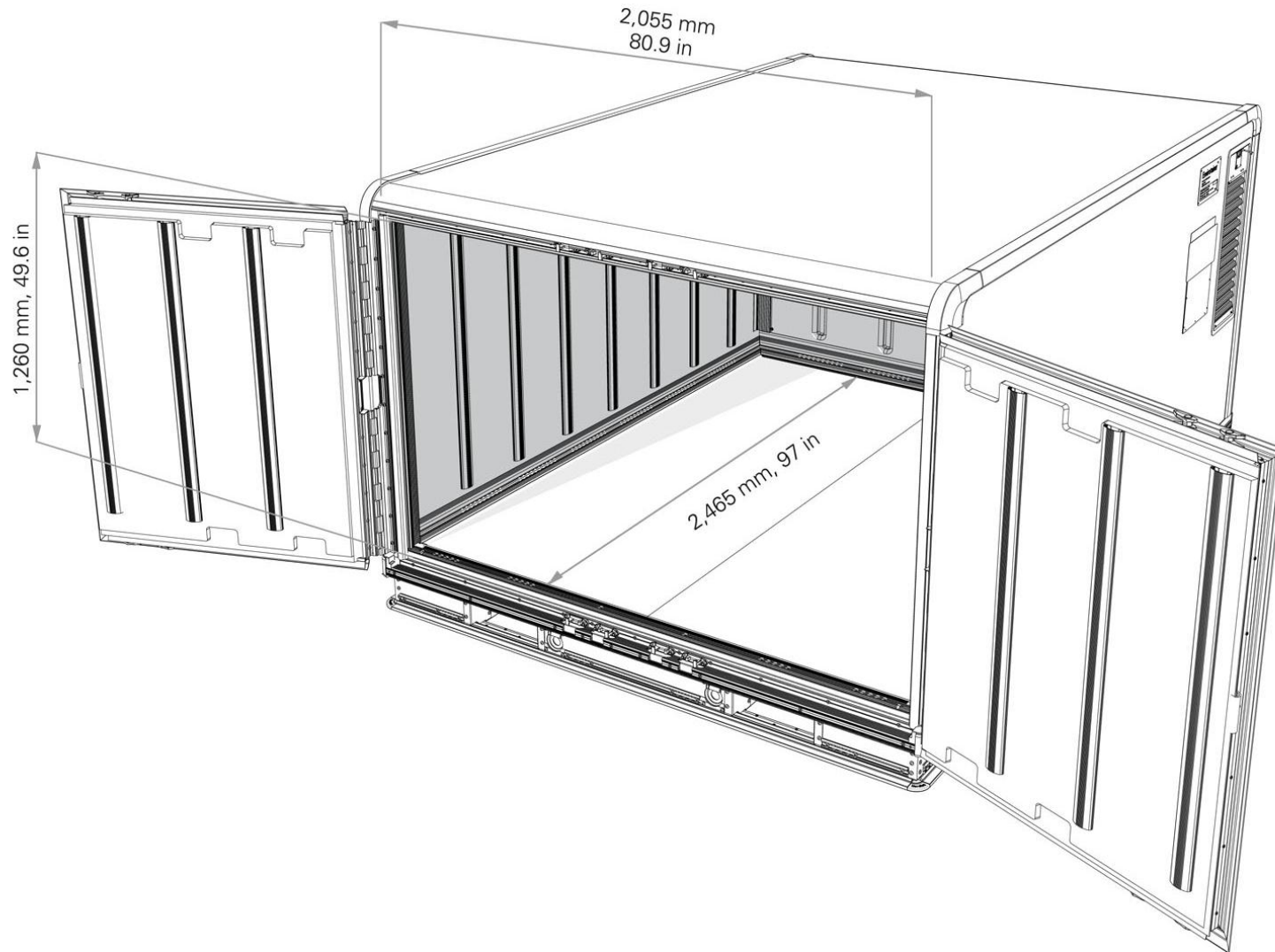


Optimized loading for four US or five EUR pallets, forklifable from four sides

RAPe2 ease of handling



RAPe2 details

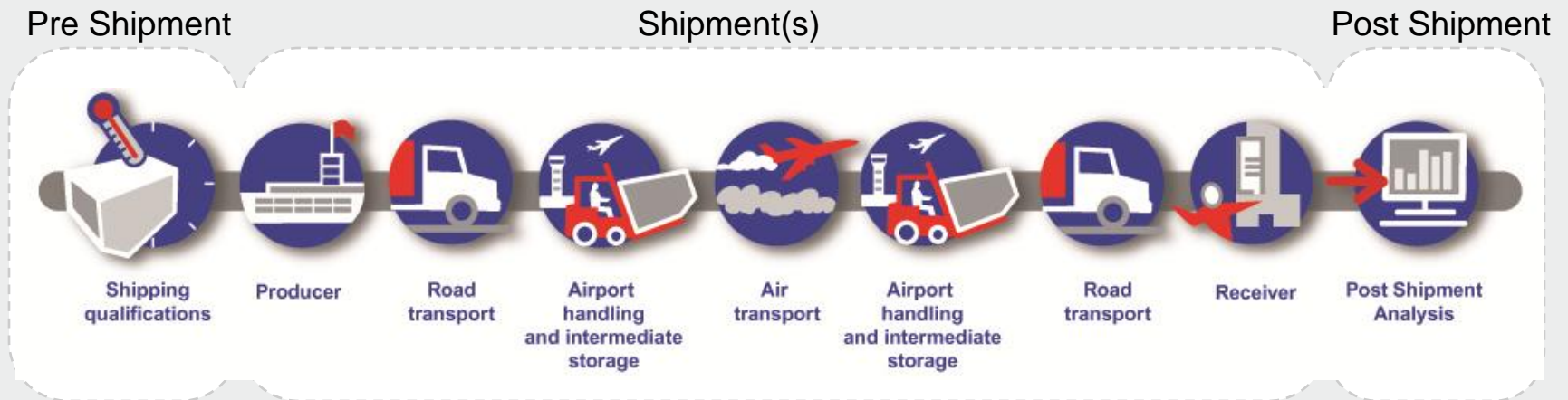


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What we do

We deliver advanced solutions for unbroken cold chains



Global presence for global customers

- From our 44 stations you can reach more than 200 unique destinations
- Open platform for airline carriers
- Operations Centers covering all time zones
- Representation in all major healthcare production regions world wide



An established supplier to the healthcare industry



Strong partners securing availability to and from any destination

AIRLINES	FORWARDERS	AFFILIATIONS
