Public Cold Storage for the Pharma Industry: the risk factor, the cost factor, the success factor.

> ECSLA * EUROPEAN COLD STORAGE AND LOGISTICS ASSOCIATION

Mr Winn van Bon Cold Chain Smart Solutions, 19-21 January 2011, Barcelona

Some Words about ECSLA

- 9 EU National Associations = 900 Public Cold Stores and Logistics facilities
- 40 Private Companies partly representing a national market in the EU
- 11 Companies Cold Stores suppliers (associated members)
- 50 million m³ of total storage capacity

ECSLA has a EU-wide coverage



Some Words about ECSLA (2)

Through a Permanent Secretariat in Brussels ECSLA...



- Represents the image of the industrial refrigeration sector to the general public
- Maintains close contacts for its members with European institutions
- Contribute to the development of a legislative and economic framework addressing the competitiveness of industry
- A platform for dialogue between the cold chain actors: manufacturers, distributors, suppliers, consumers...

Some Words about ECSLA (3)

- ECSLA Publications (*Positions, Newsletters, Circulars*)
- ECSLA website: <u>www.ecsla.be</u>
- ECSLA Press releases in EU medias
- Seminars on Refrigeration Technology, Food Safety and Hygiene, Safety in Cold Stores, Energy efficiency, Greening of the Supply Chain...

ECSLA Dissemination of Information



Pharma Industry: Facts & Figures

 Size of the temperature sensitive global pharma & bio-pharma industry : US\$40 billion to US\$130 billion



Market expansion : 8%-13% per annum

The stakes, due to a fragmented cold storage market

THE DANGERS

- Ineffective or dangerous drugs
- Significant recall costs
 for manufacturers
- Life hazards...

THE REASONS

- Lack of consistent regulations
- Lack of product handling protocols

Public Cold Stores leadership : too daunting? No!

- Public Warehouses entrusted with ensuring public safety by maintaining integrity in the FOOD cold chain
- Interaction with thousands of co-actors of the supply chain
- Food security as important as for pharma products



- Standardized operations for the storage and handling of product
- Facilities designed to meet product demands, safety, security
- Information systems tracking
 multiple products
- Data recording, keeping & reporting
- Cold chain approach from cradle to grave to ensure its integrity (shipping, documentation, storage, training)

The Benefits of Using Public Refrigerated Warehouses

 Outsourcing tide continues to gather momentum in nearly all industries around the globe







• one company

CAPSUGEL

CAPSUGEI

Quality Reople and Products Working Tops

- food + pharma
- different roofs

The Financial Advantage

- Manufacturers and traders can cut down—or cut out—a significant capital investment
- Freeing up capital for research and development, marketing, revenue opportunities
- The Return on Investment Question: can needs best be met through use of public refrigerated warehouses or construction and operation of private space?



The Professional Advantage

Public refrigerated warehouse facilities :

- Employ highly trained professionals
- Offer specialized personel in providing maximum protection for customer products
- Carry warehouse legal liability insurance to guarantee that they will care for your products as if they were their own



The Technology Advantage

Most Public refrigerated Warehouse and Distribution Facilities:



- Have computer and telecommunications capability to network with customer computers, provide critical transaction data and analysis
- Offer inventory management, shipment histories, production scheduling, and stock replenishment. Routinely shared between computers, or even put under <u>your</u> control
- Satisfy any particular requirements: You can have all the knowledge and information you ever want, including storage temperatures, while the refrigerated facility cares for your product.

The Distribution Advantage

- Facilities strategically located to connect with every imaginable mode of transportation
- Customers benefit from reduced transportation costs, available through consolidated shipments only
- Pharma operators enjoy greater flexibility in serving a huge but changing market
- Savings of funds necessary to acquire/construct an expensive refrigerated facility in one or several permanent locations



Control Your Costs & Increase Your Productivity



> Learn more about newest technology for distribution & manufacturing

Core Competency Advantage

- Can companies successfully focus on three or four core competencies?
- Sometimes difficult to do all of them well simultaneously
- It's easy to describe the core competency of public refrigerated warehouse and logistics companies: it is taking good care of, and adding value to customers' products.



- Public Cold Stores specialize in designing efficient facilities
- Controlling warehouse and logistics costs
- Providing high levels of sanitation
- Monitoring product temperatures
- Providing all kinds of related services—blast freezing, product labeling, repacking, import/export certification, etc.

Public Warehouse: How to calculate your return in investment?

- annual cost to use PRW space
- transport costs to convey items to from the warehouse

- total annual operating expenses **to operate** privately:
 - Operating and maintenance of refrigeration systems
 - Increased use of electric power with the possibility of peak
 power electric penalty rates
 - Additional clothing and protection equipment for employees
 working in a refrigerated environment
 - Increased safety and environmental expenses associated with ammonia refrigeration systems

• total costs **to construct** your private warehouse:

- Refrigeration equipment
- Additional insulation, including floor
- Refrigerated loading docks
- Freezer and escape doors
- Freezer clothes
- Inspection room equipment
- Underfloor heating system



The Stakes for the Refrigerated Warehouses today - 2020

- European rules on refrigeration technology,
- Future prospects for natural refrigerants,
- New chemical refrigerants,
- The worldwide financial crisis.



At stake: European rules on refrigeration technology

The European substance bans

- CFCs banned since 1996
- HCFC phase-out in progress



Regulation 2037/2000 on substances that deplete the ozone layer fully applicable in all member states

servicing with virgin HCFCs allowed <u>until</u> <u>2010</u>

servicing with recycled/reclaimed HCFCs allowed <u>until</u> <u>2015</u>

<u>after 2015</u> HCFCs banned

Latest developments on European substances bans

POSITIVE POTENTIAL

- Phase out Calendar of ODS in 2010 and 2015 remains unchanged
- Action Plan for promotion of alternatives

NEGATIVE POTENTIAL

- Installations will need to adapt to two routes when charging fluids : recycled and reclaimed
- Containment methods of HCFCs comparable to the F-Gases
- New costs implications and SMEs capacity to adapt in question?

The F-Gases containment

Regulation (EC) No 842/2006 on certain fluorinated greenhouse gases

- containment instead of ban
- requirements in force since 4.07.07 in all EU
- F-gases include all HFC refrigerants, such as R134a
- and blends containing F Gases such as R407C,R410A, R404A.
- If you are handling, recovering, supplying, installing, manufacturing or own equipment containing HFC refrigerants in stationary equipment you now have new legal obligations

The F-Gases Requirements (1)

Operators of equipment must **prevent leakage**, ensure leak checks are carried out and repair any leaks as soon as possible as well as arranging proper refrigerant recovery Only by qualified personnel

 Following a standard leak check procedure set by Commission

The F-Gases Requirements (2)

Operators must ensure **systems are checked for leaks**: • At least annually if more than 3kg charge (hermetically Sealed more than 6kg)

• At least once every six months if over 30kg. If they have an automatic leakage detection system they need only be checked every 12 months.

• Automatic leakage detection systems must be installed On applications with 300 kg or more, and these systems should be checked every 6 months.

• If a leak is detected and repaired, a further check must Be carried out on the repair site within up to one month to Ensure that the repair has been effective. Only by personnel qualified to the levels set by the Commission

• Following a standard leak check procedure.

The F-Gases Requirements (3)

Operators must **maintain records of refrigerant** in equipment with a charge of 3kg or more (if hermetic, 6kg or more).

Records to be made available to the Competent authority on demand.

Relevant information specifically identifying the separate stationary equipment of applications containing more than 30kg of F Gas must be maintained by the operator. System records should contain:

• Quantity and

type of Fgases installed, added or

recovered

Name of company or

Technician carrying out servicing

• Dates and results of leakage checks and Rectification work carried out.

The F-Gases Requirements (4)

New equipment will need to be labelled.

Most new equipment will be labelled by the manufacturer, but site assembled equipment will need to be labelled by the installer with, amongst other things, the total installed charge.

Certain equipment will need instruction manuals containing information about the F Gas in use. • Personnel involved in above work must obtain **EU recognised F Gas certification** which may be different to the existing FI qualifications

 Companies to be certified under the F Gas Regulation , applicable from 4th July 2008

The future of F-Gases in Europe

Review of the F-gas Regulation through 2011 will:

 Address current inaccuracies and strengthen enforcement of the regulation

• Likely to bring about more stringent requirements

At stake: natural refrigerants



NUMBER OF THE AUDITALIAN INCIDENT OF REPAIRATION, AND ORDER COMPLEXING with Auding from the Department of Encirclement and Mater Tensories

- Piecemeal approach to natural refrigerants
- No regulation at EU level
- Trade barriers as a result
- Uncertain and unsustainable investments in the meantime by companies
- Market opportunities
 decrease

- ECSLA => Influence policy making
- More harmonised approach => Less trade barriers
- New market potential

E.g. French regulations have been amended with the minimum distance requirements between ammonia plant rooms and neighboring properties being reduced, thus making the use of ammonia refrigeration systems easier

Case study: Dutch coldstore using natural refrigerants (1)



The building is 20 meters high and can store 12,500 pallets, spread over 15 individually-controlled temperature compartments.

Location: near the port of Rotterdam

High rise storage

Case study: Dutch coldstore using natural refrigerants (2)

The refrigeration system: A NH_3/CO_2 fluid solution has been commissioned. The use of pumped CO_2 instead of water based brine offers significant energy savings.

Automation: Fully automated cranes and conveyor systems for internal transport purposes. Main advantage of theautomated storage system is that the logistics process operates more efficiently and reliably and because the refrigerated cells are always kept closed, the refrigeration of the cells is extremely efficient, enhancing the shelf life and quality of the products being stored.

Temperature control: Danfoss values and helps to provide outstanding results in temperature control and energy efficiency in this dual temperature ammonia/ CO_2 secondary cooling system.

At stake: synthetic regrigerants

- Flammability issues
- GWP
 remains an
 issue

- Greening the supply chain & Cut CO₂ emissions by 20% by 2020 in the EU
- Carbon Footprint of the industrial refrigeration sector





"Where is the cold storage and distribution industry heading?"

- Industry adaptation to bans, containment etc should focus on sustainable solutions (that can be costly)
- 2. Divert from high GWP and ODP refrigerants (that can be cheap)
- 3. Modalities for using recycled HCFCs in the period 2010-2015 could be damageable for SMEs
- 4. Prices for raw materials and energy go down but investments are held back

Thank you for your attention! info@ecsla.be

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