Liliane,

Au moment où vous allez pouvoir prendre le temps de vivre toutes vos passions, je suis particulièrement heureux de mettre en avant votre extraordinaire enthousiasme qui a permis une merveilleuse collaboration entre Sanofi et les Masters 'Commerce International' de la Sorbonne.

Imaginez le nombre d'élèves avec lesquels vous avez pu partager votre expérience et qui ont évolué par la suite chez Sanofi...sans doute ne les citerai-je pas tous ...mais la plupart des noms suivants ne vous seront certainement pas étrangers :

Céline Morin, Laure Dessaigne, Sandrine Dubbeldmann, Charlotte Lescuyer, Clémence Ligozat, Emmanuelle Ross, Mathilde Salavert, Jennifer Khounnala, Deborah Fessard, Rebecca Rink, Karima Bouzoumita, Najet Ouriri, Emilie Crepel, Ambra Pitozzi, Estelle Gras, Cédric Martin, Cécile Agostini... Des souvenirs communs sérieux, drôles ou émouvants...

Les interventions du samedi matin à la Sorbonne et la bagarre face à un projecteur récalcitrant, le transfert dans une autre salle afin de bénéficier d'un matériel en ordre de marche,

La visite du centre de distribution de Croissy et l'étonnement de chacun devant cette réalité logistique,

Ma découverte de la Sorbonne à Abou-Dhabi avec transfert en voiture dans cet immense chantier et les installations ultra-modernes à la disposition des élèves et des enseignants...surtout à ne pas photographier !!!

Quelques repas bien agréables partagés à Antony ou à Abou-Dhabi,

Des remises de diplômes en toge et toute l'émotion que nous ressentions avec vos élèves et leur famille,

Tous les témoignages d'amitié et de reconnaissance que j'ai pu entendre de vos collègues ou de vos élèves, récents ou plus anciens,

Ma rencontre, à vos côtés, de mon homonyme, Georges Molinié, lors d'une remise de diplômes,

Votre énergie à vous battre face aux lenteurs/lourdeurs de l'administration universitaire!

La mise en place d'un travail de validation des acquis de l'expérience pour une personne de notre équipe et de contrats en alternance depuis l'an dernier...



L'espoir que tout ce travail en collaboration que nous avons initié se poursuivra au cours des années à venir.

Et puis je crois avoir compris que vous alliez, grâce à votre petite fille, devenir une spécialiste incollable des chevaux! Sachez que nous partagerons bientôt cette spécialité!

Je sais que nous resterons en contact mais d'ores et déjà, je vous souhaite de merveilleux moments 'pour vous'!

Amicalement Bernard

Bernard MOLINIE
Décembre 2011

Internal Control & Sarbanes Oxley Act

Sanofi-Aventis Approach

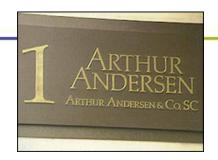
Bernard MOLINIE
Sanofi
Head of Export Customer Service



Financial Scandals of the early 2000s

















VIVENDI UNIVERSAL

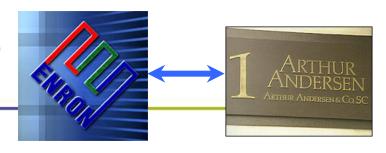






WORLDCOM.

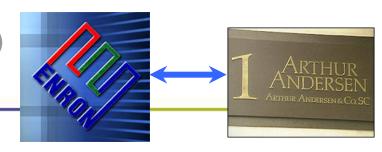
Enron/Andersen (1/4)



- Enron: founded in 1985 by Kenneth Lay through the merger of Houston Natural Gas and InterNorth, two natural gas pipeline companies
- In the early 1990, US congress passed legislation deregulating the sale of natural gas
- By 1992, Enron was the largest merchant of natural gas in North America and the gas trading business became the second largest contributor to Enron's net income.
- In 2001, Enron had revenues of around \$101 Billion and was one of the world's largest energy companies, providing electricity and natural gas
- The company also had branched out into financial and risk management service
- **FORTUNE** magazine had named Enron 'America's Most Innovative Company' for 6 previous consecutive years...



Enron/Andersen (2/4)



THE ENRON COLLAPSE

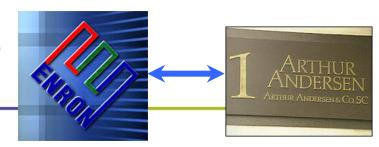
- In August 2000, Enron shares reach their peak price of \$90
- During 2001, the company became tainted by corporate scandal. Enron shares fell from \$90 per share to about 30 cents per share
- In October 2001 : Enron reports a \$638 Million third-quarter loss
- In December 2001: Enron files for bankruptcy protection and lays off thousands of workers

The Enron scandal grew out of a steady accumulation of 'special' transactions that began years before and finally spiraled out of control

 Many of Enron's recorded assets and profits were inflated or even wholly fraudulent and nonexistent. Debts and losses were put into entities formed 'offshore' that were not included in the firm's financial statements, and other sophisticated financial transactions between Enron and related companies were used to take unprofitable entities off the company's books



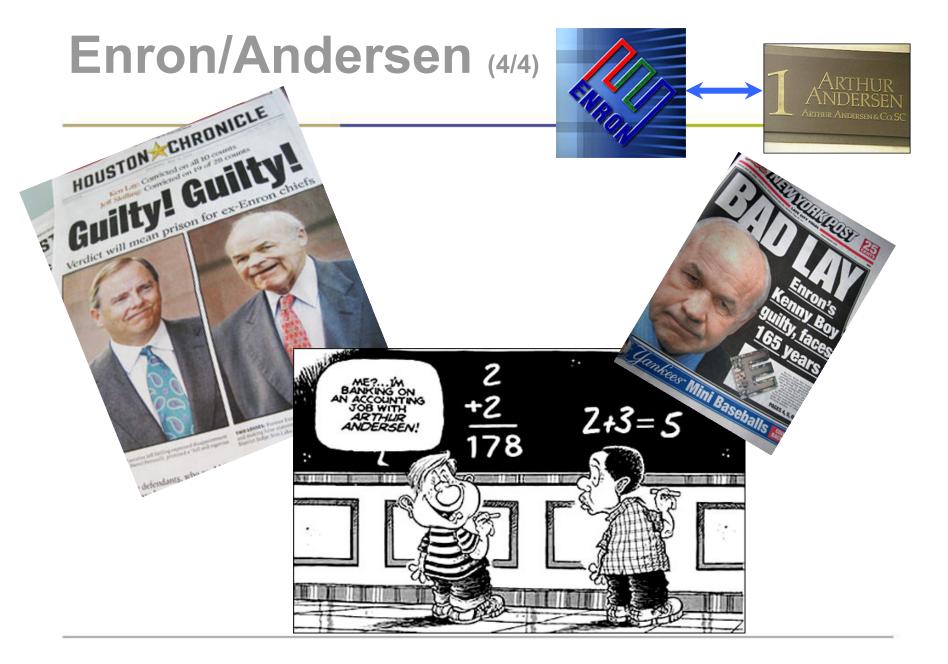
Enron/Andersen (3/4)



THE ANDERSEN DOWNFALL

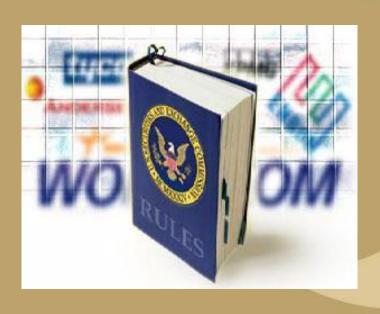
- Enron had become one of Andersen's largest clients
- In 2000, Enron reported it paid Andersen \$52 million :
 - \$25 million for the financial statement audit work
 - \$27 million for consulting services
- Andersen even maintained a permanent office space in the Enron's building and Andersen's employees attended and joined many events organized under Enron's management.
 - The sign of lack of independence (real and perceived) was clear.
- Andersen knew there were serious problems with Enron's financial statements but they signed it off anyway
- In March 2002, Andersen is indicted for destroying Enron-related documents and in June 2002, Andersen is convicted of obstruction of justice







The Sarbanes-Oxley Act







Restoring confidence and trust in the financial reporting of companies

- In the US, in the month after the Enron collapse, a lot of reforms were proposed in Congress with the following objectives:
 - Make management accountable
 - Enhance disclosure
 - Conduct regular reviews by the SEC 'Security and Exchange Commission)
 - Hold accountants accountable
 - In July 2002 as a result, the US Congress passed the

Sarbanes-Oxley Act







Senators Sarbanes & Oxley

Sarbanes-Oxley Act (SOX)

- In simple terms, the SOX is used as a guideline for making companies more accountable to recording and reporting their financial information. The Act was introduced to improve the accuracy of companies governed by the Securities and Exchange Commission (SEC), and allows the SEC to oversee any regulations in regard to this law.
- The SOX rules apply to all companies cross-listed in the US
- SOX contains 11 titles that describe specific mandates and requirements for financial reporting (corporate responsibility, Auditor Independence, Reporting requirements...). Each title consists of several sections



Sarbanes-Oxley Act (SOX) Key Sections

- <u>Title 3/Section 302</u> requires that the company's "principal officers" (typically the Chief Executive Officer (CEO) and the Chief Financial Officer (CFO) certify and approve the integrity of their company financial reports quarterly.
- Title 4/Section 404: Assessment of Internal Control
 - This section requires management and external auditor to report on the adequacy of the company's internal control over financial reporting (ICFR).
 - This is the most costly aspect of the legislation for companies to implement, as documenting and testing important financial manual and automatic controls requires enormous effort
 - This section will be the main part of my presentation today
- <u>Title 9/Section 906</u>: Criminal Penalties in case of false financial statements





Principles of the Internal Control

including Sarbanes-Oxley Section 404
processes



Definition of Internal Control

- The report issues by the COSO (Committee Of Sponsoring Organizations) is a commonly accepted international reference for internal control as a "process run by the Board of Directors, Top Management and all employees, in order to provide a reasonable assurance that the organization's three following objectives will be met:
 - Run and optimize operations
 - Issue reliable financial information
 - Be compliant with law and applicable rules
- A company like Sanofi-Aventis, listed in New York & Paris, has to be compliant with the Sarbanes Oxley law (USA) and the Financial Security Law (LSF-France-2003).
- SOX: 2006 was the first year of assessment for foreign companies listed in the US, including Sanofi-Aventis



LSF & SOX

SOA legislation concerns the reliability of financial information.
 The obligation to produce and file evidence results in an absolute requirement for documenting control and testing activities.

- LSF law has a target to encourage all legal entities listed at the Paris Stock Exchange to the complete internal control process and not only the financial part of it. No documented assessment of internal control needed
 - SOX processes were clearly more complex to be implemented than LSF processes



Objectives of Internal Control

- Internal Control aims to provide REASONABLE ASSURANCE and not absolute guarantees
- Defining an internal control process means
 - assessing the risks an organization might have to face
 - indentifying control objectives to be in a position to manage those risks
 - implementing control policies and procedures
 - creating a control environment fully consistent with the business objectives
 - implementing and promoting individual & professional integrity as well as ethical values
 - supporting the development of levels of competence that can lead to efficient and effective results
 - implementing and promoting an adequate understanding of internal controls so that each individual in the company can effectively face his/her responsibility



Overview of Internal Control

Objectives of Top Management in an Organization/Group

Compliance with laws and rules

Accurate Management and efficiency of the business, run and optimize operations, safeguard assets

Reliability of Accounting and Financial information

Need for an Internal Control Process

Achievement of the Organization's objectives while minimizing the probability

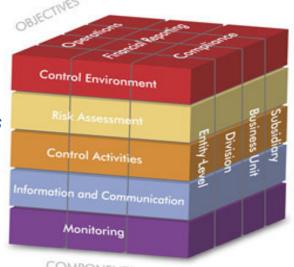
of non-identification of material errors

Control Over Operations

Monitor Business/Operations

Reasonable Assurance

- 1. Create an Internal Control Environment
- Assess the risks of non-achievement of the objectives set by topmanagement
- Control that rules are applied 3.
- 4. Inform & Communicate on the objectives to provide each individuals with the means to carry out his/her responsibilities
- **5**. Monitor: define & document all rules and operating procedures, check for the efficiency and effectiveness of control activities



COMPONENTS



Internal Control: Implementation by SANOFI



Sanofi Process Modell (including SOX 404 Process)

Category	Macro-Process	Processes
Executive	A. To Plan and to elaborate strategy	Strategic Plan, partnerships
	B. To organize and govern the group	Corporate gouvernance, Internal audit
	C. To communicate	Institutional level, media, investors

Operational	Scientific & Medical Affairs D. To search, to discover, to develop & to register new products	Scientific intelligence, discovery process, clinical activities, registration
	Industrial Affairs E. To produce and to distribute	Industrial development, storage & distribution, manufacturing, sales administration
	Pharmaceutical Operations F. To develop our presence on the world market and control operating results	Marketing, promotion, commercial activity
	Health Safety Environment / Quality G. To secure operational processes on the long term	Pharmacovigilance, Quality, sustainable development



Sanofi Process Modell (including SOX 404 Process)

Category	Macro-Process	Processes
Support	H. To purchase	Purchasing policy, suppliers selection
	I. To finance and control	Financial standards, accounting, consolidation, contractual commitments, treasory & cash, taxation
	J. To manage legal affairs	Legal policy and strategy, contractual commitments negotiation, litigation & disputes management
	K. To manage information systems	IS organization, IS processes monitoring
	L. To manage human resources	Social environment, recruitment and staff transfers, competencies, payroll & compensation, litigations
	M. To secure assets	Insurance, protection, security

Segregation of duties

The organizational chart of a structure reflects :

- the allocation of responsibilities and authority
- the organization of the hierarchy
- the distribution of tasks

Segregation of duties is directly connected to the following elements:

- organizational chart
- job descriptions
- written procedures
- consistency between access rights to Information Systems given to each employee and their job definition



The cost of the implementation of SOX



Cost of Sarbanes-Oxley

- International companies polled in 2008 to determine how much it costs to comply with Section 404 of the Sarbanes-Oxley Act.: 185 companies with average annual revenues of \$4.7 billion.
 - For these companies, the total average cost of compliance was \$1.7 million in 2007 with a decrease since SOX implementation
- The survey also asked companies with market capitalization above \$75 million about their audit fees for 2007.
 - The total audit fees for these companies averaged \$3.6 million, up a bit from 2006.
- Here are some other interesting figures:
 - Companies averaged 11,100 internal people hours to comply with Section 404 in 2007. Yet this was considered good because it was a 8.6% decrease from 2006.
 - Companies averaged 1,244 external people hours to comply with Section 404 in 2007. This was also considered good because it was a 13.7% decrease from 2006.
- And companies apparently think that Section 404 is doing some good:
 - 50.3% agreed that financial reports are more accurate; up from 46% in 2006.
 - 56.0% agreed that financial reports are more reliable, up from 48% in 2006.
 - 43.6% agreed that compliance with Section 404 has helped prevent or detect fraud; up from 34% in 2006.
 - 69.1% agreed that compliance with Section 404 has resulted in more investor confidence in their financial reports, up from 60% in 2006.







- Implementation of Sarbanes-Oxley has allowed companies to formalize their internal control procedures
- But it's sure that SOX will not stop all criminal or fraudulous acts





Interview Michael OXLEY (March 24, 2010)

Do you think Sarbanes-Oxley has been a success?

« Sarbanes-Oxley was all about accountability and transparency and restoring investor confidence. We lost almost \$8 trillion in market capitalization in 2001 and 2002 because of fraud at places like Enron and Worldcom.

Even though the recent meltdown has hurt confidence again, things could have been much worse if accounting regulations had been as lax as financial regulations. »



Is Sarbanes-Oxley a failure?







The SANOFI

Export Distribution

Focus on Operational Aspects

Bernard MOLINIE
Head of
Export Customer Service



The Export Distribution

Part of the Supply Chain Department of the Industrial Affairs



Plant Projected Inventories

Net Demand (Customer Needs)

3 Months

27/10/20





Manufacturing





Distribution

Customer (Affiliate or Third Party ♠

Factory (group or external)

Export
Distribution
Center

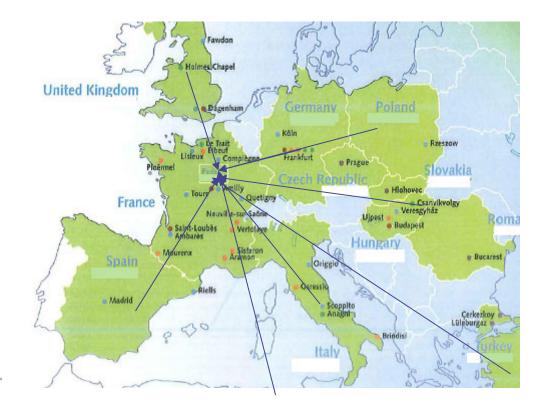
Export Customer Service





Overview of the export distribution of Sanofi-Aventis: Production in France & outside France

- Production sites (finished or semi-finished products) in France, Europe (UK, Germany, Italy, Spain, Hungary, Poland) and Other countries (Maghreb, India, Senegal...)
 - 130 sites
 - 100 third party factories
 - 30 group factories
 - 35 countries





CROISSY PICTURES

(Ethical & OTC Products)









Exporting Pharmaceutical Products A strong specificity

- Requirement for an extreme Quality level for both the storage and the transportation all along the supply process
 - (température, shocks, shelf life...each product has its own specificities and constraints)
- Never forget that there is a Patient at the end
- Major Regulatory & Pharmaceutical constraints (specificities by countries)
- **An essential Traceability**



The Export Distribution Transport



Transport

- A crucial challenge for the global Supply Chain:
 - More than 3 Billion boxes transported yearly
 - Important increase of the transport costs
 - Major impact on the environment
 - **Increased quality requirements**
- A clear strategy of Sanofi-Aventis to reduce the costs & the CO2 emissions, and to maintain quality
- Significant résults







The Export Distribution - Transport

Choice of the Transport Mode for a cleaner environment



Choice of a Transport mode in Europe

The transport by Road: about 30% of the CO2 emissions









Choice of a Transport mode in Europe

CRITERIA

Transport Costs

CO2 Emissions

Transit time

In Place

Covers all destinations?

Truck	Rail	Barge
Base		
Base	+	+
Base		
YES		
YES		



Choice of a Transport mode for Intercontinental flows

CRITERIA

Transport Costs

CO2 Emissions

Transit time

In Place

Covers all destinations ?

Air	Sea
	•
	+
+	
+	+
+	+



Choice of a Transport mode for Intercontinental flows

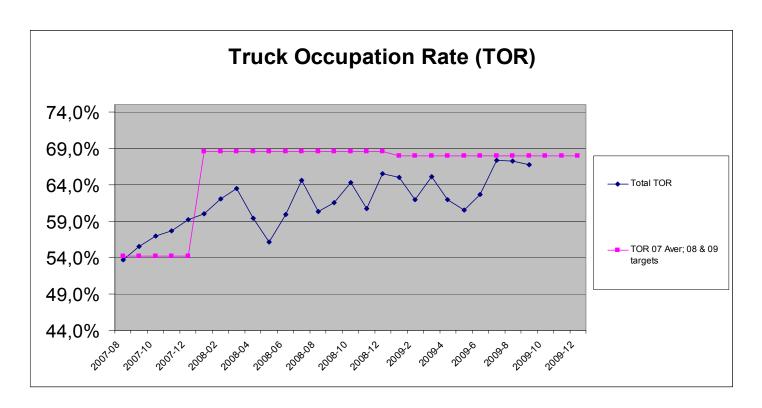
■ Example of a flow Europe -> USA

FOR ONE PALET	NEEDED TIME SPAN	COST	FUEL CONSUMPTION	CO2
	2 days	500 €	443 liters	1216 KG
SAAE LOSS	20 days	100 €	14 liters	38 kg



Some initiatives of Sanofi to reduce environmental impacts

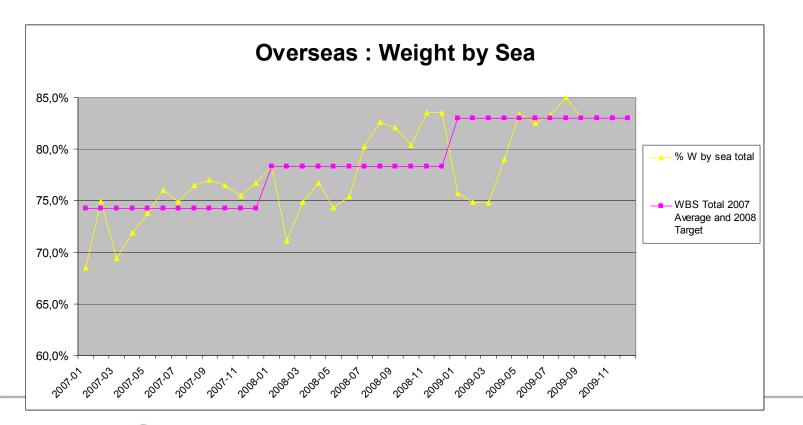
- Truck and Containers occupation
 - Monthly indicator that concerns ALL Sanofi-Aventis exporting sites worldwide :





Some initiatives of Sanofi to reduce environmental impacts

- Gradual transition from Air to Sea for intercontinental shipments
 - Monthly indicator that concerns ALL Sanofi-Aventis exporting sites worldwide :





Some initiatives of Sanofi to reduce environmental impacts

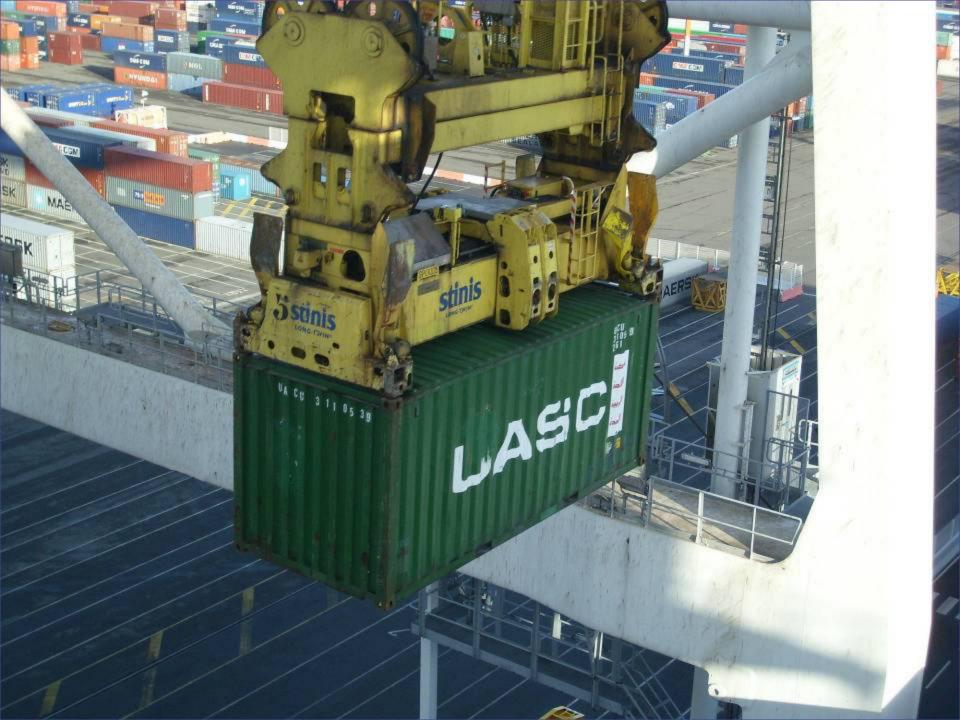
- Example of one of the most important intercontinental flows between Le Havre (France) >>> Atlanta (USA)
 - Product LOVENOX, one of the 3 major products of Sanofi-Aventis
 - # 100 million Syringes shipped in 2009
 - Gradual establishment in 2006/2007 after validation of the flow
 - Economy per year since 2007 :
 - > 15 Million Euros
 - > 45 000 Tons CO2











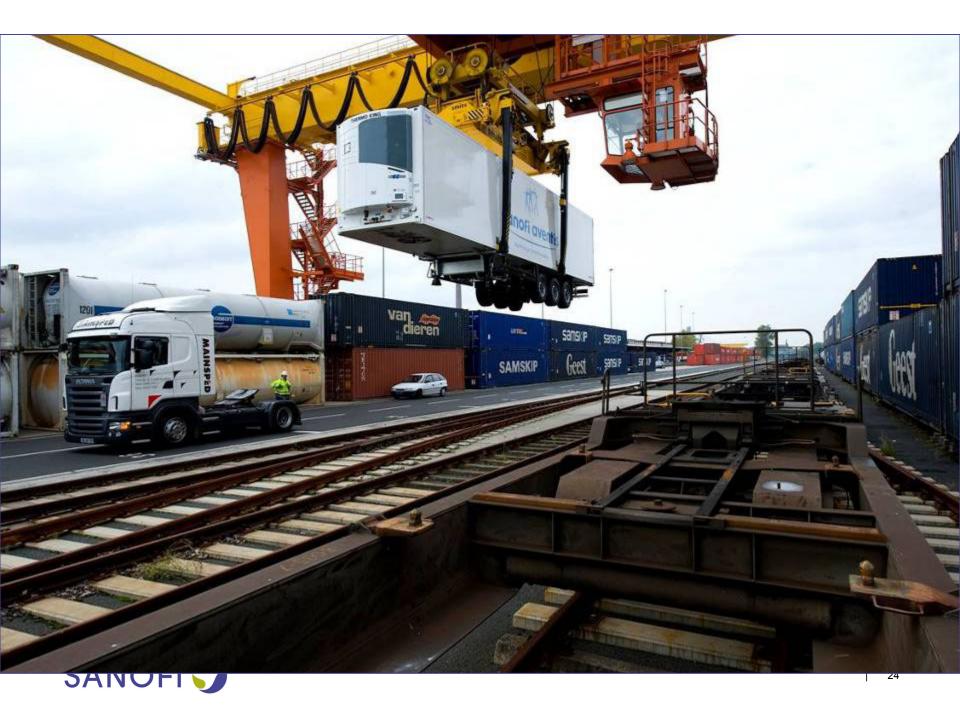
Some initiatives of Sanofi to reduce environmental impacts

- Harbor approaches, choice of an alternative solution: rail or river :
 - Rail: Valenton (near Paris) → Marseille (840km) for the Algerian Market
 - 100% of the containers shipped by Rail
 - Economy per year vs truck shipments:
 - > 150 K€
 - > 150 tons of CO2 (>250 trucks less on the road)

- Barge : Gennevilliers (near Paris) → Le Havre (330km) for North America,
 Asia, Middle East and Africa
 - 100% of the containers shipped by barges on the Seine
 - Economy per year vs truck shipments:
 - > 20 tons of CO2 (>220 trucks less on the road)
 - Same cost: 100% environmental decision



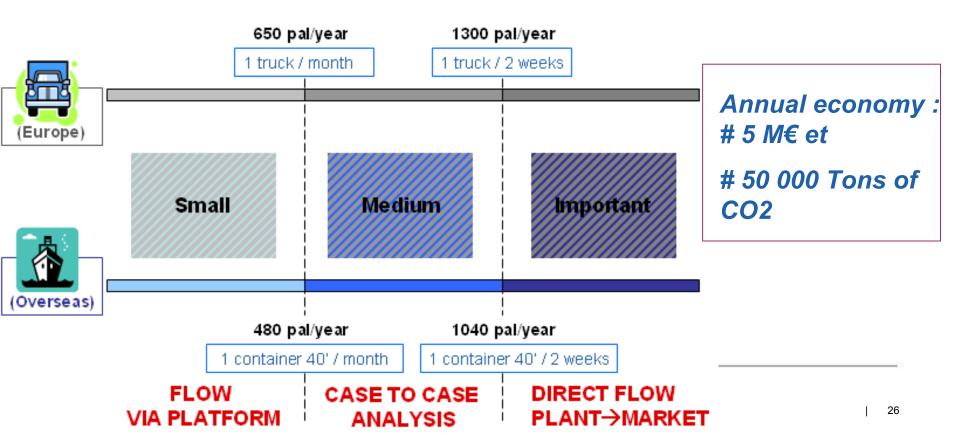






Some initiatives of Sanofi to reduce environmental impacts

- Revew of all the physical flows of our products: Intra-Europe & Intercontinental (from Europe)
 - Option to initiate direct shipments from the manufacturing sites
 - Or shipments from the manufacturing sites to a distribution center for consolidation (France, Germany, Hungary)



Statement & Prospects

 These initiatives of sustainability are only the first step of a new way of 'thinking the transport'



SUSTAINABLE DEVELOPMENT AWARDS









The Export Distribution - Transport





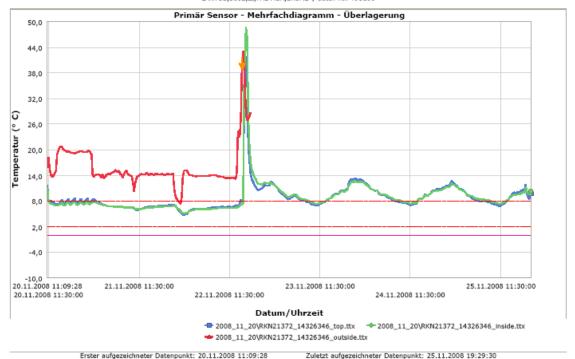
QUALITY of TRANSPORT

- Pharmaceutical products & Vaccines are :
 - High Sensitive Goods
 - Very expensive
 - Health related
- The consequences of a damage can be very important :
 - Cost of Replacement
 - Market loss
 - Tender loss
 - Company Image
 - Risk for the patient
 - adverse effects
 - discontinuation of treatments
 - QUALITY of export transport has to be the first priority



COLD CHAIN FAILURE

Chile - 20.11.2008 / RKN 21372 PC / del. 14326346 LANTUS,300E,LI,PAL MSA,1X3ML / batch no. 40U100



Gedruckt 27.11.2008 13:01:08



31

Physical Damages







Physical Damages : i.e. Water damages







Theft





TRANSPORT SECTOR

- VERY SENSITIVE SECTOR
- STRONG IMPACT OF THE ECONOMIC CRISIS
- LOCAL / REGIONAL / GLOBAL ACTORS
- NUMEROUS PLAYERS INCLUDING SUB-CONTRACTORS
- WIDE RANGE OF QUALITY STANDARDS
- MASS SYSTEM : not really adapted to Pharmaceutical standards



TRANSPORT SECTOR

- ex. Ocean Freight
- No specific care
 - Capacity:
 - over 4 500 Teus capacity
 - 700 reefer units plugs
 - Profitability:
 - loading rates: about 100 moves / hour
 - Crew:
 - less than 20 people
 - 1 electrician for 300 reefers





Wher

HOW TO PREVENT RISKS

- Choice of the forwarder / quality agreement
- Cooperation / partnership with the forwarder
- Control / Audit of the different actors of the flow
 - quality of the material (trucks, containers, temperature recorders...)
 - quality of the installations at departure and arrival points (ports, airports)
 - transport from port or airport to destination : inland transport for intercontinental flows
 - preparation & handling contraints
 - custom constraints
- Awareness campaigns for the partners of the flow
- Choice of a preparation linked to the mode of transport and the flow (wrapping, seals...)
- Adapted temperature control



HOW TO PREVENT RISKS

- We evaluate solutions for being able to follow our 'strategic' shipments'
- Real time position & temperature follow-up with RFID/GPS systems
- Alert management



The Export Distribution - Transport











Quality of the installations at departure and arrival points (ports, airports)



Handling at the airport



Handling and storage at destination

ATLANTA COOLERS

WHO TO CALL

For more detailed information, contact the Cargo Call Center at 1.800.DLCARGO (1.800.352.2746)

Hours of Operation 0600 - 0100 7 days a week

OR

email the Cool Chain Crew at coolchain.cgo@delta.com

> Hours of Operation 0500 - 2200 7 days a week

SHIPPING TIPS:

- Use the right coolant for the fransit time.
- Place cools its on the bottom and top.
 Minimize the time between packing.
- she ship ment.
 Meet all government regulations.
 hey vary from state to state, and
- they are your responsibility.

 Proport handling with lightweight packing units.

PACKAGING:

- Packing to withstand a total transit time of at least 72 hours.
- Resistance to external puncture is critical.
- Bands must not out containers.



SPECIAL HANDLING

Shipper is responsible for packing to with stand a total transit time of all cast 72 hours internationally, but of refrigeration.

Transit time begins at normal tendentime at the originating oily and ands all the time of consignee notification of the shipments sinival. Wasternia

Trozen i ems being held by I shank Wildlife will be handled by the Atlanta Perishables Cemer

DOCUMENTATION

A typed International AVVB must accompany each stripment.

5: for ents should be disarly labeled as Perishable.

Your shipment must be legibly marked on two adjuding sides with the name, stood adjuding sides with the results of the both shipper and consignes. Old labels and makings must be in move or obligated.

REGULATIONS

Dry Ide transforms into CO2 and can displace mages in encloses places. The classifier as fidelyness goods for an transport and sist in or in expanding powers mentingulations. You are responsible for compliance with those resulations.

GENERAL INFORMATION

This service is for Allanta informal and outbound international perishable cargo CNL**

All international perishables transiting the Allania station will be able to our zerom new cooler facility.

We have tour coolers that Range from 33°T to goes

Cooler #1 33/E/1°C Cooler #2 38 F/3°C Cooler #3 45°F/7°C Cooler #4 55°F/13°C

RESTRICTIONS

Currently De la Cargo does not have the recursed apecialty edularment for storage of Pover thems. It products requiring a close of treatment, and him get on

Shipments should not be seet in the coolers more if an 24 nours unless extensive customs held or extenuating circumstances.

We, be is prohibited.

DROP OFF/PICK UP

You need to take your shipment to your local cargo facility for shipping and pick it up at the local cargo facility at the destination.

For shipments terminating in Atlanta you will be up neighbor on the model of the facility located at 1500 Aviation 5 vo, Bullding B. Atlanta, 6A 90394. Additional beaveil apply fryou choose to pick up your an orient at any exertion other than the Bella Cargo spills.

BOOKING

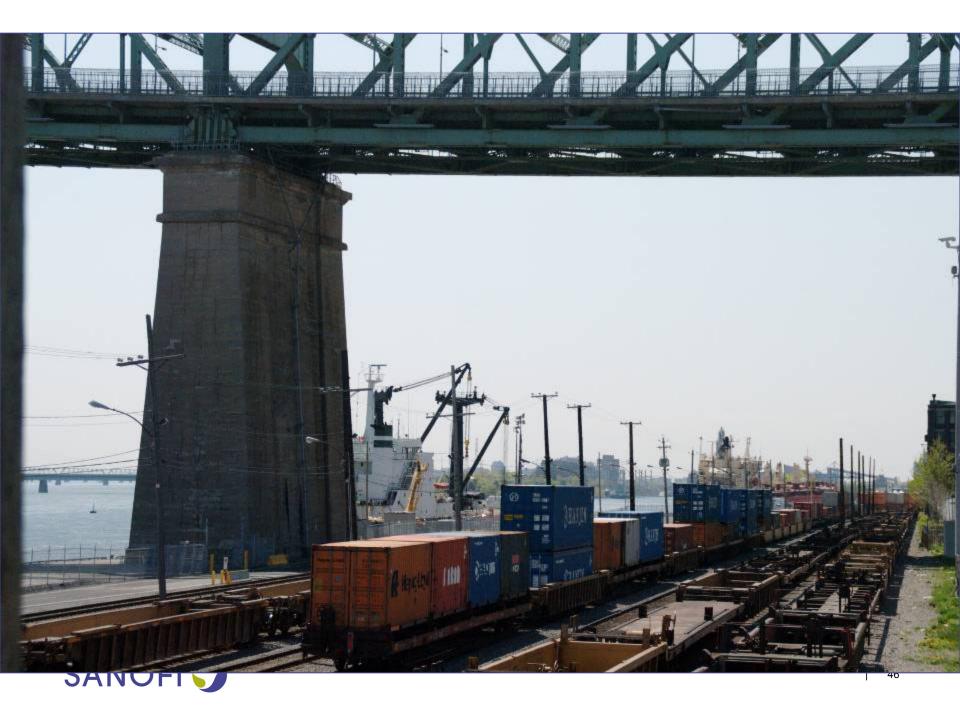
You may book your shipment on deltarargodom or call the Cargo Call Centeria 1 900 DECARSO.



Between ty (Quill)







The Export Distribution - Transport





Quality of the preparation



Pallet tags – Heat treated pallets







Bulk transport



Security Seals







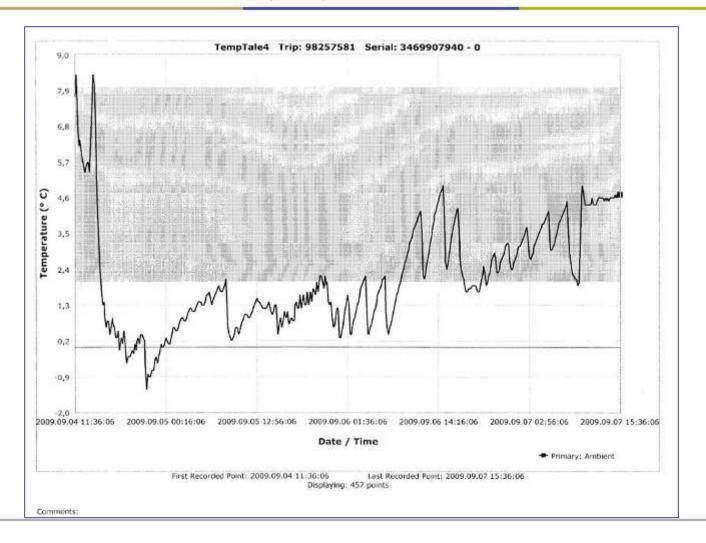
Temperature recorders





Temperature recorders

unit cooled to the set point prior arrival









The Export Distribution Communication & Partnerships



Communication / Training

- For Sanofi, the distribution is 100% part of the core business of the company
 - Key objective of controlling all the steps of the export flows
- Plan of communication inside and outside the company about our initiatives in term of distribution
- Partnership with universities (International trade, Pharmacy, Logistics...)



