



BIOMÉRIEUX



## Industrial Applications Day

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4 December 2007



Indépendance  
Indépendance



B I O M É R I E U X

International  
International

Infectiologie  
Infectiologie

Innovation  
Innovation

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- 10:40 ..... Welcome
- 10:50 ..... Industrial Applications
- 11:35 ..... Food Applications
- 11:55 ..... Biopharma Applications
- 12:15 ..... Q&A Session
- 12:35 ..... *Lunch with the Management Team*
- 13:35 ..... Product Display
- 14:20 ..... Industrial Applications Research and Development
- 14:50 ..... Customer Testimonial
- 15:20 ..... Industrial Applications Outlook
- 15:35 ..... Conclusion
- 15:45 ..... Final Q&A Session

# Today's Speakers

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**Alain Mérieux**  
*President*



**Alexandre Mérieux**  
*Corporate Vice President,  
Industrial Applications*



**Joseph Jammal**  
*Industrial Applications,  
Food Business*



**Renaud Jonquères**  
*Industrial Applications,  
Biopharma Business*



**Vincent Atrache**  
*Industrial Applications,  
Research and Development*



**Sylvain Bernard**  
*Quality Director  
Blédina*



**Stephane Bancel**  
*Chief Executive Officer*



## 1. **Industrial Applications and bioMérieux** *Alexandre Mérieux*

2. Food Applications

3. Biopharma Applications

4. Q&A Session

5. Industrial Applications Research and Development

6. Customer Testimonial

7. Industrial Applications Outlook

8. Conclusion

9. Final Q&A Session



# bioMérieux's Mission

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- ▶ Contribute to the improvement of public health worldwide through *in vitro* diagnostics
  - Clinical applications: patient health
  - Industrial applications: consumer safety and product quality



# bioMérieux: The Leader in Industrial Applications

*Ensuring consumer safety and product quality*

- ▶ Focusing on
  - Prevention of contamination
  - Control of the manufacturing process and final product
  
- ▶ In the food sector
  - Early detection of pathogens in food manufacturing
  - Enumeration of quality indicators
  
- ▶ In the biopharmaceutical sector
  - Environmental monitoring
  - Product testing





# A Strong Need for Microbiological Control

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- ▶ Frozen peperoni pizza linked to *E.coli* outbreak
  - 21 cases
  - 8 hospitalizations: kidney conditions, hemolytic syndrome
  - Nationwide product recall
  - General Mills
  - Brand at stake: 120 million pizzas produced yearly



# A Strong Need for Microbiological Control

**TIMES ONLINE**

NEWS COMMENT BUSINESS SPORT LIFE & STYLE ARTS & ENTERTAINMENT

UK WORLD POLITICS WEATHER TECH & WEB RELATED REPORTS

Where am I? Home News UK

From Times Online

October 6, 2004

## Flu vaccine blackspots warning over faulty batch

By Times Online and PA News

Doctors' leaders warned today that the licence suspension of a major flu vaccine supplier would have a significant impact on the UK's immunisation programme.

The UK-based manufacturer Chiron Vaccines said yesterday it would not supply any batches of Fluwizin around the world this winter after its licence was suspended by the UK's Health products Regulatory Agency.

**USA TODAY** Home News Travel Money Sports Life Tech

News » Health & Behavior Medical Resources Health Information Your Health: Kim Painter

## Producer stands by recalled contact lens

**FDA** U.S. Food and Drug Administration U.S. Department of Health and Human Services

[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#)

### FDA Statement

FOR IMMEDIATE RELEASE  
Statement  
March 18, 2005

Media Inquiries: 301-827-6242  
Consumer Inquiries: 888-INFO-FDA

#### FDA Issues Nationwide Alert on ONE lot of Pharmedium Services magnesium sulfate solution

FDA is issuing a nationwide alert against the use of PharmEDIUM Services Magnesium Sulfate 1 gram in 50mL D5W (piggyback) IV solution, lot number 100504900049 and expiration date 4/4/05. This product is manufactured by PharmEDIUM Services of Houston, Texas and may be contaminated with *Serratia marcescens* bacteria that can cause serious, life-threatening illness in patients with compromised immune systems.

| Save | Print | **RSS**

Tuesday it stands by the product to be

resident and chief of the marketing conference call.

Multi-Purpose Solution, to prevent infection.

which is caused by a bacterial infection. For more information, visit [FDA's Disease Control and](#)



# The Control Process



*Reagents*

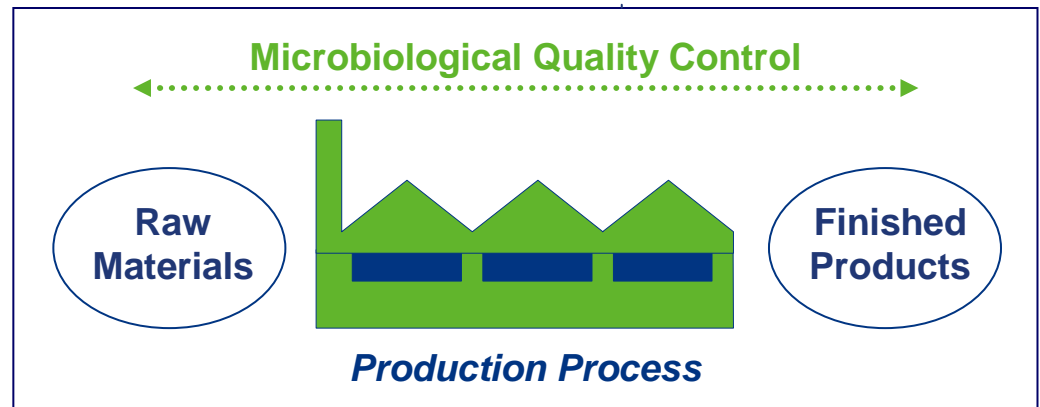
*Instruments*

*Software*



*Sampling*

*Results*



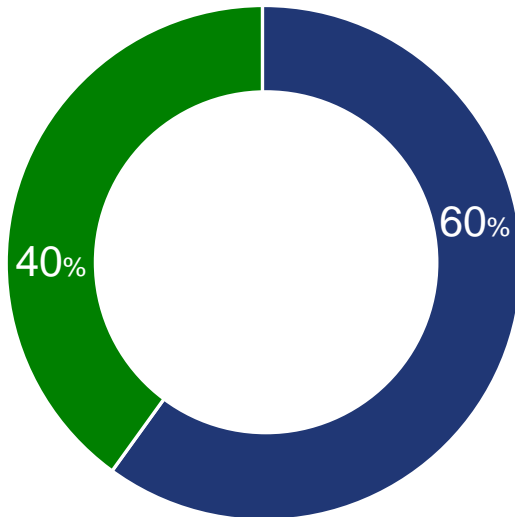
|                       |        |  |                                       |  |            |
|-----------------------|--------|--|---------------------------------------|--|------------|
| Mission / Environment | Market | bioMérieux and Industrial Applications | The Food Market: bioMérieux Solutions | The Biopharma Market: bioMérieux Solutions | Conclusion |
|-----------------------|--------|--|---------------------------------------|--|------------|



# Market Analysis

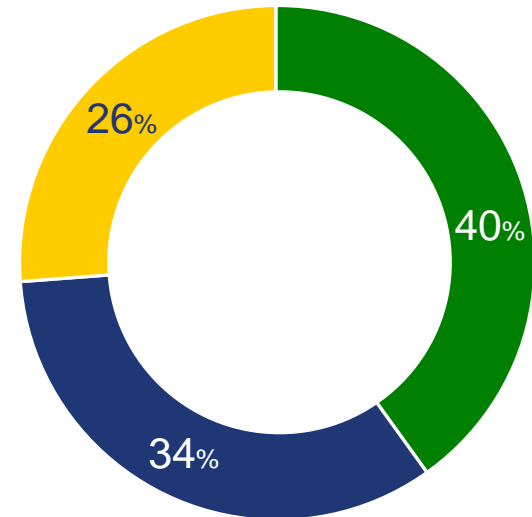
2006 Industrial Applications market: € 1.15 billion

**By Application**



- Food
- Biopharma

**By Region**



- North America
- Europe
- ROW

bioMérieux estimates

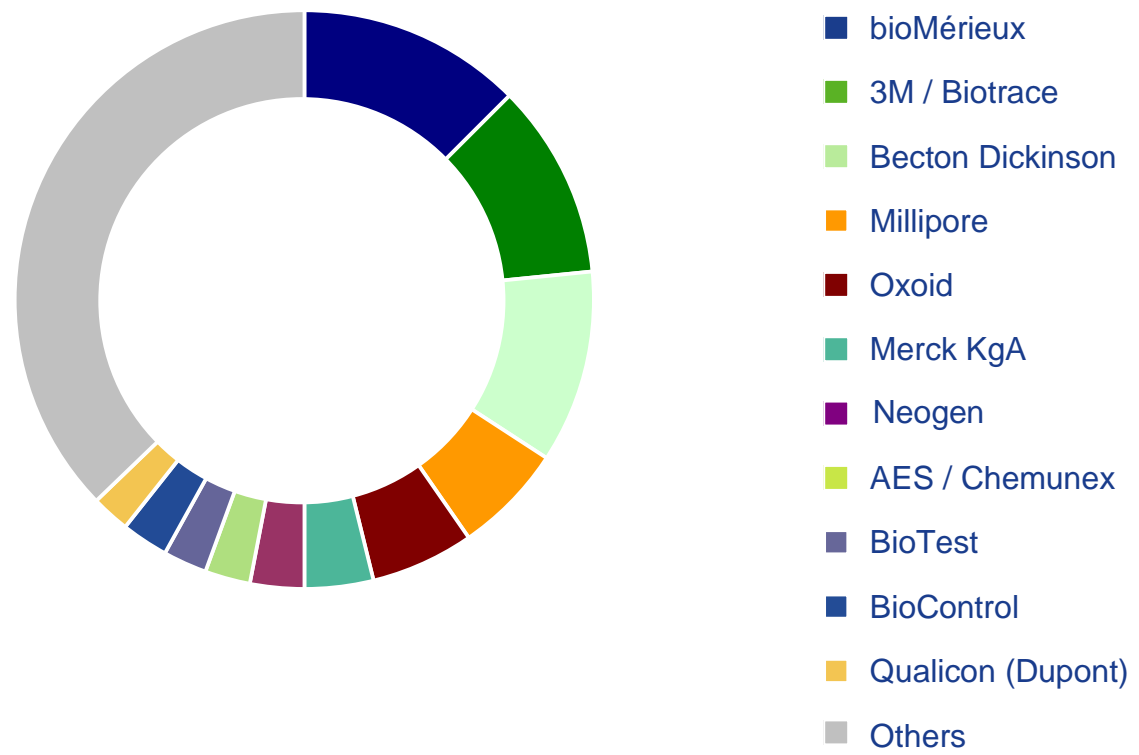
|                       |               |  |                                       |  |            |
|-----------------------|---------------|--|---------------------------------------|--|------------|
| Mission / Environment | <b>Market</b> | bioMérieux and Industrial Applications | The Food Market: bioMérieux Solutions | The Biopharma Market: bioMérieux Solutions | Conclusion |
|-----------------------|---------------|--|---------------------------------------|--|------------|



# Competitive Landscape

*A fragmented market, becoming increasingly concentrated*

▶ Top players represent about 60% of the global market

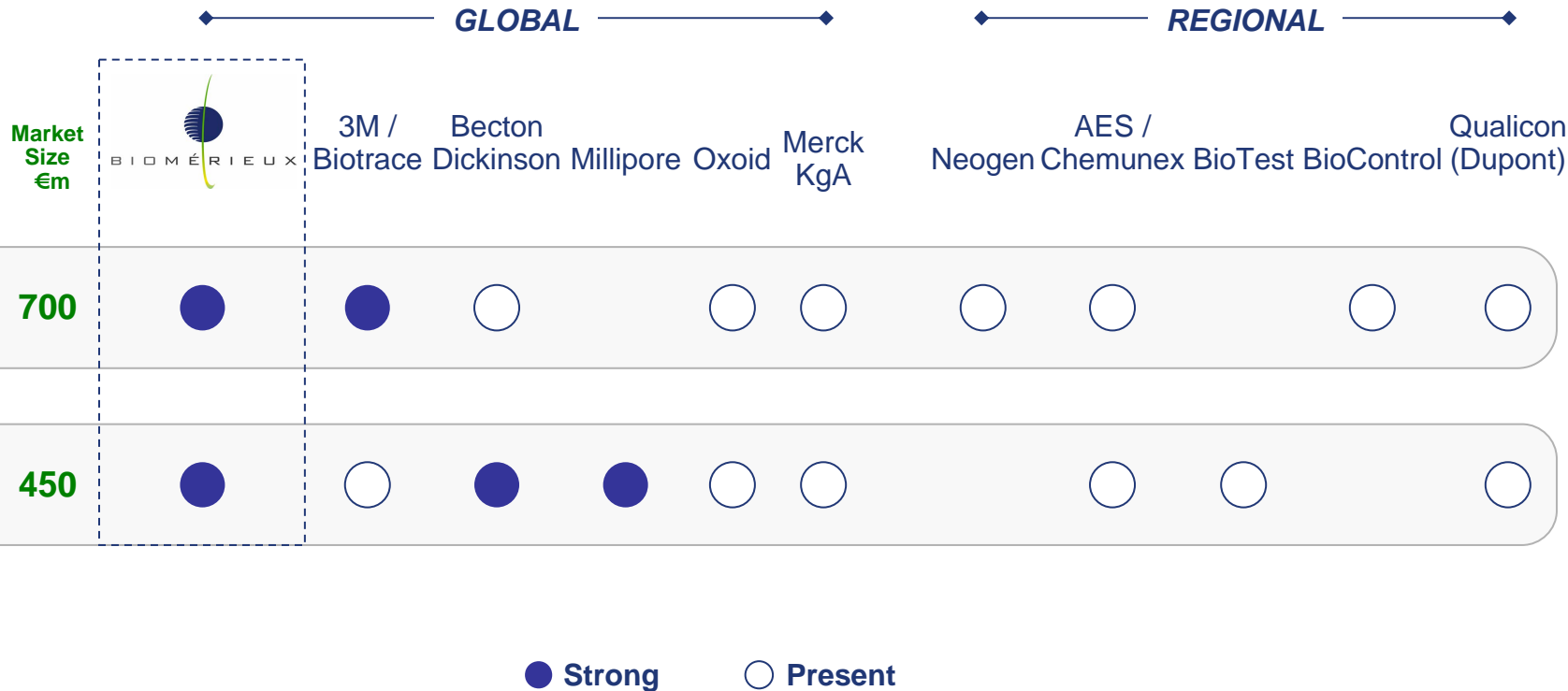


- ▶ Other players
- Local or regional
  - Food or biopharma
  - Single technology

bioMérieux estimates 12



# Competitive Landscape



bioMérieux estimates 13

# Main External Market Drivers

*A growing market: 5-7% per annum*

- ▶ Globalization of food and pharma supply
- ▶ Increasingly stringent regulations
- ▶ Increased consumer and manufacturer awareness of product quality and safety issues
- ▶ Importance of quality in the manufacturing environment  
HACCP - Hazard Analysis Critical Control Point testing



# Main Internal Market Drivers

*A growing market: 5-7% per annum*

- ▶ Importance of short time-to-result for product release
- ▶ Conversion from manual to automated
- ▶ Cost savings
- ▶ International customers/harmonization of quality practices

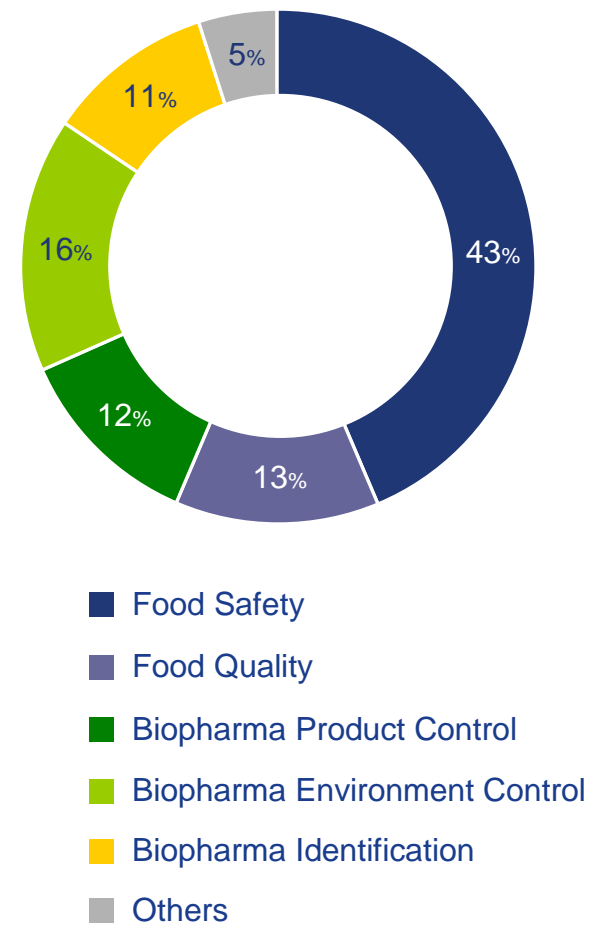




# bioMérieux Market Leader

**Breakdown of 2006 Sales**

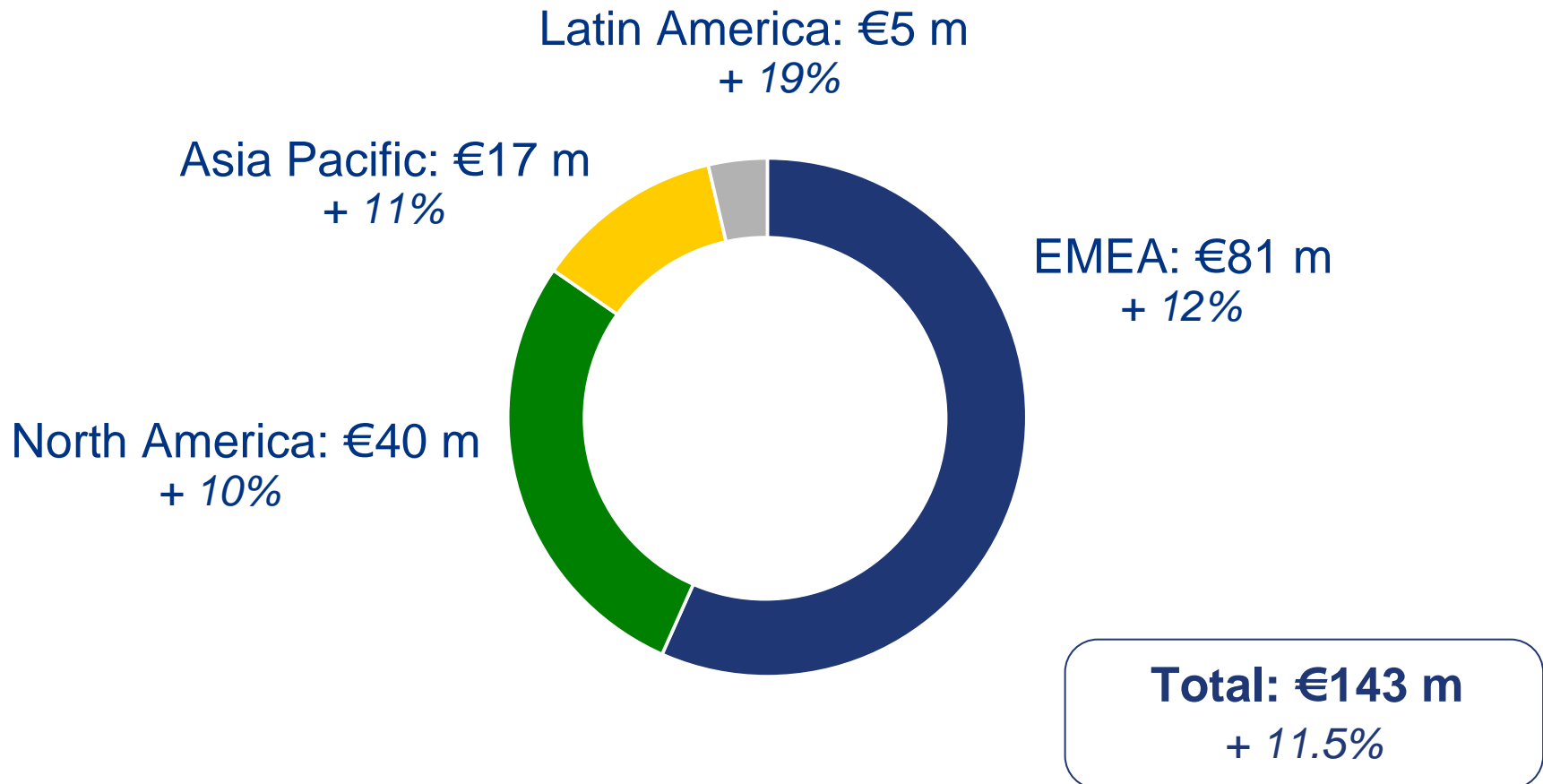
- ▶ **Worldwide leader**
  - Market share: 13%\*
  - 2006 sales: €143 m, up 11.5%
  
- ▶ **Food**
  - Leader in rapid pathogen detection\*
  - 2006 sales: €80 m
  
- ▶ **Biopharma**
  - Leader in identification\*
  - 2006 sales: €55 m



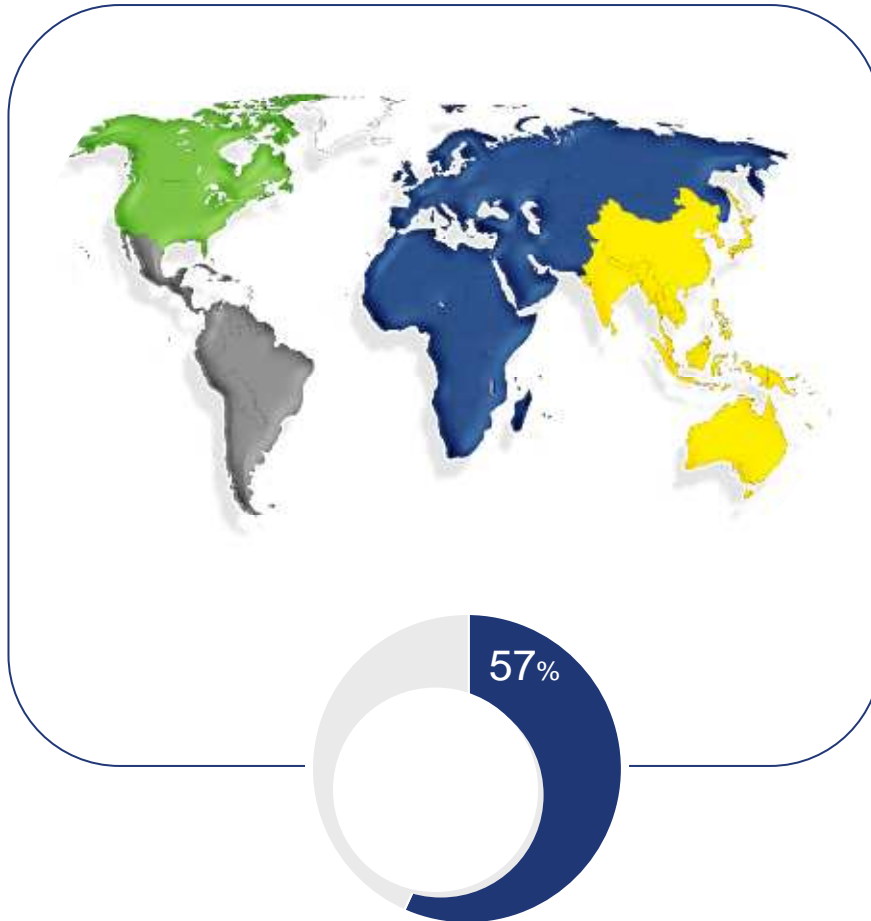
\* bioMérieux estimates

|                       |        |   |                                       |  |            |
|-----------------------|--------|---|---------------------------------------|--|------------|
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# 2006 Sales and Growth by Region



# Europe - Middle East - Africa

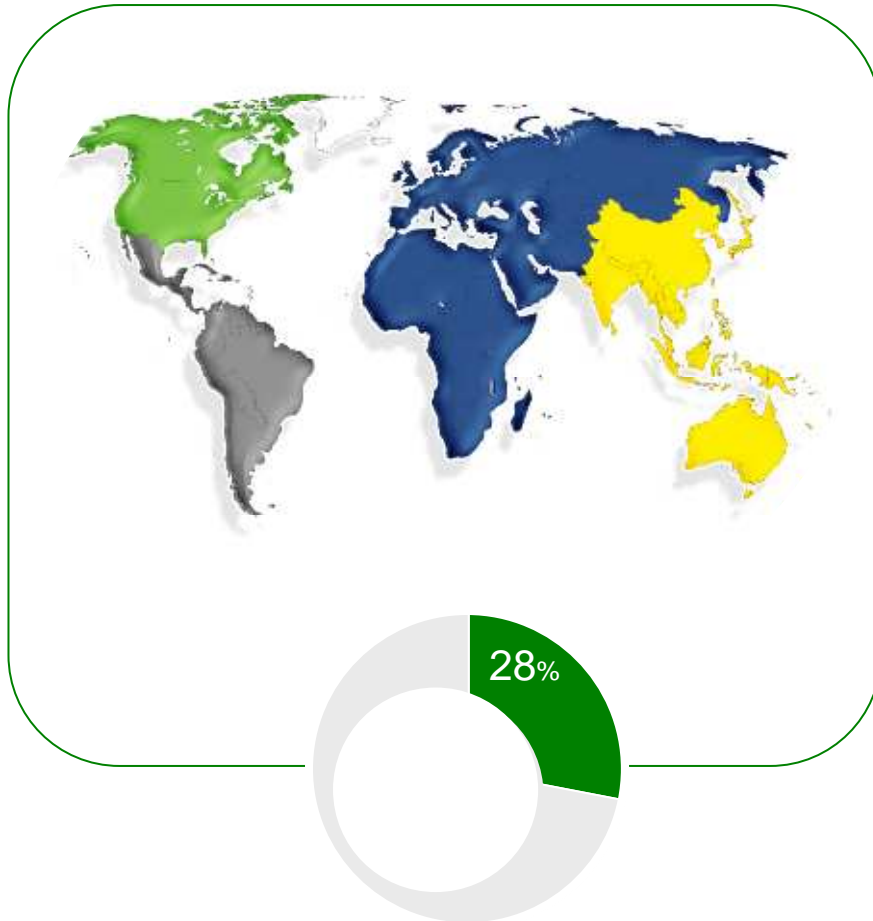


- ▶ Strong market penetration
- ▶ Highly diverse market
- ▶ Harmonization of regulations in food applications
- ▶ 2007 Q3 YTD sales: up 8.6%\*

\*Like-for-like

18

# North America

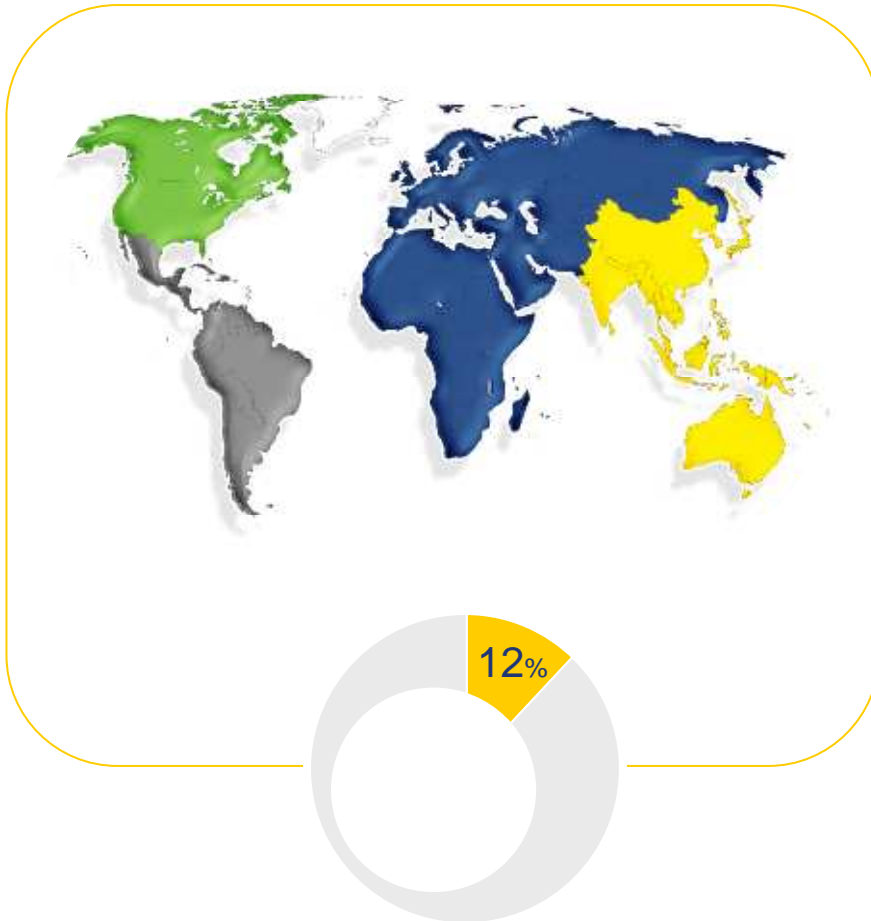


- ▶ Successive contamination outbreaks
- ▶ Recent launch of TEMPO<sup>®</sup>, with USDA recognition
- ▶ Success of VITEK<sup>®</sup>2 Compact and BacT/ALERT<sup>®</sup>
- ▶ 2007 Q3 YTD sales: up 12.4%\*

\*Like-for-like

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# Asia Pacific



- ▶ Highly diverse market
  - Mature in Japan and Australia
  - Developing in China, India and ASEAN
- ▶ Strong brand image in China
- ▶ 2007 Q3 YTD sales: up 14.9%\*

\*Like-for-like

20

# Latin America



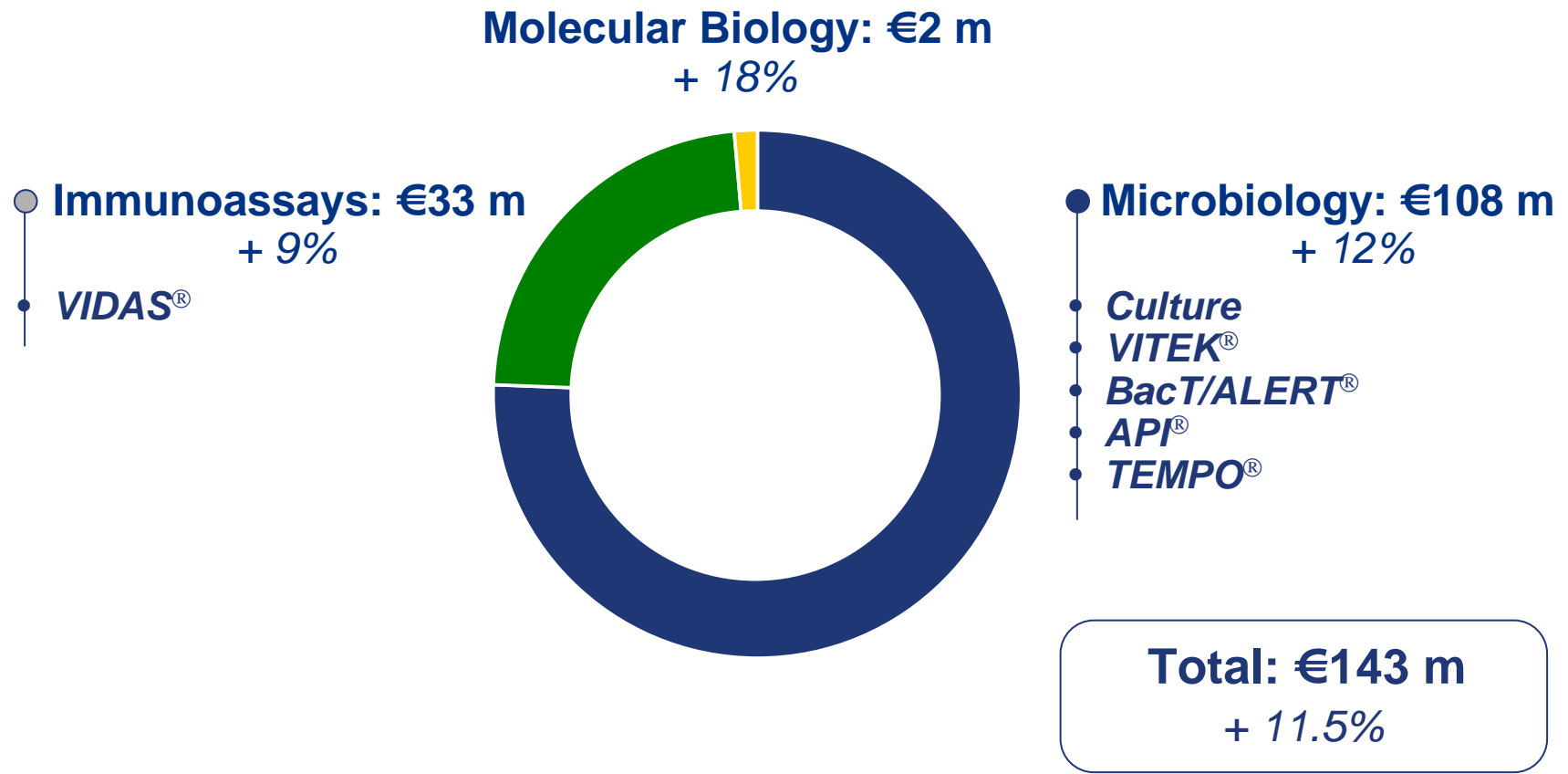
- ▶ Mainly a food market
- ▶ Export countries
- ▶ Emerging pharma industry
- ▶ 2007 Q3 YTD sales: up 27.2%\*

\*Like-for-like

21



# 2006 Sales and Growth by Technology





# Dedicated Teams

*Dedicated sales and R&D people supported by global operations*

in FTE

▶ Sales and Marketing teams\* 243

North America: 52

EMEA: 80



Latin America: 15

ASPAC: 46

▶ Research and Development 103

▶ Manufacturing 40

▶ BTF (acquired in Sept. 07) 24

\* Including customer service

FTE: Full Time Equivalent 23

|                       |        |   |                                       |  |            |
|-----------------------|--------|---|---------------------------------------|--|------------|
| Mission / Environment | Market | <b>bioMérieux and Industrial Applications</b> | The Food Market: bioMérieux Solutions | The Biopharma Market: bioMérieux Solutions | Conclusion |
|-----------------------|--------|---|---------------------------------------|--|------------|



# Food Applications: Customer Needs

## *Ever increasing expectations and needs*

- ▶ Improve performance
  - Analytical performance and menu
  - Time-to-result
  - Official validations and endorsements
  
- ▶ Speed up workflow
  - Ease-of-use
  - Hands-on time
  
- ▶ Reduce global manufacturing cost
  
- ▶ Optimize manufacturing processes
  
- ▶ Secure transcription and registration of testing results
  - Interface with LIMS (Laboratory Information Management System)



# Food Applications: The Control Process

## Food safety

Enrichment



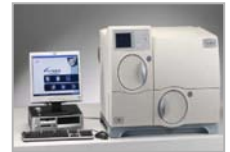
MiniBag® Tubes and Bottles

Pathogen Detection



VIDAS®

Identification



VITEK®2 Compact

Typing



DiversiLab®



API®



PPM



PPM



PPM

## Food quality

Preparation of Sample



Tubes and Bottles

Enumeration of Quality Indicators



TEMPO®

Raw material

Environmental sample

In-process product

Finished product



# Manual Solutions for Food Quality Control

## Yesterday in the lab



Preparation of medium



Preparation of sample



Decimal dilutions



Inoculation



Pouring



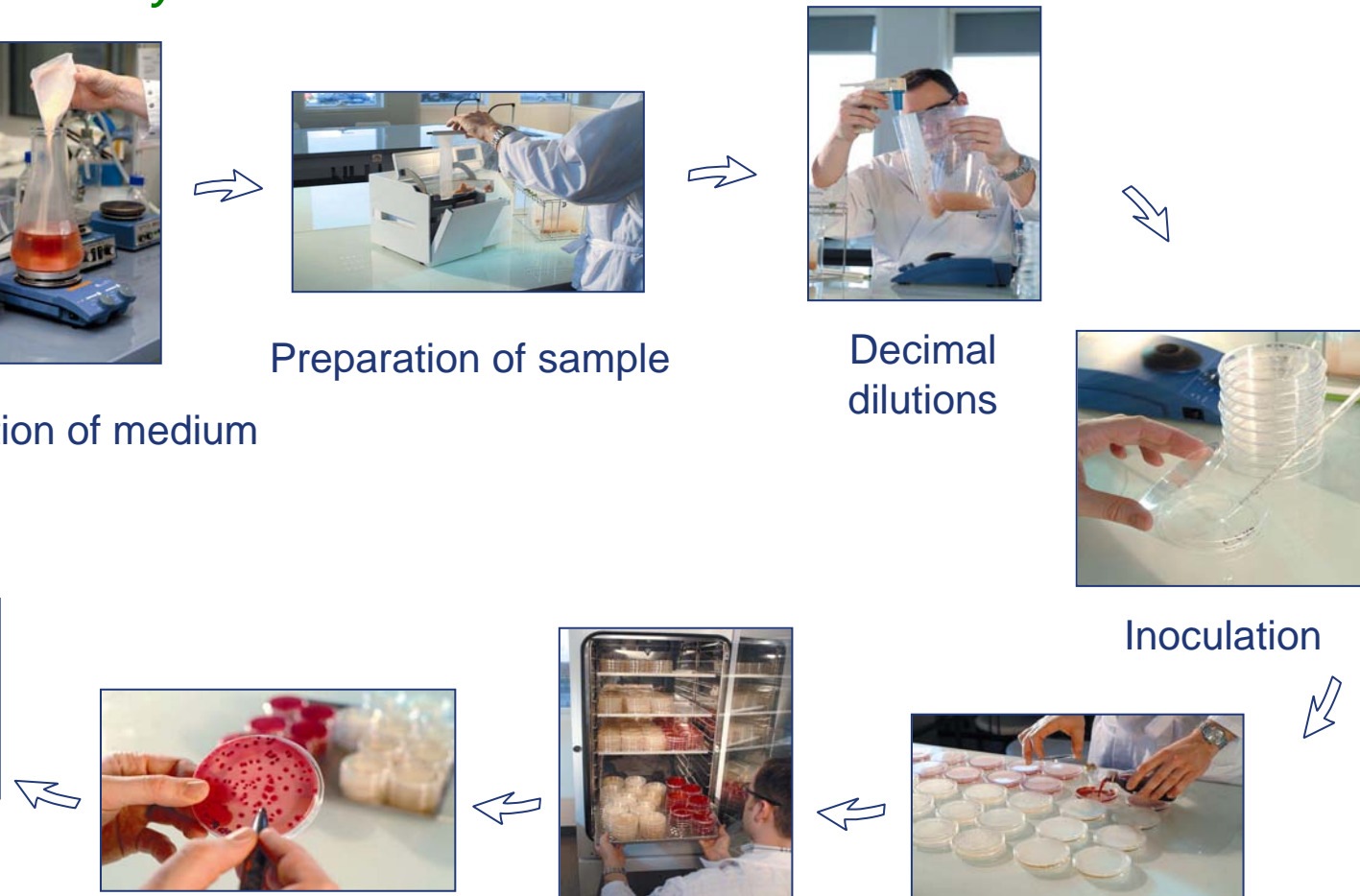
Incubation



Reading



Data input





# TEMPO®: The Solution for Food Quality Control

*Today with TEMPO®*

- ▶ **Faster processes**
  - 4 steps instead of 8
  
- ▶ **Simpler processes**
  - From manual to automated
  
- ▶ **More reliable method**
  - Traceability
  - LIMS – Laboratory Information Management System – interfacing



# Biopharma Applications: Customer Needs

- ▶ Continuous pharmacopoeia compliance
- ▶ Zero defect
- ▶ High reproducibility
- ▶ Solid documentation and quality management system
- ▶ In-process control solutions
- ▶ Information management



# The Biopharma Control Process

## Environmental control

- Air sample
- Surface sample

### Detection



*AirIDEAL™*

QUANTISWAB™



*Count-Tact™*



*DiversiLab®*

## Product control

- Raw materials
- Water
- Additives
- Finished products

### Preparation of Sample

### Detection



*Tubes and Bottles BioBall™*



*BacT/ALERT®*



*VITEK®2 Compact*



*API®*

### Identification

### Typing



# bioMérieux's Offering

- ▶ A very large offering
- ▶ Well integrated in laboratory workflow
- ▶ Covering both the needs of food and biopharma customers
- ▶ From manual to automated products
- ▶ High quality, meeting customer requirements and compliant with regulations



# bioMérieux's Unique Assets

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- ▶ Market shaper and undisputed leader
- ▶ Unique portfolio of complementary technologies
- ▶ Worldwide sales network
- ▶ Leveraging on bioMérieux's global operations and investment capacity
- ▶ Demonstrated ability to integrate external innovation and products



# Outline

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1. Industrial Applications and bioMérieux
2. **Food Applications**  
*Joseph Jammal*
3. Biopharma Applications
4. Q&A Session
5. Industrial Applications Research and Development
6. Customer Testimonial
7. Industrial Applications Outlook
8. Conclusion
9. Final Q&A Session

# Food-borne Contaminations

Each year, contaminated food leads to:

- 2 billion illnesses
- 1.8 million deaths

*W.H.O. estimates*

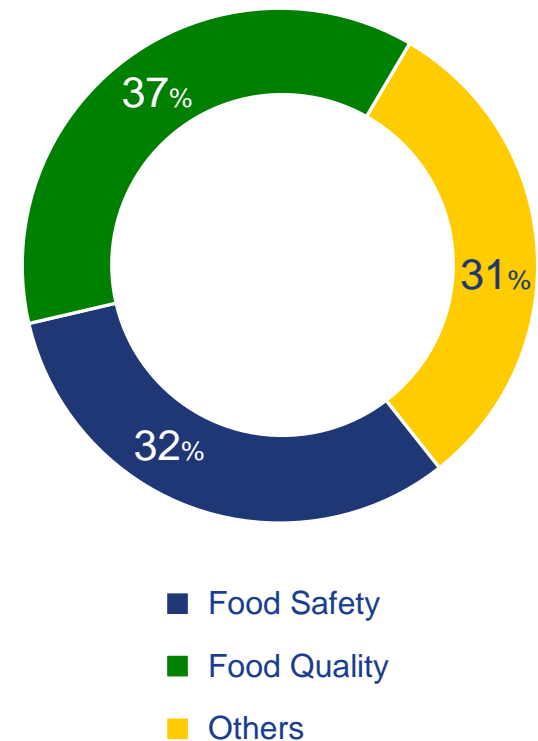
# The Food Applications Market

*A €700 million market, growing at 5-7% per year*

## ▶ 3 main segments

- **Food Safety** ⇒ pathogen flora detection
- **Food Quality** ⇒ quality indicator enumeration for food products or processes
- **Others** ⇒ antibiotic, hormone and metabolic residues, mycotoxines, allergens, pesticides, etc.

## | By Segment



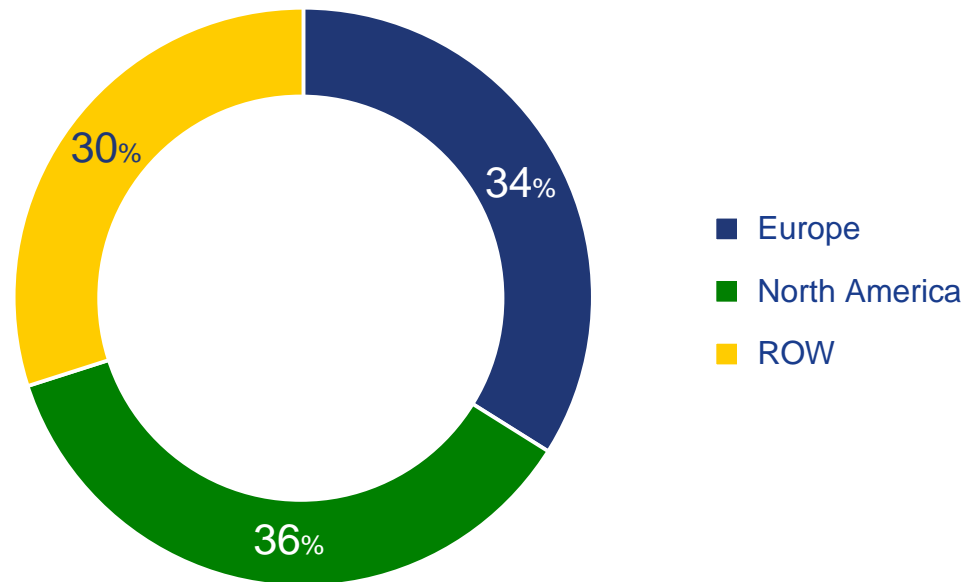
*bioMérieux estimates*

34

# The Food Applications Market

*A well-balanced global market*

## Geographical Breakdown



*bioMérieux estimates*

35

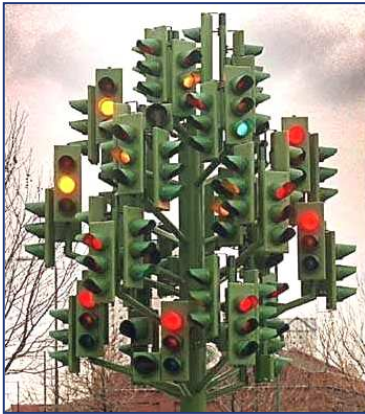
# Market Drivers

## *A growing market*

- ▶ Globalization of trade
- ▶ Growing consumer awareness
- ▶ Customer concentration
- ▶ Changing regulations

# Primary Goal of Regulations: Reduce Food-borne Illnesses

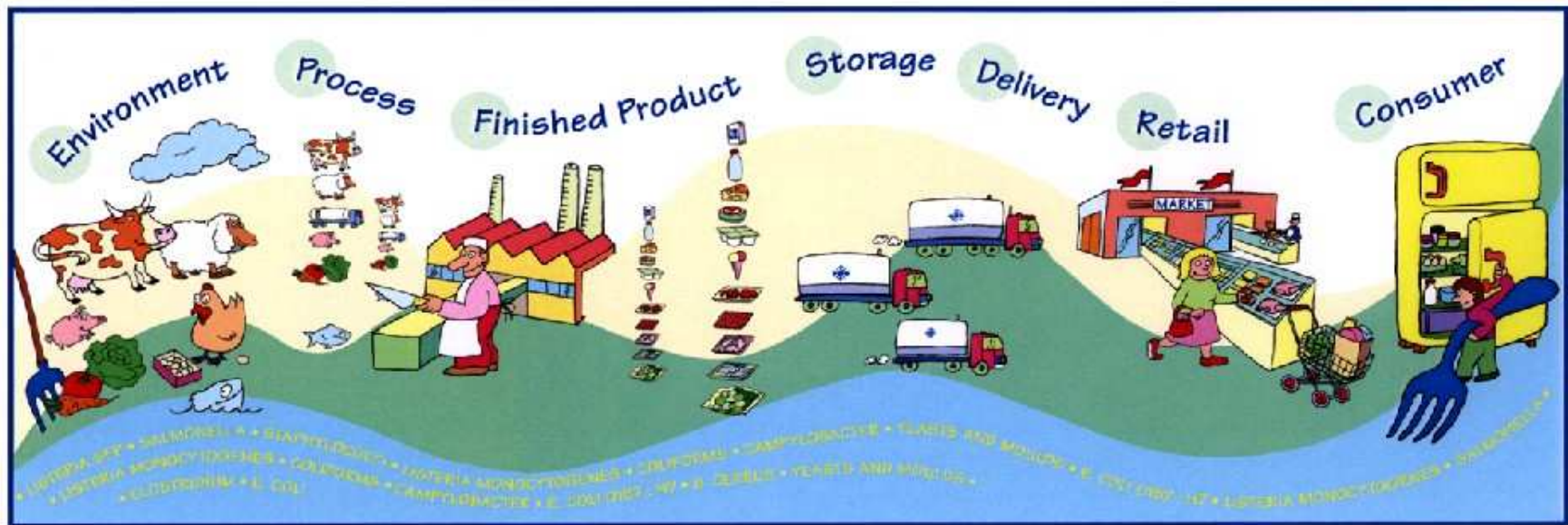
*A strong need for global regulations, consistent interpretation and enforcement*



- ▶ January 2006:  
recent harmonization of microbiological criteria  
in Europe
- ▶ No harmonization yet between Europe and the  
USA

# bioMérieux Food Customers

## *From farm to fork*



- ▶ Food industries: on site and corporate laboratories
- ▶ Service laboratories: private and public
- ▶ Others: food outlet chains, restaurant chains and retailers

# The Food Safety Market

*A €220 million market*

▶ At stake

- Consumer health
- Brand image

▶ An example

August 2006: *Salmonella* outbreak in Cadbury chocolate bars\*

- 37 people infected
- Impact on sales: 14% down
- Total cost for Cadbury: £20 million

\* *The Guardian*, 3 August 2006



# The Food Quality Market

*A €260 million market, mainly conventional*

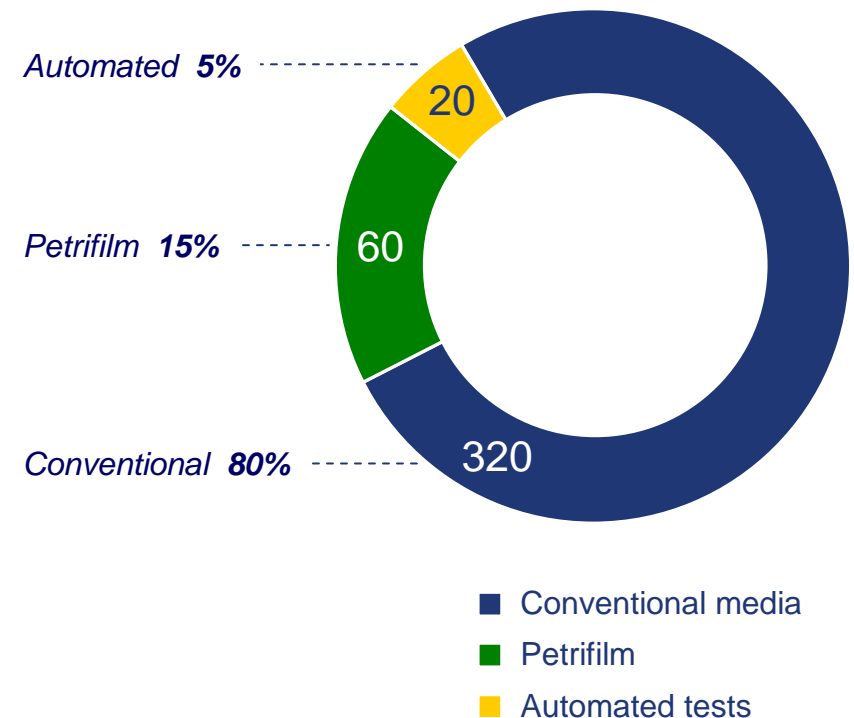
## ► At stake

- Product quality
  - Look
  - Taste
  - Texture
- Financial implications

## ► Strong potential for conversion to automation

### Market breakdown by methods

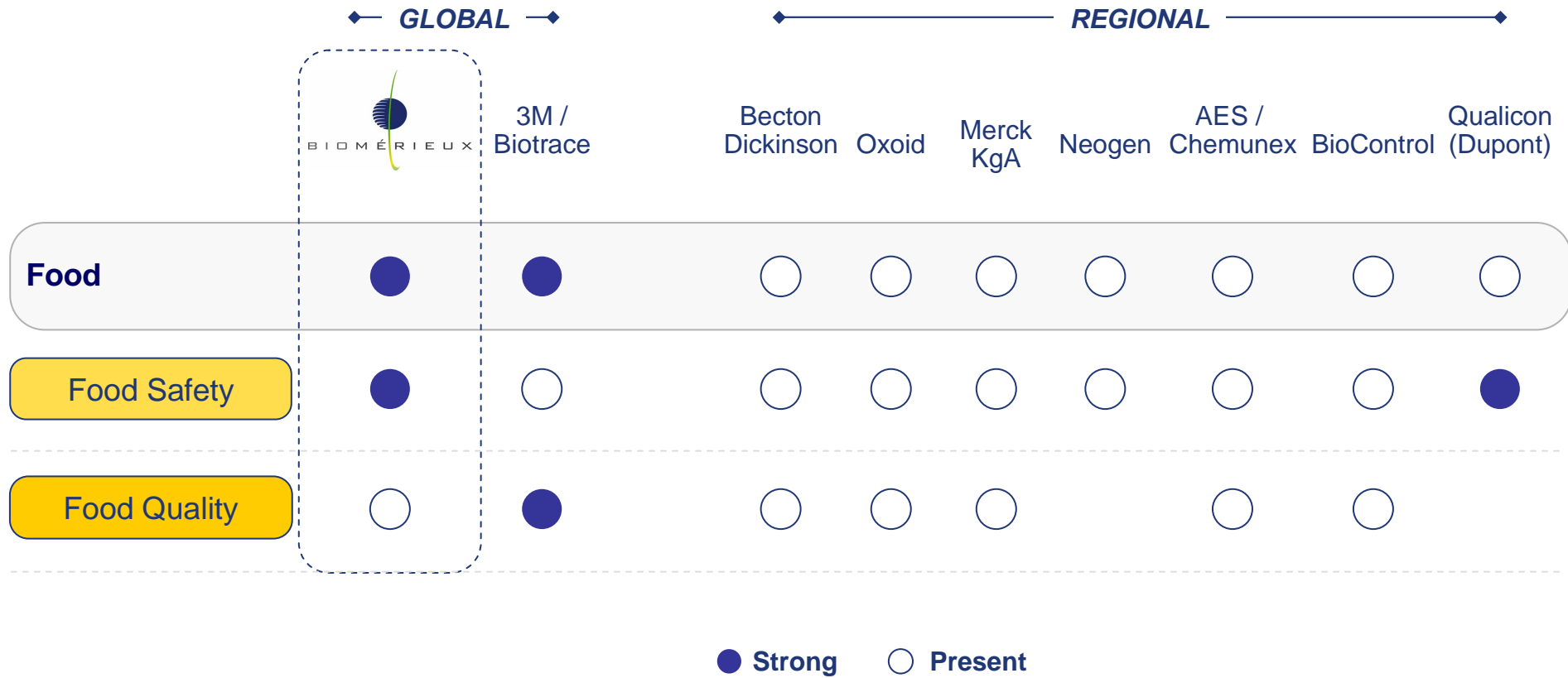
*In volume of tests per year*





# Competitive Landscape

*Two global players in a still very fragmented market*



bioMérieux estimates



# Food Safety

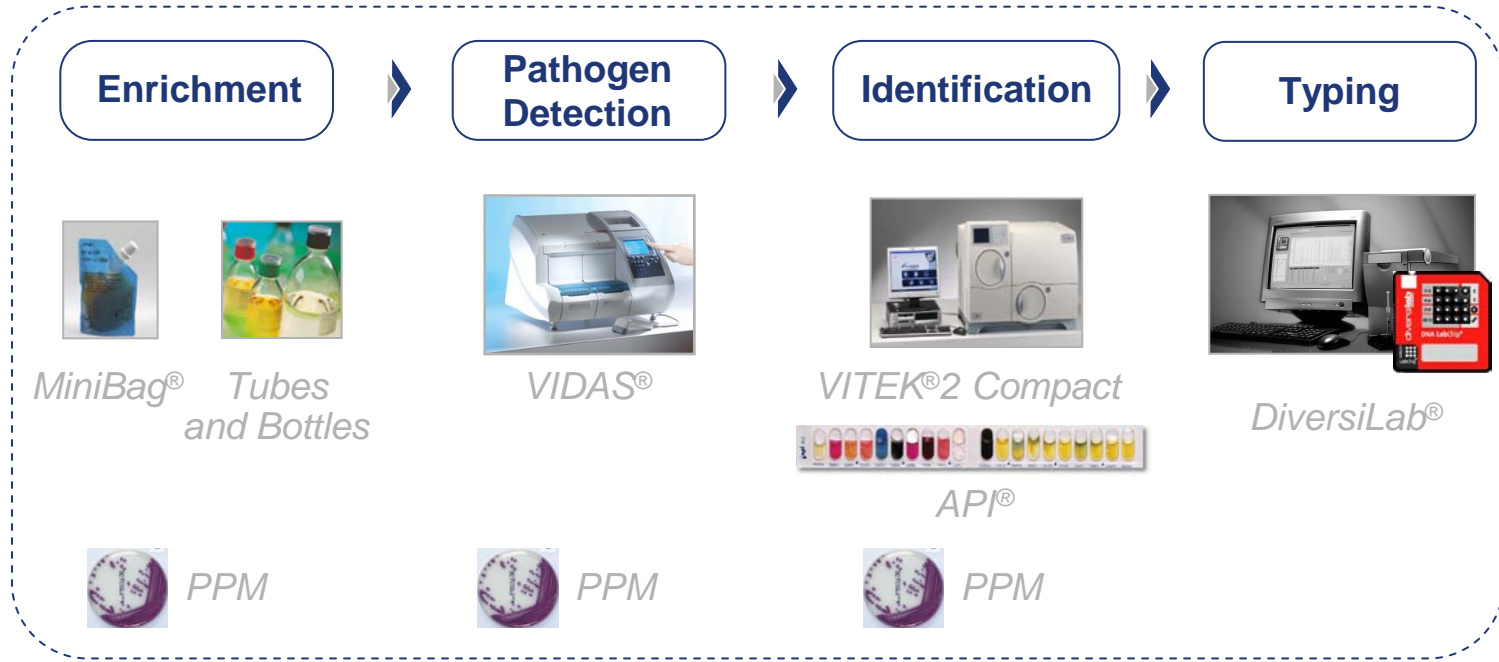
## Food Safety: the most comprehensive offering

Raw material

Environmental sample

In-process product

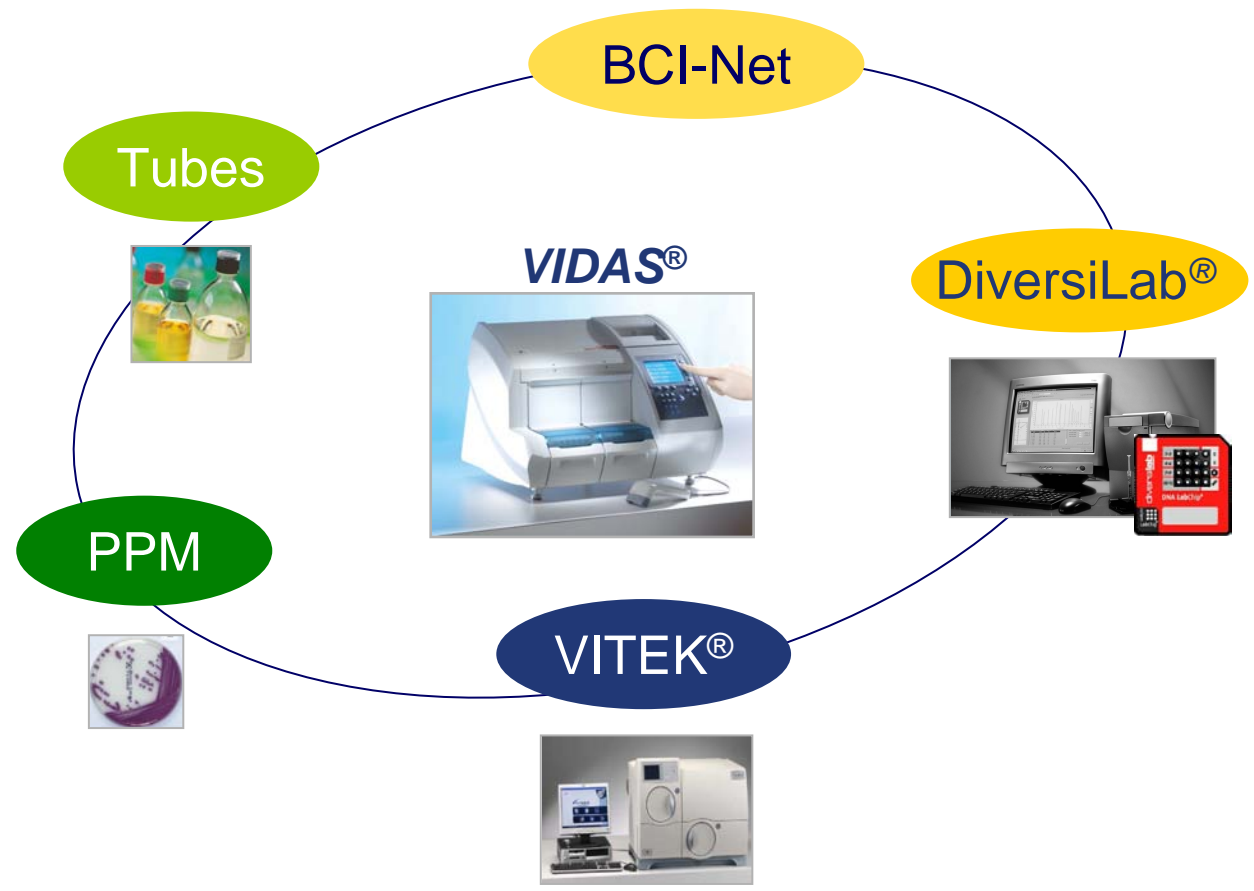
Finished product





# Food Safety: VIDAS®

*VIDAS®: a large base to build upon*



- ▶ Around 2,500 VIDAS®
- ▶ Standardization
- ▶ Robustness
- ▶ LIMS interfacing
- ▶ The largest installed base in the food safety market

# Food Quality

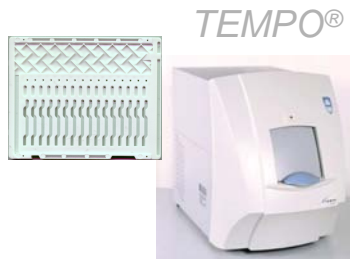
## *TEMPO®: a major technological breakthrough in food quality indicators*

Raw material

Environmental sample

In-process product

Finished product



Preparation of Sample



*Tubes and Bottles*

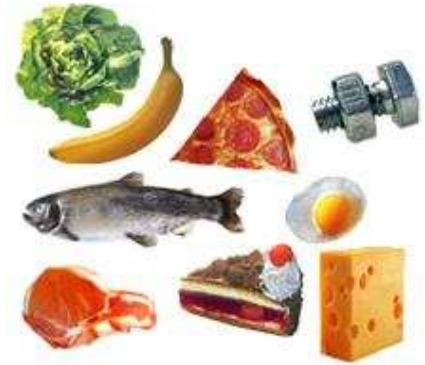
Enumeration of Quality Indicators

- ▶ Current menu:
  - Total Viable Count,
  - Total Coliforms,
  - E. coli*,
  - Enterobacteriaceae*
- ▶ Full traceability
- ▶ Standardization
- ▶ Faster time-to-result
- ▶ Labor cost savings
- ▶ Workflow optimization
- ▶ LIMS interfacing

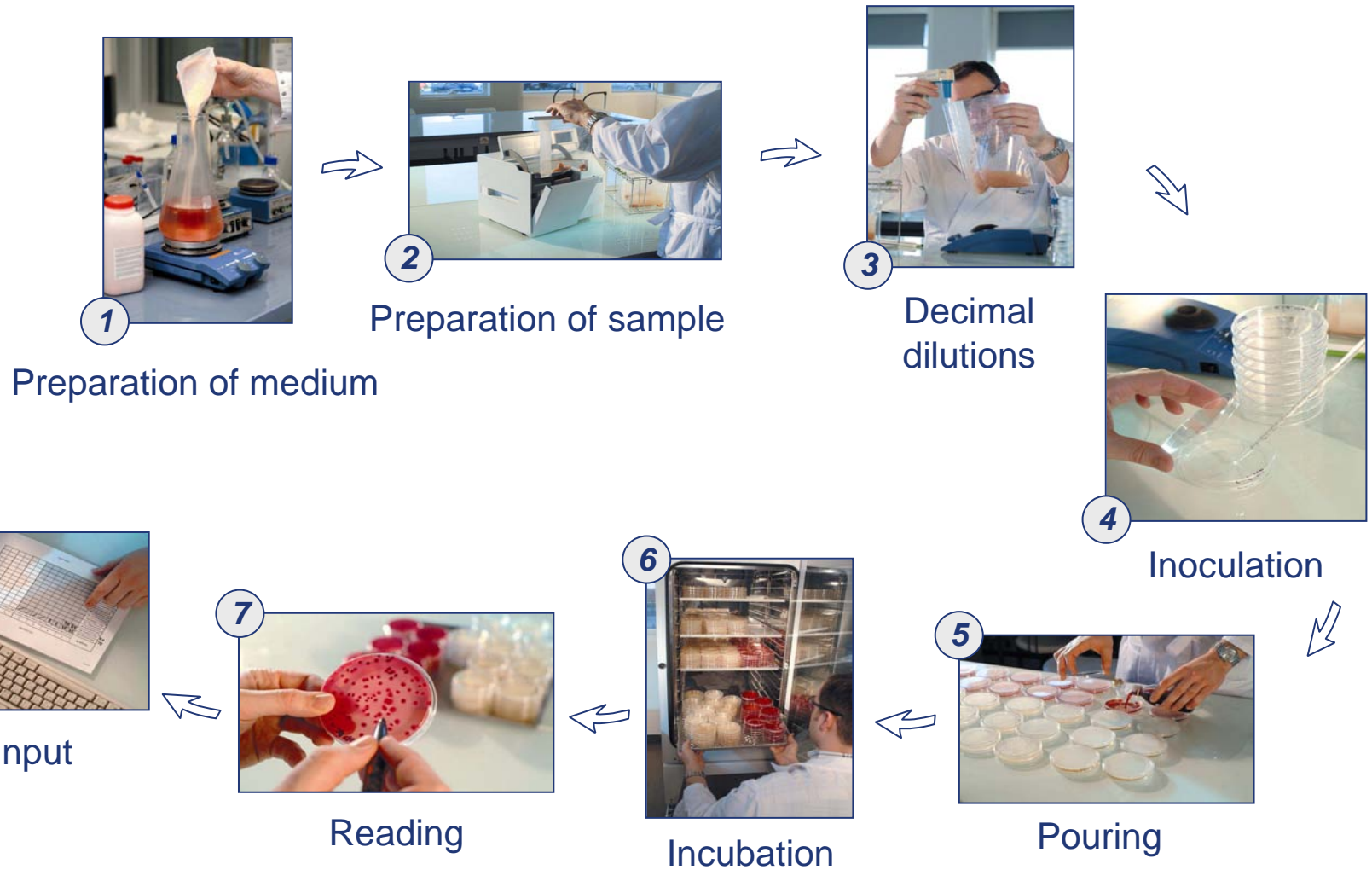
# Integration of TEMPO®: Case Study

## *Integration of TEMPO® in a manufacturer's laboratory*

- ▶ Laboratory organization before TEMPO®
  - All quality indicators
    - In all food matrices
    - In the environment
  - Using AFNOR conventional methods (8 steps)
  
- ▶ 10 people
  
- ▶ 350 samples per day
  
- ▶ From Monday to Friday for the analysis, Saturday for the reading



# Conventional Method





# Today with TEMPO<sup>®</sup>: 4 Steps



1

Preparation of sample



2

Inoculation



4

Reading and automatic data transmission



3

Incubation





# Implementation of TEMPO®

## *A very user friendly implementation in the lab*

- ▶ *Week 1:* 3 people trained by bioMérieux over 2 days
- ▶ *Week 2:* 10% of the samples changed to TEMPO® over 2 weeks
- ▶ *Week 3:* 100% of concerned samples and micro-organisms changed to TEMPO®
- ▶ *Week 4:* Rest of staff trained internally and adaptation to LIMS
- ▶ *Week 5:* All the staff trained

# TEMPO®:

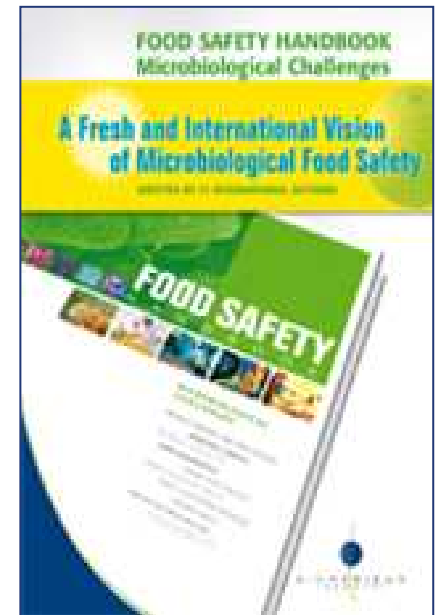
## Key Customer Benefits

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- ▶ Meets increased demand
- ▶ Ensures reliable results
- ▶ Brings flexibility to the organization
- ▶ Makes it possible to take on other activities
- ▶ Focuses staff on higher added-value tasks

# A Unique Scientific Contributor

- ▶ Strong, prestigious international support
  - 24 international experts contributed
- ▶ Pre-launch at the July 2007 Symposium of the International Association for Food Protection in Orlando
- ▶ 1,250 pre-orders
- ▶ A first edition of 2,500 copies



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## *Our strengths*

- ▶ Food Safety: the most comprehensive offering
- ▶ Food Quality: a unique platform with great room for growth
- ▶ A significant scientific contribution to microbiological food testing

# Outline

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3. **Biopharma Applications**  
*Renaud Jonquières*
4. Q&A Session
5. Industrial Applications Research and Development
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- ▶ Provide biopharmaceutical industries with solutions:
  - To guarantee the microbiological safety of their working environments
  - To ensure biopharmaceutical product safety

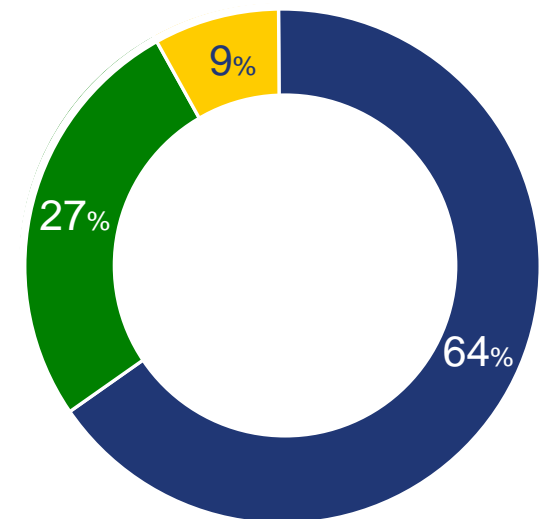
# The Biopharma Applications Market

*A €450 million market focused on three major applications*

## ▶ 3 main segments

- Product control
  - Quality control strains
  - Detection of specific organisms and bioburden
  - Alternative microbiology
  - Sterility testing
- Environmental control
  - Air
  - Surface
  - Operators
- Identification and typing
  - Routine identification
  - Investigations

## | By Segment



- Product control
- Environmental control
- Identification

bioMérieux estimates

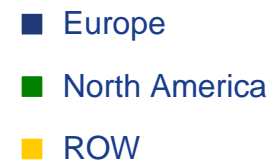
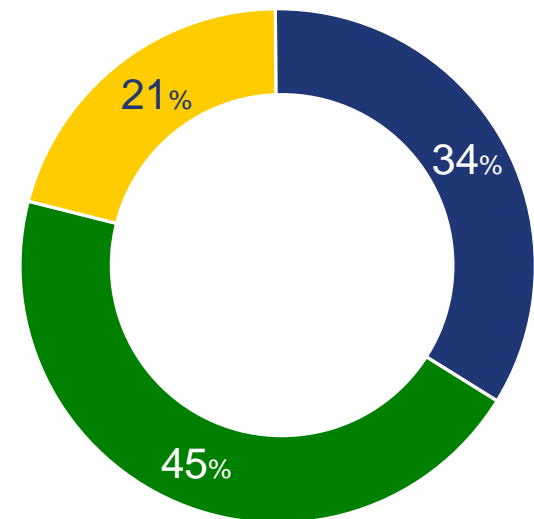
54



# The Biopharma Applications Market

- ▶ €450 million
- ▶ Worldwide accounts
- ▶ Mainly in Europe and North America
- ▶ Strong growth in Asia Pacific

**Geographical Breakdown**



bioMérieux estimates

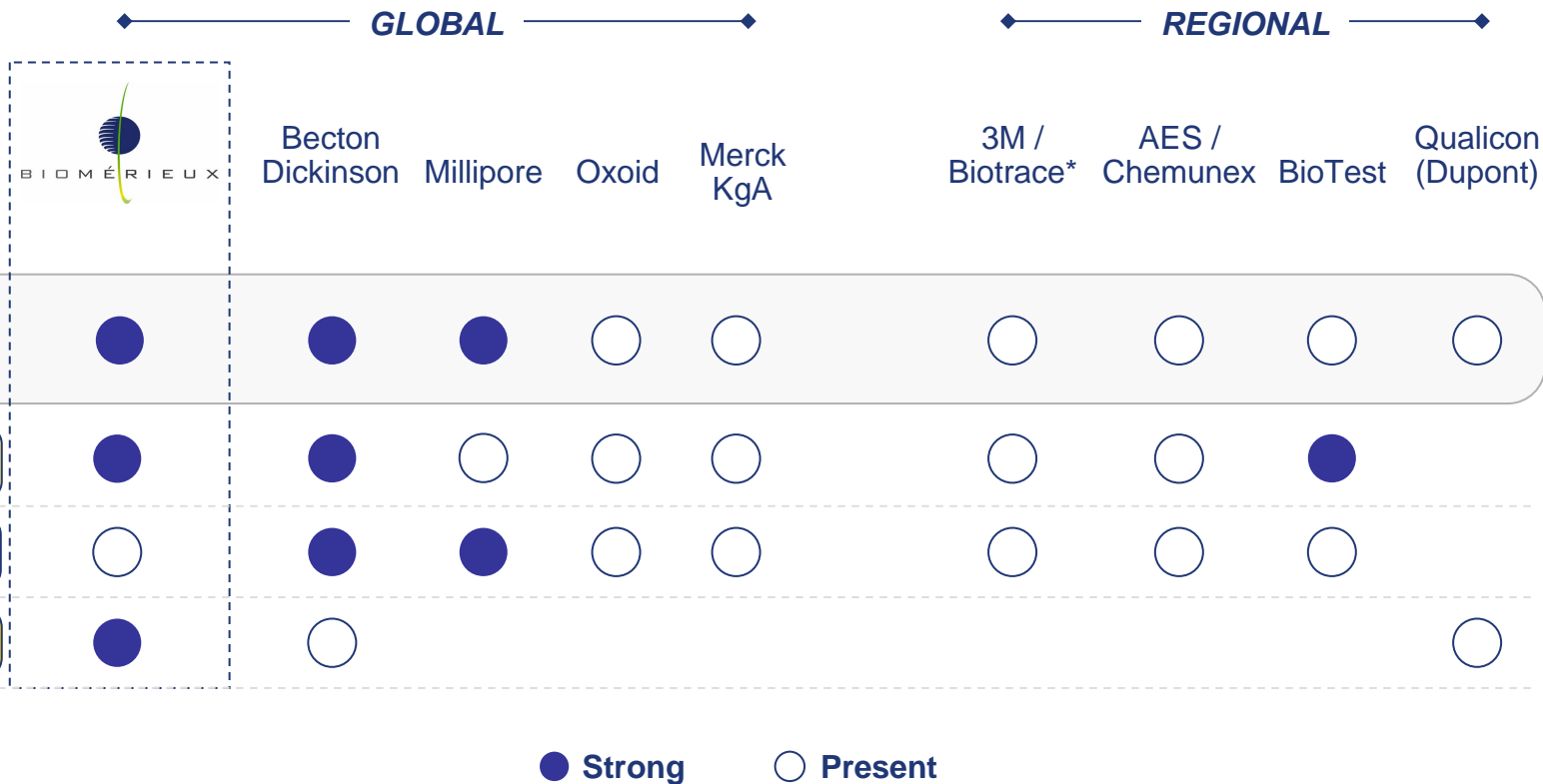
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# Competitive Landscape

*An attractive market with new niche entrants*



\* 3M via Biotrace acquisition

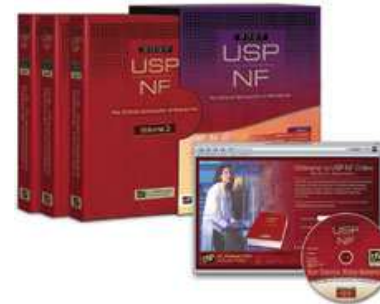
# Market Drivers

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- ▶ Public health issues: life threatening contaminations
- ▶ Brand image protection: a major issue for pharmaceutical manufacturers
- ▶ Globalization of pharmaceutical supplies
- ▶ Booming biotech market
- ▶ Better global in-process control
- ▶ Tight microbiology monitoring of expensive sterile products
- ▶ Strict and changing regulatory environment

# Regulatory Environment

- ▶ Regulations: the major business driver
- ▶ Microbiology testing is mandatory



- edqm is a logo belonging to the European Directorate for the Quality of Medicines & Healthcare
- ICH is a logo belonging to the International Conference on Harmonisation
- FDA is a logo belonging to the Food and Drugs Administration
- PIC/S is a logo belonging to the Pharmaceutical Inspection Cooperation Scheme
- USP-NF is a logo belonging to US Pharmacopeia

# Regulatory Environment

- ▶ PAT (Process and Analytical Technology) initiative:  
reinforced role of microbiology in the pharmaceutical industry
  - In-process controls
  - FDA 2006 Guidance for Industry:  
“Quality should be built into the product, and testing alone cannot be relied on to ensure product quality”
  
- ▶ Increasing requirements
  - Demonstrated performance: ISO and pharmacopoeia
  - Increasingly strict microbiology acceptance criteria

# Regulatory Environment

## *Main Milestones*

- ▶ Important regulatory moves
  - Practices move from traditional to alternative microbiology
  - 2004: FDA approves Genzyme's use of BacT/ALERT® as an alternative microbiology testing method
  - 2004-2006: FDA and pharmacopoeias publish regulations allowing use of alternative technologies
  
- ▶ Today: a real opportunity for alternative **automated** methods dedicated to process analysis
  - Many R&D protocols and instruments
  - Few high throughput methods
  - Opportunity for VITEK® 2 Compact and BacT/ALERT®



# Customer Needs in a Manufacturing Environment

*Air*  
▲

*Operators* ◀



▶ *Surface*



# Customer Needs in Biopharmaceutical Products

▶ 2 different processes

Raw material

Water

**Non-sterile drugs process** ▶



- Low contamination risk
- Moderate health consequence
- Low added-value products

Additives

Finished product

**Sterile drugs process**

Biologics process  
(including biotechnology)



- High contamination risk
- High impact on consumer health
- High added-value products



# The Biopharma Control Process

## Environmental control

- Air sample
- Surface sample



**Detection**



*AirIDEAL™*

QUANTISWAB™



*Count-Tact™*

*DiversiLab®*



## Product control

- Raw materials
- Water
- Additives
- Finished products



**Preparation of Sample**

**Detection**



*Tubes and Bottles*



*BioBall™*



*BacT/ALERT®*

**Identification**

**Typing**



*VITEK®2 Compact*



*API®*



# Environmental Control

*bioMérieux, a key player worldwide with a complete solution*

Air sample

Surface sample



**Detection**



*AirIDEAL™*

QUANTISWAB™



*Count-Tact™*



Identification



Typing



*VITEK®2 Compact*



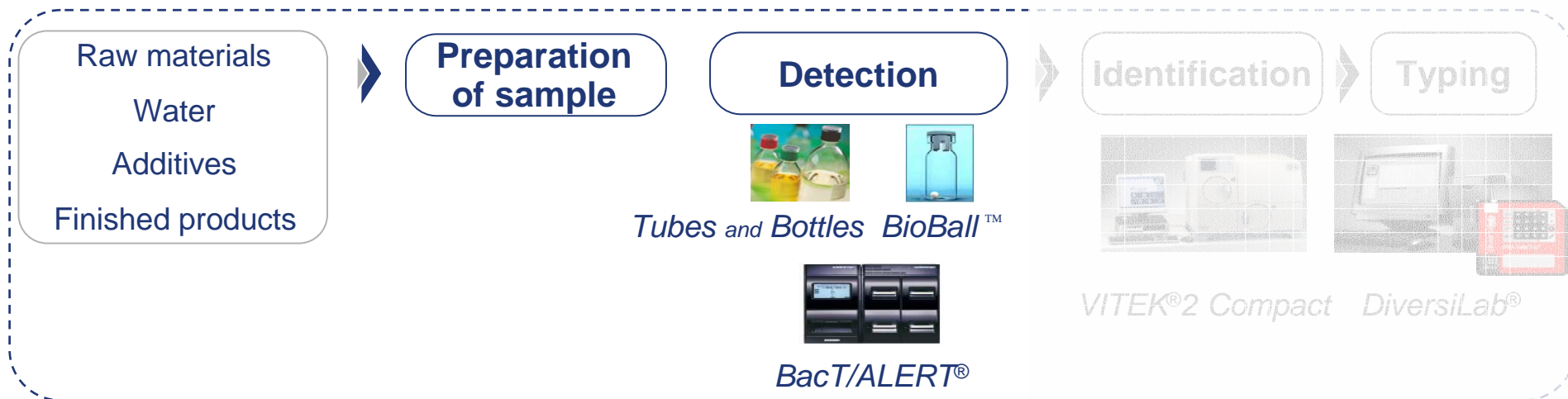
*DiversiLab®*

- ▶ Synergy among differentiated ranges
- ▶ High added-value products
- ▶ Unique performance and presence
  - Proprietary know-how and manufacturing facilities
  - Count-Tact™ #1 in Europe/Asia and #2 in USA
- ▶ Continuous range extension
  - Copan Quantiswab™

# Product Control

## Reinforced control in upstream manufacturing processes

- ▶ Synergy among in differentiated ranges
  - bioMérieux leadership in culture media
  - Unprecedented BTF-patented calibration solutions
- ▶ Unique performance and ease-of-use
  - BacT/ALERT®
- ▶ Continuous range extension
  - Internal developments and external partnerships





# Identification and Typing

## Environmental control



AirIDEAL™

QUANTISWAB™



Count-Tact™

DiversiLab®



Air sample

Surface sample

Detection

Identification

Typing

Raw materials

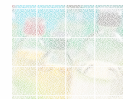
Water

Additives

Finished products

Preparation of sample

Detection



Tubes and Bottles BioBall™



VITEK®2 Compact



API®



BacT/ALERT®

## Product control



# Identification, Typing and Interpretation

---

- ▶ Identification
  - Market leadership with VITEK® range and recognized expertise
  - Product synergy unique in the market
    - PPM
    - API®
    - VITEK®
  
- ▶ Typing
  - DiversiLab® patented technology, best-in-class for its accuracy
  
- ▶ Data management solution and interface between systems
  - Partnership with Compliance Software Solutions Corporation
  
- ▶ Synergies between identification and typing ranges

# Conclusion

- ▶ The most complete offering for all major steps in microbiological control
- ▶ Global quality meets high regulatory and customer standards
- ▶ Key positions
  - Strategic segments
  - High added-value products
- ▶ Strong marketing synergies
  - Reagent/consumable, reagent/instrument, software-service/instrument
  - Increased bundling

# Outline

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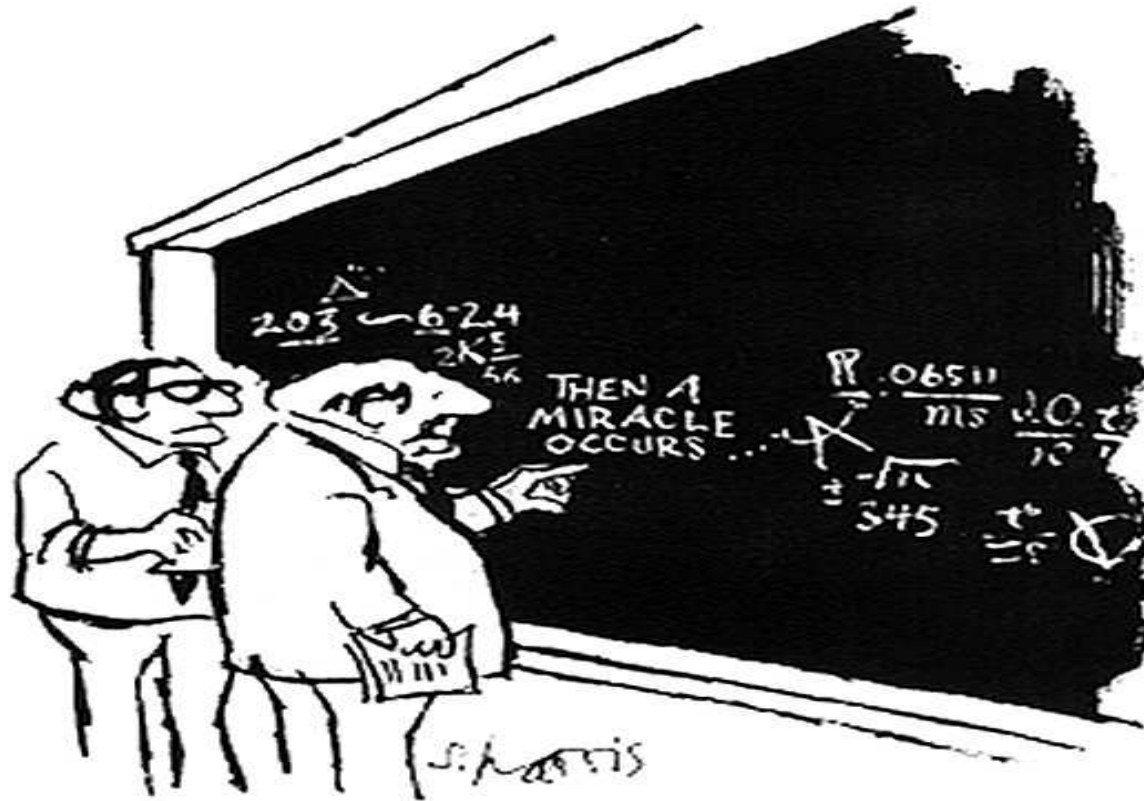


1. Industrial Applications and bioMérieux
2. Food Applications
3. Biopharma Applications
4. Q&A Session
- 5. Industrial Applications Research and Development**  
*Vincent Atrache*
6. Customer Testimonial
7. Industrial Applications Outlook
8. Conclusion
9. Final Q&A Session

# R&D: Maintain Market Leadership

Through constant innovation,  
deliver added-value,  
quality and high-performance solutions  
to our Food and Pharmaceutical customers,  
while ensuring a profitable return for bioMérieux

# From Inspiration and Invention to Innovation



***“ I think you should be more explicit here in step two ”***



# From Inspiration and Invention to Innovation

---

- ▶ Inspiration comes from scientists, engineers, marketing ...
  - Dreaming with customers and partners
  - Seeing what no one else has seen before
  
- ▶ Entrepreneurial role of R&D
  - Making sure that the creative idea becomes the right product for the customer

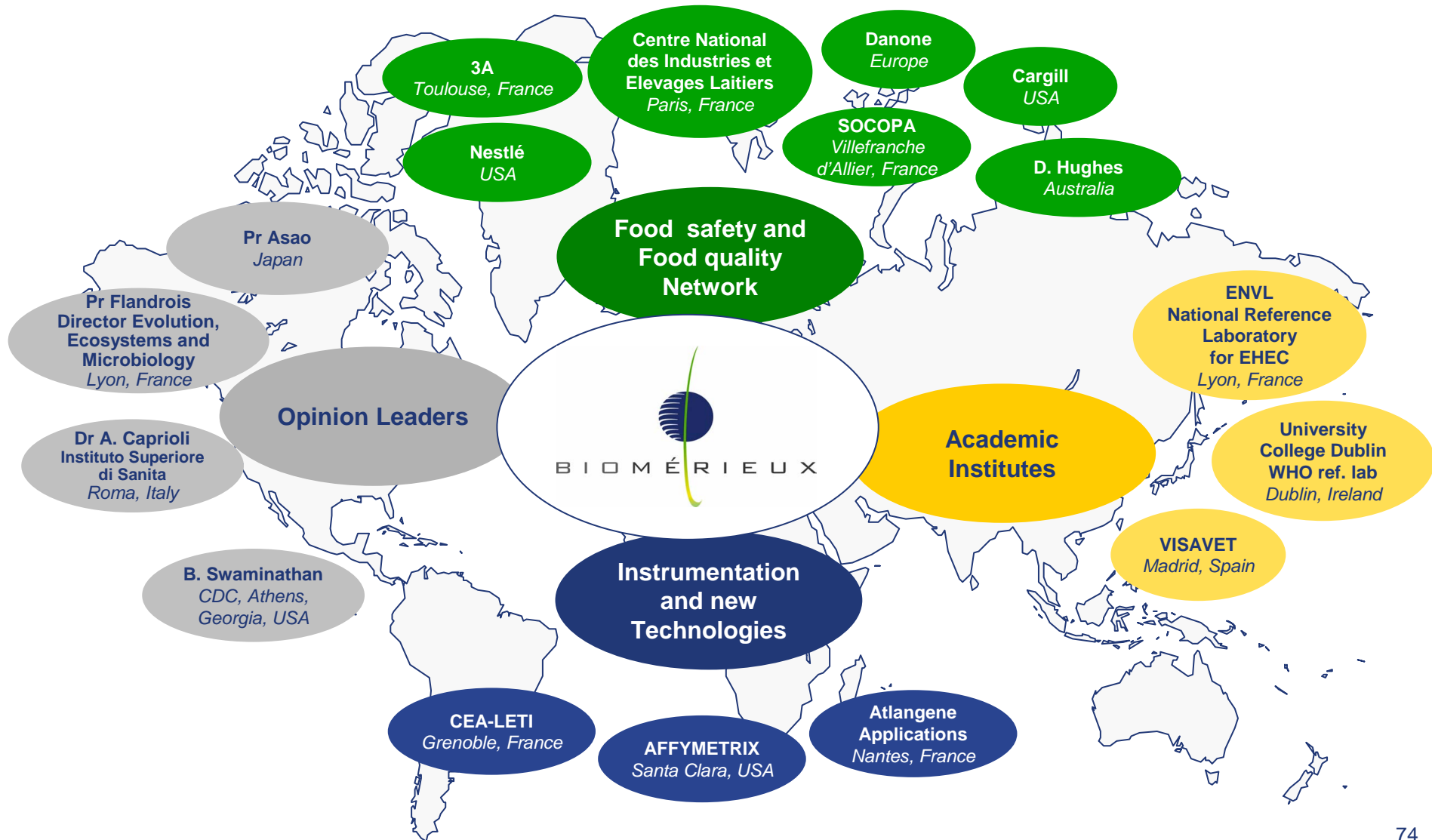
# Valuable R&D Resources

*A unique combination of assets*

- ▶ Budget
  - A dedicated €12 million budget
  - Leveraging on the enormous synergies with the clinical R&D budget and programs
  
- ▶ Strong network of partners



# An International Network and Partnerships



## *3 R&D objectives*

- ▶ Accelerate bacterial growth detection
- ▶ Streamline workflow
- ▶ Increase relevance of results

⇒ Ultimate goal: integrated bacterial detection system

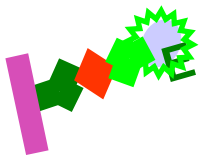
# R&D Challenges

- ▶ Detect a single organism in a product
- ▶ Need to pass through a bacterial growth step
- ▶ Enumerate from one to one million organisms
- ▶ Deal with a wide variety of matrices: air, liquid and solid
- ▶ Concentrate bacteria and remove matrix interference

# Food Safety: VIDAS® Innovation

- ▶ Won an innovation award for bringing automation to food safety testing
  - Enzyme Linked Fluorescent Assay (ELFA)
  - Single-dose unit test concept
- ▶ Launch of VIDAS® *Listeria*

ELFA



1992





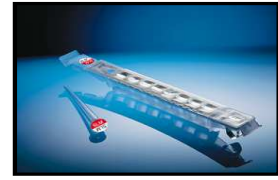
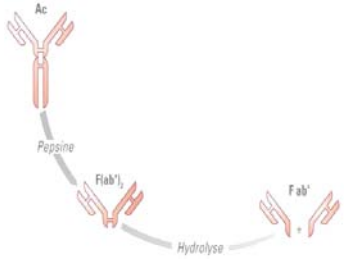
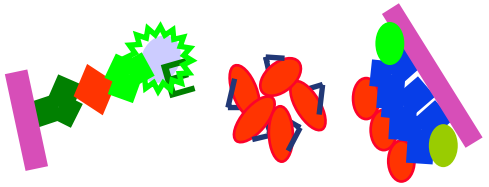
VIDAS®:

# A Continuing Innovation Pipeline

*A unique and fertile platform that readily integrates successive waves of innovation*

**ELFA**      **Immuno Concentration**

**Fab Fragment**



**Listeria**

**ICS + SLM**

**LMO2**

**SET2**

**LSX Next Day**

**Easy Salmonella**

**LDUO**

**Heat and Go**

|         |                                |                                 |            |
|---------|--------------------------------|---------------------------------|------------|
| Mission | From Inspiration to Innovation | <b>Achievements and Outlook</b> | Conclusion |
|---------|--------------------------------|---------------------------------|------------|

## *Phage capture: a breakthrough technology*

- ▶ Customer needs for food pathogen detection
  - Increased sensitivity and specificity
  - Shorter assay time, better workflow, higher throughput
- ▶ Phage
  - Co-evolved with bacteria for more than a billion years
  - Nature's mechanism for controlling bacteria even in the most hostile environments
- ▶ 2006: exclusive agreement with Profos
- ▶ VIDAS® continuous evolution







# Innovation in Identification: Phenotypic ID\*

VITEK®



VITEK® 2 Compact



1989

2005

- ▶ Reduced time to result
- ▶ Increased analytical capacities
- ▶ Specific industrial applications cards
- ▶ Improved workflow: full automation through to result

\* Identification

# Innovation in Identification: Genotypic ID\*

**DiversiLab®**



- ▶ Complements phenotypic ID
- ▶ DNA fingerprint determines the source of contamination

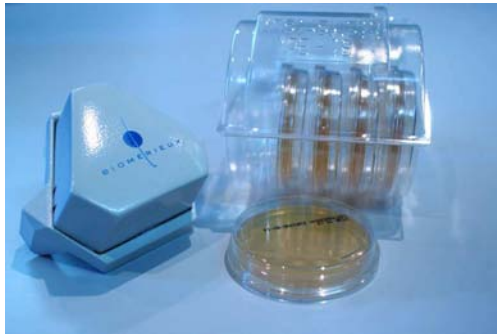
2007

⇒ Key in the “farm to fork” concept



# Innovation in Biopharma

**Count-Tact™  
fix system**



**Full range of  
irradiated plates**



**UNIDATRIX**



1999

2002

2006

- ▶ Performance
- ▶ Shelf life
- ▶ Traceability
- ▶ Room temperature storage

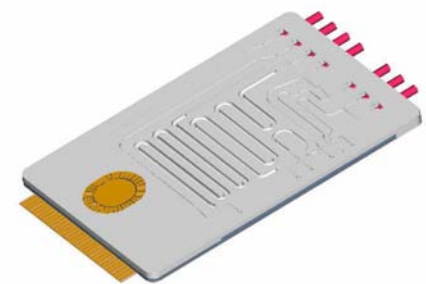


# Biopharma Outlook

- ▶ **Customer needs**
  - Reducing time-to-result
  - Detecting even a single organism
  - Being provided with live and whole organisms for further studies
  
- ▶ **Growth-based microbiology will answer these needs**
  
- ▶ **Outlook: accelerating microbial growth detection**
  - Time to result: less than 12 hours vs 48 hours
    - bioMérieux-patented technology in polymer sensors
    - On the lookout for outside technologies
  
- ▶ **Still at the very early invention stage**

# Biopharma Outlook

- ▶ Customer needs
  - Detecting even a single organism
  - At-line testing
  - Less than 2 hour cycle time
  
- ▶ Non growth-based detection
  - Amplifies nucleic acid
  - Enables at-line capability
  
- ▶ Outlook: defining technological blocks to be integrated
  - Extraction using BOOM<sup>®</sup> technology
  - Mechanical lysis using beads and high speed disruption
  - Real-time molecular detection
  
- ▶ Still at the very early inspiration stage





# Food Quality: TEMPO® Innovation

- ▶ Customer needs: labor savings and traceability
  - Automation of a highly manual test
  - 10 times more quality indicators performed than pathogen tests
  
- ▶ 4 years of brainstorming with customers, consultants and workflow engineers



# From Inspiration and Invention to TEMPO® Innovation

*The final card evolved from a family of prototypes*



*Inspiration:*  
VITEK® card



*Invention:*

Patent WO012674A1:  
card for counting and  
characterizing micro-organisms

*Innovation:*  
TEMPO® card







# From Inspiration and Invention to TEMPO® Innovation

*From prototype fillers to an ergonomically designed work-station*



Commercial launch: 2005





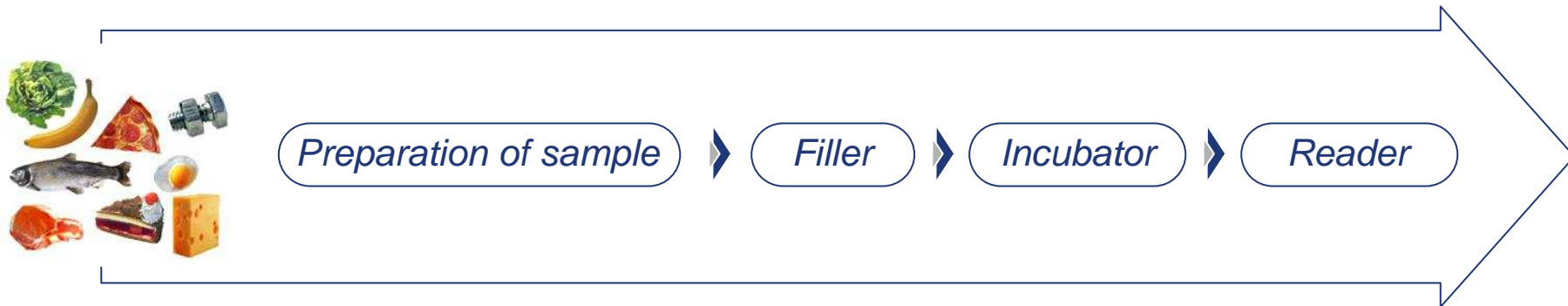
# TEMPO<sup>®</sup> Innovation

- ▶ Current menu: Total Viable Count, Total Coliforms, *E.coli*, *Enterobacteriaceae*
- ▶ Instrument features
  - Full traceability
  - Standardisation
  - Faster time-to-result
- ▶ Information management: interface with LIMS
- ▶ International validations: ISO 16140, AOAC (USA)
- ▶ Menu extension
  - Yeast and moulds
  - *Staph.aureus*
  - Lactic acid bacteria
  - Food safety testing: pathogen enumeration
  - Etc.

# Food Quality Outlook

## ▶ Tomorrow's innovation

- Integrate
- Allow at-line testing





# From Inspiration and Invention to Innovation

*A unique combination of strengths*

- ▶ An open-source innovation strategy coupled with a broad base of technologies and strong customer focus
- ▶ Providing a continuous pipeline of innovative products

# Outline

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1. Industrial Applications and bioMérieux
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- 6. Customer Testimonial**  
*Sylvain Bernard*
7. Industrial Applications Outlook
8. Conclusion
9. Final Q&A Session

# Controlling of Microbiological Hazards In the Food Industry



## Bledina

- Sales: €500 m
- Leader in the French baby food market in France (50% market share)
- Part of the Danone Group
- 3 plants in France and 12 subcontractors
- Exporting to 50 countries

## Food Safety control / monitoring

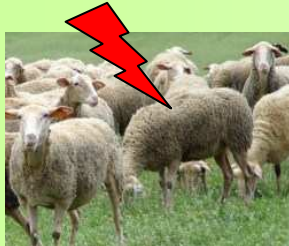
- 500,000 tests / year
- 5 million samples
- 100,000 microbiological tests
- 2 laboratories
- 50% of tests outsourced

## One Quality Director in charge of

- Food safety management
- Crisis management
- Quality assurance
- Ethics and sustainable development



► Once upon a time...in 1990...Roquefort...*Listeria* was the enemy and nobody knew where it was coming from



Listeria?



Listeria?



Listeria?



Listeria?



?  
?  
?

...our investigators tracked *Listeria* down to the farm

...and VIDAS® came and helped us to save our crown jewel!





## ► Microbiological risk in the food industry

- Low contamination levels (1/ton to 10000/g)
- Varied distribution in the food matrix
- Wide variety of food matrices and processes
- Influence of the industrial environment (processes and food matrices) on bacteria growth and survival: each bacteria → specific behavior in each process
- Selection of strains resistant to extreme environments (temperature, acidity, activity of water...)
- Dormancy is not unusual





## ► The HACCP revolution

- The old concept: *a posteriori* checking  
My goal was to comply with official standards...  
and not to be caught by public authorities!  
Accordingly, I checked the compliance of final products  
with official standards, when they existed.  
“The less I check, the less I can find”
- New HACCP concept : *a priori* testing and monitoring  
“From farm to fork”  
My goal is to bring safe products to market. This means,  
I have to evaluate microbiological risk and find the best  
microbiological criteria corresponding to my process and its  
environment.  
Microbiological testing is a key tool for running a process,  
just like a temperature or pressure sensor.



### Scope of Risk Assessment:

Evaluate where the current production stands in terms of consumer health risk

Compare the current risk status to a Food Safety Objective (FSO): maximum level of contamination that is scientifically known to be safe for consumers

**Thorough**

**EVERY HAZARD**

**Accurate**

**Contamination must be quantified**

**Relevant**

**Risk is assessed versus real health impact (FSO) and not only versus official standard**



# Sampling needed in Milk Powder to guarantee food safety

General

Assessing risks

Controlling Critical points

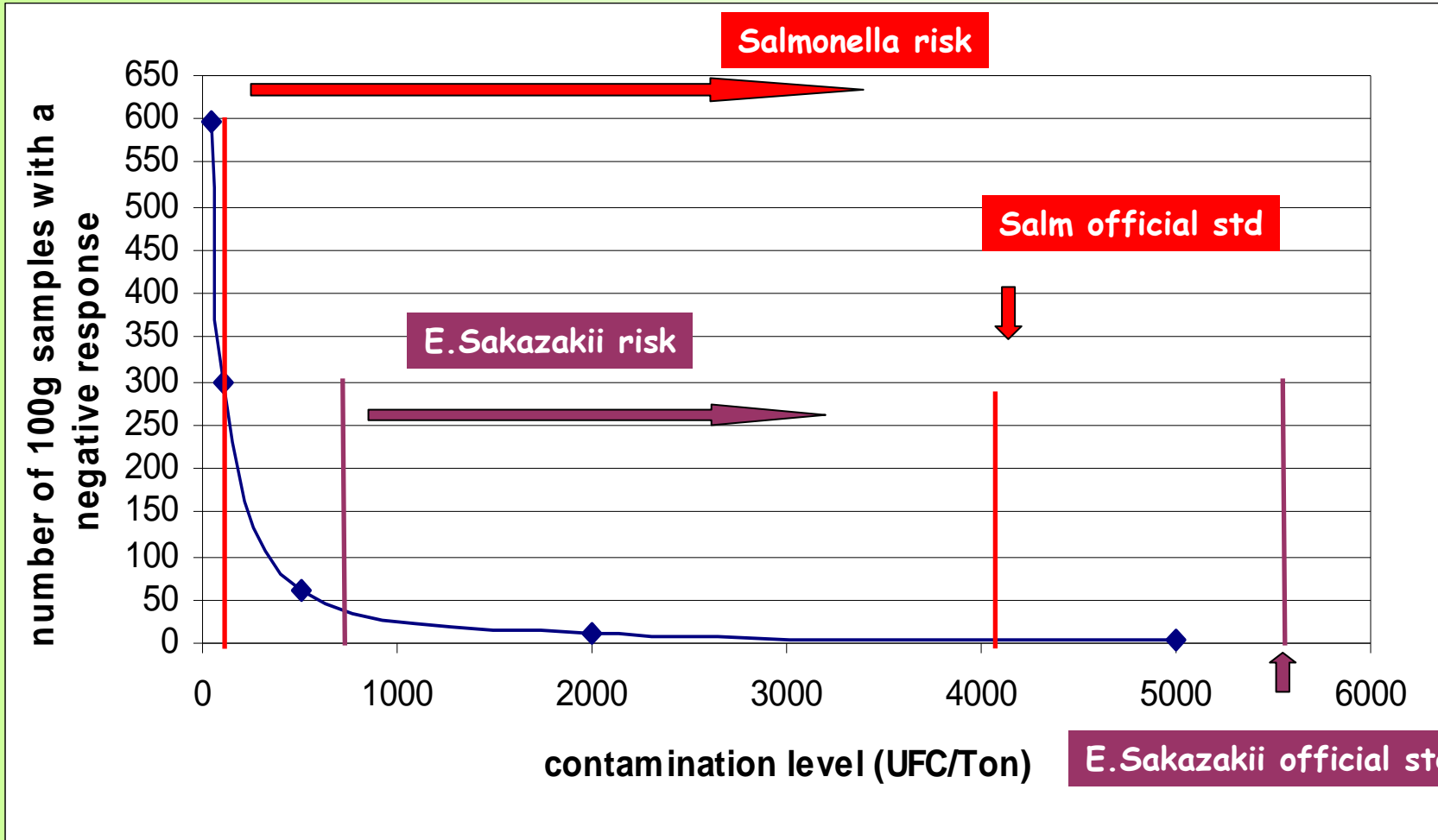
Monitoring

Salm official std

Absence in 30x25g

E.Sakazakii official std

Absence in 30x10g



General

Assessing risks

Controlling Critical points

Monitoring

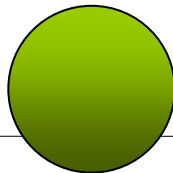


Hazard A

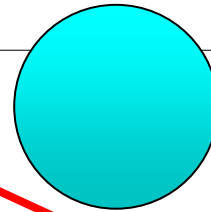
FSO

EXAMPLE OF RISK ASSESSMENT

Hazard B



Hazard C



occurrence

0

1

2

Financial impact<sup>3</sup>

4





Quantification

Speed

## ► Scope of microbiological testing

- Create microbiological profile for each process and each bacteria concerned
- Qualify process equipment and set up procedures
- Prepare product release

## ► Challenges

- Protect the consumer
- Determine the most efficient industrial options (capital expenditure)
- Improve free cash flow (quick release of finished product)
- Improve the service rate at delivery (customer satisfaction and product freshness)

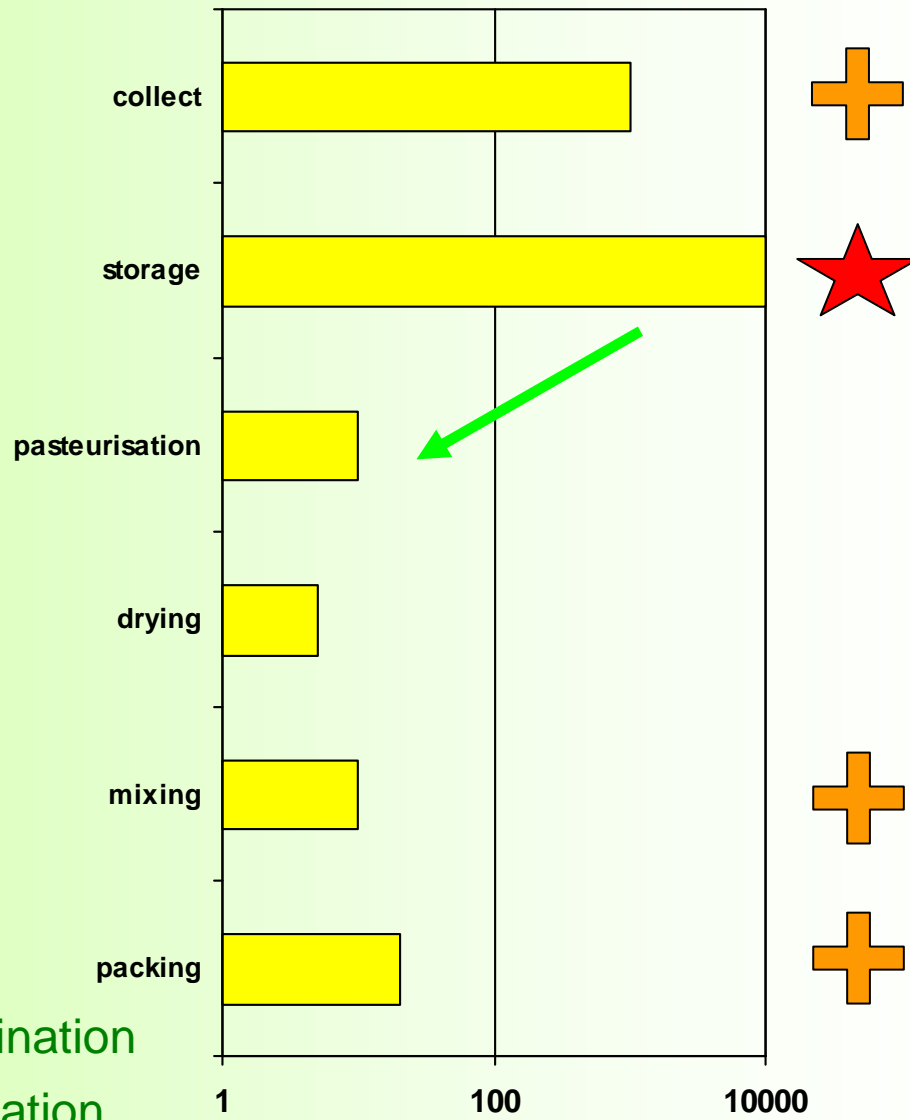


General

Assessing risks

Controlling Critical points

Monitoring



+ Contamination

★ Multiplication

- ▶ In-process control
- ▶ Environmental monitoring
- ▶ Controlling of cleaning efficiency
- ▶ Expertise
- ▶ Surveys and “quality on shelf” monitoring



- ▶ **Small equipment, reagents and media for official or investigation tests**
- ▶ **Specific multitest equipment (eg: VIDAS® for *Listeria*)**
- ▶ **New generation of quick analysis equipment (TEMPO®) currently tested by our laboratories for validation**





## ▶ THE IDEAL TEST / EQUIPMENT WOULD

- Give a very quick answer (less than 24 hours)
- Enable multi-sample testing at the same time
- Be flexible enough for multi-parameter testing (different bacteria species)
- Be adaptable to different food matrices
- Be sensitive
- Be specific
- Need only small quantities of food matrix and reagent
- Be user friendly enough to be used by non experts line workers:  
this is the key making it indispensable
  - develops employee pride
  - develops employee responsibility and empowerment
  - integrates the cost into production costs (instead of quality costs)



A close-up photograph of a baby's face and hands. The baby is looking towards the camera with a neutral expression. Their hands are clasped together in front of their chest. The baby is wearing a light blue, textured garment.

*Thanks for your  
attention!*

# Outline

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6. Customer Testimonial
- 7. Industrial Applications Outlook**  
*Alexandre Mérieux*
8. Conclusion
9. Final Q&A Session

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## *An ambitious plan for Industrial Applications*

- ▶ bioMérieux's market share:  
From 13% in 2006 to 30% target in 2012
  
- ▶ bioMérieux well positioned to maintain its leadership
  - Maintain current organic growth
  - Intensify business development
  
- ▶ bioMérieux's objective: lead market consolidation

---

*Constant innovation and improvement*

## ► Food

- Culture media
  - Enrichment
  - Chromogenic
- Food safety
  - Constant innovation on VIDAS®
  - New technologies
- Food quality: TEMPO® at the beginning of its lifecycle

## *Constant innovation and improvement*

### ▶ Biopharma

- Product control: in-process with BacT/ALERT®
- Environmental control: 3P™ range
- Identification
  - VITEK®2 Compact
  - DiversiLab®
  - Complete solution with steadily expanding menu



# Outlook by Region

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- ▶ North America: priority focus on growth
  - Food safety: growing consumer and manufacturer concern
  - Product focus on TEMPO<sup>®</sup>, VIDAS<sup>®</sup>, BacT/ALERT<sup>®</sup>
  - Boom in biotech companies
  
- ▶ Europe – Middle East – Africa
  - Europe: reinforce leadership in every market
  - Central and Eastern Europe, Middle East and Africa: seize potential
  
- ▶ Asia Pacific
  - Japan: #2 pharma market
  - India pharma industry surging
  - China and India: food safety becoming a national public health priority
  
- ▶ Latin America: refocus and reinforce our efforts

# External Growth

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## *Key element in the growth strategy*

- ▶ Integration of products or "product companies" that leverage bioMérieux's worldwide network
  - e.g.: BTF
  
- ▶ Partnerships
  - Distribution deal
  - Co-development
  
- ▶ Acquisitions





# Potential Expansion of the Business Base

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- ▶ Extend our food safety and quality offering
  - Contaminants
  - Technologies: in-process and finished product testing
  - Food viruses, shigatoxin, emerging pathogens
  
- ▶ Biopharma
  - In-process testing
  
- ▶ Zoonoses: from animal to human through food products
  
- ▶ Water: source of contamination

---

*A unique player in an attractive market*

- ▶ Public health is a growing concern
- ▶ Long-term market drivers
- ▶ Undisputed leadership
- ▶ bioMérieux's commitment



**Industrial applications will be a major contributor to bioMérieux's growth**

# Outline

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*Stéphane Bancel*
9. Final Q&A Session

## *Industrial Applications: a Great Business Franchise*

- ▶ bioMérieux: #1 position ... with double digit growth
- ▶ A market growing faster than clinical ... for many years to come
- ▶ A fragmented market ... an opportunity for external growth
- ▶ EBIT %: slightly above Group's
- ▶ Contribution to consolidated sales

| 2002 | 2007* | 2012 Target |
|------|-------|-------------|
| 11%  | 14%   | >20%        |

# Conclusion

- ▶ Leveraging synergies with the clinical business
  - R&D: VITEK<sup>®</sup>, etc.
  - Manufacturing and G&A: economies of scale
  - Business Development: DiversiLab<sup>®</sup>, etc.
  
- ▶ Backed by a premiere and growing worldwide network of subsidiaries
  
- ▶ And dedicated teams
  - R&D: TEMPO<sup>®</sup>, etc.
  - Sales & Marketing
  
- ▶ Enabling focus and agility

**Industrial applications: a critical business for bioMérieux**