



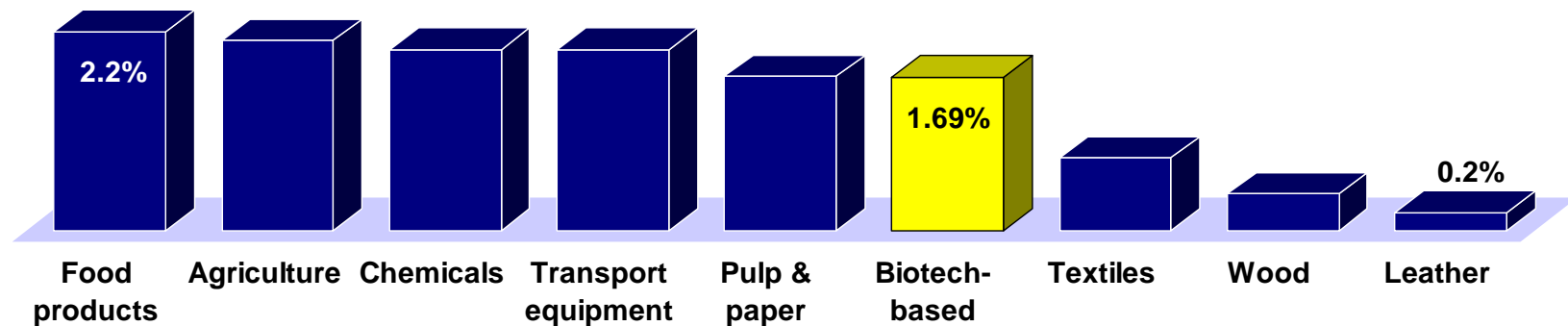
INTRODUCTION

BIOTECHNOLOGY IN THE NEW EU MEMBER STATES: AN EMERGING SECTOR

Biotechnology in the EU

Modern biotechnology in the EU economy

Biotechnology represents up to 1.69% of the EU gross value added (GVA)



This does not take into account the biotechnology investments in pharma R&D and the health effects of biotechnology products

Modern biotechnology in the EU economy

And is a multi-faceted **growing sector**:

- In the healthcare biotech sector, **more than 600 new biotech medicines and vaccines** are being tested for more than 100 diseases pushing the frontiers of science
- Biotech medicines account for more than **20% of all marketed medicines and about half of all medicines in the pipeline**
- Healthcare biotechnology continues **to grow annually at an average rate of 20%** (more than double that of traditional pharma) and that it is 7 times larger than it was 10 years ago.

Biotech is a European priority

The **Lisbon Strategy**, an action and **development plan** for the European Union, aimed at making the EU "the most dynamic and competitive knowledge-based economy in the world...by 2010" identifies '**Investment in knowledge and innovation**' as one of four top priorities towards achieving this goal.

Specific key areas under that heading:

- Research and development
- **Biotechnology**
- Information and communication technologies
- Improving infrastructure
- Innovation



Biotech is a European priority

The **Strategy for Europe on Life Sciences and Biotechnology** is a comprehensive roadmap **up to 2010**, bringing the sector to the forefront of the frontier technologies which will help the EU achieve the long-term jobs and growth targets set by the Lisbon Strategy, and establishing biotech as a European Priority.

Refocus following the interim 2007 report:

- **Promote research and market development for bio-based products** and improve the uptake of new technologies
- **Foster competitiveness** by facilitating knowledge transfer and innovation from the science base to industry
- Encourage **informed societal debates on the benefits and risk of life sciences** and biotechnology
- Ensure a sustainable contribution of modern biotechnology to **agriculture**
- **Improve the implementation of the legislation** and its impact on competitiveness

EuropaBio and InDeCS-H

Who are we?



Created in 1996, EuropaBio, the European Association for Bioindustries is an **independent, transparent, member-driven** and **biotech-specific** association representing:

72 corporate members operating worldwide

5 associate members

4 BioRegions

25 national biotechnology associations

Through our national associations, EuropaBio is also the voice of over **1800 small and medium-sized enterprises** involved in research, development, testing, manufacturing and commercialisation of biotechnology applications

Who are our Members?



**Healthcare Biotech
Companies**



**Agri Food Biotech
Companies**



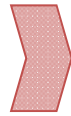
**Industrial Biotech
Companies**



National Associations

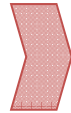
Our Goals in the Red Biotech

Better Science



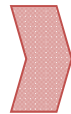
- Promote research in **Personalised Medicines and -omics technologies**
- Promote research in **rare diseases**
- Improve **SMEs contribution to IMI**

Better Regulation



- Adapt clinical Trials legislation to the **-omics and biomarkers**
- Improve **patients safety in EU : information to patients, Pharmacovigilance & counterfeiting**
- Strengthen **biosimilars** legal and policy framework

Better Access



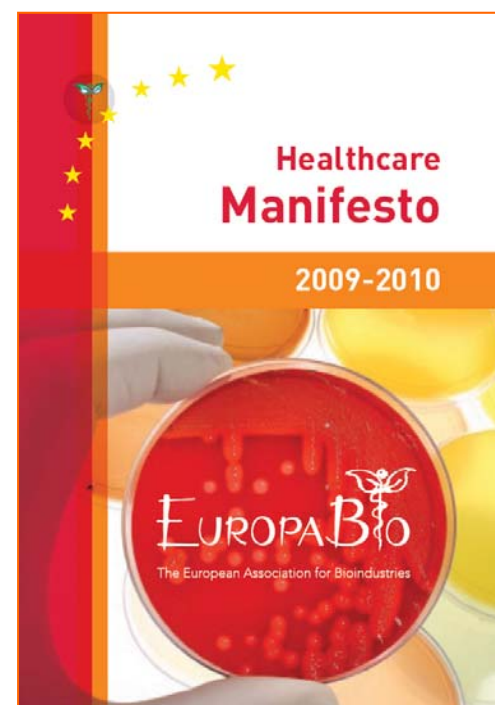
- Ensure that patients are **involved in healthcare decision** making and sharing responsibility for their own health
- **Improve timely and equity in patient access** throughout Europe
- **SMEs Access to Finance: Call for Action** to ensure that Europe will retain excellence in R&D for the benefit of patients

Healthcare Manifesto 2009-2010

Looking at our Political Road Map

Work Program

- Communicating the value of biotechnology innovation for healthcare systems
- Shaping European Union policy to ensure that emerging biotechnology solutions reach patients
- Delivering the European Union's vision for orphan drugs to patients with rare diseases
- Promoting reward for innovation as key success factor to improve progress in medicine and patient safety – taking account



Troubled times for SMEs

- Around **87%** of biotech SMEs worldwide are in the pre-profit phase
- The last 5 years, the trend has been for the larger players to place **greater reliance on external R&D**, performed by emerging companies. These programmes represent as much as **30 to 50%** of the pipeline in many major companies
- **More than 1 in 4 of the small biotech firms have less than 6 months cash in hand**, and 45 % of the publicly traded biotech SMEs have less than 1 year's cash available
- At this moment, the **IPO financing model (public market) does not exist**, and it is unpredictable when it might resume
- VCs are one of the primary sources for risk investments in biotech start-ups, but the VC investment is declining: **by almost 57% in 2008 compared to 2007**
- All forms of investment (including VC) raised by biotech firms **decreased by 54% for the first nine months of 2008**, compared to the previous year

EuropaBio's SME Platform

To **develop and propose policies supporting the development of SMEs** and facilitate access to finance

Members of the platform are representatives from:

- SMEs
- National Biotech Associations
- VCs and EVCA
- Private banks
- European financial institutions
- European Commission
- Other interested stakeholders



Access to finance: A call for action



SME Platform
Access to Finance: A Call for Action

27 May 2009

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Make the EU funding instruments more accessible to biotech SMEs

The European institutions such as the EIB should develop a short term investment vehicle to increase risk capital for VCs (in time of crisis)

Make maximum use of the European State Aid rules in these difficult times

Develop measures and opportunities to capture the value of research within Europe

Make the EU Framework Programme for Research more attractive for (biotech) SMEs

Biotech at Member State level



Until now, biotechnology data collection initiatives in Europe have tended to focus on the most developed biotechnology industries, with limited attention given to life science companies in the 12 new Member States and 2 candidate countries.

The 14allbio (InDeCS-H) project set out to fill that information gap.

Why is this important?

- Knowing the **strengths and weaknesses** of each country facilitates the implementation of appropriate measures to help countries face their particular challenges, cultivate their core competencies and take advantage of their opportunities.
- Following this report and its presentation at different events, general and **country specific recommendations** will be formulated.
- These recommendations can facilitate the development of **a favorable policy environment** for this promising industry.

14ALLBIO (InDeCS-H)

Development Capacity Index for Biotech Companies in
New Member States



- Need to understand the Biotechnology landscape in Europe
- 6th Framework Programme funded by the European Commission
- Started in 2007
- Objective: to gather, analyse and distribute data about the biotechnology industry in the 14 new Member States and candidate countries
- Website: www.14allbio.eu

About Us – Project Partners



- Independent, third party valuations
- Run global Biotech database Biotechgate
- => BioAlps, BioCom San Diego, BIOTECCanada, Biovalley, ChinaBio, Life Sciences Health Netherlands, Maryland, Medicon Valley, Swiss Biotechnology



- European Association for Bioindustries
- Biotechnology industry voice at EU level
- Representing some 1800 SMEs
- 78 members, 4 Bioregions, 25 national biotechnology associations