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Industrial and Environmental Biotechnology sector in Italy: state-of-the-art and perspectives

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Presentation outline

Structure, mission and activities of the National Committee for Biosafety, Biotechnology and Life Sciences of the Presidency of Council of Ministers (NCBB)*(D.P.C.M. March 19, 2007)*

Main features and potential of the modern *Industrial & Environmental Biotechnologies* (*White Biotechnology*)(IEB);

State-of-the-art of the IEB sector in Italy in terms of R&D and industrial potential;

R&D strategic priorities for boosting the IEB sector in Italy and for aligning it to that of the other European Countries

Conclusions and opportunities for cooperation.

National Committee for Biosafety, Biotechnology and Life Sciences of the Italian Presidency of Council of Ministers: *Composition (a)*

Chairman: Prof. Leonardo Santi

A rapresentative per each of the following Institutions:

- Ministry of Health
- Minstry of Environment and Protection of the Territory
- Ministry of Labour and Social Politics
- Ministry of Productive Activities
- Ministry of Agricultural Politics
- Ministry of Educational University and Research
- Ministry of Foreign Affairs
- Ministry for the Community Politics
- Ministry for Innovation and Technologies
- National Institute for the new Technologies,Energy and Environment (ENEA)
- National Research Council (CNR)
- Assobiotec
- National Council of the Consumers and Users

National Committee for Biosafety, Biotechnology and Life Sciences of the Italian Presidency of Council of Ministers: *Composition (b)*

The committee also relies on the cooperation of Experts in:

- Genetics
- Molecular Biology
- Chemical Engineering
- Occupational Medicine
- Agronomy
- Pharmacological Ecology
- Hygiene
- Microbiology
- Plant Biotechology

National Committee for Biosafety, Biotechnology and Life Sciences of the Italian Presidency of Council of Ministers: *Activities (a)*

- Evaluation and control of the biological risks
- Technical support for governmental and legislative actions
- Drafting of opinions on national legislative acts in conpliance with European directives in the field of biotechnology, aiming to establish direct links with the European Union
- Elaboration of a framework of programmes, initiatives and action pertinent to biotechnology carried out by Ministries, Public and Private Research Institutions and by other organizations that provide for the evaluation of the implications of innovative biotechnology in different fields of research and productivity
- Coordination of activities related to areas of biotechnology
- Information and diffusion of techincal/ scientific awareness

National Committee for Biosafety, Biotechnology and Life Sciences of the Italian Presidency of Council of Ministers: *Activities (b)*

- Working out guidelines for the safety of gene therapy trials from both experimental and clinical standpoints
- Analysis of issues pertinent to genetic testing entailing molecular diagnostics from medical, legal, ethical and psychological standpoints and with a view of allowing appropriate and effective therapy strategies
- In-depth analysis of theme related to safety and quality of in vitro expanded cells and human tissues
- Studies related to the development of biotechnology in Italy which define the most convenient strategies

National Committee for Biosafety, Biotechnology and Life Sciences of the Italian Presidency of Council of Ministers: *Activities (c)*

- Working out guidelines on cloning in order to provide a regulatory framework
- Working out guidelines on xenotransplantings
- Opinion about the directive on the biotechnological inventions
- Foster the diffusion of awareness of safety problems
- Organization of conference and events
- Studies related on Italian position on biotechnology and to define the Italian research priorities

National Observatory of Biosafety and Biotechnology *(a)*

(Art. 4 Decree 14.11.2001)

Within the National Committee for Biosafety and Biotechnology (CNBB) and according to its guidelines, an Observatory has become operative with the aim of:

- Mapping the national distribution of the biotechnological infrastructures and activities
- Setting-up a biotech database to be connected with other similar databases at national and international level
- Monitoring of the industrial background of the biotechnological field at national and international level
- Identification and organisation of information concerning more prominent lines of research
- Planning and implementation of a network of centres of exellence for technology transfer
- Planning of experimental actions to coordinate supply and demand in the field of biotechnology and arrangement of executive plans

Industrial & Environmental Biotechnology (White Biotech)(IEB): features & potential *(a)*

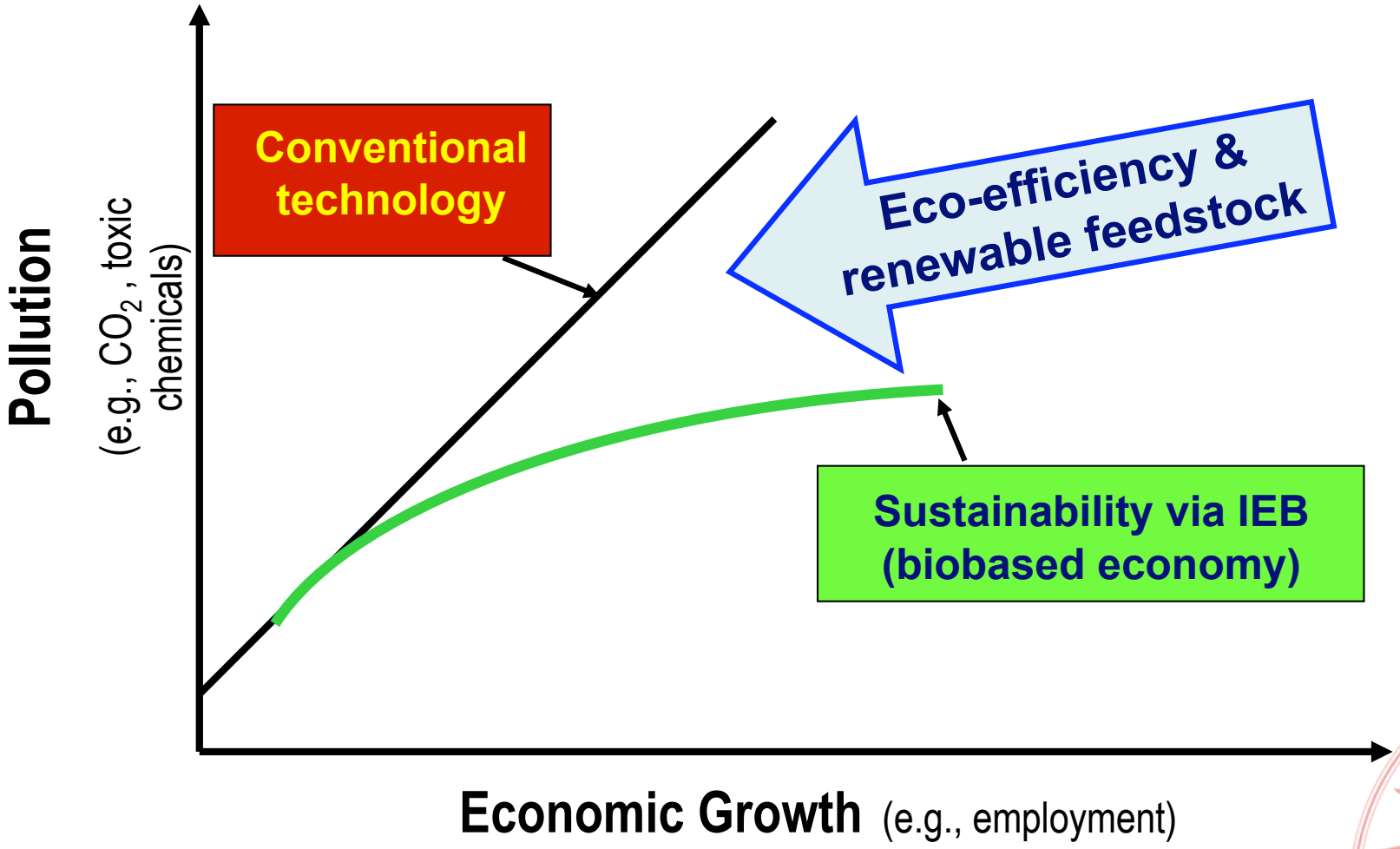
IEB uses enzymes and/or microorganisms in tailored bioreactors/ processes to produce:

- compounds not obtainable through chemical routes (I & II metabolites, organic acids, chiral compounds, hormones, vaccines, etc.);
- conventional chemicals and materials (i.e., vanillin, cephalexin, polyesters, etc.) through pathways ensuring a reduction of both energy and water consumption, waste and CO_2 generation;
- a variety of new or conventional specialty/commodity chemicals, and biomaterials from biomass, agro-food by-products, wastes, surplus, thus reducing the dependency of current industry from expensive and polluting petrochemical feedstocks.

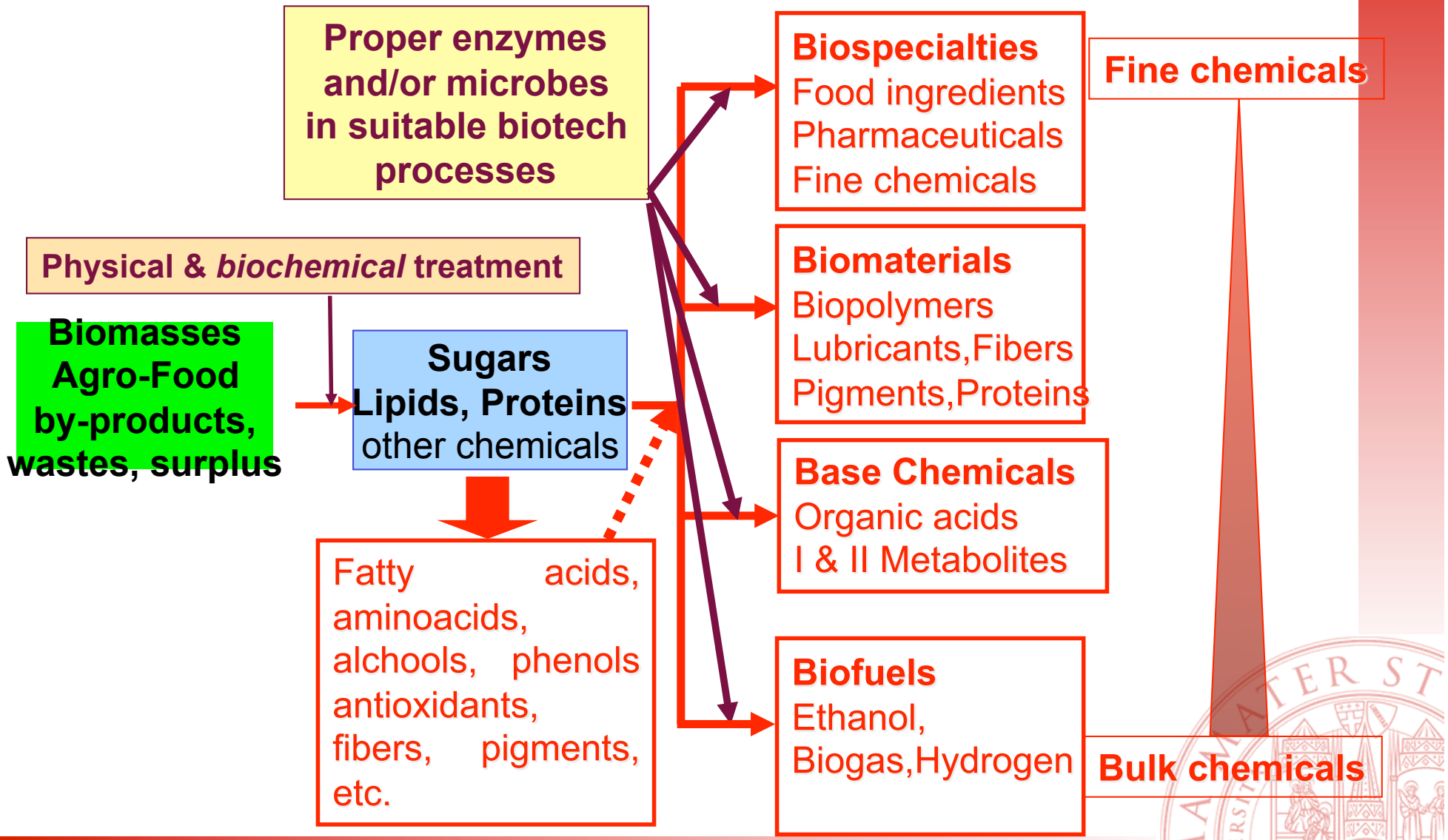
Thus, IEB would favour the transition of current chemical, pharmaceutical, textile and energy industry towards a more sustainable one. The reuse of agrofood-industry byproducts, wastes, wastewaters and surplus as feed stocks also contribute to increase the sustainability of the food industry.

IEB can also provide strategies & tools for a more efficient and sustainable (under environmental and economical points of view) monitoring and remediation of contaminated soils and industrial sites, sediments and wastewaters.

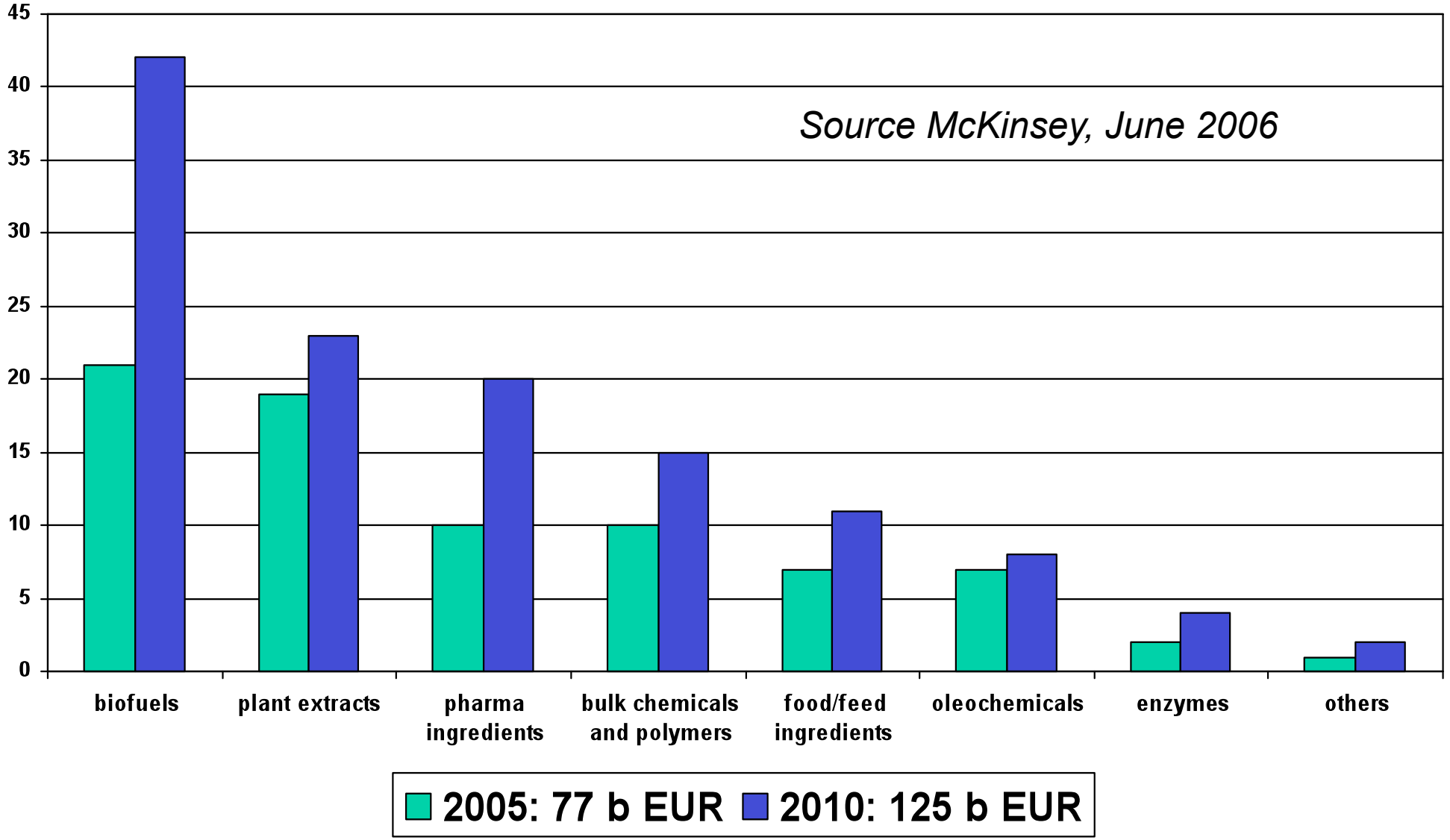
IEB: features & potential *(b)*



IEB: features & potential *(c)*

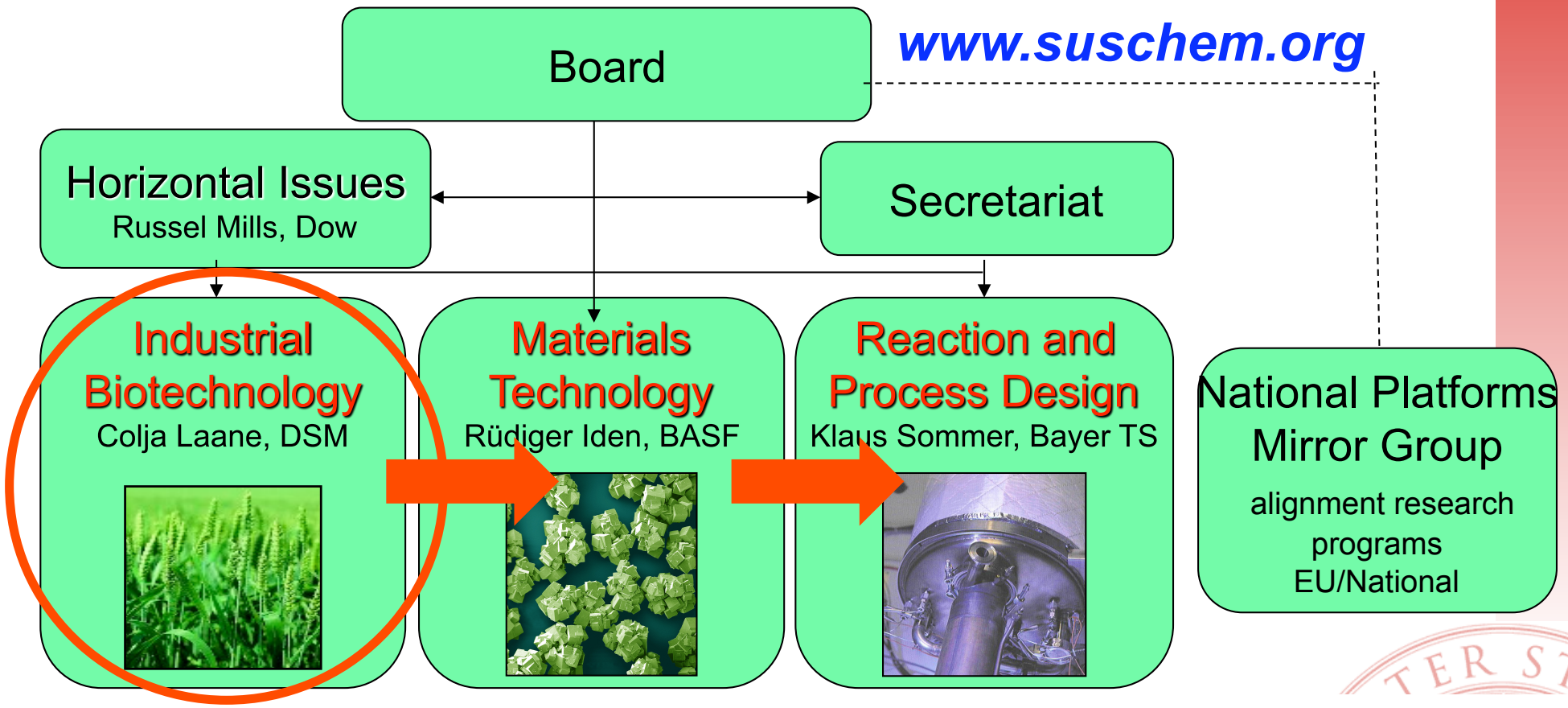


IEB: features & potential *(d)*



Tools for boosting IEB in EU: European Technology Platform *SusChem*

It is a multi-stakeholder EU platform that bridges academia, industries & SME's, NGO's, civil/environmental associations, etc



Initiated in 2004 by Cefic and EuropaBio. Aimed at identifying industrial driven R&D priorities and strategies for boosting IEB and innovation/competitiveness in the sector of sustainable chemistry for fulfilling Europe's vision of a sustainable and competitive knowledge-based economy.

Tools for boosting IEB in EU: ERA-IB

- IBNational platforms
- ERA-IB
- ERA-IB (observers)
- Israel

Tools for boosting IEB in Italy: INBB Committees for "Industrial Biotechnology" and "White Biotechnology" and IPI

Committee for "Industrial Biotechnolgy"

-Prof. Enrico CERNIA (coordinator)
-Prof.ssa Lilia Alberghina
·Dr.ssa Silvana Camilleri
·Dr.ssa Ada Cavicchini
·Dr. Francesco Cellini
·Dr.ssa Diassina Di Maggio
·Dr. Massimo Ghirelli
·Prof. Gennaro Marino
·Dr. Franco Morisi
·Prof. Danilo Porro
·Prof. Giampiero Ravagnan
·Ing. Luigi Tranchino

www.governo.it/biotecnologie

Committee for "White Biotechnolgy"

Prof. Luciano Caglioti (coordinator)
Dr Silvana Camilleri;
Prof. Filippo Conti
Dr. Carla Donnini
Avv. Michele Gallina
Dott. Edoardo Lorenzetti
Prof. Stefano Masini
Prof. Pietro Tundo
www.governo.it/biotecnologie

IPI: National Agency for Economical Development of the Ministry for the Economical Development: projects RIDITT, EUROTRANS-BIO

www.osservatoriobiotec.it; www.riditt.it

Tools for boosting IEB in Italy: Italian Technology Platform *IT SusChem*

Board

L. Busetto (Coordinator *ad interim,* UniBO)
GCenti (Sci.Coord, *ETPSusChem* Mirror group, UniME)
N.Barbini (Federchimica, Board *ETP-SusChem)*
G. Pieri (*ETP SusChem* Mirror Group*)*
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V. Pignatelli (ENEA)
S. Viticoli (CNR)
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Horizontal Issues
F.Santarelli /P.Bonora(SCI)

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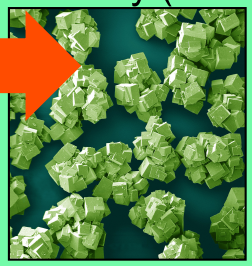
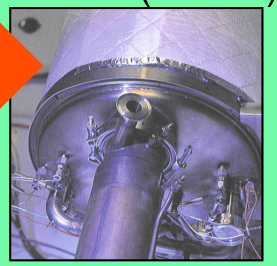
Industrial Biotechnology
F. Fava (UniBO)

Materials Technology
J.M. Kenny (UniPG)



Reaction and Process Design
E. Santacesaria (UniNA)
A. Ricci (UniBO)



Scientific committee:
57 members:

9 Companies
Federchimica/Assobiotec
Federambiente
20 Universities
4 CNR Institutes
ENEA, C.R.A.
3 Interuniversity consortia
6 Scientific associations

Promoted by the University of Bologna in March 2006 under the auspices of CRUI, in cooperation with Federchimica, Assobiotec, Federambiente, 50 SMEs, CNR, ENEA, C.R.A., SCI, 9 Interuniversity Consortia, several scientific/ environmental associations, Centers of Excellence, Banks, etc.

Main Features of Biotech industry in Italy

The Italian Biotech Industry has recently shown a rapid and considerable growth (163 Companies + 16 Technological Parks in 2005), especially in diagnostic, therapeutic and related fields. However, it is still "young", small, and mainly dominated by "red" or health care biotech productions *(1,2,3,4)*.

Only 22% of the Italian Biotech companies are active in the agro-foods and IEB field, with productions mostly focused on specific market niches not covered by the big international companies *(1)*.

A national survey performed by *IT-SusChem* IEB scientific committee identified 44 Companies operating in the IEB sector. Only a few SpA companies are active (and often partially) in the sector *(2)*.

(1) Assobiotec-Blossom Associati, "Biotechnology in Italy, Strategic and Financial Analysis, 2007; (www.blossomassociati.com)

2) IT SusChem Vision Document "Structuring & planning research innovation for a Sustainable Chemistry in Italy" (www.unibo.it/NR/rdonlyres/0F983ABC-A107-48AE-BF52-9E1D0C8D97DB/80546/VisionITSusChem13Marzo2007.pdf)

3) Documents produced by the CNBB subcommittees "Industrial Biotechnology" and "White Biotechnology" (www.governo.it/biotecnologie)

4) Documents produced by the IPI (National Agency for Economical Development of the Ministry for the Economical Development) (www.osservatoriobiotec.it)

Features of IEB Industry in Italy

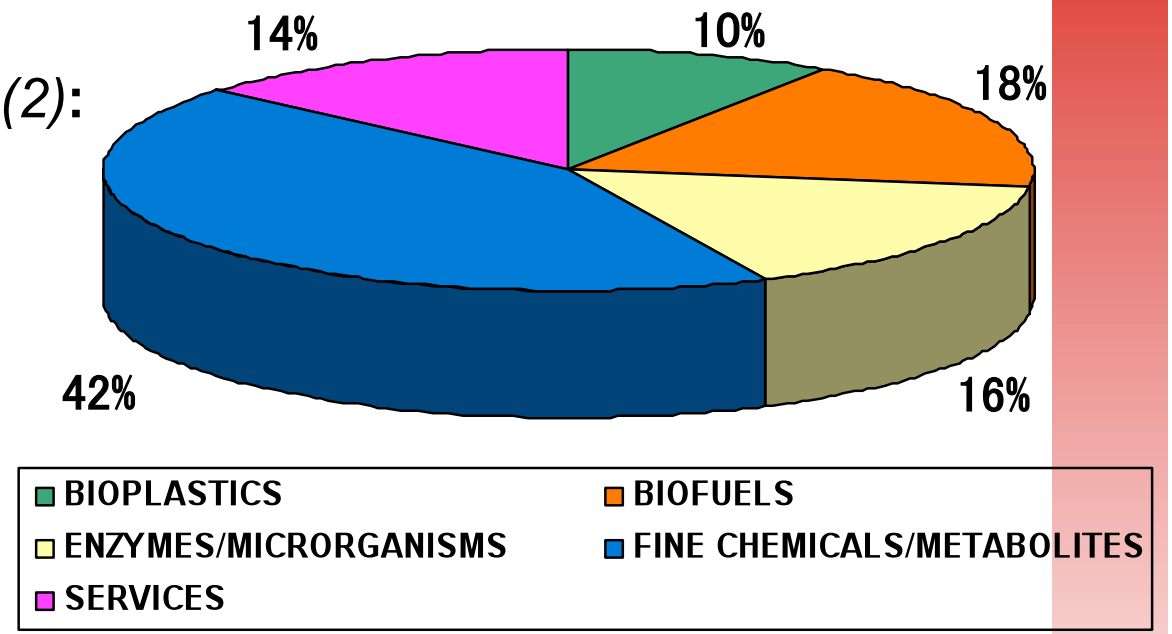
Survey on the IEB Industry *(2)*:

Industries reviewed: 44

70% SMEs, 15% spin-offs;

80% mono-product, with a avery few R&D employees;

75% in the North Italy.



The Italian Industrial Biotech sector is fragmented. However, it has shown a considerable growth, especially in terms of R&D dedicated companies. Some national SpA Companies (i.e., Novamont, ENI, Mossi-Ghisolfi, etc) are gradually incorporating biotech knowhow and tools in their productions.

Features of IEB R&D in Italy *(a)*

According to *IT-SusChem* survey, over 130 large industrial biotechnology R&D projects are in progress at Universities, Research Centers (CNR Institutes, ENEA, ST Parks, etc), spin offs and companies, thanks to funds provided by Government (i.e., PRIN, FIRB, PON, PNR, CNR projects, etc), Regions, EU (VI FP) and Companies.

They can be ascribed to the following 5 research areas:

1. Isolation, characterization, improvement of **enzymes** and **microorganisms** & development of innovative/improved bioreactor systems and modelling, scaling-up, down stream strategies for specific industrial biotech productions (~35 projects);

2. Development of new/improved integrated strategies for the **recovery** of **bioactive molecules** and **biomaterials** from biomass, agroindustrial byproducts, wastes or wastewaters, and tailored biocatalysts and processes for converting remaining compounds into **fine-chemicals, biopolymers, biofuels** (*biorefinery)*(20 projects).

Features of IEB R&D in Italy *(b)*

3. Development of industrial tailored processes for the enzymatic/ fermentative production of **chiral molecules**, I & II **metabolites**, **flavours**, **pharmaceuticals**, **heterologous proteins**, microbial **enzymes** and **biomass** from conventional media and agroindustry byproducts and wastewaters (~ 30 projects)

4. Development of new/improved strategies and/or processes for the production of **microbial polymers** and **biodegradable polymers**, **lubricants**, **biosurfactants** from biomass and agroindustrial wastewaters and wastes (~ 20 projects)

5. Development of innovative/improved strategies and/or processes for the production of **biofuels** (biogas, biodiesel, bioH_2, bioethanol) from biomass, agroindustrial and municipal wastes, and wastewaters (~ 15 projects).

Addition Features of IEB sector in Italy

Italian Industries involved in the remediation of contaminated sites and wastewater : about 50 SMEs, with a little o none R&D expertise *(2)*

Biomonitoring and Bioremediation techniques are applied in only 10-15% of the remediation projects, and they mostly consists of *ex-situ* approaches (*landfarming* or biopile/composting). Those applied *in situ* are generally *bioventing* and *biosparging*. Very limited is the use of innovative *in situ* techniques (MNA, ENA, biobarriers, etc).

Industrial wastewaters are mostly treated through conventional (activated sludge) aerobic processes and only rarely through innovative/improved technologies such as membrane-bioreactors (10%) and packed/fluidized bed biofilm reactors (10%).

R&D Projects undrway on the biomonitoring and bioremediation of contaminated sites, soils and wastewaters *(2):* over 30. 90% of them are national, mainly supported (95%) through public funds (Ministries and Regions), and poorly (10%) through EU grants (NATO, FP6).

Strategic R&D for boosting IEB sector in Italy

On the basis of features of the Italian IEB sector, the socio-economical needs of the Country and IEB R&D priorities identified at the EU level, the IEB areas on which future efforts/funds should be focused are *(2)*:

A) development of new/improved industrial tailored biocatalysts and bioprocesses to foster the shift of current (chemical) industry towards innovative and/or cleaner, safer, more cost effective productions;

B) development of innovative/improved integrated (bio)processes for valorising national biomass and agro- and food-industry surplus, byproducts, wastes, wastewaters;

C) development of new bioprocesses/improvement of existing technologies for biofuels production from national biomass and agroindustry surplus, by-products, wastes and wastewaters;

D) development of innovative/improved biological techniques for the characterization/monitoring and remediation of contaminated sites and waters.

Strategic R&D priorities for Italian IEB sector *(a)*

Priority A) *New/improved biocatalysts and related processes for innovative or/and cleaner, safer and cheaper industrial productions (2).*

Main Goals and Actions:

a) Improvement (via integrated evolutionary, rational design, computational approaches, and genetic engineering) of the activity, specificity and robustness of existing biocatalysts (enzymes and microbes) and searching (via bioinformatics, metagenomic, etc.) of new ones with improved industrial potential;

b) Development of rapid and efficient screening methods for new catalysts;

c) Improved/novel enzyme production hosts with enhanced productivity;

d) Development of easy-to-use formulated enzymes;

e) Improved enzymatic/microbial reaction design and engineering (high-performance integrated multiphase bioreactors, cascades of (chemo)enzymatic methods, etc.) and testing of developed systems under industrial conditions.

Strategic R&D priorities for Italian IEB sector *(b)*

Priority B) *New/improved strategies/processes for the valorisation of national biomass & agro- & food-industry surplus, byproducts, wastes (2).*

Main Goals and Actions:

1. Optimization of biotransformation strategies and processes

a) Identification of national biomass & agrofood byproducts/wastes (LCA)

b) Development of improved enzymatic/fermentation processes

-Microbial genomics and bio-informatics;

-Metabolic engineering and modelling for robust fermentation microbes;

-Process scale-up and intensification (novel reactor configurations and process management and monitoring procedures);

-Down-steam processing.

2. Improvement of integrated biorefinery strategies

a) Development of strategies aimed at water recycling and energy saving

b)Improvement of biorefining procedures/technologies (pretreatment of biomass, recovery of biomolecules and biotransformation of remaining constituents).

Strategic R&D priorities for Italian IEB sector *(c)*

Priority C) *New bioprocesses and improved technologies for biofuel production from Italian biomass and agro-industrial surplus, by-products and wastewaters (2).*

Main Goals and Actions:

1. Development of bioethanol producing processes from Italian crop-waste (straw, corn cobs) and food-industry surplus, wastes and wastewater;

-Improved strategies for raw materials (enzymatic) pretreatment;

-Improved biomass fermentation to ethanol and ethanol recovery.

2. Improved production of biogas (CH_4, H_2) from agro-food industry byproducts and surplus, organic wastes and fraction of municipal wastes, etc. through optimization of existing medium/full scale anaerobic digesters and development of innovative tailored biotech processes.

Production of electricity by means of MCFC (melting carbonate fuel cells) fuelled with CH_4 and H_2.

Strategic R&D priorities for Italian IEB sector *(d)*

Priority D) *Development and implementation of biotechnological processes for the remediation of contaminated sites and wastewaters (2)*

Main Goals and Actions:

1-Develop new knowledge on microrganisms occurring in contaminated environments to identify strategies for maximizing their biodegradative potential *in situ* and in *ex-situ* treatment

2-Improvement of efficiency and specificity of current *ex-situ* and *in-situ* bioremediation tecniques

3-Development of innovative tools for the chemical, microbiological and ecotoxicological monitoring and characterization of sites and wastewaters and for the *scale up* and *down stream* of innovative bioremediation techniques

4-Development of strategies/guidelines for the good conduction and scaling-up of bioremediation of contaminated sites

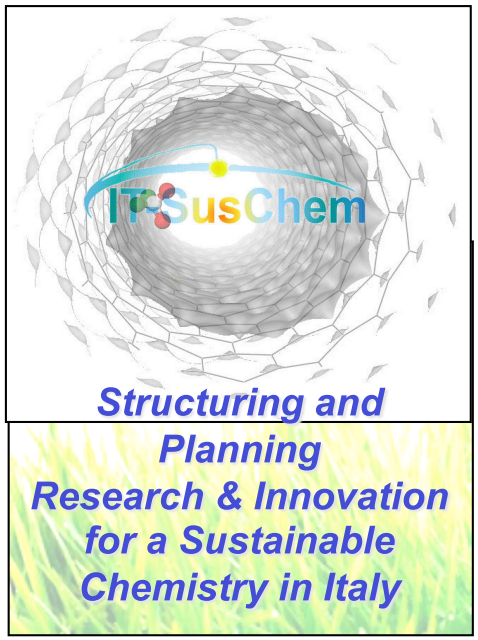
Actions for boosting IEB R&D in Italy

1. Aiming at top-performance & excellence, increasing focus and mass on the priorities;
2. Support a limited number of academic and industrial collaborative research projects on few priorities, by allocating funds for all phases of innovation, from its design to its scale-up and assessment;
3. Reserve a part of R&D funding for high risk frontier science projects;
4. Enhance professional training, in particular in the process scaling-up;
5. Improve attitude to patenting and reducing the cost of Intellectual Property Protection for SMEs;
6. The formation of consortia of IEB technology providers.
7. **Intensify international cooperation through the development of R&D tailored cooperation programs on priorities of common interest.**

Actions for boosting IEB industry in Italy

1. To boost the networking and clustering processes through national and international Platforms and also Technological Districts, usually on a sub-regional scale, rely on excellence of technological and scientific activity and local industrial sectors using R&D results
2. To foster the biotechnological enterpreneurship through tax relief
3. To ease the credit to the biotech enterprises and to boost immaterial investments to develop the hi-tech enterprises
4. To develop the *Venture Capital market* with particular regard to *seed and early stage capital*
5. To speed the implementation of the community directives
6. Adopt new communicating ways to consumers, to create a trust and market pull for IEB products;
7. **To stimulate the incoming of investments from abroad, to encourage the internationalization.**

For more details on the *IEB* sector in Italy and the strategies for boosting it:



Vision document of IT-SusChem: (www.unibo.it/NR/rdonlyres/0F983ABC-A107-48AE-BF52-9E1D0C8D97DB/80546/VisionITSusChem13Marzo2007.pdf)

Available (also in Italian) at the site: *http://www.unibo.it/Portale/Ricerca/Servizi+Docenti+Ricercatori/finanzeuropei/ITSuschemPlatform.htm*

Assobiotec-Blossom Associati, "Biotechnology in Italy, Strategic and Financial Analysis, 2007" (*www.blossomassociati.com*)

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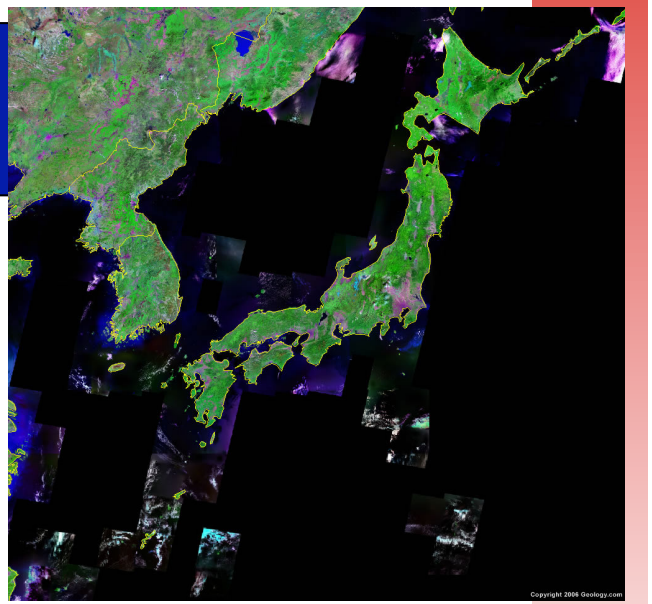
White Biotechnology: a strategic opportunity for the industry and the environment (biobased economy), a challenge to face together.....



Thank you

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