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Biotechnology in Italy 2012

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Report Highlights:
Again, this year, the biotechnology industry in Italy is characterized as a dynamic and promising sector, despite the worsening economic situation that biotech companies have to confront on a daily basis. Italy has a large and profitable biotech industry operating in the medical, industrial, and agricultural sector, ranking 3rd in Europe in the number of pure biotech companies.

OVERVIEW

Table 1 – Italian biotech industry main figures

	2011	2012
Number of companies	396	394
Total turnover (€mln)	6.8	7.1
R&D Investments (€mln)	1.7	1.8
Number of employees in R&D	6,647	6,872

Source: Assobiotec report 2012.

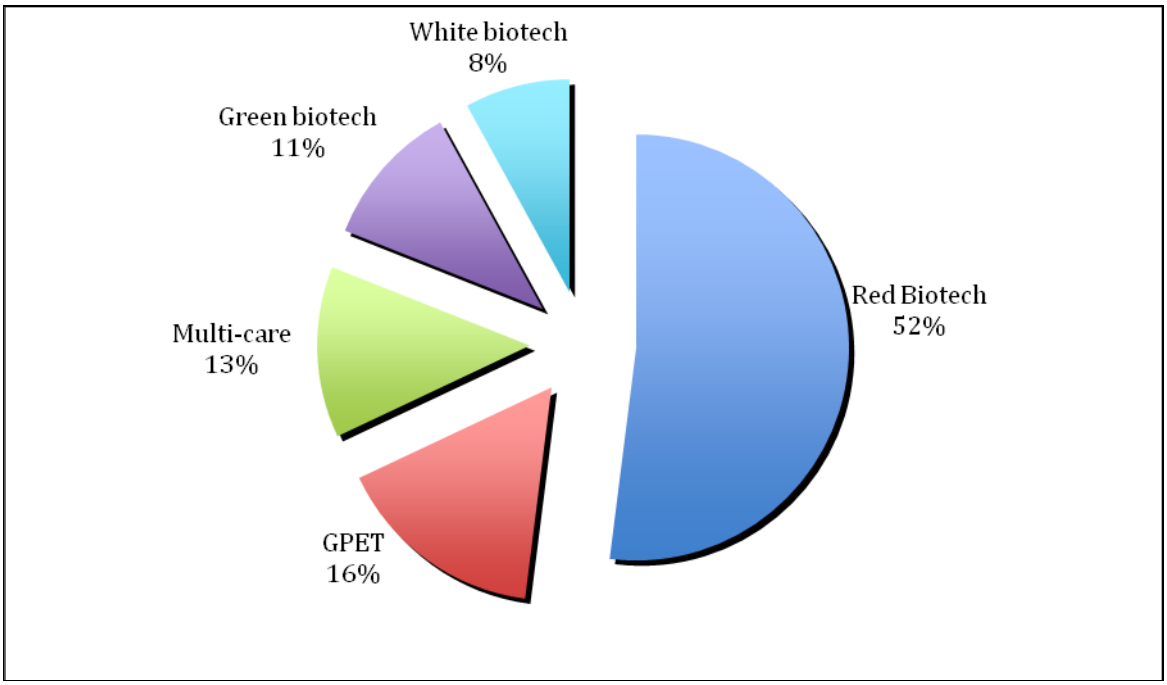
Again, this year, the biotechnology industry in Italy is characterized as a dynamic and promising sector, despite the worsening economic situation that biotech companies have to confront on a daily basis. The number of biotech companies in Italy has sharply increased over the last decade. At the end of 2011, 394 biotech companies engaged in research and development were recorded. Among these, no less than 248 falls under the definition of pure biotech companies (whose core business activities are exclusively related to biotechnology) ranking third in Europe just behind Germany and UK (Biotechnology in Italy 2012 - Assobiotec and Ernst & Young, in cooperation with Farmindustria and ICE).

Biotechnology companies can be divided into the following categories according to their field of operation:

- **Red Biotech**: medical biotechnology
- **Green Biotech**: agricultural biotechnology
- **White Biotech**: industrial biotechnology
- **Genomics, proteomics and enabling technologies** (GPET)
- **Multi-core**: mix of the previous categories.

Of the 394-recorded companies, 238 are active in health biotechnology, 61 in the GPET (Genomics, Proteomics, and Enabling Technologies) sector, 43 are dedicated exclusively to the green biotech field, 34 are active in white biotech, and 50 operate in more than one application field (multi-core). The majority of companies that operate in the field of biotechnology (77 percent) are micro-sized or small (47 percent micro and 30 percent small), having a number of employees less than 50 units. Companies that have between 50 and 250 employees (classified as medium-sized) are 12 percent of the total, while 11 percent are large-sized (more than 250 employees). These are mainly pharmaceutical companies representing 10 percent of total biotech companies, and accounting for 82 percent of total turnover.

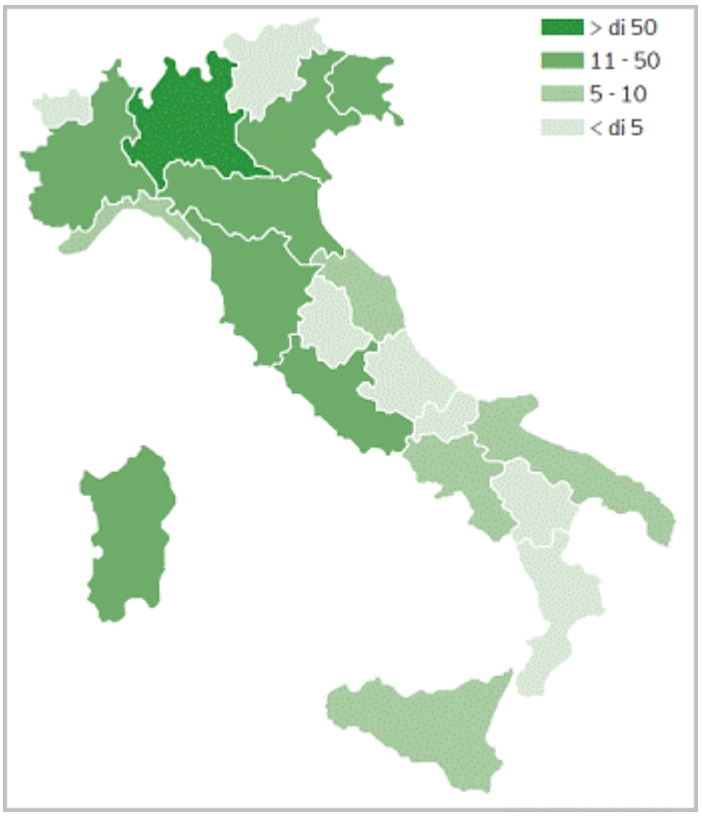
Figure 2 - Distribution of biotech companies among the 5 sectors in Italy



Source: Assobiotec Report 2012

As with most innovative businesses, biotech companies are concentrated mostly in the center-north of Italy (Figure 3): Lombardy (33 percent), Piedmont (11 percent), Latium (11 percent), Emilia-Romagna (9 percent), Veneto (6 percent), Tuscany (6 percent), Sardinia (6 percent), and Friuli Venezia Giulia (5 percent). Particularly, Lombardy was praised for its university infrastructure, strong tradition of entrepreneurship, and its regional government's dedicated funds to biotech companies. As to their location, 54 percent of biotech companies have independent headquarters, 35 percent work within science parks or incubators, while the remaining 11 percent is located near universities, clinical centers, or research institutes.

Figure 3 – Geographical distribution – number of biotech companies



Source: Assobiotec Report 2012

MEDICAL BIOTECHNOLOGY (RED BIOTECH)

Table 4 - Italian Red Biotech industry main figures

	2011	2012
Number of companies	240	238
Total turnover (€mln)	6.6	6.8
R&D Investments (€mln)	1.6	1.7
Number of employees in R&D	5,508	5,671

Source: Assobiotec report 2012.

Red biotech accounts for 96 percent of total turnover of the whole biotech industry, representing 92 percent of total investments.

Red biotech companies' activities can be breakdown as follows:

- **Therapeutic:** development of drugs and other therapeutic approaches, such as gene- or cell-based therapies for the treatment of various diseases;
- **Vaccines:** biological preparations for prophylaxis and treatment;
- **Drug delivery**: technologies to convey the drugs to a specific site through optimization of their absorption and their distribution (advanced materials, liposomes, antibodies, cell therapy, etc.);
- **Molecular diagnostics**: DNA/RNA-based tests for the diagnosis, prognosis, and detection of any predispositions to specific diseases and for the analysis of pathogenic mechanisms;
- **Drug discovery**: synthesis, optimization and characterization of drug candidates; assay development, screening, and validation activities on medicinal products.

Currently, 238 enterprises are active in red biotech: 87 percent is made up of biotechnology companies dedicated exclusively to human health, while the remaining 13 percent consists of multi-core companies. Most of the latter are active in GPET, which also includes Nanobiotechnology, confirming the fact that companies tend to manage their ancillary activities internally. As regards their origin, 38 percent of the companies that operate in the red biotech field derive from start-ups, 19 percent from subsidiaries of multinational companies, 18 percent from academic spin-offs, 8 percent from Italian pharmaceuticals, and 8 percent from industrial spin-offs or spin-outs.

INDUSTRIAL BIOTECHNOLOGY (WHITE BIOTECH)

Table 5 - Italian White Biotech industry main figures

	2011	2012
Number of companies	49	54
Total turnover (€mln)	130	161
R&D Investments (€mln)	22	28
Number of employees in R&D	430	456

Source: Assobiotec report 2012

The industrial white biotech refers to the use of modern biotech methods for the processing and the production of chemicals, materials, and fuels, including "bioremediation" technologies for the environmental protection. Currently, 54 companies deal with industrial biotech, 40 specifically dedicated to white biotech, and 14 multi-cores. The largest majority of white companies (87 percent) are micro-sized or small. 52 percent of the white companies originate from start-ups, 19 percent from academic spin-offs, and 7 percent from industrial spin-offs or spin-outs. Almost all the white biotech turnover can be attributed to pure Italian biotech companies. Total revenues reached €161 million, representing a € 31 million increase compared to 2009— result that originates from the growth in revenues (24 percent) of one single pure biotech company of medium size.

AGRICULTURAL BIOTECHNOLOGY (GREEN BIOTECH)

Table 6 - Italian Green Biotech industry main figures

	2011	2012
Number of companies	83	82
Total turnover (€mln)	116	103
R&D Investments (€mln)	84	111
Number of employees in R&D	709	745

Source: Assobiotec report 2012

The green biotech category includes the use of modern biotech methods for the production of transgenic plants with applications in the food, chemical, material or fuel sector, molecular pharming (production of drugs in plants), and testing to reveal the presence of ingredients/contaminants in food. The majority of companies (76 percent) operating in the green biotech sector are made up of pure biotech, while the remaining 24 percent is divided among other Italian biotech (21 percent) and Italian subsidiaries of multinational companies (3 percent). In terms of size, the predominant presence of small (56 percent) and micro (24 percent) companies, followed by medium (14 percent) and large organizations (6 percent), characterize the green sector.

Italy has been one of the first European countries to start Genetically Modified plants and/or organisms (GMO) field experiments. Therefore, many public and private research projects were launched

regarding various crops, such as olive oil, grapevines, cherries, strawberries, reaching more than 250 experimental projects at a national level. Nevertheless, the national political debate on biotech crops (and plants experimentation) gradually deteriorated reducing Italy's commitment on GMO's research and cultivation. Public and private research funding on agro-biotechnology has gradually been cut to zero and currently no GMOs field trial is being conducted in Italy. In 2001, the Italian Ministry of Agriculture (ITMinAg) issued a decree banning biotechnology experimentation in agriculture.

However, later on, Italy had to transpose the EU Directive 18/2001 on the deliberate release into the environment of GMOs. In 2005 then, the ITMinAg issued another decree establishing the main requirements to evaluate the risk linked to GMO experimental plantings and tasking regions to find out crops and sites where GMO field trials could be conducted. Given such provisions, some regions in 2008 approved 9 crops-site dossiers (citrus, kiwifruit, strawberry, sweet cherry, corn, olive, eggplant, tomato, grape) to carry out GMO experimentations. Nevertheless, the Ministry of Agriculture never implemented a decree to authorize those experimental sites, due to the absence of coexistence rules. Moreover, many Italian Regions and Provinces have declared themselves "GM-free," further hampering the scope for new research and plantings.

Testing represent a relevant share of the green biotech. Below is a short list of applications that biotechnology provides to the Agri-food sector in Italy:

- **Identification of a pathogen genotype in food**: the use of DNA-based test allows distinguishing different bacterium varieties (i.e. Salmonella, Listeria, and Escherichia coli) and identifying the pathology source;

- **Analysis of food allergens**: the use of advanced DNA-based technologies (PCR) allows identifying food allergens much easily than using traditional methods;

- **GMO Identification**: the analysis to investigate the presence of GMO products through biotechnology is a widely spread standard procedure, as indicated by the EC Regulation N. 1830/2003, concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

GENOMICS, PROTEOMICS AND ENABLING TECHNOLOGIES (GPET)

Genomics, proteomics, and enabling technologies (GPET) include all genomic (investigation of the structure and function of genes) and proteomic activities (analysis of protein regulation, expression, structure, post-transitional modification, interactions and function), bioinformatics, biochips and other

bio-related tools, biopharmaceutical production, molecular basic research, and further enabling technologies.

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