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Biotechnology in Italy 2011

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Report Highlights:
Italy has a large and profitable biotech industry operating in the medical, industrial, and agricultural sector. In 2010, the Italian biotech industry increased its turnover by 6 percent with 6 new companies entering the market. Despite a late start, the Italian biotech sector is rapidly growing trying to catch up with the main international leading countries. It now ranks 3rd in Europe in the number of pure biotech companies.

General Information:

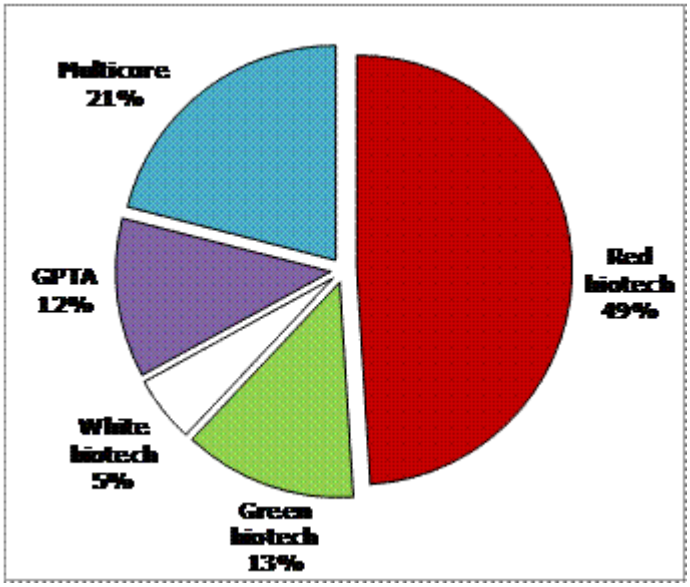
OVERVIEW

In 2010 Italy's biotech industry reported turnover of €7.4 billion, up 6 percent from previous year. The number of biotech companies in Italy has sharply increased over the last decade. Recent figures indicate that as many as 375 companies currently operate in the Italian biotech sector. In 2010 there were 221 Italian biotech companies (59 percent of total companies) dedicated exclusively to research and development (R&D) in biotechnology, also called *pure biotech* companies, ranking third place in Europe just behind Germany and UK. Most of these companies are fairly small: almost 90 percent of all Italian biotech companies have less than 250 employees and sales slight above 22 percent of total turnover, while 75 percent of all Italian biotech companies have less than 50 employees indeed.

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** (GPTA)
- **Multicore**: mix of the previous categories.

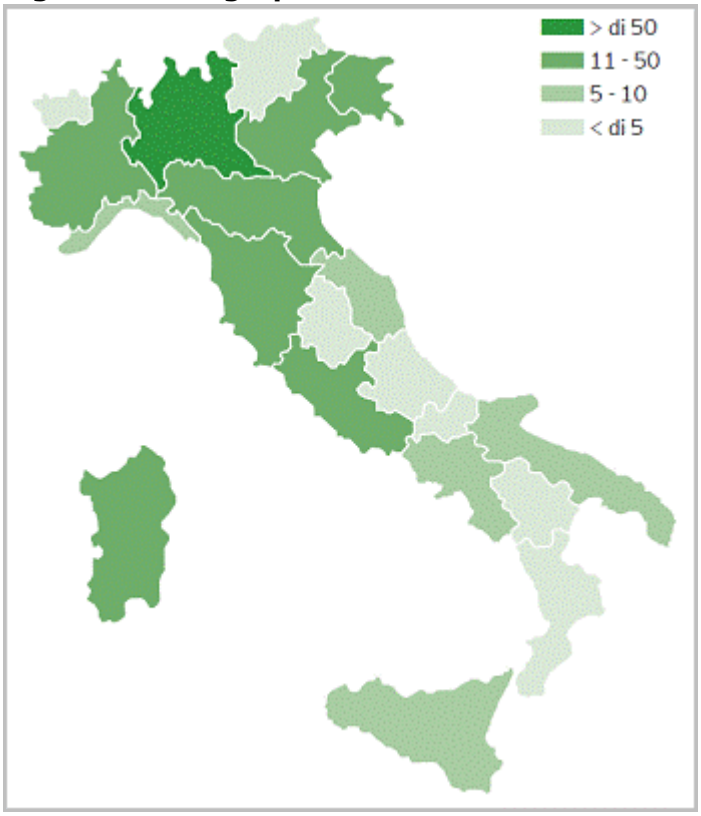
Figure 1 - Distribution of biotech companies among the 5 sectors in Italy



Source: Assobiotec Report 2011.

As with most innovative businesses, biotech companies are concentrated mostly in the center-north (Figure 2): Lombardy (34 percent), Piedmont (9.8 percent), Veneto (8.3 percent), Tuscany (8 percent), Lazio (8 percent), and Emilia-Romagna (6.9 percent). Lombardy in particular was praised for its university infrastructure, strong tradition of entrepreneurship, and its regional government's dedicated funds to biotech companies.

Figure 2 – Geographical distribution – number of biotech companies



Source: Assobiotec Report 2011.

MEDICAL BIOTECHNOLOGY (RED BIOTECH)

The most relevant field of the Italian biotech industry is the one related to human health, both for the number of companies and for the economic value (table 1). Red biotech companies' activities can be breakdown as follows:

- Therapeutics: development of drugs and other therapeutic approaches such as gene- or cell-based therapies for the treatment of various diseases.

- Drug discovery technologies and services: early drug discovery technologies (synthesis, optimization, and characterization of drug candidates), screening and validation activities, assay development, and drug testing services.

- Drug delivery: bringing drugs to their site of action by directed, specific, or efficient delivery (advanced materials, liposomes, antibodies, viral, or cell-based).

- Tissue engineering: biological substitutes for the restoration or replacement of tissue or organ function (also called regenerative medicine) based on the application of stem cells and other cell therapies as well as on novel biomaterials and growth factors.

- Molecular medical diagnostics: DNA-/RNA-based tests and methods for the detection of a disease, the proneness to a disease, or pathomechanisms, paternity testing.

Table 1 - Italian Red Biotech industry main figures

	2009	2010
Number of companies	243	246
Total turnover	7.0	7.2
R&D Investments	1.6	1.7
Number of employees	5,489	5,587

Source: Assobiotec report 2011.

With respect to the total sample, consisting of 375 companies, 246 (66 percent) are active in the red biotech field and 185 of these are focused solely on red biotech, while 61 have activities in other fields. Most of these companies are Italian however, 19 percent of total red biotech firms are multinational companies gaining almost 80 percent of total turnover.

INDUSTRIAL BIOTECHNOLOGY (WHITE BIOTECH)

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, 41 companies deal with industrial biotech, 21 specifically dedicated to white biotech and 20 multi-core. Total turnover is about €103 million (2009) increasing sharply from previous year. Moreover, approximately 23 percent of the white biotech companies' turnover has been invested in R&D.

AGRICULTURAL BIOTECHNOLOGY (GREEN BIOTECH)

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), testing to reveal the presence of ingredients/contaminants in food. The companies which operate in the green biotech field are 94, 49 of which are fully dedicated (defined "green dedicated") and 45 operating also in other fields (red and white). Total Italian green biotech turnover was estimated at €144 million (2009).

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 on 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 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 to be "GM-free," further hampering the scope for new research and plantings.

However, green biotech is not only related to the production of GM plants. Several research projects are carried out inherent to the production of drugs in vegetable organisms, nutraceutics, functional foods and probiotics, and also diagnostics useful in the agricultural and animal husbandry field.

Moreover, testing represent a relevant share of the green biotech. Below, a short list of applications that biotechnology is providing to the agri-food sector in Italy:

- **Detection of food contamination**: nowadays there are new quick methods replacing the traditional food microbiology ones which allow to rapidly indentify (24-48 hrs) the possible presence of pathogenic agents in food (ex. Salmonella, Listeria and Escherichia coli).

- **Identification of a pathogen genotype in food**: the use of methods based on the DNA test allow to distinguish the different bacterium varieties and identify the pathology source.

- **Analysis of food allergens**: advanced technologies such as those based on DNA technologies (PCR). allow to identify 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 regulations in the products' tag label (Reg.1830/2003)

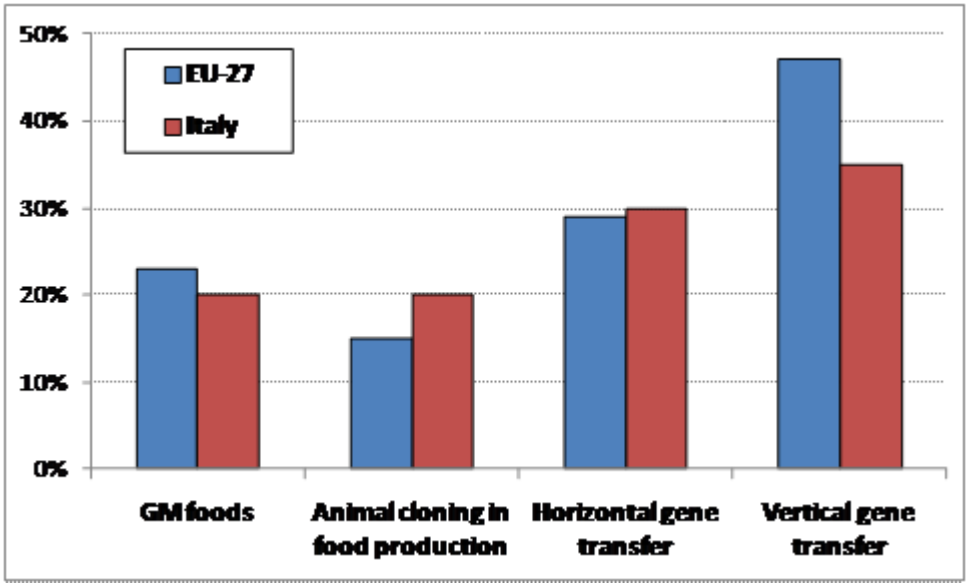
GENOMICS, PROTEOMICS AND ENABLING TECHNOLOGIES (GPTA)

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.

PUBLIC OPINION

Italians support for biotechnologies is quite close to the average European citizen (figure 3). However slight differences can be reported on their opinion regarding GM food and vertical gene transfer where Italians are less in favor than other Europeans. On the contrary, Italians are more willing to support animal cloning and horizontal gene transfer.

Figure 3 – Support* for biotechnologies in the EU-27 and Italy

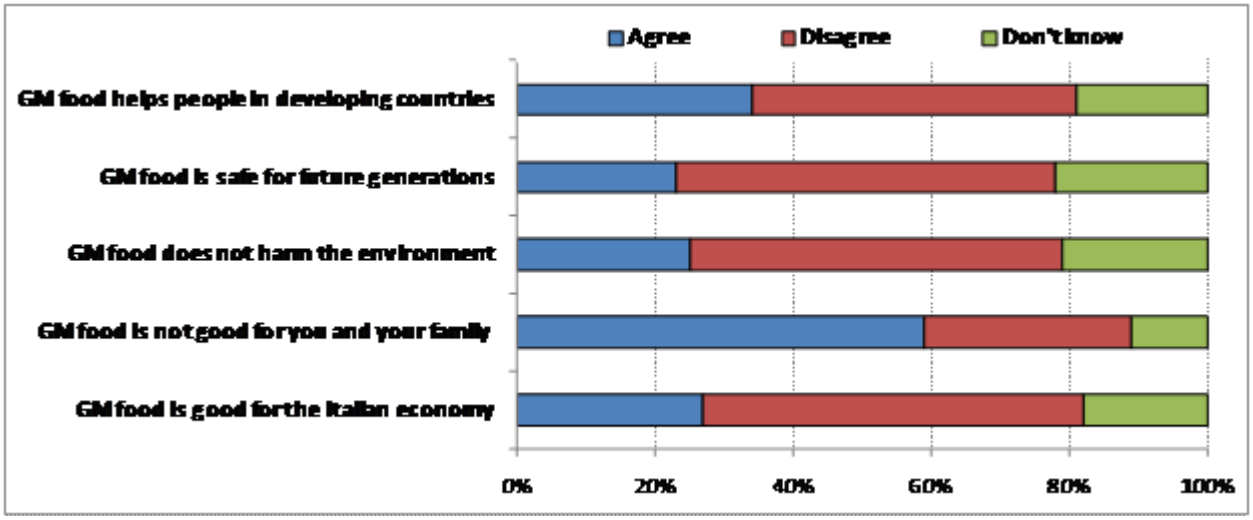


*Agree to the fact the biotechnology should be encouraged
Source: Eurobarometer – Biotechnology report 2011.

Overall, the Eurobarometer survey reveals that Italian public opinion is split about biotechnology. In 2010, just over half of respondents (52 percent) believed that it will have a positive effect on our way of life over the next 20 years while less than a third of Italians feel strongly about biotechnology.

In particular, the survey shows that, overall, Italians do not see the benefits of genetically modified food and consider these to be unsafe or even harmful. This explains the low percentage of Italians generally in favor of the development of GM food (figure 4).

Figure 4 – Attitude of Italians towards Genetically Modified Foods



Source: Eurobarometer – Biotechnology report 2011.

Looking at Italians' attitude towards other biotechnologies such as gene transfer techniques, they do not see the benefits of horizontal gene transfer and have strong reservations about its safety. There is clear consensus that special labeling of food products is necessary and that it should not be encouraged. On the other hand, half of the respondents accept the potential benefits of vertical gene transfer. Considering some reservations about its safety and the potential impact on the environment, the tendency is that it should not be encouraged although special labeling of food products is considered necessary. In addition, the public has strong reservations about animal cloning in food production and Italians do not see the benefits of this science. There is a general feeling that animal cloning in food production should not be encouraged.

As for biotechnologies related to health, Italians think that the science of regenerative medicine should be allowed to develop but they have some reservations about ethical issues, such as the use of human embryos. Close to 40 percent of Italians agree with the statement that research involving human embryos should be forbidden, even if this means that possible treatments are not made available to ill people. However, a large part of respondents (50%) disagree, while about one in ten lacks an opinion.

Finally, there is also broad approval of stem cell research, transgenic animal research and human gene therapy.

Definitions used in this report

Gene transfer is where an organism receives genetic material from another and can be divided into two types. Firstly, there is horizontal gene transfer a process whereby an organism incorporates genetic material from another, unrelated organism. In the second form - vertical gene transfer - an organism receives genetic material from a related organism, or ancestor.

Regenerative medicine is the process of creating living, functional tissues to repair or replace tissue or organ function lost due to age, disease, damage, or congenital defects. This field holds

the promise of regenerating damaged tissues and organs, of scientists being able to grow tissue and organs in the laboratory and implant them in the body which may eventually lead to solving the problem of organ donor shortage and rejection of donor organs by the body.

Stem cells are found in most, if not all, multi-cellular organisms. There are two broad types of stem cells: embryonic stem cells, which can potentially develop into any type of specialized tissue, and adult stem cells, which are cells of a particular type that act as a repair system of the body and replenish specialized cells in regenerative organs.

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