

Italy

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1.7. ITALY

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Recently there have been major changes in the organisation of Italian biotechnology. In 1985 biotechnology R&D was fragmented without real direction or co-ordination. No national priorities had been defined.

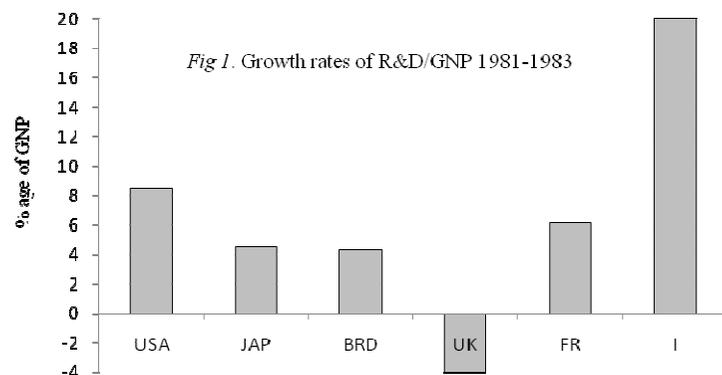
Most of the nation's biotechnology programmes were at that time focused on human health and supported by the National Research Council, CNR.

Table 1. Finalised Biotechnology Projects 1985 National Research Council.

Genetic Engineering and the molecular basis of inherited disease
Infectious diseases
Oncology
Biomedical technology
Improvement of agricultural production
Fine and secondary chemistry

This initial set of projects gave rise to competence in several key aspects of biotechnology, such as monoclonal antibody production and molecular recognition. Significant short term advances were made in the area of gene manipulation and the production of recombinant products.

In the context of the fine chemistry projects several advances in enzymology were funded, and in the domain of agriculture some rationalisation of modern plant genetics was undertaken at national level.



The investment made in this first round of funding was judged inadequate, but none the less it demonstrated Italy's commitment to meeting the levels of R&D expenditure sustained by other developed countries.

Figure 1 compares the rate of growth of R&D expenditure as a %age of GNP up to 1984. The data are derived from a report of the Italian Chemistry Federation, Federichimica, on biotechnology entitled 'Le Biotecnologie in Italia: un'opportunita di sviluppo industriale'. Milano 1986.

In 1985 a National Biotechnology Committee had been created, supported by the Committee for Development and Innovation in the Chemical Industry Federation. These bodies recommended the pursual of a National Biotechnology Policy, charged with organising, funding and directing programmes.

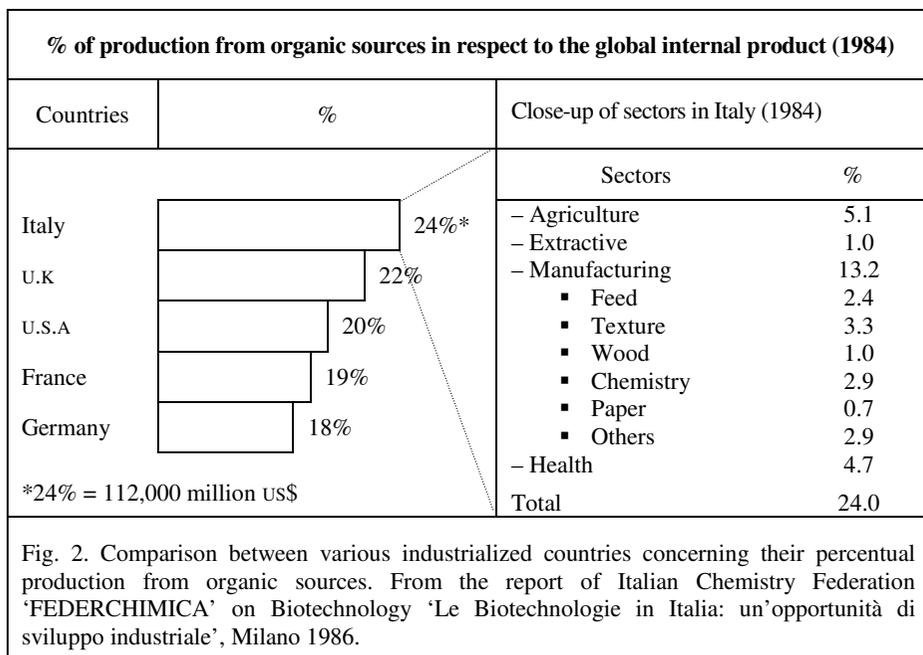
The National Programme represented a logical development, for 24% of Italy's revenues are based on organic or biological products with a 1984 value of 112 billion US\$ (see Figure 2). This percentage is higher than for other countries and illustrates why biotechnology is of such keen interest; several key market areas of relevance to Italian industry are affected.

The areas illustrated in the following diagrams have several common features:

- They are big markets with potential for large expenditure;
- They are characterised by imported products;
- SMEs have a high profile in this market. They need a common development policy.

The Italian health care market was worth US\$6 billion in 1984, about 35% of that spending going on diagnostics, pharmaceuticals and biomedical. By 1990 this area could be 25-35% dependent on biotechnology products.

Agriculture accounts for total invoices of US\$32 billion, spent mostly on animal breeding, cereals and vegetables. Consumption increases are causing an import boom. The animal feed sector in particular, worth US\$26 billion (1984) is characterised by a significant excess of imports over exports.



Several factors influence this:

- Feed habits orient towards a strong feed industrialisation (with low cost);
- Trend to 'natural feed' with high quality food from direct agricultural sources and wide availability throughout the year (with high cost).

Biotechnology might solve the problem by providing high quality food at low prices. Production and storage technologies might also be favourably influenced.

Ecological considerations will play an increasingly important role in the industrialised nations. The processing and recovery of industrial and agricultural wastes is a market worth perhaps US\$15 billion within a decade. Lack of ecological surveillance could precipitate high costs in both social and economic terms.

Ecologically relevant companies have increased by more than 75% in number since 1980.

In the Chemicals sector the global market for Italian products was estimated at US\$26 billion. This potential is compromised however, by a massive dependence on imported products.

All sectors of industrial activity are therefore open to the influence of biotechnology. An industrial representative committee has considered the following theoretical areas of application.

- 40% of biotech products would be new, not realisable by existing technologies.
- 60% of biotech products could represent the consequence of improvements to existing processes.
- 70% of ideas generated could be realised in the short to medium term that is up to 5 years from now.

In 1985, in response to these ideas the National Research Council, CNR, created a Task Force to mobilise activity in well focused research areas. Focused on CNR and university laboratories the resulting programme: Strategic Project, Advanced Technology in Biology, was divided into three major subprogrammes:

- Biotechnologies
- Agro-industrial technologies
- Aquaculture

Table 2. National Research Council: Strategic Project Innovative Technologies in Biology' (1986-1987)
Funding: US\$2.1 million
Subprojects:
1. <i>Biotechnologies</i>
▪ Enzymology, natural or modified enzymes
▪ Agro-industrial biotechnologies
▪ Oligonucleotide synthesis and molecular probes
▪ Cellular carriers
▪ Biosensors
2. <i>Agrotechnologies</i>
▪ Cultivated plant technologies
▪ Molecular and biological control of parasites and abiotic stresses
▪ Models of agroecosystem productivity
3. <i>Aquaculture</i>
▪ Artificial reproduction and genetic improvement in fish breeding
▪ Reproduction and breeding of new fish species
▪ Breeding of molluscs

In the first two years the budget for this programme was low, only US\$2.1 million, but the idea was to orientate a number of research groups to just a few well defined technologies.

Following on from this programme is the: Special Project: Biotechnology and Bioinstrumentation, with funding of US\$68 million over the five year period, 1987-1991. This programme will focus on precompetitive aspects of biomedical and chemical areas. Addition of important new subprogrammes in vaccines, cell culture and transplantation biology is a feature. The CNR will involve universities and research institutes in the programme.

<p>Table 3. National Research Council: Special Project 'Biotechnology and Bioinstrumentation' (1987-1991)</p> <p>Funding: US\$68 million/5 years</p> <p>Subprojects</p> <ol style="list-style-type: none"> 1. Molecular and Cellular Engineering 2. Innovative vaccines and bio-diagnostics 3. Biosensors, cellular bioreactors 4. Applied biotechnologies: cell culture, organ transplants 5. Bio-drugs 6. Bio-instrumentation
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<p>Table 4. Ministry of Scientific and Technology: National Project Advanced Biotechnologies' (1988-1992)</p> <p>Funding: US\$308 million/5 years</p> <ol style="list-style-type: none"> 1. Medicine and veterinary areas <ul style="list-style-type: none"> ▪ Diagnostics ▪ Plasma proteins ▪ Fibrinolytics enzymes ▪ Biological response modulators ▪ Immunotherapeutics 2. Chemistry, Energy and Environment <ul style="list-style-type: none"> ▪ Biocatalysis ▪ Biopolymers ▪ Biological control of pollution 3. Agriculture and Food <ul style="list-style-type: none"> ▪ New plants ▪ Micro-organisms ▪ Animal husbandry ▪ Food bio-conversion ▪ Food diagnosis

A third major programme designed to stimulate industrial competitiveness and innovation through government support, is entitled: National Programme, 'Advanced Biotechnologies', funded by the Ministry of Scientific Research and Technology. This programme envisages expenditure totaling US\$308 million over the five year period to 1992.

<p>Table 5. Nonmedical applications of biotechnology.</p> <p>Chemistry, energy and environment</p> <ol style="list-style-type: none"> A) New enzymes B) Innovation on bio-conversion and enzyme catalysis C) Polysaccharides from natural sources D) Control and recovery of environments E) Bioprocessing of minerals <p>Agriculture and Feed</p> <ol style="list-style-type: none"> A) <i>In vitro</i> plant generation B) Introduction and expression in plants of exogenous genes C) Plant nitrogen metabolism D) Biological defence of plants E) Improvement of growth and nutritional properties of breeding animals F) Enzymes for feed industry G) Treatment of agricultural wastes H) Control of food safety

In Table 5, two of the areas considered above are examined in closer detail. There is broad accord with the aims expressed by the European Commission, particularly with regard to the stimulation of agro-industrial development.

The Italian response to the recent Commission 'Call for Expressions of Interest' on the theme, 'Stimulation of Agro-Industrial Development', was most encouraging (see Fig 3). Some 70% of the Italian 'expressions' were from industrial organisations (see Fig 4).

Agro-industrial development – Results of call for interest

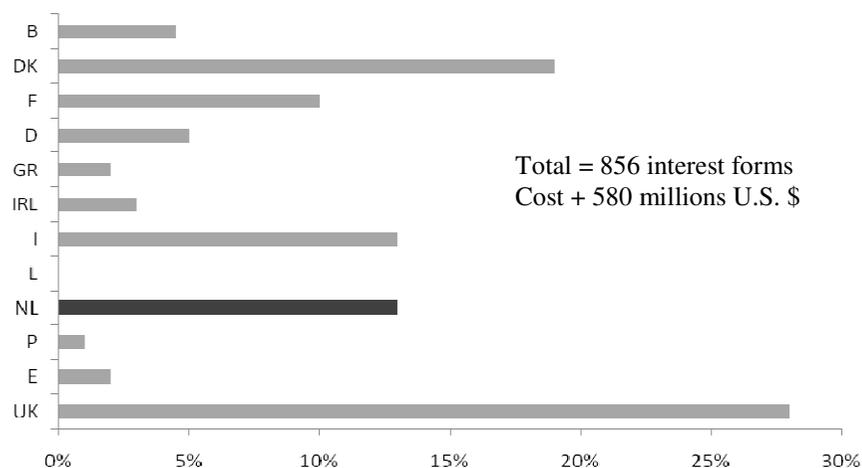


Fig. 3. Results of call for interest concerning the 'Stimulation of Agro-Industrial Development' from EEC expressed as national percentual of the total responses. From EEC document CUBE-XII/233/87.

Industry Interest

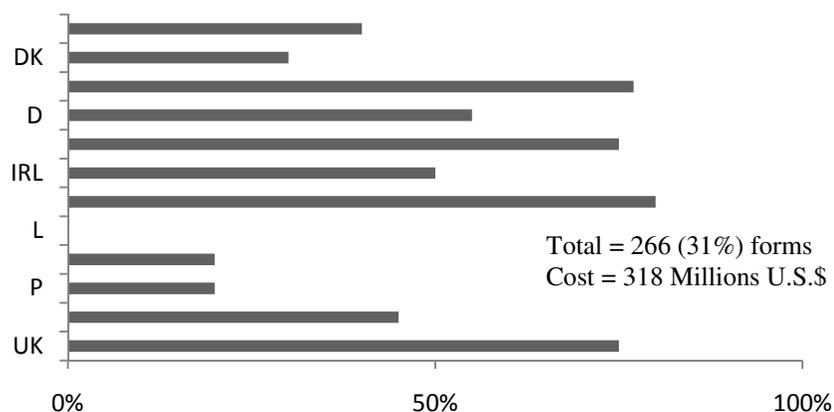


Fig. 4. Industry interest for stimulation of agro-industrial development. Results are expressed as percentual of total responses from each country. From eec document cube-xii/233/87

Other public programmes with an element of biotechnology are summarised in Table 6.

In the planning stage is an agricultural programme with a provisional budget of several hundred million US\$. Focus will be on crop production, animal breeding and adding value to agricultural by-products.

Programme	Focus	Value US\$ million
<i>CNR Special Projects:</i>		
Fine chemistry:	Biologically active products	18
Genetic engineering:	rDNA technology vs genetic disease	23
<i>Ministry of Science and Technology, National Programmes:</i>		
Technology in oncology	Monoclonal antibodies and DNA probes	14
Pharmaceuticals:	Targeting of cytotoxic drugs	4

In Figure 5 the present state of national funding programmes in biotechnology is recapitulated. The overall commitment of funds is seen to exceed US\$430 million over the present five year period. This major funding is intended to bridge the gap between industrial innovation and academic research, so strengthening the Italian presence in this key area of technology.

Public fundings for Biotechnologies

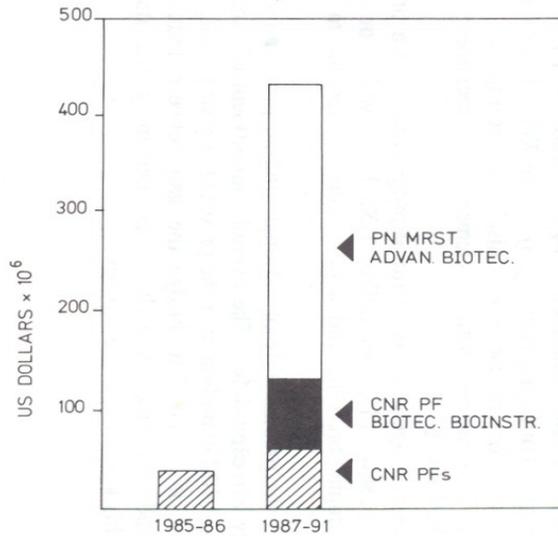


Fig. 5. Comparison between two periods of public fundings to biotechnology in Italy. PN MRST: National Program from Ministry of Scientific Research and Technology. CNR PF: Finalized Project from National Research Council.