New Issues in Assessing Biotech Sector: Some Empirical Evidences and Policy Implications

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Abstract: A common view among many academics and policy makers is that biotech offer enormous opportunities for improving competitiveness and economic growth. For this reason there is a growing need to set up appropriate policy to improve the adoption and diffusion of biotech innovation. Nevertheless, there are many interpretative problems about the identification of the biotech firm, due to the uncertainty about the border of the sector itself. The main objective of this paper is to provide a contribution to better define biotech industry considering the pervasive nature of innovation in this sector. The paper provides an Italian data set survey and a new data base consistent with OECD statistical standards. The paper includes both an evaluation of the degree of functionality of the OECD firm classification on our data and an information source survey for statistical indicators for the main policy areas.

Keywords: Biotech innovation, Italian biotech industry, Industry assessment, OECD statistical model, Policy indicators

1 Introduction

The emergence of biotech as a new industrial technology, at the end of '70s, can be considered as a gradual changing process. This process implies new firms and a new competitive regime within different industrial sectors. The ongoing process takes with it some interpretative problems about the exact definition of the new biotech firms and of the sector they shared to create.

In fact, the pattern of biotech innovation differs across countries in relation with the level and distribution of scientific and technological capabilities and the institutional set up (Orsenigo, 1989). The path through which the growing knowledge flows –especially arising out of molecular biology - goes to find profitable market applications go by different routes. It can be expressed by a new firm or took place into an established large firm. In this way, it is possible that the biotech industry would include different actors. It is possible also because of the nature of biotech innovation that is characterised by a strong degree of multidisciplinarity. As result, biotech sector boundaries remain variable.

It follows an informative lack that is evident considering NACE (*Nomenclature générale des activités économiques*) classification that completely misses biotech activities.

The objective of this paper is to propose a definition for biotech sector using a methodology organised into two steps. First, a data base has been built on a generic definition of biotech activity. Second, a specific inventory based on the OECD biotech firms taxonomy has been set up. In addition, the paper explores the main policy needs for biotechnology and the types of indicators that can be obtained from existing data sources.

The paper has been organised in the following sections. After this introduction, the research background is outlined in order to clarify the nature of the biotech sector definition problem (section 2). In section 3 a description of methodology is given. In section 4, are reported the results and finally, section 5, contains the conclusions and some implication for future research.

2 Research Background

A coherent and homogeneous biotech firm and/or sector definition meets a fundamental measurement need (requirement). In fact, as happens for any emergent firm given the intrinsic uncertainty associated with its technological and economic success, it is hardly possible to define, compare and rank new firms ex-ante (Dosi, 1984). In the case of biotechnologies, in addition, technological advances are built upon some portion of publicly available knowledge – which may be located in universities, other research institutions or other industries and firms – and upon the development of the internal, specific and tacit capabilities of any one company (Orsenigo, 1989).

On the other hand it is possible to classify biotech activity if we (exclusively) look at it from a policy point of view. In this way, it becomes possible, for example, to distinguish a small and autonomous lab firm from an established and bigger one.

Main recent issues about policies for innovative firms assess the importance of driving *knowledge flows* into the firm itself to make it grow through its innovative skills (Kline and Rosenberg, 1986; Freeman, 1987). In a knowledge-intensive industry such as biotech, a critical role is played by the strategic alliances/collaborations made to facilitate these knowledge and information flows within and outside the firm. In this sector, collaboration is used to facilitate the learning process (Powell, Brantley, 1992). Some policies have already been introduced in Europe to increase knowledge flows among firms and between firms and public research organizations, such as Universities or other Research Departments etc.

In such a scenario, in which the focus is on the policies, the definition of a biotech firm and consequently the measurement problem becomes more specific and the policy choices require some statistical indicators both of knowledge production and of the size and extension of knowledge-based transactions (Arundel, Constantelou, 2006).

From a policy point of view we need to explore the extent, density and mechanism of innovation-related knowledge flows affecting the innovative capacity of firms and the mechanism that support such a flow, as well as examining incentives to access and transmit results and the determinants of knowledge transmission (Arundel, Constantelou, 2006).

In this regard, an interesting question concerns the geographic proximity between knowledge producers and innovators. In the Italian case, for example, a strong concentration of non-profit research bodies in contact with foreign firms persists (Iorio, Labory, Paci, 2007).

From an organizational research perspective, the central role of weak ties for the information transfer useful to better results in biotech field has been assessed. In particular, better results are associated with better governance solutions into biotech networks (Powell, Grodal, 2005).

On these critical policy dimensions our search for related statistical indicators leads to different international data sources and to a fundamental need for the adaptation of our information system to them.

In other words, the paper attempts to give an answer to the following questions:

1) is it possible to rank Italian biotech firms using OECD codes?
2) among the actual data sources, which can we choose to set up the adequate statistical indicators linked to the main policy areas? And, what kind of information remains completely unknown?

For these reasons, it has been necessary to start from the data base setting and after by a specific inventory based on the OECD biotech firms taxonomy.

3 Research Method

Starting from the classic social research method of classification, we chose to rank biotech activities on the basis of a specific goal: the policy need. Subsequently, it is possible to apply the existing OECD firm classification to our data.

The research method has been selected because of the availability of two fundamental tools: a) some Italian biotech firm population lists; and, b) the OECD *Statistical Framework for Biotechnology* (2001).

The research is carried out in the following phases:

1) A setting up data base through the matching of population list data;
2) Biotech activity classification by OECD firm taxonomy;
3) Examination of evidence on the differences between OECD firm taxonomy and our data set;
4) Examination of official Italian data sources about R&D biotech investment;
5) Collection of policy indicators from Italian and other international data sources.

4 Main Results

Our Italian biotech activities data base (RP Biotech Data Base) has been set up using multiple alternative sources. Since there is not yet a complete inventory of these activities but it was made possible by using a large number (14) of different population lists. These population lists produced by different organizations, such as public research institutions, professional associations or local development agencies, focus on different targets using different definitions and classifications of biotech activities.

The first research step involved the matching of all the information from the population lists. Table 1 shows just a selection of these population lists by illustrating the number of biotech activities in each class. Each class is based on an unique and homogeneous standard: the Italian Biotech Data base/IBD catalogue system.

As table 1 shows, the IBD catalogue system divides biotech activities up to 8 classes. It is important to note that there is a strong difference among the number of activities considered by each population list.

Through the intersection of population list information it has been possible to create a bigger data base of 995 cases generically defined and ordered according to the IBD catalogue system (Table 2).

Table 1 A comparison among selected Italian population list (2005)

	Number of biotech activities by IBD catalogue system							
Population list	**S**	**Br**	**B**	**MT**	**BI&S**	**C**	**I**	**NPO***
Italian Biotech Data base (IBD)	121	115	33	51	33	25	6	54
Annuario della biotecnologia Italiana	17	68	41	22	0	8	0	138
Italian biotechnology directory	18	30	21	24	9	29	5	63
Assobiotec	7	23	22	8	2	0	2	7
Sistema informativo biotecnologie	18	83	57	32	6	21	3	243
Others	15	96	40	28	9	13	1	170

Source: our elaboration on 14 Italian population lists

* S=supplier
Br=biotechnology related
B=biotechnology
MT=medical technology
BI&S=biotechnology instrumentation and services
C=consulting
I= investor
NPO=no profit organization

Table 2 RP Biotech Data Base (2005)

	Number of biotech activities by IBD catalogue system								
	S	**Br**	**B**	**MT**	**BI&S**	**C**	**I**	**NPO**	**tot**
RP Biotech Data Base	127	251	93	37	67	48	7	365	995

Source: our elaborations on 14 Italian population lists

The OECD *Statistical Framework for Biotechnology* (2001) introduced some important definitions (a single definition of biotechnology, deliberately broad; a more specific list-based definition of biotechnology; and, other definitions to cover basic activities, actors and investments) useful to obtain the policy indicators. At the same time, this statistical standard, if applied by every OECD national information system, can make biotech data comparison possible among countries. The OECD framework divides biotech activities into 6 classes as showed in table 3. The first distinction is between production and service activities. Second, among production activities, it distinguish between active, innovative and dedicated biotech firms in order to identify activities more or less focused on biotech. In particular, a biotechnologically active firm (BAF) is defined as a firm engaged in key biotechnology activities such as the application of at least one biotech technique to produce goods or services and/or the performance of biotechnology R&D. A dedicated biotech firm (DBF) is a BAF whose *predominant* activity involves the application of biotech techniques to produce good or services and/or the performance of biotech R&D. An innovative biotech firm (IBF) is defined as a BAF that applies biotech techniques for the purpose of implementing new products or processes.

Among service activities, it distinguishes R&D, market and other service oriented firms. In particular, a Biotechnology R&D firm with no product sales is classified by national statistical offices into the R&D service industry category. Targeted firms, include firms classified as wholesalers, for instance local operations of large foreign pharmaceutical firms, whose local affiliate performs biotechnology research but acts mainly by a wholesale distributor. Other types of services firms are included if they are using biotech techniques for the purpose of providing a services (for example waste management and environmental remediation firms).

At this point, we had applied the OECD biotech activity taxonomy to our data (RP Biotech Data base). The result is shown in table 4.

The first important thing to note is that the OECD taxonomy covers our data base almost completely (87%).

Table 3 Biotech firm typologies in OECD taxonomy

• Biotechnology **active** firm (BAF) • **Innovative** biotechnology firm (IBF) • **Dedicated** biotechnology firm (DBF)	Production
• Biotechnology **R&D** firm • **Targeted** firm • Other **service** firm	Services

Source: OECD Statistical Framework for Biotechnology (2001)

Table 4 Italian biotech firm distribution (OECD typologies), 2005

Firm typologies	Profit	No profit	
BAF	50	1	
IBF	139		
DBF	61		
Total A	250	1	251
R&D	58	278	
Targeted	83		
Other services	110	85	
Total B	251	363	614
Total A+B	501	364	865

Source: RP Biotech Data Base

130 cases (i.e. 995-865) are taken into a residual category (out), as firms to be excluded. This residual category includes service firms that only provide routine contract research (such as diagnostics and testing) or consultancy services; biotechnology equipment suppliers as well as other goods suppliers and firms that only distribute biotechnology products; and, end users of biotechnology products and processes.

Table 4 shows that the Italian biotech industry is essentially composed of service activities (70%), of which 45% is composed of non-profit R&D biotech firm (essentially academic research centres) followed by other service firms (that includes environmental service firms and others non-profit organizations such as local environmental agencies, scientific and technological parks, public foundations, etc.); and finally by the targeted firms (13%) acting only as suppliers of biotech product/processes. R&D biotech firm profit-making are less numerous and include research enterprises located in scientific and technological parks or private labs acting in specific market segments.

As regards production activities, the main operator is the innovative firm (55%). This category includes established firms already acting in others sectors (pharmaceutical or chemistry) that adopt biotech innovations; as well as dedicated firms. This production structure means that in Italy it is easier to find the innovative biotech adopters within established firms rather than in new, biotech focused activities.

The official Italian data sources (National Institute of Statistics/Istat) supply data on the percentage of R&D activities related to biotechnologies since 2001 (published 2004).

The National Institute of Statistics/Istat added a question on biotechnology R&D to their annual business enterprise R&D survey as of 1991. As of 2002, the survey included the OECD definition of biotechnology. The business enterprise R&D Istat survey is a mandatory census-based survey. The survey does not apply any size cut-off for R&D performers. The firms are classified using the NACE economic activities classification. The information are collected by Istat and published by the OECD.

In 2003 (table 5), 67 of the biotechnology R&D active firms were in the manufacturing sector and 62 in the service sector. In the same year, the largest number of biotechnology R&D active firms was in the Research and Development sector with 42 firms, followed by the chemical industry, with 36 firms.

As is clear, this data contains no information on dedicated biotech firms.

Finally another kind of result refers to the available data sources linked to the specific policy need that we briefly mentioned in section 2 above. Summarising on the basis of the main work on these issues (Arundel, 2003), we can divide biotech policy into four broad areas as follows:

1) supporting biotechnology research, 2) diffusing biotechnology knowledge and expertise among different actors, 3) supporting technology transfer and 4) the adoption of biotech innovation.

Table 5 Italian biotech firm active in R&D biotech, 2003

	Firms	%	Million PPP$	%	R&D biotech/ R&D total
Food, beverage and tobacco	12	7	8.8	4.0	6.9
Textiles	7	4	2.0	1.0	4.0
Chemical industry	36	21	47.8	20.0	4.9
Electrical machinery	5	3	1.9	1.0	1.0
Precision equipment	7	4	2.1	1.0	0.5
Wholesale trade	4	2	10.5	4.0	4.2
R&D	42	24	103.4	44	13.3
Technical services	14	8	0.9	0	0.3
Health related services	2	1	3.4	1.4	39.4
Other	43	25	55.4	23	1.2
Total	172				

Source: OECD Biotechnology Statistics, 2006

Table 6 Main policy need, statistical indicators and data sources

POLICY areas	Available indicators	Data source
supporting biotechnology research	1. public expenditure in R&D biotech; 2. Intermediate output measures of public biotech research: patenting by public research institutes and citations to public research papers.	1. Biotech Statistic Compendium, 2001 (with available data for Italy); 2. EU Framework Programme (only specific data) 3. OECD Compendium of Patent Statistics.
diffusing biotechnology knowledge	Public-sector and other patents, citations, alliances and licensing activities.	Available data only for some countries and for specific projects (not available for Italy).
supporting technology transfer	1. Venture Capital investments; 2. Biotech spin-offs 3. Alliances	1. Biotech Statistic Compendium, 2001 (not available data for Italy); 2. CATI-MERIT data base; 3. OECD Biotechnology Statistics (2006)
supporting the adoption of biotech innovation	1. Acquisition of skilled personnel; 2. No. of service centres supporting adoption of biotech innovation; 3. Researchers current stock; 4. Input-output flows of researchers.	1. Biotech Statistic Compendium, 2001 (data available only for Canada and New Zeland and for some kind of biotechnologies).

Fonte: our elaboration on Arundel, 2003

As showed in table 6, we can link some relevant indicators such as basic data on public R&D spending in biotechnology and intermediate output measures of public biotechnology research, such as patenting by public research institutes and citations to public research papers to the first policy issue (supporting biotech research). The useful data sources for this kind of information are the OECD Biotech Statistic Compendium, the EU Framework Programme and the OECD Compendium of Patent Statistics.

A second policy area relates to the movement of knowledge across firms and regional and national boundaries. Many public policies provide incentives for collaborations in order to diffuse knowledge and expertise among different actors. These include subsidies to private firms to contract out research to public institutes, passive incentives to increase the number of contacts between public research and private firms, research subsidies for private firms that require collaborative networks. Relevant indicators include public-sector and other patents, citations, alliances and licensing activities. On this issue, data are only available for some countries and for specific projects (not available for Italy).

As regards the commercialization and the transfer of national biotechnology research, several European countries provide subsidies or grants to increase seed and start-up capital for small biotechnology firms, including university spin-offs and start-ups. Relevant indicators include venture capital investments, alliances, number of new biotech firms, etc. Main data sources includes the Biotech Statistic Compendium, 2001 (not available data for Italy), the CATI-MERIT data base, and OECD Biotechnology Statistics (2006).

Finally, in order to support the adoption of biotech innovation, policies include procurement, demonstration projects, information programmes, technology adoption subsidies and appropriate regulatory approval systems. Relevant indicators include sales revenue, types of biotechnology use and exports of biotech products. Data sources for biotech products are not available except for health products available in the European Medicines Agency (EMEA) reports.

5 Conclusion and Implications

The emerging sector of biotechnologies is hard to define because of the nature of the technologies, complex and pervasive. The measurement problems linked to these technologies creates a great problem of comparability between national information systems. In particular, the Italian information system lacks a complete inventory of biotechnological firms.

At the same time, the OECD biotech firm taxonomy is useful for the construction of policy indicators and is a good standard to rank biotech activities.

Our research activity involve the translation of a 995 case biotech data base into a specific inventory based on the OECD taxonomy in order to verify the adherence of this taxonomy to the Italian biotech system.

The empirical evidence shows that this translation is closely possible. The Italian biotech sector is covered by the OECD taxonomy in 87% of cases.

A wide range of indicators could be obtained only starting by the implementation of a complete biotech firms inventory. This necessity is not satisfied by national data sources and just partly satisfied by RP Biotech data base as it is a free subscription data base (not obtained by a field survey).

In conclusion, while the official data sources supply is composed of information regarding just the established firms (particularly their R&D biotech investment), on the other side, through the RP Biotech data base and the selection of its cases by firm typologies, a structural sector analysis is possible.

Some indicators such as direct subsidies or innovation grants supporting R&D biotech, represent an indirect information. More difficult is the construction of knowledge flows through the acquisition of skilled personnel, also for the others advanced national information systems. These kind of data can be obtained through specific case studies.

Regarding the sector definition problem, the paper demonstrates that the OECD categories are useful to collect the main portion of the Italian cases.

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