European Economic and Social Committee

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Life Sciences and Biotechnology

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OPINION

of the European Economic and Social Committee

on the

Communication from the Commission to the European Parliament, to the Council and to the European Economic and Social Committee on Life Sciences and Biotechnology – A strategy for Europe
Progress report and future orientations

(COM(2003) 96 final)

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On 6 March 2003 the European Commission decided to consult the European Economic and Social Committee, under Article 262 of the Treaty establishing the European Community, on the

> *Communication from the Commission to the European Parliament, to the Council and to the European Economic and Social Committee on Life Sciences and Biotechnology – A strategy for Europe, Progress report and future orientations*
> (COM(2003) 96 final).

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 25 June 2003. The rapporteur was **Mr Braghin**.

At its 401st plenary session (meeting of 16 July 2003), the European Economic and Social Committee adopted the following opinion by 111 votes to one, with two abstentions.

1. Introduction

1.1 In January 2002 the Commission presented a Strategy for Europe on life sciences and biotechnology, consisting of two parts – policy orientations and a 30-point plan to transform policy into action.

1.2 The European institutions have supported the integrated approach proposed by the Commission, and the EESC has commented in depth on the documents it received[1].

1.2.1 In its Opinion on the Communication on Life sciences and biotechnology - A Strategy for Europe, the EESC put forward a series of proposals, including the call for the precautionary principle to prevail - also in the context of biomonitoring - and to be applied at every stage; for the principle of liability for the cost of damage/inconvenience resulting from the use of such technology to be clearly stated; for the action plan to be fleshed out to include aspects such as educating all young Europeans to be aware of these sciences; for a precise definition of the responsibilities of each of the players; for transparency at every stage of research; for traceability and clear and understandable labelling; for consumer expectations to be recognised at international level by adopting risk-benefit criteria in all negotiating fora; for a continuous debate to be conducted to ensure proper assessment of scientific advances; for a communication strategy to be defined and for information to be objective.

1.3 The Barcelona European Council examined the strategy and stressed the importance of frontier technology as a key factor for future growth. It also called for appropriate measures and a timetable to be developed to enable Community businesses to exploit the potential of biotechnology while taking account of the precautionary principle and addressing ethical and social concerns.

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1 EESC opinions: OJ C 96 of 18.4.2002 and OJ C 61 of 14.3.2003.

1.4 The Competitiveness Council of 26 November 2002 adopted a series of important conclusions covering a vast array of measures, including the development of human resources, greater resources for research, intellectual property protection, the creation of online platforms available on the Internet, the pro-active role for public authorities, the participation of society and social dialogue, the regulatory framework and international cooperation.

1.5 The Communication in question is the first report on this matter. It sets out the results achieved in policy development and on the ground, and anticipates a number of emerging issues which are fundamental to the success of the Action Plan.

1.6 Some Member States have not yet been able to transform the aims of the European Council conclusions into action in areas which are vital to the development of biotechnology and life sciences.

1.7 The biotech industry, considered one of the sectors of the economy with the greatest potential for medium to long-term growth, groups together various technologies where innovation and competitiveness play a key role. Biotech enterprises largely grow out of the spin-off from universities or large businesses (following mergers or acquisitions) and operate with venture capital or "business angel" type arrangements (local networks of private investment providing funding and consultancy to young enterprises).

1.8 Biotech enterprises are predominantly SMEs, typically widely inter-disciplinary and highly specialised, although very diverse, with great capacity for invention and a high rate of growth (despite the crisis faced by the biotech food business). It has been found[2] that a high concentration of such businesses are located in clusters where it is easier to build a technological basis and a critical mass of knowledge, and interact in terms of exchanging expertise and selecting staff with high potential.

1.9 Breaking new ground in the field of molecular biology and biotechnology has driven the sector into rapid expansion throughout the world over the past thirty years, with substantial growth recorded both in R&D activity and in terms of employment. The motor for such progress in knowledge and business partly lies in the inter-disciplinary nature of the industry and cooperation between academia and business, forging particularly effective synergies.

1.10 The features of the industry as detailed above provide insight into the concerns raised in the Communication with regard to some strategically-important areas, such as research, securing funding and a system for protecting intellectual property, since negligence and delays risk jeopardising the long-term success of biotechnology in the EU.

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2 Innovation and competitiveness in European biotechnology, (Various authors), Enterprise Papers No 7, 2002, European Commission.

2. Comments on the main aspects of the strategy and on the proposals

2.1 *European research*

2.1.1 European research, including research in life sciences and biotechnology, suffers from insufficient resources and from fragmentation, and cooperation between Community and national programmes, science and industry is still underdeveloped, with resources trailing behind those in the main competing nations.

2.1.1.1 The amount of Community resources allocated appears inadequate when compared to the amount invested annually by the main American research centres and the level of national investments is not high enough to compensate for this shortfall. In addition, national research activities lack the coordination needed to improve efficiency.

2.1.1.2 It is also true that in the life sciences and biotechnology industry, research and development generally do not require large, centralised European infrastructures or major projects, and progress is often the product of a variety of approaches and procedures, which may also involve SMEs and smaller research institutes. On the other hand, the process of transforming promising research ideas into competitive and marketable results is often long and very risky (especially when complex authorisation procedures are required, such as for medicinal products). Therefore, for this approach to be successful, enterprises must have solid financial support, plenty of flexibility and the ability to absorb risks.

2.1.1.3 Funding policy must be better designed for interaction and complementarity between SMEs and large enterprises. This is the only way to accelerate the process of translating knowledge into products, which otherwise lack the coherence and resources needed for development.

2.1.1.4 The fragmentation of funding for research is not only due to the large number of funds of insufficient size, but also to an organisational problem. Thus far there has been a lack of a coordinated strategy to combine different skills and roles and to properly coordinate the range and spread of activity. There is also a need for close, effective, interdisciplinary cooperation between research institutes and industry and, in addition, to improve mobility and cooperation between industry and research institutes.

2.1.1.5 Research and education must be better integrated in order to enrich the scientific basis, but in this respect, Europe is hampered by institutional and organisational barriers including limited mobility of researchers and excessive bureaucracy. It would be useful to examine specific initiatives to attract academic researchers to industrial projects by developing science parks and providing ad hoc venture capital.

2.1.2 The Sixth Framework Programme (FP6) is a useful starting point, provided that the topics laid down and the selection criteria take account of the diversification of this sector of research and ensure long-term programming can be secured. However, the level of private sector spending

needed to reach the objective of 3% of annual GDP by 2010 is only realistic if a range of suitable policies is developed swiftly and coherently and if the conditions (political, institutional, infrastructure etc.) are created to encourage private investment in research and development (R&D).

2.1.3 The EESC considers that priority should be given to putting together a complete package of regulatory, entrepreneurial, fiscal and financial measures to encourage both dedicated businesses and universities and public research centres to take on the business risk. Notably, this implies simplifying access to public funding, flexibility within a clear framework (due to the long timeframes of research, which must however show flexibility in adapting to the rapid, unpredictable pace of scientific development), fiscal and financial support for innovative businesses and capital markets that encourage access to venture capital and support start-up companies as they grow, with funding to help during economic downturns and the inevitable periods of crisis.

2.1.4 Recent experience has shown that the financial world tends to target short-term profitability, without considering that research in the biotech industry demands long timeframes, often in excess of ten years. This makes it difficult to build assets which could become profitable given more time for their development. Moreover, the fact that biotech businesses may produce services as well as products is often neglected. These businesses present less of a risk but capital gains and investment returns are slower to materialise. An overly speculative approach penalises biotech service providers, which nonetheless represent a European business asset.

2.1.4.1 The EESC believes that the European Union should take steps to introduce the concept of long-term support for entrepreneurship, of development strategies hand in hand with the assessment of intermediate objectives and staff training plans, including business training, in order for the concept of investment to be translated into tangible action. This approach is all the more necessary given that venture capital often abandons new initiatives as soon as they become listed or if they are not extremely profitable, which harms SMEs that may have the potential to grow given financial support which is better suited to the needs of the industry.

2.1.5 The EESC is aware that these policies are a matter for the Member States, but the EU should play an active role in promoting an open method of cooperation with a view to developing a method to assess successful policies (benchmarking in various sectors), creating the means to set up a more coherent, harmonised and stimulating environment for research and innovation, as well as encouraging public funding to address this need and providing Community policies with the indirect mechanisms that can promote research.

2.1.6 The Commission should take a more robust approach in ensuring Member States apply the principles and adopted policy choices across the board. It should play the role of "facilitator" in finding appropriate solutions and should promote fora, conferences and high-level meetings to exchange ideas and solutions.

2.2 *Science and society*

2.2.1 In its Communication, the Commission states that it is committed to ensuring that the ethical, legal, social and wider cultural aspects, as well as the different schools of thought, are taken into account and form part of the research and development process. It also states that it will take steps to make the ethical and social debate an integral part of the research and development process.

2.2.2 This approach stems from the fact that the swift development of the life sciences industry has given rise to great expectations for curing disease and improving quality of life, which at the same time raises concern over the ethical and social repercussions.

2.2.3 The EESC endorses the approach and shares the view that public authorities, research institutes and businesses must take on board concerns over the conditions in which key decisions are made in this industry, otherwise the concerns of a poorly or misinformed public will provoke delays and crises in the development of new technologies.

2.2.4 The EESC considers education and training procedures crucial to foster proper understanding of the life sciences and biotechnology. Equally crucial are integrated Community policies in the field of education, as previous opinions have discussed in detail[3].

2.2.5 The EESC endorses the ban on human cloning as laid down in Article 3 of the Charter of Fundamental Rights of the EU, reaffirmed by the European Group on Ethics in Sciences and New Technologies (EGE), and calls for the European institutions to support the initiatives under way to set up a world convention on this issue.

2.2.6 The EESC also supports the cautious approach taken in limiting FP6 funding for research on human embryonic stem cells and calls for the Commission's draft proposals to strike a fair balance between ethical concerns and research needs.

2.2.6.1 Opinions remain divided over this issue, addressed in the inter-institutional seminar of 24 April 2003, not only amongst the institutions, but also within the scientific community. Although Member States agree on the use of adult stem cells, some do not permit research to be carried out on embryonic stem cells.

2.2.6.2 In fact, over and above the ethical concerns involved, there is no consensus on the benefits and risks of using embryonic rather than adult stem cells. As a result, the precautionary principle favours maintaining the moratorium on European funding for research on embryonic stem cells until a consensus is reached on the document that the Commission is preparing on this matter.

2.2.6.3 However it should be noted that the research techniques practised by biotech enterprises do not make practical use of human embryonic cells due to the problems of rejection and

3 On this issue, see the Opinion on the consultation document submitted in 2002, published in OJ C 61 of 14.3.2003

the risks of developing undesired cells and contamination with animal matter, despite the increased difficulties of isolating, cultivating and differentiating adult stem cells.

2.3 *Intellectual property*

2.3.1 The Commission states that a clear, equitable, affordable and effective patent regime applied consistently across the EU is crucial to fully exploit the potential of biotechnology and regrets the delay in transposing Directive 98/44/EC on the legal protection of biotech inventions.

2.3.2 The EESC shares this view and therefore supports the Commission's efforts to speed up implementation of this directive and calls for the political agreement reached on 3 March 2003 on the Community patent to lead to the swift adoption of the respective regulation.

2.3.3 Although it does not fully take on board the recommendations put forward by the EESC in its opinion on the Community patent[4], the compromise reached must rapidly close the current legislative loophole and provide an essential boost to European competitiveness.

2.3.4 The EESC emphatically urges the Commission to take steps to ensure the biopatent Directive is swiftly transposed, as the biotech industry needs the legal protection of a patent regime for biotech inventions.

2.4 *Genetically Modified Organisms (GMOs)*

2.4.1 The Communication welcomes the significant progress made on the regulatory framework for GMOs, including the political agreement reached on the two Commission proposals establishing a comprehensive Community system to trace and label GMOs, and the steps towards implementing the Cartagena Protocol.

2.4.2 The EESC welcomes the two proposals on tracing and labelling GMOs, which it supported in its recent opinions, and the progress made in implementing and transposing the Cartagena Protocol, which grants all signatory countries the freedom to carry out a risk assessment prior to authorising import of a new GMO.

2.4.3 The EESC however regrets that so far only a few countries have transposed Directive 2001/18/EC, which provides for a more comprehensive authorisation procedure for GMOs. It calls on the Commission to take decisive action to make the directive operational, which may include initiating proceedings against those Member States in default.

2.4.4 The EESC welcomes the creation of the European Network of GMO Laboratories (ENGL) on 4 December 2002 in Brussels, which acts as a scientific and technical EU network of excellence with regard to Community GMO regulation. It particularly endorses the fact that the

4 EESC opinion OJ C 155 of 29.5.2001.

Commission's Joint Research Centre (JRC) will coordinate ENGL's activities and act as the EU reference laboratory.

2.4.5 However the EESC does not support the statement made in the Communication (paragraph 3d, page 17) declaring that openly explaining and documenting the benefits of the use of GMOs is, first and foremost, a task for the biotech industry. This is a cultural and educational problem that can only be properly tackled by public authorities, whether at national, local or Community level, jointly and in cooperation with stakeholders. Failure to do this will lead to a lack of credibility, fragmentation and unsatisfactory efforts, as well as an economic burden for SMEs that would jeopardise the balance and competitiveness of the sector.

2.5 *International issues*

2.5.1 The Communication states that the debate on biotechnology and related issues is being extended in an array of international fora and new initiatives led by several international organisations. Moreover it notes that, despite the fact that they play a key role in specific sectors, there is no appropriate platform to promote open and transparent dialogue between interested parties.

2.5.2 The EESC would like to see the Commission carry out an active role in setting up a multilateral consultative forum to foster dialogue between parties that currently represent widely-ranging positions and to promote greater coherence between the agreements reached in different fora. This would provide a proper context for the new EU regulations that have been approved or are in the pipeline, and overcome the existing differences of opinion, notably in the Word Trade Organisation (WTO).

2.5.3 The EESC supports such initiatives, and is convinced that in order to manage innovation in the biotech industry, common standards and principles must be identified at international level, whilst respecting the legitimately diverse approaches adopted in different parts of the world.

2.6 *Competitiveness*

2.6.1 Uncoordinated and contrasting initiatives have hitherto reduced the impact, efficacy and coherence of the European strategy in this industry, and have led to the persistence if not the widening of the existing gap between Europe and its main international competitors. The European biotech industry is still lagging behind in terms of size of enterprise, direct and indirect employment, profitability and product distribution networks.

2.6.1.1 Public authorities, both at national and Community level, must be aware of the importance of a coherent set of actions providing clear and transparent information, training, a clear reference framework and appropriate incentives in order to achieve more rapid growth in this industry which represents great potential for sustainable development.

2.6.2 The study carried out on "Innovation and competitiveness in European biotechnology"[5] begins by noting that the competitiveness of the industry does not only concern enterprises, but also the wider complement of institutions, infrastructure and policies which have a dynamic impact on business activity. It goes on to identify situations and methods that should be backed up through long-term public action. The EESC invites the Commission and the Member States to discuss the content and the proposals listed herein, and use them as a launch pad for more robust policies, to be implemented according to a set timetable.

3. **Recommendations**

3.1 The competitiveness of the biotech industry is a key element in achieving the Lisbon objectives. The EESC considers it a matter of top priority that the EU and Member States take on board this objective and identify all appropriate means by which to achieve it, working together to eliminate all barriers to competitiveness.

3.2 The "cluster" and "biotech incubator" models represent a yardstick to assess competitiveness, synergies, technological transfer and the most useful approaches for funding. Cooperation between Member States and the Commission and learning and sharing best practices should be particularly strong in this sector, in order to find ways to trigger a more accelerated process of growth.

3.3 The innovative biotech industry is predominantly made up of a large number of SMEs, which form the grassroots of innovation. However, the existing tools to stimulate research, technological transfer and finance are not always designed with SMEs in mind. More effort should be made to understand the types of businesses that compose the industry (products and services) and the specific needs for funding. This especially implies simplifying access to European funding, and to funding for technological processes instead of just research in the strict sense (notably by ensuring the quality of processes as well as products, potential for industrial replication, building capacities and fine-tuning tested methods).

3.4 Taking on board such details would involve revising the very concept of risk capital in order for it to adapt to the specificities of the industry, and in order to ensure that aspects such as the duration of research, the professionalism of staff and the requirements of regulatory bodies are taken into account.

3.5 The EESC notes with a degree of pessimism that, on the one hand, the Member States have not taken sufficient steps to swiftly achieve the goals laid down in the conclusions adopted by the Competitiveness Council on 26 November 2002, and on the other hand, that the Commission report does not specifically address the delays and the difficulties encountered in developing the 30-point plan (European Commission working document SEC(2003) 248). The Committee therefore

5 Enterprise Papers n. 7, 2002, European Commission.

hopes that the next annual report will include a detailed analysis of the achievements, failings and delays with respect to the approved plan.

Brussels, 16 July 2003

The President of the European Economic and Social Committee	The Secretary-General of the European Economic and Social Committee
Roger Briesch	**Patrick Venturini**