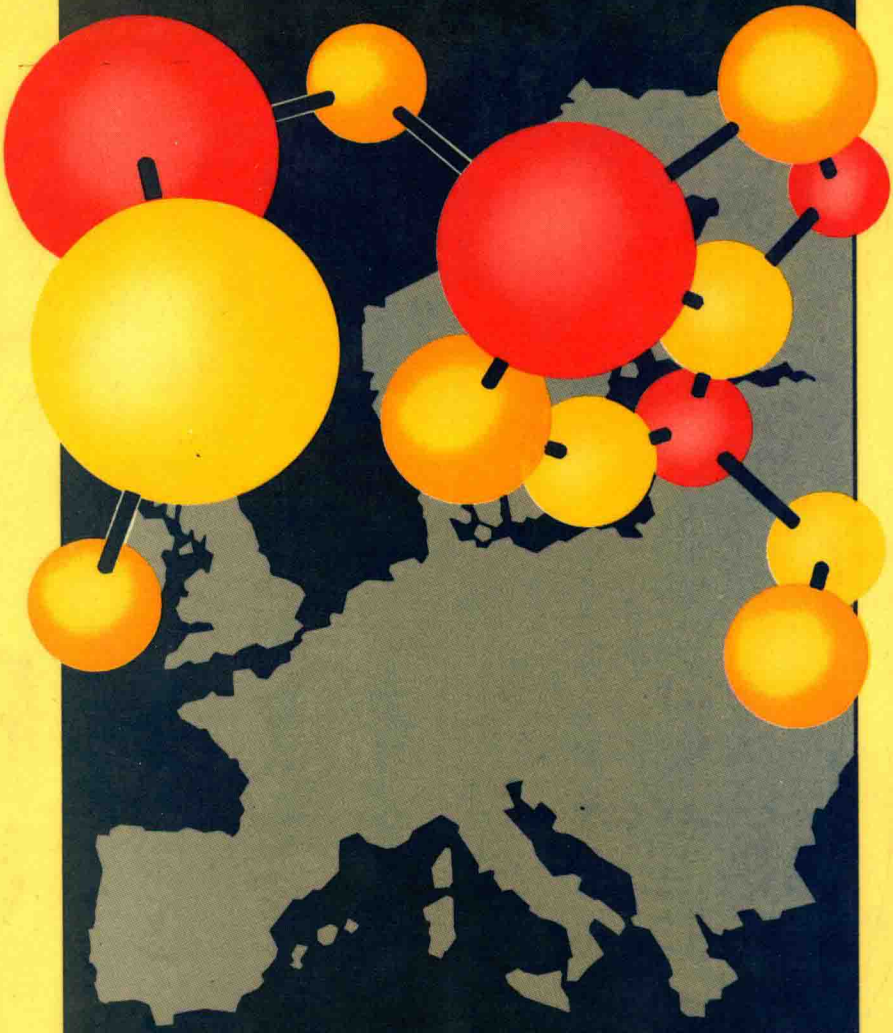
INDUSTRIAL BIOTECHNOLOGY IN EUROPE

ISSUES FOR PUBLIC POLICY



EDITED BY

DUNCAN DAVIES

A CEPS — EEC CONFERENCE

Industrial Biotechnology in Europe

Issues for Public Policy

edited by
Duncan Davies

Summary and proceedings of a conference organized by the
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Industrial Biotechnology in Europe

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Brussels, 7–9 November, 1985

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Preface

Biotechnology is multidisciplinary, multi-sectoral, in the European Community environment certainly multinational, and in the context of the Commission—that modest and multi-faceted bureaucracy—it demands policy responses based upon inter-service collaboration. Not the least of the achievements of the conference whose proceedings are presented here was its stimulus to such collaboration, to which the multiple authorship of this preface bears witness.

These proceedings illustrate the many facets of public policy to which industrial biotechnology is relevant, ranging from the price of sugar to problems of ethics and philosophy. Biotechnology is no respecter of boundaries. It poses challenges not only to research, but to agricultural policy, to many areas of regulatory policy, to patent law, and from the standpoint of protection of the environment. The industrial developments expand and spill over into social and political challenges. They are based upon a science that has altered and is altering man's perception of himself and his potential.

The conference was held in November 1985, at a time when both self-doubt and self-awareness were sharply increasing in European biotechnology. Current reports (mainly American, but widely cited) were placing Europe number three in rank after the US and Japan. Key scientists were emigrating. The Common Market remained uncommonly fragmented. Public opinion was uneasy and alert.

Two basic questions seemed to underlie the conference. Firstly, was Europe performing well enough? Secondly, could public policy do anything to influence this? To the first, one might say it is too soon to tell; but before that leads to a complacent answer to the second, one has to add that by the time the answer can be clearly

told, it will evidently be too late to alter it. The consensus of the conference was that there are many useful and sensible policy actions which could help.

The editor and rapporteur of these proceedings have effectively summarized the key points, and there are many important contributions which require no gloss from us. The authors have expressed themselves without constraint or censorship from CEPS or the Commission.

We would like, however, as three of the Directors-General responsible within the Commission for areas particularly relevant to industrial biotechnology, to commend this book to its readers. For, although not a statement of Commission policy, it casts a timely and focused light on policy issues of central concern to the Community: the concept of a 'European Technological Community', the future of agricultural policy (particularly in non-food outlets), and the development of a harmonized regulatory framework for these innovative new industries.

Nineteen eighty-five was an important year for the biotechnology industry in Europe: it acquired a sense of identity. That biotechnology is multidisciplinary in its bases, and multi-sectoral in its applications, is by now a cliché. The multidisciplinarity has been eloquently demonstrated by the success of the European Federation of Biotechnology, founded in 1978, grouping nearly 50 learned societies and spawning a dozen active working groups, each reflecting the international and academic-industrial complexion of the parent body. But until 1985, one had to question whether there was, in reality, a 'biotechnology industry'. The Americans and Japanese believed so, and that belief was itself a motive force; but old Europe was sceptical and confident—confident in its strengths in pharmaceuticals, in chemicals, and in the food and drink industry.

In December 1984, (then) Vice-President Etienne Davignon invited an influential group of Europe's leading biotechnology industrialists to a meeting, and a few months later the European Biotechnology Coordination Group was born, based on the associations of five industries: chemicals, pharmaceuticals, food and drink, enzymes and agrichemicals together with UNICE, the Community's general representative body for industry.

The CEPS conference of November 1985 was thus a timely occasion for Vice-President Narjes to recall the extensive and long-standing Community commitment to biotechnology, to mention

the current research programmes, and to announce two significant new initiatives for the future. Appropriately enough, one of these concerns advanced research and related infrastructure at the interface between biotechnology and information technology; the other concerns the development of new opportunities for its application, at the interface between agriculture and industry.

These initiatives underline the need for responses flexibly co-ordinated across the several areas of public policy involved, within the Community institutions, within national administrations, and between the two levels.

This conference also provided a valuable channel for dialogue between industry and public policy-makers. Biotechnology is a knowledge-based, footloose industry: the key assets of capital, know-how, and management are inherently mobile, and companies choose and move to the most attractive locations. Europe is attractive on several counts, but the speakers at the conference emphasized also the areas where much more remains to be done: on regulations, patents, raw material prices, underpinning research, and effective public information, the last of these a factor of growing strategic significance. What is needed above all by industry is regulatory clarity: a legislative framework based on rational scientific assessment, which ensures environmental protection, but which is so designed as to permit careful learning by experience in areas where uncertainty inevitably remains and which offers the scale advantages of a single common market.

The conference organizers are to be congratulated on providing an effective focus for the complex range of interests and policy areas involved in European biotechnology, and for providing an opportunity to demonstrate the commitment of Europe's public policy-makers to the responsible promotion and encouragement of this industry.

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Introduction

At present there are probably more frequent conferences on biotechnology than on any other scientific or technological topic. Most of these are specialized—bringing together groups of scientists, engineers, managers, lawyers, or financiers. The conference which assembled the contributions printed in this volume was noteworthy in that it was *multidisciplinary*. It gathered representatives from the public and private sectors of *all* the fields involved in the bioindustries.

The conference was organized by the Centre for European Policy Studies (CEPS, an independent research institute and policy forum) and was co-sponsored by the Concertation Unit for Biotechnology in Europe (CUBE) of the Commission of the European Communities. The meeting took place in Brussels on 7–9 November, 1985.

The main aim of the conference was to discuss the issues for public policy being raised by the development of industrial biotechnology in Europe. Was Europe maintaining its initially excellent position, or was it losing ground? What was needed from the public sector to improve European competitiveness in this field? How should Europe respond to the environmental and ethical questions? CEPS invited experts from the private and public sectors in Europe, the United States, and Japan to speak on the industrial, political, and societal dimensions of biotechnology in the context of technical and commercial realities.

The Commission of the European Communities had already instituted a modest biotechnology scheme that was beginning to create European perceptions and joint capabilities. It was just launching broader initiatives, bringing firms and national skills together across European frontiers, along the same lines as the

Community's ESPRIT (electronics and information technologies) and BRITE (basic technologies in industry) programmes. However, experience in other areas was showing that international work only led to self-sustaining results if the firms that would have to design the new products and processes were involved in the programmes as active participants right from the start. Programmes that were entirely in the public sector, however well chosen or conducted, were liable to lead to little or no substantive commercial follow-up unless government paid the bills (as in the case of military programmes). Thus it was timely to hear a discussion about needs and obstacles in the bioindustries as perceived by firms and regulators.

The fact that the conference was well attended by influential and busy people showed that the subject was relevant. The discussions by participants were penetrating, exploratory, and innovative.

The conference papers and discussions, summarized by the rapporteur, Dr. Pauline Creasey, show that European capability and competitiveness is slipping. This is partly because others have mobilized finance and organizational methods better and achieved economies of scale, which are natural in the United States and disciplined Japan but still seem a new concept in what is still, in some repects, a *Europe des patries*. Diversity of regulatory procedure also plays a part. Agreeing on the need for a truly common market in which the bioindustries could operate, those present at the conference were inclined to give more support to the EC's initiatives than was forthcoming for the first Community biotechnology programme, which had rather a rough ride.

There is no evidence to weaken the general consensus that biotechnology will be the most important technological area for the early decades of the 21st century. Equally, events to date show that the important new products and processes—especially those for human health care—will not be earning very large sums before 1990. However, the range of attractive and important development products is increasing fast enough for there to be good hopes, a decade or so ahead, of truly substantial and sustainable cash flow from sales of new products, even with quite a high failure rate. Thus long-term confidence in the importance of the field is strengthened even though earnings in the short term may be disconcertingly limited. It is likely that Europe will need the united strengths of the public and private sectors—as deployed in Japan—