Biotechnology in Europe: Challenges and Policy Responses*

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1. Background: from a sense of history, to a "knowledge-based society"

Before focussing on some of the policy controversies which are in the news today, it may be useful to approach them with some sense of history: countries and policy-makers around the world have been arguing about "modern" biotechnology for over 30 years. The European Union has been engaged in policy discussions on biotechnology since the late 1970s, and has been funding research programmes in biotechnology since 1982. It has participated actively in related international discussions for a similar period – in scientific conferences, at the OECD, in United Nations fora, and in the context of international agreements.

These recent decades have seen an astonishing surge of knowledge in our understanding of the structure and functioning of all living systems: that knowledge will remain forever, available to everybody around the world with the capability to read it, understand it, and put it into application in a multitude of different ways, but in particular in the ways relating to health care, food supply, and our interaction with our environment.

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** Opinions expressed are those of the author.

Jumping to the recent past, the present and the future, the heads of state of the Member Countries of the European Union, meeting as the European Council in Lisbon in March 2000, adopted a bold strategic goal for the coming decade – to become:

"the most competitive and dynamic knowledge-based economy in the world capable of sustainable economic growth with more and better jobs and greater social cohesion".

The connection is evident: a huge surge of knowledge in the life sciences and technologies, making possible an information-intensification of all bio-industries and bio-services, traditional and modern; responding precisely to the political challenges of shifting to a more competitive, knowledge-based society; while promoting also the transition of our industry, economy and society to a more sustainable pattern. This is the challenge.

2. A century of research, an emphasis on bio-safety

In the early years, biotechnology was seen primarily in two dimensions: **research**, and **safety**.

The **research story** is well-known and has a long history. The 20th century started with the rediscovery of Mendel's work on genetics in 1901, almost at the mid-point was the discovery of the double helix structure of DNA, in 1953. At the ¾-point was the birth of modern, precision genetic engineering in 1973, and the century of discovery and innovation closed with the publication in 2001 of the first draft of the human genome sequence. The pace of research effort and technical innovation is not slackening, as we rush into the era of genomics, array technologies, and globally accessible bioinformatics infrastructure. There is a "Moore's Law" also in the life sciences, indicating that the speed of sequencing genomes, or synthesising genes, will continue to improve by further orders of magnitude, with corresponding declines in cost[1].

In the knowledge-based economies of the 21st century, the life sciences and biotechnology will be key players: there will be new sectors such as bioinformatics, and there will be the penetration and transformation of traditional established sectors, such as food production, health care, and the management of our interactions with the environment. The new knowledge will be crucial for the shift towards a sustainable economy, and fundamental to competitiveness.

[1] For a graphical summary and discussion, see Carlson Robert, "The Pace and Proliferation of Biological Technologies", 1 Feb 2003, at **<http://www.molsci.org/~rcarlson/Pace%20of%20Biol%20Tech%20v%202.9.pdf>**.

The **safety issue** should be a minor annex given the long track record of almost perfect safety with the innovations of modern biotechnology, and the obvious advantages of more precise techniques and practices. Today, vaccines are being designed offering multiple protection against diseases and for enhanced safety. The foxes in Belgium – and hence the human population – have been among the first beneficiaries of the widespread release of a genetically manipulated virus, which provided oral vaccination against rabies; the first of many success stories, from an EC-supported project started in the 1980s[2]. The environmental advantages of modern biotechnology in agriculture are already clear in terms of dramatic reductions in use of agrichemicals, fuel, and spraying; enhanced flexibility for the farmer[3]; and reduced impacts on soil biodiversity and erosion achievable by low-till and no-till cultivation practices.

However, various interests argued for technology-specific regulation in Europe, and since 1991, a number of measures have been adopted, relating to protection of the environment, authorisation for placing genetically modified products on the market, their labelling and traceability. Debate on these measures continues within Europe and internationally, in particular with the United States, who have maintained the position that the potential risks raised by products of biotechnology do not differ in kind from those of conventional products. Therefore they have handled regulatory aspects under existing statutes with considerable benefits to their agricultural competitiveness and the environment.

The debates about risk and safety have had policy consequences in Europe. On the side of biosafety research, the Commission has participated actively in international discussions on biosafety, e.g. at OECD and on the Cartagena Protocol on Biosafety under the Convention on Biological Diversity, and has financed some 80 projects over the past fifteen years, spending some € 70 million, and involving over 400 laboratories[4]. On the political front, public perception has become seen as a significant political factor, linked with the demands of consumer organisations for consumer information, e.g. regarding the labelling of products of modern biotechnology.

3. The need for coordination leads to a strategy

As modern biotechnology has increased in significance, the number of agencies and ministries involved has steadily increased in every national capital and within the European Commission. Responding to this increasing need for coordination, the

[2] For a summary of this and many other projects on biosafety, see **"A Review of Results: EC-sponsored Research on Safety of Genetically Modified Organisms"**, European Commission, 2001; available online at **<http://europa.eu.int/comm/research/quality-of-life/gmo/>**.

[3] See, for example, Phipps R.H. and Park J.R. "Environmental benefits of genetically modified crops: Global and European perspectives on their ability to reduce pesticide use", Journal of Animal and Feed Sciences, 11, 2002, 1-18.

[4] See footnote 2.

Commission has on several occasions sought to launch an integrated response to the policy challenges of modern biotechnology; the latest being the launch in early 2002 of **"Life sciences and biotechnology: A Strategy for Europe"**, containing a 30-point Action Plan[5]. This strategy has been endorsed by the European Parliament[6] and the Council of Ministers[7], and is now being implemented. In its endorsement, the European Parliament has called for a lifting of the *de facto* moratorium on new authorisations of gm products, which has been imposed over the previous five years by the Environment Ministers of several Member States.

The strategy document includes a 30-point Action Plan now being steadily implemented[8]. The actions can be summarised as follows:

3.1. Harvesting the potential

- The resource base
  - Investing in people
  - Generating and exploiting knowledge
  - Intellectual property protection
  - Capital base
- Networking Europes biotechnology communities
- A pro-active role for public authorities

3.2. Governing life sciences and biotechnology

- Societal scrutiny and dialogue
- Developing life sciences and biotechnology in harmony with ethical values and social goals
- Demand-driven applications through informed choice
- Confidence in science-based regulatory oversight

[5] European Commission, 2002, "Life sciences and biotechnology: A strategy for Europe", COM(2002)27.

[6] See European Parliament, 23 October 2002, Report A5-0359/2002 Final, "on the Commission communication on Life sciences and biotechnology – A Strategy for Europe (COM(2002) 27 – C5-0260/2002 – 2002/2123(COS))", RR\480793EN, docPE 316.254.

[7] See press release following the 2467th Concil meeting, 23 November 2002, Competitiveness (Internal Market, Industry, Research), Section "Biotechnology", 13-19.

[8] See "Life sciences and biotechnology – a strategy for Europe: progress report and future orientations", European Commission, 5 March 2003.

3.3. Responding to global challenges

- A European agenda for international collaboration
- Europe's responsibilities towards the developing world

3.4. Implementation and coherence across policies, sectors and actors

The strategy is necessarily a compromise between the research, industrial and other interests favouring rapid development and application of biotechnology, and the demands from some segments of public and political opinion and from certain non-governmental organisations, for a stringent regulatory framework. Europe has on balance been more prudent than the United States, with a more cautious approach not only to product authorisations, but even to research releases – notifications of the latter have fallen from 264 in 1997 to 35 in 2002. Similarly, the EU and its Member States have ratified the Cartagena Protocol on Biosafety under the Convention on Biological Diversity, while the US has not.

The 30 points of the Action Plan sound rather numerous, but cover a wide range of detail in many policy areas. For example, on intellectual property where the European Union is currently implementing the Directive 98/44 on the protection of biotechnological inventions, conforming to the terms of the WTO TRIPS agreement, and engaged in discussions with rich and poor trading partners about the follow-up to the Doha declaration on the next phase of international trade negotiations.

4. Current policy debates – public perceptions, regulatory initiatives and competitiveness

There is a risk that public perceptions and scientific opinion diverge, and that the political response to sceptical public opinion demands more stringent regulations than are objectively necessary. This carries the risk that administrative and scientific resources, and political energies are diverted from the most serious real problems to those which are perceived as such – in effect, subtracting resources from where they are most needed. The Commission has responded in part by regulatory proposals, but also by an increased emphasis on more effective scientific communication with the general public.

5. Take-home messages

Whether in a country or in a company, it is difficult to abstract from the mass of incoming information the messages and the materials relevant to one's own specific

situation. The following are offered as "take-home" messages to address the problem of information overload:

1. **BE CAREFUL** – its easy to get it wrong – look around you

2. **BE AWARE** – plenty of information (too much?) is readily available

3. **LEARN** – especially from the mistakes of others (there are plenty)

4. **AVOID BEING "CAPTURED"** by the interests or ideologies of others

5. **RISKS?** The biggest risk is to be excluded from the new technologies

6. **THINK FOR YOURSELF!** Your country / company has particular strengths, weaknesses, opportunities, threats. Learn to use the new knowledge