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How should public policy respond to the challenges of modern biotechnology?

Mark Cantley

Modern biotechnology has been a topic of public and political debate around the world for over 30 years; continuing scientific breakthroughs keep it high on the agenda. Policy responses have been diverse, fragmented and incoherent, at levels ranging from local regions to agencies of the United Nations, but particularly in national administrations and the European Union. Reactions have been ambivalent, combining fears about conjectural risks with concern to maintain competitiveness and exploit beneficial applications. Adverse public perceptions have become a significant influence on policy, in combination with more cynical and self-interested motives of some of the players in policy debates. Future options, in Europe and elsewhere, are constrained by past and continuing mistakes and over-reactions.

Addresses

European Commission (SDM-8/19), B-1049 Brussels, Belgium
e-mail: mark.cantley@cec.eu.int

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Abbreviations

EC	European Commission
EU	European Union
FSE	farm-scale evaluation
GMO	genetically modified organism
OECD	Organisation for Economic Cooperation and Development
WTO	World Trade Organization

Introduction

Do the makers of public policy need to respond to the challenges raised by modern biotechnology? Many have answered, ‘Yes, certainly’; we review below some of the resulting responses — and their consequences.

The twentieth century has seen a surge of new knowledge in the life sciences and related technical advances – starting with the rediscovery of Mendel’s work on the nature of heredity [1–3], through the identification of DNA as the genetic message [4] and elucidation of its double helix structure mid-century [5] followed by the first expressions of concern about conjectural risks of modern biotechnology in the 1970s [6], and culminating in the

launch of genomics, the draft sequence of the human genome hailed in March 2001 by the leaders of the UK and the US [7]. The knowledge mill continues to turn fast, as the cost of genome sequencing continues to plunge. In 1965, Intel co-founder Gordon Moore predicted — so far, more or less correctly — that the number of transistors on a chip would double every 2 years (and later reduced that to 20 months). A similar effect seems to be at work in biology [8]; the National Institutes of Health is now aiming to reduce the cost of sequencing by at least four orders of magnitude in the next 10 years [9^{••},10^{••}]. Electronic tools and technologies enable us to capture, store, manipulate and transmit the new data and ideas instantaneously around the world. This presents a challenge to every society, to assimilate and manage the new knowledge. Furthermore, the European Union (EU) has set as a strategic goal to become by 2010 ‘the most competitive and dynamic knowledge-based economy in the world’ [11]. So, modern biotechnology is indeed important — but this does not necessarily justify the prominent place it currently occupies in public affairs, nor the criticisms it attracts.

Yes, we need a ‘science policy’ for biotechnology, to support basic research, infrastructure, training and intellectual property. We also need such a policy to be part of a rational framework of public policies within which to facilitate and encourage applications and innovations, without undue risks to health or the environment — matters on which scientific advice is also relevant. We review below the evolution of such policies.

The evolution of the public policy agenda

In 1973, scientists expressed concern about possible risks [6] from newly discovered techniques for ‘cutting and pasting’ pieces of DNA, and accepted a voluntary moratorium on certain types of experiment [12^{••}]. There followed several years of intense international debate, extending to public and political circles: did these new techniques pose special risks, requiring technology-specific regulations? By 1986, there was near consensus across the developed world: there were no special risks, existing legislation could handle it, with some adaptation. This was expressed in a consensus recommendation of the Organisation for Economic Cooperation and Development (OECD) Council [13] and reflected in both the US Coordinated Framework [14] and a Council Recommendation in Europe [15]. The progressive relaxation of regulatory oversight as research advanced and experience accumulated was in fact a classic example of the precautionary approach, as later outlined by the European Commission (EC) [16].

As applications expanded, more ministries and agencies of government addressed aspects of biotechnology. In Europe in 1986, Denmark was first to introduce technology-specific legislation [17]; the EC had studied the technology, and foresaw the need for a strategy to promote it [18]. The European Parliament stressed the need for 'an integrated approach' [19]. Motivations were diverse: in the US, a safe track record and the competitive interests of pharmaceutical and agro-food industries supported a continuing absence of new regulation, and the Supreme Court confirmed that existing patent law could defend biotechnological inventions, including living matter [20]. In Europe, the debate was complicated by tensions between national interests and the European level and by different perspectives of the various ministries and agencies, at both national and European levels. To head off diverse national legislation, in 1990 the Europeans adopted technology-specific legislation on genetically modified organisms (GMOs) and their placing on the market [21,22], although sectoral legislation could still apply if it updated its environmental risk assessment to equivalent stringency.

An OECD survey conducted in 1982 had warned the Europeans of their relative disadvantages in biotechnology patenting [23]. The EC proposed legislation in 1988, adopted after ten years of protracted debate [24], but by early 2004 only seven Member States had transposed it into national law.

The long debate on the patentability of human genes was one of several ethical issues that had risen up the political agenda. Foreseeing such needs, the EC created in 1991 a 'Group of Advisers on Ethical Implications of Biotechnology', which gained in standing over subsequent years by producing a series of careful opinions [25]. In 1998, it was renewed with the broader title, 'European Group on Ethics in Science and New Technologies', and its standing was further underlined by its inclusion as a point of reference in legislation.

In the 1990s, regulations on biotechnology proliferated; the need for clearer policy coordination was increasingly evident.

The current European strategy for the life sciences and biotechnology

The EC has on several occasions recognized this need. A Biotechnology Steering Committee was established in 1984, but under the leadership of the Research Directorate-General, could not impose coherence across the growing range of policy areas that became involved. Responding to the concerns of science and industry about regulatory constraints, EC President Jacques Delors in 1991 created a 'Biotechnology Coordination Committee', which has sought with mixed success to impose such coherence. In practice, the regulation of biotechnology

was driven increasingly by Environment Ministries, and other ministers — of Research, Industry, Agriculture, Health, Education, Trade, and Development — were ineffective in controlling the resulting legislation. 'Environmental' Non-Governmental Organisations claimed that it was 'green' to oppose products and processes that, in fact, offered the best hope of a shift to more environmentally sustainable practices.

Public confidence in scientific advice to government fell sharply through the 1990s, as various high profile scandals — contaminated cooking oil, contaminated blood, the emergence of bovine spongiform encephalopathy (BSE) and (contrary to the expectations of scientific advisers and the assurances of government) its jumping to humans in the form of new variant Creutzfeldt-Jakob disease — contributed to a climate of growing public concern. Although the cases cited were unrelated to biotechnology, the suspicions were politically potent, stoked by other hostilities against multinational companies, American policies, globalisation, and the 'industrialisation' of agriculture. The result was that in 1998, Environment Ministries in eight Member States of the EU announced a *de facto* moratorium: they would no longer be prepared to authorise commercialisation of GMOs until more stringent legislation had been put in place. The years of resulting non-authorisation have inhibited research in the EU: experimental releases dropped from 264 in 1997 to 56 in 2002, rising to 81 in 2003 [26,27]. The US government launched a complaint against the EC at the World Trade Organization (WTO) disputes procedure, because of the losses to US exporters resulting from the moratorium.

The EC responded with more regulations — and a strategy. Regulatory initiatives were developed, published, debated, amended and (from 2001 onwards) adopted (see Box 1) [28–32,33,34–36].

Box 1 Recent EC regulatory initiatives.

- The field release directive of 1990 was replaced in 2001 by a more stringent measure [28].
- Traceability and labelling requirements were imposed on GM food and feed [29,30].
- In line with the Cartagena Protocol (see text), a regulation was adopted on transboundary movement of GM products [31]. The implementation of this regulation will pose severe problems for international research collaborations with developing countries [32].
- Stringent limits are being written into seed legislation regarding adventitious presence of GMOs.
- A directive on environmental liability is being adopted [33], adding to the disincentives to use the technology, and as has been observed by some in the insurance industry, 'the question is not whether biotechnology is dangerous or not, but whether it is perceived to be dangerous' [34].
- Although the EC has advocated that the 'coexistence' [35] of conventional, GM and organic agriculture should be addressed pragmatically by guidelines at national level, there are calls for European legislation [36].

EC President Prodi recognized the need for a renewed and more visible strategy, which following a year of consultations and meetings was published early in 2002 [37]. This emphasizes the need for Europe to harvest the potential of the new technologies, defends the strict regulatory framework as essential to the rebuilding and maintenance of public confidence in the technology, and presents a 30-point Action Plan, with defined responsibilities, involving Commission, Member States, industry and others. Annual progress reports [38,39] have followed, their preparation overseen by a high level Biotechnology Steering Committee. The continued prominence of biotechnology in public policy debate makes it likely that the strategy will survive the turbulent transitions of the year 2004, as ten countries join the EU, and a new Parliament and new Commission take up office.

International dimensions

The policy debates of the early years were conducted mainly within the developed world. OECD expert groups continue to produce useful reference documents [40], but the biotechnology debate has become global; reference has been made to the ongoing WTO dispute between the US and the EC. Three examples are given in Box 2 and illustrate the various fora in which such policy debates are conducted [41–45].

International dimensions of biotechnology have also been prominent in discussions of the needs of developing countries for improvements in food production, health care and management of impacts on the environment. These needs are typically much greater than those of the developed world, and reports [46,47] from the UK Nuffield Foundation on Bioethics have stressed that ‘The moral imperative for making GM crops readily and economically available to developing countries who want them is compelling’.

The risk is that owing to policy disputes elsewhere in the world, developing countries, which have the greatest

needs for modern biotechnology, will have difficulty in obtaining it, or in gaining market access for exports produced with its assistance. The United Nations Industrial Development Organisation, in its Global Biotechnology Forum in Concepción, Chile, in March 2004, addressed the problem that after years of fine talk, the reality is that biotechnology is not yet delivering on its promises to the developing world [48].

The biosafety debate

The safety of the new technology and its products was the starting point of the policy debates in the 1970s and remains prominent on the policy agenda.

The EC from its first biotechnology research programmes has devoted ever-increasing resources to biosafety, and in 2001 published a review of the results of the preceding 15 years work — some 70 million Euro invested in 80 projects involving over 400 laboratories [49]. The results give little cause for concern, whereas there is mounting evidence from around the world of the environmental benefits of the new products and practices [50,51].

An extended farm scale evaluation (FSE) of three spring-sown crops was carried out by the UK government, comparing GM and non-GM varieties, and the results were published in 2003 [52]. This evaluation raised more questions than it resolved. With the GM herbicide-tolerant crops, weed control was shown to be more effective than with conventional practice; thus, if impact on biodiversity was assessed by reduced populations in species dependent on weeds for their food, the effect of the GM crops was ‘adverse’. The differences, as was pointed out [53], were of statistical rather than biological significance: in fact, the choice of crop has a much greater effect on insect populations. Indeed, one of the FSE papers [54**] noted that, ‘The FSEs arguably constitute the most comprehensive and realistic experimental assessment yet undertaken of ecological impacts

Box 2 Examples of topics and arenas for international policy debates on biotechnology.

Biodiversity

Following the adoption in 1990 of the Convention on Biological Diversity [41], negotiations based on Article 19.3 of the Convention led to the adoption in 2000 of the Cartagena Protocol on Biosafety [42,43]. This protocol came into force in September 2003, following its ratification by 50 countries. EC legislation gave effect to the resulting obligations [31]. Discussions of the implementing provisions are in progress, and started with a meeting in Kuala Lumpur in February 2004, which reached conclusions on the compliance procedure and mechanism, the launch of negotiations on procedures on liability and redress for damage from GMOs, rules for the functioning of the Biosafety Clearing House, and adoption of an Action Plan for capacity building [42].

Food safety standards

The Codex Alimentarius Commission in June 2003 agreed guidelines on assessing the safety of foods derived through modern biotechnology [44]. Codex principles are referred to specifically in the Sanitary and Phytosanitary Agreement of the WTO, and can be used as a reference in case of trade disputes.

World trade in food

The WTO agreements — on sanitary and phytosanitary issues, technical barriers to trade, and trade-related intellectual property matters — are all seen as important points of reference in the context of international trade in products of modern biotechnology [45].

resulting from agricultural change. It is accepted, however, that the choice of a comparable system as a benchmark may be enough to change a given ecological impact from being considered a hazard to being considered a benefit. The analysis here identified that there was no logical benchmark or ideal system for the arable habitat'.

The papers have been widely cited, but often with simplistic interpretation and biased reportage [55]. The 'risks' of biotechnology remain persistently conjectural, but are too valuable to abandon as a political weapon.

Public opinion: the joker in the pack or the king?

'Public opinion' has become a major factor in the societal response to biotechnology. Politicians cite public concern as rationale for increasingly restrictive legislation (or, as recently in Europe, *de facto* moratoria), and bow to Non-Governmental Organisation and media campaigns — disregarding both scientific opinion and the fact that real-life consumer behaviour is not as predicted by opinion polls (e.g. in the Netherlands [56]). The UK has conducted extensive public debates — generating more heat than light [57]. In fact, as evidence of risk has diminished, Europe's regulatory framework has become more stringent. Restrictive regulation and political hostility deter research, innovation and investment — witness the collapse of research releases in the EU since 1997 [26] — but it is easier to adopt tough regulation than to recognize its destructive effects.

We might note in passing the 1998 Swiss referendum [58], a real-life experiment in public debate about acceptance of biotechnology. Here the scientific community — academic and industrial, thrown on the defensive — organized themselves effectively, as their professional activities and very livelihoods were at stake. The resulting victory was impressive, but it was far from certain, and they surely benefitted from the tactical incompetence of their opponents. The subject is reviewed by Gaskell elsewhere in this issue, and in other reports [59–61].

Conclusions

The case for benign neglect of biotechnology has been largely lost in Europe at present, but the current Commission strategy may slowly correct this. Europe has supported research, while burdening the technology with disproportionate legislation; preaching the gospel of competitiveness, but forgetting that precautionary regulation should be dynamic and adaptive to scientific evidence and experience. As resources (scientific, administrative and political) are always limited, devoting more to small or non-existent risks subtracts them from more serious needs, thus actually increasing risks.

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