Delegation of regulation

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YESTERDAY (23 October) was D-day for European biotechnology — the day when the European Communities' (EC) directives on contained use (EC/90/219) and on the deliberate release into the environment (EC/90/220) of genetically modified organisms first took effect. Their gestation period has been long and, at times, acrimonious; even now much detail still has to be finalized and implementation, the responsibility of member states, will at best be patchy.

Publication of this report on the development of EC policy towards biotechnology is therefore timely. It is a wholly factual account of the emergent regulatory regime, with sections on the three main areas of regulation — contained use, deliberate release and pharmaceuticals. There is also coverage of the main issues in the debate over intellectual property rights, and a detailed summary of the various framework programme initiatives to promote research and training.

An account of this nature dates very quickly. Although issued in 1991, the report is already badly out of date in several important respects and could seriously mislead any manager, administrator or scientist (the audience at whom one assumes it is aimed) relying on it to provide the necessary background information for the implementation of new directives. Indeed, it is difficult to make sense of the current situation, for example the dispute between commission, council and parliament over the regulation of genetically modified pesticides, without knowing something of the fragmentation of responsibilities in Brussels and the shifting sands of the negotiations over regulation as the various directorates general in Brussels battle among themselves.

Omissions

The report is seriously lacking also as a critique of policy. There is no attempt to analyse the rationale of chosen policies, or to cover areas of dispute. As a result, significant issues are ignored — for example, the question of whether regulation should be by product (as is happening in the United States) or by process (as generally happens in Europe). Nor is there discussion of the concept of 'pre-cautionary' regulation developed in Germany, nor of whether regulation should be horizontal (covering all products across sectors) or vertical (with separate

regulations applying, for example, to pharmaceuticals or pesticides). Even more surprising, perhaps, is the absence of any discussion of the infamous 'fourth hurdle', the moves on the part of some directorates general to introduce into the regulatory framework an explicit socio-economic assessment of proven market need.

These criticisms highlight an opportunity missed. What has been achieved after a decade of policy-making? Where does European biotechnology stand in global terms? Where is it heading? And what difference, if any, can community policy make? We will have to look elsewhere for the answers.

Industrialists' answers to these questions are gloomy. They point, rightly, to Europe's lagging competitiveness — poor patenting performance, low public expenditure on research and development, and the flight of capital and trained manpower to the United States. They conclude, predictably but also correctly, that the crucial decisions for the future of biotechnology in Europe lie with private industry, and in particular with the investment decisions of the major companies, which require an environment 'conducive' to such investments.

Three interrelated issues are central to their concerns: public confidence, the regulatory framework and intellectual property rights. Industry recognizes the need for regulation, even in the absence of known hazard, to secure public confidence but, although it prefers the present stance to earlier uncertainties, it tends to take the view that the commission has given way too readily to the environmentalists on regulation and to the traditionalists on intellectual property rights. Industry would like to see Europe adopt the more liberal stance of the United States. Europe's failures in biotechnology, according to industry, are in large part self-inflicted and attributable to these causes.

Obviously, industry is anxious to minimize the impact of regulation (because regulation costs money and effort) and to maximize patent life. The delays and uncertainties created by the lengthy and ill-tempered debates on regulation have undoubtedly deterred investment. But there are times when perhaps industry doth protest too much. The much-quoted example of BASF's decision to locate its biotechnology department in

the United States is a case in point. BASF was already set on a course aimed at internationalizing its research and development locations; given the strength of the US base in the life sciences, the decision to move was logical. Other companies have done exactly the same. It is a moot point in these circumstances whether such overseas investment is 'capital flight' or merely 'globalization'.

One view suggests that it matters little whether a research laboratory is located in Cambridge, Massachusetts or Cambridge, England — or in Munich or Lyon. We all benefit in terms of use and ultimately the profits will be repatriated. Such a view, however, ignores two important factors. First, the need to create and keep high-value-added jobs, and second, the cumulative nature of research and development in these high-technology fields — once the leading edge of research moves elsewhere, it is difficult to regain competence. Europe cannot afford to be cavalier about the loss of research jobs in biotechnology.

Issues

What role, then, for public policy? It is worth mentioning three issues. First, more than other new technologies, biotechnology depends upon science; hence there is a need to foster the research base in the life sciences and industry's links into that base. EC programmes such as BRIDGE can help, but the prime responsibility for supporting the research base still rightly lies with member states. Second, as the technology matures, the crucial decisions are the investment decisions of private industry and the regulatory framework perforce takes centre stage. Although the needs of industry should not always be paramount, the EC are ill-advised to ignore them.

Finally, we all need to acknowledge that biotechnology raises a host of social, political and moral issues which cannot be swept under the carpet — witness the debates that have already taken place over the patenting of life forms and over animal welfare. These issues require constructive and informed debate. The committee being set up to consider the moral and ethical issues associated with the human genome project is an example of good practice. But is it enough? Should not the EC consider strengthening and extending the European parliament's small Office of Technology Assessment (OTA) to give the EC an institution comparable to the OTA in the United States? □

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