Coordinating European Biotechnology Efforts

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Industry in Europe needs to develop clear and coordinated policies on the issues raised by modern biotechnology, particularly by genetically engineered products. It needs clear and coordinated views on technical aspects, and clear and coordinated dialogue with governmental bodies at both the national and European levels. Coordination is needed because of the cross-sectoral application of the technology and because of the European Council's insistence on legislation that focuses on biotechnology as a set of techniques, rather than on legislation that takes a product or risk-based approach.

However, industry's coordinated approach must not gloss over or ignore the continuing importance of national differences within Europe. If it does, the result will be to make industry actions and arguments less effective.

To understand how central these national differences are, one only has to consider national reactions to the European directives covering recombinant DNA. We realize that when the European Commission (Brussels, Belgium) formulated its technique-based legislation in 1990, it did so in response to public concerns at the time. In some countries, notably Denmark, this legislation has helped industry achieve public consent for its genetic engineering activities, consent that is absolutely necessary in a modern society. However, elsewhere in the European Union, subtle cultural differences alter the way legislation is perceived by the public.

In some countries, for example, there may not be much attention paid to gene technology and its regulation. But in yet other member states, the risks that the public has already perceived in genetic engineering are emphasized by the very act of legislation: In those countries, therefore, rather than providing reassurance, the legislation served only to perpetuate the initial fears.

This is just one example of the difficulties inherent in making legislation for a union of twelve culturally very different countries. While technical standards should and can be harmonized, legal and administrative traditions are not so easily changed.

All of this points to the need for a stronger emphasis on national biotechnology input to the regulatory process. When a biotechnology directive has been adopted, its national implementation naturally involves the national bioindustry association. But by then, it may be too late to take into account the industry view on national differences: There may be little flexibility left for national implementation. It would make sense to involve national bioindustry associations early, and in any case the coordination between national associations—and between national associations and European representative organizations—remains essential.

Combining the coordination of national views with the coordination of sector views is a complicated task that the European bioindustry has not yet fully mastered.

The short-term goal for industry, therefore, is full coordination of the presently somewhat fragmented representation of industry views. At the European level, the Senior Advisory Group Biotechnology (SAGB, Brussels) coordinates industry input and views together with the European sectoral federations that make up the Forum for European Bioindustry Coordination (FEBC, Brussels) These European federations, in turn, liaise with their national counterparts in the member states. In several member states, there are cross-sectoral national biotechnology associations linked by the Brussels-based European Secretariat of National BioIndustry Associations (ESNBA).

Behind the complexity of European bioindustry organization is a limited number of companies to whom both national and sectoral aspects are sufficiently important to merit their membership in organizations in several member states and in several sectors, as well as in SAGB. These companies have an interest in making the present complex organization work. This, I believe, benefits all other companies. There is no basis for the misconception that ESNBA represents small companies and SAGB the larger ones. That schism is not real. The size of a company is not relevant to its interest in biotechnology and to whom it wishes to be represented by.

For some time yet, there will be a need for cross-sectoral industry views at both national and European level, and the European companies involved in SAGB, the sector federations, and the national bioindustry association must ensure their proper cooperation.

It is probably not possible to achieve—at a stroke—what our U.S. colleagues did when they merged the Industrial Biotechnology Association and the Association of Biotechnology Companies into a single association, the Biotechnology Industry Organization (Washington, D.C.). However, we expect to see preparation for a similar development before the end of this year.

The long-term desire of European industry is that biotechnology will one day be treated as a set of tools that are useful in various industry sectors. The products developed using those tools should, however, fall only under sector-based legislation. Ultimately, with the sectors well-represented in member states, and member-state views well coordinated within sectors, there would no longer be the same need for biotechnology-specific associations—either national or international—to represent industry in regulatory matters. Until that time, however, national, biotechnology-specific perspectives must be an integral part of industry's influence on centralized European legislation on biotechnology. ///