Relaxing European Regulations

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The biotechnology industry in Europe has for some years been subject to unnecessarily strict regulation. This has been the industry's view all along, and is now, at last, being recognized by those in authority within Europe. Although credit must be given to those responsible for lobbying efforts so far, much remains to be done. There is uncertainty about how far recent promising words will be translated into specific action, and the pressure must be kept up.

The basis of the regulatory framework in Europe is set out in two European Directives referred to as the "contained use" and "deliberate release" directives. They regulate processes rather than products. In the U.S., and increasingly in Japan, this is not the case, and the resulting stricter framework in Europe puts the European industry at a competitive disadvantage. Again, this is a point that industry has been making for many years. Now European regulators seem to have gotten the message.

The move toward relaxation of the framework began in 1993 with encouraging comments from the administrative and executive arm of the European Union, the European Commission (EC, Brussels), about the importance of the biotechnology industry to growth, competitiveness, and employment in Europe. This was followed in June 1994 by a communication from the EC to the Council of Ministers (one Minister from each of the national parliaments) and the European Parliament (Strasbourg) setting out proposals for encouraging the development of the European biotechnology industry. These included amendments to the "contained use" and "deliberate release" directives; changes said to be necessary to take account of recognition that the risks to human and environmental safety are lower than was thought when the directives were adopted.

The changes proposed in June to the "contained use" directive included making the notification and authorization requirements simpler and more flexible; ensuring that classification of genetically modified organisms (GMOs) and of the activities in which they are used reflect the real (rather than perceived) risks involved; making the conditions imposed for the use of GMOs reflect the real risks involved; and making the directive itself more flexible to allow for its adaptation to new technology. There were also proposals to redefine risk categories of GMOs by revising the annex to the directive that sets out the criteria for classifying GMOs considered to be inherently safe. The communication sought industry comment with a view to the EC proposing modifications to the directive before the meeting of the Council of Ministers in December of this year. Changes were also proposed to the "deliberate release" directive, but these were less specific and not considered to be as urgent; it was suggested that specific proposals should be considered in the first half of 1995.

Since then, the Industry Council (Council of Ministers) has met (at the end of September, 1994), and firmly endorsed these proposals. The Council concluded, ". . .there is broad consensus that this topic should be dealt with swiftly in the competent bodies—particularly the Environment Council [Council of Ministers]—so that decisions can be taken quickly on the necessary adjustments to Community rules in the light of the current status of international science, research and technology."

This is all very encouraging. However, there may yet be a catch, and it is highlighted in the Industry Council's conclusion. Responsibility for changes to the directives rests ultimately with the Environment Council, and it has so far remained silent. (Indeed, it did not even have the issue on its agenda at its most recent meeting in early October.) Will it, too, be sympathetic to the industry's concerns? Perhaps, but only if it is told what they are and is persuaded of their merits.

So what does all this mean for the biotechnology industry? In short, keep the pressure up. Any softening of the regulatory framework is to be welcomed. That does not mean, however, that the biotechnology lobby can rest easy. Convincing the EC and the Industry Council of the merits of its arguments is commendable. But the efforts must not stop there. Many feel that the proposed changes do not go far enough, and it is far from clear that the force of the arguments even for these (limited) changes has been appreciated by the Environment Council. The biotechnology industry must ensure that its arguments are put to the various national environment ministers at least as strongly as those that will, inevitably, be raised by the environment lobby.

And it is not the only industry in Europe that should play a role. For those organizations that are content to restrict their markets to the U.S. or Japan, the proposals are perhaps of very limited relevance. But for companies with broader geographical markets in mind, the changes are likely to have a significant impact. Not only will they affect their business in the European Union, but also in other parts of the world where regulatory regimes for the biotechnology industry are not yet finalized, as these countries may well decide to use the (modified) European regime as a model. ///