EU plans to streamline GMO regulations

The EU approach should allow parts of the current GMO regulations to be changed with a minimum of fuss on the basis of increased understanding of the risks associated with GMO use.

OXFORD—The European Union's (EU, Brussels) European Commission (EC)—the EU's regulation-drafting body—is preparing to streamline the regulations governing the contained use of genetically modified organisms (GMOs) and the deliberate release into the environment of GMOs.

Indeed, European biotechnologists have long complained that the current GMO regulations have held them back. In fact, the outgoing EU president, Jacques Delors, summed up these complaints in a December 1993 white paper entitled "Growth, Competitiveness, Employment: The Challenges and Ways Forward into the 21st Century," stating that the EU "should be open to review its regulatory framework, with a view to ensuring that advances in scientific knowledge are constantly taken into account and that regulatory oversight is based on potential risks. Furthermore, if the EU is to avoid becoming simply a market for, rather than a producer of, biotechnology-derived products, then it is vital that EU regulations are harmonized with international practice."

The EC plans to implement a two-track approach to ease current GMO regulations. Overall, the approach should allow some parts of the current regulations to be changed with a minimum of fuss on the basis of a substantially increased understanding of the risks associated with the use of GMOs. The EC states that, through one track, it will exploit "existing possibilities for revising measures/procedures/degree of oversight/requirements through the use of the light procedure of adaptation to technical progress" and that, through a second track, it will bring "forward amendments to existing legislation in order to incorporate changes which cannot be achieved by technical adaptation, while leaving the basic structure of the framework intact."

Concerning the contained use of GMOs, the EC wants to ease the administrative/notification/consent requirements, where such easing does not compromise safety. It also wants to redefine the risk categories of GMOs and revise the

guidelines for classifying GMOs. Furthermore, the EC believes that there may be scope for lightening consent requirements when GMO experiments involve activities now known to present low risks to human health and the environment. "This would allow a greater focusing of attention on higher-risk possibilities," notes the EC. It plans to add a number of specific amendments to the contained-use directive, including:

- for certain low-risk activities, replacing consent requirements by record keeping or notification for information purposes;
- for certain higher-risk activities, replacing explicit consent requirements by implicit consent;
- reducing the time periods involved in such consent procedures;
- removing the differentiation between activities in research labs and those in production plants.

Changes are already underway to the directive on the deliberate release of GMOs into the environment. These changes include two EC decisions made in April that revised the notification requirements for releases of genetically modified plants. Initially, the directive was devised with microbes in mind, but, so far, 95 percent of all GMO releases have involved plants. Another change, made in October 1993, established criteria for introducing simplified procedures for the release of modified plants, and, indeed, the EC is about to introduce these simplified procedures. The EC, though, recognizes that further streamlining of the directive might be needed, and it has pledged to conduct a further review of the directive during the first half of next year.

Yet not all parties to the EU share the EC's enthusiasm for easing the current GMO regulations. For instance, Hiltrud Breyer, a German member of the European Parliament (Strasbourg, France) who represents Germany's Green Party, is currently preparing a report that is expected to come down heavily against any moves to ease the GMO regulations. Also, a number of EU member states—including Greece, Ireland, Luxembourg, and Spain—haven't even fully implemented

the current GMO regulations, even though these regulations were supposed to be in effect throughout the EU by October 1991.

The European biotechnology industry, of course, is backing the EC's efforts to ease the GMO regulations. "We want to see the establishment of directives that are scientifically sound and that do not discriminate against products because of the way they are made," explains Brian Ager, director of the Senior Advisory Group Biotechnology (Brussels).

Germany is also pushing for the easing of GMO regulations. This is ironic because Germany was the prime mover in pushing for tough GMO regulations in the first place. The current GMO directives, in fact, are far more restrictive than the EC had originally intended, in response to pressure from the Germans. Indeed, it was the Germans who called for compulsory public consultation of GMO experiments, although the EC eventually made such consultation voluntary.

Germany, moreover, succeeded in mandating that the contained-use directive come under Article 130 of the Treaty of Rome, the EU's legislative constitution, which allows member states to introduce laws that are stricter than those required by a directive. Had the EC had its way, the directive would have come under Article 100A of the Treaty of Rome, which does not allow member-state deviation from a directive.

Clearly, the exodus of the biotechnology efforts of such German multinationals as Bayer (Leverkusen), Hoechst (Frankfurt), and BASF (Ludwigshafen) has impacted the German government's view of biotechnology regulation. Many biotech watchers, in fact, believe that the German government is pushing for regulatory changes at the EC level because the German public has such an unfavorable image of biotechnology. By this thinking, the German public is far more likely to accept biotech regulatory change if it believes that this change is being forced upon it by the EC, rather than its own government.

—Mike Ward