small-scale release, which would include most research experiments, the commission would merely require that it be notified.

In general, Europe's biotechnology companies are enthusiastic about the idea of a single, harmonized set of regulations, particularly since the procedures currently being considered are close to those already proposed by its own lobbying organization, the European Biotechnology Coordination Group. "We need rules which will give the biotechnology industry the same operating conditions in each country; otherwise there is a danger that they will move to where the least restrictive regulations are found" says Jórgen Mahler, head of regulatory affairs for the Danish pharmaceuticals company Novo Industri AS and chairman of the Association of Microbial Food Enzyme Producers, one of the five founding bodies of the coordinating group.

In their current form, however, several aspects of the Commission's proposals, which are scheduled for publication for public comment early next year, remain highly controversial. One is the fact that, once an application for a large-scale release has been submitted for approval to the EEC, it will then be passed to the other 11 member states. These will then have time (the current suggestion is 60 days) to file an objection.

In theory, this could make it possible for authorities in one country to try to veto a planned experiment in a neighboring country; in practice, EEC officials envisage a review procedure involving both government representatives and independent scientists designed to resolve any disagreements that emerge. But many companies are unhappy about the delays that could result.

"We could be waiting for permission to come through, and find that we have missed the growing season," says one scientist with the Belgian company Plant Genetic Systems, one of the first companies in Europe to have begun field tests with transgenic plants.

Even more controversial is the question of whether some countries should be allowed to step out of line and impose harsher restrictions than others. Would Denmark, for example, be permitted to maintain its ban? In general, the biotechnology community is adamant that no deviations from a European norm should be allowed—including the mutual recognition of the conclusions of risk-assessment studies. "What is dangerous in Denmark is also dangerous in West Germany," says Mahler of Novo Industri.

However, the argument that harmonization is necessary for guaranteeing maximum safety is strongly contested by many environmental groups. "The companies seem to be asking the European Commission to help them circumvent national legislation that they find unacceptable, while at the same time countries such as West Germany might be happy to adopt an EEC directive as a way of avoiding a real public debate on the issues," says Benedikt Härlin, a representative of the German Green Party in the European Parliament.

Härlin says he supports the principle that a strict assessment of the risks of a particular release should be made and approved before the release is carried out. But he argues that there should be a moratorium on all such activities in Europe until an adequate procedure for doing this has been set up.

The biotechnology companies accept the idea that more rigorous risk-assessment techniques are needed. But they are concerned that excessive caution could itself prove harmful. "We in Europe must stop talking and start acting if we want to stay in the race," says Mahler. "The winner [in international competition] will be the one who can obtain informed public consent without delaying its industrial development plans; we can still save Europe from a divergence [of regulations], but the Danish move shows the need for fast action."

Ernst von Weizsäcker, director of the Institute for Environmental Policy in Bonn, agrees that there is an urgent need for action, but for different reasons. "The public has a strong and intuitive understanding—which may not be so wrong—of the novelty of the dangers posed by genetic engineering, and it is worried," he says. "Unless something sufficiently comforting is proposed in terms of a regulatory mechanism, the public is not going to calm down; that is the urgency." ■ **DAVID DICKSON**

# Indo-U.S. Vaccine Pact Disputed

A cooperative Indo-U.S. vaccine development program has been the subject of a sharp exchange of criticism in the Indian press and rebuttal by the Indian government. A main contention of the critics, denied by the government, is that U.S. drug companies intend to use the agreement to make India a testing ground for bioengineered vaccines, thereby bypassing stringent U.S. regulations on vaccine field trials on humans.

Target of the critics is a memorandum of understanding for a vaccine action program signed on 9 July by the two countries. The agreement calls for U.S. spending of $7.6 million over 5 years. India will spend $2 million in its own funds.

Under the agreement, collaborative efforts are to be directed at high-priority vaccines "which can be developed or adapted to the Indian situation." Cholera, typhoid fever, rotavirus, hepatitis, dysentery, rabies, pertussis, pneumococcal pneumonia, and malaria are described in project documents as "priority areas."

The controversy was generated by a report on the agreement from the Press Trust of India (PTI) and two articles and an editorial calling for cancellation of the project in the *Times of India* of New Delhi. Both the PTI report and the *Times* follow-up were based on broad presumptions on how the agreement will be implemented.

Critics charge that the agreement called for a patent accord that would impose strong, U.S.-style patent protection on patentable results produced in India under the program, replacing India's existing patent provisions which provide less protection to developers.

The original PTI story dated 16 August referred to concern about a proposal to establish an epidemiological research and training center under the agreement, citing such a center's "potential uses to biological warfare specialists." The critics had also complained about the weakness of the agreement's provisions for safeguards on the introduction of genetically engineered organisms into the environment.

The Indian government responded in detail to a number of the critics' points in a "clarifying" statement on 19 August. The statement said, for example, that no vaccine developed elsewhere will be tested in India unless it has been cleared for testing in the country in which it was developed.

Indian-U.S. cooperation in health R&D has a long history, but has been subject periodically to hostile comment in India in incidents usually reflecting Indian suspiciousness toward U.S. intentions. At this point, categorical answers to the current questions about U.S. motives are unavailable. The memorandum of understanding provides only a framework for activities under the agreement. Still to be negotiated are appendices that will govern two of the most sensitive issues—protection of subjects in field trials of vaccines and provisions on patents, copyrights, and other intellectual property. The memorandum directs that these loose ends be tied up within 90 days after the signing, so the furor will insure ample attention to what the negotiations produce. ■ **JOHN WALSH**