REGULATION

BRUSSELS SPROUTS NEW RULES

LONDON—Nine months overdue, the Commission of the European Communities has at last given birth to two sets of draft regulations dealing with genetically modified organisms. At the same time, it has also issued proposals for protecting workers who handle potentially hazardous microbes.

One set of the new—and unavoidably controversial—regulations deals with deliberately released organisms; the other addresses contained microorganisms. For the former, the Commission has steered a middle course between the existing European extremes, but this path may still not suffice to avoid problems when the regulations are considered by the Council of Ministers (drawn from the member states of the European Communities) and by the European Parliament.

With deliberate release all but banned in Denmark and the Federal Republic of Germany—but under no regulation in Italy, Spain, and Portugal—the Commission suggests adopting a system much like that operating in the United Kingdom and France, but somewhat more officious. The principle is that of case-by-case notification of planned releases to a national agency, which would be charged with the review and eventual endorsement (which seems to be synonymous with authorization) of each proposal.

In the case of *experimental* releases, a national authority would have 90 days to respond to any proposal. During that period, a summary of the request would be sent to other agencies, which could do no more than suggest modifications.

In the case of a proposal to *market* a genetically modified organism, the national authority would first endorse a proposal before passing on the information, except for anything withheld for reasons of commercial secrecy. A 90 day period would then be allowed for other agencies to raise objections on the grounds of risk. If no agreement could be reached, the Commission would have the final say.

For the *contained* use of genetically modified microorganisms, the Commission would be routinely informed only when the requests came from industry and involved microorganisms not classified as "minimal hazard." In such cases, the national authority would also have to consult "other Member States likely to be affected in case of an accident." Contained use of "minimal hazard" microorganisms and non-industrial applications would at most need a 15-day period of notification.

In technical matters and in suggesting a case-by-case approach to approving deliberate release, the Commission claims to have followed the 1986 recommendations of the Organisation for Economic Cooperation and Development, which has just begun a process of updating its views. In general, says Mark Cantley of the Commission's Concertation Unit for Biotechnology in Europe, the proposals "are designed to rebuild public confidence in science."

In two respects the Commission has obviously had some semantic difficulties in drafting its proposals. First, is an organism in a greenhouse "contained" or "deliberately released"? And second, what does the term "genetically modified microorganism" encompass? It includes, declares the Commission, mammalian and plant cell cultures but excludes anything modified by processes carried out "under normal physiological conditions" and not involving the use of recombinant DNA techniques. To accommodate the view that it is illogical—if inevitable in the present circumstances—to single out the technique of recombinant DNA, the Commission promises to examine if and how its proposals could be extended to cover organisms modified by other means.

There is no set timetable for progress on converting the proposals into directives that would bind member states to make them law. Much will depend on the level of opposition there is from representatives of the more restrictive nations in the European Parliament.

Attention will also be paid to industry's reaction. The European Biotechnology Coordination Group, representing most industrial sectors, expects to respond in June and is likely to look particularly closely at the level of regulation proposed for pilot-scale experiments. **—Peter Newmark**

ASM ANNUAL MEETING

OPENNESS AND VERIFICATION URGED FOR DoD BIORESEARCH

MIAMI—When U.S. Department of Defense (DoD) officials skirmish at scientific conferences with experts from outside DoD on the topic of the Army's biological research, the sniping can get pretty intense. Such was *not* the case, however, at the 88th Annual Meeting of the American Society for Microbiology held here in May. In fact, all the panel members at a well-attended roundtable discussion on "Defense-Related Biological Research" agreed that "openness" is a crucial first step in defusing this potentially explosive area of R&D.

"The entire scientific program is non-classified," stated Thomas Dashiel, director of DoD's environmental and life sciences division. The Department of Defense annually presents an itemized budget to Congress, he said, and DoD researchers publish about 150 scientific papers a year.

Dashiel stressed that Defense's biological program has two main objectives: to provide U.S. armed forces with an adequate level of protection from biological weapons, and to serve as a deterrent to biological warfare via a strong defensive posture. Toward these ends, DoD is developing improved warning, detection, and prophylactic technology.

In accordance with the 1972 Biological Weapons Convention, Dashiel added, the U.S. is not developing any offensive applications. He cautioned, however, that some other countries—including the U.S.S.R.—may indeed be working on bioweapons.

The major problem today is monitoring compliance with the 1972 agreement, according to Robert Mikulak of the State Department's Arms Control and Disarmament Agency: "We don't know how to verify this Convention." One recent step in the right direction has been the international exchange of information on the number and location of maximum-containment bioresearch facilities—a move pioneered by the U.S. and the U.S.S.R. but followed by relatively few countries.

"Declarations by themselves aren't far-reaching enough," stressed Matthew Meselson of Harvard University (Cambridge, MA), and traditional site visits would probably raise as many questions as they satisfy. He suggested that the best way to way to achieve true verification would be through long-term scientific exchanges—with programs involving scientists from the Soviet Union and the Eastern Bloc. **—Arthur Klausner**