COMMENTARY

INCHING TOWARDS UNIFORMITY ON EURO-RELEASE

by Bernard Dixon

Next month, the environment ministers of the European Economic Community are to discuss a directive prepared by the European Commission on the deliberate release of genetically modified organisms. This follows two earlier landmarks of Eurobiopolitics 1989. In June the ministers unanimously approved a parallel directive on the contained use of modified organisms. And in May the European Parliament rejected by just 68 votes to 67 a Green/Social Democrat call for a five-year moratorium on the sale, production, and release of certain products of genetic engineering.

Europe, in short, is inching towards uniformity of approach to the regulation of recombinant DNA and associated technologies. The talented but under-resourced drafters and toilers in Brussels are winning support for their directives (which have to be approved by both the Council of Ministers and the European Parliament). But there is still substantial territory to cover. On the one hand, the fight will continue in a newly constituted Parliament, elected in June, which contains twice as many Green members as before. On the other hand, even the directive on contained organisms sets only minimum conditions, allowing individual countries to impose stricter rules if they wish. There are already widespread disparities, and some continued geographical variation seems inevitable.

In the midst of all this action, I ponder one simple possibility, which I put forward with due modesty—that we in Britain have actually got this whole thing about right. Despite our longstanding and growing passion for secrecy in government, this issue has been handled rather well. Three years ago, guidelines were issued calling for research workers and industrialists to give prior notification of intended releases of recombinant organisms into the environment, and laying down points to be considered in assessing the risks of doing so. Proposals are dealt with by the Advisory Committee on Genetic Manipulation (ACGM) and its Planned Release Sub-Committee, operating under the Health and Safety (Genetic Manipulation) Regulations of 1978.

The Sub-Committee is a broadly based body, embracing not only gene-splicing but also ecological expertise, as well as representatives of trade unions, employers, and local authorities. Where relevant, proposals are also referred to bodies such as the Departments of Health, the Environment, and Agriculture. Both the ACGM and its Sub-Committee, chaired by rhizobia expert John Beringer of Bristol University, enjoy the respect of the scientific community and the confidence of the politicians and public. Under Beringer's leadership, the Sub-Committee functions as a "watchdog," rather than simply a peer review body, and takes a wider view of its social responsibility than that laid down in its formal terms of reference.

When the ACGM and its Sub-Committee deliberate, the outcome is either permission to proceed, refusal on safety

grounds, or authorisation conditional on the research team building in specific safeguards and/or doing additional preliminary studies to answer safety questions. Although this system has until now been voluntary, it has been fully supported by researchers. There have been no clandestine, unapproved releases of the sort that have caused public consternation elsewhere in Europe. Two years ago, the Health and Safety Commission reviewed the 1978 regulations and sought responses from the scientific community and other interested parties to a series of proposed changes. One result, expected later this year, is a change in the law so that notification and authorisation for both large-scale work with engineered organisms and deliberate releases become compulsory.

But this system too is being augmented. Last year, the Department of the Environment established a new advisory committee concerned with risk assessment of planned releases and is now (with a closing date of 25 August for receipt of replies) circulating a consultative paper recommending further legislation specifically to protect the environment from adverse consequences of intentional release. Pointing out that the ACGM and its associated legislation were directed originally towards the safety of persons, the paper proposes parallel machinery centred on the biosphere. Details remain to be ironed out, but the additional law should impose on those releasing organisms a duty to protect the environment. Another arm of government, the Department of Trade and Industry, has also become involved recently. Together with industrial companies, it has launched the PROSAMO programme to assess the ecological impacts of organisms introduced into the environment, and the "underpinning technologies required for risk assessment purposes." (*Bio/Technology* 7:654, June '89.)

If this were not enough, there is a third strand—an additional source of independent evaluation. For the past three years, a Royal Commission has been laboring over this very same subject, taking evidence from a wide range of interests and lobbies, and evolving a recently published report (see "U.K. Notice Requirements Proposed," in this issue). The government is now digesting the Commission's findings, which it will take into account, together with responses to the Environment Department's paper, in putting forward proposals for legislation in Mrs. Thatcher's so-called "Green Bill" in the next session of parliament.

Some readers may feel that this is, indeed, more than enough. My hunch is that the U.K.'s approach continues to be a prudent blend of permissiveness towards well-designed, potentially beneficent experimentation and of wide-ranging, rigorous evaluation of proposed releases. Above all, a sound, open, and respected system of regulation should be more than enough to disarm those who wish to put a full stop to all work of this sort. I hope I am right.