GENETIC ENGINEERING

New advisory board approved

Washington

LOUIS Sullivan, Secretary of the Department of Health and Human Services, surprised the biotechnology research community two weeks ago with the announcement that he was about to give his formal approval now to the establishment of a new government advisory body on biotechnology, to be called the National Biotechnology Policy Board (NBPB). It will concentrate on technology transfer from university and federal research laboratories and the competitiveness of the US biotechnology industry.

Congress directed the National Institutes of Health (NIH) to establish the board last year and wanted to see its first report in January 1990, but members of the board have not yet been selected from a list of about 80 candidates. Responsibility for establishing it lies with the NIH Office of Recombinant DNA Activities, whose director, Nelson Wivel, says that it might be in place early next year, now that Sullivan is ready to sign the charter.

The board will consist of representatives from all the federal agencies that support or regulate biotechnology research, four university researchers, four representatives of the biotechnology industry, two members from state biotechnology development programmes, one member of a charitable institute and a bioethicist.

The Congressional Bioethics Board (CEB) was charged with reviewing reports from the NBPB, but is unlikely now to do so: after a short and controversial life, the CEB was dissolved on 1 October (see *Nature* **341**, 6; 7 September 1989). It made no progress on any of its planned studies, the board members spending most of their time arguing over the selection of members for its advisory committee, with a candidate's views on the abortion issue being the deciding factor. Bob Cook Degan, former executive director of the board, says that for the moment he thinks the board is "dead permanently. It's certainly dead transiently".

Some of the NBPB's responsibilities, such as its mandate to "enhance basic and applied research", might overlap with those of the existing Biotechnology Science Coordinating Committee (BSCC), yet another advisory body in this field which has likewise not been without its share of controversy. The president's Office of Science and Technology Policy set up the BSCC in 1985 to coordinate the regulation of biotechnology across all the federal agencies. Last year it became bogged down in a dispute between the Environmental Protection Agency (EPA) and the Food and Drug Administration over whether the EPA should regulate non-coding as well as coding genetic sequences. An EPA rule on the regulation of genetically manipulated microorganisms was delayed. Last week, Bill Reilly, the EPA administrator, said it would be ready early next year.

But a report published two weeks ago, written by Sidney Shapiro of the University of Kansas for the Administrative Conference of the United States, a Washington-based think-tank, is highly critical of the BSCC and recommends that it should be dismantled. BSSC's chairman, John Moore, who is also a deputy director at the National Science Foundation, says the committee is at present discussing how the new NBPB will affect its role. But he says that although some of the criticisms might have been valid in the past the BSCC is "on a pretty good keel right now".

Shapiro says that gaps still exist in the regulation of genetically manipulated organisms and that the existing biotechnology regulation framework "is a prescription for inconsistent regulation and litigation". He recommends that a new committee be set up with a broader membership and permission to consider a wider range of issues. It should be more accessible to the public. Margaret Mellon of the National Wildlife Federation says that Shapiro's criticisms are not out of date, and that the burden lies with the BSCC to prove that it is not a "creature of industry". **Christine McGourty**

Britain regulates organism release

London

REGULATIONS put before the British Parliament two weeks ago will make it compulsory, from 1 November, to notify the government's Health and Safety Executive (HSE) of the use or deliberate release of genetically manipulated organisms. HSE must be given 90 days' notice to allow time for a safety assessment of any proposed activity.

The new scheme, first put forward in 1987 by the Health and Safety Commission (HSC) and its Advisory Committee on Genetic Manipulation (ACGM), replaces the present voluntary system of notification. Richard Clifton, chief administrator of the executive's medical division, said the changes were necessary to keep up with advances in the field. He said the HSE had adopted a "pragmatic" and "step by step" approach to safety regulation.

The new provisions also require that laboratories assess the risks involved using a method approved by the HSE and that a genetic manipulation safety committee be set up at each centre undertaking such work. The regulations revise the definition of 'genetic manipulation' to include the incorporation of heritable material into an organism either directly or indirectly, using vector systems, and also provide for simplified annual retrospective notifications for low-risk activities.

In due course, the regulations now imminent in Britain may be overtaken by impending legislation. The European Commission has yet to agree the form of a directive, which may well be more stringent, while there is every likelihood that the British government's expected bill on environmental matters will also deal with the release of engineered organisms.

Ben Webb

Microinjection patent granted

Washington

THE US patent for microinjection, the most widely used technique for creating transgenic animals, was granted this month to Thomas Wagner of Ohio University and Peter Hoppe of Jackson Laboratories in Bar Harbor, Maine. The patent is not restricted to any particular species of mammal or the transfer of any specific gene.

Wagner and Hoppe have assigned the patent to Ohio University, which has licensed the commercial rights to the small biotechnology company DNX Inc. University researchers can continue to use the technique free of charge, but biotechnology companies that wish to make use of microinjection for research purposes will have to pay an annual licence fee. Companies wanting to use the technique to create commercial products will be able to obtain an exclusive or a non-exclusive licence, which will be negotiated on a case-by-case basis.

Holtzman estimates that about 35 companies are now using microinjection; its applications include the development of the multi-million dollar-clot-dissolving drug TPA (tissue plasminogen activator), and of Factor V111, the blood-clotting protein used to treat one form of haemophilia. It was also used to develop the 'oncomouse', the first patented transgenic animal, which is being sold by Dupont and is expected to be useful in the testing of drugs against cancer. Wagner has assigned his royalties to the university's Edison Animal Technology Center.

Wagner and Hoppe filed for the patent in 1981, shortly before they published an account of the research in which they were the first to achieve, in a single experiment, the introduction of a foreign gene into a different species of mammal and its transmission through the germ line into a second generation of animals. Although microinjection was being used by other researchers at the same time, no competing patents are thought to have been filed and Stephen Holtzman, Ohio University's vice-president for corporate development, says the patent is "strong and enforceable". Ohio University has also filed for the patent in Europe.

Christine McGourty