

Gene manipulation in Britain

SIR—Joseph Palca's article "Living outside regulation" (*Nature* 324, 202; 1986) reports that a genetically manipulated yeast developed in the United States may be tested in England at least in part to avoid the US regulatory process. The article might be interpreted by some readers as implying that in England regulatory requirements for this type of work are more relaxed than in the United States.

Although I am not in a position to make direct comparison between regulatory requirements in the United States and Britain, I would like to make the point that in Britain the safety issues raised by genetic manipulation have traditionally been handled in a balanced and flexible way as exemplified by the framework for notification, risk assessment and laboratory containment established by the former Genetic Manipulation Advisory Group (GMAG) and the Health and Safety Executive (HSE) in the 1970s.

The Advisory Committee on Genetic Manipulation (ACGM), HSE and other involved government agencies intend to continue this tradition as genetic manipulation finds increasing application outside the laboratory.

Existing requirements in this area are for those proposing to carry out large-scale fermentation of recombinant DNA organisms to notify HSE in advance according to guidelines issued by GMAG in 1979 (revised 1982). Each proposal is then considered on a case-by-case basis by HSE and ACGM. Also, revised and more detailed guidelines on the risk assessment and notification of this type of work are under preparation. In common with genetic manipulation laboratories, large-scale sites are subject to inspection under the Health and Safety at Work etc. Act 1974 by HSE's specialist microbiology inspectors who are also available for advice.

For the environmental release of recombinant organisms, guidelines were issued in 1986 calling for prior notification and setting down risk assessment factors for such work. Notifications are considered by ACGM, its Planned Release Sub-Committee, HSE and other relevant government agencies (the Department of the Environment, the Ministry of Agriculture, Fisheries and Food (MAFF), the Department of Health and Social Security and the Nature Conservancy Council) in advance of any release.

Also the Health and Safety (Genetic Manipulation) Regulations 1978 are under review and this review is expected to take full account of the growing importance of large-scale fermentation and release into the environment. For genetically manipulated organisms as pesticides, the requirements of the Control of Pesticides Regulations 1986 are relevant. The

Food Act 1984 places a duty on the processor/manufacturer/retailer to ensure that food offered for sale for human consumption is safe. There is also a notification scheme for novel foods operated by MAFF in the United Kingdom that would apply to the use of free-living microorganisms. Data on foods under this scheme are evaluated by the Advisory Committee on Irradiated and Novel Foods.

It is important that the oversight of genetic manipulation by government strikes the right balance between avoiding undue restraint and ensuring that appropriate consideration is given to potential concerns. On the international front it is to be hoped that the recently published OECD report *Recombinant DNA Safety Considerations* will do much to harmonize national regulatory positions. Meanwhile, reports of regulatory difficulties in one country do not automatically mean that others have the balance wrong.

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An open question?

SIR—Michael Wagner (*Nature* 323, 664; 1986) implies that a sincerely held belief has the same status as an informed opinion and cites Feyerabend¹ in opposition to Scriven while neglecting to mention that Feyerabend is a 'philosopher' who therein contends that there are different paradigms of rationality and reliance on faith healers is justified because our own paradigm of scientific rationality is founded on irrational elements. Elsewhere², Feyerabend maintains that science without sensory experience is possible by means of telepathic communication with a somewhat pre-existing, pre-programmed computer. Such is the present state of philosophy.

In countering Marks' claim that there are no theories of paranormal investigation Wagner asserts that "there are, of course, philosophically cautious theories of the paranormal and different models of objective transcendence". One reference given to justify this assertion accepts reincarnation as a fact at the outset and goes on to say that we interact with other realities via higher bodies centred around our physical body, and furthermore: "The hierarchy of realities is topped by the 'absolute'. The absolute is the basis of all realities. In its nonmanifest form, it is potential, intelligent energy. When rippled or modulated, it becomes the basis of

our tangible physical matter and individual matter"³. This model of philosophical caution provides the considerations that render Marks' "philosophical outlooks" somewhat "problematical".

Wagner admits that there are no scientific theories of paranormal investigation, but only because it "has as yet no paradigm (in the Kuhnian sense)". It is "not yet a mature science" being "in the pre-paradigm stage" and anyhow many would reject the "assumption that scientific thinking is necessarily analytical thinking". The desirability of scientific, analytical thought is thus "an open question".

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1. Feyerabend, P. *Against Method* (New Left Books, London, 1975).
2. Feyerabend, P. in *The Journal of Philosophy* (Columbia University, 20 November 1969).
3. Bentov, I. *Stalking the Wild Pendulum* (Bantam, New York, 1971).

Preventing feticide

SIR—In a recent News article (*Nature* 324, 202; 1986), Radhakrishna Rao reports on the proposed government legislation to restrict the use of antenatal sex determination in India because of the growing problem of female feticide, but the problem may not be restricted to India. For some time now, we in the West Midlands have been aware of the problem of selective termination of chromosomally normal fetuses following amniocentesis for a legitimate purpose, for example to screen for Down's syndrome. It has been our practice (in common with most cytogenetic laboratories in the United Kingdom) to report the karyotypes of individual cases in full, including chromosomal sex. In order to prevent the possible abuse of a costly diagnostic procedure, we have, however, now decided to withhold sex from our reports, unless it has some direct clinical relevance (for example sex-linked disease prediction).

From 1 January 1987, it will be possible for an individual consultant to learn the fetal sex upon special request to the laboratory, but no longer will the chromosomal sex be routinely reported upon and freely displayed in the obstetric notes.

Perhaps the Indian government could make it similarly difficult to learn the chromosomal sex from written laboratory reports, rather than legislate against the useful diagnostic practice of antenatal chromosome analysis *per se*?

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