UK agricultural research

Penury brings radical reappraisal

ADVERSITY (mostly financial) has persuaded the most threatened of the British research councils, the Agricultural and Food Research Council (AFRC), to canvass a radical plan of reorganization. One proposal would reduce the number of separate institutes from about twenty (with seven separate Scottish research institutes) to perhaps half that number.

It is also proposed that there should be a management board for agricultural research to which would belong research council officials and a representative of the Department of Agriculture and Fisheries, Scotland, as well as the "ten or fewer" institute directors.

The discussion document, *A long-term view*, says that the number of research institutes would be reduced "by successive amalgamation and restructuring", and that wherever possible institutes will be sited on or near a university campus. Under such a regime, institute directors would have a greater degree of independence in the direction of management of the research for which they were responsible. The document suggests that it should be possible, within such a framework, to give research groups more flexibility, by specifying "the questions to be answered rather than the areas of science to be studied".

Part of the council's management problem is that many of the research institutes for which it is the chief source of financial support are not formally directly under its control, but are historically independently constituted. The Rothamsted Experimental Station is one of these. Thus, in the discussion document, AFRC suggests that people whose salaries it pays should in future be its own employees, which would entail both a change of status and, for some people, a greater degree of insecurity. No doubt the council would benefit through the greater freedom it would have to move people from one place to another.

The discussion document says little about its immediate origin, the proposed reduction of funds for research commissioned by the Ministry of Agriculture, Fisheries and Food of £10 million in the current financial year and twice as much during 1986-87. The question is to be considered by the priorities board for research in agriculture at a meeting later in the summer, but it appears that there is very little prospect of relief from the Treasury edict that these substantial sums of money should be lopped from what has become, in effect, part of the council's budget.

Among the other proposals put forward in the discussion document is the suggestion that the need to avoid duplication of research effort within Europe may make it necessary for the council to withdraw from some fields of research.

But the council is plainly also hoping that it would win research support from elsewhere for some of the research that it carries out at present. The document also repeats the council's expressed intention, during the past several years, of increasing its income from research contracts with private industry as well as from other government departments than those responsible for agriculture.

On people, the council promises to consult trades unions on the reorganization outlined in the document, and says that it acknowledges the need that creative scientists should have a secure environment in which to work. But it also says that it needs to plan for change, for which reason it will continue to recruit many of its staff on short-term contracts.

Flying a more adventurous kite, the council says that part of its case for continued existence is that AFRC is responsible for the "largest non-medical biological research capability" in Britain, which will be widely taken as a reference to the fondness of Sir Ralph Riley, the recently-retired secretary of the council, for the creation of a new research council with responsibility for basic biological research, medical and non-medical.

Comments on the discussion paper are invited by 15 July. □

Tumour necrosis factor

Drug agency jumps TNF gun

Washington

IN an unusual move, the US Food and Drug Administration (FDA) has allowed human tumour necrosis factor (TNF) produced by recombinant DNA technology to be given to a cancer patient. FDA had previously maintained that there are insufficient animal data on the effects of TNF to approve clinical trials, but it has now allowed Dr Herbert Oettgen of Memorial Sloan-Kettering Cancer Center in New York to treat a gravely ill patient with TNF manufactured by the Asahi Chemical Industry company of Japan.

In the normal course of events, FDA grants a so-called Investigational New Drug exemption — permission to enter clinical trials of a putative therapy — only when there are sufficient data to provide a reasonable expectation that the therapy will be safe and effective. FDA allowed a compassionate exemption for the Sloan-Kettering patient on condition that Sloan-Kettering's institutional review board accepts full responsibility for the case, since FDA had no prior information on the TNF used, and the data submitted with the compassionate exemption request covered only basic safety requirements such as pyrogenicity and sterility.

FDA itself appears to be confused about the exemption. Even after granting Sloan-Kettering permission to use TNF on its patient, FDA officials were insisting that the substance was not being used on patients in the United States.

The Sloan-Kettering patient is said to be a member of the staff of the institution. The request to FDA for a compassionate exemption was approved unanimously by over 30 members of Sloan-Kettering's institutional review board on 9 April; according to Dr John Lewis, chairman of the board, FDA was provided with a treatment protocol, a detailed clinical assessment of the patient's condition and "voluminous" information about TNF.

Dr Doris Hutchison, head of the institute's investigational drug committee, said that FDA's bureau of biologics had been "very co-operative" in dealing with the request.

FDA not infrequently grants Investigational New Drug exemptions on compassionate grounds when the relevant animal data have been submitted for FDA's consideration but are held up in the bureaucratic pipeline. Patients with acquired immune deficiency syndrome (AIDS) have been treated under compassionate exemptions with drugs approved for other conditions, for example. Compassionate exemptions have also been granted for trials on seriously ill patients who fall just outside the age range specified in the protocol for a clinical trial. It is, however, less common for FDA to approve what amounts to a clinical experiment when the data are as fragmentary as they are for recombinant human TNF. Some authorities on medical ethics speculate that FDA might feel justified in making an exception if the patient concerned has a sophisticated understanding of the risks and benefits of the treatment.

Dr Lloyd Olds, associate director of scientific development at Sloan-Kettering, is one of the original researchers on TNF, first produced from mouse serum. Dr Olds is being supplied with genetically engineered human TNF for research purposes by Genentech Inc.

Although this material is being used only for animal and *in vitro* studies, according to Genentech, Asahi's TNF is undergoing clinical trials in Japan. After the publication of scientific reports detailing the cloning and expression of the human TNF gene (*Nature* **312**, 721 and 724; 1984 and **313**, 803; 1985), researchers at Genentech and Asahi were deluged with enquiries from anxious cancer sufferers and their families about where TNF could be obtained.

It is still unclear how soon organized clinical trials of TNF will start in the United States, or whether the Sloan Kettering case will serve as a precedent for future compassionate exemptions in similar cases.

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