in state and local debates on recombinant DNA research stems from the fact that the NIH guidelines do not apply to industry, and are not backed by any enforcement mechanism. In that regard, a little-known committee, established last year by President Ford, could prove influential. The committee, which consists of representatives of a variety of federal agencies, is looking into ways to extend the NIH guidelines to cover all recombinant DNA research in the United States. The committee, which meets in closed sessions, is expected to issue recommendations in mid-March.

According to one participant, a broad consensus has been established in the committee that the NIH guidelines should be transformed into enforceable regulations, but it seems that no existing agency has the power to enforce them. For obvious reasons, NIH doesn't want to be placed in the position of both supporting and regulating the research, and the committee is now debating whether to recommend that several regulatory agencies be given the responsibility jointly, or whether to recommend that

Congress should pass legislation to give the authority to a single agency. The basis of the regulations, in any case, will be the present NIH guidelines.

In the meantime, a bill was introduced into both the House and the Senate last week to establish a federal licensing scheme for recombinant DNA research, which would apply to both industrial and academic research. Drafted by Senator Dale Bumpers of Arkansas, the legislation is designed to enforce the NIH guidelines as a bare minimum. When he introduced the bill, Bumpers said that if he had his choice, "there would be a moratorium declared right now on all recombinant DNA research". Senator Edward Kennedy's health subcommittee is expected to hold hearings on the bill early in April, after the inter-agency committee has issued its proposals.

Underlying a good deal of the concern is a deep suspicion of what industry is intending to do with recombinant DNA technology, and those suspicions have surfaced dramatically in the past couple of weeks following the publication of a proposal by the Department of Commerce to expedite

patent applications involving recombinant DNA techniques.

The proposal, drafted by Assistant Commerce Secretary Betsy Anker-Johnson, would require patent applicants to state that they will abide by the NIH guidelines, though they would be permitted to "include an explanation of any deviations (from the guidelines) considered essential to avoid disclosure of proprietary information". That exemption has attracted criticism because it would allow industrial companies to proceed with their research without notifying anybody.

Such criticism last week prompted Joseph Califano, the new Secretary of Health, Education and Welfare, to ask Secretary of Commerce Juanita Kreps to withdraw the proposal. Dr Anker-Johnson pointed out in a telephone interview last week, however, that the proposal in fact forces industry to disclose more information than it is required to under existing regulations. Further disclosure could result in loss of patent rights in many countries which preclude the award of patents on processes for which there has been any prior disclosure. □

CANADA

Guidelines recommended

Canadians are now discussing guidelines for recombinant DNA experiments. David Spurgeon reports

AN ad hoc committee of Canada's Medical Research Council has presented its recommendations on guidelines for handling recombinant DNA molecules. The guidelines are similar to those adopted by Britain and the United States, although they are designated differently, but they go further in that they include guidelines also for experiments involving animal viruses and cells.

The committee's report was made public recently in a press conference held by the MRC, which is the federal granting agency for medical research in the universities. If adopted, the guidelines will apply to all MRC grantees, but not to industry. A federal interagency committee has been studying the question as it applies to industry. Dr G. Malcolm Brown, the MRC president, said the ad hoc committee's recommendations would be discussed at a meeting of the council near the end of February, when they could be approved, rejected or modified. It is considered almost certain, however, that the council will accept them.

The recommendations were drawn

up by a group that included researchers in the appropriate fields and also a member of Queen's University's law faculty. The committee also included a member of the Defence Research Establishment, a member of the University of Alberta's pediatrics department and an observer from the National Research Council.

The Chairman of the committee was Dr Louis Siminovitch, chairman of the department of medical genetics at the University of Toronto and geneticist-in-chief at the Hospital for Sick Children. Dr Siminovitch was influential in the MRC decision to include animal viruses and cells in the committee's terms of reference.

At present, no research involving recombinant DNA is being conducted in Canada, but some experiments have been proposed. A total of one-sixth of MRC's grants could be affected by the proposed guidelines, totalling about \$8-10 million a year, because of their effect on animal viruses and cells.

The earliest the recommendations could be put into effect would be April 1, according to Dr Brown, but Dr Siminovitch said many precautions have already been introduced. If the guidelines are approved, the MRC will insist that all recommendations for laboratory safety are carried out before granting funds. The mechanism for

enforcing guidelines is thus similar to that adopted in the United States, though different from that in Britain.

The guidelines themselves provide for six levels of containment, ranging from a statement of good microbiological laboratory practice (level A), plus suitable containment measures for agents of no known or potential risk, to requirements for very hazardous materials, such as the virus that causes lassa fever (level F). The technique and equipment described cover all aspects of laboratory research, including the design of laboratories, treatment of effluents, protective clothing and handling of animals.

In the section on recombinant DNA molecules, biological containment methods involving the use of strains of viruses and bacteria that have been altered so that they will not survive outside the laboratory, are included. In the section on cells and viruses, viruses known to cause infectious diseases, and those known or thought to be associated with cancer, are classified according to risk on the basis of their infectivity for man, and also for animals, the severity of the disease they cause, and the range of animals they can infect. Various factors, such as the type of cell, culture conditions, and the manipulations involved, are used to assign the various experiments with animal cells in culture to the containment levels described. Three levels of responsibility are described: the prin-

cial researcher, the institution where the work is performed, and the MRC. The chief responsibility lies with the principal investigator.

In its report, the ad hoc committee attempted to relate its proposed standards to those of the US National Institutes of Health and the UK Working Party on the Practice of Genetic Manipulation. "Level A requires no special design features beyond those suitable for a well-designed laboratory," the report said. The level is similar to the NIH's P1, but less stringent than the UK's Category I.

Level B requires a ventilated cabinet and is similar to the NIH P2 and the UK Category I. Level C requires a segregated room or cubicle from which all air is exhausted directly to the outside or is recirculated after passage through a high efficiency particulate air filter. In addition, all air exhausted from protective hoods must be passed through a HEPA filter. This level is more stringent than the NIH P2, less stringent than NIH P3, and similar to UK Category II.

Level D requires a directed airflow through the entire laboratory and

thence directly to the outside. All exhaust air must be filtered through a HEPA filter. This level is similar to NIH P3 but less stringent than UK Category III. Level E requires the addition of an air lock, a Type III biological safety cabinet, an emergency plan and alarm system, and a safety cabinet outside the laboratory area. It is more stringent than NIH P3 and similar to UK Category III.

Finally, Level F calls for an isolation unit geographically separate from other areas. This separation may be by means of a separate building or by a separate air system in a multipurpose building. It is the equivalent of NIH P4 and UK Category IV.

A number of experiments with uncharacterised or partially characterised DNA are forbidden at present:

- The deliberate creation of recombinant DNA expected to make harmful products, such as plant pathogens of increased virulence.
- The deliberate release into the national environment of an organism containing recombinant DNA.
- The use of recombinant DNA to

transfer drug resistance to micro-organisms not known to acquire it naturally, if such transfer could compromise the effective use of the drug in human or veterinary medicine or agriculture.

Other experiments are to be individually assessed by the MRC to determine whether they should be allowed to proceed and, if so, what containments are necessary. These include etiological agents that may pose a special hazard because of particular reasons (that is, that they do not occur in Canada); plants, animals or insects that are either poisonous or whose entry into Canada requires a special permit because of pathogenicity; and all viruses that require containment levels above B.

The report pointed out that guidelines would require periodic review in the light of new information, and that there would still be experiments for which guidelines do not provide explicit containment requirements. For these reasons, the committee proposed that the council set up a standing committee to review the needs and advise the council. □

BRITAIN

Windscale: no escape

No development connected with the Windscale plant operated by British Nuclear Fuels Ltd (BNFL) now escapes national headlines. Chris Sherwell outlines some of the latest problems

WINDSCALE remains in the front line of an increasingly controversial debate over nuclear power in Britain. What encouragement there was last week for BNFL came in the House of Commons, when at the end of a second reading debate on the Nuclear Industry (Finance) Bill a vote was recorded of 196 to 22 in favour. Among other things, the bill provides for an increase from £75 million to £300 million (£500 million by order of parliament) in the limits of the capital which BNFL can raise with government backing.

BNFL is reluctant to place any interpretation on the vote for the bill or on its content, but late last year, when expansion at Windscale came under heavy scrutiny, Mr Con Allday, BNFL's managing director, did draw encouragement from the support which he said the existing guarantees represented.

In the House last week, Mr Anthony Wedgwood Benn, the Secretary of State for Energy, implied that the bill was at least a case of prudent prepara-

tion. Although he was at pains to stress that the authority provided by the bill would not become operative without planning authority for the expansion, he said it was important that the company should be able to keep open with its customers the option of undertaking reprocessing business should that authority be forthcoming.

On both these aspects there have been some further developments recently. It was just before Christmas that Mr Peter Shore, the Secretary of State for the Environment, announced that BNFL's application to build its proposed oxide fuel reprocessing plant would require the sanction of a public inquiry. Mr Shore also indicated that such a procedure would be unlikely in respect of applications for Magnox fuel facilities and for proposed research projects.

BNFL has since submitted a separate application for the latter expansion to Cumbria County Council, but by last week had yet to announce that it proposed to go ahead with the oxide plant application.

On the related matter of the need for BNFL to keep its options open with its customers, the possibility has now emerged that, when it makes its application, BNFL will split it in two, one asking for permission to build the reprocessing plant itself, and the other

seeking permission to construct ponds in which oxide fuel might be stored pending reprocessing. Whether the latter proposal could be sanctioned without an inquiry is not clear, since no one is actually admitting that it is under active consideration. But in the House Mr Benn did manage to give a hint on the matter.

Responding to a question on the building of storage ponds, he said that it was necessary for the company to take discussions to the point of concluding provisional contracts, and that he was having discussions with BNFL "about procedures along these lines". It is thought that this might be a way for BNFL to give additional assurances to the Japanese, at the moment the most important overseas customers. A high level delegation from Japan was in Britain last week for talks with the Departments of Energy and the Environment, with BNFL and with the Cumbria County Council.

Whether the whole issue remains one for the relevant British and Japanese authorities alone, however, is another question. The United States, as supplier of nuclear fuel for stations in Japan and other countries, is in a position to exercise a veto over what happens to spent fuel earmarked for reprocessing.

BNFL are not prepared to comment on this authorisation procedure, which derives from the requirement that any transfer of fissile material of US origin