two drug regulatory reform bills currently under joint consideration in the House of Representatives.

Both bills are intended to speed up the licensing process, one introduced by the Administration, the other drawn up by Senator Edward Kennedy and passed last autumn by the Senate. For example, an arbitration process would be set up for scientific disagreements between the FDA and potential licensees.

Both bills meet the concern of the FDA that, in particular, it should be given greater flexibility in licensing. They propose, for example, that the review procedure should be speeded up for exceptionally important new drugs and that licences should be issued restricting the use of a drug to specified circumstances where general release might be undesirable.

The pharmaceutical companies are, in general, keen on such revisions. Consumer groups are less happy. "Greater licensing flexibility for so-called breakthrough drugs could provide the camel's head under the tent as far as weakening the general protection provided by the drug laws", says Ben Gordon of the Nader-affiliated Health Resources Group.

But the most important factor may prove to be a recent arrival, namely growing congressional enthusiasm for moves to stimulate industrial innovation in the face of declining productivity and increasing foreign competition, Japanese in particular.

The wish to meet this threat may prove the most potent weapon in the regulation reformers' armoury.

David Dickson

Comecon

Links with West

East-West scientific exchange, except at the Academy/Royal Society level, tends to become associated with other, not strictly academic, matters, as no fewer than three events in London during the past fortnight have demonstrated.

The first, a working visit of the Polish Minister of Metallurgy, Franciszek Kaim, resulted in the signing of two contracts between his ministry, on the one hand, and the British Steel Corporation and the British Metallurgical Producers Association respectively on the other. Although these agreements deal mainly with highly specific themes, such as new technologies for producing coke from non-coking coal, and the perennial theme of energy and raw materials saving, Mr Kaim indicated that on the Polish side at least, a great number of institutes and "other organizations which specialize in scientific research" would be involved in working out "ways and means".

At a later stage, Kaim said, there might be joint research between UK and Polish scientists, both in developing new types of steel and in basic metallurgical research.

Environment, too, he stressed, was a subject where there could be "very effective joint cooperation". (This is a sensitive issue for his ministry — only a few days before his visit, workers at the giant Lenin Steel Mills at Nowa Hut had passed a resolution that existing environmental protection measures there were insufficient.)

This was the third such UK-Polish agreement to be signed — one on mining was signed some three years ago, and one on electricity in February 1980. It comes within the framework of the Joint Commission on Trade and Technology (a linkage that arises, at least in part, from the way in which the former UK Ministry of Technology was dismantled). So did the GDR Engineering Week in Britain (2-5 June 1980).

The East Germans, however, are far less happy about the linking of technological exchange with trade, and are constantly pressing for separate international agreements to cover both. Yet for the purpose of the "Week", Dr Gerhard Beil, Secretary of State in the Ministry of Foreign Trade of the GDR, was prepared to waive these demands — the objective, he said, was "to deepen economic, scientific and technological relations".

The mighty instrument firm of VEB Zeiss-Jena makes no distinction of this kind. After a comprehensive lecture on its latest measuring instruments for the metallurgical industry, the Zeiss delegates made it quite clear that there is no distinction between the scientific and industrial instruments produced by Zeiss in the minds of the 4,000 scientists on the staff.

The third event in the past two weeks had, by contrast, little or no commercial application. Bulgaria is at present preparing for next year's celebrations of 1300 years of statehood, and, in the past few years, has been doing some quite remarkable work in molecular biology. As part of the celebrations, therefore, last week, at the Bulgarian Embassy in London, Sir John Kendrew, in recognition of his services to molecular biology, was invested with the Order of the Madara Horseman and, at the same time, made an honorary foreign member of the Bulgarian Academy of Sciences.

Vera Rich

Biotechnology

Canada stirs

Anxious not to be left behind, the Canadian government is setting up an independent working group to tell whether and how it should promote the growth of biotechnology.

The nine members of the working group are to report back within a year to the Minister of State for Science and Technology, Mr John Roberts, who announced the government's decision on Tuesday at a meeting of the Chemical Institute of

Canada.

The chairman of the group is Dr Maurice Brossard, director of research at the Institut Armand Frappier in Laval, Quebec. Of the remaining eight members, three are from universities and five from industry; others, including government scientists, will be involved as consultants. Although one objective of the working group is to assess the potential of Canada to compete directly with other countries in fields such as the biological production of industrial chemicals and health care products, it is hoped that the group will pay special attention to Canada's characteristic resources and needs — in fields such as energy, mining, food, agriculture and forestry.

Accompanying Mr Roberts's announcement was the publication of a background paper prepared by Dr Louis Slotin, secretary of the committee, listing current Canadian research efforts in biotechnology, broadly defined to include genetic and cellular manipulation, enzyme technology and fermentation techniques.

The report reveals a moderate amount of effort, with total support amounting to about several million dollars a year. But it tends to be thinly spread. The 100 university research workers listed, for example, are distributed among 22 universities; and of the 33 companies indicating an interest in biotechnology research, only ten have more than one or two research workers involved.

To a certain extent Canada makes up in quality what it lacks in quantity. Scientists in the National Research Council's Division of Biological Sciences, for example, are acknowledged to be among the world's leaders in the study of the insulin gene; and several prominent Canadian biologists are already employed as advisers and consultants to US-based biotechnology companies.

The most serious difficulty ahead is a familiar one for Canada — how can an industrial sector largely dominated by foreign-based companies — often with their main research facilities in the United States or elsewhere — be encouraged to support research in Canada and to use what is already being done? There is also a gulf between university research and its potential applications. No Canadian university has a department of applied microbiology, while microbiological research is carried out almost exclusively in medical schools.

A broader issue for the working party will be that of government policy on innovation and whether it should provide direct support for broad-based industrial initiatives — as recommended in Britain's Spinks Report — or instead to follow US strategy with tax incentives and the like.

The inclination of both scientists and industrialists is towards less rather than more government involvement but with a different industrial structure and a smaller supply of individuals prepared to make

high-risk investments, some judicious mixture of private and public involvement seems the most likely recommendation.

David Dickson

Radiation limits

EEC rules soon

A new and legally binding directive on radiation protection for those occupationally at risk, based on recommendations which have provoked controversy in the United States, may be adopted by the European Community within two months. But in contrast to the situation in the United States (*Nature*, 5 June, p350), opposition to the proposed directive has been sporadic and individual.

The European Community has been preparing for a uniform treatment of radiation

safety for several years. In 1976, the Community adopted a comprehensive directive on the subject which was to have come into force in 1978. But a publication of the independent International Commission on Radiation Protection (ICRP 26) caused the Community to have second thoughts.

ICRP 26 recommended a thorough revision of the principles on which radiation exposure should be limited; and the more recent ICRP 30 has derived from these principles the limits on intake of radionuclides implied by ICRP 26 in the light of up to date information on the uptake, retention and effects of radionuclides on the body. The new recommendations differ from those earlier in force by allowing for the risk from an ingested nuclide to all the organs of the body, not simply to the "critical" organs primarily at risk.

The proposed EEC directive takes the views of ICRP into account, and according to an EEC official "differs only in minor detail" from the recommendations of ICRP 26. It would become binding on member states 30 months after adoption.

One feature of the calculations of ICRP 30 is that some of the recommended limits on the rate of ingestion of particular radioactive nuclides are changed by large factors of up to 300; some limits would be more stringent, others less stringent. The US Nuclear Regulatory Commission has argued that it would be impolitic to adopt less stringent limits.

However, the chairman of the committee that prepared ICRP 30 (and its principal author), Dr Jack Vennart of the MRC Radiobiology Unit, Harwell, UK, says that it was incumbent on ICRP to take full account of up to date scientific data and of recent understanding of the physiology and metabolism of radionuclides.

In the case of airborne tritium, for example, it was now recognised that its beta emission was of too low an energy to penetrate to the epithelial tissue of the lung (the most susceptible tissue to cancer). This and other factors resulted in the recommended permitted airborne concentration rising to 2×10^{10} Bq m⁻³. By contrast, the recommended limits on tritiated water are more stringent because of the likelihood that it will quickly distribute itself throughout the body (whereas tritium gas is poorly absorbed). The ICRP 30 limit on gaseous tritiated water is thus 8×10^5 Bq m⁻³.

Vennart also points out that it is not ICRP's role to set regulations; that is the business of the relevant national and international legislative bodies. ICRP in fact indicates what seems scientifically the case, and then recommends that levels be set "as low as reasonably achievable, economic and social factors being taken into account". So ICRP is strictly not recommending legislated rises in any exposure level. Vennart believes it unfortunate that "politicians simply adopt the figures wholesale".

Individual criticisms of the ICRP documents in the UK have centred mainly on ICRP 26, which sets radiation — rather than radionuclide — dose levels. Professor Joseph Rotblat, emeritus professor at St Bartholomew's Medical School, for example, says that the dose limit of 5 rems per year recommended in ICRP 26 implies that 2-3 per cent of workers would die of radiation-induced cancer if they worked continuously at that limit, on the basis of the ICRP's own figures.

Rotblat also considers that there may be frequent misuse of the concept of "dose equivalent", which sums up weighted contributions from different organs (see below). In practice, exposure will be assumed to be largely in one organ, he believes, although it may be in more; and if that organ has a low weight in the ICRP 26 scheme, unknown and dangerous high

ICRP standards derived

Dose equivalent in ICRP 26 is defined as follows. First, the absorbed dose after exposure to ionising radiation is given by the energy per unit mass deposited by the radiation in the tissue. It is measured in J kg⁻¹, called Grays (Gy). (In the old units, 1 Gy = 100 rad.) Because some particles are more potent than others in causing biological effects, the absorbed dose of a given radiation is multiplied by a quality factor — a function of the particle type and energy — to yield the dose equivalent. This is measured in Sieverts (in old units 1 Sv = 100 rem).

The dose equivalent limit in ICRP 26 is then defined as a weighted sum of dose equivalents over 5 'organs' of the body (gonads, breast, red bone marrow, lung, thyroid, bone surfaces and 'the remainder'), the weights taking into account the different sensitivities of these organs to given dose equivalents. (For example, for a given dose equivalent to the tissue, the breast is estimated to be five times more likely to become cancerous than the bone surfaces, so it gets a weight five times higher). The sum must be less than 0.95 Sv; and individual tissue doses must not exceed 0.5 Sv.

The limit to the sum (0.05 Sv) is chosen to control 'stochastic effects': in other words the probability of contracting cancer. Assuming all cancers are fatal, and that an average worker in the nuclear industry would receive one-tenth of the dose equivalent limit, the limit is set to produce a probability of death about the same as is already tolerated in other 'safe' industries (about 3 per thousand for a 30-year lifetime). ICRP 26 says that "long-continued exposure of a considerable proportion of the workers at or near the dose-equivalent limits would be only acceptable if a careful cost-benefit analysis had shown that the higher resultant risk would be justified".

The limit to individual tissue exposure

(0.5 Sv, except the eye, whose limit is 0.3 Sv) is designed to eliminate 'non-stochastic effects': cumulative radiation damage which is not lethal and is undetectable below some threshold. (Cataract of the cornea and hair loss are examples.)

ICRP 30 then applies these limits to various radionuclides, taking into account (to a much greater extent than ICRP 26) their chemical form, and transmissibility from gut to bloodstream and from lung to bloodstream (which depends on particle size).

This results in an 'annual limit of intake' (ALI) which is the intake that would cause the dose equivalent limit of radiation to be reached; and the 'derived air concentration' (DAC) which is the concentration which, breathed each week for 40 hours, leads to the absorption of the ALI.

Comparisons of ICRP 30 with ICRP 26 are not direct, because the isotopes are divided into chemical classes in different ways (ICRP 26 distinguishes only 'soluble' and 'insoluble' for example) and ICRP 26 considers limits for each organ separately. However, its DACs derived from ICRP for soluble and insoluble compounds of an isotope can be compared.

Here are a few examples in Bq m⁻³. (1 Becquerel = 1 s⁻¹ = 2.7 × 10⁻¹¹ Ci.) In some cases only one value is quoted.

Radionuclide	DAC, ICRP 2	DAC, ICRP 30
³ H as ³ H ₂ O	2 × 10 ⁵	8 × 10 ⁵
³ H as ³ H ₂	8 × 10 ⁷	2 × 10 ¹⁰
⁶⁰ Co	360-12,000	50-3,000
⁹⁰ Sr	12-200	60-300
¹³¹ I	360-12,000	700
¹³⁷ Cs	400-2,400	2,000
²²⁶ Ra	1.2-8,000	10
²³⁹ Pu	0.08-0.16	0.09-0.3

Some of these figures make ICRP 26 more stringent, some ICRP 30.

Robert Walgate