Risk assessment by numbers

Washington

Is comparative risk assessment an idea whose time has come? Or a political attempt to short-circuit necessarily complex sets of rule-making procedures?

The answer seems to be a bit of each. Professional scientific organisations such as the American Chemical Society are now pushing for comparative risk assessment as a way of rationalising government controls on technological activity, and Congress, responding to industry's demands to lighten the burden of controls, is looking at the type of legislative backing needed to increase its role in the regulatory apparatus.

Congressman Jim Ritter of Pennsylvania, for example, has introduced a Bill that would require the Office of Science and Technology Policy to set up a government-wide mechanism for assessing the comparative risks involved in actions in "scientific, technological and related fields".

The Carter Administration is reluctant to enforce centralised risk assessment as a federal policy. But individual agencies are already giving it increasing prominence within their administrative procedures, accepting that the absolute standards of zero-risk, popular with law-makers in the mid-1970s, may be neither practicable nor scientifically sound.

The push for comparative risk assessment is part of a general drive to restructure the regulatory process by separating the scientific judgment of whether a substance or process poses a health hazard from the administrative judgement of how this hazard, once characterised, should be dealt with.

Not all agree that such a separation is desirable. "The location of a centralised entity for performing comparative risk assessment within OSTP undermines the basic consideration that risk management decisions are social policy decisions which are based only partly on hard science", Dr Nicholas Ashford of the Massachusetts Institute of Technology told the House Science and Technology Committee two weeks ago.

Others, however, including the powerful National Association of Manufacturers, see it as an essential step towards rational regulation. "Before a regulator is faced with deciding how much the public needs to be protected from a substance, he or she should be supplied with an objective assessment of the degree of risk which the substance provides", Dr William J McCarville, Director of Environmental Affairs for Monsanto, told the same committee.

Prompted by such concerns, William Wampler, senior Republican member of the House Agriculture Committee, has introduced another Bill to set up a National

Science Council. This would also operate under the auspices of OSTP, and would be responsible for deciding questions of scientific fact arising from debates on the potential harmfulness of substances involved in food production, decisions which would be binding on all federal agencies.

A similar proposal is being canvassed by the American Industrial Health Council, a body of over 100 chemical companies and trade associations, which wants the National Academy of Sciences to set up a panel of eminent scientists to evaluate the qualitative and quantitative aspects of human chronic health risks associated with all forms of industrial activity.

Neither proposal has yet provoked much enthusiasm within the Administration. But on the question of comparative risk assessment, there is a greater consensus that this should play a more prominent role in decision-making — although reluctance to impose it in a too heavy-handed way, stressing instead the need to build up the research capabilities of the regulatory agencies.

OSTP officials point out that several moves have already been taken in this direction. Two years ago, for example, in issuing an executive order on regulatory reform, President Carter directed that analyses of the costs and benefits of proposed regulation should be prepared before the regulation was introduced.

Furthermore, procedures for standardising the scientific evaluation of hazards across the federal government are being developed by the Interagency Regulatory Liaison Group which has already produced a uniform regulatory policy on carcinogens.

But there remains the problem that different agencies have had their legislative mandates written at different times and in different circumstances, giving rise to what OSTP Acting Associate Director Denis Prager describes as a "crucial and necessary" pattern of diversity and pluralism in dealing with technological risks.

The US Department of Agriculture, for example, must observe meat and poultry inspection acts which state unambiguously that no substance, whatever its benefits, may be added to either food if it poses any risk to human health.

Similarly, the Occupational Safety and Health Administration has no legal requirement to take factors other than the safety of workers into account in devising exposure levels to toxic substances (although this could change as the result of an imminent Supreme Court ruling on whether cost-benefit calculations should be taken into account).

Perhaps the greatest push for comparative risk assessment has come in the nuclear field, and in particular over

arguments that base their support for nuclear power on a direct comparison with the health and environmental risks from other energy sources.

At the Environmental Protection Agency, however, which perhaps more than any other agency has had to develop different risk assessment procedures for different types of hazards, there is doubt that comparative risk analysis can be tuned sufficiently finely to meet the needs of specific regulatory situations.

"A comparison of risks within a particular regulatory context may be a useful decision-making tool, and we at EPA are ready to use it as such", Dr Richard Dowd, Chairman of the Agency's Science Advisory board, told the Congressional committee, "but I question how useful it is to go beyond the context of one statute to several statutes, or from one risk situation to a different risk situation."

David Dickson

Research animals

Two bills too many

REGULATIONS to control the use of animals in scientific experiments in Britain are likely to change within the next year or two. Before it took office in April last year, the Conservative Party pledged itself to update the existing legislation, based on the Cruelty to Animals Act of 1876. At the end of last year, Mr Timothy Raison, Minister of State at the Home Office, reaffirmed that intention when he said that the government would like to base the new legislation on the European Convention on laboratory animals, now being drawn up in Strasbourg.

Home Office officials estimate that the European Convention will not be ready until April, 1981. This means that the new UK legislation proposed by the government could not be introduced until the middle of next year at the earliest. Not everyone is prepared to wait that long. Two individual members of parliament — Lord Halsbury and Mr Peter Fry — have prepared their own bills for consideration by the Houses of Lords and Commons respectively. Debates on both bills have been proceeding throughout this session of Parliament.

Lord Halsbury's bill is further than Mr Fry's in the parliamentary process. It received its second reading last October and has just been through several months of scrutiny by a House of Lords select committee. An amended version of the bill, based on the select committee's recommendations, was published last week.

Mr Fry's bill is currently embroiled in debate in a House of Commons standing committee. The committee has so far amended the first six and three quarters of the bill's 38 clauses. At the current rate of amendment the committee will be sitting until August 1982.

Parliamentary procedure, however, will not allow Mr Fry's bill to last that long. It was introduced as a private member's bill and, as such, has to be passed into legislation this session if at all. If it fails to complete the course by late summer, it will have to go back to compete with other private members' bills in the ballot box for the next session.

The Halsbury Bill seems the more likely of the two to survive the parliamentary hurdles. It is also more likely to have the support of the scientific community because it does not advocate prior judgement of the value of scientific research with animals. Its amended form acknowledges and builds on the Protection of Animals Act 1911 but would repeal the Cruelty to Animals Act 1876. The 1911 Act prohibits general cruelty to animals, such as kicking, beating or over-working, and deals specifically with laboratory animals.

In re-drafting Lord Halsbury's Bill, the House of Lords select committee has also produced a report summarising the evidence it has taken and the need for new legislation. The report, which was made available to *Nature* last week, but is not yet publicly available, says that new legislation is needed because of the great increase in the number of animals used in laboratories over the past century and the greater variety of procedures, not in practice in 1876, to which they may be subject.

Lord Halsbury's Bill follows the 1876 Act in requiring all experimenters with animals to obtain a licence from the Home Office. However, it differs in demanding greater specification by those applying for a licence of the number and type of animals to be used and the procedures to be done on them. Applicants for licences would also be required to state the degree of pain or suffering likely to be experienced by the animal and the measures that would be taken for relieving it.

Lord Halsbury's Bill also incorporates the 'pain' and 'anaesthesia' conditions. These are that an animal that appears to be suffering severely under any procedure must be given immediate relief or be humanely killed, and that animals undergoing procedures which may be expected to cause severe pain or suffering must be properly anaesthetised before the procedure starts, be relieved of any pain afterwards or killed humanely. If this is not feasible it should be humanely killed. The 'pain' and 'anaesthesia' conditions are not written into the 1876 Act, though they have been effectively enforced by the Home Office cruelty to animals inspectorate.

Other points of difference between the 1876 Act and the Halsbury bill concern

- the nature of the sponsors. Both require applicants for licences to have two sponsors; the 1876 Act says that one must be a professor of biology, the other a president of a learned biological society; the Halsbury Bill says that the two sponsors must be chosen from a panel nominated by the Secretary of State.

- the term of licences. The Act allows licences to run indefinitely, the Halsbury Bill for only five years.

- the constitution of an advisory committee. The 1876 Act does not provide for an advisory committee on laboratory animals, although one has been in operation since 1906. The Halsbury Bill would incorporate the advisory committee in the legislation and would give it greater powers than at present. For example, the committee would be required to monitor the extent to which animals are used in painful or stressful procedures, review the possibility of alternatives, and inform the Secretary of State on public opinion. It would also have to consider ethical matters.

- the function of a code of practice. One does exist, although it is not written into the 1876 Act. The Halsbury Bill would incorporate it, increase its status to the equivalent of the highway code in Britain. Although infringement of the code would not constitute an offence in itself, it could be used as evidence against someone suspected of malpractice.

- batch testing of sera and vaccines. This is not included under the 1876 Act but would be under the Halsbury Bill. Under this provision, the number of procedures notified to the Home Office and the number of licences would increase considerably. Although the idea behind the Halsbury Bill is to include procedures not covered at present, most survey, field, and school work would be exempt. For example, simple injecting of animals or ringing birds would not be included.

- species of animals covered. The 1876 Act covers all vertebrates; the Halsbury Bill would extend protection to chordates and embryos or larvae capable of independent existence.

The Halsbury Bill is also broader in scope than the existing legislation. But it does not specify detail, preferring to leave that to the secretary of state. For example, he would be able to extend the bill to include other species if he chose. He would also appoint the advisory committee.

The amended Halsbury Bill will go to a committee of the whole House of Lords on 20 June. Once it has been through the report stage, it can be presented to the Commons but it is unlikely that the Commons will consider it before next session. It could then be thrown back at the Lords. Although some believe that new legislation could be passed this year, others believe that the government is likely to stick to its plan of seeing the European Convention first.

Judy Redfearn

X-rays

Selling a new source

THE European Science Foundation — normally a quiet body conducting its catalytic business behind the closed doors of committee rooms — is supporting a proposal that Europe should spend £55 million on a new, 5 GeV super-bright European Synchrotron Radiation Source (ESRS). Last week at Daresbury, UK, it tried to convince the British synchrotron users that it was right. The result was cautious approval.

Britons are probably the hardest to convince of the case. Their own dedicated source, the SRS, will start producing data at Daresbury later this year, and it will be well ahead of other European sources (see figure). Moreover their purse-holder, the Science Research Council, is committed to other large accelerator projects (the Nuclear Structure Facility at Daresbury and the Spallation Neutron Source at the Rutherford Laboratory) up to 1984. And the cash available to run the SRS will only be enough to operate half its beam ports.

The challenge, though, comes from the US. The £12 million National Synchrotron Light Source — a two-stage source under construction at Brookhaven Laboratory, Long Island — will come on line in July 1981 (0.7 GeV) and October 1981 (2.5 GeV). The second stage should exceed the brilliance of the 2 GeV, £5 millions SRS by a factor of ten — giving the SRS just a year as world leader.

So Yves Farge, chairman of the ESF *ad hoc* committee on synchrotron radiation and director of the DCI synchrotron radiation laboratory at Orsay, France, argued last week that Europe will need a more advanced source if it is not to be in the second league. Pressure is also high from countries without access to a national synchrotron source — particularly the Scandinavians, Belgium and The Netherlands — for a European facility to be built.

According to Farge, the Scandinavians — will make the construction of the ESRF a condition of their acceptance of LEP, the next high energy physics accelerator contemplated by the European centre for nuclear research (CERN). The Scandinavian view, says Farge, is that the ESRF should be constructed in the tunnel vacated when the CERN intersecting storage rings (ISR) are shut down as a preliminary to LEP.

Farge is unhappy about that approach, however. There are no biologists at CERN, and one of the attractions of synchrotron radiation is that it is a general tool of structural analysis useful to most disciplines. Biologists, however, would feel isolated at CERN. It would be better, he