OSHA defends leap in carcinogen regulation

David Dickson describes a debate over US proposals for dealing with workplace carcinogens

IT WAS not quite the sell-out that had been predicted. Indeed the polite sparring that characterised the first day of public hearings in Washington last week on the US administration's new proposals for regulating occupational carcinogen was rather an anti-climax.

Yet the presence of ranks of lawyers alone was enough to indicate the wide potential impact—both national and international—of the proposals that have been put forward by the Department of Labor's Occupational Safety and Health Administration (OSHA).

For they are likely to provide the basis for dealing with known or suspected carcinogens across the complete spectrum of government agencies, including the Food and Drug Administration and the Environmental Protection Agency. The chemical industry claims that, as presently conceived, the proposals would add billions of dollars to the costs of production.

What OSHA is proposing is, in

effect, a quantum leap in the way that workplace carcinogens are identified, classified and regulated. At present this is done on a case-by-case basis, a thorough but laborious process which partly explains why, in its seven years of existence, OSHA has only developed regulations covering 20 of 1,500–2,000 suspected carcinogens.

Under the new proposals, all chemicals shown, under defined conditions, to cause cancer in experimental animals will be classified as carcinogenic. And the steps required to protect workers will be based not on any risk assessment or cost/benefit analysis, but on an assessment of what protective measures are felt to be economically and technically feasible.

The new proposals have been widely welcomed by many members of the scientific community—as well as trade unions and environmentalist groups—as an appropriate response to the current lack of precise knowledge

about the mechanisms or carcinogenicity, and to increasing evidence of the dangers of low levels of exposure which were previously considered safe.

Dr Arthur Upton, director of the National Cancer Institute and one of the scientific witnesses OSHA has asked to provide evidence at the public hearing, said last week that he believed the proposal "has a sound scientific basis and represents a prudent and justifiable approach to the identification and classification of chemical carcinogens". However, the proposals are being strongly contested by private industry, concerned at their potential economic impact.

Industry's attack is being spearheaded by the American Industrial Health Council, an ad hoc group established after the new proposals were announced by Labour Secretary Mr Ray Marshall last autumn. The AIHC now includes among its member 90 companies and 60 national trade associations, and is reputed to have raised over \$1 million to dispute OSHA's proposals. It has asked for

A summary of the proposals

All toxic substances shall be classified and subsequently regulated by the Secretary for Labor as follows:

Classification

Category I: All toxic substances that meet the definition of "potential occupational carcinogen"* in (i) humans, or (ii) two mammalian test species, or (iii) a single mammalian species, if those results have been replicated in the same species in another experiment, or (iv) a single mammalian species if those results are supported by short-term tests. Also any substance for which the Secretary considers there is sufficient evidence to classify as Category I.

Category II: Any substance defined as a "potential occupational carcinogen" in tests on animals or humans, but for which the evidence is considered only "suggestive". Also, any substance that meets such a definition in an unreplicated experiment in a single test species, and any other substance for which the Secretary considers there is sufficient evidence to classify as Category II.

Category III: Any toxic substance which is used in the US workplace, but which is not classified in Category I or Category II.

Category IV: Foreign toxic substances, ie, those not found in the US workplace.

Regulation

On classifying a substance as Category I, the Secretary shall immediately issue an Emergency Temporary Standard containing provisional exposure limits. Within 60 days, he or she shall issue a notice of proposed rule-making in order to establish permanent permissible exposure limits. These limits shall be set as low as feasible, and if suitable substitute materials are available, no occupational exposure shall be allowed.

Within 60 days of such classification, the Secretary shall issue a notice of proposed rule-making for permissible exposure limits. These would be (i) present OSHA standards, or (ii) where none exists, an appropriate level based on acute or chronic effects of exposure to the toxic substance other than carcinogenicity, or (iii) lower exposure levels if these are felt necessary. Further research would be stimulated to obtain additional data.

No exposure limits would be suggested, but information would be requested on whether substances should be considered for inclusion in Categories I or II.

No exposure limits would be suggested, unless information was subsequently received that the substance was used in the US workplace.

*"Potential occupational carcinogen" means any toxic substance which (1) causes, at any level of exposure or dose, as a result of any oral, respiratory or dermal exposure, or any other exposure which results in the systemic distribution of the substance under consideration in the organism tested, an increased incidence of benign or malignant neoplasms, or a combination thereof, in (i) humans, or (ii) in one or more experimental mammalian species, or (2) in a statistically significant manner decreases the latency period between exposure and onset of neoplasm in (i) humans or (ii) in one or more experimental mammalian species.

almost 20 hours to present evidence at the hearings and is bringing a number of scientists from Europe.

OSHA, emphasising the uncertainty that surrounds the interpretation of current scientific findings about carcinogenicity, has stated that, for the purposes of policy, it is basing its proposals on a number of propositions. The basic philosophy—a philosophy close to the heart of OSHA's director Dr Eula Bingham, until last year year professor of environmental health at the University of Cincinnati Medical School—is that where uncertainty exists, the prime concern is to protect the health of the worker.

Thus the administration claims that, given the lack of any conclusive evidence for a "threshold" below which carcinogenic effects can be ignored, any attempt at precise risk assessment at low level is unlikely to produce reliable results. It is therefore suggesting that exposure levels should be reduced "as low as feasible".

Similarly, OSHA states that because of the difficulties and limitations of human epidemiological studies—and the moral arguments against waiting for demonstrable proof of carcinogenicity from these studies—in general "as a practical rather than a theoretical matter, positive animal data should supersede negative human data".

Concerning the interpretation of evidence that a substance may cause only benign, rather than malignant, tumours, OSHA again comes down on the side of caution. It proposes "to place as much weight on an experiment in which only benign tumours are observed, as upon experiments in which both are induced."

In contrast to this approach, industry is arguing that the only "rational" basis for regulation should be firmly established scientific knowledge, which would include quantifiable parameters such as the relative potency of different carcinogens, and that such knowledge is a pre-requisite for regulation. Thus the lack of evidence for a threshold is interpreted as lack of evidence that no threshold exists, casting doubts on any regulatory principle based on the latter hypothesis. "No-effect levels have been repeatedly demonstrated for carcinogens in animals and man", claims Dr Hoerger of Dow Chemicals, chairman of AIHC's scientific committee.

And in questioning OSHA's proposal to give greater weighting to animal than human studies, the AIHC says that "since human epidemiological data are free from the uncertainties of extrapolation from animal tests, it seems quite unscientific not to use the data when available".

There are similar differences of approach over short-term tests, such as those for mutagenicity developed by

US firms accused of exporting health hazards

INCREASINGLY stringent control of hazardous production processes appears to be leading US companies to switch the work to countries with lower safety standards, particularly in the Third World.

In a number of industries, the banning of certain processes in the US has been followed by a significant increase in the import of materials made by these processes (in the case of benzidine dyes, for example, principally from Romania, Poland, India and France). And in other industries, American companies are shifting their own facilities elsewhere.

Some of the more dramatic examples of 'hazard export' have come from the asbestos industry. At least one study of the effects of lowering exposure levels to US workers has concluded that this is economically feasible provided that some of the more hazardous operations are conducted outside the US.

The import of asbestos textiles, for example, has risen dramatically in recent years from countries such as Mexico, Taiwan and Brazil as home

producers have experienced the need to meet lower levels of exposure.

Many of the production facilities are American-owned (although Japan owns plants in Taiwan and South Korea). And although most asbestos companies are careful to maintain the same safety standards at home and abroad, this is not always achieved.

Last year, for example, an environmental health scientist from Washington State University, Dr William M. Johnson, reported having found large quantities of loose asbestos both inside and outside a textile plant that had been opened by a large American-owned asbestos company in the Mexican border town of Agua Prieta in 1969.

Following the publicity surrounding his report, workers have been required to wear uniforms to cover street clothes, and the outside of the factory has been regularly cleaned. However, on revisiting the plant Dr Johnson claimed that the effects were mainly "cosmetic", and that the ground outside the factory on which children frequently played, for example, was still composed of 20% asbestos (see picture left).

Such situations are causing considerable concern to officials of the Occupational Safety and Health Administration (OSHA). "Cancer knows no national boundaries," says Dr Joseph Wagoner, head of carcinogens at OSHA.

US officials are uncertain about how to proceed. Working conditions outside the US are beyond the direct control of Washington; and many countries openly express a willingness to accept new jobs—however hazardous—because of unemployment problems.

David Dickson

Photographs taken by Dr Johnson outside Amatex asbestos textile plant, Agua Prieta, Mexico. March 1977.

Dr Bruce Ames of the University of California. Here the uncertainty arises from the fact that, although the correlation between the mutagenicity and the carcinogenicity of a substance is close, it is far from perfect.

OSHA, accepting this uncertainty as the grounds for suggesting that such tests should not be used as a sole basis for identifying carcinogenic potential, nevertheless feels they are sufficiently reliable to corroborate evidence of carcinogenicity gained from one animal test. Industry interprets this uncertainty in the opposite direction. Accepting that short-term tests have values as screening tools and as guides for more complete tests and studies, the AIHC adds that "the results of such tests are so unreliable as predictors of human response as to be

unsuitable as a basis for regulatory decisions".

Much of the public hearing which started last week, and will continue until the middle of July, is expected to hinge on such differences of interpretation of evidence in areas of scientific uncertainty. But in practice, although minor changes may be made to the details of OSHA's proposals, few expect any major shift in philosophy.

The real test, however, is likely to come later in the courts, where the issues will be determined not so much on scientific as on procedural ground. OSHA has already experienced difficulty here. Current moves to regulate benzene, for example, have come under heavy legal fire. The carcinogen proposals are one pudding whose proof will be the eating. □