

Watershed for poisons

Colin Norman reports from Washington on US efforts to legislate on the controversial matter of toxic substances

A FEW years ago, a group of industrial chemicals called polychlorinated biphenyls (PCBs) were enjoying spectacular commercial success, finding their way into a vast assortment of products ranging from electrical transformers to copying paper and food packaging. In fact, PCBs are so ubiquitous, and so indestructible, that virtually everybody living in an industrialised country now has detectable levels of the chemicals in his or her tissue. They are even turning up in human breast milk, they are present in the flesh of fish from many lakes and rivers, and they have been found in the bodies of animals from such remote places as Greenland. A number of studies have shown that, when fed in relatively large amounts to animals, they may cause cancer, reproductive disorders, metabolic abnormalities, hair loss, skin eruptions, and other health problems.

Use of these versatile substances has now been curtailed in the United States. After five years of trying, the US Congress has finally passed landmark legislation requiring many manufactured chemicals to be screened and tested for toxic effects before being marketed. The grim saga of how PCBs became widespread environmental contaminants long before their health hazards were fully known is, unfortunately, far from unique. Other well-known cases include vinyl chloride, asbestos, bis(chloromethyl) ether, carbon tetrachloride and so on. And, though such occurrences are far from new (one novel theory even suggests that the decline of the Roman Empire may have been caused, in part, by lead poisoning from cooking utensils and wine vessels), they seem to be growing more numerous.

It is not surprising that there are such frequent outbreaks of panic about the toxic effects of widely used chemicals. Civilised man is surrounded by thousands of synthetic chemicals, few of which have been screened for toxic effects, and even fewer have been exhaustively tested. According to an estimate published last year by the Manufacturing Chemists' Association, for example, some 6,500 new chemical products reach the market each year. Yet only about 3,000 chemicals have even been tested for cancer-causing properties, in spite of widely accepted estimates that between 60 and 90% of human cancer is caused by environmental factors.

In short, until now, chemicals have generally been accorded the same legal rights as people—they are assumed innocent until proven guilty. But last week, after years of argument, Congress took a significant step toward writing a new bill of rights for manufactured chemicals. It passed legislation, known as the Toxic Substances Control Act, which gives the Environmental Protection Agency (EPA) broad authority to require pre-market testing of some compounds, and the power to seek a court order to keep potentially hazardous chemicals off the market.

The bill is a landmark piece of legislation for which environmentalists, some trades unions and health scientists have long fought. For the first time, it gives the federal government the power, in theory, to keep an eye on all manufactured chemicals, and it provides at least a coarse filter to screen out potentially troublesome compounds before they do much damage. In the colourful words of Senator Warren Magnuson, a key supporter of the bill, it will "no longer allow the public or the environment to be used as a testing ground for the safety of these products".

Five years of effort

It took five years of intense argument in Congressional committee rooms and behind the scenes to get any toxic substances legislation passed at all. The bill's genesis was a 1971 report by the Council on Environmental Quality, which noted that although some classes of chemicals (such as pesticides, drugs and food additives) are regulated by individual laws, there is no federal authority to control the thousands of other compounds which flood the market each year. A year later, the Senate and the House both passed toxic substances bills, but they were markedly different, and intense lobbying by industry and by the Nixon Administration prevented a final version being passed. The same thing happened in 1973 and 1974, and until very recently it looked as though Congress would again fail to reach agreement on the legislation. The deadlock was broken during what one participant described last week as "three intense bargaining sessions" between Senators and House members.

What emerged was consequently very much a compromise measure, a fact which is reflected in comments last week from spokesmen for groups on

both sides of the fence. "We support the bill as a workable compromise", says Linda Billings, a Sierra Club lobbyist who has been following the legislation throughout its tortuous journey through Congress. She noted, however, that it contains a number of weaknesses and loopholes which will keep many corporate lawyers busy. Similarly, a spokesman for the Manufacturing Chemists' Association (MCA), the industry's lobbying arm, said that the bill, "while tough", is acceptable to the industry. He added, though, "I wouldn't say that we are real happy with everything that's in the bill". Spokesmen for some trades union organisations have also expressed satisfaction that a bill has finally been passed.

One lingering doubt, however, is whether or not President Ford finds the bill to his liking. Throughout the Congressional fight on the legislation, the Administration has lobbied against the measure, arguing that it would be expensive and would constitute too much government regulation of private industry (a theme frequently sounded in Ford's campaign rhetoric). But, since the bill now has broad support, and since a Presidential veto would give Jimmy Carter a gilt-edged campaign issue to exploit, Ford is expected to sign the legislation.

A key feature of the bill—which Ms Billings describes as a "watershed"—is a requirement that EPA must be informed at least 90 days before any new chemical compound is placed on the market, or an existing compound is sold for a new use. (The bill specifically exempts chemicals produced in small amounts for research purposes, it should be noted.) The manufacturer must also send along whatever information he has on the toxicity of the compound, the amount to be manufactured, the likely human exposure, and so on.

Then, if the EPA Administrator decides that the compound is likely to pose a hazard to the environment or to human health, or if he finds that there is insufficient information to judge the hazards, he can issue an order restricting or banning sale of the compound, at least until the required test data is available.

Sticking point

The EPA Administrator is clearly given very flexible authority to determine which compounds should be exhaustively tested, and which should be let through the filter. That aspect of the bill has been the chief sticking point which has held up final agreement in Congress for the past five years. The deadlock was broken by writing into the bill a provision requiring that the Administrator's decisions

must be reviewed by the courts if a manufacturer feels he has been unfairly treated. In short, if a manufacturer objects to an EPA ruling, the agency must seek a court injunction to put the ruling into effect. If EPA doesn't go to court, the ruling would be nullified.

Although that provision may seem like a huge loophole through which smart corporate lawyers can emasculate the legislation, many observers feel that in fact it will be relatively easy for the EPA to obtain an injunction. All that would be required, according to the bill, is a showing that the compound "may present an unreasonable risk of injury to health or the environment", or that it "may reasonably be anticipated to enter the environment in substantial quantities", or that there has been insufficient testing for the hazards to be "reasonably determined or predicted".

Thus, the wording is so general that EPA should have a fairly easy time in proving its case, a fact which made the provision acceptable to environmentalists. "We don't like it", Ms Billings said last week, "but we recognise that it is the best we could get". Similarly, the chemical industry sees some merit in the provision. James Hanes, chief counsel for Dow Chemicals, who has been one of the most outspoken opponents of the bill, told *Nature* that the idea "at least gives the industry the chance to contest the decision out in the open", though he noted that "I don't really see the courts requiring an overwhelming burden of proof here".

If EPA obtains its injunction, it can then specify what tests it requires, and the industry would then be in the position of having to prove that a product is safe before placing it on the market.

Priorities committee

As far as existing chemicals are concerned, the bill requires the setting up of an inter-agency committee charged with the task of drawing up a list of chemicals whose toxicity is open to

question. The committee will assign priorities to chemicals and, within 12 months, the EPA Administrator is required either to issue orders for testing the top 50 compounds, or to explain why he feels testing isn't necessary.

The bill will clearly place a huge burden on EPA, which is required to go through masses of data on thousands of chemicals, decide which need testing and which should be allowed on the market, go to court to obtain injunctions, and exercise considerable judgment on what actions are necessary. Therein lies the bill's greatest potential weakness, according to many observers.

To carry out this Act, the bill authorises expenditures of only \$10 million this year, rising to \$12.6 million next year and \$16 million the year after. Those figures should be compared with the \$125 million which EPA was budgeted to enforce the Clean Air Act, or the \$200 million a year budget of the Food and Drug Administration. It is difficult to see how EPA can effectively enforce the Toxic Substances Act with such small resources, and some observers have suggested that the upshot will be that EPA will be forced to concentrate on a few chemicals and allow many to slip through the net.

Monetary matters have also been a major source of concern to the chemical industry throughout the long Congressional fight over the bill, though for different reasons. There have been numerous studies of what the bill may cost the industry in terms of testing facilities, legal costs and administrative requirements. Large-scale animal tests are very expensive to conduct—according to estimates given in testimony before a House committee by officials from DuPont, for example, a complete battery of tests can cost up to \$500,000. Such figures have thus led to arguments that the bill will stifle the development of important chemicals which may only have a short production run. Some of that concern

has, however, been reduced by the provision exempting research chemicals from the bill.

Assessing the cost

As for the total impact of the bill on the industry, Dow Chemicals has so far come up with the highest figure, estimating that the legislation will cost chemical manufacturers up to \$2,000 million a year. The MCA thought that the cost would probably lie between \$360 million and \$1,300 million, while EPA suggested that it would only be about \$80–140 million.

Whatever the cost may turn out to be, it will be relatively small compared with the massive total sales volume of the industry, or with the costs of treating cancers and other diseases related to environmental factors. The large cost of animal tests, moreover, should provide a strong incentive for industry to develop accurate, short-term *in vitro* tests, such as the system developed by Dr Bruce Ames at the University of California. Already, many large firms are looking closely at such systems, and are using them as rapid screening devices, essentially to develop priorities for animal tests.

It now remains to be seen whether or not President Ford will sign the bill. If he refuses, he not only runs the risk of the matter developing into a campaign issue, he would also probably do the chemical industry more harm than good. This bill swept through the Congress with support from both Democrats and Republicans, there is certainly strong public pressure for such legislation—especially since the panics over PCBs, vinyl chloride and so on—and the polls now indicate that the Democratic majority in the Congress will be much stronger next year. All those considerations suggest that an even tougher bill would emerge from the next Congress if this bill expires. That is one reason why the chemical industry has decided to give this bill at least its lukewarm support. □

USA

Science Court on guard

A number of prominent scientists and government officials met last month to discuss a proposal to establish a 'Science Court' in the United States, to examine complex scientific issues which have a bearing on public policy. The proposal (see box) has recently been receiving considerable publicity in the United States. Wil Lepkowski reports from Leesburg, Virginia

At first blush, the idea of a Science Court sounds a bit intriguing if not a mite exciting: a forum of distinguished scientists and engineers gathered together in court for sifting, filtering, and distilling contradictory facts into one sparkling supernatant of truth. The world of political decision-making is so messy, proponents of the science court assert, that officials would welcome a little plain, unvarnished truth from a

forum that has no political stake in public issues.

This is a fairly accurate, if not precise, description of the idea behind the science court, which is mainly the invention of Dr Arthur Kantrowitz, president of the Avco Research Laboratories. For about a decade, Dr Kantrowitz has been tirelessly giving on and off the cuff speeches on the need to establish such a court and, after a good deal of effort, he finally succeeded in securing government support for a colloquium on the subject. It was held last month at the Xerox Cor-