THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HAZARDOUS CHEMICALS

Second Report on the Inquiry into Hazardous Chemicals

REPORT OF THE HOUSE OF REPRESENTATIVES STANDING COMMITTEE ON ENVIRONMENT AND CONSERVATION

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Terms of Reference of the Committee[1]

That a Standing Committee be appointed to inquire into and report on:

(a) environmental aspects of legislative and administrative measures which ought to be taken in order to ensure the wise and effective management of the Australian environment and of Australia's resources; and

(b) such other matters relating to the environment and conservation and the management of Australia's natural resources as are referred to it by—

  (i) the Minister responsible for those matters; or

  (ii) resolution of the House.

Terms of Reference of the Hazardous Chemicals Inquiry[1]

To inquire into and report on:

the management of chemicals potentially hazardous to health and the environment, particularly;

  (a) the adequacy of existing Commonwealth and State legislative arrangements;

  (b) research, assessment and dissemination of information; and

  (c) international cooperation.

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1. The terms of reference of both the Committee and the Inquiry in the Thirty-Second Parliament remain unchanged from those of the Thirty-First Parliament.

Members of the Committee in the 32nd Parliament

Chairman	The Hon. M. J. R. MacKellar, MP[1]
Deputy Chairman	Dr H. A. Jenkins, MP
Members	Mr M. A. Burr, MP Mr E. C. Cameron, MP Mr P. H. Drummond, MP Mr B. L. Howe, MP Mr A. J. MacKenzie, MP Mr S. J. West, MP
Secretary to the Committee	Mr J. R. Cummins
Secretary to the Inquiry	Mr A. J. Kelly
Specialist Adviser	Dr D. G. McPhee

Members of the Committee in the 31st Parliament

Chairman	Mr J. C. Hodges, MP[2]
Deputy Chairman	Dr H. A. Jenkins, MP[2]
Members	Mr M. Baillieu, MP[2] Mr B. Cohen, MP Mr J. F. Cotter, MP[2] Mr P. S. Fisher, MP Mr B. L. Howe, MP[2] Mr B. D. Simon, MP
Secretary to the Sub-committee	Mr A. J. Kelly

1. The Hon. M. J. R. MacKellar replaced the Hon. J. C. Hodges as Chairman on 19 August 1982.
2. Members of the Sub-committee on Hazardous Chemicals

Abbreviations

AAC	Australian Agricultural Council.
ACIC	Australian Chemical Industry Council.
ACTDG	National Advisory Committee on the Transport of Dangerous Goods.
ACTU	Australian Council of Trade Unions.
ADEC	Australian Drug Evaluation Committee.
AEC	Australian Environment Council.
ATAC	Australian Transport Advisory Committee.
COSH	Committee on Occupational Safety and Health in Commonwealth Government Employment.
CTHC	Capital Territory Health Commission.
DIRT	Department of Industrial Relations and Technology (NSW).
DOLAC	Departments of Labour Advisory Committee.
EEC	European Economic Community.
EPA	Environmental Protection Agency (US). Environment Protection Authority (Victoria).
IAEA	International Atomic Energy Authority.
IARC	International Agency for Research on Cancer.
ILO	International Labour Organisation.
IMCO	International Maritime Consultative Organisation.
IMDG	International Maritime Dangerous Goods Code.
IRPTC	International Register of Potentially Toxic Chemicals.
LD50	Median Lethal Dose.
NACC	National Advisory Committee on Chemicals.
NH&MRC	National Health and Medical Research Council.
NIOSH	National Institute for Occupational Safety and Health.
NLCC	National Labour Consultative Council.
OECD	Organisation for Economic Cooperation and Development.
OSHA	Occupational Safety and Health Administration (US).
PACC	Pesticides and Agricultural Chemicals (Standing) Committee of NH&MRC.
PBB	Polybrominated biphenyls.
PCB	Polychlorinated biphenyls.
PHAC	Public Health Advisory Committee of NH&MRC.
ppm	parts per million.
PSC	Poisons Scheduling Committee of NH&MRC.
SAA	Standards Association of Australia.
SECV	State Electricity Commission of Victoria.
TCAC	Technical Committee on Agricultural Chemicals.
TCDD	2,3,7,8-Tetrachlorodibenzo-p-dioxin.
TCVD	Technical Committee on Veterinary Drugs.
TLV	Threshold Limit Value.
UNEP	United Nations Environment Program.
WHO	World Health Organisation.

Glossary

Abortifacient	Any agent which induces abortion.
Asbestosis	A form of pneumoconiosis (which is the general name applied to a chronic form of inflammation of the lungs which is liable to affect people who constantly inhale irritating particles). It is caused by the inhalation of asbestos dust.
Cancer	The general name for malignant tumours. It includes carcinoma, leukemia, lymphoma and sarcoma.
Carcinogen	An agent which causes cancer to appear at increased frequency in an exposed population. Many chemicals which cause cancer do so because they are mutagenic, producing mutations in cells other than those which are transmitted from generation to generation. Thus most mutagens are carcinogens and vice versa.
Chloracne	An acne like eruption on the skin caused by chlorinated hydrocarbons.
Emphysema	A pulmonary disorder characterised by overdistention and destruction of the air spaces in the lungs.
Encephalopathy	A term used to describe certain conditions in which there are signs of cerebral irritation without any localised lesion to account for them. The symptoms are attributed to a deficient blood supply to the brain or to spasms of the arteries in the brain.
Epidemiology	The study of the mass aspects of disease. In this Report it refers to the identification of causal agents of disease through correlational studies.
Fibrosis	The formation of excess fibres or scar tissue in a body organ which is usually due to either infection or deficient blood supply.
Mutagen	An agent which causes damage to genes which are transmitted from generation to generation i.e. it causes heritable genetic damage.
Pesticide	Substances used for preventing, destroying or controlling any forms of insect, animal or plant life which are pests.
Silicosis	Pneumoconiosis due to inhalation of particles of silica into the alveoli of the lungs, where they produce fibrosis.
Synergistic	When the effect of two or more causal agents acting together is not merely additive but multiplicative.
Teratogen	An agent which causes damaging changes to the developing foetus e.g. by inhibiting normal development of particular organs or limbs. Teratogens may be, but are not necessarily, mutagenic.
Toxic	In this Report toxic is not intended to be a scientifically precise term but encompasses any chemically induced deleterious effects on the health of an organism.

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Summary

The purpose of this Inquiry has been to examine legislative and administrative arrangments to ensure that all chemicals are properly assessed, hazards made known and appropriate regulatory controls implemented. The Inquiry covered the manufacture, transport, storage, use and disposal of chemicals with occupational health being of particular interest. It has been a wide-ranging Inquiry as the Committee sought to ensure the comprehensiveness of arrangements.

The Report does not set out to assess or evaluate individual chemicals but reference is made, where appropriate, to particular substances for illustrative purposes. The Committee has included four studies to illustrate the extent of the hazards of just a few chemicals and to examine the way in which they are regulated.

The Committee has canvassed the kinds of hazards posed by chemicals and found that where chemical hazards are immediately obvious they tend to be better regulated than those which do not become obvious until long after exposure. Carcinogens and mutagens are in this latter category. The Committee has heard evidence of large scale disasters where many people have been seriously affected by chemicals. The Committee has also heard of numerous instances of lesser damage which nonetheless are cause for serious concern. Unregulated chemical hazards can lead to enormous personal, social and economic costs.

Chemicals play a large part in our everyday lives and our current standard of living and well-being is dependent upon chemical products. It is essential that such gains are consolidated by controlling any associated deleterious effects.

The Committee has examined the assessment and subsequent control machinery for chemicals in Australia. There are a number of deficiencies in these arrangements not least of which are the gaps in their coverage.

The Committee believes that the overall control of hazardous chemicals in Australia is poor, particularly when compared with other developed countries. The Committee does not believe that the fragmentation between State and Commonwealth jurisdictions and the resultant lack of uniformity are acceptable. The principal regulatory mechanisms where they exist are pre-marketing assessment leading to assessment of some kind; labelling requirements; sales restrictions; and exposure or emission limits.

The Committee looked at the bodies responsible for the assessment of pesticides, poisons, pharmaceuticals and industrial chemicals. These are: the National Health and Medical Research Council Committees; the National Advisory Committee on Chemicals; the Australian Drug Evaluation Committee and the Technical Committees on Agricultural Chemicals and on Veterinary Drugs.

Most industrial chemicals, as well as cosmetics and toiletries, do not currently require assessment and clearance prior to marketing. A voluntary notification scheme for industrial chemicals is being operated by the National Advisory Committee on Chemicals. The Committee has recommended that a mandatory system should be introduced as soon as possible. This is best achieved by the Commonwealth fully exercising its constitutional powers. These should have effect until each State and Territory can implement its own legislation of a similar standard.

The Committee believes that all environmental assessments of chemicals should be undertaken by the National Advisory Committee on Chemicals.

The Committee has found that the Public Health Committee structure of the NH & MRC is not sufficiently comprehensive. Important areas such as carcinogens and mutagens are inadequately covered. Some Committees do not meet frequently enough to adequately fulfil their functions. The Committee found health authorities were generally slow in coming to grips with the problems posed by hazardous chemicals, tending to play down their significance rather than instituting effective controls.

The Committee has recommended the establishment of a coordinating council with the major assessment bodies as members. This should require few additional staff but ensure that the range of assessment and regulatory processes are both comprehensive and coordinated. For example, the occupational health aspects of most industrial chemicals are not being assessed under the present structure. Such gross omissions should not continue.

The testing on which Australian assessments are made is carried out overseas. It is essential that the integrity of this data is assured. International machinery is being established to further ensure the acceptability of data from other countries. Australia lacks any significant chemical testing facilities of its own. The Committee believes that Australia should establish testing facilities of its own, not so much to conduct testing of new chemicals but to shoulder part of the international burden of testing existing chemicals. Such facilities would provide training in specialist assessment skills which are in short supply in Australia and internationally.

There is considerable misunderstanding of the nature of chemical carcinogens and mutagens which hampers their effective control. As well as improvements to the relevant parts of the NH & MRC the Committee has recommended a public information campaign to explain the nature of carcinogenic hazards so as to place them in perspective and encourage individuals to take an increased responsibility for their own health.

There is a need for a much greater degree of disclosure of the hazardous nature of individual chemical products than occurs at present. The presence of hazardous ingredients, the nature of the hazards and procedures for safe handling, use and disposal must be provided by the manufacturer or supplier of a product.

Assessment and registration procedures are at present shrouded by excessive secrecy. They should be made much more open to public scrutiny while still protecting essential trade secrets.

Transport accidents, fires and other emergencies involving hazardous chemicals are of increasing concern. The Committee has examined and made recommendations on means of reducing the risks involved and providing emergency services with necessary information. These cover transport, storage and handling of hazardous chemicals. Adequate labelling of containers and vehicles is an essential part of this process.

It is necessary for labelling requirements to be comprehensive and uniform throughout Australia. Labels must readily convey the hazardous nature of the material together with correct storage, handling and emergency procedures. This information frequently needs to be conveyed to non-English speakers. The Committee has recommended that manufacturers and suppliers be required to provide product safety data sheets for any potentially hazardous product they sell. Much more detailed information will be provided than can be put on a label.

There is a need for much more chemical information to be made readily available. This is an international problem and those seeking information range from lay people to specialists, such as toxicologists. The Committee has recommended a coordinating council to ensure that the range of information needs in Australia are met, are cost effective and best use is made of overseas data banks. Easy access to information is an important aspect.

Hazardous chemicals have one of their greatest impacts in the workplace. In the absence of proper controls high levels of exposure over long periods can occur. Legislative and administrative arrangements are weak and enforcement of the few provisions is limited. There are few, if any, workplaces where potentially hazardous chemicals are not used.

The split responsibility for occupational safety and health between labour and health authorities has contributed to the ineffective control of chemical hazards. The time lost due to industrial accidents and disease is about four times that lost due to industrial disputes.

Information on the hazards of many products and awareness by employees and employers is frequently lacking. Regulatory authorities at present seem unable to disseminate the amount of information required. The problem is not confined to Australia and there are international workplace hazard information systems being established.

The number of chemicals involved, the number and variety of workplaces and the substantial training required for inspectors mean that it is not feasible to provide enough inspectors to regularly inspect workplaces and enforce standards. Workplace health and safety committees, with equal employer and employee representation, are necessary to the operation of sound occupational health and safety procedures. Information has to be made available to those in the workplace so that they can be fully aware of the hazards involved and make a contribution to their own health and safety.

Medical practitioners frequently fail to identify the occupational origins of diseases they treat. Better medical training is necessary along with better occupational health services. Workers' compensation legislation is not as comprehensive in its coverage of chemically induced disease as it is of other injuries.

Other countries have established single national organisations to deal with occupational safety and health on a tripartite basis with equal representation of governments, employers and employees. The Committee has recommended that such an approach be adopted in Australia with Commonwealth legislation overcoming much of the fragmentation that exists at present and enabling a high standard of uniform provisions to apply in all workplaces throughout Australia.

The Commonwealth has State responsibilities in the Australian Capital Territory (ACT). The Committee is extremely concerned that many of these have been neglected. Basic legislation covering environmental protection, occupational health, pesticides, consumer goods and the transport of dangerous goods, is absent. Chemical hazards exist in the ACT as they do throughout Australia. It is irresponsible of regulatory authorities to await various tragedies before introducing legislation. Legislation should anticipate and prevent disasters rather than being a ritual response to them. The Committee has made a number of specific recommendations concerning legislation in the ACT.

The Commonwealth is the largest single employer in Australia and is responsible for the occupational health of its own employees. All departments and authorities are required to observe a Code of General Principles on occupational safety and health but evidence indicated that most were unaware of the Code and its implications.

While the Commonwealth has power over imports and exports of hazardous chemicals only a few categories of chemicals are controlled in this way. Similarly under the Trade Practices Act few standards have been set for the chemical safety of consumer goods and few unsafe chemical goods have been banned. The Committee has recommended greater use of the Trade Practices powers to control chemical hazards.

The Commonwealth has extensive powers under the Constitution which allows it to regulate most chemical hazards. The Committee has recommended that these powers

be exercised to their fullest extent. Commonwealth legislation would then continue to apply until such time as States and Territories enacted similar comprehensive legislation.

RECOMMENDATIONS

The Committee recommends that:

NH&MRC

1. the Minister for Health review the National Health and Medical Research Council's Public Health Committee system to ensure assessments are carried out by a comprehensive set of expert committees.

(paragraph 134)

2. the assessment of teratogenicity, mutagenicity and carcinogenicity, be conducted by three specialist committees of the NH & MRC.

(paragraph 187)

3. funding of NH & MRC public health assessment committees should be adequate so as to enable them to effectively fulfill their function.

(paragraph 125)

NACC

4. (a) a mandatory notification and assessment scheme for new chemicals be implemented without delay;

   (b) the Commonwealth exercise its full constitutional powers to provide the legislative backing for the scheme as a matter of urgency. This legislation to have effect until each State and Territory implement their own legislation.

(paragraph 137)

5. environmental assessments of all new chemicals be undertaken by the National Advisory Committee on Chemicals.

(paragraph 138)

6. a national incident reporting system be established and maintained by the National Advisory Committee on Chemicals.

(paragraph 252)

7. staffing of the secretariat of the National Advisory Committee on Chemicals be substantially increased to meet its responsibilities.

(paragraph 141)

Coordinating Council on Chemical Safety

8. (a) a coordinating council for chemical safety be established to ensure the comprehensiveness and coordination of assessment and regulatory processes for hazardous chemicals;

   (b) the coordinating council have as members representatives of the Australian Agricultural Council, the Australian Drug Evaluation Committee, the Australian Environment Council, the National Health and Medical Research Council and the National Occupational Safety and Health Office;

   (c) prior to the establishment of the coordinating council a task force investigate the additional coverage necessary by each body to ensure the comprehensive notification and assessment of all potentially hazardous chemicals.

(paragraph 148)

9. The coordinating council for chemical safety:

(a) establish and coordinate a national chemical information system;
(b) ensure the comprehensiveness of the system;
(c) coordinate access to overseas elements of the information system; and
(d) ensure the reliability of access to components of the system.

(paragraph 301)

Disclosure and Labelling

10. manufacturers, importers and suppliers be required to disclose the presence of hazardous ingredients in products and the full nature of the hazards.

(paragraph 197)

11. the Attorney-General introduce legislation as a matter of urgency to require commercial containers of potentially hazardous chemicals to be clearly labelled in accordance with Australian Standard 1216.

(paragraph 249)

12. the Trade Practices Act be amended as soon as possible to require consumer goods containing hazardous ingredients to be clearly labelled to indicate their hazardous nature and the precautions necessary for safe use and disposal of the product.

(paragraph 278)

13. (a) the Trade Practices Act be amended as soon as possible to require that product safety sheets be provided with all potentially hazardous chemical substances sold in Australia;
(b) it be a standard condition of Commonwealth purchasing that if a product contains potentially hazardous chemicals, product safety sheets be provided in sufficient quantities for each workplace where it is to be used; and
(c) imports of potentially hazardous chemicals for which product safety sheets are not available be prohibited under the Customs (Prohibited Imports) Regulations.

(paragraph 291)

14. (a) the Commonwealth Government coordinate the adoption throughout Australia of legislation requiring placarding or labelling of buildings, plant and storage with the Hazchem code and any other relevant warning code for dealing with chemical emergency situations;
(b) the Minister for Home Affairs and Environment seek the adoption by the Australian Environment Council of measures to ensure the coordination, compilation and operation of an emergency chemical information service to be available nationwide 24 hours a day and that industry should provide the necessary information to that service concerning its products, including contacts for expert advice.

(paragraph 225)

Transport of Dangerous Goods

15. if State Governments have failed to incorporate the Australian Code for the Transport of Dangerous Goods by Road and Rail into legislation by 1985 the Commonwealth should legislate to enforce the Code to the fullest extent of its power.

(paragraph 240)

16. the Australian Code for the Transport of Dangerous Goods by Road and Rail be amended as soon as possible to include comprehensive and detailed response

measures which take into account environmental hazards associated with chemical emergencies.

(paragraph 241)

Major Hazards

17. the Minister for Home Affairs and Environment seek the adoption by the Australian Environment Council of measures to ensure the development of standards:
    (a) to determine installations requiring hazard assessment;
    (b) for the assessment of hazards; and
    (c) for town planning guidelines to maintain a suitable degree of separation of facilities involving hazardous chemicals and land used for residential purposes, including schools and hospitals.

(paragraph 264)

Occupational Health

18. (a) a national occupational safety and health office be established as a cooperative organisation of Commonwealth, State and Territory Governments;
    (b) the office be responsible to a tripartite governing council with equal representation of employers, employees and governments;
    (c) national occupational safety and health legislation be drafted by the office for approval by the governing council to be implemented as quickly as possible;
    (d) the resultant legislation should be enacted in the first instance by the Commonwealth using its full constitutional powers until such time as individual States have their own comprehensive legislation in place;
    (e) such legislation be enforced with substantial penalties for breaches; and
    (f) occupational safety and health legislation should be binding on the Crown.

(paragraph 414)

19. health and safety committees be a requirement for each workplace with their rights and obligations specified in legislation.

(paragraph 332)

20. the Commonwealth legislate with a minimum of delay to implement International Labour Organisation conventions on occupational safety and health.

(paragraph 417)

21. the Australian Bureau of Statistics be required to collect and publish uniform national statistics on the cost and time lost due to occupational accidents and disease.

(paragraph 316)

22. the Minister for Education direct the Tertiary Education Commission in consultation with the Council of Medical Deans to ensure that all undergraduate medical training includes the recognition of occupational causes of disease.

(paragraph 348)

23. the Minister for Social Security seek the cooperation of the States and the Northern Territory to:
    (a) prepare model workers' compensation legislation provisions covering occupational disease;

(b) prepare a comprehensive list of specified diseases and machinery for regularly updating them; and

(c) implement uniform national workers' compensation legislation covering occupational disease.

(paragraph 362)

24. the Prime Minister appoint a panel of experts to:

(a) examine the Commonwealth's overall responsibilities in occupational safety and health, including those of national coordination; and

(b) recommend specific policies and objectives and appropriate administrative machinery to give effect to such policies and objectives.

(paragraph 408)

Australian Capital Territory

25. the Minister for the Capital Territory introduce the Air Pollution (Stationary Sources) Ordinance and the Water Pollution Ordinance within six months of the tabling of this Report and that such legislation be binding on the Crown.

(paragraph 427)

26. the Minister for the Capital Territory introduce legislation adopting the Australian Code for the Transport of Dangerous Goods by Road and Rail within six months of the tabling of this Report.

(paragraph 429)

27. the Minister for the Capital Territory introduce a consumer protection ordinance covering product safety matters within six months of the tabling of this Report.

(paragraph 431)

28. the Australian Capital Territory through the Chairman of the Capital Territory Health Commission be a member of the National Health and Medical Research Council.

(paragraph 444)

29. the Ministers for Health and the Capital Territory introduce, as a matter of urgency, legislation to control the manufacture, sale, use and disposal of pesticides and veterinary chemicals and to license commercial pest control operators in the Australian Capital Territory. The legislation should be binding on the Crown.

(paragraph 447)

30. the Ministers for Health and the Capital Territory introduce, as a matter of urgency, legislation and appropriate administrative measures to safeguard occupational safety and health in workplaces in the Australian Capital Territory. The legislation should be binding on the Crown.

(paragraph 448)

31. the Minister for Primary Industry, the Minister for the Capital Territory and the Minister for Health make the necessary arrangements for the Australian Capital Territory to be represented on the Technical Committee on Agricultural Chemicals and the Technical Committee on Veterinary Drugs.

(paragraph 114)

Other

32. the Commonwealth Institute of Health and other suitable research centres be funded to further develop testing facilities in Australia and train specialists in the relevant areas of assessment.

(paragraph 159)

33. the Department of Health conduct a public information program in Australia to:
    (a) make clear that not all substances are carcinogenic;
    (b) explain the significance of positive carcinogenic results in animal tests; and
    (c) explain that methods do not yet exist for determining safe levels of exposure to carcinogens.

(paragraph 180)

34. after consultation with the States and the Northern Territory comprehensive chemical safety provisions be incorporated in the Air Navigation Orders under the Air Navigation Regulations.

(paragraph 119)

35. if State Governments fail to introduce effective and comprehensive legislation and administrative machinery for the regulation of chemical hazards by 1985, the Commonwealth legislate to control these hazards to the fullest extent of its power.

(paragraph 473)

PREFACE

This is the Second Report of the Committee on its Inquiry into Hazardous Chemicals. The First Report which dealt with the storage, transport and disposal of hazardous chemical wastes was tabled in the House of Representatives on 29 April 1982. The Second Report covers the remaining areas of the Inquiry.

CHAPTER 1

Introduction

1. Concern has increased sharply during the last 15 years over the safety of the many chemicals that we come into contact with in everyday living. While the long-term hazardous effects of some agents such as lead or asbestos have been recognised for some time, the insidious effects of other widely used products have only become known much more recently. Concern has been greatest where people have extensive contact with chemicals, for example pesticides, or where they are ingested, for example food additives. Even after hazards have been identified, this information often does not reach those using the materials. Worse still, these people have sometimes been assured that the substance they are using is safe. Public health authorities, who have traditionally erred on the side of caution in regulating possible health risks have been strangely slow to act in the area of overall chemical safety.

2. New hazards are being identified at frequent intervals and many more are suspected. Concern is heightened when newly identified hazards involve substances in common use and thought to be completely safe.

3. The community has properly sought greater assurances as to the safety of chemicals being used and has sought firmer controls over them.

4. The assurances given by health and other regulatory authorities have been frequently received with scepticism. These authorities have been unable to satisfy the information needs of many sections of the community. The present labelling of hazardous products provides a minimum of information to the user and many industrial chemicals are labelled only with a code number.

5. Most developed countries have introduced legislation providing greater control over chemical use and the introduction of new chemicals. Australia still lacks comprehensive legislation and adequate information systems. Problems with chemicals exist in Australia. Workers are exposed to hazardous materials such as asbestos, acrylonitrile, coke oven emissions and vinyl chloride. Householders come into contact with adhesives, cleaners, pesticides, swimming pool chemicals and solvents. Craftworkers, hobbyists and home handymen use metal oxides, dyes, epoxy resins, asbestos materials, solvents and paints. These materials represent a small percentage of the potentially hazardous materials we commonly use and often take for granted. Frequently, the precautions necessary for safe use of these materials are not clearly specified. When they are, they are frequently disregarded by users because no ill-effects are noticed immediately or other risks appear remote.

6. This Report does not set out to comprehensively assess or evaluate individual chemicals but reference is made where appropriate to particular substances for illustrative purposes. The purpose of this Inquiry has been to examine legislative and administrative mechanisms and make recommendations which should ensure that all chemicals are properly assessed, hazards made known and appropriate regulatory controls implemented. The Inquiry covered the manufacture, transport, storage, use and disposal of potentially hazardous chemicals with occupational health being of particular interest.

Nature of Hazards

7. Chemicals can be hazardous to man and the environment through their toxicity, through being bioaccumulative, persistent, carcinogenic, mutagenic, teratogenic, corrosive, radioactive, explosive, flammable or strongly reactive. Chemicals may create a hazard during part or all of their 'life cycle' which includes their development, manufacture, handling, transport, storage, use and disposal. In fire and other emergency situations, chemicals may become more hazardous than they are normally. Certain chemicals which enter and accumulate within food chains without breaking down pose environmental hazards threatening plant and animal life. While many chemicals in commercial use have little or no adverse potential effects on man or the environment, others pose quite serious environmental and health hazards. These hazards are not always immediately obvious.

8. Some substances, such as lead and mercury, accumulate in the body over time, consequently increasing their toxic effects. Where adverse effects become obvious only after a long period of exposure to a substance it is known as chronic toxicity. Where adverse effects are experienced soon after exposure to a substance this is referred to as its acute toxicity. It is in the area of carcinogens, mutagens and teratogens that quite a deal of the evidence has focussed. They are of concern in that their effects become obvious long after exposure. Mutagens damage gene structure. It is claimed that 90 per cent of carcinogens are mutagens and 90 per cent of mutagens are carcinogens. Teratogens are agents which damage developing foetuses without damaging genes (e.g. Thalidomide). Exposure to certain chemicals over long periods induce diseases or other symptoms such as sterility. Mutagens and carcinogens present the greatest difficulty in that their effects are not noticed for quite some time, sometimes 20 or 40 years or in later generations. Many chemicals act as irritants or sensitisers to the skin, the eyes or bronchial tract. As a broad generalisation the legislative arrangements, including workers compensation, to cover those deleterious effects of chemicals that are evident soon after contact are more adequate than for those with long periods of latency.

9. There are many examples of widespread damage from hazardous chemicals. They include:

- Vinyl chloride which is a basic chemical in the plastics industry being used in the manufacture of polyvinyl chloride (PVC) and other resins. It is also used as a chemical intermediate and as a solvent. It was believed to be so safe and stable that it was used for a time as an aerosol propellant in widely used products such as hair sprays. It has been in widespread industrial use since World War II, but it was not until the early 1970s that it was identified as being a potent human carcinogen and having other serious effects on health.
- In 1959 an unusual disease was described in Japan from around Minimata Bay which was eventually associated with the discharge of mercury wastes into neighbouring waterways. The mercury accumulated in fish and over 1 000 people who had regularly eaten the fish became ill with more than 50 dying. The syndrome became known as Minimata Disease.
- Two youths died last year in a Melbourne paint factory when overcome by trichloroethylene fumes while cleaning out a degreasing tank.
- In Michigan, United States, in 1973 polybrominated biphenyls (PBBs), used as a flame retardant, were inadvertently mixed with animal feed. Despite many thousand farm animals being destroyed, human food was contaminated with this persistent chemical. Ninety-seven per cent of the State's population still have PBB in their bodies. While some symptoms of poisoning occurred fairly quickly other long-term

hazards such as cancer and nervous system disorders may take decades to become apparent.

- In 1968 a supply of rice oil in Japan was accidentally contaminated by polychlorinated biphenyls (PCBs) during processing. Over 1 000 people became ill as a result of using the contaminated oil in cooking. This incident highlighted the fact that relatively low exposures repeated over a long period could have toxic effects.
- Between 1943 and 1966 blue asbestos (crocidolite) was mined at Wittenoom in Western Australia. At least 220 workers contracted asbestosis, a frequently fatal lung disease, 46 have contracted mesothelioma, a fatal cancer of the chest cavity, and an unknown number have died from lung cancer as a result of asbestos exposure at the mine. (The health hazards of asbestos are further dealt with in Chapter 11).
- In 1961 the dramatic effects of the so-called tranquillizer Thalidomide were recognised. This apparently innocuous medication was found to produce particularly distressing deformities in some children whose mothers had taken the drug during pregnancy. This recognition of chemical teratogenesis had a profound effect on the development of toxicology from both a scientific and legislative point of view.

10. The incidents above have received considerable media attention but do not give a full picture of the range of problems associated with hazardous chemicals. The problems are not confined to major disasters but include a much larger number of lesser incidents of environmental damage, disease and ill health. These lesser incidents by their very nature often go unrecognised for long periods by health and other regulatory authorities. The Report of the United States Toxic Substances Strategy Committee to President Carter in May 1980 catalogued some of the effects of hazardous chemicals:

> Human health effects include cancer, birth defects and other reproductive anomalies, neurological and behavioural disorders, kidney damage, lung and heart disease, acute and chronic skin disease, and acute poisoning. Certain subtle effects, such as on intelligence, may be totally undetected. For example, the immediate effects of high level exposures for a short time include burns, rashes, nausea, loss of eyesight, and fatal poisoning. Prolonged exposure to low doses can cause chronic lung disease (i.e. from coal or cotton dust), heart disease (from exposure to cadmium or carbon monoxide), sterility (from dibromochloropropane (DBCP)), and kidney, liver, brain, nerve, or other damage. Exposure to industrial solvents can cause depression, and carbon disulfide is associated with a higher suicide rate among workers than in the general population. Although most chemicals do not cause cancer, exposure to some has been linked to cancer. Some workers exposed to asbestos, even for a short time, have developed a rare cancer of the chest and stomach linings 30-40 years after initial exposure. Vinyl chloride gas is linked to a rare liver cancer, to a brain cancer, and possibly to lung cancer. Diethylstilbestrol (DES), when taken by pregnant women to prevent miscarriage, led to increased risk of vaginal cancer in their daughters and abnormal sexual organs in their sons. Methyl mercury, formed by the action of bacteria in sediments on mercury metal and on mercuric ions, can cause acute poisoning, deafness, brain damage, and a range of birth defects. A single substance can have several kinds of adverse effects, depending on the route and level of exposure.[1]

11. The identification of causal factors and the effective testing of substances for long-term effects in humans is difficult.Testing of chemicals for their possible effects on humans is done almost exclusively with animals. This testing is carried out overseas as Australia lacks the facilities for any significant testing of chemicals. While generally speaking animal responses are accurate predictors of possible effects on humans, the existence of a few exceptions creates an element of uncertainty. The use of chemicals by humans without prior assessment of the chemicals is, in effect, testing on humans.

12. Hazardous chemicals most frequently referred to in the evidence are those encountered at work. The effects on workers of constant and prolonged contact with offending substances are more readily observed than in individuals with less frequent

contact. Chemical exposure is at present inadequately assessed and regulated in Australia. As a result, avoidable injury is occurring. The personal, social and economic costs of such injuries must be reduced. Causative agents are more readily identified where an employee contracting a disease has always worked in the one job.

13. There is little reliable data on the number of chemicals used within Australia. Several witnesses have given widely varying figures for the numbers of chemicals in use. The variations are due to different definitions of what constitutes a chemical as well as to inadequate statistics on chemical usage in Australia. The following figures based on a number of submissions provide some perspective:

Known chemicals (identifiable by fully defined structures)	34 000 000
Chemicals in the environment	4 000 000
Chemicals produced commercially (worldwide)	50-70 000
Chemicals or processes evaluated for human carcinogenicity (IARC Monographs)	572
Suspect human carcinogens (positive in animal tests)	294
Known human carcinogens (See Tables 1a & 1b)	43
New chemicals coming onto the world market each year	approx. 500

14. Witnesses from the Australian Chemical Industry Council (ACIC) indicated that they expected chemicals in common use in Australia to be around 5 000. The United Nations Transport of Dangerous Goods classification lists about 3 000 chemicals. There is little reliable data on the volume of chemicals used within Australia.

15. While the chemical industry has a much longer history it has grown to its present size largely since World War II. Innovation and expansion in the chemical industry have made a major contribution to the economic growth of industrialised nations in that period. The chemical industry more than doubled its world output between 1965 and 1975. Its main features are well known: a high degree of innovation, a varied range of interdependent products, a small number of multinational firms (at least those dealing with raw materials), an output of $440 billion in 1976 mainly concentrated in the OECD area, sales which flow through the whole of the economy (especially the chemical industry itself, textiles and clothing, construction, electrical and electronic equipment, services, agro-food, business, metals, and printing and publishing).

16. Although the chemical industry's capacity for innovation is far from exhausted, there are signs of slower growth in the developed countries' markets for many of its products. It will thus play a less decisive part in the economic development of those countries in future than it has done over the last 30 years. As it approaches maturity, its growth rate will come closer to the average for industry as a whole.

17. The chemical industry has become an increasingly important segment of the manufacturing sector during the past two decades, with turnover tripling to $4.8 billion in the ten years to 1977-78. The chemical industry's share of the turnover of the manufacturing sector increased from 8.5 per cent in 1968-69 to 10 per cent in 1977-78. During this period, turnover increased at an average annual rate of 13.2 per cent, compared to 11.1 per cent for the whole manufacturing sector. Value added by the chemical industry rose by an average of 13 per cent a year, slightly outpacing the 11.7 per cent recorded for the manufacturing sector as a whole.

18. The Australian chemical industry is highly concentrated. Although around 500 enterprises manufacture chemicals and chemical products in Australia, most sections of the industry are dominated by a handful of large, foreign-owned multinational corporations.

19. Foreign-owned enterprises contributed 66 per cent of the value added for the industry in 1972-73, and foreign controlled enterprises 75 per cent. This compares to 31 and 34 per cent respectively for the whole manufacturing sector.

20. Chemicals play a large part in our everyday lives and much of our current standard of living and well-being is dependent upon chemical products. It is essential that such gains are consolidated by controlling any associated deleterious effects. Not all chemicals are hazardous. It is a matter of accurately identifying those that are and developing procedures for their safe management. Control measures at present, where they exist, are generally fragmented and inadequate. The rate of introduction of new chemicals has been so great as to outstrip the ability of regulatory authorities to adequately assess the impact of these chemicals on health and the environment. Different authorities within Australia have developed their own approaches to assessment and determined relevant criteria. Some groups of chemicals such as pharmaceuticals and agricultural and veterinary chemicals receive a comparatively high level of assessment while the remainder receive little or none unless serious ill effects are clearly observed.

21. Other developed countries began developing and enacting legislation in the early 1970s to control hazardous chemicals. Ten out of 24 OECD countries have introduced wide-ranging legislation for pre-manufacture or pre-marketing controls over chemicals. Ten years later Australia has not introduced similar legislation. As the major companies in the industry operate in a number of countries across the world, Australian legislation should exercise comparable controls so that Australia does not gain chemicals or processes regarded as unsafe in those countries with strong legislation. The present federal system with its division of responsibilities for hazardous chemical management has made the implementation of effective controls difficult. The vast and ever increasing amounts of information that have to be gained, interpreted and acted upon are daunting to even the largest, well coordinated and most technologically advanced administration.

22. It is important that the economic cost of controlling chemicals be minimised without compromising community health and the natural environment. The failure to regulate hazardous chemicals can lead to enormous economic and social costs. Examples would include the cost of cleaning up chemical waste disposal sites such as Love Canal or the costs to life and health due to the unregulated use of asbestos. Regulation is necessary so that problems are resolved at least cost to the community as a whole.

23. The risks posed by chemicals to the natural environment depend not only on their toxicity characteristics but also on their access to environmental pathways. There are a number of largely physico-chemical properties of hazardous chemicals which determine their pathway into and through the environment. These include volatility, chemical reactivity, density, tendency toward bioaccumulation, solid adsorption properties and water solubility.

24. Research into the effects of toxic substances upon living organisms, both individually and as ecosystems, is quite advanced in Europe and the US. Some questions have been raised as to the reliability of overseas environmental toxicity data to Australian organisms and ecosystems. There have been proposals to undertake toxicity testing on species of fish, algae and invertebrates using a few common toxicants to compare results with North American and European patterns of toxic effects. However, such projects have not yet commenced.

25. Most pollution of the natural environment is more readily controlled if possible sources are assessed and regulated before emissions begin. While this is a basic aim of notification schemes for new chemicals, such schemes will not cover existing chemicals

and other industrial processes. Natural pollution, e.g. heavy metals in waterways, would also need to be assessed separately.

Cancer

26. Exposure to chemicals can affect health in many ways. As many of the submissions referred to chemically induced cancer the Committee has chosen to concentrate, by way of example, on cancer. In the absence of overall figures for Australia, United States figures show that one in four people will develop some form of cancer during their life, from which one in five of the total population will die. Approximately 80-90 percent of human cancer is regarded as being due to environmental factors. These may be naturally occurring as well as man-made.

27. Environmental factors incriminated as causes of human cancer encompass a wide range of influences. These include smoking, natural and man-made radiation, ultraviolet rays from the sun, naturally occurring plant, fungal, bacterial and chemical carcinogens as well as industrial chemical carcinogens contaminating air, water, food, other consumer products and the workplace. Dietary and social factors are also suspected of playing important roles.

28. It appears that there are three main directions in which the fight against cancer is being pursued:

(a) by medical treatment, including surgery, chemotherapy and irradiation of cancers after they have occurred. The overall success rate in this area is comparatively low with limited hope for the foreseeable future, although early detection techniques are important.

(b) by the identification in the laboratory of individual carcinogens and co-carcinogens by examining how they act in bacteria, mammals and human tissues. Such information has the potential of leading to preventive action before a chemical is in widespread use. The problems here are: the cost of long-term tests, allocating priorities for the testing of existing chemicals and the limited number of skilled personnel to carry out the assessment of test results.

(c) by identification of carcinogenic risk factors through epidemiological studies. This identification of factors involved in those cancers already occurring is intended to lead to preventive action. The limitations here are the lack of skilled epidemiologists and the lack of data bases in Australia for epidemiological purposes.

29. While there have been some improvements in cancer mortality figures due to successful treatments these have unfortunately been limited. After some marked improvements around the mid-century there has been little improvement in overall trends since. Improvements have occurred in the treatment of some specific cancers but the remainder have shown little or no improvement. This is despite substantial funding in the area. Some observers warn that there is little likelihood of dramatic improvements in the success rate of treatment for the near future. The Committee is mindful though of the continuing importance of treatment in reducing the pain and suffering of cancer victims and their families. These gloomy predictions mean that greater emphasis must be placed on prevention; prevention being in the form of identification and control over known carcinogens as well as in behaviour modification to overcome social habits known to cause or promote cancer, such as smoking.

30. The medical approach still seems to focus more on treatment and early intervention than on prevention, although recent years have seen attitudinal changes

reflected in campaigns to reduce cigarette smoking and exposure to the sun. The Commonwealth Department of Health denied this bias but a number of preventive programs they described were in fact early detection procedures. Of all the anti-cancer councils invited to make a submission only two did so. The contribution to health costs of preventable cancer and other effects of hazardous chemicals must be considered when weighing the costs and benefits of regulation. It has been estimated that at least 75-80 per cent of the total of all cancers in both sexes in the United States in 1970 might have been avoidable.[2] While including other than chemically-induced cancers, this figure stresses the need for greater emphasis to be placed by health authorities on prevention.

31. Many human cancers are considered to have a multifactorial origin. While quite a number of carcinogens have been identified and some confirmed as human carcinogens, other factors or agents while not themselves carcinogens appear to play an important part by promoting the cancer. Some researchers suggest that initiation of cancer may be frequent but often incomplete such that the outcome is significantly influenced by promoting agents. Initiation and promotion are therefore seen as two separate stages.[3] Tables 1a and 1b show two slightly different lists of established human carcinogenic agents and circumstances.

32. State Governments and State cancer councils have in recent years established registers for the incidence of cancer to provide basic incidence statistics and supply, other epidemiological data. It is essential that information on an individual's past occupations be sought and recorded. A Peri-natal Statistics Unit has recently been established within the Commonwealth Institute of Health to develop a data register of birth defects but does not include spontaneous abortions. The Institute also has an Environmental Toxicology Section and an Epidemiological Section which provides specialised training in areas where personnel resources are quite limited both within Australia and internationally. These should enable Australian epidemiological research to be undertaken rather than having to rely almost solely on overseas experience. Projects to establish epidemiological data bases such as cancer registries are new, consequently it will be quite some time before the data they are collecting will be able to be put to full use.

Occupational Cancer

33. The extent to which occupational exposure contributes to total cancer incidence has long been a subject of debate. Estimates quoted range from one per cent to 40 per cent and over. The one point of agreement is that there is insufficient epidemiological data on which to base accurate estimates. The best that can be attempted are educated guesses. Conservative estimates have for some time put the figure somewhere between one and five per cent. In 1978, the US Department of Health, Education and Welfare submitted in a report[4] to the Occupational Safety and Health Administration (OSHA) that:

- cancer has a combination of causes, which cannot be divided into percentages totalling 100 per cent; and
- future consequences of past exposure to occupational carcinogens may comprise as much as 20 per cent or more of total cancer mortality.

These findings prompted considerable controversy. The US Congress Office of Technology Assessment was prompted to commission two eminent experts, Sir Richard Doll and Dr Richard Peto, to review the available data on cancer risks from the environment. Doll and Peto, with a number of significant qualifications, estimated the proportion of cancer deaths attributed to occupational causes at four per cent (17 000 out of 400 000 US cancer deaths).[5]

Table 1a: Established human carcinogenic agents and circumstances[a,b]

Agent or circumstance	*Exposure*[c]			*Site of cancer*
	Occupational	*Medical*	*Social*	
Aflatoxin			+	Liver
Alcoholic drinks			+	Mouth, pharynx, larynx, oesophagus, liver
Alkylating agents:				
Cyclophosphamide		+		Bladder
Melphalan		+		Marrow
Aromatic amines:				
4-Aminodiphenyl	+			Bladder
Benzidine	+			,,
2-Naphthylamine	+			,,
Arsenic[d]	+	+		Skin, lung
Asbestos	+			Lung, pleura, peritoneum
Benzene	+			Marrow
Bis(chloromethyl) ether	+			Lung
Busulphan		+		Marrow
Cadmium[d]	+			Prostate
Chewing (betel, tobacco, lime)			+	Mouth
Chromium[d]	+			Lung
Chlornaphazine		+		Bladder
Furniture manufacture (hardwood)	+			Nasal sinuses
Immunosuppressive drugs		+		Reticuloendothelial system
Ionizing radiations[e]	+	+		Marrow and probably all other sites
Isopropyl alcohol manufacture	+			Nasal sinuses
Leather goods manufacture	+			Nasal sinuses
Mustard gas	+			Larynx, lung
Nickel[d]	+			Nasal sinuses, lung
Estrogens:				
Unopposed		+		Endometrium
Transplacental (DES)		+		Vagina
Overnutrition (causing obesity)			+	Endometrium, gallbladder
Phenacetin		+		Kidney (pelvis)
Polycyclic hydrocarbons	+	+		Skin, scrotum, lung
Reproductive history:				
Late age at 1st pregnancy			+	Breast
Zero or low parity			+	Ovary
Parasites:				
Schistosoma haematobium			+	Bladder
Chlonorchis sinensis			+	Liver (cholangioma)
Sexual promiscuity			+	Cervix, uteri
Steroids:				
Anabolic (oxymetholone)		+		Liver
Contraceptives		+		Liver (haematoma)
Tobacco smoking			+	Mouth, pharynx, larynx, lung, oesophagus, bladder
UV light	+		+	Skin, lip
Vinyl chloride	+			Liver (angiosarcoma)
Virus (hepatitis B)			+	Liver (hepatoma)

(*a*) Expanded from IARC working group, 1980.

(*b*) By restricting this table to firmly established causes, we undoubtedly have omitted some of the more important determinants of human cancer. (A few borderline cases might not command uniform agreement; e.g., we have on balance just included cadmium and just excluded beryllium.)

(*c*) A plus sign indicates that evidence of carcinogenicity was obtained.

(*d*) Certain compounds or oxidation states only.

(*e*) For example, from X-rays, thorium, thorotrast, some underground mining, and other occupations.

Source: R. Doll and R. Peto, 'Avoidable Risks of Cancer in the U.S', Journal of National Cancer Institute, Vol. 66, No. 6, June 1981. p. 1203

Table 1b: IARC carcinogens for humans

A. Carcinogenic

4-Aminobiphenyl	Diethylstilbestrol
Arsenic and certain arsenic compounds	Underground hematite mining
Asbestos	Manufacture of isopropyl alcohol by the strong acid process
Auramine manufacture	Melphalan
Benzene	Mustard gas
Benzidine	2-Naphthylamine
N,N-bis (2-chloroethyl)-2-naphthylamine (chlornaphazine)	Nickel refining
Bis (chloromethyl) ether and technical grade chloromethyl methyl ether	Soot, tar and mineral oils
Chromium and certain chromium compounds	Vinyl chloride

B. Probably Carcinogenic

High degree of evidence:	
Aflatoxins	Cyclophosphamide
Cadmium and certain cadmium compounds	Nickel and certain nickel compounds
Chloramubucil	Tris (1-aziridinyl) phosphine sulphide (thiotepa)
Lower degree of evidence:	
Acrylontrile	Dimethylsufate
Amitrole (aminotriazole)	Ethylene oxide
Auramine	Iron dextran
Beryllium and certain beryllium compounds	Oxymetholone
Carbon tetrachloride	Phenacetin
Dimethylcarbamoyl chloride	Polychlorinated biphenyls

Source: R. Althouse, L. Tomatis, J. Huff & J. Wilbourne. Evaluation of the carcinogenic risk of chemicals to humans: chemicals and industrial processes associated with cancer in humans. Supplement No. 1 to Volumes 1-20, IARC Sc. Pub. Lyon, France. 1979. pp. 1-71.

34. While the 20 per cent estimate made to OSHA has been strongly criticised on its epidemiological calculations a number of commentators have observed that the 20 per cent figure may not be incorrect.

35. Doll and Peto qualified their findings as follows:

> The hazards that have been recognized thus far tend to be those which increase the relative risk of some particular type(s) of cancer very substantially, and important occupational hazards may quite possibly exist that have not yet been detected because the added risk is small compared with that due to other causes, or because only a few people have been exposed, or simply because a hazard has not been suspected and so not looked for. It must also be borne in mind that cancer in humans seldom develops until one or more decades after beginning exposure to a carcinogen, and it is too soon to be sure whether agents are human carcinogens if they were introduced into industry only during the last 20 years.
>
> On present knowledge, therefore, it is impossible to make any precise estimate of the proportion of the cancers of today that are attributable to hazards at work (let alone how many future cancers may arise from past occupational exposure during the years before 1980), and none of the estimates that have been made are claimed to be anything more than informed guesses.[6]

36. Doll and Peto's estimate must be regarded as conservative as:

- their estimates are limited to their own list of known occupational causes of cancer, contained in Table 2a.[7] Doll and Peto include only one of the six high-volume production human carcinogens listed in Table 2b.
- their estimates are restricted by the current extent of epidemiological studies of occupational groups. They have measured the results of past exposures. As Doll and Peto note, the effect of carcinogenic substances whose use has commenced within the

Table 2a: Established occupational causes of cancer

Agent	*Site of cancer*	*Occupation*[a]
Aromatic amines (4-aminodiphenyl, benzidine, 2-naphthylamine)	Bladder	Dye manufacturers, rubber workers, coal gas manufacturers
Arsenic[b]	Skin, lung	Copper and cobalt smelters, arsenical pesticide manufacturers, some gold miners
Asbestos	Lung, pleura, peritoneum (also probably stomach, large bowel, oesophagus)	Asbestos miners, asbestos textile manufacturers, asbestos insulation workers, certain shipyard workers
Benzene	Marrow, especially erythroleukemia	Workers with glues and varnishes
Bischloromethyl ether	Lung	Makers of ion-exchange resins
Cadmium[b]	Prostate	Cadmium workers
Chromium[b]	Lung	Manufacturers of chromates from chrome ore, pigment manufacturers
Ionizing radiations	Lung	Uranium and some other miners
Ionizing radiations	Bone	Luminizers
Ionizing radiations	Marrow, all sites	Radiologists, radiographers
Isopropyl oil	Nasal sinuses	Isopropyl alcohol manufacturers
Mustard gas	Larynx, lung	Poison gas manufacturers
Nickel[b]	Nasal sinuses, lung	Nickel refiners
Polycyclic hydrocarbons in soot, tar, oil	Skin, scrotum, lung	Coal gas manufacturers, roofers, asphalters, aluminum refiners, many groups selectively exposed to certain tars and oils
UV light	Skin	Farmers, seamen
Vinyl chloride	Liver (angiosarcoma)	PVC manufacturers
—[d]	Nasal sinuses	Hardwood furniture manufacturers
—[d]	Nasal sinuses	Leather workers

[a] Typical occupations in which exposure to the listed agents has been proved to confer a hazard of cancer of one or more of these sites. (Some of these broad occupational categories also include, of course, many people who have never worked with the listed agents.)

[b] Certain compounds or oxidation states only.

[c] Studies of American asbestos workers have reported a significant excess of deaths certified as being due to cancers of the digestive tract, but various studies elsewhere have not. Although probably real (rather than representing miscertified mesotheliomas or respiratory tract cancers), there is not yet general agreement on this point.

[d] Causative agent not known.

Source: Doll and Peto, p. 1238.

last two decades are not included in the estimates. They note that many of these substances are mutagenic to bacteria and carcinogenic in one or more species of laboratory animals and therefore 'some harmful effects must be anticipated'.[8]

- of 442 chemicals and industrial processes evaluated by IARC in 1980, epidemiological data was available for only 60, although evidence of experimental carcinogenicity was considered to be sufficient for 143.
- epidemiological studies are better able to identify causal factors of less common cancers than they are able to apportion causes to common cancers such as lung cancer.

- they do not appear to give adequate consideration to synergistic effects. The multifactorial causation of cancer means that the summation of known causes would exceed 100 per cent.

37. The International Agency for Research on Cancer (IARC) is a specialist arm of the World Health Organisation. Doll and Peto and the IARC agree that, on the basis of present United States cancer mortality statistics, there is no rapid rising of overall cancer onset rates to indicate a cancer epidemic induced by industrial chemicals as claimed by some witnesses. If anything, among people under 65 years of age, most of the trends in recorded mortality are downward. While some decreases are due to improved treatment, many cannot be accounted for in this way.[9] Overall cancer incidence figures are of little use in assessing the impact of individual chemical carcinogens. Doll and Peto observe:

> although some thousands of Americans every year are now dying of asbestos-induced cancer, this public health disaster cannot be clearly seen in the national trends (except perhaps for the still rare asbestos-induced mesotheliomas).[10]

Table 2b: Risk factors associated with workplace exposures to six high-volume human carcinogens

Chemical	*Sites of primary cancers*	*Occupations at risk*	*Latency period for cancer (years)*	*1981 NIOSH estimated numbers of workers potentially exposed*	
				Full and part time	*Full time*
Acrylonitrile	Colon, lung	Chemical workers and plastics workers	20+	374 312	25 245
Carbon tetrachloride	Liver	Drycleaning, machinists		1 378 982	21 457
Ethylene oxide	Leukemia, gastric cancer (suggested)	Hospital workers, laboratory workers, fumigators		144 329	2 767
Beryllium	Lung	Beryllium workers, defense and aerospace industry, nuclear industry	15+	855 073 (oxides)	106 633
Cadmium	Prostate, respiratory tract, renal	Electrical workers, painters, battery plant and alloy workers		1 376 756 (oxides)	230 607
Vinyl chloride	Angiosarcoma, lung, brain, hematolymphopoietic	Plastics industry	20+	239 347	8 186

Source: D. L. Davis, K. Bridbord and M. Schneiderman, 'Cancer Prevention: Assessing Causes, Exposures, and Recent Trends in Mortality for U.S. Males 1968-1978', Teratogenesis, Carcinogenesis and Mutagenesis, 2:105-135, 1982.

Doll and Peto, again supported by the IARC, made the following observation:

> Occupational cancer, moreover tends to be concentrated among relatively small groups of people among whom the risk of developing the disease may be quite large, and such risks can usually be reduced, or even eliminated, once they have been identified. The detection of occupational hazards should therefore have a higher priority in any program of cancer prevention than their proportional importance might suggest.'[11]

There are currently approximately 23 000 cancer deaths per annum in Australia. Four per cent equals 920 deaths per year, ten per cent equals 2 300 and twenty per cent equals 4 600 deaths. None of these are acceptable figures for avoidable morbidity or mortality.

38. The IARC advises that 'The role of occupation in human cancer should be considered from the viewpoint of high risk, point-source chemical exposures at the workplace'.[12] This prescription for action is directed at known potent human carcinogens. The IARC believes that the work on further identifying and evaluating discrete carcinogens within the environment should be intensified as it is not only essential for identifying hazards already present but in providing early warnings of potential new hazards.[13] Epidemiology is essential at present in identifying and evaluating those factors which at present are not identifiable in the laboratory situation such as the effect of dietary and social habits on cancer formation. While its long-term objective is identification and prevention, the shortcoming of epidemiology is that it is limited to counting the victims after the event. The Committee believes that the first line in the prevention of chemical cancers is the identification and control of carcinogenic agents before they are unleashed in the human environment.

Conclusion

39. The overall control of hazardous chemicals in Australia is poor, particularly when compared with other developed countries. It is relevant before further describing the situation in Australia to examine overseas control mechanisms.

Endnotes

1. Toxic Chemicals and Public Protection, A report to the President by the Toxic Substances Strategy Committee, Washington, May 1980.
2. Doll and Peto, p. 1205.
3. IARC Annual Report 1979 p. 17, WHO p. 242.
4. D.L. Davis, K. Bridbord, and M. Schneiderman, 'Cancer Prevention: Assessing Causes, Exposures, and Recent Trends in Mortality for U.S. Males 1968-1978', Teratogenesis, Carcinogenesis and Mutagenesis, 2:105-135, 1982.
5. R. Doll and R. Peto, 'Avoidable Risks of Cancer in the U.S.' Journal of National Cancer Institute, Vol. 66, No. 6, June, 1981, p. 1203.
6. Doll and Peto, p. 1239.
7. Doll and Peto, p. 1258.
8. Doll and Peto, p. 1258.
9. Doll and Peto, p. 1256.
10. Doll and Peto, p. 1256-7.
11. Doll and Peto, p. 1245.
12. IARC Annual Report 1979, p. 20.
13. IARC Annual Report, p. 22.

CHAPTER 2

Chemical Control in Other Countries Including International Cooperation

Introduction

40. Many countries are developing or have recently enacted legislation that provides for assessment of the effects of chemicals in commerce, at the pre-market stage, or at the premanufacture stage. Countries which introduced chemical control legislation during the 1970s include Japan, Norway, Sweden, Switzerland, France, Canada, the United States and the United Kingdom. Although national regulatory control programs for toxic substances differ substantially, they have a common objective—the protection of human health and the environment. The primary objective with respect to the entry of hazardous chemicals into the environment has become prevention rather than cure.

European Economic Community (EEC)

41. In June 1979 the EEC Council adopted the Sixth Amendment to the 1967 Directive on Packaging and Labelling of Dangerous Substances. The Sixth Amendment requires manufacturers of new chemicals to notify the responsible national authorities of their intention to introduce a new chemical into commerce. Notification must be submitted 45 days prior to marketing and must be accompanied by a dossier of specified technical information. The required information includes identity, physical/chemical properties, anticipated production and uses, and a 'base set' of toxicological and ecotoxicological data. As the volume of production increases, further notification must be given and additional testing by the manufacturer may be required.

42. Like all Community Directives, the Sixth Amendment was required to be implemented by national legislation in each country within two years of adoption. Existing chemical control or notification legislation, such as that in France, the United Kingdom, and Denmark, was modified as necessary to conform with the Sixth Amendment.

43. The Sixth Amendment requires a pre-market testing of new chemicals with testing and hazard assessment procedures being determined by production volumes. It does not cover existing chemicals and makes no provision for public access to health and safety data submitted by manufacturers.

United States of America (USA)

44. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) first enacted in 1947 and amended over the years, requires the pre-market registration of pesticides. FIFRA requires the submission of confidential data for registration and makes health, safety and other data routinely available to the public. Pesticides are classified for general or restricted use. Notice of applications for registration are published in the Federal Register to allow for comment.

45. The Toxic Substances Control Act (TSCA) was enacted by Congress in 1976 and came into full effect in mid-1979. Under the Act the Environmental Protection Agency (EPA) is authorised to obtain data from industry on the production, use, health effects

and other matters concerning chemical substances and mixtures. If warranted, the EPA may regulate the manufacture, processing, distribution in commerce, use, and disposal of a chemical. Products which are regulated under other laws, such as pesticides, drugs and food additives are exempted.

46. The Toxic Substances Control Act provides that the Environmental Protection Agency can require testing by manufacturers of any new or existing chemical deemed to present an unreasonable risk to health or to the environment. In the case of new chemicals entering the market, the manufacturer (including importers) must give 90 days notice before manufacture. Significant new uses of an existing chemical are similarly covered. These notices are to include the chemical's name, identity and structure, proposed use, estimates of amount to be manufactured, by-products of manufacture, processing and disposal, and test data relating to health and environmental effects of the chemical. Under the laws, manufacturers have the responsibility of developing data on health effects, although the EPA can grant exemptions to small scale producers. The Administrator of the EPA may prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical if additional data is required to ascertain whether the substance does not present an unreasonable risk. The Administrator may find that the new chemical presents an unreasonable risk to health or the environment and order limitation (even to the extent of prohibition) of its manufacture, use and disposal. A court order is necessary if the company concerned objects. Chemicals controlled under existing laws are excluded. The Agency must give reasons when it elects not to act, and it is also open to private citizens to petition it. Its regulation is to be preceded by informal hearings, although to cope with extreme hazards, provision is made for rules having immediate effect. In 1979 the EPA administration produced a list of 43 000 existing chemical substances. Chemicals not in this listing are regarded as new chemicals. A provision of about $10 to $16 million annually is made for administration of the Act.

47. Imported chemicals are subject to the same regulations and restrictions as those manufactured in the United States. However, these regulations do not apply to chemicals which are exported to other countries.

48. In the case of chemicals already in use, an interagency expert committee designates chemicals of priority concern. The EPA Administrator may then require testing and evaluation of these chemicals for potential risks to the environment.

49. The EPA has established an Office of Pesticides and Toxic Substances to administer the Act. It is understood that this office presently employs a staff of approximately 3000. Its annual operating budget has grown rapidly to US$100 million.

50. The TSCA provides for premanufacture (as distinct from pre-market) notification. It applies to existing as well as new chemicals but does not specify mandatory testing of all new chemicals. Recent United States legislation provides for the release of certain health and safety data to the public.

Japan

51. Japan was amongst the earliest of the industrialised nations to introduce, in 1974, a comprehensive law providing for the pre-marketing examination of new chemical substances for biodegradability, bioaccumulation and possible health hazards, and for regulation of the production, import and use of chemicals. Early introduction of the law, and its provision for evaluation and monitoring of existing chemicals as well as for new chemicals, no doubt reflects the concern generated by the disastrous incidents involving chemicals in Japan.

Stockholm Meeting

52. A high-level meeting in Stockholm in April 1978, attended by 16 countries including Australia and six international organisations, was an important step toward co-ordinated international control of toxic substances. The discussions were far-ranging, covering environmental and public health aspects of toxic substances, information and data, trade secrets, and risk-benefit assessment. A list of priority tasks requiring action at national and international levels was agreed upon. The Organisation for Economic Cooperation and Development, whose member nations produce approximately 70 per cent of the world's chemicals, was considered the most appropriate organisation for action on these items. Recognition was also given to the important roles of the World Health Organisation, the United Nations Environment Program, the Economic Commission for Europe, the International Labour Organisation, and other organisations. Most delegations agreed that 'consideration should be given to preparatory work for a future international agreement in the area of toxic and hazardous chemicals'.

Organisation for Economic Cooperation and Development (OECD)

53. During the past four years the OECD has strengthened and expanded its chemicals program, in part as a result of agreements reached at the Stockholm meeting. In addition to the regular elements of the OECD Chemical Program (wildlife sampling and analysis, information consultation procedure, information exchange and development of methods for assessing economic and trade effects of regulatory actions), the development of testing guidelines under the Chemicals Testing Program has been a major effort since 1977. Rapid progress has been made in comparison to other international bodies. The goal of the OECD Chemicals Program is to establish an international framework to make testing of chemicals more systematic, relevant and cost effective so as to achieve increased exchange and acceptance of test data between countries. This program is centered in the activities of six expert groups in the following areas: physical-chemical properties, long-term toxicology, short-term toxicology, ecotoxicology, degradation/accumulation, and step-sequence testing. The groups' reports were published in 1980.

54. In October 1978 the OECD Council approved a Special Program on the Control of Chemicals to undertake supplementary work to develop and harmonise chemical control practices. The Program had three priority projects for 1979-81:

- good laboratory practices;
- confidentiality of data; and
- international glossary of key terms.

55. Development of consistent standards for good laboratory practices and a means of enforcing them is a very high priority. If national regulatory agencies cannot be assured of the quality of data presented to them, efforts to harmonise regulation cannot succeed. In regard to confidentiality of data, recent US legislation provides for the release of certain health and safety data to the public, whereas most other major chemical-producing countries do not disclose information on chemicals. These differences pose serious policy and economic difficulties. The third priority project, development of an international glossary of key terms, is critical to international data sharing.

56. More recently the Chemicals Group has focussed on investigations into the economic implications of national policies for the management of chemicals. A

substantial initiative has commenced to develop an international collaborative effort on evaluating the possible hazards of chemicals already in use in OECD countries.

57. Industry participates in OECD consultations through the Business and Industry Advisory Council (BIAC). A BIAC sub-committee involves industry in the work of the six expert testing groups and in the projects of the Special Program on the Control of Chemicals. The sub-committee enables industry views to be represented in the development of OECD positions affecting them and enables companies and trade associations to be informed of OECD activities.

58. In late 1980 the OECD Council adopted recommendations on chemicals testing guidelines, minimum pre-market data, generic good laboratory practices, mutual acceptance of data, and future activities of the Chemicals Program.

59. The Department of Home Affairs and Environment through the secretariat of the National Advisory Committee on Chemicals is actively involved in the OECD Chemicals Program. The notification and assessment procedures being developed by the NACC are based on the OECD notification scheme.

United Nations Agencies

60. A number of United Nations agencies play important roles in international cooperation on hazardous chemicals management. These are the United Nations Environment Program (UNEP), the International Labour Organisation (IL0), the World Health Organisation (WHO) and the Food and Agricultural Organisation (FAO).

The International Register of Potentially Toxic Chemicals (IRPTC)

61. The International Register of Potentially Toxic Chemicals is part of Earthwatch, the global environmental assessment program of the United Nations Environment Program (UNEP). The IRPTC is a system for collecting and collating data on chemical substances for use in risk assessments worldwide. Although the idea originated in 1971, the Register was only recently begun.

62. The IRPTC will combine national registers and produce information bulletins on particular chemicals. It is cooperating with the World Health Organisation on a chemical safety program. The NACC is hoping to incorporate IRPTC data in its National Chemicals Information System.

The World Health Organisation (WHO)

63. The World Health Organisation, a United Nations organisation with more than 20 years' experience in chemical assessment, has gained international acceptability because of its scientific standards and impartiality. Panels of experts assembled by WHO have developed principles for the toxicological assessment of chemicals. The International Agency for Research into Cancer is a specialist body of WHO which develops principles for assessing carcinogenicity and which publishes monographs on the carcinogenic hazard of individual chemicals and processes. The Department of Health maintains direct contact with WHO.

64. The UNEP, WHO and ILO are cooperating on an International Program of Chemical Safety. The principal objectives of the program are to:

- carry out and disseminate evaluations of the risk to human health from exposure to chemicals, based on existing information and data;

- encourage the use and improvement, and in some cases the validation, of methods for laboratory testing and epidemiological studies that are suitable for health risk evaluations; and propose appropriate methods for assessing health risks, hazards, benefits and exposure;
- promote effective international cooperation with respect to emergencies and accidents involving chemicals; and
- promote training of the manpower needed for testing and evaluating the health effects of chemicals, and for the regulatory and other control of chemical hazards.

65. Other objectives include the coordination of laboratory testing and of epidemiological studies where an international approach is appropriate and the promotion of research to improve the scientific basis for health risk assessment and control of chemical hazards. Both the Department of Health and the Department of Home Affairs and Environment are maintaining contact through UNEP with the Effect of Chemicals on Health Program.

The Food and Agricultural Organisation (FAO)

66. The Food and Agricultural Organisation of the United Nations is addressing international harmonisation of pesticides registration requirements and developing guidelines for environmental hazard assessment. Unlike toxic substances in general, pesticides have been subject to national controls for many years, making harmonisation of requirements extremely difficult at this stage.

67. The FAO and WHO are also involved in the activities of the Codex Alimentarius Commission relating to food standards. The Commission is an international body in which government and industry representatives participate to establish common food standards, including standards for maximum acceptable limits of pesticide residues in food. To assist in the effort, a joint FAO-WHO committee of experts has been providing toxicological evaluation of food additives. Because the process of using such expert committees has been slow, plans are being made to use cooperating centres of technical advice in several locations.

68. The Department of Primary Industry has strong connections with FAO, WHO and the Codex Alimentarius Commission. FAO and WHO have promoted and facilitated international cooperation on agricultural and veterinary chemicals. In 1979, FAO produced international guidelines on the environmental criteria for the registration of pesticides.

69. The Department of Health maintains direct contact with WHO, and indirect contact with Codex Alimentarius.

The International Labour Organisation (ILO)

70. The International Labour Organisation, a specialised United Nations agency, sponsors the International Program for the Improvement of Working Conditions and Environment and the International Occupational Safety and Health Hazard Alert System. The latter is a worldwide information network for newly discovered occupational safety and health dangers.

71. The International Labour Organisation has a computerised data bank in Geneva which can be accessed by the Department of Employment and Industrial Relations. The system, called the CIS system, provides searches of all journals in the fields of health, safety and toxicology as well as computer data bank searches. The main

computer data bank provides a wide range of information on health and safety aspects of chemicals as well as radiation and physical agents.

Other Forums

72. Some environmentally hazardous substances affect the world environment in a way that can be controlled only through international action, for example, wastes dumped in the ocean and chlorofluorocarbons in the stratosphere. The Committee dealt with marine pollution and the London Dumping Convention in its First Report which was on Hazardous Chemical Wastes.[14]

Endnotes

14. Hazardous Chemical Wastes —Storage, transport and disposal, House of Representatives Standing Committee on Environment and Conservation, AGPS, Canberra, March 1982 (Paragraphs 218-227).

CHAPTER 3

Present Legislative and Administrative Arrangements

Legislative Arrangements

73. The legislative arrangements through which potentially hazardous chemicals are presently managed in Australia are numerous and fragmented. Commonwealth legislation includes Acts such as:

- Customs
- Environmental Protection
- Therapeutic Goods
- Environment Protection (Sea Dumping)[15]
- Trade Practices
- Navigation
- Air Navigation

State and Territory Acts include titles such as:

- Dangerous Goods
- Pesticides
- Poisons
- Noxious Trades
- Health
- Factories and Shops
- Food and Drugs
- Agricultural Chemicals
- Stock Foods & Medicines
- Inflammable Liquids
- Liquified Gases
- Explosives
- Radioactive Substances
- Aerial Spraying
- Consumer Protection
- Environment Protection

74. Many of the powers for the regulation of hazardous chemicals are regarded as being constitutionally State powers. The principal regulatory mechanisms, where they exist, are pre-marketing assessment leading to registration of some kind, labelling requirements, sales restrictions, and exposure or emission limits. Many witnesses representing industry, consumers, professional and conservation groups called for more comprehensive controls over chemicals and uniformity of regulation across Australia. Some have also called for a greater international uniformity of controls. A number of witnesses have sought a single body to be responsible for screening, assessment, operation of a data bank and other dissemination of information on hazardous chemicals to avoid costly duplication and confusion.

75. The Committee has been concerned from the outset of the Inquiry to ensure that legislative and administrative arrangements are comprehensive in their coverage of all potentially hazardous chemicals, are coordinated and are uniform in their requirements between State and Commonwealth responsibilities and between the States themselves. The Australian Constitution was obviously not drawn up with the management of hazardous chemicals in mind. Controls, which have grown in a piecemeal fashion, are split between State and Commonwealth responsibilities although the majority of regulatory mechanisms are State responsibilities. Within both State and Commonwealth jurisdictions regulation is divided between a number of departments. The task then is to seek mechanisms to overcome constitutional difficulties and ensure uniformity and coordination of measures within and between the States and between the States and the Commonwealth. Such mechanisms should provide advice and regulation of a high order. The opportunity is provided in an inquiry such as this to take a broad view. Many of the fragmented mechanisms which exist at present are due to

their each having been conceived and developed within the administrative framework of a single department and in many cases being amendments to Acts originally designed for other purposes. On the other hand a single department controlling all chemical hazards may not provide the most effective control in all areas. For example, transport regulations are best administered by transport authorities.

76. A number of cooperative bodies already exist which allow assessment to be undertaken at a national level, with the participation of State and Commonwealth Governments. The major bodies under which assessment of potentially hazardous chemicals is undertaken at the national level prior to some form of registration are the Australian Agricultural Council (AAC), the Australian Drug Evaluation Committee (ADEC), the National Health and Medical Research Council (NH&MRC), and the Australian Environment Council (AEC). The ADEC is a Commonwealth body while the others are State/Commonwealth cooperative bodies. The AAC, AEC and NH&MRC have as members representatives of State, Territory and Commonwealth Governments. The NH&MRC also has a number of non-government members.

77. The matters considered by these bodies are in general considered by member governments to require a uniform approach. These mechanisms avoid costly duplication of assessment and allow the best use to be made of the limited expertise available in Australia. The cost to each State, Territory and the Commonwealth of undertaking its own assessment and the subsequent cost to industry and the community of the likely different regulatory requirements have no doubt played a large part in ensuring the acceptance by governments of these cooperative bodies and their recommendations. Increasing community pressure for the assessment of a wider range of chemicals would raise even further the cost to governments of each State and Territory conducting individual assessments. While the implementation of the recommendations of these bodies eventually occurs in most matters, some of the exceptions are important. Implementation does not always result in uniformity. The Committee believes that the system of cooperative State/Commonwealth bodies could be improved. It is essential that assessments and regulatory measures are both comprehensive and fully coordinated. At present they are neither.

78. While the AAC, ADEC and NH&MRC generally cover the assessment and regulation of food additives, pharmaceuticals, veterinary and agricultural chemicals, poisons and pesticides, the remaining chemicals used in industry and in the home have not been subject to assessment. The occupational health situation is still characterised by a 'wait and see' approach where, until chemicals are shown beyond doubt to have deleterious effects, they go unregulated. Under State and Territory Poisons legislation many of those existing chemicals posing hazards should have been assessed by the Poisons Scheduling Committee (PSC) of the NH&MRC. But it appears that not all chemicals covered by Poisons Acts are submitted to the PSC. In 1977, the Australian Environment Council formed the National Advisory Committee on Chemicals (NACC) to assess the environmental effects of chemicals used in industry. The NACC has members from each State, Territory and the Commonwealth and provides a framework within which a uniform approach to assessing and regulating environmentally hazardous chemicals can be achieved.

Australian Agricultural Council

79. The Australian Agricultural Council, which commenced in the mid-1930s, has as its members the Ministers for Agriculture from each State, the Northern Territory and the Commonwealth. Within the Council's structure are two assessment bodies which conduct the evaluation of chemicals prior to registration. Registration of these

chemicals is withheld by state authorities until clearance from the relevant technical committee is obtained. Registration by the state authority is then in accordance with the terms specified by the technical committee. Chemicals must be re-registered either annually or every three years depending on the State. Re-registration does not ordinarily involve reassessment. Control over availability, sale and labelling of pesticides is regulated in four States by agriculture departments and in the other two by health departments. Veterinary drugs and feed additives are regulated by agriculture authorities. Both committees have an explicit responsibility to refer data, where appropriate, to the relevant NH & MRC committee for:

(a) Poisons Schedule classification;

(b) setting of Maximum Residue Limits in specific commodities.

The health assessment of these chemicals is conducted by the two relevant NH & MRC Committees. Assessment procedures would appear to take approximately four months.

Technical Committee on Agricultural Chemicals (TCAC)

80. The TCAC has as members a representative of the Governments of each State and the Northern Territory (usually the Registrar of Agricultural Chemicals or Pesticides), the NH & MRC and is chaired by the Department of Primary Industry. The ACT is not represented on the Committee. It assesses proposals for new chemicals or new uses for existing ones.

81. An agricultural chemical is defined as:

(a) any substance or mixture of substances used or intended to be used for preventing, destroying, repelling, attracting, inhibiting or controlling any insects, rodents, birds, nematodes, bacteria, fungi, weeds or other forms of plant or animal life or viruses, which are pests; and

(b) any substance or mixture of substances used or intended to be used as a plant regulator, promoter, defoliant or desiccant;

in agricultural, food storage, household, industrial and non- agricultural applications.

Technical Committee on Veterinary Drugs (TCVD)

82. The TCVD has as members a representative of the Governments of each State and the Northern Territory, the Bureau of Animal Health, the NH&MRC and is chaired by the Department of Primary Industry. The ACT is not represented on the Committee. It assesses veterinary drugs used for the medication of food producing animals.

83. A veterinary drug is defined as:

(a) any substance or mixture of substances used or intended for use in preventing, destroying, inhibiting or controlling any parasites, diseases or conditions of farm animals including poultry, fish and bees;

(b) any substance or mixture of substances added to the basic feed mix for continuous long term administration to livestock for specific purposes; for example enhancing production, or maintenance of health above the levels obtained from the basic feed, improvement of storage qualities and/or the palatability of the basic feed mix; and

(c) preparations which purport to cure, alleviate or diagnose disease of or injury to stock, or improve the capacities of stock for progeny production or work;

used for the mass medication of food producing animals.

Australian Drug Evaluation Committee

84. While the Committee does not intend to look at pharmaceutical assessment and control in any detail the mechanisms by which pharmaceutical drugs are assessed and controlled are of interest because they are Commonwealth controlled and they cover an important segment of potentially hazardous chemicals.

85. The Commonwealth Therapeutic Goods Act 1966 covers therapeutic goods: imported into or exported from Australia; subject of trade or commerce among the States; supplied as a pharmaceutical benefit under a law of the Commonwealth; and, supplied to the Commonwealth. Since the majority of new drugs reaching the marketing stage in Australia have been imported, at least in the first instance, the Commonwealth's responsibility for assessing and regulating imported therapeutic substances has formed the basis of Australia's principal drug evaluation system. There are, however, a number of pharmaceutical products manufactured in Australia from local ingredients which therefore escape control by this mechanism.

86. Control over imports is exercised through the Customs (Prohibited Imports) Regulations which require, in effect, that all importations of therapeutic substances and their subsequent distribution in Australia, must be approved by the Commonwealth Director-General of Health. Further Commonwealth controls are provided under the Narcotic Drugs Act and the Quarantine Act.

87. The Therapeutic Goods Act establishes under its Regulations the Australian Drug Evaluation Committee (a Commonwealth body) which makes extensive medical and scientific evaluation of preparations subject to the Act. This includes pharmacology, toxicology and metabolism studies and measures of their teratogenic and carcinogenic potential. (A large proportion of known human carcinogens were medicinal ingredients while the drug Thalidomide is perhaps the best known teratogen). The National Therapeutic Goods Committee has as members, representatives of each State, Territory and Commonwealth Government. It recommends action to coordinate legislation and administration of controls on therapeutic goods.

National Health and Medical Research Council

88. The Council was constituted by the Governor-General by Order in 1936. The Council has as members the Commonwealth Director-General of Health as Chairman, two officers of the Commonwealth Department of Health, a representative of the Commonwealth Serum Laboratories Commission, the permanent head of each of the State and Northern Territory Health Commissions or equivalent authority and 16 other members representing mostly professional medical associations. The Chairman of the Capital Territory Health Commission is not a member. The Council and all of its committees are serviced by the Commonwealth Department of Health.

89. Reporting directly to the NH&MRC are three Advisory Committees devoted to Medical Research, Medicine and Public Health. The public health functions of the NH&MRC are:

(a) to inquire into, advise and make recommendations to the Commonwealth and the States on matters of public health legislation and administration and on any other matters relating to health, medical and dental care and medical research.

90. The Public Health Advisory Committee (PHAC) of the NH&MRC has as its terms of reference:

(a) to inquire into and advise the Council on all matters of public health and preventive medicine and matters involving health legislation and administration by the Commonwealth and State Governments;

(b) to receive and consider reports of a number of expert committees (currently 16) and transmit to Council its recommendations on the reports of these committees.The structure of the NH&MRC and its committees is shown in Figure 1.

91. Committees and sub-committees reporting to the PHAC and relevant to the Inquiry are the the Pesticides and Agricultural Chemicals Committee, the Poisons Scheduling Committee, the Carcinogenic Substances Committee, the Consumer Products Safety Committee, the Environmental Health Committee and its sub-committees on Air Quality and Water Quality Criteria, the Food Science and Technology Sub-committee of the Food Standards Committee, the Occupational Health Committee and its sub-committees on Asbestos and Occupational Hygiene, and the Radiation Health Committee. The membership of these committees comprises relevant expertise from government, industry, universities and colleges and professional and community organisations.

92. Three of these committees, the Food Science and Technology Sub-committee, the Pesticides and Agricultural Chemicals Committee and the Poisons Scheduling Committee operate in a similar way to the Australian Drug Evaluation Committee in that they assess and make recommendations on submissions from individuals or companies for the use of the particular chemicals referred to them. There is usually a legislative requirement that these chemicals be registered. In general, State authorities do not register chemicals which come within the terms of reference of these committees until the recommendation of the relevant committee has been considered and approved by the NH&MRC.

Food Science and Technology (Reference) Sub-committee (FST)

93. Whenever it is proposed to use a new food additive or to extend the use of an existing approved food additive, an application, prepared according to a set format, must be submitted for assessment to the FST. Once the use of a specific food additive is recommended by the Sub-committee it is considered by the Food Standards Committee for inclusion in the relevant model Food Standard. This is then subject to ratification by Council for recommendation to States and Territories for incorporation into appropriate legislation.

Poisons Scheduling (Standing) Committee (PSC)

94. The Department of Health told the Committee that:

> Before any poisonous substance can be marketed a detailed application must be prepared to a standard format for consideration by the Committee.[16]

95. Poisonous substances, including drugs, pesticides and agricultural chemicals are categorised into schedules according to their toxicity, hazard to health and approved use. After assessment, substances are either exempted from scheduling, allocated to one of eight schedules or listed as a prohibited substance. The PSC then makes recommendations to Council on the scheduling, labelling, first aid instructions, packaging and advertising of hazardous products. State and Territory Poisons Acts and Regulations control the distribution, sale of poisons and licensing of dealers in poisons.

Pesticides and Agricultural Chemicals (Standing) Committee (PACC)

96. The PACC is required to inquire into and make recommendations on maximum residue limits and associated problems concerning pesticides, veterinary medicines and incidental agricultural chemicals in food. Before a new pesticide (which includes a new use for an existing pesticide) can be used on food for human consumption a detailed application must be made for a maximum residue limit (MRL). The Committee uses the same information as provided to the Poisons Scheduling Committee plus specific material relating to residues.

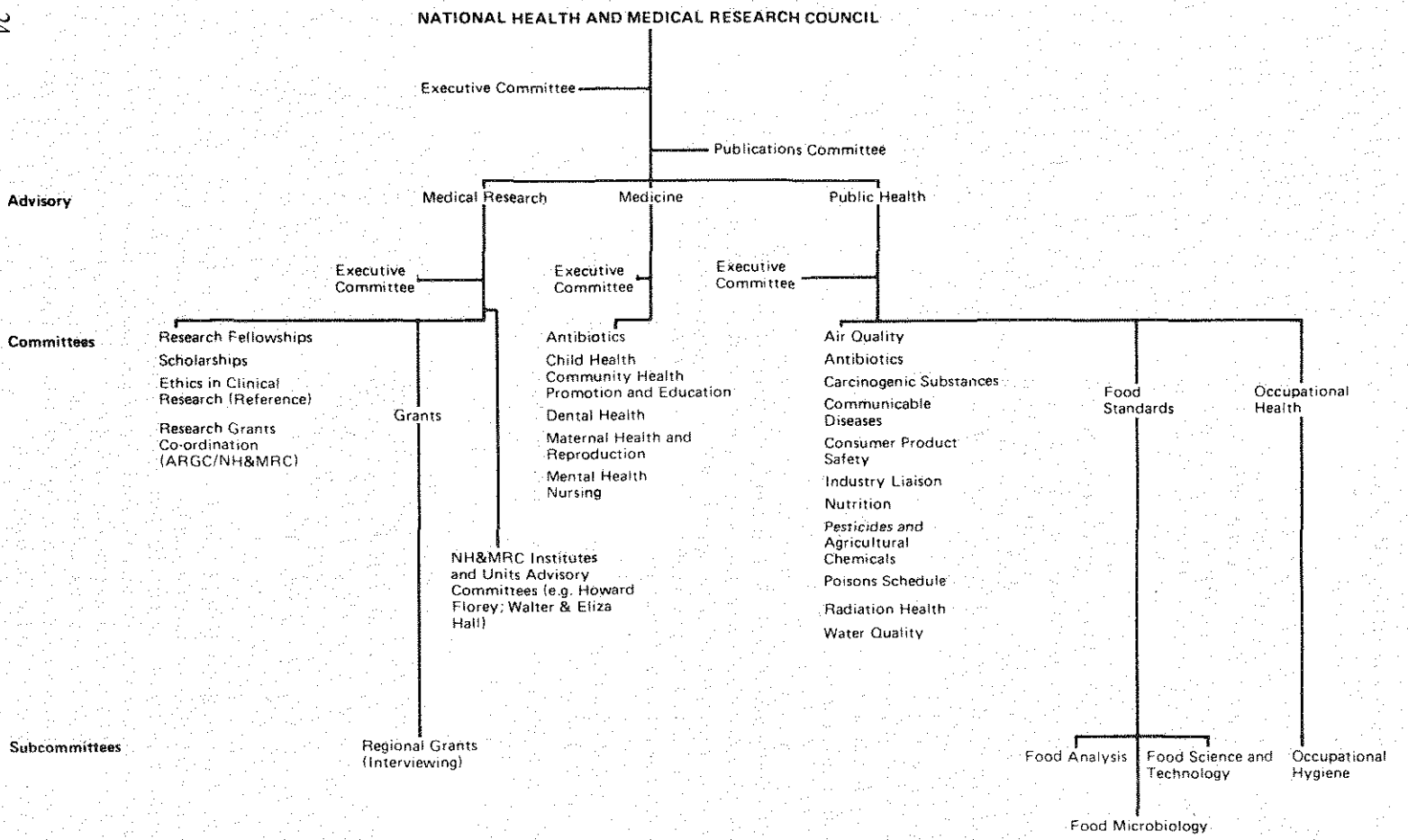
NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL
Executive Committee
Publications Committee
Advisory
Medical Research
Medicine
Public Health
Executive Committee
Executive Committee
Executive Committee
Committees
Research Fellowships
Scholarships
Ethics in Clinical Research (Reference)
Research Grants Co-ordination (ARGC/NH&MRC)
Grants
NH&MRC Institutes and Units Advisory Committees (e.g. Howard Florey; Walter & Eliza Hall)
Antibiotics
Child Health
Community Health Promotion and Education
Dental Health
Maternal Health and Reproduction
Mental Health
Nursing
Air Quality
Antibiotics
Carcinogenic Substances
Communicable Diseases
Consumer Product Safety
Industry Liaison
Nutrition
Pesticides and Agricultural Chemicals
Poisons Schedule
Radiation Health
Water Quality
Food Standards
Occupational Health
Subcommittees
Regional Grants (Interviewing)
Food Analysis
Food Science and Technology
Occupational Hygiene
Food Microbiology

Figure 1

Australian Environment Council (AEC)

97. Until recently, chemicals not requiring notification and assessment by the bodies described above, went largely unassessed. This included the bulk of chemicals used in industry. In August 1977 the Australian Environment Council (AEC), which consists of the State, Territory and Commonwealth ministers having prime responsibility for the environment, agreed on a National Action Plan on Environmentally Hazardous Chemicals. The recommendations in the report of the Working Party which constitute the Plan are at Appendix 4. At the same time, the AEC decided to establish a National Advisory Committee on Chemicals (NACC) to implement the Plan.

National Advisory Committee on Chemicals (NACC)

98. The NACC comprises representatives of the Commonwealth, States and Territories, the NH & MRC and the AAC. The thrust of the National Action Plan and program is towards the development of a national notification and assessment mechanism and appropriate coordination of control actions across Australia. The three basic elements of the plan are:

- notification and assessment of new chemicals and identification and assessment of existing chemicals;
- recommendations on environmental aspects of control measures; and
- information, monitoring and research.

99. A retrospective survey was undertaken of new chemicals which have entered the Australian market since 1974 to gauge the pace of introduction of chemicals. The response level of industry to this voluntary survey was unsatisfactory with less than half the companies responding. An interim voluntary notification scheme providing for the assessment of notified chemicals which was expected to commence late in 1980, finally got underway in September 1981.

100. This is the first major step towards a comprehensive notification and assessment scheme. The rate of notifications to date is lower than expected and there appears to be underreporting of new chemicals.[17] The NACC has established a technical committee similar to those of other assessment bodies to undertake the assessments required under the notification scheme.

101. As part of the assessment scheme for existing chemicals, NACC has given priority to a small group of chemicals. These are: alkyl phthalates, arsenic trioxide and other arsenic compounds, chlorine, copper-chrome-arsenate, cyanide, chromium, nickel, organic peroxides, pentachlorophenol, phenols, polycyclic aromatic hydrocarbons and toluene diisocyanate. These will be assessed in consultation with member governments. Background papers have been produced on TCDD, PCBs, cadmium and mercury.

102. The areas that NACC will be looking at in developing coordinated controls across Australia are manufacturing, import, export, transport, labelling, packaging, sale, use and disposal. Priority has been given to disposal of wastes and to a lesser extent transport and storage. A national study on waste disposal management by Maunsell and Partners Pty Ltd was completed in May 1981 but has still not been published by the AEC. NACC's involvement in developing a national strategy for the disposal of hazardous wastes was dealt with in the First Report. A national chemicals information system will be dealt with in Chapter 7.

103. Under the interim scheme, notification and provision of information is sought for:

- new chemicals;
- new chemicals contained in mixtures;
- certain new complex mixtures; and
- certain new uses of chemicals.

104. For the purpose of the scheme:

- a chemical is defined as a chemical element and its compounds as they occur in nature or as produced by man, and includes pure, technical and commercial grades of chemical substances.
- a new chemical is defined as a chemical which is being introduced in Australia by a particular manufacturer or importer for the first time.

105. The booklet describing the Interim Scheme specifies the following categories of chemicals as being excluded from the scheme.

- chemicals specifically subject to existing notification procedures, i.e. agricultural chemicals, pharmaceuticals, veterinary drugs, explosives and food additives (except where such chemicals are used or handled in a manner not dealt with under these other procedures);
- foodstuffs, feedstuffs and cosmetic products;
- chemicals obtained from an Australian supplier;
- chemicals used solely for research, development and analytical purposes, in quantities up to one tonne per annum;
- chemicals which are used solely as intermediates and which do not have a significant potential to enter the environment in the course of storage, transportation, etc.

  (An intermediate is defined as a precursor chemical, not including catalysts, which occurs or is introduced into a chemical process between the introduction of the basic reactants and the formation of the end products and is consumed by chemical reaction during that process.); and
- finished articles, such as moulded plastics, which are fabricated to a specified final form.

A target date for the introduction of a mandatory notification scheme has yet to be announced. This is dealt with further in the next Chapter.

Endnotes

15. This legislation was passed in 1981 but has still not been proclaimed. Proclamation has been delayed pending consultations with the States.
16. Transcript, p. 110.
17. Transcript, p. 3514.

CHAPTER 4

Adequacy of Existing Arrangements

106. It is clear that the assessment and registration of chemicals and the enforcement of standards and regulations are inadequate at present. Regulatory controls are far from comprehensive in the range of chemicals they cover. The fragmentation of controls between State and Commonwealth and within each level of government has prevented the full and rational coordination of controls of a high standard. In the EEC, a large number of diverse countries have agreed to be bound by firm legislative controls, such as the 'sixth amendment'. Australia as a federation of only eight governments has failed to devise and implement strong legislative and administrative controls over the range of chemical hazards.

107. The Committee believes that the Commonwealth has much greater power under the Constitution than it currently exercises, to set standards and legislate to control chemical hazards (see paragraphs 245 and 246 and Appendix VII of the First Report). The Committee believes that the Commonwealth should exercise these powers to introduce appropriate legislation as a matter of urgency. This legislation would have effect until such time as each State and Territory had in place its own legislation of an equivalent standard and extent. The Environment Protection (Sea Dumping) Act 1981 utilised such an approach.

Australian Agricultural Council

108. Several important groups of preparations are not assessed by the AAC's Technical Committees and it is most appropriate that they be covered by these committees rather than other assessment bodies.The Technical Committee on Agricultural Chemicals does not assess fertilisers or those feed additives not covered by the Technical Committee on Veterinary Drugs. Not every category of agricultural chemical is registrable in every State. Household and industrial insecticides are not required to be registered in Queensland and only recently gained some coverage in Victoria. As the chemicals excluded from assessment or registration may pose a risk to health or the environment they should be included in the assessment and registration process.

109. The Technical Committee on Veterinary Drugs covers only feed additives and veterinary drugs used in the mass medication of food producing animals. Other veterinary drugs would appear to escape assessment at the national level. The Standing Committee on Agriculture recently reviewed this question but made few changes. Most veterinary drugs not covered by the TCVD are covered by stock medicine boards in the States and are referred to the Poisons Scheduling Committee for assessment. The Commmittee believes that all such drugs should be fully assessed for the protection of the community and it appears appropriate that these should be conducted at the national level by the TCVD.

110. The Commmittee has had evidence of ointments used on dogs and horses producing serious injury to humans when used over a long period. In one instance the product had been repacked by a veterinarian without providing adequate labelling. A child died several years ago when exposed to a preparation for cattle, repacked by a veterinarian for use on a dog. Packaging and labelling requirements need greater enforcement in this area.

111. The Department of Primary Industry says that the work of both Committees is closely integrated with that of the relevant NH&MRC Committees with assessment proceeding concurrently and a system of interlocking membership. The Department of Health advised that clearance of a chemical by the Technical Committees requires full support from the NH&MRC and that if the NH&MRC recommends against clearance on toxicological grounds, the application is not proceeded with.[18] Health assessment is not simply in terms of clearance or rejection but involves the acceptability of risks from often highly toxic chemicals weighed against the need for a chemical and the controls proposed over its use. The adequacy of the assessment of health implications of agricultural and veterinary chemicals considered by the technical committees is therefore solely the responsibility of the NH&MRC.

112. There is some question as to whether the environmental assessment by these committees is as comprehensive as that intended eventually by NACC. The Committee believes that it is more appropriate that the environmental assessment of all chemicals is conducted by the NACC which will have the degree of environmental expertise required.

113. Despite machinery to coordinate assessment at the national level, State legislation is revised from time to time in an uncoordinated way. The Department of Primary Industry described it as:

> a leapfrogging arrangement—the one with the oldest legislation updates it and takes the benefit of all the knowledge of the others and the latest developments overseas.[19]

The low priority given to having up-to-date legislation and the slow rate of change together with the absence of regulation in the ACT are a cause for concern. The agricultural and veterinary chemicals situation provides a strong case for developing uniform legislation and administrative mechanisms at a national level which can develop high standards and implement changes quickly and uniformly.

114. The Australian Capital Territory has the same responsibility as the States and the Northern Territory to assess and regulate agricultural and veterinary chemicals but is not represented on the two Technical Committees. It is not represented on the Australian Agricultural Committee nor on the Standing Committee on Agriculture. It was clear from the evidence given by the Department of Primary Industry that neither the Minister for Primary Industry nor the Department represents the Australian Capital Territory on these Committees. This omission has to be considered along with the fact that the ACT has no legislation to control agricultural or veterinary chemicals. The Australian Capital Territory should be represented on these bodies for the same reasons that the States and the Northern Territory are. The Committee recommends that:

> **the Minister for Primary Industry, the Minister for the Capital Territory and the Minister for Health make the necessary arrangements for the Australian Capital Territory to be represented on the Technical Committee on Agricultural Chemicals and the Technical Committee on Veterinary Drugs.**

115. Many agricultural and veterinary chemicals were registered many years ago when little or no toxicological assessment was necessary. Although these chemicals require re-registration every year (three years in some States) there is no program for their re-evaluation in the light of current toxicological knowledge.[20] Some existing chemicals are reassessed but only after deleterious effects are noticed. While some deleterious effects may be identified over a long period of use this is not always the case. There are few epidemiological resources to enable detection of less obvious but often serious effects.

116. Assurances were given on the safety of agricultural chemicals by the Department of Primary Industry that:

> If the product is used with reasonable common sense and in compliance with the directions on the label the hazard will be absolutely minimal.[21]

These assurances may be relevant to recently registered chemicals but in the absence of defined programs to ensure the assessment of chemicals not previously assessed, these assurances are quite misleading. The Committee has further reservations about current assessments which are discussed later in this and the next Chapter.

117. The aerial application of agricultural chemicals has been referred to in submissions as a problem area. Not all chemicals applied aerially pose significant health hazards. Those that do require careful control. Incidents involving hazardous chemicals include:

- persons and food producing animals being sprayed;
- non-target land being sprayed through pilot error or wind drift; and
- houses and schools being sprayed with subsequent contamination of yards, drinking water and dams.

118. The control over aerial spraying or dusting is fragmented and incomplete. The control over aircraft movements is exercised by the Commonwealth Department of Aviation (formerly the Department of Transport) under the Air Navigation Orders. These regulate the aircraft equipment for containing and dispensing chemicals and the horizontal and vertical clearances from occupied buildings. These orders are related solely to aircraft operational safety and noise considerations. Chemical safety provisions of aerial application are regulated by State and Territory Governments although New South Wales, the Northern Territory and the Australian Capital Territory lack any effective controls over aerial application of agricultural chemicals. The NH&MRC has produced a model code for the safe aerial application of agricultural chemicals.

119. The Committee believes that there is wide scope for chemical mismanagement and hazard from aerial spraying with legislation being so fragmented and in many cases lacking. Uniform national legislation is necessary with the same provisions binding both State and Territory legislation and under the Air Navigation Orders. The Committee recommends that:

> **after consultation with the States and the Northern Territory comprehensive chemical safety provisions be incorporated in the Air Navigation Orders under the Air Navigation Regulations.**

National Health and Medical Research Council

120. Under the umbrella of the NH&MRC Public Health Advisory Committee, the Pesticides and Agricultural Chemicals Committee, the Poisons Scheduling Committee and the Food Science and Technology Sub-committee assess chemicals prior to some form of registration. Other committees such as the Carcinogenic Substances Committee and the Occupational Health Committee have an ad hoc advisory role, rather than one of screening or mandatory assessment following notification. They frequently have substances referred to them from one of the mandatory assessment committees. To effectively protect community health from hazardous chemicals the three assessment committees would have to assess all chemicals, other than therapeutic goods, prior to registration and marketing but many chemicals do not require notification to, and assessment by, these Committees.

121. The committees under the Public Health Advisory Committee have the appearance of having grown in an uncoordinated way. The Department advised that the Carcinogenic Substances Committee arose out of a growing concern over carcinogenic substances by the Occupational Health Committee.[22] The NH&MRC still has no notification and assessment mechanism for the bulk of industrial chemicals. Despite the NACC being formed by the Australian Environment Council in 1977 to devise and implement a notification and assessment scheme for industrial chemicals; despite having an NH&MRC representative on the NACC and despite the NACC commencing its interim notification scheme in September 1981, the NH&MRC has still not provided an assessment body to assess the health implications of chemicals notified to the NACC. The assessment by the NH&MRC of chemicals is not comprehensive. For example, cosmetics and other toiletries which are applied directly to the skin or may be ingested do not require assessment. The gap in chemical assessment and regulation are serious.

122. The South Australian Government said of the public health side of the NH&MRC:

> In spite of its own committee to review committees there is a good deal of overlapping of functions. Most of the committees consist of part-time members, meeting at most twice yearly. After matters have been shuffled between committees and finally resolved, they then pass to the Public Health Advisory Committee, which meets twice yearly; if that committee does not refer the matter back to another committee, it finally passes to the plenary session of the National Health and Medical Research Council.[23]

This process has recently been streamlined by giving the Public Health Advisory Committee some autonomy. The South Australian Government and the Australian Chemical Industry Council also pointed out that standards setting committees had not met as frequently as they should because funds for travel were limited.[24] While frequency of meetings is not the sole criterion for determining effectiveness, several witnesses have criticised the slowness of the NH&MRC in dealing with identified problems.

123. The Australian Chemical Industry Council criticised the current NH&MRC schedule of carcinogenic substances. These are incorporated in the Model Carcinogenic Substances Regulations prepared by the Carcinogenic Substances Committee. The New South Wales Government in introducing legislation based on the code has had to add carcinogens not on the list.[25] The International Agency for Research on Cancer, a part of the World Health Organisation, lists 43 known human carcinogenic substances or processes. The NH&MRC lists only 13. The NH&MRC table of Threshold Limit Values has a more extensive list of carcinogens than that attached to the model carcinogen code. Twice there has been virtually a year between meetings of the Carcinogenic Substances Committee.[26] It has met six times in the four years since it was established in November 1978.

124. One must question the effectiveness of the Carcinogenic Substances Committee given the above shortcomings, the infrequency of meetings and the lack of resources available. The dearth of information available to such a specialist committee is appalling. One member of the Carcinogenic Substances Committee, Dr S. F. McCullagh, of James Hardie and Co. Pty Ltd, pointed out that the Committee had wanted a list of carcinogens, but none was available. This had hindered the work of the Committee.[27] This is a Committee which requires specialist knowledge and resources.

125. The Department of Health noted that the proliferation of information and concern about hazardous chemicals has not been matched in Australia by proliferation of the resources and finance available.[28] The very purpose of NH&MRC public health committees is to make the best use of a small number of members and staff to produce assessments and set standards of a high order. They should maximise efficiency by

preventing the costly duplication of these functions in each State and Territory. To skimp on the staffing and resources of these committees is to defeat their purpose. The costs of failure in the areas considered by the major public health committees is high. The Committee recommends that:

funding of National Health and Medical Research Council public health assessment committees should be adequate so as to enable them to effectively fulfill their function.

126. The Committee's comments relate only to deficiencies in the public health assessment area of the NH&MRC. The NH&MRC has otherwise been a very worthwhile body achieving a great deal in attaining high standards and uniformity in many health areas throughout Australia. It has overcome many of the constitutional barriers to developing a national approach in health matters.

127. Poisons scheduling, in conjunction with the State and Territory legislation which enforce it, is a control over marketing, labelling and packaging of drugs and poisons. It is somewhat disjointed, with its functions no doubt having evolved over time. The Department of Health stated that:

> The PSC inquires into . . . drugs, poisonous and other substances hazardous to human health. Before any poisonous substances can be marketed a detailed application must be prepared to a standard format for consideration by the Committee.[29]

When asked how a manufacturer determined whether a product was a 'poison' requiring scheduling the Department of Health advised that: 'all chemicals sold on the domestic market irrespective of their degree of toxicity are regarded as poisons and are therefore subject to scrutiny by the PSC. Legally no chemical has to be put to the PSC before release onto the market. However, the system of State inspection under various legislation ensures that virtually all such chemicals have been or will be subject to scrutiny'. If this were true then it would overlap to a large extent with the NACC notification and assessment scheme for new chemicals but despite this, it does not appear to have systematically identified and assessed all new chemicals in the past other than notifiable drugs and agricultural and veterinary chemicals. A quick visit to a hardware store, an art and craft supplier or supermarket will yield a number of poisons, as defined above, but lacking some or all of the required warnings or controls. These would appear not to have been assessed by the PSC.

128. Several witnesses have pointed to confusion in the mind of the public and lack of consistency in the schedule. In scheduling, products are allocated to one of the seven schedules, to the prohibited substances list or exempted from scheduling. These seven schedules are not on a sliding scale. The Committee believes that while poisons scheduling may be effective in specifying materials to be available only on prescription it is not an adequate control mechanism for ensuring the safety of the wide range of hazardous chemicals available. As mentioned earlier, not all hazardous chemicals are scheduled as poisonous. This is particularly a problem with industrial chemicals.

129. Poisons legislation requires certain categories of chemicals to be sold only by a licensed seller of poisons and that other conditions of sale be met. The Committee was told by the Capital Territory Health Commission that methyl ethyl ketone peroxide (MEKP) 'can only be sold by a holder of a licence under the Poisons and Dangerous Drugs Ordinance 1933'. Section 18 of the Ordinance states:

(i) Any person who sells any poison to any person who is under eighteen years of age or who is unknown to the vendor, unless the sale is made in the presence of some witness who is known to the vendor and who knows the purchaser, shall be guilty of an offence.

(ii) The witness in whose presence the sale is made shall, before the delivery of the poison to the purchaser, sign the entry (including the entry of his own name and place of residence) in the Poisons Register required by section twenty-two of this Ordinance.

130. Despite these provisions the fibreglass ingredient referred to above can be purchased by anyone in self-service hardware stores in the ACT. MEKP can also be purchased from specialist fibreglass materials suppliers or from some art and craft suppliers. The Committee does not believe that these inadequacies are limited to the ACT. Retailers and even some wholesalers are increasingly relying on self-service methods. Stock and station agents are not generally subject to the same restrictions on the sale of similar poisons as are pharmacists for example.

131. The labelling requirements of poisons scheduling ensure the provision of some basic essential warnings and instructions but fall far short of full safety instructions. Quite a number of witnesses pointed to the inadequacies of warnings such as 'avoid breathing the vapour', particularly on products intended for spraying. Poisons schedule warnings and instructions give little idea to the average user of the relative hazard of a substance or of how to handle it safely. The Committee deals further with basic safe handling information in Chapter 7.

132. The New South Wales Government pointed out that 'Under the Poisons Act, for example, we are more particularly concerned about acute toxicity although we take into account chronic toxicity and use because these also contribute a hazard.' Questions have been raised as to how carcinogens, mutagens and teratogens are scheduled where their acute toxicity is low, and how such products should be labelled. It was claimed by the Department of Health that potential carcinogens are included in the Prohibited Substances List or in Schedule 7. When asked how mutagens were scheduled the Department gave the unhelpful advice that 'Potential mutagens are assessed in the context of supporting toxicological data'.[30] When asked how powdered asbestos was scheduled, as this known carcinogen has been available at the retail level to home handymen as a filler for fibreglass and plaster, the Department of Health advised: 'Powdered asbestos is an industrial product and is not subject to poisons legislation. The carcinogenic activity of asbestos derives from its morphology, not its chemical nature'.[31] The Capital Territory Health Commission advised that there were no controls over asbestos in the ACT. The hazards of asbestos have been known for a long time and are spelt out in Chapter 11.

133. The Committee does not believe that public health authorities in Australia generally take the hazards posed by carcinogenic or mutagenic substances sufficiently seriously. In the best traditions of public health administration if a doubt exists as to the risks involved then administrative decisions should err on the side of caution to provide the greatest protection to public health. This approach is lacking in the case of substances suspected of being, or even known to be, human carcinogens. The illustrative studies on asbestos and coke oven emissions describe some of the worst examples of this. In contrast, large quantities of canned salmon from the United States were recently recalled and destroyed because of the risk of botulism contamination. Botulism is highly toxic in the acute sense and is frequently fatal. Low cure rates for cancers other than skin cancers make four out of five cancers fatal yet the commitment to prevention is not comparable. In the United States the Occupational Safety and Health Administration regards a substance as a cancer agent if it is known to cause cancer in humans or is carcinogenic in two independent animal tests.

134. The NH & MRC lacks a systematic and comprehensive approach in the structure of its public health assessment committees. This is particularly obvious in its handling of

occupational safety and health, mutagenicity, and carcinogenicity. The Committee recommends that:

> **the Minister for Health review the National Health and Medical Research Council's Public Health Committee system to ensure assessments are carried out by a comprehensive set of expert committees.**

The Committee comments further on NH&MRC assessment deficiencies in the next Chapter.

National Advisory Committee on Chemicals

135. In its assessment program NACC will be looking at chemicals hazardous to the environment in a broad sense that will include human health. Apart from having a member representing the NH&MRC, neither the NACC nor its technical assessment committee will have the expertise necessary to comprehensively evaluate human health, particularly occupational health, aspects of chemicals. The present NH&MRC committee system does not have the capacity to fully evaluate chemicals in the occupational health context. This aspect of assessment would still need to be undertaken by occupational health assessment experts. The comprehensiveness of NACC coverage of chemicals is an issue if the AAC, ADEC, NACC and NH&MRC are each to provide a thorough coverage of their respective areas and thus ensure an overall comprehensive coverage.

136. It is not clear, given the delays in the introduction of the interim voluntary notification scheme, when the non-voluntary notification scheme will be implemented. The longer a comprehensive mandatory scheme takes to implement the longer those companies cooperating in the voluntary scheme will be economically disadvantaged in relation to their non-cooperating competitors. The greater also will be the possible cost to the community of having to pay for any health or environmental costs arising from the non-assessment of those chemicals not notified during the voluntary notification scheme. As mentioned earlier, the response rate to the voluntary scheme has to date been low. The other notification and assessment bodies rely on State legislation making notification mandatory. Legislation making mandatory the notification of chemicals covered by NACC has not yet been drafted, let alone enacted, in all States and Territories.

137. The notification and assessment scheme has been in the pipeline since 1977. The time has come to stop adding to the backlog of untested chemicals. Industry sought time to introduce into Australia those new chemicals that have not required full assessment in other countries. It was argued that the cost of assessment could not be recouped in the small Australian market. Sufficient time has now been allowed for the introduction of any such chemicals. The Committee recommends that:

- **a mandatory notification and assessment scheme for new chemicals be implemented without delay**
- **the Commonwealth exercise its full constitutional powers to provide the legislative backing for the scheme as a matter of urgency. This legislation to have effect until each State and Territory implement their own legislation.**

138. To enable the NACC to undertake assessments a chemicals review sub-committee has been established consisting of representatives of the Commonwealth, two State environment authorities and the NH&MRC in addition to several experts in chemistry and environmental science.[32] The number of experts

available in Australia to carry out assessments is limited. The Committee recommends that:

environmental assessments of all new chemicals be undertaken by the National Advisory Committee on Chemicals.

139. The development and implementation of the mandatory notification and assessment scheme is not completed and must be given a high priority. The identification and assessment of existing chemicals will be a substantial continuing function. The development of environmental control measures, information and monitoring systems and research will also require substantial manpower resources. The NACC has a staff of eight spread across its three functions. Four staff are working on the notification and assessment scheme. The other four work on the remainder of the functions. If the NACC is to effectively carry out its function of providing a comprehensive assessment of chemicals within its areas of responsibility then it will need much greater resources than it currently has. As noted in the First Report of this Inquiry, the very purpose of the NACC is to make the best use of a small number of staff and prevent duplication of these functions in each State and Territory. To skimp on the staffing of NACC is false economy and defeats the purpose of the NACC.

140. The Department of Health, in a similar area, employs eleven science graduates, three medical officers and a specialist toxicologist. This is in addition to senior staff and the large amount of work done by the expert committees of NH&MRC. Members of these receive expenses but no other reward, apart from sitting fees if they are academics. They are expected to do a large amount of this work in a voluntary capacity.

141. On the grounds of priority that must be given to regulating hazardous waste disposal alone, the Committee recommended in its First Report that:

staffing of the secretariat of the National Advisory Committee on Chemicals be substantially increased to meet its responsibilities.

From considerations in this and subsequent chapters the Committee is further convinced of the necessity of such an increase.

Notification System

142. The range of assessment bodies described above, while having interlocking membership to provide some coordination, generally cover mutually exclusive areas. These assessment bodies have developed and grown in a disjointed way and are not fully coordinated and comprehensive. The Committee is concerned that as well as some categories of chemicals not being assessed at all, others are not assessed by the appropriate body. While not all those chemicals notified to other assessment bodies, e.g. pharmaceuticals and agricultural chemicals, need thorough environmental assessment, those that do will not be assessed for environmental hazard to the same extent as chemicals notified to the NACC. It is appropriate that all environmental assessments be conducted by the technical committee of the NACC. The claim by the Department of Health that 'The poisons scheduling process deals with substances which are specifically excluded from the considerations of the NACC[33] shows an inadequate approach to the problem. Poisons are highly likely to have environmental effects and these effects should be assessed by an expert environmental body. Similarly, it appears that chemicals notified to the NACC are not going to be assessed by the NH&MRC for their effects on human health. This is an extremely important area in which the NH&MRC should be providing health assessment of chemicals.

143. It is the view of this Committee that the AAC, ADEC, AEC, and NH&MRC together with a national occupational safety and health body, have the capacity to provide a comprehensive assessment of chemicals entering the Australian environment. Considerable expansion of coverage is required if these bodies are to collectively provide a comprehensive coverage, to identify potential hazards and to ensure that regulatory procedures minimise any hazards. Some hazardous chemicals may still escape the notification procedures of these bodies. These are by-products and intermediate products in the manufacturing process, hazardous wastes and naturally occurring hazardous substances. The Committee has dealt with the control of hazardous chemical wastes in its First Report. Vigilance on the part of the occupational health and safety body will be needed to regulate by-products and intermediates.

144. The Committee believes that the coordination and comprehensiveness of assessment bodies would be significantly improved by having a central notification agency for all chemicals requiring notification and assessment. Very few staff would be required but would ensure that all applications are considered by each of the relevant assessment bodies before clearance.

145. There seems a good case for the same submissions to go to each of these bodies:

- to reduce the number of separate bodies to which submissions need to be made;
- to allow some of the toxicological and other considerations of one committee to be carried over to another;
- to ensure that a substance is considered by all of the relevant specialist bodies; and to ensure that the recommendations on a substance, by several committees, are consistent.

There should be no restriction on the exchange of confidential information between these committees.

146. The criteria requiring notification for different classes of chemicals might vary but they should still be referred to the one central agency. This would ensure that substances are adequately assessed by all relevant bodies where necessary. For many substances, full assessment would not be required by all bodies. Those bodies not requiring a full assessment could clear a proposal very quickly. Where a substance is not relevant to a committee, that committee could clear it automatically. Similarly, recommendations from the various bodies for labelling, packaging and regulation of sale could be coordinated so as to be uniform and succinct.

147. The Committee believes that the single registry should be responsible to a coordinating council comprising representatives of the AAC, ADEC, NACC, NH&MRC and the national occupational safety and health body. This council would also be responsible for resolving final recommendations on control measures such as the labelling of a substance.

148. The primary function of the coordinating council would be to ensure the comprehensiveness of chemical notification and assessment procedures and to coordinate the assessment and regulatory measures of its member agencies. It would also play an important role in coordinating information systems. This is dealt with further in Chapter 6. Other countries, most notably the United States, have recognised the necessity of coordinating the activities of the major regulatory agencies in the hazardous chemicals area. This is essential if best use is to be made of limited resources and if regulation is to be fully effective. The Committee recommends that:

- a coordinating council for chemical safety be established to ensure the comprehensiveness and coordination of assessment and regulatory processes for hazardous chemicals;
- the coordinating council have as members representatives of the Australian Agricultural Council, the Australian Drug Evaluation Committee, the Australian Environment Council, the National Health and Medical Research Council and the national occupational safety and health body; and
- prior to the establishment of the coordinating council a task force investigate the additional coverage necessary by each body to ensure the comprehensive notification and assessment of all potentially hazardous chemicals.

A schematic diagram showing the relationship of the coordinating council to its member bodies is shown in Figure 2.

Effective Regulation

149. Assessment is only the first step in the regulatory process. Subsequent steps involve legislation to control manufacture, transport, storage, use and disposal and enforcement of that legislation. Most of the powers presently exercised for the regulation of hazardous chemicals are state-type powers and the introduction of uniform legislation is not without its difficulties. In addition to achieving uniformity, special care is necessary to maintain uniformity in any subsequent amendments. Enforcement is a major problem. The widespread use of chemicals in a multitude of situations indicates that legislation needs to be subject to the widest agreement and understanding of those affected, if it is to be effective. Community understanding of the nature of the hazards involved is critical to the effectiveness of regulatory control. This is dealt with further in Chapter 6.

150. The largest problems within the State jurisdiction are the fragmentation of control across a number of uncoordinated departments together with a lack of inspection and enforcement of adequate standards. The Commonwealth appears no better in terms of fragmentation and in regard to legislative and administrative arrangements in the Territories.

151. To be effective, regulations under the legislation have to be free from legalisms so as to be readily understood by individuals. Similarly, consolidated amendments should be made at regular, not too frequent, pre-determined intervals so that those subject to the regulations have up-to-date information. Irregular amendments notified in Gazettes tend not to be noticed or understood. This would not preclude unscheduled gazettals in emergency situations. The implementation of the Australian Code for the Transport of Dangerous Goods by Road and Rail, which is discussed further in Chapter 6, has been designed to overcome these barriers to uniformity and operator awareness.

152. As many hazardous chemicals are used by individuals lacking informed supervision, education to the dangers of a product and to its proper use are probably more effective than legislative controls. Nonetheless, the imposition of controls and the availability of adequate legal remedies is necessary to reinforce the awareness of hazards in users. For example, the NSW Pesticides Act obliges users of pesticides to comply with the directions on the label. Insofar as some manufacturers or users might be avoiding paying the full economic cost involved in their activities, (e.g. health costs are often borne by affected individuals, their families, health funds or government) legal restrictions and remedies are necessary to ensure that costs are allocated to those incurring them.

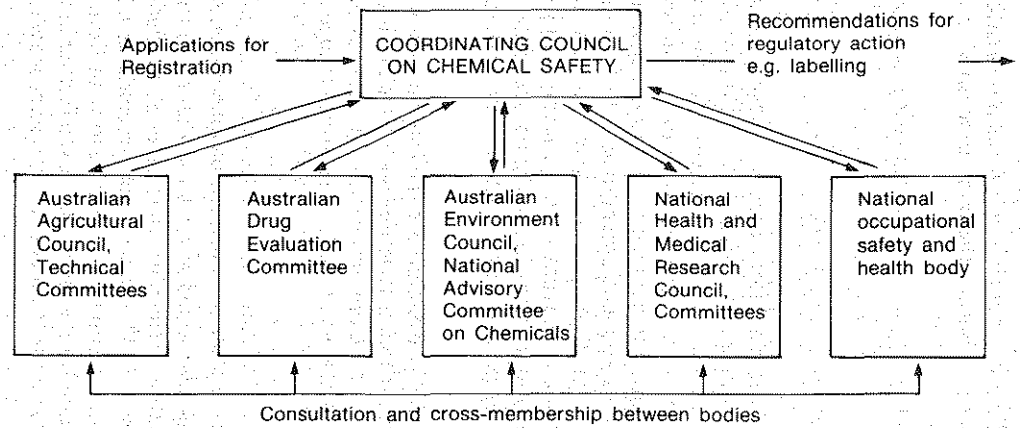
Applications for Registration
COORDINATING COUNCIL ON CHEMICAL SAFETY
Recommendations for regulatory action e.g. labelling
Australian Agricultural Council, Technical Committees
Australian Drug Evaluation Committee
Australian Environment Council, National Advisory Committee on Chemicals
National Health and Medical Research Council, Committees
National occupational safety and health body
Consultation and cross-membership between bodies
Coordinating Council on Chemical Safety

Figure 2

Radioactive Materials

153. While the regulation of radioactive substances is seen as primarily a State responsibility and is exercised in Australia by health authorities, there exists a mix of State and Commonwealth legislation covering the area. The Commonwealth has legislation covering matters such as uranium mining and milling codes and the Australian Atomic Energy Commission. This year the Commonwealth has provided under subsection 9 (1) of the Environmental Protection (Nuclear Codes) Act 1978 a Code of Practice for the Safe Transport of Radioactive Substances. This Code is available for adoption by States and Territories. There is no general regulation in the ACT.

154. Radioactive substances are being increasingly used in industry, commerce, medicine, research and in the home. The Committee has received comparatively little evidence on the control of radioactive materials. The weight of evidence, and hence the Committee's time, has concentrated on non-radioactive chemicals. The regulation of radiation effects extend beyond chemicals to machines such as x-ray machines which are outside the Committee's terms of reference. Despite the small volume of evidence received, the Committee is able to make a number of observations.

155. The controls being exercised over low-level radioactive materials would appear to be no more effective than those over hazardous chemicals generally. Within some workplaces handling mainly radioactive materials, such as the Australian Atomic Energy Commission, controls would appear to be effective but in other situations controls appear lacking. A number of instances illustrate the situation. Several of them were mentioned in the First Report:

- there has been a lack of effective control over known radioactive waste from sandmining operations such that schools, hospitals and houses have been built on top of them;

- a radioactive monitoring device melted down in a large volume of scrap metal resulted in the scrap having to be brought back to Australia from Singapore;

- a Commonwealth laboratory licensed by a State Government to hold a certain level of radioactive material had several times this level installed in the form of gaseous tritium lighting devices for emergency lights. This occurred without the knowledge of the radiation safety officer. These devices were imported into Australia yet do not appear to satisfy the import criteria. There would appear to be little control over the storage, use and disposal of these devices generally, given that in their expected usage they would often be handled by people without the relevant knowledge. The Committee is unaware of the controls over warehousing of these units before sale to users. Quite formidable levels of radioactive material could occur in these situations; and

- there is a lack of adequate disposal facilities for low-level but long-lived radioactive wastes. The Commonwealth, for example, has filled its present storage facilities and generating departments are being asked to retain radioactive material until the problem is resolved.

156. The Committee concludes that more effective legislative and administrative machinery is needed to control radioactive materials.

Endnotes

18. Department of Health, answer to written question.
19. Transcript, p. 862-3.
20. Department of Health, answer to written question.
21. Transcript, p. 867.
22. Transcript, p. 3605-6.
23. Transcript, p. 1684.
24. Transcript, p. 1695-6 and 3670.
25. Transcript, p. 659 & 3670.
26. Department of Health, answer to written question.
27. Transcript, p. 3753.
28. Transcript, p. 2515.
29. Transcript, p. 109-110.
30. Department of Health, answer to written question.
31. Department of Health, answer to written question.
32. Transcript, p. 3513.
33. Department of Health, answer to written question.

CHAPTER 5

Assessment

157. The difficulty of assessing the hazards posed by chemicals is summed up in a quote from the US Toxic Substances Strategy Committee report to President Carter in 1980:

> Obtaining all the data and information needed to understand toxic substances and to select effective methods of reducing or eliminating hazardous effects is a herculean task. It is not yet known how many of the tens of thousands of chemicals in commercial use pose hazards, much less the amounts and the circumstances. Chemical testing is a lengthy and costly process and requires skilled personnel. Information on the transport and fate of toxic substances in the environment, on the nature, degree, and effects of exposure of various population groups, and on the effects on the environment is also difficult and costly to obtain.

Testing

158. From the evidence to date it would appear that relatively little testing of chemicals is conducted within Australia into the adverse effects of chemicals on health and the environment. The data on which assessment for registration by Australian authorities is made is based on the results of testing conducted overseas. Some registration procedures for agricultural chemicals require field tests under Australian conditions but apart from these, all toxicological and other data for the pre-marketing assessment of new chemicals is generated overseas.

159. The Commonwealth Institute of Health conducts some limited testing of chemicals for mutagenesis and potential carcinogenesis. There are also a number of individual research projects within universities. The NACC is assessing a priority group of existing chemicals but this does not involve any new generation of test data. There is no program of research with set priorities for the testing of particular chemicals or groups of chemicals. One submission has recommended that Australia should shoulder its share of the burden of the testing of existing chemicals but that it be coordinated with international research to avoid duplication. At present, Australia does not have sufficient skilled manpower or suitable facilities for testing on the scale required. Australian companies requiring testing of a chemical would have to have it carried out overseas. The Committee recommends that:

> **the Commonwealth Institute of Health and other suitable research centres be funded to further develop testing facilities in Australia and train specialists in the relevant areas of assessment.**

160. Assessment is a complex scientific area involving a number of specialist skills such as pharmacology, toxicology, genetics and ecotoxicology. There are many pathways and mechanisms by which effects may occur even within the one species such as man.

161. Toxicological testing involves exposure of the subject organism to graded doses of the test chemical under carefully controlled conditions. Rats and mice are the most commonly used test species with some further testing being carried out on dogs and primates. Standardised laboratory procedures have been developed for testing and the resultant effects, both short and long-term, are then observed and recorded.

162. Chemical assessment details also include some basic physical and chemical data such as boiling point, melting point and evaporation rate. These can increase or decrease the risk posed by a material, e.g. a highly volatile substance is likely to pose a higher risk than an insoluble stable solid of the same toxicity. These physico-chemical characteristics are also important in determining testing procedures, such as method of dose administration.

163. It is generally regarded in the scientific community that animal tests at their present stage of development provide a sound basis for assessing the potential risk of a substance to humans. This principle has been accepted by major bodies such as WHO, IARC, UNEP and OECD. Animal testing techniques and assessment can undoubtedly improve as we learn more about how chemicals are metabolised within, and affect, both animals and humans. There has been increasing pressure to end unnecessary tests on animals and it may be possible with further development of test techniques to make greater use of tests with lower organisms or use mathematical or theoretical models. For example, chemical structures are used at present as an indication of likely toxicity where they are similar to substances with known high or low toxicity. This is a worthwhile objective but while techniques are at their current stage of development, controlled animal testing is far preferable to uncontrolled testing on humans. Releasing chemicals into the community without prior assessment is in fact testing on humans without even the benefit of carefully observing the results. It is clearly unethical to use humans for testing unless exhaustive animal and other tests have shown no serious adverse effects.

164. Many different kinds of tests need to be conducted since no one test can predict the wide range of possible effects. The results of these tests are then assessed and various risk factors considered. Comprehensive testing of chemicals for a range of toxicological effects, as occurs for the registration of agricultural and veterinary chemicals, is a lengthy process and quite costly. Costs are in the order of $100 000-$250 000. Several short-term tests have been developed in recent times such as the Ames Test and mammalian cell culture systems which assess mutagenicity but which can give some indication of the likelihood of a substance being carcinogenic. These cost $100 to $500 each but are only a part of the assessment process. Several submissions suggest that a battery of these tests might indicate those chemicals which warrant further investigation for carcinogenicity and mutagenicity. This is particularly relevant in developing priorities in the selection of existing chemicals for assessment.

165. Toxicity in a general sense includes all adverse effects that occur when an organism is exposed to a chemical by different routes, at varying doses and over different exposure periods. Quantification of toxicity therefore necessarily includes specifying the test organism, size of dose[34], the route and period of administration, the type and extent of effects and the pattern of their development over time. The primary routes by which people are exposed to chemicals are inhalation, ingestion and skin contact.

166. Environmental considerations over and above mammalian toxicology include toxicity to lower organisms, solubility, volatility, biodegradability, bioconcentration through fatty tissues, photodegradation, and degradation and accummulation in soils.

167. One measure of acute toxicity frequently quoted is the LD50 or median lethal dose. This is the theoretical dose that will kill 50 per cent of the exposed group. While it is useful in providing comparative measures of acute toxicity and is used for that purpose by those with little or no toxicological knowledge, it is a theoretical measure and cannot be regarded as an absolutely reliable hazard measure, as it is dependent on a

number of variables which can readily change. One important variable is the differing sensitivity of individuals to a chemical.

168. The results of chronic and subchronic tests are used in establishing a 'no effect' level below which no toxic effects are expected. This concept underlies tolerance measurements such as Threshold Limit Values (TLVs) and acceptable daily intakes. Where teratogenic, mutagenic or carcinogenic effects are involved it is now widely accepted, although there is still some small dispute, that there can be no 'no effect' level. Even the smallest dose is capable of inducing changes which may lead to deformity of offspring, spontaneous abortion, ongoing genetic damage or cancer. The term cancer is used here, as in common usage, to include sarcomas, leukemias, and lymphomas as well as carcinomas. While small doses are capable of initiating such damage they are by no means certain of doing so. The higher the dose, within certain limits, or the longer the period of exposure, then the greater the risk is likely to be.

169. The terms of reference of the Carcinogenic Substances Committee of the NH & MRC were changed in 1982 from:

> To inquire into and advise the Public Health Advisory Committee and other committees as necessary on the public health aspects of carcinogenic, mutagenic and teratogenic substances.
>
> to
>
> To inquire into the health effects of carcinogens of importance in the Australian environment and report to the Public Health Advisory Committee.

Separate specialist committees have not been established to cover mutagenic and teratogenic substances. A number of submissions have suggested that the current approach to assessing and regulating these potential effects in Australia is less than adequate. In contrast the submissions from the Department of Health did not indicate any major concern.

Mutagens

170. Heritable mutations are mutations that are transmissible to later generations and the target cells are the germ cells of either sex. Mutations include chemical transformation of an individual gene (point mutations) or changes involving rearrangement of parts of one or more chromosomes (chromosome mutations). Resultant defects can range from gross body malformations to impairment of a single enzyme system.[35] Major genetic defects affect between 3 and 12 per cent of live-born children in Australia, depending on the method of classification used and the source of the data.[36] Transmissible genetic damage may result from exposure to mutagens of either the male or the female reproductive cells at any time prior to a conception, although there are stages at which certain of the cells involved are more sensitive than they are likely to be at other times. The mutations produced may be dominant, sex-linked (in either of which cases they will be expressed in the next generation), or recessive, in which case they may not be expressed for many generations. Because almost all mutations are harmful, it is extremely important that we take as stringent measures as possible to avoid increasing the mutation rate to any significant extent.

171. As 80-90 per cent of carcinogens are mutagens and the converse also applies, the ability of a chemical or physical agent to produce mutations is frequently associated with its carcinogenicity. While there is a close correspondence between animal cancers established in long-term laboratory tests, and the occurrence of cancers in man there is no similarly well established correspondence between mutagens identified in laboratory tests and heritable mutations in man. Such a correspondence can only be inferred. A group of experts sponsored by UNEP and WHO stated:

> The inference, however, is extremely strong and not subject to serious doubt . . . . The lack of full correlation stems more from the lack of appropriate studies in man than from any uncertainty concerning the underlying biological considerations. At present, methods for the detection of mutations in man are difficult, cumbersome, and insensitive, and it is imperative to operate on the assumption that agents capable of producing germ cell mutations in laboratory studies would also be capable of producing similar mutations in man.[37]

They go on to say:

> The potential hazards of mutations (to man) are such that every effort should be made to reduce the risk . . . the available body of information from nonhuman mammals and lower life forms clearly points to the ability of chemicals to produce alterations in germ cells which are inherited in succeeding generations. Accordingly, the implications of such data for man are so persuasive that they must be taken into account in establishing safety measures for the introduction of chemicals into use. This is especially true, at this time, since techniques for detecting mutations in human populations are so insensitive that a significantly mutagenic chemical could easily escape attention.
>
> These considerations will almost certainly lead to increasing concern in establishing regulatory and control procedures. In fact, the Environmental Protection Agency in the USA has recently proposed preliminary guidelines for conducting tests for heritable mutations as part of the routine registration procedure for pesticides.[38]

172. The United Kingdom has a committee within the Department of Health and Social Security called the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment. This Committee is chaired by a clinical geneticist, and has a membership of nine professional scientists expert in the field of genetic toxicology.

173. The Department of Health appears to treat possible human mutagenic effects as if they were much less important than carcinogenic effects.[39] The Department seems to regard human mutagenic effects as somewhat hypothetical and not capable of assessment and regulation.[40] This is at variance with the view of WHO outlined above and with the United Kingdom authorities. The United Kingdom Committee recently published guidelines for mutagenicity testing in which it said:

> Many chemicals are known to possess mutagenic properties and the Committee accepts that response to these in humans might present a hazard to future generations. It is therefore necessary to identify and limit the spread of such chemicals into the human environment. The Committee also accepts that if substances have demonstrable mutagenic activity in several test systems this implies possible carcinogenic activity (it being accepted that mutation and malignancy may originate via similar processes), but advises that the mutagenic hazard should be considered in its own right.[41]

The Committee believes that mutagenic effects should be properly assessed by a Committee on Mutagenic Substances with relevant specialist membership. This matter is dealt with later in this Chapter.[42]

Short-term Tests for Mutagenicity and Carcinogenicity

174. As stated previously about 80 per cent of carcinogens have been shown to be mutagenic and vice versa. There are a number of short-term tests, such as the Ames Test, which test for mutagenicity much more quickly and cheaply than the long-term animal tests. They are not at present substitutes for long-term carcinogenicity tests but together with mammalian cell culture, represent a valuable system for screening chemicals to establish priorities for long-term testing. A number of chemical companies are now using the tests as an early indicator of likely problems. Each of these short-term tests relies upon a different underlying principle. It is essential that the differences as to what each of these tests measures is is understood so that the results can be clearly

interpreted. It has been suggested that a battery of these short-term tests be used to strengthen positive correlations and minimise or eliminate the possibility of false negatives prior to long-term testing. It is hoped that with further research and development such tests may at some future date provide a much quicker and cheaper overall test for mutagenicity and perhaps carcinogenicity. It is important that assessment authorities have a better understanding of these short-term tests than they do at present so that their use can be maximised. This requires a clear understanding of what each does, and does not, measure so that batteries can be designed and test results assessed accordingly. The United Kingdom Committee recommends a basic package of four testing screening procedures for mutagenic properties of chemicals.[43]

175. Given the large numbers of existing chemicals that have not been fully assessed for carcinogenic or mutagenic potential and the high cost of testing these chemicals, short-term tests will play an important role in screening and establishing priority chemicals on which longer term bioassays are then conducted. Not all chemical groups are assessable by these short-term tests and other methods will be required for those groups.

Long-term Tests for Mutagenicity and Carcinogenicity

176. Long-term bioassays of the carcinogenicity of environmental chemicals are carried out to more fully assess any possible risk to man and to estimate the extent to which preventive measures are required. Experience in long-term carcinogenicity testing has shown that nearly all compounds that are carcinogenic in man are also carcinogenic in one or more animal species, even though the tumour type may not be the same as in man. The group of experts sponsored by UNEP and WHO, developing principles and methods for evaluating chemicals, state that a compound should be tested on two animal species:

> Although a positive (that is carcinogenic) effect in one species is considered as adequate warning, only negative findings in two species can be regarded as adequate negative evidence.[44]

177. Concern has frequently been expressed in the media that tests establishing the carcinogenicity of a substance were conducted with rats or mice and the levels administered were extreme in comparison with likely human exposure levels. Concern that tests on rats are not relevant to the human exposure situation is frequently expressed by those opposed to regulation of the substance concerned. It is sometimes claimed that most things will give you cancer if the dose is high enough. These concerns show a lack of understanding of the nature of chemical carcinogens and it is essential to community understanding and to proper regulatory controls that these misunderstandings be cleared up. It is agreed by the international expert bodies already mentioned that animal tests with high doses are reliable indicators of carcinogenic potential. It must be remembered that not all chemicals are capable of causing cancer or mutation, even with extremely high doses. It is a comparatively small proportion of chemicals that have these properties and it is important that they be clearly identified.

178. The close correlation between cancer in the whole animal in laboratory tests and cancer in man is well established and not seriously questioned. Testing sets out to obtain the maximum possible carcinogenic effect of the test chemical in order to compensate for the limited number of animals tested. Consequently large doses are used. If this were not done many carcinogenic substances would go undetected. It is a matter of concern that such testing with small numbers of animals may only show substantial carcinogenic risks and may not always detect smaller but still important risks. Comparative studies of the effects of various chemicals on the metabolism have indicated that primates and dogs are not necessarily closer to man in this respect than rodents.[45]

179. Health authorities in Australia have been slow to act in clarifying public understanding of the significance of positive carcinogenic results in animal tests. President Carter's Toxic Substances Strategy Committee recommended that the United States Government improve public understanding of the results of animal tests for carcinogens and explain that methods do not yet exist for determining safe levels of human exposure. Facts alone do not constitute a preventive health program but without the basic factual information just outlined the prevention of chemically induced cancer cannot begin. Community education is necessary if human exposure to carcinogens is to be minimised by individual decision and action. The US Department of Health, Education and Welfare has produced effective public information material in this area.

180. The Committee recommends that:

the Department of Health conduct a public information program in Australia to:

- **make clear that not all substances are carcinogenic;**
- **explain the significance of positive carcinogenic results in animal tests; and**
- **explain that methods do not yet exist for determining safe levels of exposure to carcinogens.**

181. The Committee is strongly of the opinion that it is far preferable for a limited number of animals to be exposed to possible carcinogens where the effects can be carefully monitored than for large numbers of humans to be exposed with, or more usually without, adequate monitoring to detect carcinogenic effects. Animal tests provide results within a few years. Human tests, as well as being unethical, would take 20 to 40 or more years to give results during which time many more people are being exposed. The regulation of carcinogenic and mutagenic substances must proceed on the basis of appropriate animal testing wherever possible and not have to await avoidable damage to humans. Epidemiology should be used for identifying those factors not detected in laboratory tests but should never be used as the primary means of identifying carcinogenic or mutagenic properties of new chemicals.

182. WHO has said:

> . . . . in most instances where a chemical was found by epidemiological investigations to be associated with cancer in man, the incidence was so high that the association was clear without animal studies. This has been the case for high risk groups such as occupational cancer groups. However, the risk is not confined to these groups but also applies to other populations where cancer incidence may be too low for detection by normal epidemiological methods, hence the need to carry out animal experiments under conditions that permit confident judgement of the carcinogenicity or inactivity of a chemical.
>
> Cancer testing in animals has reached a relatively sophisticated stage and an exhaustive study of a chemical in animals is sufficient evidence of a potential cancer risk for man. An assessment of the validity of experimental results is essential for the successful prevention of cancer in man.[46]

183. Long-term tests also allow the investigation of the effect of more than one agent, which, when given simultaneously, may approximate the actual environmental situation, where there is never exposure to a single chemical. In particular, such approaches are useful in revealing the carcinogenic effect of a chemical of very low carcinogenic potency and thereby help to identify situations or populations that may be exposed to an otherwise unsuspected high risk.[47]

Assessment

184. The assessment process follows the testing and collection of data. While the data from the testing is empirically derived, assessment involves interpreting that data as well as ensuring that the data measures what it claims to measure. It is in the area of assessment that differing interpretations arise, leading to disputes about the degree of hazard and of regulation. Some of the disciplines involved, such as environmental toxicology, are fledgling sciences and not as well developed and extensive as other areas of knowledge.

185. Toxicological interpretations are essential to social judgements that must be made in weighing the risks of a chemical to society against the benefits that it brings. Toxicological assessment measures the hazard and the probability of its occurrence. Concern has been expressed that traditional or classical toxicological principles are being applied in the assessment of teratogenic, mutagenic or carcinogenic hazards. Three main reasons for this are:

- the commonsense appeal of classical toxicology principles i.e. the higher the dose the greater the effect;
- the traditional training of those responsible for assessment; and
- the relatively recent insights into mechanisms of mutagenesis and carcinogenesis.

Some of the evidence given to the Committee confirmed this tendency.

186. The misuse of classical toxicology principles in genetic toxicology was described as follows:

> How often, for example, have we read or heard the toxicologists say —in the context of a suggested cancer or genetic hazard —'the reported results relate only to very high doses in animals. A human would have to consume 35 000 (or 100 000) tubes of toothpaste (or cans of soft drink) a day . . . to develop cancer'. This argument is based on an irrelevant principle, which itself is often used (wrongly) to denigrate predictions of potential for long-term hazard. The principle (often worded slightly differently to add emphasis to its apparent 'common sense' nature) is basically this: 'I believe in the old-fashioned view that everything is toxic (. . . or poisonous), whether or not any harm will be done all depends upon the dose'. Examples usually follow, tailored to the circumstances or the audience, but almost always includes such things as water and common salt. Unstated, but heavily implied, are two further things: (1) high doses are always more dangerous than low doses, and (2) these basic principles also apply to mutagenic and carcinogenic effects.[48]

A toxicologist from the Department of Health and the NH & MRC said in evidence:

> It is still true that all compounds are toxic. It is a matter of degree. That is a very ancient statement which has been with us for a long time. It remains true. The phenoxy herbicides in question would be better classified in terms of acute toxicity in the moderate classification rather than to ascribe them nil toxicity. There is a condition recognised in medicine as water intoxication. People can, in fact, become intoxicated with water. Every compound has a potential for toxicity but it becomes a matter of degree.[49]

This statement was made by the same witness who claimed:

> Overemphasis of any one component (of toxicity testing), such as mutagenesis, would detract from other aspects and could result in an overall imbalance in any hazard assessment.[50]

187. The Committee believes that it is important that regulatory authorities in Australia recognise that genetic toxicity must be assessed in terms of quite different

principles to classic toxicology. This is made clear in the WHO publication 'Principles and Methods for Evaluating the Toxicity of Chemicals, Part 1'. The Committee recommends that:

> **the assessment of teratogenicity, mutagenicity and carcinogenicity, be conducted by three specialist committees of the National Health & Medical Research Council.**

The mutagenicity and carcinogenicity committees may need to meet jointly from time to time, or have some members in common, given the similar processes involved for many mutagens and carcinogens.

Acceptability of Risk

188. A major issue in the assessment area is the question of who should determine the acceptability of the risks posed by a substance. The assessment panels are comprised of specialists from a number of disciplines. From information such as the test data, the proposed uses, and production quantities of a chemical, these panels assess the hazards posed to human health and the environment. On the basis of this assessment, recommendations for clearance or rejection are made and appropriate warnings and safety measures are specified.

189. In making these determinations, panels weigh any hazardous effects against the need for the product and the efficacy and the cost of the product, compared with available alternatives. It is not clear how the social and economic costs of the hazard are estimated in these exercises. The view of the regulatory authorities might be summarised by saying that assessment is a highly technical task and can only be carried out by experienced personnel. A view voiced in a number of submissions opposed to this is that the person(s) being exposed to the risk should be able to assess the risk and decide whether or not it is personally acceptable. This group asks that ingredients be disclosed and the toxicological and other data made freely available.

190. The Committee agrees that assessment of risks from test data is a specialist task to be undertaken by experts. The acceptance of risks is a different matter. While some substances may be so hazardous as to be prohibited or severely restricted by regulators and many so innocuous as to be made freely available, the Committee is concerned with those chemicals which fall in between. The hazard assessment of these chemicals should be made public so that individuals can decide the acceptability of the risks involved. This is not to say that conditions should not be imposed on the sale, use and disposal of a chemical but that the risks accepted on behalf of the community as a whole should be spelt out so that they are open to public scrutiny and available for private decision making. The obligation of doctors to inform patients of possible adverse effects of treatment is now widely accepted. Assessors of risks to public health of chemicals should be under a similar obligation.

191. The South Australian Government observed:

> The committees concerned with hazardous chemicals are largely drawn from State and federal bureaucracies, company medical officers and a few selected academics. Whilst the individual decisions may often be correct, they are nevertheless decisions affecting people in a manner in which they have no knowledge or input, nor for that matter is there any perceived need for the Parliament to be aware of what transpires.[51]

192. Confidentiality of certain aspects of test data is necessary for commercial reasons but the present assessment procedures are unnecessarily secretive. The Committee believes that people have a right to know what the risks are of a substance they buy or work with and to decide the acceptability of the risk. It is necessary that expert

assessors spell out the risks more than at present, e.g. 'avoid breathing the vapours' or 'the concentration of chemical x should not exceed y parts per million in the workplace atmosphere'. Some risks are acceptable to some people but not to others. For example, substances that possibly lead to sterility might be more acceptable to an older person who has a family than to a young person without children. Product data sheets that provide more data than a label would go a long way to resolving this difficulty. Third parties affected by chemicals are a more complex problem not being in a contractual or employment arrangement with the supplier or user. They appear only to have recourse to common law actions for damage and negligence, where the burden of proof is a heavy one for individuals. The greater availability of information concerning likely hazards should assist in this area.

Confidentiality

193. Confidentiality is a major area of contention, with one side arguing for substantial or full disclosure of ingredients and toxicity data and the other side claiming that disclosure would breach trade secrets. Major considerations in this argument are:

- the necessity to disclose the nature of hazardous ingredients; the extent to which ingredient chemicals or chemical types can be disclosed without breaching trade secrets and rights to intellectual property;
- the availability and accuracy of modern analysis techniques; and
- the commercial value of test data.

These difficulties do not apply to all hazardous chemicals due to their use in a relatively pure form, the ease of their analysis and replication or their protection through patent rights.

194. On the question of disclosure of hazardous ingredients there would appear little alternative. Where there is a risk of hazardous chemicals coming into contact with people or the environment, their presence and their hazardous nature must be public knowledge. This includes any deleterious effects on human health or the environment.

195. The Australian Chemical Industry Council (ACIC) have argued that 'Only agreed essential safety information should be revealed by the assessment authority to any other party. It must be recognised that test results and test methods are highly valuable property of the notifier in terms of both money and lead time for marketing a new product'. The Committee acknowledges that the cost of testing on top of development and marketing costs is considerable and the protection of the owner's rights to this intellectual property is necessary to protect the owner from unfair competition. However, the results of toxicological and other testing, essential to ensuring safe management of the chemical, such as would appear in product safety sheets, could readily be disclosed while still protecting the owner's exclusive rights to the rest of the extensive testing data necessary for registration purposes. Information on the likely or known effects of a chemical on human health cannot be withheld.

196. Some essential elements of the full toxicological data provided by testing bodies must be capable of being kept confidential, to protect the commercial value of the test data without hindering access to data on likely human or environmental effects. The data to be released would be far from sufficient for another company to use as notification data. Registration authorities should ensure that procedures for verification of the authenticity of test data supplied would preclude registration without full test data being provided. Such verification is also necessary to prevent frauds involving test data. A sufficiently extensive summary of the data should be made

public so that scientific observers and the public in general can be assured of its implications and its adequacy.

197. The ACIC also claimed that for some preparations, such as those used in the veterinary and agricultural areas, it is the formulation of the product which determines the effectiveness of the product and which is the valuable intellectual property. In other instances, it is the way the product is made that is the trade secret. ACIC acknowledged in evidence that companies in the industry do analyse their competitors' products but while they know the analysis they do not always know how to make the product. The Committee therefore does not accept that disclosure of hazardous ingredients would breach confidentiality in any significant way, while non-disclosure of hazardous ingredients is unthinkable. The Committee recommends that:

manufacturers, importers and suppliers be required to disclose the presence of hazardous ingredients in products and the full nature of the hazards.

198. Present assessment procedures are shrouded in excessive secrecy. Assessment and registration processes must be more open to public scrutiny. The US Toxic Substances Committee in its Report to President Carter in May 1980 recommended that regulatory agencies which do not permit the disclosure of confidential health and safety data in raw form, release detailed summaries of that data.

199. Given the dissatisfaction shown in a number of submissions with clearances by NH&MRC and AAC of certain pesticides, a review or appeal mechanism needs to be devised. However, the acceptability of a review decision to the bodies that take up the recommendations of NH&MRC and AAC would be a major obstacle. An appeal mechanism would have to be acceptable to State, Territory and Commonwealth Governments. The present extent of confidentiality of test data would put appellants at a disadvantage and the costs and delays involved might be considerable. Most US regulatory bodies have some provision for the review or testing of regulatory decisions but their applicability in Australia would be doubtful due to constitutional constraints.

200. At present, recommendations of assessment bodies go to State registration authorities for adoption into regulation having legal force. There appears to be no avenue of legal appeal against decisions of the assessment bodies themselves. If the State legislation is not ultra vires, i.e. beyond the legislative power of the relevant Parliament, or does not include appeal provisions then there is again no avenue of legal appeal. It is highly desirable that there be available some form of appeal or judicial review of assessment and registration decisions. Where Commonwealth decisions are involved, the Administrative Appeals Tribunal might be a suitable mechanism to perform such a task. It has the ability to have experts as members of tribunals. It is claimed that the NH&MRC already has most of the relevant experts on their panels, so that forming independent panels might be a problem. The Committee believes this could be overcome.

Overseas Data

201. A great many of the existing chemicals used in Australia are imported or are manufactured under licence from overseas companies. Consequently, information on these chemicals gained through testing or experience is often available from overseas sources. The extensive testing program in the US clearly indicates that it is quite impractical for any one country to thoroughly test all new chemicals coming onto its home market. The widespread testing of those chemicals already in use would be even more difficult.

202. Reliance on overseas data is essential in the assessment in Australia of new chemicals. Virtually all of the test data provided to the NH & MRC, AEC, ADEC and AAC committees comes from overseas. It is imperative that the adequacy and integrity of this data is assured. The Department of Home Affairs and Environment is involved, through the NACC secretariat, in an OECD program to establish chemical test guidelines for international acceptability of the data generated. These tests include provision of a minimum pre-marketing set of data. Data generated in one country in accordance with OECD Test Guidelines and OECD Principles of Good Laboratory Practice will be accepted for purposes of assessment in other OECD countries.

203. The objectives of the scheme are to provide thorough, independent testing at the least cost to industry and government and ensure that innovation is not unduly curtailed. The OECD tests cover:

- physical and chemical properties;
- effects on biotic systems other than man;
- degradation —accumulation;
- long-term health effects; and short-term health effects.

204. The OECD Chemicals Testing Program involves a tiered sequential approach to testing. Initially, the minimum pre-marketing set of data provides a battery of tests to screen chemicals for adverse health and environmental effects. The results from these are then used to determine whether more complex or extensive testing is required.

205. The completed test guidelines and ancillary measures were adopted by the OECD Council at the end of 1980. Work is being conducted in the following areas:

- control of existing chemicals;
- concerted action on specific chemicals;
- economic aspects of chemicals control;
- decision making on chemicals;
- updating and compliance; and
- information exchange.

206. The Committee strongly supports the development of machinery to ensure the reliability of overseas data. It has been alleged that some overseas testing has been conducted with inadequate care and that results have been fabricated or altered in some instances. While these instances would appear to be rare, registration authorities must be assured of the integrity of data both from home and abroad.

207. The Committee concludes that the hazardous properties of chemicals, whether to health or the environment, where these chemicals are at risk of contact with people or the environment must be public knowledge. Preventive health management requires ready access to information. The access to adequate information on chemical hazards should not only be readily available and free but should also be actively disseminated by manufacturers, suppliers and by the relevant government authorities.

Endnotes

34. Size of dose is much less relevant in assessing genetic toxicity.
35. Principles and Methods for Evaluating the Toxicity of Chemicals. Part 1, World Health Organisation, Geneva, 1978 p. 236, 244.
36. Transcript, p. 1937. Environmental Quality —1980, Eleventh Annual Report of the Council on Environmental Quality, Washington DC, 1980. p. 200.
37. WHO, 1978, p. 236.
38. WHO, 1978, p. 263-4.

39. Transcript, p. 3620.
40. Transcript, p.3622-3.
41. Committee's emphasis. Guidelines for the Testing of Chemicals for Mutagenicity, Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment, Department of Health and Social Security, HMSO, London, 1981, paragraph 1.4.
42. Paragraph 187.
43. Paragraph 7-13.
44. WHO, 1978, p. 238.
45. WHO, 1978, p. 238.
46. WHO, 1978 p. 260.
47. WHO, 1978, p. 242.
48. Transcript, p.1941.
49. Transcript, p. 3744.
50. Transcript, p. 3620.
51. Transcript, p. 1684.

CHAPTER 6

Transport, Storage and Emergencies

Emergency Services and Emergency Response Systems

208. Chemical accidents, explosions and spills are prominent features of the hazardous chemicals problem. Accidents, including fire, can occur at any stage in the life cycle of a chemical. A number of chemicals which are safe under normal conditions become hazardous when burnt, heated or wet. Submissions have been received from employer and employee fire fighting organisations seeking the implementation of a universal emergency procedure and product coding system to cope with fires, spillages and other accidents where fire brigades are the first called emergency service. All favoured the Hazchem system developed by the London Fire Brigade.

209. Emergency service personnel at an accident scene can unknowingly be exposed to hazardous chemicals or be unaware of special control procedures. For example:

- A fire at a freight terminal in Sydney in 1968 involved 44 gallon drums containing a cyanide compound. A number of firemen were overcome by fumes from the drums and had to be taken to hospital.
- Firemen called to fight a fire at a New South Wales Electricity Commission substation in 1980 were exposed to PCBs.[52]

In both of the above cases no warning was given, no information was available regarding the substances contained on the premises and firemen were unable to prepare themselves for exposure to them.[53]

In a similar incident:

- Eighty people were taken to hospital for examination and two firemen and two television cameramen were admitted following an accident in the ACT in 1982 involving a semi-trailer carrying drums of toluene diisocyanate. The chemical gives off toxic fumes when mixed with water, and firemen, while extinguishing the flames enveloping the burning semi-trailer, unwittingly activated the chemical which had spilt from cracked drums.

Fire brigades and their employees have pointed out that these are not isolated incidents. The lack of information in many emergency situations puts firemen and others at increased and unnecessary risk.

210. In the early 1960s the National Secretary of the United Firefighters Union of Australia published a booklet called 'The Australian Firefighter and Hazards of Nuclear Radiation at Fires'. In relation to the location of radioactive materials in industry the document states:

> The thing that concerns the United Firefighters' Union of Australia is the complete lack of knowledge by firefighters as to where they are likely to meet this hazard and the complete apathy of the State Governments and Fire Boards to this very urgent problem.

Although that booklet related only to radioactive substances, the requirements proposed apply equally to other dangerous and toxic substances. The New South Wales Fire Brigade Employers' Union points out that some 20 years later the problem has not been resolved.[54]

211. Under Victorian regulations, buildings are required to be placarded for materials such as explosives, inflammable liquids and those presenting a radiation hazard, but in

the case of toxic or corrosive materials there is no specific requirement. The Country Fire Authority considers the lack of regulation in this area a major deficiency.[55] There is a clear need for factories, plant, warehouses and shops to be placarded if significant volumes of hazardous chemicals are stored within.

212. While New South Wales Fire Brigade by-laws require the officer in charge of a fire station to make himself familiar with the hazards he may encounter within the station's area, information required to be provided under the Dangerous Goods Act is not passed on to the fire brigade. There is no requirement for owners of premises to advise of any change in occupancy or materials stored. It is entirely up to the brigade to establish what the risks are in a particular area.[56] Better coordination between government agencies is required in these matters.

213. There should be a requirement on the part of owners of premises or manufacturers to provide detailed information about the nature of their stored hazardous goods to local fire brigades and to the authority responsible for the maintenance of a hazardous chemicals response system.[57] Several fire brigades are now on a computerised control system and have the facility to store this type of information which is then retrievable immediately for use by the fire brigade concerned.[58] A standard code for the placarding of buildings containing dangerous goods should be adopted nationally.

214. The Hazchem system has been in use in the United Kingdom for approximately nine years. The principle of the system is to provide direct information to the fire officer at the site on the correct action to take during the initial stages of a chemical incident without reference to text books and without the need for a detailed knowledge of chemistry.[59] This is provided through a simple two or three figure code which indicates:

- the correct fire-fighting medium to use;
- the type of personal protection required;
- whether the chemical substance is likely to react violently;
- whether to control spillage or run-off from the fire; and
- whether there is a need for public evacuation.

215. The code is simple and effective and all firemen and emergency services can be issued with a small plastic card containing the information. Following at Figure 3 is an example of the Hazchem Card used by the ACT Fire Brigade.[60]

216. Providing emergency personnel with the code card is quite simple and has already been done by most fire brigades. Ensuring that the necessary codes are placed on vehicles and other hazard producing equipment or facilities requires a much greater legislative and administrative effort. The Hazchem system has been incorporated in the Australian Code for the Transport of Dangerous Goods by Road and Rail. Unfortunately, to date, the Code has been adopted by only two States, South Australia and New South Wales, although the other States and Territories are expected to adopt the Code some time in 1982-83.

217. Preliminary stages of the introduction of the Hazchem system for other than transport have been reached in South Australia and Western Australia. Representatives of the New South Wales Department of Industrial Relations stated that where hazardous material is stored, it could be made mandatory under the Dangerous Goods Act that the Hazchem code be displayed in conjunction with the diamond sign which is currently required on premises. They said that there had been no representations to them for this to be done.[61]

218. Another chemical hazard facing firemen arises when toxic fumes are given off from normally safe materials, such as building materials and furnishings, when they are burnt. Serious incidents include:

- Recent major hotel fires in the United States in which many people died from exposure to toxic fumes released by burning plastics used in the structure and furnishings. A Lockheed Tristar burst into flames on the apron at Riyadh airport, Saudi Arabia, and all 301 passengers were asphyxiated by toxic fumes from polyurethane foam interior fittings.[62]

219. In New South Wales, the fire prevention departments of the fire brigades consult with builders, examine plans and discuss materials to be used in the various stages of construction. The main problem occurs when occupation of the building results in the introduction of potentially hazardous drapes and furnishings. The continued use of synthetic paints and carpeting with nylon content contribute to the problem of hazardous gases being released in the event of a fire.[63]

220. Hazchem provides instant guidance on initial emergency responses. Further, more detailed information is frequently needed for management beyond the initial phase. To provide more comprehensive information, Commonwealth and State Governments and industry have for some time been looking at developing a broader information base to back-up the Hazchem system. At one stage, Hazfile, a computer-based system developed in the United Kingdom, was being evaluated to ascertain whether there would be some benefit in its adoption. The Department of Transport is in favour of the adoption of some form of Hazfile system and has suggested as a possible first step that data cards and a microfiche reader be set up at fire brigade control centres in each State.[64]

221. The Hazchem code and the Hazfile system were both part of the Chemsafe system which the Australian Chemical Industry Council had proposed.[65] The Hazfile system which has been on trial for a number of years in the United Kingdom has

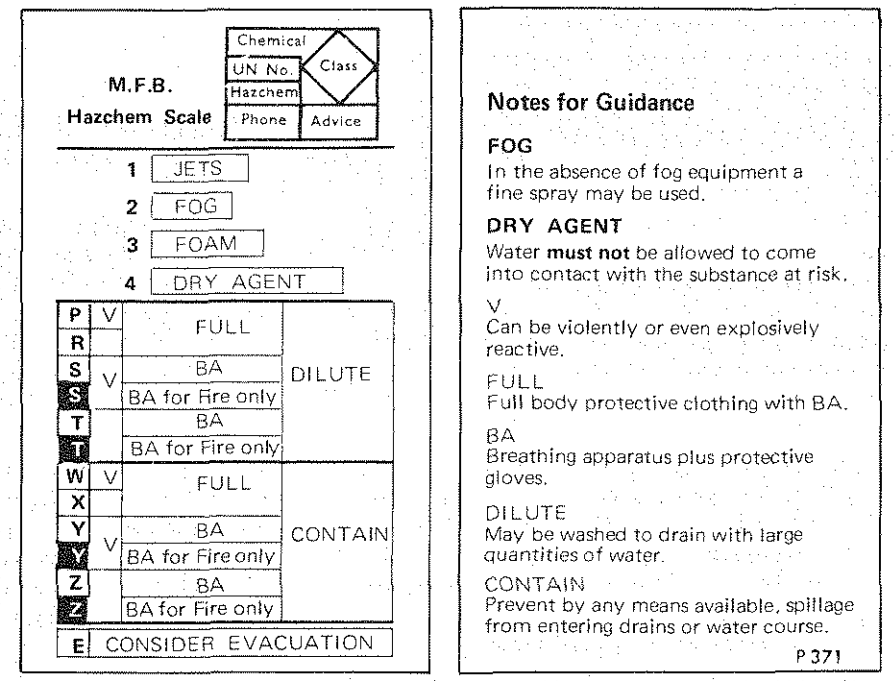

Figure 3

recently proved to be too complicated and is no longer used. No new data is being fed into the system and the usefulness of Hazfile has declined.

222. The ACIC recently brought to Australia a demonstration package of the United Kingdom Chemdata system which is a truncated version of Hazfile. The ACIC envisages buying the system and mounting it on computer in Australia and charging authorities that contract to use the system. The efforts of the ACIC to establish such a service is praiseworthy, particularly when government agencies have been so slow to establish an information system. The Committee believes that it is a government responsibility to provide emergency services and essential back-up machinery.The ACIC does not represent all producers and handlers of chemicals and the Committee is concerned that a system run by a segment of industry could have an incomplete data base particularly where other segments are reluctant to supply necessary information. There could be problems in the future cost of accessing the system with a risk that industry might be charging the public sector to reduce industry's own liability. Industry has a responsibility to provide information on their products for inclusion in emergency response data systems.

223. The Committee believes that the most satisfactory and reliable way for a complete chemical emergency information system to be developed is for it to comprise one national cooperative data facility, coordinated by a State/Commonwealth agency. The Committee envisages a single data bank with copies kept at a number of centres readily linked by telephone or VDU to fire authorities and other emergency services. Access to the data bank through these centres should be freely available.[66] Instant access to some data bases in Australia and overseas is not always available due to peak periods, shutdowns or equipment failure. If each fire service has its own computer mounted copy of the data bank these could be regularly updated and would provide emergency backup to breakdowns in other systems.

224. Although there is overwhelming agreement on the need to adopt a comprehensive emergency response system there has been no strong coordinated movement to press the issue at the national level. Left in its present state, it will have little or no legislative priority. The Commonwealth does not have a clearly identifiable fire fighting and emergency services body at the national level. Bodies such as the Commonwealth Fire Board, the ACT Fire Brigade and the Departments of Aviation and Defence each have a necessarily limited involvement. The NACC is currently coordinating national chemical data banks to form a National Chemicals Information System. To avoid duplication and make the best use of existing resources, the Committee believes that the NACC is the appropriate body to coordinate the compilation of a data bank for the use of emergency services. It would need to work with the Australian Assembly of Fire Authorities and other emergency service organisations in setting up the data bank and access machinery.

225. The Committee recommends that:

(a) **the Commonwealth Government coordinate the adoption throughout Australia of legislation requiring placarding or labelling of buildings, plant and storage with the Hazchem code and any other relevant warning code for dealing with chemical emergency situations.**

(b) **the Minister for Home Affairs and Environment seek the adoption by the Australian Environment Council of measures to ensure the coordination, compilation and operation of an emergency chemical information service to be available nationwide 24 hours a day and that industry should provide the**

necessary information to that service concerning its products, including contacts for expert advice.

Transport of Dangerous Goods

226. Community concern for safety in the transport of dangerous goods has been increasing for some time. New substances are continually being introduced for use in industry. Growth in the use of these substances, and the expanding market for such materials as liquid petroleum gas (LPG) and vinyl chloride, has led to greater amounts of dangerous substances being transported. This in turn has resulted in larger bulk tankers for use in the transport of these materials, which has raised the potential for injury and destruction.

227. The consequences of an accident involving such substances can be enormous. Several notorious incidents serve to highlight the problem:

- A train carrying LPG, acetone, styrene and chlorine derailed and caught fire in Florida, USA. Seventy families were evacuated and the rail cars blown up to prevent the fire getting out of control.
- In 1978 a train was derailed in Tennessee, USA and two full 30 000 gallon LPG tank wagons, though 'slightly' damaged, did not leak or catch fire. Two days later one ruptured, caught fire and exploded. Sixteen persons were killed and two million dollars damage was caused.
- A road tanker carrying propylene ruptured in San Carlos, Spain in July 1978. The resulting fire killed more than 150 persons and injured 600 others.
- A railway accident at Missassauga, Canada in 1979 involved a train carrying butane and chlorine. The butane exploded, spilling chlorine over the surrounding community and 240 000 residents were evacuated.

In several of these incidents, inadequate container vehicle design was a major contributing factor.

228. Fortunately, Australia to date has not experienced accidents of these magnitudes. Existing State Government regulations and voluntary controls by industry have contributed to this situation. However, accidents involving hazardous loads do occur.

229. Lack of uniform legislation has long been a problem. The multiplicity of existing regulations make it a time consuming, confusing and, at times, frustrating task for those involved in the interstate transport of dangerous goods. The importance of a uniform, nationwide approach to the regulation of the transport of dangerous goods has been stressed by both industry and governments. The Australian Transport Advisory Committee (ATAC), which consists of the Commonwealth, State and Territory Ministers for Transport, has been working for some time to develop a system of uniform regulation of the land transport of dangerous goods.[67]

230. The 1973 ATAC Model Code for the Transport of Dangerous Goods by Road was intended to provide for uniform regulation of road carriage of dangerous goods. Unfortunately, the Code was not widely adopted by the States and Territories.[68] At the same time, the various railway authorities, through the national coordinating body, Railways of Australia (ROA), developed broadly similar dangerous goods requirements and incorporated them into the Railway System Code of 1973. ROA supported and participated in the development by the National Advisory Committee on the Transport of Dangerous Goods (ACTDG) of the Australian Code for the Transport of Dangerous Goods by Road and Rail.[69] This Code resulted from

substantial revision and updating of the earlier Model Code and has been endorsed by ATAC.

231. The first edition of the Code was gazetted by the Commonwealth on 19 December 1980, thus enabling the States and Territories to legislate, by reference, those provisions applicable to them. The Code makes provision for subsequent uniform amendment. A revised edition of the Code was gazetted on 24 January 1982.[70] The Code has been fully implemented in only two States, South Australia and New South Wales and ROA has adopted the latest edition for all Australian rail systems. The process of adopting the Code in legislation has been slow but all other States and Territories are expected to complete this some time in 1982-83.

232. The Code covers:

- classification of Dangerous Goods (UN/IMDG system);
- marking and labelling;
- packaging;
- tanks and containers;
- safe stowage and regulation of loads;
- transport procedures; and
- listing some thousands of chemicals by name and identification number, giving United Nations hazard classification, packaging group number (intensity of hazard indication), packaging methods, Hazchem emergency action code, environmental hazard indication and emergency action requirement.

An example of the placarding required by the Code is shown below:

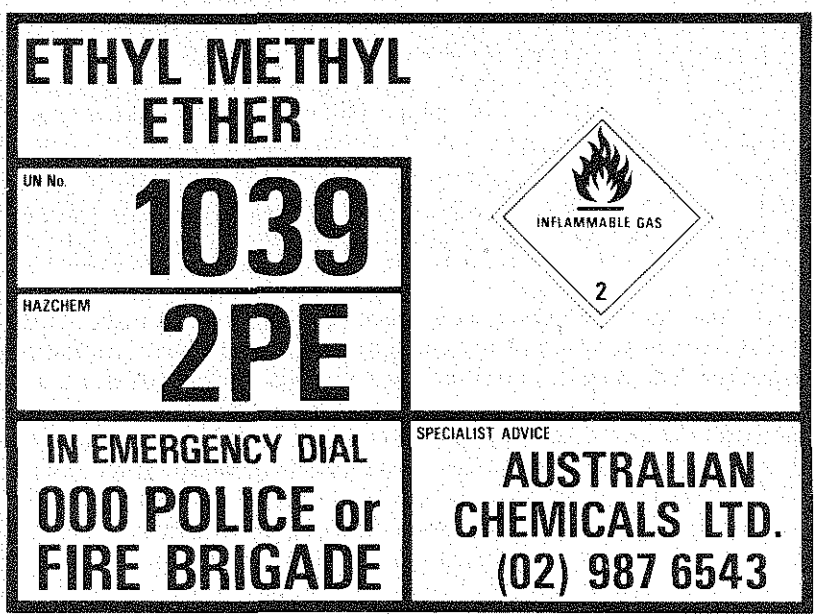

Figure 4

233. The quantity and variety of dangerous goods transported by road and rail have increased substantially in recent years and include many substances which have been landed in Australian ports after despatch from worldwide sources. It is therefore essential that Australian safety requirements are compatible with international standards. This is achieved by the Australian Code which is based on recommendations

prepared by the United Nations Committee of Experts on the Transport of Dangerous goods and uses the UN number to identify chemicals. The Code harmonises with the provisions of the International Maritime Dangerous Goods Code (1977 edition as amended). All the substances appearing in the International Maritime Dangerous Goods Code have been included together with a number of substances peculiar to Australia.

234. The Australian Code is designed to apply to all land transport in Australia, and has been prepared with the intention that adherence to the Code will ensure near compliance with the requirements for transport by sea from Australian ports. The Code makes provision for additional requirements for road and rail transport of dangerous goods arriving from overseas, where the authority is not satisfied with the safety standards of the packaging.

235. The Code stipulates package marking and envisages a packaging approval system which incorporates package marking readily recognisable by the various regulatory authorities. Amendments to the Code will be made on a continuing basis in order to keep it up to date. A separate Code of Practice for the Transport of Radioactive Materials has been prepared pursuant to the provisions of the Environment Protection (Nuclear Codes) Act 1978. The Code is now available for adoption by States and Territories. Within Australia, radioactive materials are currently transported under the International Atomic Energy Authority (IAEA) Transport Regulations, the International Air Transport Association Regulations and regulations made under radioactive substances Acts of the various States.[71] The new Code provides for adoption of the IAEA Regulations except that standards for radiation exposure limits are those recommended by NH&MRC.

236. The United Kingdom has established National Arrangements for Incidents involving Radioactivity (NAIR) and similar arrangements have been set up in other countries. The NAIR scheme, which is administered by the National Radiological Protection Board, is divided into two stages. The first stage consists of a network of health physicists at hospitals and nuclear establishments. Each police station has the name and telephone number of its nearest health physicist who, in the event of a road or port accident involving radioactivity, can be called out immediately to monitor the situation and declare the presence or absence of a radiation hazard. The second stage involves nuclear establishments with greater resources than the health physicist, such as more sophisticated instruments, special clothing, barriers, signs and clean-up equipment. Their role is primarily to stabilise the situation by fuller investigation, erection of barriers and limited decontamination. There is in effect a third stage in that the consignor or consignee will be called upon to advise on and assist in restoring the situation to normal.

237. In 1980, a truck carrying containers of radioactive material, Americium-241, Caesium-137, and toxic chemicals overturned near Port Macquarie. Fortunately an Australian Atomic Energy Commission officer holidaying at Port Macquarie at the time of the accident was able to make an examination and declare the containers carrying the radioactive material undamaged. The Committee believes that such an incident highlights the need for adequate emergency response arrangements for incidents involving radioactive materials.

238. In addition to the more obvious dangers to persons and property are the potential dangers to the environment, both long and short term, from such things as water pollution from chemical spillage.[72] The 1982 edition of the Australian Code classifies chemicals according to their environmental hazard and the nature of the response to chemical emergencies takes into acccount environmental hazards. However, present coverage of the environmental hazard aspect is not considered

adequate. The ACTDG has approached the Department of Home Affairs and Environment concerning the compilation of a comprehensive and detailed set of response measures which take into account environmental hazards associated with chemical emergencies. It is intended that such measures be incorporated into the Code.

239. The Code does not impose route restrictions on the transportation of hazardous loads which might, for example, prohibit or restrict their passage through shopping centres, tunnels, water catchments and other sensitive environmental areas. The Code has been implemented in a way which facilitates amendments and the Committee believes that this permits the development, over time, of a more comprehensive Code. The Committee considers that with further refinement of the Code, route restrictions on some classes of dangerous goods should be implemented through the Code.

240. The Committee repeats the recommendation of its First Report that:

if State Governments have failed to incorporate the Australian Code for the Transport of Dangerous Goods by Road and Rail into legislation by 1985 the Commonwealth should legislate to enforce the Code to the fullest extent of its power.

241. The Committee further recommends that:

the Australian Code for the Transport of Dangerous Goods by Road and Rail be amended as soon as possible to include comprehensive and detailed response measures which take into account environmental hazards associated with chemical emergencies.

242. The Australian Code for the Transport of Dangerous Goods by Road and Rail is designed to apply to land transport only. Several international efforts are concerned with development of standards for international transport of hazardous substances. They are:

- The Committee of Experts on the Transport of Dangerous Goods, a standing committee of the United Nations Economic and Social Council and its subsidiary bodies;
- The Sub-committee on the Carriage of Dangerous Goods of the Intergovernmental Maritime Consultative Organisation;
- The Dangerous Goods Panel of the International Civil Aviation Organisation; and
- The International Atomic Energy Agency.

243. The International Air Transport Association (IATA) has maintained, since 1950, a set of Restricted Articles Regulations to which Australia is a signatory. These were based on the Transport of Dangerous Goods and the International Atomic Energy Agency Regulations for the Safe Transport of Radioactive Materials. Restricted articles include explosives, compressed gases, flammable liquids or solids, poisonous articles, radioactive materials and corrosive materials. Although these regulations are generally considered to be quite satisfactory, IATA is an industry association. Some countries prohibit the direct adoption of industry-developed regulations into law. The International Civil Aviation Organisation (ICAO) has drafted a set of regulations so that regulations will be set by a governmental rather than an industry body. The ICAO regulations come into effect on 1 January 1983 and will operate in Australia in parallel with the IATA regulations until 1 January 1984 when the ICAO regulations alone will apply. The Committee believes that the carriage of hazardous chemicals as airfreight is relatively well controlled, as volumes are comparatively small and the enforcing agencies, mainly officers of the airline companies, have a vested interest in strict control.

244. The Intergovernmental Maritime Consultative Organisation (IMCO) has produced an International Maritime Dangerous Goods (IMDG) Code which takes account of the UN Committee of Experts Recommendation on the Transport of Dangerous Goods. This has been adopted by Australia with some adaptations, allowed by the Code, to fit the classifications of Commonwealth and State Explosive Acts. The Code has been endorsed by the Marine and Ports Council of Australia and is currently being implemented so that it will be applicable in all Australian ports. This overcomes the problem of uniformity between State and Commonwealth (and overseas) sea transport legislation.

Storage and Handling of Dangerous Goods

245. In many instances, chemicals are handled by persons such as storemen or truck drivers who handle a wide variety of goods and cannot be expected to be aware of the hazards posed by particular chemicals. Certain chemicals have specific storage requirements (e.g. storage in cool or well-ventilated rooms, segregation from other categories of chemicals, must be kept dry). Granulated chlorine chemicals for swimming pools can become quite unstable if allowed to become damp. They become highly reactive if they come in contact with organic compounds such as cardboard containers, leaves, petrol, kerosene or brake fluid. Ammonium nitrite and diesel are both commonly used on Australian farms but if inadvertently mixed, say by spilling one on the other, become unstable and highly explosive. Proper labelling of packaging containing chemical materials is necessary to ensure that those people handling, storing or using them are aware of:

- their chemical constituents
- their toxic and other hazardous properties
- the precautions to be taken in their storage, handling and use.[73]

246. The Standards Association of Australia (SAA) are in the course of preparing standard codes of practice and safety information cards aimed at personnel protection during manufacture, handling and storage of a range of hazardous chemicals.[74]

247. There will be a card for each chemical which will include information on:

- Storage conditions
- Segregation requirements
- Labelling
- Safe handling procedures
- Protective equipment and precautionary measures
- Containment of spills and disposal of spilled material
- First aid
- Fire control procedures
- Environment protection.[75]

A sample card is shown at Appendix 8.

248. The SAA has produced Australian Standard AS 1216 which includes a hazard label which shows:

- Dangerous goods label according to class
- Description of material (name)
- UN number
- Hazchem code number

- NFPA symbol.[76]

The NFPA symbol is explained at Appendix 9. Labelling should readily convey hazard information. It must be able to convey that information to non-English speaking workers. The NFPA symbol serves both functions.

249. The Committee recommends that:

the Attorney-General introduce legislation as a matter of urgency to require commercial containers of potentially hazardous chemicals to be clearly labelled in accordance with Australian Standard 1216.

This legislation would be complementary to that recommended in paragraph 278.

250. The Australian Chemical Industry Council (ACIC) has an incident reporting system which deals mainly with factory and warehouse incidents. Information gained on causes and results of accidents both in Australia and overseas is circulated to member companies. The Australian Fire Protection Association Ltd (AFPA), a non-profit national organisation which receives an annual Commonwealth grant, classifies reports on fires which have occurred both in Australia and abroad, with the object of identifying particular problem areas. Some of these fires have involved chemical hazards. Several submissions have called for incident reporting systems to monitor and remedy the hazards created by chemicals.

251. In March 1980, a National Seminar on the Transport of Dangerous Goods, sponsored by the Department of Transport and the Transport Industries Advisory Council (TIAC) under the auspices of ATAC, recommended that ATAC, as a matter of urgency, move to establish of a system for the reporting and centralised analysis of incidents occurring in the transport of dangerous goods. This system would provide for the dissemination of information throughout Australia concerning incidents involving dangerous goods, including hazardous chemicals.[77] The Committee recognises the need for a single incident notification system, coordinated at the national level, to cover all incidents, not just transport, involving dangerous goods including hazardous chemicals. The Committee believes that the NACC would be the appropriate body to operate such a system, with inputs from State authorities, industry, and organisations such as ATAC, AFPA, ACIC, and the Australian Institute of Petroleum.

252. The Committee recommends that:

a national incident reporting system be established and maintained by the National Advisory Committee on Chemicals.

Major Hazards

253. Several submissions canvassed the potential for disaster in chemical plants both large and small. Through equipment failure or other mishap, large numbers of people could be exposed to the hazardous effects of chemicals from a plant. Examples include:

- A safety disc ruptured at the Hoffmann-LaRoche trichlorophenol plant at Seveso, Italy, in 1976, releasing a cloud of toxic chemicals from a reaction vessel including an estimated 1 to 5 kg of the dioxin TCDD (2,3,7,8—rodibenzo-tetrachlo-p-dioxin). Animals died, people became ill and more than 800 people eventually were evacuated from the most contaminated regions. There is doubt about whether the most seriously affected area can be decontaminated and so little is known about the effects of dioxin on humans that the casualty list must be regarded as open-ended.
- In 1974, an explosion at the Nypro plant at Flixborough in the United Kingdom, killed 28 workers after cyclohexane leaked from a chemical reactor.

254. The potential for disaster on this scale in Australia is more than just hypothetical. For example:

- Police closed off roads and evacuated more than 500 workers from plants in and around the B.F. Goodrich plant in the petrochemical complex at Altona, Victoria, when nearly 700 tonnes of vinyl chloride monomer escaped from a high-pressure storage tank. Vinyl chloride monomer is flammable and is a human carcinogen. Air concentrations were so high at several points that a spark could have resulted in a devastating explosion.

255. The Committee shares the concern of the Botany Bay Sub-Region Community Advisory Committee about the movement and storage of hazardous chemicals, especially in areas of concentrated industrial development such as Botany in New South Wales.[78] A major concern is that developments of a hazardous nature are often approved without an adequate assessment of the hazard potential of the proposal and without due regard to the cumulative disaster potential or 'domino effect'. The Committee believes that hazard assessments should be carried out on all significant existing and future installations. Assessment should include the installation itself as well as related aspects, including movement of hazardous material to and from the site and hazardous materials on nearby sites.[79]

256. The Committee was told that the New South Wales Government has established an inter-departmental committee to investigate the hazard and disaster potential in the Botany/Port Botany area.[80]

257. In 1974, an Advisory Committee on Major Hazards was set up by the Health and Safety Commission in the United Kingdom, to consider the safety problems associated with large-scale industrial premises conducting potentially hazardous operations. That Advisory Committee noted that the task of identifying those types of installations which may present a major threat is an extremely difficult one. Attention was focused on certain of the more obvious threats to safety, that is, those which arise from the escape of significant quantities of flammable and/or toxic materials as a consequence of loss of plant integrity or loss of process control.[81]

258. Hazard assessment of installations where significant amounts of hazardous chemicals are stored, handled or processed, is fundamental to any improved mechanism of control. The Committee believes comprehensive, coordinated counter-disaster plans should be prepared to deal with possible accidents or disasters in major industrial complexes. Such plans should cover all installations in a complex and should be regularly monitored and tested, as is done for airport disaster plans.

259. On a lesser scale, but capable of disastrous effects, is the lack of coordination in the storage of hazardous chemicals by independent companies on adjoining sites. Responsible companies do liaise with their industrial neighbours but there is no requirement to do so or for regulatory authorities to oversight the compatability of adjacent storage or plant facilities.

Location of Hazardous Installations

260. The location of hazardous chemical plants in relation to residential areas is of concern to the Committee. An important consideration is to ensure that, despite all efforts to prevent a major accident, the consequences of any such accident affect as few people as possible. Of greater importance on a day-to-day basis is the exposure of nearby residents to hazardous emissions from a plant or from storage or handling areas.

261. The petrochemical complex at Altona was deliberately established away from residential areas but very shortly afterwards, local authorities permitted urban development to occur close to the area.[82] Residential development has been allowed to encroach in a similar way on previously isolated plants such as the Cleanaway liquid waste facility at Tullamarine.

262. The Committee believes that greater consideration should be given to locating potentially hazardous installations away from urban areas and in environmentally acceptable zones and in maintaining this separation. Safety zones or buffer areas around such installations should be mandatory and provided for in town planning schemes.[83]

263. It is vital that planning authorities should reach decisions on the basis of full information about the hazards associated with proposals for new installations; for changes at existing premises which involve the introduction of, or alteration to hazardous activities; or for developments in their vicinity. Present planning procedures are not adequate to provide and maintain sufficient separation of chemical hazards from urban and other sensitive areas. Standards developed at a national level by the NACC would assist planning authorities.

264. The Committee recommends that:

the Minister for Home Affairs and Environment seek the adoption by the Australian Environment Council of measures to ensure the development of standards:

(a) to determine installations requiring hazard assessment

(b) for the assessment of hazards

(c) for town planning guidelines to maintain a suitable degree of separation of facilities involving hazardous chemicals and land used for residential purposes, including schools and hospitals.

Endnotes

52. Transcript, p. 668.
53. Transcript, p. 668.
54. Transcript, p. 671.
55. Transcript, p. 2060.
56. Transcript, p. 684.
57. Transcript, p. 682.
58. Transcript, p. 683.
59. Transcript, p. 671.
60. Transcript, p. 673.
61. Transcript, p. 660.
62. Transcript, p. 2079.
63. Transcript, p. 689.
64. Transcript, p. 986.
65. Transcript, p. 984.
66. Transcript, p. 676.
67. Transcript, p. 949.
68. Transcript, p. 949.
69. Transcript, p. 950.
70. Transcript, p. 950.
71. Transcript, p. 2339.
72. Transcript, p. 958.
73. Transcript, p. 2340.

74. Transcript, p. 412.
75. Transcript, p. 413.
76. Transcript, p. 413.
77. Transcript, p. 953.
78. Transcript, p. 2584.
79. Transcript, p. 2584.
80. Transcript, p. 2584.
81. H&SC Ad. Comm. on Major Hazards, p. 3.
82. Transcript, p. 2667.
83. Transcript, p. 2585.

CHAPTER 7

Information Systems

265. Many submissions refer to the problems of gaining accurate information about hazardous chemicals. Those experiencing difficulty range from employees and private citizens to universities and government instrumentalities. Others have pointed to the problem of coping with increasing volumes of information. Most submissions refer to information problems and the majority of these have called for some form of central data bank system to digest, store and supply information.

266. Better access is needed to information than is available at present. There is a bewildering array of information sources, some extensive, others quite limited but all of them partial or selective in their coverage. Some rationalisation of the many data bases is necessary at both the national and international level if the information problem is to be managed effectively and efficiently.

267. The two most effective methods of informing the end user of hazardous chemicals is through labelling and the provision of product safety sheets.

Labelling

268. Labelling is the single most effective form of dissemination of information on hazardous chemicals in that it is assured of reaching the end user, subject to its legibility and comprehensibility. This would include difficulties due to language barriers. A considerable number of submissions have referred to problems in labelling of hazardous and potentially hazardous substances. These suggest the need for:

- uniform labelling requirements throughout Australia;
- adequate instruction for safe use including storage and disposal;
- warnings of adverse effects and precautions to be undertaken, including:
  - readily understood warning symbols
  - first aid measures
  - emergency codes and symbols on large quantities for storage and transport;
- the listing of ingredients.

269. The following bodies have some involvement in the development of labelling and packaging requirements, particularly for potentially hazardous chemicals: NH & MRC, ADEC, AAC, NACC, the Standards Association of Australia, the Australian Transport Advisory Committee and consumer affairs offices.

270. The general question of labelling and packaging is regarded throughout Australia as a consumer affairs matter. The Attorney-General now has the major responsibility for achieving and maintaining uniformity in labelling and packaging at the Commonwealth level. The Minister for Business and Consumer Affairs had written to all Commonwealth Ministers with responsibilities for matters involving labelling and packaging seeking their cooperation. Consumer information standards are being developed and work is continuing to achieve uniformity between various Commonwealth standards and classifications.

271. The State, Territory and Commonwealth Ministers for Consumer Affairs, who have been nominated by their respective governments as responsible for packaging and labelling, meet twice a year. This group acts as a clearing house to look at new

requirements and to resolve differences in requirements between States. A couple of States have nominated an officer in the Premiers Department to monitor new legislation to check for uniformity in packaging and labelling requirements. Disparities might occur between labelling requirements under the poisons schedule, consumer information standards and environment regulations.

272. Some submissions have questioned the adequacy of warnings such as 'Do not breathe the vapours' on products in aerosol cans or to be otherwise sprayed. Evidence was received that 'Use in a well ventilated room' often meant having forced draught ventilation rather than an open window. Persons using such products, especially those using them intensively, should be provided with more accurate information.

273. For example, a warning proposed in the US for certain hair dyes reads 'Warning—Contains an ingredient that can penetrate your skin and has been determined to cause cancer in laboratory animals'. This warns the consumer of a potential danger and allows the purchaser to decide whether the risk is acceptable or not.

274. It is claimed by manufacturers that there would not be enough space on the label to print all the information, warnings and symbols that are sought by different agencies. Other manufacturers have argued that labelling requirements detract from the attractiveness of the package or limit the freedom of the manufacturer in product presentation and marketing. The Committee recognises that the space available for warnings and symbols for safe usage on many packages is sometimes limited but cannot accept that marketing considerations should take precedence over health and safety considerations. Those products which pose potential hazards to man or his environment should bear adequate instructions and warnings.

275. The Committee believes that purchasers and users of the product are entitled to know the risks involved in the use of the product. While information other than a hazard warning cannot always be included on a label, product data sheets should be made available for each product, by manufacturers, to those asking for it. Their availability should be mentioned on the label. Where the hazard risk is high, registration authorities should require more information to be included on labels. The pre-marketing assessment bodies described earlier in the Report, have an important role in achieving these objectives. It is important to distinguish between labelling consumer products and bulk chemicals used in industry, although some product containers may fall in between.

276. The NH & MRC recommended in June 1982 that a hazard rating be displayed on the containers of chemicals used in the workplace and that proprietary products sold under a trade name not be purchased unless a hazard rating could be established. The NH&MRC have suggested a hazard rating system which classifies materials on a hazard rating from one to five in each of three categories; internal effects, external effects and flammability/reactivity.[84]

277. The Committee has received considerable evidence on people regularly handling drums which contain only a code number or trade name. They are frequently unaware of the hazards involved in regular exposure and of necessary safety precautions. They also lack accurate information on what to do in the case of spillage. The Committee believes that uniform national legislation is needed to ensure that all containers of chemical materials are adequately marked to indicate their chemical constituents, toxic properties, safe handling, storage and emergency procedures. The labelling should readily convey information on the hazard to non-English speaking workers.

278. The Committee recommends that:

the Trade Practices Act be amended as soon as possible to require consumer goods containing hazardous ingredients to be clearly labelled to indicate their hazardous nature and the precautions necessary for safe use and disposal of the product.

Penalties for breaches should be substantial to ensure compliance. This legislation would be complementary to that recommended in paragraph 249.

Product Safety Sheets

279. Perhaps the most effective method of providing detailed information to the end user of hazardous chemicals is through product safety sheets. These provide considerably more information than can be placed on a label and provide basic toxicological information, first aid procedures and safe handling instructions and precautions.

280. Following the enactment in the United States of the Occupational Safety and Health Act and the Toxic Substances Control Act, manufacturers and importers are now required to make available safety data on all products containing hazardous materials. These safety data sheets are available from the United States for many hazardous products now being imported into Australia. Along with several other witnesses, the State Electricity Commission of Victoria has called for the mandatory provision of product safety sheets.

281. According to evidence from the Australian Chemical Industry Council, product safety sheets are provided to bulk users of chemicals but would not appear to be easily available to all users. Employees would not appear to have the same access to product safety sheets as their employers. Goods sold to the general public are often hazardous if used intensively or in confined spaces, e.g. some epoxy resins. Some are carcinogenic or mutagenic, for which there is no safe level of exposure. In some situations, home handymen, housewives and small scale manufacturers such as craft workers are exposed to large amounts of these products, although their general use across the community might be expected to be low and intermittent. The availability of product safety sheets, where they are available, is not widely known. In the United States, product safety sheets are supplied by the Occupational Safety and Health Administration (OSHA). The Occupational Health Committee of the NH&MRC has produced a limited number of codes of practice and guides to the use of a number of hazardous substances. The general level of awareness of their availability is not known. The Australian Chemical Industry Council believes the provision of product safety sheets should be the responsibility of the supplier.

282. One witness stated that some safe handling sheets provided by companies in Australia were very general and while they provided some protection if followed, they did not provide the basic information required for people to inform themselves of the risks involved.

283. While supporting the introduction of a system of product safety sheets, several witnesses have sought improvements to the OSHA standard format.[85] A copy of the OSHA form is Appendix 10. The NH&MRC, in July 1982, produced guidelines for occupational chemical safety which calls for product safety data in the OSHA format. The SECV claimed that a weakness with some manufacturers to date is the non-specificity of their data. There is very little information on synergistic effects when two or more toxic compounds are included in a product. There is also a tendency to emphasise acute effects from oral ingestion rather than long-term chronic effects and effects of skin absorption or inhalation. The SECV went on to say that, in fairness, part of the answer to the above criticisms would be that the information does not yet exist. If this is

so, then manufacturers should positively say as much on the data sheets and indicate whether programs have been instituted to obtain this information.

284. The Workers Health Centre (Melbourne) recommended inserting data on: recognition of the hazard if a single compound (e.g. odour, taste, odour threshhold, hygiene level—TLV, MAC, etc); allergenic properties, and results of mutagenicity and carcinogenicity tests. The Centre also suggested that, were such a revised OSHA safety sheet made mandatory, this would perhaps be an acceptable compromise with regard to the amount of information chemical manufacturers must make public.

285. While waste disposal methods are included in the OSHA sheet, it is not clear to what extent environment hazards and safeguards are described in the sheet. Such data should be specified.

286. The cost of producing these sheets should be low for most suppliers. For many products the data already exists, often in product safety sheet form. In the context of a comprehensive notification and assessment scheme, most of the data for safety sheets would be contained in the notification data.

287. Safety sheets should be in a standard format and should contain specific chemical names rather than chemical group names. While safety sheets would be provided automatically for all new chemicals or products, some difficulties exist for many existing products. As the disclosure of the hazards posed by all hazardous chemicals, whether new or old, should be mandatory, the only problem is the provision of adequate test data in the relevant sections of the form. Many of the eligible substances should have been notified to the Poisons Scheduling Committee and the data known. Perhaps a system allowing limited time exemptions for some test data could be considered. Known hazards and other data would still have to be provided. Where data is not known, this should be stated and not left blank, which implies no effect.

288. Despite being required to provide these sheets in the United States, evidence was given to the Committee that some United States companies operating in Australia would not provide the kind of information they contain to Australian users asking for it. This situation is even more ludicrous when users have been able to gain the information readily, by writing to the Occupational Safety and Health Administration in the United States. In several instances, the information would not appear to be held in Australia and had to be gained from the parent company. It is irresponsible of companies not to maintain comprehensive information on the hazards of materials they sell in Australia.

289. The Committee believes that product safety sheets, such as those required in the United States, contain the minimum information that should be made available to users and do not breach any critical confidentiality aspects. The provision of product safety sheets by manufacturers, importers or suppliers should be mandatory, as should their availability to workers using those materials on the shop floor. Product safety sheets should be provided in a standardised format, so that specific sections of information, such as first aid action, can be found quickly.

290. The Committee has heard evidence of quite a number of companies and government agencies that have established their own product safety sheet system to cover all potentially hazardous substances used. These employers, such as GMH in Brisbane, the Utah Development Company in Queensland and the State Electricity Commission of Victoria have had to devote quite a lot of time and effort to developing the system, gaining the information from suppliers and then rewriting it into their own standard format. The State Electricity Commission of Victoria pointed out how time consuming and costly this exercise is, especially when suppliers claim that such information is confidential. The common approach of those purchasers is to insist on

the provision of this information as a condition of purchase. Unfortunately, in a number of cases, there is no alternative supplier. It is an incredible waste of resources that responsible employers have to individually go to so much trouble to gain data essential to ensuring the occupational safety and health of their employees. It is clearly the responsibility of suppliers that they supply such information with their products and a responsibility of all employers to gain such information and to ensure that it is made available to employees using the materials.

291. The introduction of legislation across Australia relating to product safety sheets may take some time. The Committee believes that the Commonwealth Government should take immediate action in areas where it has clear constitutional responsibilities. Accordingly the Committee recommends that:

- **the Trade Practices Act be amended as soon as possible to require that product safety sheets be provided with all potentially hazardous chemical substances sold in Australia;**
- **it be a standard condition of Commonwealth purchasing that if a product contains potentially hazardous chemicals, product safety sheets be provided in sufficient quantities for each workplace where it is to be used; and**
- **imports of potentially hazardous chemicals for which product safety sheets are not available be prohibited under the Customs (Prohibited Imports) Regulations.**

Data Banks

292. A great deal of information in a standardised format will become available on new chemicals when comprehensive systems are in place for the notification and assessment of all potentially hazardous chemicals. While the data would be most efficiently stored in a computerised form, it should not be the only form in which it is available. Some of the data should be reproduced in Product Safety Sheets, Emergency Procedure Guides, etc.

293. There are already a number of centralised data systems operated by government agencies or being introduced both nationally and internationally. The NACC has commenced work on the establishment of the National Chemicals Information System. In an endeavour to have the basis of a system in operation as quickly as possible, the Toxicology Data Bank of the United States National Library of Medicine has been purchased and operates through the Medline computer network. A program is underway to substitute Australian manufacturing and supply data for the US information.[86] The Department of Health operates a National Poisons Information Service, which contains details of 40 000 commercial products, although this is confidential and only allows restricted access. The United Nations is establishing an International Register of Potentially Toxic Chemicals. Most of these data banks appear to operate independently, with different priorities and with little coordination.

294. There is a strong possibility, with increasing computerisation, of a multitude of these registers being created with duplicated or overlapping responsibilities and perhaps providing conflicting advice. Wasteful duplication is likely to occur insofar as each system is involved in acquiring and codifying information from research and the literature.

295. Different users have differing information requirements (e.g. emergency fire procedures, emergency poisons medical procedure, long-term toxicology information, safe handling practices). It is unlikely that a single register with separate sections, some perhaps with limited access to trade secret material, could service the wide range of

information user requirements. A limited number of specialised but coordinated registers is more appropriate. The NACC, in establishing its National Chemicals Information System, is looking at setting up several different data banks within Australia, with other parts of the system relying on access, via satellite, to overseas data banks. The cost of overseas access is not as high as purchasing the same data banks for setting-up in Australia, with regular updating. The objective of the National Chemicals Information System is to ensure that the data banks selected satisfy the range of chemicals information requirements at the most economic cost. Reliability of access is an important consideration.

296. The coordination of basic data banks at the national level is essential, with amalgamation wherever possible. This is necessary to ensure the widest availability of information and avoid the economic and social costs of duplicated and disjointed information systems. The Committee believes that a chemicals information coordinating body is required if this vital part of an overall chemicals management program is to function effectively. To be fully effective, a coordinating agency would require the support of State, Territory and Commonwealth Governments. The Committee believes that an agency comprising representatives of the major national coordinating bodies such as the AAC, AEC, NH & MRC, ATAC, and the national occupational safety and health body would be most appropriate. As the Committee has already recommended, in Chapter 4, that a coordinating council representing most of these bodies be responsible for the coordination of notification and assessment of chemicals, the same council could undertake the information coordination task.

297. Australia is not alone in being concerned at the proliferation and lack of coordination of chemical information systems. The Toxic Substances Strategy Committee in its Report to President Carter said:

> Federal toxic substances control could be greatly enhanced by coordinated chemical data systems serving the information needs of all agencies. An integrated network of data systems could provide opportunities to reduce duplication of information-gathering, delay, and some uncertainties in decision making. It would be useful to state and local government, industry, labor, public interest groups, academic institutions, international organisations, and foreign governments as well as to federal agencies.
>
> An integrated data network does not yet exist. At present, the many federal agencies involved with toxic substances use more than 200 independent data systems, all organised differently, ranging from computer systems to simple manual files. Additional state and private data systems are maintained without being linked to each other or to similar federal systems.[87]

298. The development of a smaller number of comprehensive, coordinated chemical information systems at the international level is also essential and Australia should be working to achieve this.

299. A number of witnesses, including the Commonwealth Department of Primary Industry, point to the problem of coping with ever-increasing volumes of information. A central agency might also coordinate abstract, bibliography and similar services without duplicating existing library systems. A considerable amount of this material is available from overseas. The coordinating body could ensure that digests and bibliographies of Australian material are available for international information systems.

300. Rapid advances in information systems and communications technology are likely to enable telephone subscribers in the near future to have direct access to a number of computer based information services, including video display and remote printers. This would greatly improve general community access to such data. While

some data banks will need to satisfy specialist technical information needs, as does the Toxicology Data Bank, evidence clearly indicates a need for chemical information that can be used by the intelligent layman. This is particularly relevant to occupational health, craft and domestic users.

301. In addition to the functions of the coordinating council for chemical safety recommended in Chapter 4, the Committee recommends that:

the coordinating council for chemical safety:

- **establish and coordinate a national chemical information system;**
- **ensure the comprehensiveness of the system;**
- **coordinate access to overseas elements of the information system; and**
- **ensure the reliability of access to components of the system.**

Dissemination of Information

302. As well as systems providing information to those who seek it, a number of submissions have sought public education campaigns to alert the general population to potential hazards. This applies particularly to substances whose common or long established use or availability might lead people to believe to be completely safe. For example, while caution has been urged in a number of submissions, toward contact with certain types of chemicals by women who are pregnant, or likely to become pregnant, other evidence emphasises the risk to offspring when men are exposed to mutagenic chemicals prior to conception. It has been noted that there is a perception by parts of the community, of a high hazard risk attached to particular chemical groups. Pesticides, the transport of dangerous goods and hazardous waste disposal are subjects where public education would put public concern in perspective.

303. As mentioned in Chapter 4, education on the dangers of particular chemicals or groups of chemicals and the explanation of safety precautions are probably more effective than legislation alone. People generally have an interest in their own health and when provided with the right information can effectively reduce the impact of hazardous chemicals on health and the environment. The importance of community understanding in effective environmental protection machinery cannot be overemphasised.

304. Public education is not simply the printing of explanatory brochures or otherwise making information available. It requires the study and implementation of effective communication and promotion strategies for the particular educational purpose.

305. The New South Wales Department of Agriculture has been conducting a well organised campaign ('Citizen Sam says . . . .') following the introduction of new pesticides legislation to reinforce the legislative requirements. The campaign has been aimed mainly at primary producers. Some recent material from the Agricultural and Veterinary Chemical Association has utilised effective strategies to encourage users to observe safety precautions. There is a large amount of passive health and safety information available, although this is far from comprehensive. Commonwealth and State Departments of Primary Industry produce literature on the dangers and proper methods of using the different kinds of pesticides. The Occupational Health Committee of the NH & MRC has developed codes and guides for the handling of a number of hazardous occupational substances. The Committee believes that chemical health and safety information should be more actively disseminated, utilising effective preventive health promotion strategies.

306. Access to data should be as free as possible, subject to certain confidential trade information.

Endnotes

84. NH & MRC Approved Occupational Health Guide 'Recognition and Appraisal of Chemical Hazards', Appendix 4, June 1982.
85. Ibid.
86. Transcript, p.3524-5.
87. *Toxic Chemicals and Public Protection*, p. xvii.