National Competition Policy Review of the:

Health Act 1958;

Health (Infectious Diseases) Regulations 1990;

Health (Prescribed Accommodation) Regulations 1990;

Health (Pest Control Operators) Regulations 1992

Final Report

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Summary of Recommendations

Part 2, Division 3 – Local Administration

- That the Health Act be amended to provide that local councils may employ as an environmental health officer a person with prescribed qualifications.

- That the Secretary to the Department of Human Services be given power to prescribe the qualifications of environmental health officers.

Part 5, Division 2A – Pest Control Operators

- That the requirement for registration of pest control operators be repealed from the Health Act.

- That the Health Act continue to require people who apply pesticides in the course of the business of a pest control operator to be licensed.

- That the Health Act be amended to remove commercial chemical control applicators licensed under the *Agricultural and Veterinary Chemicals (Control of Use) Act* 1992 from the licensing requirements of the Health Act and regulations where they apply pesticides in the course of a business in areas where there is no substantial risk to public health.

- That the controls on the use of prescribed pesticides in the Health Act be repealed.

- That the requirement that licensees submit to regular medical examinations in the Health Act be repealed.

Part 6, Division 6 – Special Provisions Relating to HIV

- That the Health Act continue to provide qualification or experience requirements for a person providing pre test and post test counselling.

- That the Health continue to limit which laboratories can conduct HIV testing.

- That the Health Act continue to require prescribed places to provide information about the incidence of HIV.

Part 12 – Accommodation

- That the Health Act continue to require the registration of prescribed accommodation.

- That Regulation 7 of the *Health (Prescribed Accommodation) Regulations* 1990 be amended to bring the room size requirement in line with NSW and South Australian requirements (one person for every two square metres) and to amend the short stay accommodation exclusion from 14 to 31days or less.

- That Regulation 15 of the *Health (Prescribed Accommodation) Regulations* 1990 be amended to bring the toilet, bath and shower facilities requirement in line with the BCA requirement of one per 10 persons.

Part 14 – Drugs, Substances and Articles

- That sections 230, 231, 238, 242, 245, 246, 270A, 271 and 274 of the Health Act be repealed.

Part 15 – Meat Supervision

- That sections 305 and 309 of the Heath Act be repealed.

Part 19 – Registrations

- That the Health Act continue to require registration of premises from which the activities of hairdressing, beauty therapy and skin penetration procedures are conducted.

1 Introduction

1.1 Principles and Purpose of the Review

In 1995 the Council of Australian Governments (COAG) agreed to implement the National Competition Policy (NCP) based on the recommendations of the National Competition Policy Review Committee chaired by Professor Fred Hilmer.[1] NCP represents a commitment by all Australian governments to a consistent national approach to fostering greater economic efficiency and improving the overall competitiveness of the Australian economy.

NCP is being given effect through the implementation of three intergovernmental agreements signed by COAG in April 1995, namely:

- The *Conduct Code Agreement* which committed governments to the application of uniform competition laws.
- The *Competition Principles Agreement* which established consistent principles governing pro-competitive reform of government business enterprise and government regulation.
- The *Agreement to Implement National Competition Policy and Related Reforms* which incorporated a timetable for reform and a commitment by the Commonwealth to make additional general purpose payments to the States conditional upon compliance with the agreed reform agenda and timetable.

As part of the *Competition Principles Agreement*, all governments agreed to adopt the following **guiding legislative principle**:
Legislation should not restrict competition unless it can be demonstrated that:

- The benefits of the restriction to the community as a whole outweigh the costs; **and**
- The objectives of the legislation **can only** be achieved by restricting competition.

To give effect to this principle, governments have agreed to:

- Review, and where appropriate, reform all existing legislative restrictions on competition against the guiding legislative principle; and
- Ensure that all new legislative proposals are assessed against this principle.

The *Competition Principles Agreement* provides that in assessing the costs and benefits of a restriction on competition, the following matters, where relevant, are to be taken into account:

- Government legislation and policies relating to ecologically sustainable development;
- Social welfare and equity considerations, including community service obligations;
- Government legislation and policies relating to matters such as occupational health and safety, industrial relations and access and equity;
- Economic and regional development, including employment and investment growth;
- The interests of consumers generally or of a class of consumers;
- The competitiveness of Australian business; and
- The efficient allocation of resources.

The *Competition Principles Agreement* also requires that legislation reviews consider the following:

- The objectives of the legislation;
- The nature of the restriction on competition;
- The likely effect of the restriction on competition and on the economy generally;

[1] *National Competition Policy: Report by the Independent Committee of Inquiry*, Australian Government Publishing Service, Canberra, 1993

- The costs and benefits of the restriction and their balance; and
- Alternative means for achieving the same result including non legislative approaches.

The purpose of the guiding legislative principle is to critically assess whether restrictions on competition are necessary to achieving the objectives of the legislation in which they appear. As is stated in the Victorian Government's *Guidelines for the Review of Legislative Restrictions on Competition*[2]*:*

> *These [restrictions] typically evolved to serve wider public policy objectives, including protection of the consumer, the environment or the wider public from unscrupulous, unsafe or environmentally destructive practices, processes or products. The guiding legislative principle established under the Competition Principles Agreement does not imply that competition objectives should take precedence over these important policy objectives. However, the form which regulation takes often creates unwarranted barriers to entry to relevant markets, limiting consumer choice, stifling innovation and generating monopoly rents for existing producers which result in higher prices to consumers.*

Application of the guiding legislative principle is intended to establish whether particular restrictions on competition remain necessary to the achievement of specific public policy objectives through a rigorous assessment of the benefits to the public of each restriction compared with the costs involved, and assessment of non-regulatory alternatives.

The general proposition underlying these reviews is that open and unrestricted competition in markets is generally the most efficient method of allocating the community's resources, and that the benefits of a restriction on competition will generally only outweigh the costs in situations of "market failure". Therefore, intervention in markets should generally be restricted to those situations.

1.2 Conduct of the Review

The Victorian Government Timetable for the review of legislation and the Terms of Reference for this review (a copy of which are set out in Appendix I) provide for the review to be conducted in accordance with the In House Review Model outlined in the Victorian Government's *Guidelines for the Review Of Legislative Restrictions On Competition.*

A review panel that satisfies the necessary independence criteria has conducted this review. Information about the review panel is set out in Appendix II.

The In House Review Model has no minimum consultation requirements. In this review extensive public consultation was undertaken in the form of a discussion paper released in November 1998 and a series of public forums. This was as part of a wider review of the Act in general. More than 100 public submissions were received over a period of three months from a variety of sources including local government, professional associations, peak health bodies, health workers in the respective areas, industry representatives and members of the general public.

The panel has prepared this report for the Minister of Health who commissioned the review. The findings and recommendations contained in the report are those of the panel and they do not necessarily represent the views or policies of Government. Following receipt of this report by the Minister, the Department of Human Services (DHS) will prepare a proposed Government response for the Minister's consideration.

[2] Victorian Department of Premier and Cabinet, 1996, p 29.

1.3 Methodology for the NCP Review of the Health Act and Regulations

The review will be conducted in accordance with the Victorian Government's *Guidelines for the Review of Legislative Restrictions on Competition.* Those Guidelines suggest a four step approach to the review of legislation for NCP purposes. These are as follows:

Step 1: Describe the industry as it currently exists and the existing or proposed legislative framework.

Step 2: Identify the restrictions on competition in the existing or proposed legislation.

Step 3: Show that the restriction is necessary to achieve the objective which the legislation is attempting or will attempt to achieve. This involves:

- stating the objectives of the legislation or proposed legislation;
- showing why the restriction on competition is necessary in order for that objective to be achieved; and
- demonstrating that there are no alternative means of achieving that objective which do not involve a restriction on competition, or at least which involve a lesser degree of restriction on competition.

Step 4: Assess the costs and benefits to the community of the restriction on competition. This involves:

- identifying who is effected by the restriction on competition;
- identifying likely effects of the proposed restriction on the economy;
- assessing the costs of the restriction to the community as a whole;
- assessing the benefits of the restriction to the community as a whole; and
- analysing whether the benefits outweigh the costs to the community as a whole.

2 Legislation and Objectives

Public Health is said to be the organised response by society to protect and promote health and to prevent illness, injury and disability[3]. Strategies used to achieve this are, broadly speaking, health protection, prevention of disease and health education and promotion. Underpinning these strategies is the use of epidemiological analysis to understand disease and trends in health as well as research.

Public health aims at preventative measures and intervention to minimise potential health problems and risks with a clear focus on the health of populations rather than the treatment of individuals. Part of the organised response to public health concerns is the implementation of legislative mechanisms to support public health strategies.

One of the main pieces of legislation in Victoria that addresses public health issues is the *Health Act* 1958. The Health Act legislates for an extremely diverse range of matters from the control of infectious diseases to nuisance to the regulation of pest control operators. Only a few matters governed by the Health Act create restrictions on competition however these few restrictions cover a significantly diverse range of public health issues.

The *Health Act* 1958 does not have any stated objectives however, given an understanding of public health and considering the subject matter regulated, it can be inferred that the principle objective of the legislation is the protection of public health. When wide ranging amendments to the Act were introduced into Parliament in 1988, the Minister in his second reading speech stated that "The current law applying to public health is found, essentially, in the Health Act 1958…Despite its shortcomings, the Health Act underpins a wide range of public health programs."

At the time of those amendments, a new section 5A containing objects was inserted into the Act in 1988 but this section has never been proclaimed. The unproclaimed section is:

5A. Objects
The objects of this Act are—

a) to ensure equity in health; and
b) to help people live as full a life as possible no matter what their pre-existing level of health; and
c) to reduce the incidence of disease, disability, distress and symptoms of ill health; and
d) to reduce the incidence of untimely death.

Whilst these objects are not operational, they do give a concise statement of the role of the Act and the objectives that underpin it. In addressing the question of whether the objectives of the legislation can only be achieved by restricting competition, the review team take the view that it can reasonably be implied that the objectives of the *Health Act* 1958 are the protection and promotion of public health.

[3] Definition of Public Health in the memorandum of understanding signed by all jurisdictions to establish a national public health partnership.

3 Market Failure and Regulation

Some public health legislation intervenes in the operation of markets or otherwise involves the imposition of costs on society in order to safeguard public health. It is a principal function of public health law to help ensure that society avoids the significant human and economic costs that would result from market failure in the delivery of the goods and services necessary to safeguard, maintain and improve public health. Therefore, there may be times when legislation intervenes in the operation of markets or otherwise imposes costs on society in order to safeguard public health.

Most commonly, market failure arises in the presence of one or more of the following:

- *Public goods* - where goods would not be provided if left to the free operation of the market;
- *Externalities* - where an activity or a transaction confers benefits or imposes costs on people who are not involved in it;
- *Natural monopolies* - where it is open to a firm to abuse its market power; and
- *Information asymmetries* - where the seller of a good or service has more knowledge about it than the buyer, meaning that the buyer is unable to adequately protect himself or herself during the transaction or incurs unacceptably high costs in finding a suitable provider.

All of the restrictions on competition which appear in the *Health Act* 1958*,* the *Health (Infectious Diseases) Regulations* 1990*,* the *Health (Prescribed Accommodation) Regulations* 1990 and the *Health (Pest Control Operators) Regulations* 1992 and some alternative ways in which the objectives of those pieces of legislation might be achieved were identified in the Discussion Paper.

4 Legislative Restrictions on Competition

A list of the legislative restrictions contained in the *Health Act* 1958 the *Health (Infectious Diseases Regulations* 1990 ("ID Regulations"), the *Health (Prescribed Accommodation) Regulations* 1990 ("PA Regulations") and the *Health (Pest Control Operators) Regulations* 1992 ("PCO Regulations") and the chapters in which they are discussed are as follows:

Chapter 4:	**Part II, Division 3 - Local Administration**
Section 30A	Restriction on who may be an environmental health officer

Chapter 5:	**Part V, Division 2AA - Radiation Safety**
Sections 108AC - 108AE	Registration of radiation apparatus and sealed radio active sources
Section 108AF - 108AG	Licence to operate, use, manufacture, store, transport, sell, possess, install, service, maintain, repair, test, dispose of or otherwise deal with radiation apparatus
Section 108AL	Registration of persons to practice in radiography or nuclear medicine technology

Chapter 6:	**Part V, Division 2A - Pest Control Operators**
Section 108B	Registration of pest control operators
Section 108C	Licensing of pesticide users
Section 108D	Control on use of pesticides
Section 108F	Deregistration of pest control operators
Section 108G	Requirement for medical examinations
PCO Regulation 9	Qualifications required for licensing as a pest control operator
PCO Schedule 2	Courses Approved for purpose of obtaining qualifications as a pest control operator

Chapter 7:	**Part VI - Division 6 - Special Provisions Relating to HIV**
Section 127	Restrictions regarding pre and post test counselling
Section 130	Limitations on laboratories which can test for HIV
ID Regulation 18	Prescription of qualifications for HIV Counsellors

Chapter 8:	**Part XII - Accommodation**
Section 210	Mandatory registration of prescribed accommodation
PA Regulation 5	Specifies the classes of prescribed accommodation that are subject to the Act
PA Regulation 7	Limit on the number of persons per square metres of area
PA Regulation 8	Requirement of standard of maintenance
PA Regulation 9	Obligations in relation to cleanliness of facilities and bed linen
PA Regulation 10	Obligation to provide continuous and adequate water supply
PA Regulation 11	Obligation to provide drinking water fit for human consumption
PA Regulation 13	Obligations with respect to rubbish receptacles
PA Regulation 14	Obligations with respect to refuse disposal
PA Regulation 22	Obligation to keep register of occupants
PA Regulation 23	Prohibition on advertising that premises are registered or approved for any accommodation purpose other than that set out on the certificate of registration
PA Regulation 24	Consent required for change of use of any room

Chapter 9:	**Part XIV - Drugs, Substances and Articles**
Section 230	Prohibition on selling and mixing injurious ingredients in drugs
Section 231	Prohibition on sale of improper food and drugs
Section 238	Prohibition of sale of any adulterated or improperly packed articles
Section 242	Restriction on sale of disinfectants, germicides, antiseptics, preservatives or household insecticides
Section 245	Prohibition on manufacture or sale of toys, wall-papers, and serviettes containing substances exceeding a prescribed quantity
Section 246	Prohibition on manufacture or sale of textiles or leather containing specified substances in greater than prescribed quantity
Section 249	Restriction on advertising of drugs, medicines and appliances
Section 270A	Requirement that specified formularies be used when preparing medicines
Section 271	Labelling requirements for drugs
Section 274	Only approved drug analysts be permitted to make analysis under that division

Chapter 10:	**Part XV - Meat Supervision**
Section 305	Restriction of certain activities to licensed meat processing facility
Section 309	Prohibition on sale of flesh of prohibited animals

Chapter 11:	**Part XIX - Registrations**
Section 366C	Mandatory registration of premises conducting business of hairdressing, beauty parlour or similar business, tattooing, ear piercing, acupuncture or any other process involving skin penetration
Section 368	Fee for registration
Section 369	Refusal of registration or renewal of registration

5 Part 2, Division 3 - Local Administration

5.1 Background

There is a long standing partnership between state and local government in the administration of health legislation. Local government has always been the front line of operational activities in traditional public health matters, with DHS having a primarily policy and advisory role which involves superintendence of the legislative framework.

Section 29A of the Act states that it is the function of every council to seek to prevent diseases, prolong life and promote public health through organised programs including prevention and control of environmental health dangers, diseases and health problems of particularly vulnerable population groups. This is to be achieved by a range of measures specified in the Act. These are:

- Isolating the special factors affecting the health of people within the municipal district;
- Developing and enforcing up-to-date public health standards and intervening if the health of people within the municipal district is affected;
- Monitoring the activities of and assisting other agencies whose work has an impact on public health and, if necessary, advocating on behalf of the people within the municipal district for adoption and enforcement by those agencies of appropriate standards;
- Coordinating the immunisation of children living or being educated within the municipal district; and
- Ensuring that the municipal district is maintained in a clean and sanitary condition.

Section 30A (1) of the Health Act requires local councils to appoint one or more Environmental Health Officers (EHOs). Section 30A (2) of the Act specifies that EHOs must be eligible to be members of the Australian Institute of Environmental Health. EHOs perform many of the functions of authorized officers under the Act but an authorized officer does not have to be an EHO.

The qualification requirements for a person performing functions of EHOs for local council is a restriction on competition because it creates a barrier to entry to the market for these services.

5.2 Description of the Market

In *The Role of Local Government in Public Health*, the National Public Health Partnership (NPHP)[4] has provided an overview of the structure of local government in Victoria. There are a total of 78 Councils, 31 in metropolitan Councils and 47 rural Councils. A breakdown of local councils by population was provided as follows:

Rural Councils:
9 Councils less than 10,000 people
15 Councils less than 20, 000 people
11 Councils less than 30,000 people
5 Councils less than 40,000 people
2 Councils less than 50,000 people

Metropolitan Councils:
4 Councils less than 60,000 people
3 Councils less than 80,000 people

Greater Geelong 186,307
Greater Bendigo 86,451
Ballarat 80,330
La Trobe 70,822
Greater Shepperton 55,117

[4] National Public Health Partnership. *The Role of Local Government in Public Health*, Draft Consultation Report, September 2000.

Metropolitan Councils (cont):
5 Councils less than 100,000 people
4 Councils less than 120,000 people
8 Councils less that 140,000 people
2 Councils less than 150,000 people
5 Councils over 150,000 people

The position of EHOs has been an important one in the delivery of health programs at the local government level. At present the Health Act requires that every Council must appoint one or more EHOs, and that such appointment can only be made for a person who is, or who is eligible to be, a member of the Australian Institute of Environmental Health (AIEH).

All persons employed in an environmental health or related area may gain membership with AIEH, at a level appropriate to their qualifications. However, AIEH policy provides that to professionally practice as an EHO under Australian or State/Territory Acts, Regulations or Awards requires the successful completion of an AIEH accredited Bachelor Degree majoring in environmental health.[5] Currently two courses are accredited in Victoria: the Bachelor of Applied Science (Environmental Health) at Swinburne University of Technology; and The Bachelor of Public Health (Environmental Health) at LaTrobe University (Bendigo Campus). The AIEH has advised that as at November 2000, there were 290 EHOs either employed or contracted by the 78 Local Government Authorities in Victoria. The AIEH has reported that there are several vacancies for qualified EHOs meeting the above professional standard.[6] The shortage of EHOs in Victoria was also reported by a number of local councils in submissions to the Health Act Discussion Paper.

Stakeholders in the EHO service industry affected by the restriction include:

- Local councils who have a statutory requirement to employ one or more EHOs;
- EHOs;
- AIEH;
- The community generally which has to bear the costs to the public health system and the environment if the duties of EHOs are not conducted by appropriately qualified and experienced persons.

5.3 Market failure

The potential source of market failure in the environmental health service area is information asymmetries due to knowledge disparity which may exist between the provider of services (EHOs) and the consumer who entered into the contract for the provision of environmental health services (local councils). Many different disciplines contribute to environmental health - basic sciences such as chemistry, microbiology, engineering, statistics, physiology, epidemiology, toxicology, virology and sociology. Local councils may not have the technical expertise, information, time or resources to assess the suitability or appropriateness of qualifications in this diverse range of disciplines.

5.4 Objectives of the Legislation

The objective of the requirement that EHOs have membership of the AIEH is to help to ensure that EHOs have the relevant qualifications and experience to assist local councils meet their obligations under the Health Act as they relate to public health, that is, to prevent disease, prolong life and promote public health through organised programs.

[5] www.aieh.org.au
[6] www.aieh.org.au

5.5 The Rationale for Legislative Intervention

The public health role of local government is vital in improving, promoting and protecting the health of their communities. A survey of local government conducted by NPHP[7] provided an overview of the activities undertaken by local government in relation to public health, including:

- Involvement in monitoring the local physical environment for health and safety concerns, eg. environment protection, public health planning, tobacco control, mosquito control and monitoring water quality;
- Considering health objectives in local council planning activities, eg. assessment of planning applications for environmental health impacts;
- Water supply and waste management roles, eg. waste depots, kerbside recycling, water management;
- Food safety and nutrition activities, eg. food safety surveillance and enforcement, education programs on food hygiene;
- Health measures/services targeted at particular groups, eg. childcare, immunisation activities, support services like, meals on wheels, youth activities, aged care, community transport, crime prevention, provision of sport and recreation facilities; and
- Other health related measures, eg. cemeteries, Legionella control, monitoring pesticides.

The community places a high value on access to clean water and services such as waste removal and sewerage, but they are often taken for granted until a breakdown in the system occurs. Public health crises such as the recent Legionella outbreak in Victoria demonstrates the serious health, social and financial consequences of breakdowns in the health protection system.

The status of EHOs in the community is an important factor in their recognition by the community and consequently in having their recommendations implemented. Qualifications and membership of professional bodies are important contributing factors in recognition of EHO status.

However, the question is raised as to whether EHOs should be specified in the Health Act and whether the Health Act ought to dictate their membership of a particular body. There is no such requirement in similar Australian legislation. Some examples of more recent public health legislation include the *Public and Environmental Health Act* 1987 (SA), which makes provisions for the appointment for authorised officers with qualifications approved by the South Australian Health Commission. The *Public Health Act* 1997 (Tas) gives power to the General Manager of a Council to appoint persons with approved qualifications as EHOs. In the *Public Health Act* 1991 (NSW), the definition of 'authorised officer' includes:

- An EHO employed by the local authority for the area in which the premises are situated; or
- An EHO of the Department of Health; or
- A person authorised by the Minister or the Director-General to exercise the powers conferred by this Part on an authorised officer.

The *Public Health Act* 1997 (ACT) empowers the Chief Executive to create and maintain one or more offices in the Government Service, the duties of which include performing the functions of a public health officer. Section 14 allows the Chief Health Officer to authorise a public health officer to carry out specified functions.

[7] ibid,p.27

5.7 Costs and Benefits of the Restrictions

The Health Act Review Discussion Paper sought comments on the costs and benefits of the restrictions, whether the costs outweigh the benefits and whether there are any less restrictive means of achieving the objective of the restriction.

5.7.1 Costs

The restriction imposes direct costs of AEIH membership on persons working as EHOs in local council. The annual AIEH membership fee for 2000/2001 was $220. An additional Certificate of Recognition is issued by AIEH to members who fulfil the requirements to professionally practice as an EHO. The administration costs of AIEH membership and the costs of issuing certificates, borne by the organization, is offset some degree by the membership fees charged.

The costs imposed on local councils by the requirement that they employ persons eligible for AIEH membership may be the higher salary rates associated with their employment relative to other potential applicants for the position of EHO. The AIEH has reported the gross salary range for EHOs in the first five years of practice is $40,000 to $45,000.

The cost to rate payers may result from local councils electing to pass on compliance costs to reduce their overheads.

5.7.2 Benefits

The undergraduate training of EHOs provides a broad scientific base and equips them well to perform in areas of environmental health practice. The traditional role of EHOs has been the enforcement and monitoring of legislative requirements. The traditional duties of EHOs, therefore, has involved the technical aspects of monitoring and surveillance of environmental health issues such as food safety, waste management, management of water control and pest control. However, the role of EHOs has evolved with the changes in the way that environmental health is now approached. The key agents for change have been reported in *The National Environmental Health Strategy*[8] as follows:

- Moves away from government regulation to co-regulation;
- Performance-based management;
- The outsourcing of services;
- Third-party compliance;
- The broadening of environmental health; and
- Local government mergers and downsizing.

Changes to the field of environmental health has seen the need for EHOs to constantly update and adjust their skills and knowledge base, for example, there has been an increasing need to specialize in areas such as food safety or waste management.[9]

The majority of submissions to the Health Act Discussion Paper supported the importance of the role of EHOs as the primary officers responsible for undertaking health protection strategies for local councils and the expansion of their role into health promotion and health planning strategies. There was broad recognition of the need for relevant qualifications and experience to fulfil the role of an EHO.

[8] Commonwealth Department of Health and Aged Care. *The National Environmental Health Strategy*, Commonwealth of Australia, 1999.
[9] ibid, p.29

The submission received from the Mildura Rural City Council stated that:

> *EHO's in Local Government deal with a huge range of issues especially in the rural municipalities ranging from noise, animal and odour all relating to the quality of life of their community in which we live. Some even have local laws, fire and emergency management roles in addition to the traditional public health ones. The professional qualifications necessary for these officers to operate needs to be maintained and any suggestion to lessen qualification or to authorise unqualified persons will obviously lead ultimately to a degradation of our public health system.*

The submission received from the AIEH (Vic.) stated that:

> *The Health Act review should recognise the important public health reasons for maintaining restrictions on the class of persons who may act as EHO's specifically in the areas of infectious disease control; food safety and public nuisances. The public health reasons include:*
> - *total de-regulation may expose local councils to risks associated with employment of practitioners not adequately trained to undertake local public health work;*
> - *knowledge that all EHO's have specialist skills and qualifications in the areas of infectious disease control; food safety and nuisance prevention in field based settings;*
> - *the significant powers and responsibilities that are administered and the need to maintain high quality standards and transparency to maintain public confidence in the public health system; and*
> - *the move away from prescriptive legislation which places greater emphasis on professional judgements and standards.*
>
> *The Health Act review should recognise that a number of functions contained within the Act may be fulfilled by a range of health practitioners and that levels of responsibility should be aligned to relevant qualifications and competencies.*

The submission received from LaTrobe Shire stated that:

> *The [Health Act] Review should take account of the need to expand the range of practitioners and specialists involved in public health work, noting that public health practice requires and calls upon a diverse range of skills and knowledge in developing effective interventions.*

A number of submissions supported the establishment of a registration body for EHOs for the purposes of setting minimum and optimum qualifications to be obtained for a person wishing to practice as an EHO and to monitor standards of practice, both on an individual and industry wide basis. The public benefit case for registering EHOs has not been considered as part of this NCP Review as such a system is considered more restrictive in relation to entry into, and conduct within, the market for EHO services than provided by the current regulatory system under the Health Act.

The benefits to EHOs of professional membership, in addition to eligibility to be employed as an EHO under the Health Act, as outlined by AIEH[10], include:

- Professional recognition (where appropriate);
- 'Networking' on a local, state, national, international basis;
- Ability to participate in a Continuing Professional Development scheme;
- Having a say in the development of various government policies;
- Having the opportunity to contribute to the profession of environmental health;

[10] www.aieh.org.au

- Receiving a national journal (quarterly) and state newsletters;
- Participation in Conferences and Workshops;
- Being kept informed of developments in the profession;
- Receiving Minutes of State Council meetings (in some States);
- Attending Conferences /Workshops and training courses developed by the Institute specifically for members and at special discount prices to members;
- Advice of overseas contacts and overseas conferences;
- Access to professional codes, plans, strategies, which are especially developed for the Institute's members; and
- Participation in discussion, advocacy and promotion of Environmental Health issues.

The benefits to the local council and the community generally of suitably qualified and experienced EHOs undertaking health protection and prevention activity include:

- Protection and promotion of a healthy environment;
- Prevention of unnecessary morbidity and mortality;
- Avoidance of lost work hours;
- Savings in health care costs.

5.7.3 Analysis of the costs of the restrictions against the benefits

The costs borne by local councils to employ appropriately qualified persons to fulfil the role of EHOs under the Health Act would be a requirement of councils whether or not the restriction was imposed. The main benefit of employing appropriately qualified EHOs is to help to ensure fulfilment of the statutory requirements of local councils under the Health Act.

It is AIEH policy that to professionally practice as an EHO under Australian or State/Territory Acts, Regulations or Awards requires the successful completion of an AIEH accredited Bachelor Degree majoring in environmental health. Therefore, the costs borne by AIEH in maintaining a system of professional membership would be borne by the organization whether or not EHOs were required under the Health Act to have professional membership of that organization.

Persons seeking employment as EHOs would benefit from the removal of the restriction on entry into this market for services, including the financial saving of the annual membership fee. There are potential benefits of AIEH membership, however, EHOs would be able to choose whether or not these are of individual benefit to them in fulfilling their professional roles. The benefits of professional membership and minimum qualification requirements include recognition of EHOs by the community and consequently assist in having their recommendations implemented.

The community benefits from the employment by local council of appropriately qualified EHOS through the prevention of serious health, social and financial consequences of breakdowns in the health protection system enforced by EHOs under the Health Act.

5.8 Alternatives to these Restrictions

5.8.1 No regulation

If there are no regulations governing the persons who are suitable for appointment by local councils as EHOs, there is the concern that those appointed may not have the qualifications and expertise necessary to implement public health protection and promotion strategies. The risks to public health are such that there is a strong public health advantage to be gained from setting minimum qualification requirements for practice as an EHO.

5.8.2 Removal of professional membership and relying on general qualification requirement

Professional membership of AIEH is not the least restrictive option to ensure that EHOs have appropriate qualifications and experience to assist local councils meet their obligations. The requirement for professional membership of AIEH could be removed from the Health Act, and replaced with a general requirement for EHOs to have prescribed qualifications. This is consistent with the approach taken in other jurisdictions (see section 5.5). As the net public health benefit of setting qualification requirements is positive, such as system would be expected to continue to support the adequate recruitment and supply of well trained and competent graduates.

5.9 Conclusion

Whilst it is considered that EHOs will continue to play an important role in health protection and promotion in Victoria, it is not necessary for the Act to specify an organization to which such officers should belong. It is consistent with a more flexible and less restrictive approach to allow councils to employ any individual to carry out the duties of EHO as currently set out in the Health Act, as long as they have the proper qualifications. The Health Act should state that the Secretary to DHS could prescribe qualifications to be held by EHOs.

5.10 Recommendations

5.10.1 That the Health Act be amended to provide that local councils may employ as an environmental health officer a person with prescribed qualifications.

5.10.2 That the Secretary to the Department of Human Services be given the power to prescribe the qualifications of environmental health officers.

6 Part 5, Division 2AA - Radiation Safety

Part 5, Division 2AA of the *Health Act* 1958 regulates the use of radiation in order to protect medical patients, people who use radiation, members of the public and the environment from the dangers of radiation. It does this by:

- Requiring radiation apparatus and sealed radioactive sources to be registered;
- Requiring people who deal with radiation apparatus and radioactive substances (other than registered medical radiation technologists) to be licensed;
- Providing for the making of regulations in respect of radiation safety;
- Establishing the Radiation Advisory Committee; and
- Establishing a system of registration for medical radiation technologists.

The registration and licensing requirements established by the Act are restrictions on competition because they are barriers to entry into the market for the provision of services which involve the application of radiation.

Whilst these requirements are restrictions on competition, they are not being considered as part of this report. Radiation safety has been the subject of a significant amount of national work to develop national uniformity. As part of this process it was agreed between jurisdictions that the various State, Territory and Commonwealth radiation protection legislation would be the subject of a national review under national competition policy. Part 5, Division 2AA of the Health Act has been included as part of this national review.

The timelines for the review set out in the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Issues Paper[11] are as follows:

- August to mid-October 2000: Complete an Issues Paper, obtain National Uniformity Implementation Panel (Radiation Control) [NUIP(RC)] agreement and prepare for the consultation phase [*completed*].
- Mid-October to end-November 2000: Widely publicise the Issues Paper and call for written submissions [*closing date for submissions is 30 November 2000*].
- December 2000 to January 2001: Prepare a (draft) final report, incorporating the cost-benefit analysis that will form the basis for the recommendations.
- February 2001: Focussed consultation with key stakeholders on (draft) final report.
- March 2001: NUIP(RC) to finalise report and make submission.

[11] ARPANSA, *National Competition Policy: Joint Review of Radiation Protection Legislation, Issues Paper*, October 2000.

7 Part 5, Division 2A - Pest Control Operators

7.1 Background

When assessing the restrictions in relation to Part 5, Division 2A of the Act, it should be noted that "pests" and "pesticide" are defined broadly in the Act. "Pesticide" includes:

- All substances which are used to deal with any animal, plant or other biological entity which injuriously affects another animal, plant or thing or the use or enjoyment of any place;[12] and
- Any household insecticide.

"Pests" includes:

- Insects or other pests which affect or attack or are likely to affect or attack persons, animals, plants or fruit;
- Pest animals, fungi or other parasitic plants and bacteria; and
- Weeds or other vegetation which inhibit primary intended growth on urban, industrial, municipal or public lands.

It is important to note that the restrictions only apply to businesses whose primary purpose is pest control and to persons who work within those businesses. Therefore, for example, they do not apply to farmers, municipal councils, plant nurseries, golf courses and schools who apply pesticides in the course of their businesses, or to the people who are employed in those businesses. People who apply pesticides in their own home would also obviously not be doing so in the course of a pest control business, and therefore the restrictions do not apply.

7.1.1 Business registration system

Section 108B of the Act sets out the pest control business registration. That section provides that people who carry on or hold themselves out in any way as carrying on the business of controlling, destroying or repelling pests and who use or intend to use pesticides in the course of that business shall not carry on that business unless they have paid the prescribed registration fee ($230) and had their name entered on a register kept by the Secretary to DHS.

DHS' *Guidelines for Pest Control Business Registration* require that the business in question have a person who is licensed at the technical manager level and whose licence is endorsed so as to allow him or her to conduct the type of pest control activity which the business intends to perform. Therefore, for example, if the pest control operator seeking registration intends to perform control of weeds, the relevant business must employ a person who is licensed at the technical manager level and whose licence is endorsed so as to allow him or her to control weeds. The guidelines also require that there be at least one person licensed at the technician level for every four people licensed at the trainee level. Finally, they state that for a pest control operator to be registered, the technical manager must demonstrate the required knowledge and skills and that the operator's equipment and storage facilities are adequate.

DHS ensures that these guidelines are complied with by pest control operators before their business is registered, and also checks ongoing compliance with the guidelines when it investigates complaints which have been made against particular operators.

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[12] Paragraph (a) of the definition of "pesticide" in section 108A says that it includes any agricultural chemical within the meaning of the *Agricultural Chemicals Act* 1958. That Act has been repealed and replaced by the Agricultural and Veterinary Chemicals (Victoria) Act 1994, and therefore [by virtue of s.15 of the *Interpretation of Legislation Act* 1984] "agricultural chemical" has the same meaning as the equivalent term in the Agricultural and Veterinary Chemicals (Victoria) Act. That Act defines "agricultural chemical product" to have the same meaning as in the Agvet Code of Victoria, which, by virtue of s.5 of the Agricultural and Veterinary Chemicals (Victoria) Act, is the Code set out in the Schedule to the Commonwealth's Agricultural and Veterinary Chemicals Act 1994. S.4 of that Code defines "agricultural chemical product" broadly enough to include all substances which are used to deal with any animal, plant or other biological entity which injuriously affects another animal, plant or thing or the use or enjoyment of any place (this is a summary of the actual definition which appears in s.4 and the definition of "pests" which appears in s.3).

Section 108F of the Act states that the Secretary may deregister a pest control operator if the pest control operator is convicted of an offence against the Act or Regulations.

This business registration system, and in particular the staffing, equipment and storage requirements imposed by the Secretary as a condition of registration, represents a restriction on competition because it constitutes a barrier to entry into, and restricts conduct within, the market for the provision of pest control services.

7.1.2 Occupational licensing system

Section 108C of the Act specifies that individual pest management technicians employed in pest control businesses be licensed. That section provides that a person shall not use or permit any other person to use any pesticide or class of pesticides in the course of the business of a pest control operator unless the user of the pesticide holds a valid licence as an authorised user of that pesticide. In order to gain such a licence, a person must pay the prescribed fee ($115), and satisfy a number of criteria which are set out in the *Health (Pest Control Operators) Regulations* 1992. These include:

- Completing one of the pest control courses nominated in Schedule 2 to the Regulations;
- Passing the relevant examination conducted by DHS;
- Being at least 18 years of age;
- Demonstrating the necessary practical skills.

DHS' *Guidelines for Pest Control Licensing* state that applicants for a licence may apply for endorsements to their licences for the types of pest control they wish to do, and for which they qualify. These licences are granted at one of three levels, namely technical manager, technician and trainee.

Section 108D(b) of the Act states that when pesticides are used in the course of the business of a pest control operator, the person so using the pesticides shall not use any pesticide prescribed as a regulated pesticide except as permitted in the *Health (Pest Control Operators) Regulations* 1992. No pesticide has been prescribed as a regulated pesticide and therefore this provision is currently not being used.

Section 108G of the Act provides that every licensee who uses any pesticide in the course of the business of a pest control operator shall submit to a medical examination as and when prescribed in the Regulations. The Regulations require that any person who holds a valid licence as an authorised user of Aldrin, Chlordane, Ethylene dibromide (EDB), Heptachlor or Methyl Bromide shall submit to a medical examination in March each year. The Act provides that after considering a report relating to this medical examination the Secretary may suspend or cancel the authorisation of the licensee to use a particular pesticide or class of pesticides or the licence as a whole. In fact the only one of these chemicals which is still in use in Victoria is Methyl Bromide, and production and use of that chemical is being phased out.

Any occupational licensing system for pest control operators and conditions on conduct, such as the requirement for an annual medical examination, represent restrictions on competition because it is a barrier to entry into, and conduct within, the market for the provision of pest control services.

7.2 Description of the Market

The pest management industry is comprised of the pesticide manufacturing industry, characterised by a small number of major chemical companies, and the pest control services industry, comprised of a few major companies and numerous smaller businesses.

IBIS Business Information has summarised the characteristics of the Australian pesticide manufacturing industry. [13] The industry accounts for 0.05% of GDP, which is small to medium relative to other industries in the Australian economy. The major market for pesticides is the agricultural sector (71.9%), the balance distributed in the non-agricultural sector, comprised mainly of livestock and dairy industries. The pesticide management industry is highly concentrated, with the top four companies estimated to account for approximately 60-80% of total industry turnover. Industry turnover in 1999-00 was approximately $1,385 million. Turnover has increased at an annual average rate of 10.4% over the five years to 1998-99, and is expected to grow at an annual average rate of 3.7% from 1998-99 to 2003-04.

IBIS Business Information has also presented data on the Australian pest control services industry.[14] The industry accounts for 0.03% of GDP, which is small relative to other industries in the Australian economy. Victoria represents 11.7% of the Australian pest control services industry. The industry can be divided into pest control (90%) and weed control (10%) services. The pest control industry services three main sectors: industrial, retail, hospitality and other commercial sectors (50%); households (20%) and Government (20%). The pest control services industry is less highly concentrated, with the two largest operators having an estimated market share of 46%. The balance is distributed over a large number of small operators. Industry turnover in 1999-00 was approximately $297 million. Turnover has increased at an average annual rate of 7.1% over the five years to 1998-99, and is expected to grow at an annual average rate of 4.3% from 1998-99. It was estimated that there were 1207 businesses in 1999-2000 which employed 4124 staff.

Key market characteristics and sensitivities were identified, including:

- Demand can be affected by seasonal factors, plagues, droughts;
- Demand is also affected by residential, and in particular, non-residential construction, in areas such as retail, general commercial and accommodation;
- A significant amount of price based competition occurs in the industry, particularly during recessions or slow economic growth periods;
- The industry was until recently in a mature stage of development, but new growth is occurring via franchised operators; and
- Income is derived from selling pest control services on a contract (75%) or on an as required basis to business, government and households industry segments.

The Environmental Health Unit of the Public Health Division, DHS, maintains a database of all registered businesses and licensed pest management technicians. As at November 2000, there were 539 registered pest control businesses and 1,430 licensed pest management technicians in Victoria.

[13] IBIS Business Information, C2544 Pesticide Manufacturing, 2000
[14] IBIS Business Information, L7865 Pest Control Services, 2000

The following table presents trends in the number of pest control businesses registered in Victoria, 1995-2000:

Year	Total No of businesses	No of New Businesses	Yearly Cancellations	New Applications as a Percentage of Total No Businesses	Cancellations as a percentage of Total No Businesses	Cancellations as a Percentage of New Businesses	New Business Retention Rate
1995	339	111	44	33%	13%	40%	60%
1996	360	51	40	14%	11%	78%	22%
1997	377	40	46	11%	12%	115%	-15%
1998	406	40	40	10%	10%	100%	0%
1999	480	72	10	15%	2%	14%	86%
2000	539	82	29	15%	5%	35%	65%
Yearly Average	**417**	**66**	**35**	**16%**	**9%**	**67%**	**36%**

The following table presents trends in the number of pest management technicians licensed in Victoria, 1995-2000:

Year	Licence Grade	Total No of Licences	Number of New Applicants	Yearly Cancellations	New Applications as a Percentage of Total Licences	Cancellations as a Percentage of Total Licences	Cancellations as a Percentage of New Licences	New Licence Retention Rate
1995	L	64	32	17	50%	27%	50%	50%
1995	M	347	53	21	15%	6%	15%	85%
1995	T	296	71	46	24%	16%	24%	76%
Subtotal		**707**	**156**	**84**	**22%**	**12%**	**22%**	**78%**
1996	L	141	103	21	73%	15%	73%	27%
1996	M	384	21	19	5%	5%	5%	95%
1996	T	303	49	34	16%	11%	16%	84%
Subtotal		**828**	**173**	**74**	**21%**	**9%**	**21%**	**79%**
1997	L	168	90	39	54%	23%	54%	46%
1997	M	417	18	22	4%	5%	4%	96%
1997	T	343	57	29	17%	8%	17%	83%
Subtotal		**928**	**165**	**90**	**18%**	**10%**	**18%**	**82%**
1998	L	182	113	46	62%	25%	62%	38%
1998	M	472	20	27	4%	6%	4%	96%
1998	T	386	64	54	17%	14%	17%	83%
Subtotal		**1,040**	**197**	**127**	**19%**	**12%**	**19%**	**81%**
1999	L	262	171	47	65%	18%	65%	35%
1999	M	556	51	26	9%	5%	9%	91%
1999	T	473	87	30	18%	6%	18%	82%
Subtotal		**1,291**	**309**	**103**	**24%**	**8%**	**24%**	**76%**
2000	L	328	209	74	64%	23%	64%	36%
2000	M	573	47	34	8%	6%	8%	92%
2000	T	529	101	63	19%	12%	19%	81%
Subtotal		**1,430**	**256**	**108**	**18%**	**8%**	**18%**	**82%**
Yearly Average		**1,245**	**251**	**117**	**20%**	**9%**	**20%**	**80%**

*Technician; **Technical Manager; ***Technician

Stakeholders in the pest management industry include:

- Pest control businesses;
- Employees of those businesses who are required to apply pesticides as part of their work;
- Consumers who purchase pest management services, including households, businesses and municipal councils;
- The chemical companies which manufacture pesticides;
- Members of the public who live or work close to areas in which pesticides are applied;
- Government regulatory authorities, in particular DHS and the Department of Natural Resources and Environment (DNRE);
- The community generally which may have to bear the costs to the public health system and the environment if pesticides are applied inappropriately.

7.3 Market Failure

The pest control business registration and occupational licensing systems are intended to address two possibilities for market failure in respect of the pest management industry. The first of these are the costs which the application of pesticides may impose on persons other than the pest management business and the consumer who entered into the contract for the provision of pest control services (negative externalities). These persons might be:

- The pest management technicians who are called upon by their employer to apply the pesticides in a way which is unsafe;
- Persons living or working close to a place where pesticide has been applied unsafely;
- Members of the community who may be called upon to pay for the cost to the public health budget or to suffer a degradation of their environment as a result of inappropriate pesticide application.

The second potential source of market failure in the pest management industry is the knowledge disparity which tends to exist between the provider of pest control services and the consumer of the services (information asymmetries). The provider of the services is clearly in a better position to know what is required to carry out effective pest control and the effect on health of the application of the relevant pesticide(s) than the consumer.

7.4 Effects of Other Legislation and the Common Law on these Market Failures

7.4.1 Agricultural and Veterinary Chemicals (Control of Use) Act and Regulations

The availability of chemical products used for pest control and the activities of businesses and individuals using such products are currently regulated in Victoria by several pieces of State legislation in addition to the pest control provisions in the Health Act. The most important of these is the *Agricultural and Veterinary Chemicals (Control of Use) Act* 1992, which includes among its purposes protection of the health of the general public, the users of chemical products and the environment. In furtherance of these objectives, the Act creates a number of offences including:

- Use of a chemical product that is not registered under the Agricultural and Veterinary Chemicals Code ("the Agvet Code") (section 6).[15]
- Use of a chemical product other than in accordance with its labelling instructions (section 19).

[15] This Code appears as a Schedule to the Commonwealth's *Agricultural and Veterinary Chemicals Code Act* 1994. It is adopted in Victoria by s.5 of the *Agricultural and Veterinary Chemicals (Victoria) Act* 1994.

- Use of a chemical product in contravention of an Order made by the Governor in Council (section 25A).[16]
- Spraying an agricultural chemical product (that is, pesticide[17]) in contravention of an Order made by the Governor in Council (section 38).[18]
- Spraying a pesticide in a way which damages any valuable plants or stock or any land outside the target area (section 40).
- Failing to comply with a notice not to use, or to repair, pesticide spraying equipment (section 46).

This Act also requires any person who carries on a business, or offers a service for fee or reward, which involves controlling pests through the application of herbicides, insecticides, fungicides or growth regulators to obtain a commercial operator licence (section 30).[19] This has the potential to overlap with the system which is established in the Health Act for registering pest control operators who use pesticides in the course of their business (the business registration system). This problem is avoided by an Order of the Governor in Council made under section 5 of the Agricultural and Veterinary Chemicals (Control of Use) Act exempting any person who is a registered pest control operator under the Health Act from the requirement to obtain a commercial operator licence.[20]

Any person operating an aerial agricultural spraying business requires an agricultural aircraft operator licence and a pilot conducting spraying for that business requires a pilot (chemical rating) licence (section 42).

As with the pest control business registration system under the Health Act, primary producers and home owners who apply pesticides on their own land are not covered by these licensing requirements, because they are not doing so in the course of a pest control business.

The commercial operator and agricultural aircraft operator licences described above both require the operator to maintain detailed records of chemical use and hold an approved insurance policy with at least $30,000 liability for property and personal damages caused by spraying. In addition, the operator must have demonstrated competencies relevant to its business. For a ground contractor this entails completing an approved course such as the Farm Chemical User Course (Farmcare) or a recognised equivalent. For an aerial contractor this entails being accredited at a standard equivalent to the Aerial Agricultural Association of Australia's Operation Spray Safe.

In respect of the licensing requirements in the Agricultural and Veterinary Chemicals (Control of Use) Act, it should be noted that section 28, which requires any person who uses a prescribed chemical product to be certificated regardless of whether he or she does so in the course of a business, is not presently in operation. This is because no chemicals have been prescribed under that section.

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16 The only Order made under s.25A appears in the *Victoria Government Gazette* No. S 86, dated 31 July 1997.

17 "Agricultural chemical product" is defined to have the same meaning as in the Agvet Code. The definition of this term which appears in s.4 of the Code is broad enough to include all substances which are used to deal with any animal, plant or other biological entity which injuriously affects another animal, plant or thing or the use or enjoyment of any place (this is a summary of the actual definition which appears in s.4 and the definition of "pests" which appears in s.3). Therefore, "agricultural chemical product" in effect means any pesticide used to deal with any biological entity.

18 The only order made under section 38 appears in the Victorian Government Gazette No. G 30, dated 1 August 1996.

19 s.30 requires a licence for a business involving the use of a "prescribed chemical product". The relevant chemical products are prescribed in r.8 of the *Agricultural Chemicals (Control of Use) Regulations* 1996 as being herbicides, insecticides, fungicides or growth regulators. Chemical product" is defined in s.4 of the Act as an agricultural chemical product within the meaning of the Agvet Code of Victoria. As explained in fn.5, this in effect means any pesticide.

20 *Victoria Government Gazette* G 30, 1 August 1996, pp.2008-9.

Regulation of the use of pesticides other than in the course of a business is instead done through the Order made under section 25A referred to above. This states that a person must not apply certain particularly dangerous chemicals unless he or she has an Agricultural Chemical User Permit (ACUP), or comes within one of the other nominated exceptions [which include being licensed under the Agricultural and Veterinary Chemicals (Control of Use) Act or registered as a pest control operator under the Health Act]. An ACUP is issued upon completion of the Farm Chemical User Course or a recognised equivalent.

Finally, the Agricultural Chemicals (Control of Use) Act gives authorised officers extensive powers to investigate possible misuse of pesticides, and allows for the seizure and destruction of pesticides whose sale or use is prohibited (Part 8).

The *Agricultural Chemicals (Control of Use) Regulations* 1996 also contain a number of provisions designed to protect pest management technicians, consumers and the environment from the dangers of pesticides. These include:

- A prohibition on the possession of certain pesticides (regulation 5);
- Record-keeping requirements in respect of certain particularly dangerous pesticides (regulation 6);
- Record-keeping requirements in respect of pesticides which are sprayed from the air and pesticides which are sprayed on the ground for fee or reward (regulation 7);
- Requirements for chemigation and aerial spraying equipment (regulations 9 and 10).

7.4.2 Occupational Health and Safety Act

Provisions of the *Occupational Health and Safety Act* 1995 (Vic.) which are of particular relevance in protecting pest management technicians and consumers from the dangers of pesticides are as follows:

- Employers shall make arrangements for ensuring so far as is practicable safety and absence of risks to health in connexion with the use, handling, storage and transport of substances [section 21(2)(b)];
- Employers shall provide such information, instruction, training and supervision to employees as are necessary to enable the employees to perform their work in a manner that is safe and without risks to health [section 21(2)(e)];
- Employers and self-employed persons shall ensure so far as is practicable that persons (other than the employees of the employer or self-employed person) are not exposed to risks to their health or safety arising from the conduct of the undertaking of the employer or self-employed person (section 22);
- Any person who manufactures, imports or supplies any substance for use at a workplace shall ensure, so far as is practicable, that the substance is safe and without risks to health when properly used (section 24);
- Employees shall, while at work, take reasonable care for their own health and safety and that of anyone else who may be affected by their acts or omissions at the workplace (section 25).

Offences against these provisions carry a maximum penalty of $250,000 for a body corporate and $50,000 for a natural person (section 47).

7.4.3 Dangerous Goods Act and Regulations

The *Dangerous Goods Act* 1985 (Vic.) includes among its purposes promotion of the safety of persons and property in relation to the manufacture, storage, transfer, transport, sale, purchase and use of dangerous goods.

The Dangerous Goods Act depends largely on its regulations to give content to its framework. The *Dangerous Goods (Storage and Handling) Regulations 1989* detail provisions concerning licensing of premises, impose general safety obligations applicable to almost all premises where any quantity of dangerous goods is stored, and prescribe in detail methods of storage and handling dangerous goods. They introduced the concept of assessment factors as a measure of risk posed by premises where dangerous goods are present. Depending on the assessment factor, the occupier of a premises may be required to either:

- Periodically self-assess the premises and their compliance with the regulations (section 200);
- Register the premises with WorkCover (section 201);
- Notify WorkCover of information about the premises (section 202); or
- Apply for a licence to keep dangerous goods (section 205).

The Regulations impose general safety obligations applicable to most premises where dangerous goods are stored, and prescribe in detail methods of storage and handling dangerous goods, including:

- An exemption process, including exemption from requirements where compliance is not practicable and safety and health of persons and property will not be adversely affected (section 110);
- Provision for placarding of premises, emergency planning and accident reporting (Part 3)
- Duties to regulate the construction, location and operation of dangerous goods premises, design of package storage areas, bulk storage of dangerous goods, avoidance of ignition sources, packaging and labeling (Part 4).

The Act gives authorised officers extensive powers to investigate dangerous goods or any container, equipment, fittings, piping or appliance used for or in connection with the manufacture, supply, transfer, storage, transport, sale or use of dangerous goods, where there is any reasonable grounds for suspecting contravention of the Act, and allows for the seizure and destruction of dangerous goods where those goods pose immediate danger to any persons or property (Part 2).

The maximum penalty for these offences is $40,000 plus a further maximum penalty of $5,000 penalty units for each day the offence continues after conviction for a body corporate and $10,000 plus a further maximum penalty of $1,000 penalty units for each day the offence continues after conviction for a natural person (section 45).

7.4.4 Environment Protection Act

Relevant offences in the *Environment Protection Act* 1970 (Vic.) include:

- Handling a substance in such a manner as to cause or permit an environmental hazard (section 27A);
- Polluting water (section 39), air (section 43) or land (section 45).

The maximum penalty for these offences is $20,000 plus a further maximum penalty of $8,000 for each day the offence continues after conviction or after service by the Environment Protection Authority of a notice of contravention.

The *Environmental Protection (Prescribed Wastes) Regulations* 1998 deal generally with issues related to the disposal of pesticides.

7.4.5 Nuisance provisions in the Health Act

The provisions in the *Health Act* 1958 which allow municipal councils to investigate and deal with nuisances which are occurring in their districts could be used to respond to the dangers caused by an unsafe application of pesticides.

7.4.6 National Scheme for registration of pesticides and approval of labels

The Agvet Code[21] establishes a national system for the registration of chemical products and approval of container labels. Section 14 of the Code requires that the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) must satisfy itself of a number of matters before granting registration of a chemical product, including that the proposed use would not cause an undue hazard in respect of:

- Occupational health and safety;
- Public health;
- Unintended environmental impacts;
- Trade and commerce.

Registered products are required to be supplied with labels which are also approved under the Code as containing adequate information regarding their safe and effective application (section 19(3)(g)). Under section 19 of the Agricultural and Veterinary Chemicals (Control of Use) Act it is an offence to use a chemical product other than in accordance with the information contained on these labels without a permit.

The NRA is responsible for a compliance program involving inspections of chemical products to ensure that they comply with the registered formulations, and that the labels on them are as approved.

7.4.7 Consumer protection legislation and civil litigation

The *Trade Practices Act* 1974 (Cth) and the *Fair Trading Act* 1985 (Vic.) operate to protect consumers who purchase pest control services. The *Trade Practices Act* 1974 (Cth) and the *Fair Trading Act* 1985(Vic.) provide for:

- Prosecutions to be instituted in respect of false representations or misleading conduct in relation to the supply of goods or services; and
- Proceedings to be taken in relation to the supply of defective products in contravention of those Acts.

In addition to the above legislative controls, it would be expected that the threat of litigation and increased workers' compensation premiums would encourage safe handling of pesticides.

7.5 Objectives of the Legislation

The objectives of the business registration and occupational licensing systems described above are to protect pest management technicians, consumers, members of the public and the environment from the dangers of pesticides.

[21] As explained in fn.3, this Code is a Schedule to the Commonwealth's *Agricultural and Veterinary Chemicals Act* 1994, and is part of the law of Victoria by virtue of s.5 of the *Agricultural and Veterinary Chemicals (Victoria) Act* 1994.

7.6 The Rationale for Legislative Intervention

Victorians are sometimes subject to invasions that they would prefer to ward off. Termites, mites, spiders and rodents are some of the unwelcome invaders against which pest control measures may be taken. Also, land can be overtaken by weeds or other pest plants and owners may wish to use pest control measures to deal with the problem. This kind of work often entails the application of potentially harmful chemicals, particularly where fumigation is involved. A number of studies have documented the risks associated with pesticide exposure (see section 7.7.2.1). It is important that people who work in the pest management industry have a proper understanding of the chemicals with which they work and adopt proper methods and processes to help to ensure the health and safety of themselves, their employees, members of the public and the environment.

7.6.1 Business registration system

The business registration system seeks to advance the objectives of the legislation by ensuring that pest control businesses:

- Contain people with the necessary ability, experience and qualifications;
- Have an appropriate ratio of experienced and qualified staff to trainees; and
- Have adequate equipment and storage facilities.

It also advances the objectives by ensuring that there is a central database showing the location of pest control businesses, which can be used to assist the Department to conduct information campaigns and safety inspections.

New South Wales, South Australia, Tasmania and Western Australia also have a business registration system similar to that which exists in section 108B of the Health Act. NSW recently advised that it was going to abolish its business registration system as a result of its NCP review.

7.6.2 Occupational licensing system

The system for the licensing of pest management technicians themselves seeks to achieve the objectives of the legislation by ensuring that people who apply pesticides in the course of a pest control business have the skills and experience necessary to apply pesticides safely. The requirement for licensees who use pesticides in the course of their business to submit to annual medical examinations aims to protect those persons from the harmful effects to health of exposure to high levels of toxic chemicals.

All of the other States and Territories except Tasmania and the Australian Capital Territory have legislation which requires that people who apply pesticides be licensed. Tasmania requires that persons or organizations who carry on a pest control business must hold a Commercial Operator Licence and that any person actually applying the chemicals, must hold a Pest Management Technician Certificate of Competency.[22] However, individual pest management technicians employed in those businesses are not required to hold a Commercial Operator Licence. In the Australian Capital Territory the commercial use of pesticides requires authorisation under its *Environment Protection Act* 1997.

All jurisdictions recently agreed to recognsie the *National Standard for Licensing Pest Management Technicians*.[23] This Standard provides for pest management technicians to be licensed to apply pesticides on the basis of assessed competencies. Under this system there

[22] Under its *Agricultural and Veterinary Chemicals (Control of Use) Act* 1995.
[23] National Environment Health Forum Monographs General Series No.4, South Australia, 1999.

would be a common criteria for the licensing of pest management technicians in all Australian jurisdictions based on units 5, 6 and 18 of the *National Pest Management Competency Standards* which have been developed by the National Occupational Health and Safety Commission (NOHSC). People would also be authorised to conduct fumigation by completing units 6 and 11 of those competency standards.

In order to satisfy units 5, 6 and 18 of the competency standards the applicant for a licence would need to demonstrate competency in the modification of the environment to manage pests, the application of pesticides to manage pests and the proper maintenance and storage of equipment and pesticides. Unit 11 specifically focuses on competency in the eradication of pests through fumigation.

7.7 Costs and Benefits of the Restrictions

The Health Act Review Discussion Paper sought comments on the costs and benefits of the restrictions, whether the costs outweigh the benefits and whether there are any less restrictive means of achieving the objective of the restriction.

7.7.1 Costs

As stated in the Discussion Paper, the main cost of the business registration and occupational licensing systems described above is that they restrict the number of businesses and individuals who are able to provide pest control services, thereby allowing those businesses and individuals who are registered and licensed to charge higher fees for their services than they might be able to do in the absence of those restrictions.

There would also be costs to businesses and individuals of complying with the conditions of registration or meeting the licensing standards, which they would be expected to pass on to the consumer in the form of higher fees.

The table on the following page presents the estimated compliance costs against the estimated turnover of the Victorian pest control industry. The Cost of compliance is the sum of the cost involved in training and the business registration and occupational licences fees. Other set up and maintenance costs for equipment such as chemical storage, safety equipment and first aid equipment, would be incurred as part of operating a pest control business, even in the absence of these legislative standards, as the result of pest management businesses and technicians seeking to comply with their other legal obligations to apply pesticides safely and effectively.

Given these costs, the total cost of compliance for the whole industry was estimated at $384,419. With an estimated turnover for the pest control industry of $33,930,000, the compliance costs represent just 1.1 per cent of the pest control industry turnover.

Business Category[1]	No Businesses[2]	Estimated No Employees [3]	Percentage of total No employees	Turnover per total employees[4]	Turnover per business	Total compliance costs for all employees per year [5]	Total compliance costs per business per year	Compliance Costs Per Year for Businesses as a percentage of Average Turnover
1	331	331	23%	$7,899,578	$23,866	$114,195	$345	1.4%
2 to 5	169	592	42%	$14,116,617	$83,530	$159,540	$944	1.1%
6 to 10	23	184	13%	$4,391,306	$190,926	$42,796	$1861	0.9%
11 to 15	7	91	6%	$2,171,787	$310,255	$20,159	$2880	0.9%
16 to 20	4	72	5%	$1,718,337	$429,584	$15,596	$3899	0.9%
26 to 30	1	28	2%	$673,015	$673,015	$5,937	$5937	0.9%
31 over	4	124	9%	$2,959,358	$739,840	$26,195	$6549	0.9%
Total	539	1422	100%	$33,930,000	$62,950	$384,419	$713	1.1%

1. Business Category by number of employees per business.
2. Number of Businesses in each Business Category sourced from DHA database.
3. Estimated number of employees per business category was obtained by calculating the average of the range of the number employees in each Business Category by the number of businesses per Business Category, eg. Business Category 2 to 5: 2+3+4+5/4*169=592 employees.
4. Estimate of the total turnover for Victorian Industry was obtained by using the IBIS estimate for the Victorian share (11.7%)[24] of the Turnover for the Australian Pest Control Industry for 1998-99 ($290m).[25]

5 Compliance costs calculated using the following data:

Training:

- The average number of trainees over the last 5 years was 185 according to DHS database;
- The total number of employees excluding owner-operators was 1091. Training costs do not apply as owner-operators must have completed their training in order to obtain business registration under the Health Act;
- The average percentage of the pest control industry in each Business Categoryin training per year is therefore 185/1091*100=17%;
- The direct costs involved in training per student were estimated using the cost of completing the Certificate of Pest Control course at Northern Metropolitan College of TAFE ($300). This course was used as it imposed the greatest cost impact on industry of approved pest control courses;
- The indirect costs involved in training include lost work hours which was estimated at 26 hours (class contact hours for TAFE Certificate Course) at $8.56 per hour (calculated by taking the average wage/salary per employee of larger and smaller companies reported by IBIS[26]);
- Total Training costs per trainee per year is $522.56.

Licence Fees:

- $115 per pest control applicator.

Registration Fees:

- $230 per pest control business.

[24] IBIS Business Information, L7865 Pest Control Services, 2000, p.5
[25] ibid, p.6
[26] ibid, p.14

The submission received from the Australian Pest Managers Association, a national association representing the interests of the professional pest management industry in Australia stated that:

> *…we do not consider the cost of registration as being excessive in respect to the total costs of operating a pest control business. Barriers to entry are insignificant…*

DNRE argued that these registration and licensing systems should be limited to insects, vermin and other pests which are associated with pathogens adversely impacting on public health, and not extend to weeds and other pest plants. It also argued that these restrictions should be limited to areas where a significant human population exists, or a significant impact could be expected on human health, and to situations in which no other existing statute law provides for control of pesticides in terms of protecting public health.

Finally, there is a cost to DHS in enforcing these registration and licensing systems, estimated at $136,300 in 2000. These costs are attributable to staff costs, including salaries, oncosts and administrative support. Other costs include safety equipment and vehicles for inspectors, computers and costs of prosecutions. However, these costs are fully funded out of registration and licensing fees.

An outline of the costs incurred and offset by the revenue received by the Department in administering and enforcing the registration and licensing systems are as follows:

(i) Costs	**Dollar Amount**	**Explanation**
Data Base	$3,600	The data base cost $15,000 + $3,000 of estimated maintenance, depreciated over 5 years
Admin staff	$60,000	This represent 50% of salary cost of the administration section for Environmental Health Unit
Technical staff	$38,700	This represents 90% of salary costs for one inspector
Manager	$24,000	This represents 40% of the salary cost for the manager of the Regulatory and Administrative Program
Operational	$10,000	Various operational expenses
On costs	$35,871	On cost for salaries estimated at 33.5%
Total costs	**$136,300**	The total costs of running the Pest control Registration and Licensing Program
(ii) Revenue	**Dollar Amount**	**Explanation**
Registration Fees Received	$123,970	Total revenue received from registration fees for the year 2000
Licences fees received	$164,335	Total revenue received from licensing fees
Total Revenue from 2000 Licensing and Registration	**$288,305**	
(iii) Surplus Funds	**$188,205**	Amount of money surplus to requirements under current system.

7.7.2 Benefits

All respondents (except DNRE, see section 7.7.1) to the Discussion Paper recommended that regulation of the pest management industry is necessary from public health and environmental protection perspectives.

The submission received from Gannawarra Shire Council stated that:

> *While councils do not have the control and regulation of pest control operators and pesticides they do receive many complaints regarding the operations of pest control operators and their use and misuse of pesticides. There is considerable alarm and concern in the community about the use of chemicals of all types and there should be no consideration for any watering down of the regulation of the users of chemicals.*

The submission received from the Australian College of Midwives stated that:

> *The control of pest animals, insects, weeds and other matter frequently involves the use of poisons which can harm women contemplating child bearing, and their infants. It is therefore in the interests of PH that the pest control industry be strictly controlled through appropriate legislation, and that all who provide such services be registered and fully accountable to the statutory authority.*

The submission from the Environment Protection Authority stated that:

> *EPA is supportive of the continued licensing of the pesticide applications industry, and would support the investigation of reform options which will provide greater assurance of protection of humans and the environment from inappropriate application or drift of pesticides. We expect that there would be a very significant net public benefit in terms of ensuring that adverse human health and environmental impacts are avoided through careful management of the application of pesticides within the community.*

Reduction in the risks associated with pesticide exposure

The rationale for business registration is that it protects pest management technicians, consumers, members of the public and the environment from the dangers of pesticides. However, there is no empirical evidence to link business registration with health and safety benefits for the workplace or the community.

The principal benefits of the regulation of the pest control industry arise from the occupational licensing systems contained in the Act. These benefits are a decrease in the occupational, public health and environmental risks associated with the storage, mixing, disposal and application of pesticides. The licensing system achieves this by:

- Establishing minimum standards for people who work within pest management businesses; and
- Enabling a database to be established which identifies where pest management technicians are located, the type of pests they are dealing with, and the type of pesticides they are applying. This database can be used to assist DHS to conduct information campaigns or safety audits in respect of pesticides or pest management practices which have been shown to represent a particular hazard.

The risks involved in pesticide use were summarised in a draft discussion paper prepared by the NOHSC in 1996 as part of the work done towards the national licensing standard for pest management technicians referred to earlier.[27] That paper noted that a wide variety of pesticides are used in pest management, with differing applications and differing chemical compositions, and a correspondingly wide variety of toxicities. Some pesticides are known to be acutely toxic to adult humans, including the organophosphate and carbamate pesticides commonly used in agriculture and in urban pest management. It noted that some pesticides can also accumulate in the body if there is chronic

[27] National Occupational Health and Safety Commission, *Draft National Occupational Health and Safety and Public Health Certification Standard for Pest Management Technicians*, pp.73-76. This discussion paper was developed after a series of consultations involving relevant industry, union, educational and government authorities. [Note that this draft Discussion Paper was never published. The work towards a national certification/licensing scheme was taken over by the National Environmental Health Forum, and was co-ordinated by DHS' Pest Control Unit.]

exposure, causing long-term and adverse effects on health, and that others may have relatively low acute and chronic toxicities, but have an irritating effect on the skin.

The NOHSC particularly noted the dangers inherent in the application of fumigants. All fumigants are gases with extreme acute toxicity that can be used in large quantities. They remain in a gaseous state at normal ambient temperatures and pressures. The high mobility of these gaseous materials increases the risk to third parties in the case of misapplication or accident, as well as the possibility of residue contamination of food. It noted that a number of fatalities had resulted from exposure to fumigants in Western Australia and Queensland prior to the introduction of regulations controlling their use, and that in Victoria there had been no recorded fatalities and few adverse incidents involving fumigants since the introduction of certification of pest management technicians in 1972.[28]

Further details of the occupational, public health and environmental risks of pesticide exposure as identified by the NOHSC are detailed below.

Occupational risks

The NOHSC quoted the following studies which suggest that there is a significant health risk to pest management technicians associated with excessive pesticide exposure:

- Maroni and Fait[29] reviewed published literature from 1975-91 comprising of 440 papers and identified a number of pesticides where the evidence of human health effects from prolonged exposure is well established and many more cases where evidence exists but further confirmation is required.

- The International Agency for Research on Cancer[30] concluded that spraying and application of non-arsenic insecticides entail exposures that are probably carcinogenic to humans.

- A recent US study indicated that "commercial pesticide applicators encountered substantial exposures" to pesticides and that "proper precautions for reducing exposures are not always followed. Practical steps, in particular the use of good work practices, may be taken to reduce exposure in this population."[31] Biological monitoring of this group suggested that absorbed doses were not related to the amount of pesticides handled but rather "other factors, such as work practices, were greater determinants of absorbed doses".[32]

- A study of agricultural pesticide applicators exposed to a variety of pesticides (organochlorines, organophosphates and synthetic pyrethroids) had significantly more chromosomal aberrations than control subjects.[33]

- A cohort of 168 pesticide applicators in Rome had increased risk of liver and bile duct cancer (no other cancer risks were statistically significant).[34]

- A study of German pest management technicians showed higher skin melanoma and cancer rates among them than in the German population.[35]

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28 ibid, p.76

29 Maroni M, Fait A. Health effects in man from long-term exposure to pesticides: A review of the 1975-1991 literature, *Toxicology,* 1993; 78 (1-3).

30 International Agency for Research on Cancer. *Occupational exposures in insecticide application and some pesticides.* Monographs on the evaluation of carcinogenic risks to humans, vol.53, IARC, Lyons, 1991.

31 Sanderson WT, Ringenburg V, Biagini R. Exposure of commercial pesticide applicators to the herbicide alachlor, *American Industrial Hygiene Association Journal,* 1995;56: 890-897.

32 Sanderson WT, et al. Biological monitoring of commercial pesticide applicators for urine metabolites of the herbicide alachlor, *American Industrial Hygiene Association Journal,* 1995;56:883-889.

33 Rupa DS, Reddy PP, Reddl OS. Clastogenic effect of pesticides in peripheral lymphocytes of cotton-field workers, *Mutation Research*, 1991;262:177-180.

34 Figa-Talamanca I, Mearelli I, Valente P, Mortality in a cohort of pesticide applicators in an urban setting, *International Journal of Epidemiology*, 1993;22:674-676.

The NOHSC also advised that examination of data obtained from the National Workers' Compensation Database[36] for the Pest Control Services Industry[37] shows that there were on average 70 compensation claims per year in Australia in the three years between 1991/92 and 1993/94. Over the three years and 209 claims examined, six incidents involved poisoning and toxic effects of substances.

In respect of these figures, the NOHSC noted that workers' compensation data only provides partial coverage of total work-related injuries and diseases. It does not provide a good measure of the prevalence of work-related illnesses/diseases with long latency periods or conditions which arise from exposures to hazardous substances that cannot conclusively be linked to the workplace. The ability to trace diagnosis of a cancer, organ dysfunction or infertility back to chemical exposure(s) is highly problematic. Pesticide exposures are usually sublethal and accurate determination of the effects of long-term chronic dosage through direct exposure is not generally possible. In addition, compensation data is known to underestimate the true accident and injury rates in industries such as pest management that support a large number of self-employed persons who are not eligible for workers compensation.

The NOHSC pointed out that the risks faced by pest management technicians are increased by the isolated and moveable nature of their workplace.[38]

Public health risks

The NOHSC noted that pesticides can also pose potentially serious threats to the wider community when not applied correctly. Public health concerns extend to the long-term impacts of pesticide exposure, particularly the risks of carcinogenicity and teratogenicity as a result of chronic exposure and exposure of sensitive populations such as children and the elderly or infirm. The use of toxic or persistent pesticides for termite treatment or nuisance pests in domestic/commercial situations was nominated as posing a significant public health concern. Acute effects of direct exposure to pesticides in domestic/commercial situations have been reported where proper precautions have not been taken.[39]

Environmental risks

The NOHSC advised that the environmental impacts of the pest management industry are also a concern. Environmental hazards associated with improper pesticide application can be significant depending on the toxicity of the pesticide in question, its persistence in the soil, bioaccumulation in living organisms (e.g. fish), and contamination of groundwater supplies.

More effective pest control

By establishing minimum standards in the pest control industry, the licensing requirement in the Act would be expected to assist in achieving more effective pest control, which in turn would lead to a decrease in the disease and economic loss caused by pests. Effective pest control is particularly important in meeting the food import requirements of other Australian jurisdictions and other countries, and therefore operates to protect Victorian food industries.

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35 Bartel, E. Retrospective increases in mortality of cancer of the oesophagus, stomach, colon and melanoma in pesticide workers in Germany (DDR), *Archivs Geschwulforsch*, 1985;55:481-488.

36 Sourced from the National Data Set for Compensation-Based Statistics (NDS) administered by Worksafe Australia.

37 Australian Standard Industrial Classification 6386, including fumigation but excluding agricultural pest management services.

38 ibid, p.78

39 Sanderson WT, et al. Biological monitoring of commercial pesticide applicators for urine metabolites of the herbicide alachlor, *American Industrial Hygiene Association Journal*, 1995;56:883-889.

Benefits to the pest management industry

The licensing system would be expected to confer a number of benefits on the pest management industry. These would include:

- Improved public perception of the industry. This would be expected to lead to an increase in demand for the pesticides and pest control services supplied by chemical companies and pest control businesses, and an increase in the overall level of employment and economic activity generated by the pest management industry.
- The institution of a "level playing field" for pest control technicians who are prepared to incur the costs involved in complying with appropriate safety standards.
- An improvement in the skill level of the pest management industry's workforce, which would be expected to result in higher levels of productivity and consumer satisfaction.
- A reduced accident rate, which will result in reduced workers' compensation and insurance premiums and sick leave, as well as reduced chance of being subject to legal action from consumers or regulatory authorities.

Improved information for consumers

The licensing system provides a yardstick against which consumers can judge whether a particular pest management technician is appropriately qualified. This reduces the time which consumers might otherwise have to spend in choosing a pest control service and the chance of consumers engaging a pest control service which is not suitable.

Reduced investigation costs for Government

As stated above, the licensing system would be expected to result in a reduction in the risks associated with pesticide use and an improvement in the effectiveness of pest control services. This would be expected to lead to a reduction in the costs to Government of investigating accidents and consumer complaints.

7.7.3 Analysis of the costs of the restrictions against the benefits

In order to assess whether the costs of the pest control business registration and occupational licensing systems in the Health Act outweigh their benefits it is useful to examine the way in which these restrictions on competition affect the particular stakeholders which have been identified earlier.

Pest control businesses

If the Health Act did not seek to regulate pest control businesses, they would benefit from not having to pay registration fees. They would also not be required to pay the costs of meeting the registration requirements which are additional to those which they would have had to meet anyway to satisfy their other legal obligations.

There are no attendant risks to public health or the environment in the removal of the business registration system. The business registration provides no demonstrable health and safety benefits for the workplace or the community.

The requirement for registration in order to operate a pest control business imposes a direct cost on industry without providing any benefits. The saving of the registration cost plus the reduction in the administrative burden for industry would be expected to lead to improvements in productivity.

Pest management technicians

If the Health Act did not seek to regulate pest management technicians, they (or the pest control companies which employ them) would benefit from not having to pay licence fees. They would also not be required to spend the time and money necessary to gain the qualifications or competencies necessary to satisfy the licensing standards.

On the other hand, they would face increased occupational risk from pesticides which are more likely to have been applied inappropriately from either themselves or other untrained operators.

No pesticide has been prescribed as a regulated pesticide and therefore this provision imposes no current restriction on conduct of business.

Consumers

If all barriers to entry into the pest control industry were removed, the numbers in that industry would be expected to increase, which would lead to some downwards pressure on the price of pest control services. In other words, consumers would be expected to benefit from lower prices in the short term as new entrants come into the market who would otherwise not be willing or able to meet the registration and licensing requirements. The overheads which are imposed by those registration and licensing requirements and which would not have been incurred anyway in meeting other legal obligations would also be removed, which should also lead to some downwards pressure on prices.

However, this again needs to be balanced against the significant benefits which consumers derive from the controls on the pest management industry which appear in the Health Act. These benefits derived from the occupational licensing of pest management technicians include:

- Protection against the increased risk which would result from pesticide application from the ill-equipped and unqualified people who would inevitably be attracted into the industry;
- Increased likelihood that the pest control services which they purchase will be effective.

Pesticide manufacturers

Manufacturers of pesticide may derive some short term increase in sales if restrictions on entry into the pest management industry were removed, but these are likely to be eroded in the long term as consumer confidence in that industry declines.

People who live or work close to the site of a pesticide application

These people would only derive a benefit from controls which reduce the risk of inappropriate pesticide application.

Government regulatory authorities

Removal of the restrictions on pest control businesses and pest management technicians would be expected to lead to savings in resources required to administer and enforce the business registration and occupational licensing systems.

Removal of the restrictions on pest control applicators would be expected to lead to an increase in the costs to Government of investigating accidents and consumer complaints.

The community at large

Removal of the barriers to entry into the pest management industry would be expected to lead to some increase in activity within that industry, at least in the short term, which would benefit the economy generally.

However, by reducing the risks to the public health and the environment from pesticide use, the licensing requirements confer economic and social benefits to the community which are likely to be greater and more lasting than the benefits which would flow from an increase in economic activity within the pest management industry. The business licensing system provides no demonstrable health and safety benefits for the workplace or the community and could be removed without increasing risks to the public health and the environment from pesticide use.

7.8 Alternatives to these Restrictions

Given that the costs of the restrictions on competition in the pest management industry which appear in the Health Act do not outweigh their benefits, the next question which needs to be asked is whether there are any other less restrictive ways of achieving the objectives which those restrictions are designed to achieve. The Health Act review Discussion Paper described a number of alternative ways in which pest management technicians, consumers, the general public and the environment might be protected from the dangers of pesticides. The following is an analysis of those alternatives.

7.8.1 Removal of business registration and relying solely on occupational licensing

The Discussion Paper raised the question as to whether it is necessary for the businesses of pest control operators to be registered under the Health Act, given that people who apply pesticides in the course of those businesses are required to be licensed under that Act.

The matters which a pest control operator needs to establish under the guidelines in order to have his or her business registered under the Act, namely the appointment of adequate numbers of appropriately experienced staff and proper equipment and storage facilities, may be justified in light of the potential hazards of pesticide use. However, the criteria which DHS uses to determine whether a business should be registered, in terms of having sufficiently experienced management, a minimum ratio of experienced to inexperienced staff, and adequate equipment and storage facilities, would be required anyway in order for the business to meet its general obligations under other legislation, in particular the Occupational Health and Safety Act.

If those provisions relating to business registration were repealed in favour of reliance upon other laws which establish minimum standards, eg. education and training, for pesticide use, any shortfalls may be addressed by an expanded occupational licensing system under the Health Act through mechanisms such as the imposition of appropriate conditions on the licences held by individual pest management technicians.

Also, the information which is presently captured through the business registration system and is used to help DHS keep track of what is happening in the pest management industry could be obtained through an increase in the information required from individuals when they fill out a licence application form.

Against this, it should be noted that if the pest control business registration system in the Health Act was abolished, those pest control businesses which are presently registered under the Health Act would then become required to be licensed under the Agricultural and Veterinary Chemicals (Control of Use) Act which is administered by DNRE. Currently, section 30 of that Act requires any person who carries on a business, or offers a service for fee or reward, which involves controlling pests through the application of herbicides, insecticides, fungicides or growth regulators to obtain a commercial operator

licence. An Order in Council made under section 5 of that Act exempts any person who is a registered pest control operator under the Health Act from this requirement.[40] If the system of registering pest control operators is removed from the Health Act, then obviously this exemption will have no effect, and the requirement to obtain an operator licence under the Agricultural and Veterinary Chemicals (Control of Use) Act will arise. The result of this would be the dual requirement for pest control applicators to obtain a commercial operator licence issued by DNRE under the Agricultural and Veterinary Chemicals (Control of Use) Act and a pest management technician licence with DHS under the Health Act.

Duplication or overlap with the DNRE licensing controls over ground based chemical control applicators under the *Agricultural and Veterinary Chemicals (Control of Use) Act* 1992 places additional and unnecessary costs on pest control applicators. A more streamlined licensing system may be achieved by amending the Health Act to remove commercial chemical control applicators from the licensing requirements of the Health Act and regulations where they apply pesticides in the course of a business in areas where there is no substantial risk to public health. Pest control activities that take place in commercial and domestic premises such as treatment for arthropods and rodents are considered to have a greater public health risk than herbicide and vertebrate pest controllers where there is a reduced opportunity for human exposure to pesticides. DNRE currently issues herbicide licenses, and is responsible for training in weed control for landcare groups and farmers. DNRE also runs a number of vertebrate eradication programs for rabbits, feral dogs, foxes and feral cats. The transfer of these licensing functions from DHS to DNRE would complement existing DNRE core functions.

7.8.1.1 Cost-benefit analysis of this alternative

The following table demonstrates the cost-benefit analysis for the removal of business registration, transfer of license to DNRE, and reliance solely on occupational licensing:

(i) Transfer Arrangements	**Dollar Amount**	**Explanation**
Transfer License to DNRE	$71,300	Approximately 620 weeds and vermin applicators would be transferred to DNRE valued at $71,300
Forecasted Licensing Fees at current rate	$93,035	Under the new Licensing system there would be approximately 809 Pest Applicators
Shortfall/ Surplus in fees	-$8,385	Short fall due to giving up Registration fees of $123,970 and transfer of revenue from 620 weed and vertebrate pest controllers to DNRE valued at $71,300.
New cost for Licence	$125.36	This is an increase of $10.36 on the current licensing charge required. However, this forecast fee is based on the assumption that there will be no growth in the number of pest Controllers entering the industry.

(ii) Cost- benefit to industry	**Dollar Amount**	**Explanation**
Additional Costs: Cost increase for licences	$8,385	Increase of $10.36 on the current licensing charge
Savings to Industry: Discontinuation of Registration Fees	$123,970	Total revenue received from registration fees for the year 2000
Total Benefit	**$115,585**	**Total savings to industry from discontinuation of fees for the Registration of pest Control Businesses**

[40] *Victoria Government Gazette* G 30, 1 August 1996, pp.2008-9.

(iii) Costs to DHS	Dollar Amount	Explanation
Data Base	$3,600	The data base cost $15,000 + maintenance depreciated over 5 years
Admin staff	$36,000	This represent 30% of salary cost of the administration section for Environmental Health Unit
Technical staff	$27,000	This represents 60% of salary costs for one inspector
Manager	$8,400	This represents 14% of the salary cost for the Manager of the Regulatory and Administrative Program
Operational	$5,000	Various operational expenses
On costs	$21,420	On cost for salaries estimated at 33.5%
Total Costs	**$100,420**	The total costs of running the Pest control Registration and Licensing Program
Revenue:		
Total revenue from licensing System	$101,420	Estimated revenue received from 809 Pest Applicators at new licence fee of $125.36
Surplus	$1,000	The new licensing system is cost neutral

In summary, this analysis has shown that removal of the business registration system and reliance on the licensing system is a viable option for regulatory reform. Industry benefits from the financial savings from removal of the business registration fees of $123, 970. The net financial benefit (after implementation of the new fee rate of $125.36 per pest applicator licence) is estimated to be $115,585. The costs to DHS in enforcing the new licensing system is fully funded out of the licensing fees. As discussed in section 7.7.2 there is no public interest benefit provided by the business registration system, that is, the pest control business registration provisions could be removed without attendant risks to pest control applicators, consumers or the community generally.

7.8.2 Negative registration and licensing

This is a system in which there would be no restriction on the right to apply pesticides, but pest control businesses and technicians who can be shown to have done so unsafely have that right removed.

This system relies on an adverse event to occur before action is taken to prevent a repeat occurrence. Given the potentially serious effects of over-exposure to pesticides which have been outlined in earlier (see section 7.7.2.1), this does not offer sufficient protection to pest management technicians, consumers, the general community and the environment.

Also, it will often not be obvious that misapplication of pesticides has in fact occurred. There are two reasons for this. Firstly, consumers usually will not have sufficient knowledge to make an assessment of the pest control services which they have purchased. Secondly, given the sublethal and cumulative effects of pesticide exposure, the consequences of poor practice on human and environmental health may not be felt for months, if not years, after the event.

7.8.3 Protection of title

This is a scheme in which there would again be no restriction on the right to provide pest control services, but only registered pest control businesses or licensed pest management technicians could

use a certain specified title. This is the system used in Victoria to safeguard the public against the dangers inherent in various forms of health care. For example, there is no restriction on the right to perform most medical procedures, but only people who have completed a certain course of study and been registered by the Medical Practitioners' Board of Victoria are able to use the title of registered medical practitioner. The reservation of a particular title to people who have obtained a relevant qualification and submitted themselves to the jurisdiction of a professional registration board is a signal to members of the public as to who might be best able to deal with their complaint, but still gives them the option of seeking relief from some other person.

The main problem with this system as applied to the pest management industry is that there is no body with sufficient coverage of that industry, and acceptance within it, to perform the functions of a professional registration board. The only industry wide body in Victoria is the Australian Environmental Pest Managers' Association (AEPMA). Membership of that organisation is voluntary.

There is also the question of whether consumers who typically purchase pest control services as a "one-off" transaction would appreciate the significance of the fact that a pest control business or technician was not registered or licensed, in the same way that they would understand the significance of the fact that a health care provider was not registered.

Therefore, reliance on a system of protection of title for registered or licensed pest control businesses or technicians would also not provide sufficient protection against the dangers of pesticides.

7.8.4 Co-regulation

This is a system in which pest control businesses and technicians would be required to be part of a relevant professional association to which the regulatory powers of Government had been delegated. Under this option it would be open to the professional association to require the attainment of specified standards or qualifications as a condition of practice or use of a particular title.

However, this system has the same basic problem as the protection of title option, namely that there is no obvious industry body which could assume a delegated regulatory role. Therefore, it also does not appear to be a practical alternative.

7.8.5 Self-regulation

This would rely on the pest management industry to set its own standards, for example through the development of a code of conduct. It differs from the co-regulatory model in that the standards which are developed are not intended to be binding on industry participants (although non-compliance could be used as evidence of negligence).

Once again, the absence of a well resourced peak body within the Victorian pest management industry leads to some doubt as to whether a sufficiently detailed code of practice could be developed and accepted. It is also of concern that, unlike the other options outlined above, this option does not allow for a requirement to be imposed that specified standards or qualifications be met before a pest management business or technician is permitted to commence practice or use a particular title. Given the dangers of pesticide use outlined earlier (see section 7.7.2.1), any effective regulatory system needs to be able to incorporate those types of requirements.

Evidence presented by individual jurisdictions to the NOHSC in the course of its work on the *Draft National Certification Standard for Pest Management Technicians*[41] also casts doubt on the ability of the pest management industry to effectively regulate itself.[42] Victoria advised that the controls which

[41] National Occupational Health and Safety Commission, *Draft National Occupational Health and Safety and Public Health Certification Standard for Pest Management Technicians*, p.75.

[42] The data presented was collected some time ago, and it is recognised that compliance may have improved in the intervening period.

are presently being evaluated were a response to frequent requests for information from technicians and complaints from the community relating to the use of pesticides.[43] The extent of non-compliance with existing regulations by the pest management industry across Australia was demonstrated by the following evidence to the Commission:

- Western Australia reported a total of 99 investigations of pest control businesses with 40 suspected breaches between July 1991 and December 1993. It also advised that there had been 65 hospital admissions for pesticide exposure in 1992.
- South Australia reported that 20% of inspection checks per year required improvements to premises, vehicles and equipment.
- Victoria reported that 80% of companies did not meet required standards for vehicles, storage, first aid and safety equipment on their first inspection.
- New South Wales reported 639 suspected breaches of occupational health and safety legislation as a result of investigations between January 1988 and August 1993, with 61 improvement notices and 11 prohibition notices issued and 10 successful prosecutions.
- Queensland reported 14 successful prosecutions between 1994-996, including offences for operating without a certificate, improper use of a regulated pesticide, inappropriate chemical storage and failure to keep prescribed reports.

The NOHSC also noted that an Australian Consumer Association survey of 27 pest management companies conducted in 1996 questioned whether technicians had sufficient knowledge of pesticide toxicity and the hazards associated with their use.[44]

The submission received from Mildura Rural City Council stated that:

> *The control and application of chemicals has historically been proven to require prescriptive parameters. Not only have non-target species including humans been affected but water supplies, soil, physical structures and equipment have been rendered useless. To suggest self regulation for this industry, based on competitive constraints, is sheer madness. This industry not only needs to be accountable for every drop of chemicals used but also the storage and disposal of redundant chemicals, containers and waste. Methods of application, the rates, purchase and disposal all need relevant documentary proof and routinely checked and/or returned to the regulatory authority, in this case DHS. Licensing the sale and application of pesticides is paramount and any lessening in control would be detrimental to human health and the environment.*

7.8.6 Information requirements

There are a number of ways in which the disparity in information between the suppliers of pest management services and the consumers of those services could be remedied. These include:

- A certification scheme which requires pest control businesses and technicians to inform a central authority of their educational qualifications and experience in the industry which can then be accessed by consumers;
- Requiring pest control businesses and technicians to inform consumers about the pesticides they have used; or
- Conducting a public information campaign about the proper application of pesticides.

While these may be worthwhile initiatives, merely enabling consumers to be better informed about pesticides and the businesses and technicians who might be applying them is not in itself sufficient to protect those consumers against the dangers of pesticides. It also does nothing to address the occupational and environmental risks inherent in pesticide usage.

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[43] Victorian Department of Health, *Regulatory Impact Statement for the Proposed Health (Pest Control Operators) Regulations 1992*.
[44] *Choice*, January 1996

7.8.7 Reliance upon the existing law

As can be seen from the earlier discussion (see section 7.4), the pest control business registration and occupational licensing systems in the Health Act are not the only laws which operate to protect pest control technicians, members of the public and the environment from the dangers of pesticides. Other laws which operate in this area include:

- The Agvet Code, which regulates the production and labelling of pesticides;
- Various criminal offences in the Agricultural and Veterinary Chemicals (Control of Use) Act, the Occupational Health and Safety Act and the Environment Protection Act, which all operate to deter unsafe practice with respect to the use of pesticides;
- The common law and consumer protection legislation, which also deter unsafe practice by giving persons affected by such practice the right to recover their loss;
- The nuisance provisions in the Health Act, which allow municipal councils to make orders with respect to unsafe pesticide applications which have occurred in their municipal district;
- The ACUP permit system established by the Agricultural and Veterinary Chemicals (Control of Use) Act, whereby certain particularly dangerous pesticides can only be used by appropriately qualified people;
- The provisions in the Agricultural and Veterinary Chemicals (Control of Use) Act which require that certain pest control businesses be licensed.

The question arises as to whether it would be sufficient to rely on these other laws, and not also require pest control businesses to be registered and/or pest management technicians to be licensed under the Health Act. An analysis of whether those other laws would by themselves offer sufficient protection against the risks inherent in pesticide use follows.

Agvet Code

This Code only seeks to regulate pesticides up to the point of retail sale, and is therefore clearly not capable of establishing standards for the safe use of those pesticides.

The provision for prescribed pesticides under the Health Act has been superseded by the national system for the registration of chemical products and approval of container labels and is suitable for repeal.

Laws imposing criminal and civil penalties for unsafe practice

It is likely that the criteria which DHS uses to determine whether a business should be registered, in terms of having sufficiently experienced management, a minimum ratio of experienced to inexperienced staff, and adequate equipment and storage facilities, would be required anyway in order for the business to meet its obligations under other legislation, in particular the Occupational Health and Safety Act. Therefore, provided that those obligations were known and enforced under that other legislation to the same extent as they are presently under the pest control business registration provisions in the Health Act, the pest control business registration provisions could be repealed without any increase in the overall level of risk from pesticide exposure.[45]

In contrast to the business registration system, the pest control occupational licensing system established by the Health Act has a different focus from other laws which establish minimum standards for pesticide use. While those other laws have an important place in protecting pest management technicians, the public and the environment from the dangers of pesticides, they are not specifically aimed at ensuring that the people who apply pesticides in the course of a pest control business are appropriately qualified or are able to demonstrate the necessary competencies. Therefore, repeal of

[45] If the enforcement of these provisions were to be transferred to the Victorian Workcover Authority, it may be advisable for the matters contained in the *Guidelines for Pest Control Business Registration* to be included in a Code of Practice issued under s.55 of the Occupational Health and Safety Act.

the provisions in the Health Act which require that people who apply pesticides in the course of the business of a pest control operator be licensed, in favour of reliance upon laws which impose criminal and civil penalties for unsafe pesticide use would involve an unacceptable risk to the public health, the environment and those people themselves.

Occupational Health and Safety Act

The objective of the requirement that pest control technicians submit to an annual medical examination, protection against potential health risks of the application of pesticides, is more appropriately dealt with by Occupation Health and Safety legislation. The *Occupational Health and Safety Act* 1985 section 21(2)(e) requires employers to: "... provide such information ... to employees as [is] necessary to enable employees to perform their work in a manner that is safe and without risks to health." Under section 21(4)(a) employers must monitor the health of employees, and under section 21(4)(b) employers are required to keep information and records relating to the health and safety of the employees.

Nuisance provisions in the Health Act

These provisions have a limited potential to protect against the dangers of pesticides. They can only be used to react to problems which have already been found to exist, and can only be used by municipal councils. Therefore, these provisions would not also not be an adequate substitution for the provisions in the Health Act which are aimed at preventing problems from occurring in the first place, and are able to be enforced by the state government.

The ACUP permit system

This system only applies to a narrow range of pesticides, and is therefore also not able to be used to regulate the pest management industry as a whole.

The business licensing system established by the Agricultural and Veterinary Chemicals (Control of Use) Act

The similarity between this system and the pest control business registration system established by the Health Act is demonstrated by the fact that a business is exempted from the business licensing system established by the Agricultural and Veterinary Chemicals (Control of Use) Act if it is registered under the Health Act.[46] This leads to the conclusion that it may be possible to repeal the business registration system in the Health Act and rely on the equivalent system in the Agricultural and Veterinary Chemicals (Control of Use) Act. The criteria in the Agricultural and Veterinary Chemicals (Control of Use) Act as to whether a business should be licensed focus more appropriately on record keeping and insurance issues.

Repeal of the occupational licensing system in the Health Act in favour of the business licensing system in the Agricultural and Veterinary Chemicals (Control of Use) Act would result in a reduction in the level of protection against the dangers of pesticides (except where commercial chemical control applicators are applying pesticides in the course of a business in areas where there is no substantial risk to public health, see section 7.7.3 for further discussion). This is because that business licensing system is not concerned with the question of whether all of the people who apply pesticides in the course of a licensed pest control business are themselves appropriately trained and qualified. The person who applies for a business licence must be able to demonstrate competencies relevant to his or her business, but the training requirements necessary to do so, at least with respect to ground based businesses, are easier to complete than those which all pest management technicians must complete in order to be licensed under the Health Act. If Victoria adopts the National Licensing Standard for Pest Management Technicians, this disparity between the training requirements which must be met by

[46] *Victoria Government Gazette* G 30, 1 August 1996, pp.2008-9.

applicants for business licences under the Agricultural and Veterinary Chemicals (Control of Use) Act and those which must be met by all pest management technicians seeking to be licensed under the Health Act will get even bigger.

Complete reliance on business licensing would also be inconsistent with Victoria's agreement to recognise this National Licensing Standard for Pest Management Technicians.

7.9 Conclusion

It is clear from the literature review performed by the NOHSC that there are serious implications for occupational, public and environmental health from the mismanagement or misuse of pesticides, especially fumigants. The damage to people's health and to the environment may occur immediately or accumulate slowly over time.

Requiring pest control business registration does not provide demonstrable health and safety benefits for the workplace or the community. On the other hand, the occupational licensing provisions in the Health Act do reduce those risks and thereby confer significant benefits on the Victorian community which more than outweigh their costs.

By helping to ensuring safe application of pesticides in the course of providing pest control services, the occupational licensing system would also lead to more effective pest control, with attendant benefits to the public health and the economy. The costs of these pest control provisions in the Health Act do not outweigh their benefits.

Removal of business registration and relying on occupational licensing is the only viable alternative to the pest control business registration and occupational licensing systems outlined above. All other alternatives appear to be either impractical or inadequate to deal with the risks to pesticide users, consumers, the public and the environment from over-exposure to pesticides.

7.10 Recommendations

7.10.1 That the requirement for registration of pest control operators be repealed from the Health Act.

7.10.2 That the Health Act continue to require people who apply pesticides in the course of the business of a pest control operator to be licensed.

7.10.3 That the Health Act be amended to remove commercial chemical control applicators licensed under the *Agricultural and Veterinary Chemicals (Control of Use) Act* 1992 from the licensing requirements of the Health Act and regulations where they apply pesticides in the course of a business in areas where there is no substantial risk to public health.

7.10.4 That the controls on the use of prescribed pesticides in the Health Act be repealed.

7.10.5 That the requirement that licensees submit to regular medical examinations be repealed from the Health Act.

8 Part 6 - Division 6 - Special Provisions Relating To HIV

8.1 Background

8.1.1 Qualification requirements for a person providing pre test and post test HIV counselling

Section 127(1) of the Act specifies that a person must not be tested for HIV unless the registered medical practitioner carrying out or authorising the carrying out of the test has provided, or is satisfied that a person of a prescribed class has provided, information about the medical and social consequences of being tested and of the possible results of the test.

Section 127(2)(a) of the Act specifies that a person must not be advised of the results of a positive HIV test except by and in the presence of a registered medical practitioner or a person of a prescribed class.

Regulation 18 of the *Health Infectious Diseases Regulations* 1990 states that a person of a prescribed class is:

- A person who has at least one year pre test or post test counselling experience about the HIV antibody test at the time the person is informed of the test result; or
- A person who has successfully completed a course approved by the Secretary in pre test and post test counselling in relation to the HIV antibody test.

The qualification requirements that a person providing pre test and post test counselling is a restriction on competition because it creates a barrier to entry to the market for these services.

8.1.2 Limitations of which laboratories can test for HIV

Section 130 of the Act requires that testing of the blood of humans for HIV must occur in prescribed places. The laboratories that can undertake these tests are prescribed in Regulation 19 of the *Health (Infectious Diseases) Regulations* 1990. The prescribed places set out in those Regulations are:

- The Microbiological Diagnostic Unit, Department of Microbiology, University of Melbourne; and
- The Amalgamated Melbourne and Essendon Hospital; and
- The Fairfield Hospital; and
- The Victorian Institute of Forensic Pathology; and
- Any other laboratory nominated by the Secretary.

The section also provides particulars that must be kept by nominated laboratories with respect to HIV tests.

The limitation as to who can test for HIV and conditions on conduct, such as the requirement for record keeping, are restrictions on competition because they create barriers to entry to the market for these services.

8.2 Description of the Market

8.2.1 Pre test and post test HIV counselling

The Act specifies that a person must receive pre and post test HIV counselling from a medical practitioner or a person of a prescribed class. Persons of a ‘prescribed class’ in accordance with Regulation 18(b) of the *Health (Infectious Diseases) Regulations* 1990 are required to complete an approved pre and post test counselling course prior to counselling persons requiring an HIV test in the

State of Victoria. 'Prescribed class' includes, but is not limited to, health professionals such as social workers, counsellors, psychologists, therapists and nurses, but excludes all medical practitioners.

Historically a number of agencies have offered courses in pre and post test HIV counselling for persons requiring an HIV test. In 1999/2000 two agencies in Victoria offered pre and post test counselling courses: the Centre for Social Health, based at LaTrobe University; and the Melbourne Sexual Health Centre. The agencies supply a list of candidates who fulfil the requirements of these courses to the Health Protection Services Unit [formerly the Blood Bourne Virus Unit] of the Public Health Division, DHS. The Health Protection Unit maintains a database of all participants and issues each participant with a Certificate of Recognition. There are currently 580 persons entered on the database. There are approximately 70 graduates of such courses per year.[47] In 1999/2000, 76 graduates were entered on the database: 10 (13%) were listed as employed in the public sector in rural areas; 58 (76%) in the public sector in metropolitan areas; 1 (0.01%) in the private sector in rural areas; 1 (0.01%) in the private sector in metropolitan areas; and 6 (8%) unknown/interstate.

8.2.2 HIV testing

Standard HIV antibody testing for screening or diagnostic purposes involves enzyme immunoassays (EIAs) which depend on an ability to detect a reaction between antibody and antigen. EIAs can be set up in microtitre plates and additions made mechanically, therefore making the assays highly efficient, in that they can be carried out in large numbers, and highly accurate if the quality is assured. The EIAs used for screening purposes are highly sensitive, which is the reason why those samples which show no reactivity can be designated as negative after a single test. However, this is also the reason that there is a degree of false-reactivity, and why confirmatory testing of reactive samples is required before the result is accepted as a true positive. Confirmatory testing usually involves a Western blot. More recently the use of new technology has increased, including nucleic acid amplification assays for detection of virus and for measuring viral load, rapid assays, assays for detection of HIV using body fluids other than plasma/serum as samples, and home-based testing.

In 1999, a total of 122,846 HIV tests were performed.[48] This represents a 0.5% decrease from 1998 HIV testing data.[49] The annual number of HIV tests performed in Victoria peaked in 1994, with over 135,000 tests conducted.[50] The following table shows the number of specimens tested for confirmation of HIV antibody by Western Blot (WB) between 1992 and 1999, and the number of HIV screening tests for the same period:

Test	**1992**	**1993**	**1994**	**1995**	**1996**	**1997**	**1998**	**1999**
WB	1,351	1,268	1,415	952	1,146	1,097	810	716
Screening	114,639	125,553	135,069	122,808	122,856	121,804	122,387	122,846

Most requests for HIV tests come from general practitioners working in private practice. Other sources include specialist sexual health clinics, specialist medical services, antenatal clinics (both public and private), hospitals and correctional institutions.

In Victoria, there is no limitation as to which laboratories can be approved to conduct standard HIV testing provided they comply with certain conditions. Other jurisdictions limit HIV testing, both standard and confirmatory testing, to State 'reference' laboratories. The involvement of private laboratories in standard HIV testing in other States, is predominately for insurance and visa testing purposes.[51] The 'prescribed' places in Victoria are those public [State Reference Laboratory (SRL)] and public hospital

[47] A submission received from the Disease Control and Prevention and Child Care section of Public Health in the Victorian DHS.
[48] Surveillance of STDs in Victoria 1999, DHS Report.
[49] ibid, p.18.
[50] ibid, p.18.
[51] Joint Working Party of the Australian National Council on AIDS and Related Diseases and the Intergovernmental Committee on AIDS and Related Diseases, *HIV Testing Policy*, Commonwealth of Australia, 1998.

laboratories] and private laboratories nominated by the Secretary. To be nominated by the Secretary, laboratories need to agree with the following conditions:

- To provide evidence of accreditation with the Pathology Services Accreditation Board of Victoria and registration with NATA;
- To take part in an ongoing quality assurance program for anti-HIV testing via the SRL and the National Reference Laboratory (NRL);
- To refer all reactive anti-HIV EIA results to the SRL at the Victorian infectious Diseases Reference Laboratory (VIDRL);
- To supply basic data for epidemiological purposes, as outlined in section 130 of the *Health Act* 1958, to the Macfarlane Burnet Centre for Medical Research (MBCMR) for analysis on behalf of the Department;
- To ensure confidentiality of test results according to section 128 of the *Health Act* 1958;
- To bear all costs associated with the HIV testing.

As at September 2000, there were 31 laboratories nominated to conduct standard HIV testing in Victoria, 14 (45%) public and 17 (55%) private laboratories. The nominated laboratories are distributed throughout the State with ten (32%) nominated laboratories located in rural Victoria and 21 (68%) located in metropolitan Victoria. Rural laboratories are located in all four DHS rural health regions: three (30%) in Hume, two (20%) in Loddon Mallee, two (20%) in Grampians, one (10%) in Gippsland, and two (20%) in Barwon - South West. Metropolitan laboratories are located in all four DHS metropolitan health regions: eight (38%) in Northern, four (19%) in Eastern, five (24%) in Southern, and four (19%) in Western.

In Victoria, as in all other States and Territories, confirmatory testing of samples reactive in a screening test is limited to State ‘reference’ laboratories, or equivalent.

8.3 Market Failure

Regulation of HIV pre and post test counselling and limitations on HIV testing address three types of market failure that occur with respect to the prevention of HIV; externalities, information asymmetries and under-provision of public good. The first of these relate to costs of any adverse outcomes of inadequate HIV counselling and inaccurate HIV testing which are not borne by the HIV counselling and testing industry. These costs, which arise from failure to prevent further spread of infection, either through not providing appropriate information on behavioural change to targeted individuals, inaccurate or lack of confidence in HIV test results, and inadequate epidemiological data about the spread of HIV in the community, include:

- Direct costs to the health system and welfare system which are ultimately borne by Australian taxpayers;
- Indirect costs to the Australian economy in lost production; and
- Intangible costs of pain, suffering, lost years of life, anxiety and bereavement.

The second potential source of market failure in the HIV counselling and testing industry is the knowledge disparity which tends to exist between the provider of HIV counselling and testing and the consumer of the services (information asymmetries). Consumers are generally unable to determine service quality before HIV counselling has been rendered by a provider. Consumers are not as well informed as providers or they lack the independent ability to judge the services or proficiency of the counsellor. Consumers do not have the technical expertise, information, time or resources to evaluate the quality of HIV test kits. Government regulation is generally accepted as warranted where the relevant decision making is distributed asymmetrically between market participants (that is, consumers and providers) and there is a clear public interest.

The last involves the under-provision of public good – specifically the lack of incentives for the private sector to collect and disseminate information crucial to the prevention of the epidemic. Essential

information collected on the levels and trends of HIV/AIDS and the prevalence of high-risk behaviour is almost entirely a public good, since it is impossible for a private agent to capture the resulting benefits.

8.4 Effects of other Legislation and the Common Law on these Market Failures

8.4.1 Commonwealth Therapeutic Goods Act

The *Therapeutic Goods Act* 1989 regulates the supply of therapeutic goods in Australia with the intention of protecting health care workers and the Australian public by ensuring the safety, quality and efficacy of therapeutic goods. Unless specifically exempt or excluded, therapeutic goods may not be supplied to the Australian market or exported unless they are listed or registered in the Australian Register of Therapeutic Goods (ARTG). The national scheme for the regulation of therapeutic goods is administered by the Therapeutics Goods Administration (TGA) under the Act. Regulation of therapeutic goods is exerted through five main processes:

- Pre-market evaluation and approval of registered products intended for supply in Australia;
- Licensing of manufacturers in accordance with international standards under Good Manufacturing Practice;
- Post-market monitoring, through sampling, adverse event reporting, surveillance activities, and response to public inquiries;
- Development, maintenance and monitoring of the systems for listing of medicines, and the assessment of medicines for export.

All kits registered for HIV testing are on the ARTG. Laboratories carrying out tests for HIV should ensure that they meet the requirements of these regulations. The range of registered tests and the requirements may change from time to time.

8.4.2 Victorian Therapeutic Goods Act

The *Therapeutic Goods Act* 1994 was enacted to bring unincorporated Victorian manufacturers and suppliers of therapeutic goods, who only operate within Victoria, into the national scheme for the regulation of therapeutic goods which is administered by the TGA under the Commonwealth Act.

It is an offence to import, export, manufacture or distribute " therapeutic goods" (which include HIV diagnostic kits) which do not comply with relevant standards unless the consent of the Secretary to DHS has been obtained. Standards relate to the quality, quantity, manufacturing, packaging and labelling of " therapeutic goods".

8.4.3 National Pathology Accreditation Advisory Council Standards

The National Pathology Accreditation Advisory Council (NPAAC) Standards, promulgated under the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles* (Cth) 1999, must be addressed in a report to the Minister for his consideration in the approval of premises as an accredited pathology laboratory under the *Health Insurance Act* 1973. The Royal College of Pathologists of Australia (RCPA) in conjunction with the National Association of Testing Authorities has developed a program of pathology service accreditation based on the NPAAC standards. This program is compulsory for pathology service providers seeking access to Commonwealth Medicare reimbursement.

8.4.4 Pathology Services Accreditation Act

In Victoria, the *Pathology Services Accreditation Act* 1984 ("PSA Act") prohibits the performance of a pathology test unless it is conducted in a pathology service accredited by the Pathology Services

Accreditation Board ("the Board"). A pathology service is defined by section 3(1) of the PSA Act as "a service in which human tissue, human fluids or human body products are subjected to analysis for the purposes of prevention, diagnosis or treatment of disease in human beings and includes any premises from which a service is conducted." The categories for which accreditation may be granted and the minimum qualifications for person in charge of a pathology service are specified in Schedule 1 and Schedule 3 of the PSA Act, respectively. The majority of laboratories conducting HIV testing are accredited as category 1 and category 2 pathology services (Registrar, Pathology Services Accreditation Board) which requires a pathologist (category 1) and a pathologist or a scientist who has a postgraduate qualification/prescribed experience (category 2).[52]

The crucial element of the accreditation process is the inspection report. Section 13(3A) of the PSA Act provides that an application must be accompanied by an inspection report from an approved inspection agency. The Board has approved NATA to perform inspections of all categories of pathology services on its behalf. Inspection fees are paid directly to the inspection agency. The other requirement for accreditation is documentary evidence of enrolment in relevant external QA programs. This overlaps with the system which is established in the Health Act for participation in the QA program for anti-HIV testing via the SRL and NRL.

8.4.5 Notification provisions in the Health Act

Notification provisions in the *Health (Infectious Diseases) Regulations* 1990 made pursuant to the *Health Act* 1958, provide for laboratory notification of infectious diseases, listed in Schedule 2 to the Regulations, including HIV.

8.4.6 Consumer protection legislation and civil litigation

The *Trade Practices Act* 1974 (Cth) and the *Fair Trading Act* 1985 (Vic.) operate to protect consumers who purchase HIV counselling or testing services. The *Trade Practices Act* 1974 (Cth) and the *Fair Trading Act* 1985 (Vic.) provide for:

- Prosecutions to be instituted in respect of false representations or misleading conduct in relation to the supply of goods or services; and
- Proceedings to be taken in relation to the supply of defective products in contravention of those Acts.

The common law of negligence allows civil proceedings to be instituted to compensate consumers who suffer damage as a result of a breach of a duty of care by manufacturers or suppliers of "therapeutic goods". Court procedures allow class actions to be instituted against manufacturers or suppliers of defective "therapeutic goods" on behalf of all persons who suffered injury, loss or damage as a result of a defective therapeutic product.

8.5 Objectives of the Legislation

The objective of qualification or experience requirements for a person providing pre test and post test counselling is to help to ensure that individuals who are tested for HIV infection receive informed support and advice regarding transmission of that disease, thereby reducing the risk of further spread of HIV.

A limitation on laboratories which can test for HIV and requiring records to be kept by these laboratories with respect to HIV tests is to help to ensure that particular standards apply to centres that conduct this testing and that epidemiological information in relation to HIV testing and the incidence of HIV is obtained.

[52] Schedule 1 of the *Pathology Services Accreditation Act* 1984 has been amended by Order of Governor in Council to replace the current eight categories with five new categories. The new categories accord with the revised categories adopted by the National Pathology Accreditation Advisory Council for the national program of accreditation of pathology services. The Order will take effect on 26 February 2001.

8.6 The Rationale for Legislative Intervention

8.6.1 Qualification requirements for a person providing pre test and post test HIV counselling

HIV is the retrovirus which causes AIDS. HIV infection is spread by bodily secretions of the infected person coming in contact with the recipient's blood through a break in the skin or mucous membranes. Sexual intercourse, contaminated blood transfusions, needles or other invasive instruments are the most common means of transmission. The presence of antibodies to HIV in the blood is a sign of HIV infection. These antibodies do not destroy the virus, they simply serve as markers of infection. Clinical signs and symptoms and laboratory tests confirm it.

AIDS represents the late stage of HIV infection with profound immunosuppression and the occurrence of unusual opportunistic infections and tumours. Anti-retroviral treatments, including protease inhibitors, for HIV disease can improve quality of life and delay AIDS related deaths.[53,54] However, despite these advances, there is no cure or vaccine for HIV infection. Thus, the best prevention strategy remains education of those whose activities place them at risk of infection.

A recent DHS Report has documented the 1999 surveillance data for HIV/AIDS in Victoria.[55] To the end of 1999, there was a cumulative total of 4,215 HIV diagnoses. The annual number of HIV diagnoses peaked in 1985 with 528 diagnoses, and has since decreased to 141 individuals diagnosed during 1999. The annual number of newly acquired infections during 1999 was 41 (29%). The proportion of annual diagnoses that are classified as newly acquired has remained relatively constant at approximately 25 per cent since 1994. To the end of 1999, there was a cumulative total of 1800 AIDS diagnoses notified. The diagnosis of AIDS peaked at 203 diagnoses in 1994, and has since declined with 24 new AIDS diagnoses notified in 1999. In December 1999 there were an estimated 385 people living with AIDS. There have been a total of 1043 deaths following AIDS diagnosis between 1983 and 1999 in Victoria. The annual number of deaths peaked in 1993 and 1994, with 174 deaths notified in both years, and has since decreased to 32 deaths in 1999.

In Victoria in 1999, there were 122,847 specimens tested for antibody to HIV. The reasons for testing included: sexual contact or injecting drug use (11%) and screening purposes, including antenatal, immigration and insurance screening (14%). The reason for testing was not specified for 67% of the specimens tested[56]. There is ample opportunity within this setting for minimising the incidence of HIV/AIDS infection in the wider community by advising on appropriate behavioural change for those requesting a test and those who are confirmed as positive for the HIV antibody. Several studies have shown that individual counseling combined with HIV testing can reduce risk of HIV transmission (see section 8.7.2.1).

Pre and post test counselling is integral to minimising the personal and social impact of HIV infection by providing information and support to assist in changing behaviour, managing disease, reducing anxiety and avoiding discrimination. The Commonwealth HIV Testing Policy prepared by a joint working party of the National Council on AIDS and Related Diseases (ANCARD) and the Intergovernmental Committee on AIDS and Related Diseases (IGCARD), has reported an increasing complexity in the counselling role.[57] As well as counselling to help alleviate anxieties felt by the client/patient, the practitioner discussing the test may be required to assess risk, obtain consent, arrange follow-up, determine and assess referral and identify other needs. Further, the complexity of the discussion will

[53] Bartlett JG. Protease inhibitors for HIV infection, *Ann Intern Med,* 1996;124:1086-1088.
[54] Centres for Disease Control and Prevention. Clinical update: impact of HIV protease inhibitors on treatment of HIV-infected tuberculosis patients with rifampicin, *MMWR,* 1996;45:921-925.
[55] Surveillance of STDs in Victoria 1999, DHS Report.
[56] Surveillance of STDs in Victoria 1999, DHS Report.
[57] Joint Working Party of the Australian National Council on AIDS and Related Diseases and the Intergovernmental Committee on AIDS and Related Diseases, *HIV Testing Policy*, Commonwealth of Australia, 1998.

vary from person to person dependant on their risk factors. Importantly, one of the outcomes of the pre-test counselling discussion may be not to test an individual.

Accurate risk assessment is vital given the significant consequences of improperly advising on risk and the need for HIV testing, both for the individual and the wider community. Critically, for the rest of the community, the provision of informed counselling helps to ensure that individuals are given appropriate information on behavioural change to minimise the spread of infection.

The risk in failing to ensure that those who provide pre-test and post-test counselling are adequately qualified is that they may:

- Inaccurately assess risk and the need for HIV testing;
- Be unaware of the implications of a positive diagnosis;
- Not provide accurate information about the infection or disease; and
- Not utilise the opportunity for providing appropriate information on behavioural change that will minimise the spread of infection in the community.

The need for informed counselling remains a high priority. This is further supported given the rapidly advancing field of HIV management which has implications for counselling in HIV testing – mainly for the availability and increasing use of new treatments and methods of testing.

Tasmania under its *HIV/AIDS Preventative Measures Act* 1993 requires that persons conducting pre-test counselling (section14) and post test counselling (section 15) must be a medical practitioner or approved health worker authorised by the medical practitioner.

8.6.2 Limitation on which laboratories can test for HIV

The need for accuracy is particularly important in HIV diagnosis because of the wide ranging implications of a positive (or negative) test result. A highly effective quality assurance (QA) program for ensuring accurate, cost effective HIV serology has been introduced in Australia, with participation of HIV testing laboratories, the Therapeutics Goods Association (TGA), NRL, kit manufacturers and the Commonwealth and State/Territory health departments.

The QA system has been facilitated and underpinned by period contracts, between the Commonwealth and test kit suppliers, which stipulated that kits (evaluated and registered by the TGA for marketing) be sold only to authorised laboratories, nominated by State/Territory health departments for authorisation by the Commonwealth. Authorised HIV testing laboratories made an agreement with the appropriate State/Territory health department to participate in the NRL's QA program. The goals accomplished by these arrangements by the NRL included:

- Availability of a national database which enabled the monitoring of HIV test kit performances;
- Appropriate and efficient use of test kits by screening and reference laboratories, facilitating the collection of epidemiological data;
- Verification that laboratory data were accurate and complete;
- Assurance that kits could be tracked after sale and that investigation of any problems could be coordinated through data supplied to the NRL; and
- Classification of laboratories as screening (standard) or supplemental (reference) laboratories.[58]

With the cessation of the period contracts in March 1998, individual laboratories are now able to use any available kits – ie. those which are registered on the ARTG. HIV kits are prescribed in Schedule 3 of the Therapeutic Goods Regulations and as such must undergo pre market evaluation. Their post market performance is monitored by NRL.

[58] ibid, p.22.

Authorisation of HIV testing is through State and Territory Health Departments. In Victoria, laboratories wishing to test for HIV approach DHS, who then nominate the laboratory. There is currently no limitation on laboratories that wish to conduct standard HIV testing, providing they comply with a number of conditions including involvement in QA programs. DHS then notifies the NRL of their decision. NRL notifies DHS of any failure of a nominated laboratory to comply with the QA program, and DHS may apply sanctions as deemed necessary, including suspension of authorisation to conduct HIV testing. Since 1986, one laboratory has had their approval to conduct HIV testing suspended. Their approval was reinstated when a satisfactory test panel was completed.

The need for accuracy in HIV testing remains a high priority. The monitoring data acquired from laboratories and suppliers while kits are used in the marketplace ensure continued quality in HIV testing, allow identification of problems and foster a network for the promotion of quality in the performance of HIV serology. This helps to ensure quality control and expertise in this area; that in turn has benefits for patient, community and medical professional confidence.

The other requirement on prescribed places is the collection of epidemiological information on those people being tested and persons newly diagnosed with HIV infection. It is crucially important to have epidemiological knowledge about the spread of HIV infection in the community to:

- Monitor the spread of the infection;
- Assess the effectiveness of public and targeted education campaigns; and
- Plan treatment and counselling services that will become necessary in the future.

It is also important for the accuracy of trend analysis that the information provided is consistent over time, and that records are kept for an extended period of time. This is unlikely to occur if left to the market, unless there is a financial incentive to do so. The risk associated with not implementing the regulations is that epidemiological information will not be available on which to predicate best practice in the field of HIV/AIDS prevention and treatment services.

Tasmania under its *HIV/AIDS Preventative Measures Act* 1993 limits HIV testing to institutions approved by the Secretary (section 40).

8.7 Costs and Benefits of the Restrictions

The Health Act Review Discussion Paper sought comments on the costs and benefits of the restrictions, whether the costs outweigh the benefits and whether there are any less restrictive means of achieving the objective of the restriction.

8.7.1 Costs

8.7.1.1 Qualification requirements for a person providing pre test and post test HIV counselling

As stated in the Discussion Paper, the requirement that a person providing pre and post test counselling must have a certain level of experience or qualification is a restriction on competition.

The restriction imposes direct costs of running HIV/AIDS Counsellor Accreditation courses. HIV/AIDS Counsellor Accreditation courses are already conducted at a number of professional centres several times a year, often as part of other courses. The cost ranges from $500 to $585 per course, which could be viewed as part of professional requirements in many cases. There are approximately 79 graduates of such courses per year at a total cost of $42,305. There is an additional cost to produce certificates, for those who satisfactorily complete courses, of approximately $1500 that is borne by DHS.

The restrictions may lead to delays in the provision of positive HIV test results in rural or remote areas where access to a medical practitioner or person with the requisite counselling training or experience is limited. The submission received from the Australian and New Zealand Association of Nurses in Aids Care supported the restrictions in metropolitan or well serviced areas but raised the point that:

> *In rural and remote areas, however, where access to pre- and post-test counselling services is much more limited, if not non-existent, flexibility needs to be maintained.*

The Alfred Infectious Diseases Unit submission suggested that continuing the restriction was anachronistic. The submission referred to the fact that the restriction was introduced when HIV was a new area and needed a new approach. The submission indicated that the restriction was no longer necessary because of the change in pattern of HIV care and the change in outcome of HIV disease.

8.7.1.2 Limitation on which laboratories can test for HIV

As stated in the discussion paper the limitation as to who can test for HIV is a restriction on competition.

The Act:

- Prescribes the places where HIV testing is conducted;
- Requires those places to provide epidemiological information (such as first two letters of family name and given name, date of birth, sex, postcode of current residence, risk category) of persons who test positive without any details that could identify an individual patient;
- Necessitates that the information is to be provided on a monthly basis.

The impact is therefore on prescribed places; persons, organisations, or bodies involved in HIV testing.

The prescribed places are the public and private laboratories that undertake HIV testing. There is no limitation on the pathology services that can undertake standard HIV testing, providing they comply with the established national accreditation process for accrediting pathology services and accrediting pathology services that undertake HIV antibody testing [Pathology Services Accreditation Board and National Association of Testing Authorities (NATA)] and are nominated by the Secretary, which requires agreement to a number of conditions (see section 8.2.2), including participation in an ongoing QA program for anti-HIV testing via the SRL and NRL. However, HIV confirmatory testing is currently limited to SRL. It is worth noting here that there has been no application received by DHS to date, requesting nomination by the Secretary to conduct confirmatory testing.

There is no direct cost involved with application for nomination by the Secretary under the Health Act. Costs indirectly placed on pathology services wishing to conduct HIV tests are by way of the requirement for accreditation by the Pathology Services Accreditation Board and NATA. The current fees prescribed under the PSA Regulations for accreditation or for annual renewal of accreditation for categories 1 and 2 pathology services is $378[59]. The Board has approved NATA to perform inspections of all categories of pathology services on its behalf. Inspection fees are paid directly to the inspection agency. NATA's fee schedule 2000-2001 for accreditation of medical testing laboratories –hospitals and private practice are as follows:

- Application for accreditation, which includes fees for: application ($1225); advisory visit ($130/hour); Documentation Review ($130/hour); Initial Assessment ($1040/assessment unit).

[59] A Regulatory Impact Statement has just been released for the proposed *Pathology Services Accreditation (General) Regulations* 2001. These proposed regulations essentially are remaking the exiting regulations with some minor changes, including an increase in the fees that are currently charged for accreditation and renewal of accreditation. The proposed regulations, if made, will come into operation on 26 February 2001.

All travel, accommodation and associated expenses are charged at cost in addition to fees listed above.

- Annual membership fees, which are charged at a rate dependent on the distance of the accredited organization from a capital city GPO in a city where there is a NATA office. Laboratories located within 100 km of a NATA office pay the following fees: 1 assessment unit - $1960; 2 assessment units - $3045; 3 assessment units - $4130 (etc). Laboratories located more than 100 km from Melbourne GPO pay the following fees: 0-100 km - Base Fee; 100 km-200 km - Base Fee + 5%; 200 km-750 km - Base Fee + 10%.
- Other fees including: follow up initial assessment visits ($1040/assessment unit/day plus travel, accommodation and related assessment costs); follow up initial reassessment visits ($130/hour/assessment unit plus travel, accommodation and related costs; additional/amended certificates ($52) (2 certificates gratis on accreditation of laboratory).

Victoria's approach to HIV 'standard' testing (screening/diagnostic) testing differs from other jurisdictions in that a 'user pays' system has been introduced, where patients who have specimens collected and tested by private pathology services may, at the laboratory's discretion, be charged a fee. HIV is not currently on the Commonwealth Pathology Services Table and does not attract a pathology rebate. In other States, there may be arrangements whereby private pathology laboratories can perform initial HIV diagnostic testing provided that no charge be raised by the patient. A review of DNA/RNA amplification testing undertaken by the Australian Health Technology Advisory Committee[60], a standing Committee of the NHMRC, has led to molecular monitoring of levels of HIV in patient plasma (HIV vial load testing, or PCR) now being a Medicare rebateable item.

The limitations on the laboratories which can conduct HIV testing may inflate the pricing of such tests if private laboratories view the restrictions imposed on them in the process of nomination as sufficiently demanding so as to be unattractive or prohibitive to their providing the service. In this situation the barrier, real or perceived, would restrict the market resulting in pricing not being determined by market forces. However, as there are no direct costs involved in the process seeking nomination under the Health Act and given the broad representation of the private sector in this market for services, this is unlikely.

The submission received from Dr Rob Baird, Melbourne Pathology stated that:

> *The issue when testing is not the test or the assay, but it is the training and expertise of the scientist releasing the result. I would favour any laboratory being able to offer HIV testing, but the requirement must include that a scientist trained in serology and with expertise in the HIV area must be responsible for studying the request form, overseeing the HIV assay and not releasing or authorising the result.*

This position was supported in the submission received from the Inner & Eastern Health Care Network who also expressed the view that any laboratory that has the required expertise to conduct HIV testing and keeps the required information should be permitted to conduct HIV testing. Their submission also pointed out that limiting the number of laboratories which can conduct HIV testing may cause delays in the provision of HIV test results and in the commencement of HIV treatment particularly, in rural or remote areas where blood needs to be sent away for testing.

The Commonwealth Department of Health and Aged Care's submission made the point that:

> *…regardless of whether or not there exists restrictions concerning which laboratories can and can't test for HIV, there should remain in place mechanisms which ensure the reliability of test results and these should be in line with nationally recognised standards.*

[60] NPAAC. Laboratory accreditation standards and guidelines for nucleic acid detection techniques. Amended Consultation Draft – Feb 3/2000.

The second part of the restriction placed on laboratories conducting HIV testing relates to the provision of epidemiological information. Notification of infectious diseases is an established concept, and one that is inherently accepted by the medical profession and pathology laboratories. The infrastructure is already in place to allow the notification of infectious diseases and HIV testing to continue. Laboratories supply information on testing and persons newly diagnosed with HIV infection as per Regulation 19. This information is supplied to MBCMR for data analysis and reporting as well as notification to Departmental contact tracers. Notifications from medical practitioners are supplied to DHS who can follow up with the reporting medical practitioners and the contact tracers. It is considered that the cost associated with these particular arrangements are absorbed in the usual notification costs and Departmental officers salaries.

At present, there are 31 laboratories accredited and approved to do HIV testing. The marginal costs to these laboratories is negligible as minimal data are requested, and as no reporting form is prescribed, the data can be supplied in the format they find most convenient. The marginal costs associated with the supply of non-identifying information about HIV testing and persons newly diagnosed with HIV infection are minimal. It has been suggested that it takes laboratories approximately 10 minutes to complete the information required. It may take less time as some laboratories generate the information automatically by computer.

There are no monetary costs to the individual patient and the community. However, an intangible cost lies in the erroneous belief that notification of HIV and AIDS may result in the patient being identifiable in some way. This is not the case as only coded names are used. This can be explained at the pre-test and post-test counselling.

8.7.2 Benefits

8.7.2.1 Qualification requirements for a person providing pre test and post test HIV counselling

HIV counseling and testing has been a major part of HIV prevention programs since the mid-1980s.[61] The benefit to the individual being tested is to minimize the personal and social impact of HIV infection, this being consistent with a major goal of the third national HIV/AIDS strategy.[62] Counseling plays a vital role in changing behaviour, managing disease, reducing anxieties and fear and avoiding discrimination. The benefit for the rest of the community of providing informed counselling is in ensuring that individuals are given appropriate information on behavioural change to minimize the spread of infection.

The majority of submissions received supported the continuation of restrictions on who can provide pre- and post-test HIV counseling. The submission by Southern Health Care Network stated that:

> *…without training, the likelihood of incorrectly handling this issue is raised with potential consequences including patient suicide, denial of disease, refusal of appropriate treatment due to misinformation regarding its potential benefits. It is submitted that this is an area that requires specific skills and therefore should be an exemption from competition policy reform.*

The submission from Positive Women and People Living with HIV/AIDS Victoria outlined the need for the restriction on the basis that:

> *…being diagnosed with HIV still carries significant social and medical consequences. Unless a person has had pre-test counselling to ensure a knowledge level that is adequate to deal with a potential positive diagnosis, there is the possibility that a positive diagnosis may precipitate a suicide*

[61] Roper W. Current approaches to prevention of HIV infection, *Public Health Reports,* 1991;106:111-115.
[62] National HIV/AIDS Strategy 1999-2000 to 2003-2004.

or other forms of destructive /despairing behaviour. As HIV infection is both preventable and now to a significant degree treatable, adequate counselling both pre- and post-test is necessary to:

- *Prevent further HIV infection (through educating about transmission, responsibilities and risk);*
- *Prevent untimely deaths as a result of 'HIV panic'; and*
- *Inform individuals about possible treatment options.*

The submission received from Moreland City Council stated that:

The de-regulation of the special provisions relating to HIV, including current laboratory restrictions on HIV testing and pre and post test counselling for HIV would be detrimental to the ongoing success of an approach by which Australia leads the world in controlling the transmission of the HIV virus.

Several studies evaluating the effect of HIV counselling and testing on risk behaviours have shown that individual counselling combined with HIV testing can reduce risk for HIV or STD transmission. Brief interventions have been efficacious in reducing risk behaviour and recurrent STDs among men and women in STD clinics and in primary care clinics in the United States.[63,64] Several longitudinal studies of homosexual men show significant decreases in some risks behaviours associated with knowledge of HIV status.[65,66,67] Two other cohort studies[68,69] and three cross-sectional studies[70,71,72] also found positive associations between counseling and testing and less risky behaviour. Other studies have documented improvements in needle hygiene and decreases in the number of needle-sharing and sexual partners among intravenous drug users who received counselling and testing.[73,74] Studies examining behaviour change among discordant couples showed that counseling and testing were followed by substantial reductions in unprotected sex.[75,76,77] Two studies among prostitutes and women recruited from areas of known prostitution and drug use reported increases in condom use and large reductions in anal sex following counseling and testing interventions.[78,79] Among seropositive adolescents, counseling and testing was reported to promote a reduction in number of sexual partners

[63] Centres for Disease Control and Prevention. *HIV/AIDS Surveillance Rep*. 1999;11(1).
[64] Bozzette S, Berry SH, Duan N, et al. The care of HIV-infected adults in the United States: results from the HIV Cost and Services Utilization Study. *N Engl J Med.* 1998;339:1897-1904.
[65] McKusick L, Coates TJ, Morin SF, Pollack L, Hoff C. Longitudinal predictors of reductions in unprotected anal intercourse among gay men in San Francisco: the AIDS Behavioural Research Project. *Am J Public Health*. 1990;80:978-983.
[66] Fox R, Odaka NJ, Brookmeyer R, Polk BF. Effect of HIV antibody disclosure on subsequent sexual activity in homosexual men. *AIDS.* 1987;241-246.
[67] McCusker J, Stoddard AM, Mayer KH, Zapka J, Morrison C, Saltzman SP. Effects of HIV antibody test knowledge on subsequent sexual behaviour in a cohort of homosexually active men. *AM J Public Health*. 1988;78:462-467.
[68] Cohn DL, Gourley PJ, Bartholow BN, Bujwit CA, O'Reilly KR, Judson FN. Cnages in HIV risk behaviour in a longitudinal cohort of homosexual and bisexual men. Presented at the Forth International Conference on AIDS; June 15-16, 1988; Stockholm, Sweden.
[69] Zones JS, Beeson DR, Echenberg DF, Frigo MA, O'Malley PM, Rutherford GW. Personal and social consequences of AIDS antibody testing and notification of in a cohort of homosexual and bisexual men. Presented at Second International Conference on AIDS; June 24, 1986; Paris, France.
[70] Valdiserri RO, Lyter DL, Leviton LC, Callahan CM, Kingsley LA, Rinalds CR. Variables influencing condom use in a cohort of homosexual and bisexual men. *Am J Public Health.* 1988;78:801-805.
[71] Frazer IH, McCamish M, Hay I, North P. Influence of human immunodeficiency virus antibody testing on sexual behaviour in a 'high-risk' population form a 'low-risk' city. *Med J Aust.* 1988;149:365-368.
[72] Ross MW. Relationship of combinations of AIDS counselling and testing to safer sex and condom use in homosexual men. *Community Health Stud*. 1988;12:322-327.
[73] Skidmore CA, Robertson JR, Roberts JJK. Changes in HIV risk-taking behaviour in intravenous drug users: a second follow-up. *Br J Addict*. 1989;84:695-696.
[74] Robertson JR, Skidmore CA, Roberts JJK. HIV infection in intravenous drug users: a follow up study indicating changes in risk-taking behaviour. *Br J Addict*. 1988;83:387-391.
[75] DeVincenzi I, Park RA. Heterosexual transmission of HIV: follow-up of a European cohort of couples. Presented at Sixth International Conference on AIDS; June 21, 1990; San Francisco, Calif.
[76] Tice J, Allen S, Serufilira A, van de Perre P, Ziegler J, Hulley S. Impact of HIV testing on condom/spermicide use among HIV discordant couples in Africa. Presented at Sixth International Conference on AIDS; June 23, 1990; San Francisco, Calif.
[77] Vogler M, Dugan T, Seidin M. Changes in sexual and reproductive behaviour in heterosexual couples after HIV testing. Presented at Fifth International Conference on AIDS; June 6, 1989; Montreal, Quebec.
[78] Corby N, Barchi P, Wolitski R, Smith P, Martin D. Effects of condom skills training and HIV-testing on AIDS prevention behaviours among sex workers. Presented at the Sixth International Conference on AIDS; June 23, 1990; San Francisco, Calif.
[79] Cohen JB, Poole LE, Dorman LE, Lyons CA, Kelly TJ, Wofsy CB. Changes in risk behaviour for HIV infection and transmission in a prospective study of 240 sexually active women in San Francisco. Presented at Fourth International Conference on AIDS; June 13-14, 1988 Stockholm, Sweden.

and the majority of males, but none of the females, reported increasing safer sexual practices.[80] Although behavioural studies suggest that a number of psychosocial and environmental factors influence health risk reduction, it appears from the above studies that a pre- and post-test HIV counseling does effect behavioural change in individuals. However, it should be noted that the combination of a single pre-test and post-test counseling session does not effect sustained behavioural changes in all individuals.[81] Several sessions of individual, group or couples counseling may have to be provided as well as a variety of additional interventions to achieve substantial behaviour risk reduction.

Whilst there is no guarantee that the persons who are permitted to advise of positive HIV test results will prevent all the persons that they counsel from infecting others with HIV, the likelihood of HIV infection prevention is much greater if persons advising of HIV infection are medically qualified or adequately informed about HIV transmission and trained or experienced in HIV counselling.

The overwhelming benefit to the community is in the form of lives saved by not contracting HIV/AIDS, which can be measured by the direct treatment costs alone. Feachem (1995) has cited a cost $93,000 per case of HIV infection[82], however, this has almost certainly risen as a result of:

- The advent of the triple combination therapy - the average cost per person for one year's combination anti-retroviral therapy alone is between $12,000 - $14,000 (Senior Clinician HIV Service Alfred Hospital);
- The necessity for monitoring tests – two per month at a yearly cost of $4,000; and
- The extended life expectancy of people with AIDS - a reduction of 30% and 50% respectively in progression to AIDS and death was recorded in a study undertaken by Correll *et al* (1997).[83]

There are other costs saved include intangible costs such as productive work time lost and trauma.

8.7.2.2 Limitation on which laboratories can test for HIV

The restriction on which laboratories can conduct HIV testing has a number of benefits including attempting to ensure:

- Quality control in the conduct of HIV testing;
- High levels of accuracy in HIV test results;
- Persons receiving the results are not adversely effected by being provided with misleading test results;
- Persons receiving the results can have confidence in their accuracy; and
- The quality of epidemiological data collected from HIV testing.

The need for accuracy is particularly important in HIV diagnosis because of the wide ranging implications of a positive (or negative) test result. Limiting testing to authorized laboratories is consistent with the recommendation of IGCARD and ANCARD in their recent HIV Testing Policy[84] stated that:

> *A mechanism for quality assurance should be maintained and testing be performed only in authorized laboratories participating in the national quality assurance scheme.*

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[80] Futterman D, Hein K, Kipke M, et al. HIV$^+$ adolescents: HIV testing experiences and changes in risk-related sexual and drug use behaviour. Presented at Sixth International Conference on AIDS; June 23, 1990; San Francisco, Calif.

[81] Higgins DL, Galavotti C, O'Reilly KR, et al. Evidence for the effects of HIV antibody counseling and testing on risk behaviours. *JAMA*. 1991;266:2419-2429.

[82] Feacham R. *Valuing the past…investing in the future: Evaluation of the National HIV/AIDS Strategy, 1993-94 and 1995-1996*, AGPS, Canberra, 1995.

[83] Correll PK, Law MG, MacDonald AM, et al. HIV disease progression in Australia in the time of combination antiretroviral therapies. *Med J Aust*. 1998;2,169,:469-472.

[84] Joint Working Party of the Australian National Council on AIDS and Related Diseases and the Intergovernmental Committee on AIDS and Related Diseases, *HIV Testing Policy*, Commonwealth of Australia, 1998.

The majority of submissions received supported the continuation of limitations on laboratories conducting HIV testing. The submission received from the Victorian Infectious Diseases Reference Laboratory stated that:

> *When testing for evidence of HIV infection accuracy is paramount over other considerations. The potential consequences of erroneous results include threats to public safety, and severe medical and social impacts on the individual…*
> *The centralisation [at VIDRL] provides consistency of methodology and interpretation, high quality and continuity in laboratory testing together with confidentiality and security of patient data. The Western blot is the definitive step in laboratory diagnosis HIV, and its accuracy is of critical importance*

The submission received from the Victorian AIDS Councils Gay Men's Health Centre stated that:

> *It is a basic principle which guides HIV testing in Australia that testing should be of the highest possible standard, and accurate in terms of identifying the presence or absence of infection. The need for accuracy is particularly important in HIV diagnosis because of the wide ranging implications of a positive (or negative) result. This is particularly so for the Western Blot test, which confirms whether the initial antibody test is correct.*

The submission received from Positive Women & People Living with AIDS – Victoria stated that:

> *… it is essential for the confirmatory Western blot tests to remain the sole province of the state reference laboratories, because it provides a measure of accuracy and quality control that is crucial in this regard. A relatively small number of samples need to be tested with the Western blot test, given the low rates of HIV infection, therefore it is not feasible to argue that a number of laboratories could attain expertise in this procedure over time.*

The submission received from The Alfred Infectious Diseases Unit stated that:

> *Limitation on HIV testing to specific laboratory settings has a number of benefits including epidemiological and quality assurance. These benefits are particularly important in confirmatory testing and reference activity.*

Data have been collected on HIV testing since 1985. HIV has been a notifiable disease since 1996. The collection of such information has been invaluable in monitoring the testing patterns and the disease patterns in relation to the HIV epidemic. The requirement for information about HIV testing and the requirement for notification of both HIV and AIDS by testing centers and medical practitioners is consistent with that required by other Australian States and Territories. The information is of universal benefit in comparing disease trends within Australia and with the rest of the world. Information about testing and disease patterns is important for measuring the impact of disease in the community, and has funding implications for Victoria.

From the Department's perspective, the greatest benefit from the statutory requirement for record keeping is in detecting hitherto unrecognized methods of transmission and the evaluation of current preventative strategies, as these have the potential for saving thousands of dollars. The contribution to public knowledge and the assistance in the prevention of serious diseases constitutes the benefits to practitioners and testing centers.

8.7.3 Analysis of costs of restrictions against benefits

8.7.3.1 Qualification requirements for a person providing pre test and post test HIV counselling

There is a requirement that persons providing pre and post test counselling about the HIV antibody test other than medical practitioners, i.e. persons of a prescribed class as referred to in the *Health Act*, must have completed an approved course. As such, it restricts competition in the provision of pre and post test counselling about the HIV antibody test.

The community as a whole benefits from access to informed pre and post test counselling in relation to testing for a disease as serious as HIV/AIDS. People who are not adequately informed are not likely to advise the person adequately or correctly. Such counselling also recognises the importance of prevention of transmission of HIV/AIDS. As there is no cure or vaccine available, the best protection remains education on behavioural change to minimise the spread of infection of those whose activities place them, and/or the general community, at risk of infection. This education is best provided by those who are adequately informed on the issues. As has been demonstrated, the benefits to the community as a whole outweigh the costs.

8.7.3.2 Limitation on which laboratories can test for HIV

As previously discussed, there is no limitation on the pathology services that can undertake standard HIV testing, providing they are accredited by relevant National and State bodies, and they are nominated by the Secretary to conduct HIV testing, which requires agreement to a number of conditions including participation in the NRL QA program and submitting data to the MBCMR for epidemiological research purposes. The costs associated with an application for nomination by the Secretary to conduct HIV testing and for the supply of non-identifying information about HIV testing and persons newly diagnosed with HIV infection are minimal. The benefits of maintaining a system to help ensure accuracy of HIV testing and notification for epidemiological purposes is invaluable.

The State regulation of laboratories conducting confirmatory testing may be viewed as a more restrictive interference in the market for provision of these services. In Victoria, as in all States and Territories, confirmatory (or reference testing) is conducted at state ‘reference’ laboratories, or equivalent. The limitation of laboratories conducting reference testing can be supported by the critical importance of accuracy involving consistency of methodology and interpretation, high quality and continuity in laboratory testing. The procedure is more difficult more expensive and requires expertise. Given the small number of samples that need to be tested using Western blot technology and that test numbers have been relatively stable for a number of years (see section 8.2.2), it is not feasible to argue that that a number of laboratories could attain the necessary expertise to conduct this test. Furthermore, the use of emerging technologies such as molecular monitoring of levels of HIV in patient plasma and the potential for these technologies to enter usage as definitive HIV diagnostic tests in the future, support a continuing role for the State in regulation of laboratories authorised to conduct HIV testing.

Epidemiological research is essential to achieving the objectives of this regulation, and a high degree of expertise and confidentiality is required. The production of such reports is an essential link in providing information and feed-back to the community, clinical and public health professionals. It is also important for the accuracy of trend analysis that the information provided is consistent over time, and that records are kept for an extended period of time. This is unlikely to occur if left to the market, unless there is a financial incentive to do so. The risk associated with not implementing the regulations is that epidemiological information will not be available on which to predicate best practice in the field of HIV/AIDS prevention and treatment services.

8.8 Alternatives to these Restrictions

8.8.1 Qualification requirements for a person providing information regarding a HIV positive test

8.8.1.1 Reliance on general, State-wide public education campaigns

The use of a broad media campaign for the prevention of HIV/AIDS transmission would be neither cost-effective nor expedient. For example, the total expenditure on health education (excluding salaries) on the 1998 QUIT Statewide public education campaign (considered the "best practice" model) was $1,967,000, however, such a figure in the case of HIV/AIDS education would be expended on a program:

- in which it would be not be possible to impart the volume and depth of knowledge that is required and requested by individuals seeking HIV testing by means of a general public education campaign; and
- which may well invariably and unnecessarily alarm many members of the general public who are not at risk of infection.

A State-wide public HIV/AIDS education campaign targeting the broader community is unnecessary given that the five main target groups are relatively small and discrete: (i) sexually active homosexual men (who account for 61% of all Victorian HIV transmissions in 1999[85]); (ii) intravenous drug users; (iii) sex workers; (iv) Aborigines and Torres Strait Islanders; and (v) prisoners[86].

Requiring that all people undertaking an HIV test be counselled by people with requisite experience is the more efficient and effective means of ensuring that appropriate information on behavioural change is conveyed to targeted individuals in order to minimise the spread of infection. This strategy is supported by directed information initiatives to the relevant target groups specified above[87]. Together, these strategies have contributed to the reduction of HIV diagnosed cases in Victoria from 329 in 1989 to 141 in 1999[88].

8.8.1.2 Use of voluntary codes or standards

The use of voluntary codes or standards would not guarantee that general counsellors would be sufficiently aware of issues and the latest developments in HIV/AIDS to provide informed counselling, or would have the skills required to counsel those with a positive result. This approach may jeopardise the voluntary testing regime that operates with the co-operation of those who are at greatest risk of infection, and thereby increase the risk of infection in the wider community.

8.8.1.3 Self-regulation

Self-regulation is not a viable option as there is no recognised industry body to create and maintain the requisite standards. Continuing costs would also be required to maintain an external register, which is already being undertaken by DHS at minimal cost for people completing approved courses.

[85] Surveillance of Sexually Transmissible Diseases in Victoria in 1999, DHS Report.
[86] National HIV/AIDS Strategy 1996-97 to 1998-99.
[87] For example, the Victorian Government provides funding to: (i) the Victorian AIDS Council to undertake safe sex education campaign; (ii) the Prostitutes Collective of Victoria to undertake peer education campaigns on safe sexual practices; (iii) provide clean needles and educational pamphlets to intravenous drug users; (iv) Koori organisations such as VACCHO to provide education material on STDs
[88] Surveillance of Sexually Transmissible Diseases in Victoria in 1999, DHS Report

8.8.2 Limitation on which laboratories can test for HIV

8.8.2.1 No regulation

Complete deregulation is acceptable only in a true market place. However, the pathology market place cannot be regarded as a true market place for the following reasons:

- Over 80% of services are bulk-billed;
- A capped funding agreement reduces wasteful market competition;
- Competition tends to be on the basis of service rather than on any other criteria (eg price);
- A medical service is not a simple commodity where the purchaser can make an educated choice;
- There is a bi-partisan commitment to both Medicare and public health service provision.

The nature of pathology practice is such that it is difficult for the public to be able to make informed judgments of the standards required without some degree of external monitoring.
Regulation is required to protect patients' interests by ensuring that laboratory results are reliable and of high quality, which is of particular importance in HIV diagnosis because of the serious implications of a positive (or negative result).

Without regulation, medical practitioners and laboratories are under no obligation to notify the Department of any incidence of infectious disease, and have in the past exhibited a reluctance to complete government forms unless required to do so. As a result, the Department will be unaware of the emergence of an outbreak until sufficient numbers of people have been infected to warrant individual practitioners or members of the public to notify voluntarily. The cost to the community would be significant.

8.8.2.2 Self-regulation

This would rely on the pathology services industry to set its own standards for HIV testing, for example through a code of conduct. There is no one peak body within the pathology services industry. Professional bodies include the Royal College of Pathologists of Australasia (RCPA), the Australian Association of Pathology Practices (AAPP), Australian Institute of Medical Scientists (AIMS), and Medical Scientists Association of Victoria. Membership of professional bodies may be voluntary, e.g. AAPP represents an estimated 85% of the private sector of pathology. Even if a detailed code of practice could be developed and broadly accepted by all representative professional and industry bodies, this option does not allow for a requirement to be imposed that specified standards or qualifications be met before a pathology services business is permitted to commence HIV testing.

The importance of accuracy in HIV testing given the wide ranging implications of a positive (or negative) test result to the individual and the community in general means that any effective regulatory system needs to incorporate a requirement that standards are binding on industry participants. Therefore, reliance on a system of self-regulation would not provide sufficient enforcement of compliance with QA programs in HIV testing.

8.8.2.3 Reliance upon the existing law

The regulation of pathology services under the Health Act are not the only laws which operate to ensure accuracy in pathology testing in Victoria. Other laws which operate in this area include:

- Therapeutics Goods Administration (TGA) under the *Therapeutic Goods Act* 1989 registers all kits for HIV testing on the Australian Register of Therapeutic Goods (ARTG);

- The *Therapeutic Goods Act* (Vic.) 1994 regulates unincorporated Victorian manufacturers and suppliers of therapeutic goods which would otherwise fall outside the national scheme administered by the TGA under the Commonwealth Act;
- National Pathology Accreditation Advisory Council Standards promulgated under the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles* (Cth) 1999, which must be addressed in a report to the Minister for his consideration in the approval of premises as an accredited pathology laboratory under the *Health Insurance Act* 1973;
- The *Pathology Services Accreditation Act* (Vic.) 1984 which prohibits the performance of a pathology test unless it is conducted in a pathology service accredited by the Victorian Pathology Services Accreditation Board;
- Notification provisions in the *Health (Infectious Diseases) Regulations* 1990 made pursuant to the *Health Act* 1958 which require laboratory notification of infectious diseases, including HIV;
- The common law and consumer protection legislation, which deter unsafe practice by giving persons effected by such practice the right to recover their loss.

The question arises as to whether it would be sufficient to rely on these other laws, and not also require nomination by the Secretary to conduct HIV testing under the Health Act. The following is an analysis of whether those other laws would by themselves offer sufficient assurance of accuracy in HIV testing and trend analysis.

The Commonwealth TGA approval system

The TGA system is limited to the approval and post-market monitoring of HIV test kit performance, and does not extend to other factors that are important in ensuring accuracy in HIV testing, including quality of individual test procedures, the expertise of staff and quality of general laboratory equipment and procedures. Under the TGA, the Secretary to the Department of Health and Aged Care has the power to cancel the registration or listing of goods on the ARTG and to require that steps be taken to recover cancelled goods. However, the Secretary's power does not extend to investigation and action against pathology laboratories.

Victorian Therapeutic Goods Act

The Act only regulates unincorporated Victorian manufacturers and suppliers of therapeutic goods, and is therefore clearly not capable of regulating HIV testing.

National Pathology Accreditation Advisory Council Standards

The Commonwealth accreditation system has an emphasis on regulation and control of pathology services that wish to access payment under the Medicare system. HIV testing is not currently on the Commonwealth Pathology Services Table and does not attract a pathology rebate. However, HIV testing is likely to be conducted at pathology services, accredited for conducting other medical testing.

The Commonwealth is limited in the investigative and punitive measures that it can take against substandard pathology services. If services are not meeting reasonable standards, the Commonwealth has no powers to undertake detailed investigations and the only punitive action available to it is the withdrawal of Medicare payments. Whilst this may be expected to force the closure of the service, in theory at least it could still continue to perform tests if the client was prepared to pay the full cost.

Accreditation by the Victorian Pathology Services Accreditation Board

The form for an application for accreditation or for renewal of accreditation of a pathology service, set out in Schedule 4 of the *Pathology Services Accreditation (General) Regulations 1990*, requires that applicants specify which category for which accreditation is sought, not the type of testing to be conducted, ie. HIV testing. Furthermore, it is not possible to limit HIV testing methodologies conducted

at the laboratory. As discussed earlier (see section 8.7.2.2) limitation of laboratories conducting confirmatory testing is required given the complexity, specialized nature and low numbers of tests conducted.

It is difficult to detect from the forms whether the laboratory is currently enrolled in the relevant QA program. The laboratory is "deemed" to be accredited by the Board (s.18A of the Act) following an application, to allow for the time necessary for NATA to conduct an inspection of the laboratory on behalf of the Board. Therefore, it may take up to 12 months before satisfactory enrolment in QA programs can be established and QA compliance can be examined. Continuing compliance is monitored through a requirement to submit to the Board a certified copy of all QA certificates, however, NATA are contracted by the Board only once every 3-4 years to conduct inspections to ensure compliance with QA processes. Although the Board has extensive enforcement powers, including suspension of accreditation [a pathology service operating without accreditation would be doing so illegally and therefore, be liable to prosecution], in its eleven year history little use has been made of these powers. In short, the Board has:

- Not rejected any application for accreditation (this may be attributed to the Board encouraging prospective applicants to make informal preliminary enquiries before lodging an application when there is significant doubt that an application would be approved);
- Received a total of 22 complaints since the commencement of accreditation (these complaints have been relatively evenly distributed from year to year, with a peak of six complaints received in 1998 and no complaints received in 1997). These data might be taken to indicate that there has been little dissatisfaction with the quality of pathology services. However, the Board has argued that a complaints mechanism is necessarily relatively weak as a means of detecting sub-standard practice. This is due to the indirect relationship between the provider and the ultimate consumer of the service (that is, the patient), combined with the fact that it is generally acknowledged that there is an incidence of error in pathology practice. Thus, an incorrect test result cannot necessarily be taken as evidence of poor practice;
- Held three inquiries since the commencement of accreditation – one in 1991, another in 1996 and the third in 1999. The first related to the failure of a pharmacy to apply for inspection and resulted in a six-month suspension of its accreditation. The remaining two inquiries related to the failure of two services complying with regulatory requirements relating to the direct supervision of the performance of pathology testing. In both cases, formal directions to comply were issued by the Board. In the most recent incidence, the pathology service provider sought judicial review of the appropriateness of the direction;
- Not undertaken any prosecution; and
- Cancelled or not renewed the accreditation of four pathology services.

Reliance on the State accreditation system also needs to be seen in light of the concurrent NCP analysis of the *Pathology Services Accreditation Act* 1984. The potential overlap between the Commonwealth and State accreditation systems, and the concomitant increased costs, both direct and direct being borne by the pathology industry is one of the issues that will need to be addressed by this review. As a result of this review, reliance on the regulatory mechanisms provided in the PSA Act may not be an option.

Notification provisions in the Health Act

Reliance upon the general notification provisions in the Health Act would not permit the collection of comprehensive information in relation to HIV which has been invaluable in monitoring the testing patterns and disease patterns in relation to the HIV epidemic.

Consumer protection legislation and civil liberties

Trade practices legislation, fair trading legislation and the common law are not sufficient to correct market failures in the "therapeutic goods" market. This is principally because these Acts and the

common law are reactive to adverse uses of "therapeutic goods" rather than preventative. Regulation of "therapeutic goods" requires appropriate gatekeeping to protect against the adverse consequences in a global market for unsafe "therapeutic goods".

8.9 Conclusion

The requirement that certain persons provide pre-test and post-test counselling about the HIV antibody test plays an important role in the protection of public health through the prevention of the spread of HIV. The costs are those incurred by individuals in obtaining qualifications. The benefits relate to informed counselling of individuals seeking the test, the prevention of the spread of HIV infection in the wider community and the health care costs saved as a result of this. There are no alternative regulatory or non-regulatory solutions that would achieve the same cost-benefit ratio. The requirement is beneficial and cost effective for the community.

The limitation on which laboratories can conduct HIV testing is important in ensuring quality control and expertise in this area; that in turn has benefits for patient, community and medical professional confidence. The costs associated with an application for nomination by the Secretary to conduct HIV testing and for the supply of non-identifying information about HIV testing and persons newly diagnosed with HIV infection are minimal. The benefits of maintaining a system which attempts to ensure accuracy of HIV testing and notification for epidemiological purposes is invaluable. There are no alternative regulatory or non-regulatory solutions that would achieve the same cost-benefit ratio. It is worth noting that in a recent joint statement by ANCARD and IGCARD[89] recommended that a mechanism for quality assurance should be maintained and testing only be performed in authorized laboratories participating in the national quality assurance scheme. The proposal to continue authorisation of laboratories to conduct HIV testing is therefore consistent with Nationally agreed policies in this area.

In this field, the objectives of the legislation can only be achieved by restricting competition. As was discussed in section 7.8, alternatives to the proposed regulations will not achieve the objectives of the legislation. The option of relying on national and state accreditation systems for pathology services need to be considered against uncertainty as to the future trends in the regulation of the pathology industry at both the State and Commonwealth levels.

8.10 Recommendations

8.10.1 That the Health Act continue to provide qualification or experience requirements for a person providing pre test and post test counselling.

8.10.2 That the Health continue to limit which laboratories can conduct HIV testing.

8.10.3 That the Health Act continue to require prescribed places to provide information about the incidence of HIV.

[89] Joint Working Party of the Australian National Council on AIDS and Related Diseases and the Intergovernmental Committee on AIDS and Related Diseases, *HIV Testing Policy*, Commonwealth of Australia, 1998.

9 Part 12 - Accommodation

9.1 Background

Prescribed accommodation is defined in Part 12 as:

- Any area which people are permitted to use for camping, on a frequent or intermittent basis, where payment is made to the proprietor of the land;
- Any vessel, vehicle, house, tent, caravan, building or other structure which is used as a dwelling, where a person can live on payment to the proprietor and which is prescribed to be subject to the Act.

Currently, the following classes of accommodation are prescribed in the *Health (Prescribed Accommodation) Regulations* 1990:

- Residential accommodation;
- Hotels and motels;
- Hostels;
- Student dormitories; and
- Holiday camps.

Specifically exempted from those Regulations are:

- Houses or flats under the exclusive occupation of the occupier;
- Public hospitals or health service establishments registered under the *Health Services Act* 1988;
- Houses, buildings or retirement villages under the *Retirement Villages Act* 1986;
- Houses, buildings or structures to which the *Caravan Parks and Movable Dwellings Act* 1988 applies;
- Any vessel, vehicle, tent or caravan ; or
- Premises in which, other than the family of the proprietor, not more than five persons are accommodated.

Prescribed accommodation must be registered with the local council and there are a significant number of regulation making powers which apply. These include the power to make regulations for standards of hygiene and cleanliness, safety, ensuring suitable facilities for cooking, washing and bathing, and other matters such as maintenance and advertising. The Regulations themselves specify things such as the minimum size of rooms and standards for maintenance, cleanliness of facilities and bed linen, waste and refuse disposal and toilet and bathing facilities.

The requirement for registration of prescribed premises and the minimum standards specified in the Regulations are barriers to entry into, and restrict conduct within, the market for these services, and are therefore restrictions on competition.

9.2 Description of the Market

The provisions of the Act and Regulations in relation to prescribed accommodation are administered by municipal councils throughout Victoria. A survey of Local Government Authorities in Victoria was conducted by DHS in August 2000 to obtain information about the market for prescribed accommodation (response rate 82%). The response rates per region were as follows: Eastern Metropolitan (6 of 7 Councils); Northern Metropolitan (5 of 7 Councils); Southern Metropolitan (8 of 10 Councils); Western Metropolitan (6 of 7 Councils); Barwon South Western (9 of 9 Councils); Gippsland (5 of 6 Councils); Grampians (6 of 11 Councils); Hume (10 of 11 Councils); and Loddon Mallee (9 of 10 Councils).

Results of the Survey are shown in the following tables.

The number of premises as at August 2000 in each class of prescribed accommodation registered with local councils under these provisions is as follows:

Class	Metropolitan		Rural		Total	
Hotels/motels	162	(16%)	851	(84%)	1013	**(57%)**
Hostels	23	(28%)	60	(72%)	83	**(5%)**
Student dormitories	22	(40%)	33	(60%)	55	**(3%)**
Holiday camps	14	(12%)	108	(88%)	122	**(8%)**
Residential accommodation	172	(37%)	292	(63%)	464	**(26%)**
Total	416*	(24%)	1344	(76%)	1760	**(100%)**

* Total includes 23 premises not assigned by reporting councils to a particular class of prescribed accommodation.

The distribution of prescribed accommodation as at August 2000 by DHS Regions in rural Victoria was as follows:

Region	Class of Prescribed Accommodation					Total
	Hotels/ motels	Hostels	Student accomm.	Holiday camps	Residential accomm.	
Barwon South Western	189	19	9	24	95	336 (24%)
Gippsland	208	4	3	47	9	271 (19%)
Grampians	99	8	11	6	85	209 (15%)
Hume	181	15	8	20	60	340* (24%)
Loddon Mallee	174	14	2	11	43	244 (18%)
Total	851	60	33	108	292	1400* (100%)

* Total includes 56 premises not assigned by Murrindindi Shire to a particular class of prescribed accommodation.

The distribution of prescribed accommodation as at August 2000 by DHS Regions in metropolitan Victoria was as follows:

Region	Class of Prescribed Accommodation					Total
	Hotels/ motels	Hostels	Student accom.	Holiday camps	Residential accom.	
Eastern	40	3	11	0	25	85* (20%)
Northern	35	2	4	4	17	79* (19%)
Southern	52	16	6	9	95	178 (43%)
Western	35	2	1	1	35	74 (18%)
Total	162	23	22	14	172	416* (100%)

* Total includes premises not assigned by reporting councils to a particular class of prescribed accommodation.

There is a high demand for low cost accommodation by people seeking short-term accommodation. The tourism accommodation industry is mostly comprised of small operators providing services such as small hotels, motels, hostels, backpacker accommodation, bed and breakfast accommodation (B&Bs) and host farms. Research by Tourism Victoria[90] has shown:

[90] Tourism Industry, Regulatory Audit Reform, Final Report, 1998

- A growing demand for short break holidays, accounting for 53% of domestic nights in Victoria compared to 40% nationally;
- An increase in the number of B&Bs from 300 to 1000 in the past three years; and
- An increasing demand for backpacking accommodation, with 108,000 backpackers visiting Victoria in 1996, making Victoria the third most popular destination for this group, after NSW and Queensland.

There is also a high demand for low cost accommodation by people seeking medium to long-term accommodation. Housing demand is influenced by population growth, household change, and income and employment levels within the State. A proxy indicator of the extent of demand for low cost accommodation is the demand for public housing. As at 30 June 1999, the waiting list comprised 45,934 applications, including 41,027 new applications and 4,907 transfer applications.[91] In addition, low income rental affordability, that is the ability of private renters on statutory incomes to afford lower rent properties, has remained low, and no improvement was observed in 1998-99, largely as a result of statutory incomes rising more slowly than rents, and also because of the distribution of rental properties across rent ranges.[92]

Stakeholders in the prescribed accommodation industry include:

- Proprietors of prescribed accommodation;
- Tourism operators;
- Employees of those accommodation services;
- Occupiers of prescribed accommodation;
- Government regulatory authorities, in particular DHS and Local Government; and
- The community generally which has to bear the costs to the public health system if services are provided unsafely so increasing the risk of transmission of infectious diseases.

9.3 Market Failure

The registration of prescribed accommodation is intended to address two possibilities for market failure in respect of the accommodation industry. The first of these are the costs which arise from failure to prevent further spread of infection which are not borne by the accommodation industry and the consumer who entered into the contract for provision of accommodation services (negative externalities), including:

- Direct costs to the health system and welfare system which are ultimately borne by Australian taxpayers;
- Indirect costs to the Australian economy in lost production; and
- Intangible costs of pain, suffering, lost years of life, anxiety and bereavement.

The second potential source of market failure in the prescribed accommodation industry is the knowledge disparity which tends to exist between the provider of accommodation and the consumer of the services (information asymmetries). The provider of the services potentially has greater access to information and would be expected to be in a better position to know what is required in relation to minimum standards of hygiene, sanitation and safety in prescribed accommodation and how to minimise the risk of airborne and other communicable diseases among people living in prescribed accommodation.

[91] Summary of Housing Assistance Program 1998-99, DHS Report.
[92] ibid, p.12.

9.4 Effect of other Legislation and the Common Law on these Market failures

9.4.1 Building Act and Regulations

The *Building Act* 1993 (Vic.) and the *Building Regulations* 1994 provide a framework to establish, maintain and improve standards for the construction and maintenance of buildings. The Building Code of Australia (BCA), incorporated by reference into the Building Regulations (section 1.7), primarily applies to new buildings or those undergoing renovation. The following provisions of the BCA and Building Regulations are of particular relevance in preventing overcrowding and ensuring the hygiene, sanitation and safety in buildings:

- Clause VicF3.102 of the Victorian appendix to the BCA stipulates that all habitable rooms of Class 3 buildings[93] must have a floor area of at least 7.5 square metres, but such floor area may be less, provided that the room has sufficient light and ventilation not less than that required for a room of 7.5 metres square. Table D1.13 of the BCA prescribes that hostels, hotels, motels, guest houses and boarding houses must provide a room area of 15 square metres per person, however this is calculated over the entire floor area;
- Table F2.1 provides that a building cannot be occupied if it does not provide fundamental facilities (basin, bath, shower, toilet);
- Regulation 6.1 of the Regulations stipulates that consent must be sought from the local council for the linkage of a building to soil/waste reticulation system;
- Regulation 11.2 of the Regulations stipulates that owners must provide essential services to occupants. Currently essential services are limited to fire, smoke and fire resistance matters, etc.

The following provisions of the *Building Act* 1993 may be exercised with respect to existing structures on a case-by-case basis:

- Section 102 is an emergency provision, which provides that a municipal surveyor must form an opinion as to whether the building poses a danger to life and/or property (arising out of the condition or use of the building). Typically this provision is invoked if the building is in imminent danger of collapse.
- Section 106 provides that a building notice can be issued to the building owner/manager to rectify in one of the following situations:
    - If building work was carried out in contravention of the BCA or regulations;
    - Use of the building contravenes the BCA or regulations;
    - The building is unfit for occupation; or
    - The building or building work poses a danger to life, health or safety (eg. inadequate fire fighting facilities, smoke alarms/detectors, etc.)
- Section 111 provides that if a owner does not respond satisfactorily to the notice by undertaking the required works, then the municipal building surveyor can proceed to issue a building order which, if not complied with, will ultimately incur penalties.
- Section 113 provides that the building orders may be issued for minor building work/repair e.g. repair of toilets. However, there are no objective criteria on which a surveyor can base his belief that such work must be undertaken.
- Section 118 lists the penalties for non-compliance ($10,000 for a person; $50,000 for a company).

9.4.2 Environmental Protection Act

The *Environmental Protection Act* 1970 (Vic.) specifies that:

- A low design flow rate sewerage system (under 5,000 litres/day) must be dealt with by council which issues a septic tank permit; while

[93] Class 3 buildings in the BCA are equivalent to prescribed accommodation for the purposes of the Health Act.

- A high design flow rate system (over 5,000 litres/day) must be dealt with by the Environmental Protection Authority, with problems being dealt with via a licence amendment.

9.4.3 Residential Tenancies Act

The *Residential Tenancies Act* 1997 (Vic.) defines the rights and duties of landlords and tenants of rooming house owners and residents. The Act does not apply to premises used for holidays. The following provisions of the *Residential Tenancies Act* 1997 may be exercised with respect to rooming houses:

- Section 120 provides landlords must keep the rooming house facilities, equipment and furniture in good repair.
- Section 129 provides that urgent repairs must be made where there is immediate danger to health and safety.
- Section 136 provides a resident must allow a person exercising a right of entry in accordance with the Act (rooming house owner or their agent) to enter the room.

The Victorian Civil and Administrative Tribunal deals with disputes arising under the Act. Consumer and Business Affairs Victoria can take rooming house owners or residents to the Magistrates' Court for non-compliance with certain obligations under the Act and the Magistrates' Court may impose a fine.

9.4.4 General provisions in the Health Act

The general provisions in the *Health Act* 1958 which help to ensure reasonable standards of hygiene, sanitation and safety and minimise the risk of airborne and other communicable diseases among people living in prescribed accommodation include:

- The nuisance provisions prescribed under Part 3 of the Act allow municipal councils to investigate and deal with nuisances in their districts which are, or a liable to be, dangerous to health or offensive, including nuisances arising from any building or structure and creates an offence of causing or allowing a nuisance to exist.
- Emergency powers prescribed under Part 6, Division 4 of the Act and Regulation 14 of the *Health (Infectious Diseases) Regulations* 1990. Section 123 provides that the Governor in Council may proclaim an emergency for the purpose of stopping, limiting or preventing the spread of an infectious disease. Section 124 sets out the Orders that the Secretary can make once the Governor in Council has proclaimed an emergency. These orders include the seizure of land, buildings or things in the proclaimed area to be used to prevent the spread of infectious disease or for disinfection or destruction if the land building or thing is contributing to the spread of infection. Regulation 14 of the *Health (Infectious Diseases) Regulations* 1990 provides the Secretary with powers during an outbreak or suspected outbreak of infectious disease. It empowers the Secretary to:
    - require compliance with any procedure relating to infectious disease;
    - require compliance with the provisions of Part 4 of the Infectious Diseases Handbook;
    - enter and search without warrant;
    - require the provision of information to trace the source and prevent the further spread of the disease;
    - inspect premises where the disease may be spread;
    - require cleaning or disinfection of premises where the disease may be spread;
    - require disposal or destruction of any infected article;
    - direct the proprietor of a business or the person in charge of premises to take any action necessary to prevent the spread of the disease on or from those premises;
    - direct any person to take any other action that the Chief General Manager considers necessary to prevent the spread of the infectious disease.

  Failure to comply with a direction of the Secretary issued under Regulation 14 is an offence.

- The *Health (Quality of Drinking Water) Regulations* 1991 made under section 81 provide for inspections and sampling of water supplies, reporting of waterborne illness and purification of contaminated water supplies.
- The *Health (Infectious Diseases) Regulations* 1990 made under section 87 which provide that the owner or occupier of premises must take steps to remove any conditions on the premises which are conducive to the breeding of rats and mice.

9.5 Objectives of the Legislation

The object of the Act in requiring premises of this nature to be registered is to minimise the risk of transmitting infection given the high number of people using the premises. Regulation 2 of the *Health (Prescribed Accommodation) Regulations* 1990 states that the objectives of the Regulations are to:

- Prevent overcrowding;
- Ensure reasonable standards of hygiene, sanitation and safety; and
- Minimise the risk of airborne and other communicable diseases among people living in prescribed accommodation.

9.6 The Rationale for Legislative Intervention

Accommodation factors connected to ill health include:

- Lack or sharing of amenities linked to gastroenteritis and dysentery[94], especially among young children[95] and the elderly;
- Overcrowding leading to accidents[96,97], respiratory illness[98], particularly in young children[99] and the elderly and the transmission of infectious diseases such as tuberculosis[100,101] and meningitis[102];
- Problems with insulation and ventilation can result in respiratory illness[103];
- Dampness has been linked to respiratory illness[104,105,106], particularly chest infection and asthma in children[107,108,109,110];
- Uncollected refuse can lead to spread of gastrointestinal and parasitic diseases, mainly as a result of the proliferation of insect and rodent vectors[111], and poor maintenance of sewers, food waste and tipping to increased cases of leptospirosis[112]; and
- Pest infestation can lead to the transmission of a number of infectious diseases.

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[94] Connolly J Kellehe C, Morton S, et al. Housing or homelessness; a public health perspective. London: The Faculty of Public Health Medicine of the Royal College of Physicians, 1991.
[95] Conway J, ed. Prescription for poor health. The health crisis for homeless families. London: London Food Commission, Maternity Alliance, SHAC, Shelter, 1988
[96] Archeson D. Independent Inquiry into Inequalities in Health Report: London, 1998.
[97] Williams M. Housing Health and the Longitudinal Study. Paper given at conference on Unhealthy Housing at University of Warwick, December 1991.
[98] ibid.
[99] Barker D, Osmond C. Inequalities in health in Britain: specific explanations in three Lancashire towns. *Brit Med J*. 1987;294:749-752.
[100] Elender F, Bentham G, Langford I. Tuberculosis mortality in England and Wales during 1982-92: its association with poverty, ethnicity and AIDS. *Soc Sci Med*. 1998;46:6,673-681.
[101] Stein L. A study of respiratory tuberculosis in relation to housing conditions of Edinburgh. *Brit J Prevent Soc Med.* 1950;4:143.
[102] Stuart JM, et al. Risk factors for meningococcal disease: a case control study in South West England. *Commun Med* 1988;10,139.
[103] Liu Q, Saco AJ,Riboli E, et al. Indoor air pollution and lung cancer in Guangzhou, People's Republic of China. *Am J Epidemiol.* 1990;31:753-762
[104] Hyndham SJ. Housing dampness and health amongst British Bengalis in East London. *Soc Sci Med.* 1990;30:1,131-141.
[105] Williamson IJ, Martin CJ, McGill G, et al. Damp housing and asthma: a case-control study. *Thorax*. 1997;52:3,229-234.
[106] Peat JK, Dickenson J, Li J. Effects of damp and mould in the home on respiratory health: a review of the literature. *Allergy*. 1998;53,2,120-128.
[107] Martin CJ, Platt SD, Hunt SM. Housing conditions and ill health. *Brit Med J.* 1987;294:1125-1127.
[108] Platt SD, Martin CJ, Hunt SN, Lewis CW. Damp housing, mould growth and symptomatic health state. *Brit Med J.* 1989;298:1673-8.
[109] Dales RE, Zwanenburg H, Burnett R, Franklin CA. Respiratory health effects of home dampness and moulds among Canadian children. *Am J Epidemiol*. 1991;134:196-203.
[110] Garrett MH, Rayment PR, Hooper MA, et al. Indoor airborne fungal spores, house dampness and associations with environmental factors and respiratory illness in children. *Clinical and Experimental Allergy.* 1998;28:4,459-67.
[111] United Nations Environment Programme (UNEP). Environmental Data Report 1993-94, 4th ed., Basil Blackwell, London, 1993.
[112] British Medical Association. Hazardous Waste and Human Health, Oxford Universty Press, New York, NY, 1991.

Repeated observations of influenza epidemics, particularly in the military, in schools and in other closed populations have led to the conclusion that increasing the density of the population (or overcrowding) materially increases rates of virus transmission. Overcrowding and inadequate ventilation have also been identified as key factors contributing to pneumococcal disease outbreaks in urban jails.[113] Overcrowding is considered to be a more important determinant of measles mortality than previously ascribed factors such as malnutrition.[114]

The *Health (Prescribed Accommodation) Regulations* 1990 were enacted to prevent overcrowding in prescribed accommodation and to help to ensure the maintenance of reasonable standards of hygiene and sanitation. The room size restriction seeks to target longer term prescribed accommodation where market forces have little or no influence on patrons due to their financial or physical inability to move to premises with larger bedrooms. Any premises which comes under these regulations is registered with the local council and inspected by local council EHOs, who have the power to enter any premises for the purpose of examining whether any provision of the *Health Act* 1958 is being contravened.

Western Australia, ACT and NT require registration of accommodation facilities. In some jurisdictions, local councils have adopted by-laws for the licensing and registration of lodging houses, for example, in South Australia pursuant to the *Local Government Act* 1934 and preserved powers in the *Local Government (Implementation) Regulations* 1999.

9.7 Costs and Benefits of the Restrictions

The Health Act Review Discussion Paper sought comments on the costs and benefits of the restrictions, whether the costs outweigh the benefits and whether there are any less restrictive means of achieving the objective of the registration. Additional information on the costs involved in registration of prescribed accommodation was collected in the survey of Local Government Authorities in Victoria, conducted by DHS in August 2000.

9.7.1 Costs

The cost to proprietors to register the prescribed accommodation will vary according to the council involved. Councils have the discretion to set their own fees. The methods for determining fees vary between councils, including: standard fees across all categories of prescribed accommodation; different fees for classes of prescribed accommodation; fees determined by the number of people accommodated; fees based on audit performance; base fee plus additional charges per approved bed per person; different rates for new registration and annual renewal of registration. Some Councils combine the fees for registration of prescribed accommodation with those required for registration of food premises under the *Food Act* 1984 (Vic.).

In rural Victoria, the average fee charged for registration of prescribed premises was $118 (range $113 to $126). The average fee charged by class of prescribed accommodation was as follows: $126 for hotels and motels; $118 for hostels; $113 for student dormitories; $115 for holiday camps; and $119 for residential accommodation.

[113] Hoge CW, Reichler MR, Dominguez EA, et al. An epidemic of pneumococcal disease in an overcrowded, inadequately ventilated jail, *N Engl J Med*, 1994;331:643-648.
[114] Aaby P, Bukh J, Lisse IM, Silva MC. Further community studies on the role of overcrowding and intensive exposure on measles mortality, *Rev Infect Dis*, 1988;10:474-477.

The average and range in fees charged by rural Councils within each DHS region by class of prescribed accommodation are shown in the table below:

Region	Class of Accommodation	Average	Range
Barwon South Western	hotels/motels	$122	$95 - $264
	Hostels	$108	$90 - $264
	student dormitories	$108	$90 - $264
	holiday camps	$112	$95 - $264
	Residential	$123	$95 - $264
Gippsland	hotels/motels	$97	$72 - $318
	Hostels	$97	$72 - $318
	student dormitories	$86	$72 - $318
	holiday camps	$97	$72 - $318
	Residential	$97	$72 - $318
Grampians	hotels/motels	$183	$140 - $260
	Hostels	$153	$120 - $220
	student dormitories	$153	$120 - $220
	holiday camps	$153	$140 - $220
	Residential	$153	$120 - $220
Hume	hotels/motels	$121	$70 - $250
	Hostels	$111	$100 - $250
	student dormitories	$110	$105 - $250
	holiday camps	$111	$100 - $250
	Residential	$103	$70 - $250
Loddon Mallee	hotels/motels	$106	$50 - $150
	Hostels	$117	$110 - $120
	student dormitories	$107	$80 - $120
	holiday camps	$100	$50 - $120
	Residential	$119	$50 - $120

In metropolitan Victoria, the fee charged for registration of prescribed premises ranged from $58 to $1825. The range of fees charged by class of prescribed accommodation was as follows: $65 to $1825 for hotels and motels; $58 to $1825 for hostels; $58 to $1825 for student dormitories; $65 to $350 for holiday camps; and $58 to $1715 for residential accommodation.

The range in fees charged by metropolitan Councils within each DHS region by class of prescribed accommodation are shown in the table below:

Region	Class of Accommodation	Range
Eastern	hotels/motels	$123 - $435
	Hostels	$58 - $435
	student dormitories	$58 - $435
	holiday camps	NA*
	Residential	$58 - $435
Northern	hotels/motels	$86 - $350
	Hostels	$86 - $350
	student dormitories	$86 - $350
	holiday camps	$86 - $350
	Residential	$86 - $350

Region	Class of Accommodation	Range
Southern	hotels/motels	$86 - $1825
	hostels	$86 - $1825
	student dormitories	$86 - $1825
	holiday camps	$86**
	residential	$86 - $1715
Western	hotels/motels	$75 - $195
	Hostels	$133 - $400
	student dormitories	$110**
	holiday camps	$250**
	Residential	$100 - $450

* Not Applicable
** Only located in one Council

The higher end of the range of fees charged can be explained by the amount being based on the following: number of persons/beds (e.g. Barwon South Western: City of Geelong charged $264 for more than 80 beds; Hume: Murrindindi Shire Council charged $250 for 101-125 beds; Eastern: Boroondara Council charged $435 for more than 56 beds; Northern Nillumbik Shire Council charged $350 for more than 20 beds; Southern: Port Philip Council charged $1825 for more than $100 beds); extremely poor performance audit score (e.g. Gippsland: Baw Baw Shire charged $318 for lowest score); combined food premises and prescribed accommodation fees (e.g. Hume: Strathbogie Shire Council charged $250 for combined food premises/prescribed accommodation registration); higher fees in popular tourist areas (e.g. Hepburn Shire Council charged $260 for hotels and motels).

The rate of registration fees charged were dependent on factors including: the number persons/beds; size of premises; audit performance; number of inspections conducted annually; time taken to inspect premises; public health risk; and travel and other associated costs.

In Victoria, tourism is estimated to contribute around 7.4% to the Gross State Product and Victoria's share of national tourism jobs is estimated at 24%, which in 1995/96 terms, as estimated to equate to a direct impact of around $9.4 billion and 169,000 jobs.[115] An additional 79,500 jobs in Victoria are estimated to be indirectly attributed to tourism.[116]

A number of operators having consistently argued that regulatory constraints were stifling Victoria's competitive advantage in the tourism area. In response, the Tourism Industry Regulatory Reform Task Force was constituted in 1997 to examine and report on opportunities to improve the regulatory environment, in order to promote the development of the tourism industry in Victoria. The Taskforce recommendations[117] included a recommendation to exempt short stay tourist accommodation from prescribed accommodation regulations and consolidation of the *Health (Prescribed Accommodation) Regulations* 1990 into the *Building Code of Australia* 1996 (for further discussion see section 9.8.4).

The limitation on flexibility in room sizes relative to other States is a cost imposed on the prescribed accommodation industry. The occupancy requirement is one person for every two square metres in South Australia and New South Wales, but one person for every 3.6 square metres in Victoria. The availability of fewer rooms for the same area in Victorian prescribed accommodation results in lower rate of return on capital compared to other States. This has the potential to impose higher costs upon consumers for providing a service. The room size restriction was intended to target longer term prescribed accommodation, such as rooming houses, by excluding premises where persons are accommodated for 14 days or less.

[115] Tourism Industry, Regulatory Audit Reform, Final Report, 1998.
[116] ibid, p.11.
[117] ibid, p.8-10.

A number of submissions to the Health Act Discussion Paper from local councils supported the recommendations made by the Taskforce, including a submission from Central Goldfields Shire Council, which stated that:

> *It would seem more appropriate for the structural requirements to be included in building legislation and removed from the Health Act. Experience would indicate that [prescribed accommodation] tend to reflect the local competition and therefore maintain a competitive edge by being well operated, otherwise commercial reality sees the less than professional operator cease to remain.*

A submission received from Youth Hostels Association of Victoria referred to the inconsistency between the Prescribed Accommodation Regulations and the Building Code of Australia:

> *Section 15 of the Regulations stipulates 8 guests per shower and toilet. However, Table F2.1 of the Building Code stipulates 10 guests per shower and toilet. In our experience existing and new properties that accord with the Building Code ratio are normally acceptable to Councils. In our view 10 guests per shower/toilet in existing and new developments would clarify the situation.*

The current regulations impose costs upon prescribed accommodation owners of maintenance and cleanliness, however, these constitute continuing costs of operating a business and should thus not impose an additional burden. A proprietor may incur additional costs if the accommodation is situated outside the metropolitan area and in an area where the water supply is inadequate or non-drinkable. The cost incurred will vary depending on whether tank water, disinfection or other methods of ensuring pure water is required. The waste disposal requirement should add no appreciable burden, as the proprietor would normally be required to observe council by-laws which stipulate similar waste disposal requirements. The cost to a proprietor to keep a register of occupiers would be minimal as most proprietors would normally keep a ledger of fees.

The costs to Local councils relate to implementing and enforcing the registration system, including costs associated with paperwork, issuing of certificates, monitoring inspections and inspections in response to complaints. However, these costs are funded out of registration fees, and therefore the actual costs to Local councils are minimal. Most Councils reported inspecting premises for the purposes of registration under both the Food Act and Health Act so as to contain costs.

In 1999/2000, a total of 1534 inspections of prescribed premises were conducted by local councils in rural Victoria (394 in Barwon South Western Region; 325 in Gippsland Region; 201 in Grampians Region; 386 in Hume Region; and 228 in Loddon Mallee Region) and 479 inspections were conduced in metropolitan Victoria (100 in Eastern; 75 in Northern Region; 224 in Southern Region; and 80 in Western Region). On average premises were inspected one to two times per year and inspections took 30 to 90 minutes. Councils reported that it took on average 1 to 50 per cent of their time administering prescribed accommodation and registered premises (see chapter 12). The higher end of the range was explained by time taken to administer the Food Act (including food safety plans and inspections) and an increased work load during holiday periods.

The cost to the occupier results from proprietors electing to pass compliance costs on to their customers to reduce their overheads.

9.7.2 Benefits

The link between low standard housing and poor health has been well established (see section 9.6). The Health Act and Regulations recognise the need to ensure against the problem of overcrowding and provide for ventilation, hygiene, sanitation and safety so as to minimise the risk of airborne and other communicable diseases among people living in shared accommodation.

The benefits of regulation include:

- Clear delineation of proprietors' responsibilities in relation to preventing the spread of disease;
- Healthier living conditions for occupiers;
- Reduced risk of transmission of communicable diseases to the wider community;
- Increased tourism as a result of higher standards of tourist accommodation;
- Higher standards of Victorian residential accommodation; and
- The availability of a register to allow for contract tracing during an outbreak investigation thereby avoiding further spread of disease.

The majority of submissions to the Health Act Discussion Paper supported the continued registration of prescribed premises, including a submission received form the Australian and New Zealand Association of Nurses in AIDS Care, which stated that:

> *As community nurses, many of us have observed numerous examples of very poor living conditions in residential accommodation, even now, despite regulation, so we would oppose any move which would encourage even less scrupulous owners to maximise profits at the expense of public health by overcrowding, poor sanitation and low standards of hygiene.*

The submission received by the Manningham City Council stated that:

> *Registration is appropriate method of knowing where premises are and associated fees are required if local governments are to provide the resources to monitor.*

The submission received from the Maribyrnong City Council stated that:

> *Registration enables the location of premises, regular monitoring, targeted education, and where requirements are not met registration can be revoked by councils. It also allows for recovery of costs of the service from the industry by Local Government via registration fees.*

In 1999/2000, rural Victorian Councils in DHS Survey reported receiving a total of 33 complaints. No actions were reported taken against any class of prescribed accommodation by rural councils. Between 1995 and 2000, 84 complaints were received. Councils reported surveillance of prescribed accommodation has led to a higher standard of premises and fewer complaints. Concerns reported previously included re-use of linen, usage of roof space for accommodation at ski lodges, rodent infestation, problems in relation to cleanliness of spas, and general cleanliness. Investigation of residential premises have found scabies, fleas and bed bugs. Investigations of hostels have found carpet beetles, fleas, influenza and pseudomonas infections.

In 1999/2000, metropolitan councils reported taking actions against prescribed accommodation premises including 23 explanations, 34 warnings, 3 prosecutions and one closure. Councils reported problems with fleas, rats, mice, cockroaches and bed bugs.

Preventing the spread of communicable diseases will result in significant cost reductions to the community as a result of:

- The prevention of unnecessary morbidity and mortality;
- The avoidance of lost work hours; and
- Savings in health care costs.

There may also potentially be cost savings in relation to preventing civil action. In the United Kingdom, the strength of the evidence has enabled some council tenants to sue local authorities for damage to their health caused by damp housing.[118]

[118] Black J. Cold Comfort. *Roof,* 1991;JulyAugust:10.

9.7.3 Analysis of costs of restrictions against benefits

Costs borne by proprietors of prescribed accommodation attendant to the maintenance of appropriate sanitation, water and refuse removal service would be a requirement of an appropriately operated establishment, whether or not the regulations were imposed.

In longer term prescribed accommodation, such as rooming houses, where market forces have little or no influence on patrons due to their financial or physical inability to move to alternative premises, the costs of regulations are outweighed by the benefits.

The application of the regulations to the tourist part of the prescribed accommodation market warrants separate consideration. One of the potential sources of market failure in the prescribed accommodation industry that regulation of the industry seeks to address is the knowledge disparity which tends to exist between the provider of accommodation and the consumer of the services (information asymmetries). However, in relation to the tourism industry it has been suggested by a number of local council submissions that the assumption that there is a lack of information available to consumers to enable them to select appropriate accommodation may no longer be valid. The Tourism Industry Regulatory Reform Taskforce[119] reported improved information flows to consumers through Tourism Victoria, industry associations, media and the Internet. Through the increased information flows, consumers are able to make more informed choices about the standard and quality of accommodation they select, influence the level of standards of accommodation by virtue of electing not to stay at sub-standard accommodation, repeat visits and verbal recommendations. Providers of accommodation are aware of this and respond to the incentive created by competition by delivering a certain standard of facilities.

The question is whether the objectives of the regulations may be achieved in relation to the tourist accommodation industry through reliance solely on the market. In its report, the Task Force recommended exempting short-stay (less than 30 day) tourist accommodation from prescribed regulations. Whilst consumers may be in a more informed position to judge the standard and quality of the tourist accommodation they chose to stay in, being informed to a level to discern public health risk is a different and higher level of knowledge and understanding of risk. Consumers are not in the position to identify public health risks to the same level as EHOs. The potential threat of transmission of infectious diseases in prescribed accommodation outweighs the costs of continuing to register this sector of the industry.

The cost to councils incurred by the inspection of premises is recouped from the registration fees.

9.8 Alternatives to these Restrictions

9.8.1 No regulation

If there are no regulations governing prescribed accommodation, there is concern that some proprietors, particularly those at the lower end of the market catering to vulnerable members of the community may not provide optimal standards of sanitation and ventilation to preclude the spread of infectious diseases amongst occupants.

9.8.2 Self-regulation

While self-regulation may provide savings on inspection costs for local councils and registration costs for property owners, it is contended that this would allow certain rogue operators to flout minimum hygiene and sanitation requirements in order to reduce costs further, leading to an increase potential for the transmission of disease. While it could be argued that in a competitive market, the customer

[119] Tourism Industry, Regulatory Audit Reform, Final Report, 1998

can elect not to stay in poor quality accommodation, not everyone who stays in poor quality accommodation has the financial means to exercise such an option.

9.8.3 Negative registration

Negative licensing is a system that requires registration of only those premises that have breached appropriate hygiene standards. As a result, only offenders against the set standards are removed from the industry without, at the same time, placing an undue burden of registration on the entire industry. This system allows agents to operate undetected or act inappropriately before they are detected, that is, relies on an adverse event to occur before action is taken to prevent a repeat occurrence. Continual monitoring of premises is the only effective way to prevent breaches that may result in placing the public at risk, and this role falls to local government. However, without the registration fees to fund their program of inspections, local government would be restricted in its ability to monitor compliance with appropriate standards. Negative licensing therefore does not provide sufficient protection to consumers, and the general community

9.8.4 Reliance upon the existing law

The regulation of accommodation services under the Health Act are not the only laws which operate to ensure a reasonable standard of hygiene, sanitation and safety are maintained. Other laws which operate in this area include:

- The *Building Act* 1993 and the *Building Regulations* 1994 establishes a framework to establish, maintain and improve standards for the construction and maintenance of buildings;
- The *Environmental Protection Act* 1970 which specifies the regulatory bodies responsible for sewerage systems;
- The *Residential Tenancies Act* 1997 defines the rights and duties of landlords and tenants of rooming houses;
- General provisions of the *Health Act* 1958 which help to ensure reasonable standards of hygiene, sanitation and safety and minimises the risk of airborne and infectious diseases.

Building Act and Regulations

The *Building Act* 1993 and the *Building Regulations* 1994 provide a framework to establish, maintain and improve standards for construction and maintenance of buildings. The Building Code of Australia (BCA) is incorporated by reference into the Building Regulations.

The Tourism Industry Regulatory Reform Task Force, as part of its review of the regulatory environment in respect of the tourism industry in Victoria, recommended consolidating the *Health (Prescribed Accommodation) Regulations* 1990 into the BCA.[120] The aim of the consolidation was to remove prescriptive requirements such as people number/room controls and eliminate areas of duplication, thereby creating a more flexible regulatory environment for tourist accommodation. For example, in short-term accommodation, the occupancy requirement is one person for every two square metres in South Australia and New South Wales, but one person for every 3.6 square metres in Victoria, resulting in the availability of fewer rooms in Victorian prescribed accommodation.

The Hon Rob Knowles MP, the Health Minister at the time, agreed to a review of the Health (Prescribed Accommodation) Regulations as part the tourism industry reform process in consultation with the Building Control Commission and the Office of Regulatory Reform. The following are the specific provisions of the regulations that the report identified as proposed for transfer to the BCA:

- Regulation 7 (overcrowding and stipulation of floor area of bedroom);
- Regulation 10 (continuous and adequate water supply for cooking and bathing);

[120] Tourism Industry, Regulatory Audit Reform, Final Report, 1998

- Regulation 12 (discharge of sewerage and waste water); and
- Regulation 15 (one toilet, bath/shower, wash basin for every eight people).

There are a number of areas in which the BCA provisions do not adequately cover the regulations provided under the Health Act.

With respect to Regulation 7, VicF3.102 of the BCA, which stipulates that all habitable rooms of Class 3 buildings must have a floor area of 7.5 square metres (may be less, provided that the room has light and ventilation), is not predicated on a per person basis, thus potentially enabling bedrooms to be more densely occupied than would be recommended on public health grounds. Table D1.13 of the BCA prescribes that hostels, hotels, motels guest houses and boarding houses must provide a room area of 15 square metres per person, however this is calculated over the entire floor area. The removal of regulation 7, to allow the BCA to regulate room size, would allow building surveyors the discretion to allow partial compliance. In addition, it is unlikely that a breach of the room size provision would trigger any of the inspection notices and orders provided in the Building Regulations, except in the most extreme circumstances.

With respect to regulation 10, governing the supply of water, there is insufficient coverage by other Acts and regulations. Regulation 11.2 of the Building Regulations stipulates that owners must provide essential services to occupants. Currently essential services are limited to fire, smoke and fire resistance matters, etc. Amendments to the BCA would be required to include sanitary provisions as essential services. In addition to the provision of supply of water as an essential service, there is the requirement for an adequate supply of water, which implies an acceptable level of purity to minimise the transmission of infection, which is currently indicated in the prescribed accommodation regulations.

With respect to regulation 12, Regulation 6.1 of the Building Regulations stipulates that consent must be sought from council for the linkage of a building to a soil/waste reticulation system, however, this is merely a “flagging” provision to remind proprietors that they need to contact the appropriate authorities (e.g. Council).

With respect to regulation 15, Table F2.1 of the BCA provides that a building cannot be occupied if it does not provide fundamental facilities (one basin, bath, shower, toilet) per 10 people (as opposed to the eight people specified in the health regulations). The concern in this instance is that, whilst an increase in the number of people per facility will not affect tourists, repeal of this regulation may well have an impact on the elderly and disabled in prescribed accommodation. Monitoring and enforcement procedures provided in the BCA are not strong enough, particularly with respect to existing buildings, to protect the public health interests of these vulnerable groups.

Transferring structural matters to the BCA may not necessarily meet the objects of the Health Act and Health (Prescribed Accommodation) Regulations which are to minimise the risk of transmitting infection given the high number of people using specific accommodation premises, by preventing overcrowding and ensuring reasonable standards of hygiene, sanitation and safety; and minimising the risk of airborne and other communicable diseases among people living in prescribed accommodation. Of particular concern is that the BCA primarily applies to new buildings or those undergoing renovation. The Building Control Commission does not expect or even require that public safety measures in existing buildings will be provided to the same standard as is required for new buildings.[121] While inspectors may exercise some provisions of the Building Act with respect to existing structures on a case-by-case basis (see section 9.4.1), they tend to issue building notices reactively, i.e. in response to:

- A complaint by an occupant;
- A request from an insurance company;
- A directive of a fire fighter in the event of a fire; or

[121] BCC Practice Note 15, March 1995.

- A request from a building owner.

In addition, BCC officers are not trained to determine health issues.

Whilst reliance upon the structural provisions of the Building Act and Regulations is not an alternative to regulation under the Health Act to achieve the objectives of preventing overcrowding, ensuring reasonable standards of hygiene, sanitation and safety; and minimising the risk of airborne and other communicable diseases among people living in prescribed accommodation, some changes to the regulations may address the findings of the Tourism Industry Regulatory Reform Task Force without attendant risks to public health:

- With respect to regulation 7, as there is no empirical evidence which would suggest an increased transmission of infectious disease associated with slightly smaller room sizes, the competitive advantage currently enjoyed by other states in comparison to Victoria could be removed by reducing the room size requirement from one person for every 3.6 square metres to one person for every two square metres (as in South Australia and NSW) and to amend the short stay accommodation exclusion from 14 to 31 days or less;

- With respect to regulation 15, the toilet, bath and shower facilities requirement of one per 8 persons may be amended to be in line with the BCA requirement of one per 10 persons.

Environmental Protection Act

As the average person uses approximately 100 litres of water /day, accommodation providing for up to 50 occupants would be dealt with by Council. A problem has arisen with respect to permits already issued for existing systems, which the council is not authorised to amend (i.e. by stipulating additional conditions). Thus a system may be posing a significant health hazard, but the proprietor could not be ordered to fix the fault or update the system under the Environmental Protection Act, as the system may not be technically in breach of the original permit. Thus prescribed accommodation regulations are the only means that allow for the suspension/revocation of registration in the event of such a breach.

Residential Tenancies Act

The Act provides limited, and inadequate provisions for ensuring reasonable standards of hygiene, sanitation and safety and minimising the risk of airborne and infectious diseases.

Health Act

More vigorous enforcement of public health standards in the Health Act, the Health (Infectious Diseases) Regulations and the Health (Prescribed Accommodation) Regulations with respect to those premises is an alternative to the requirement for registration. However, registration fees are the revenue source which supports local councils maintaining their inspection role. The likelihood of local council applying scarce resources to businesses which are not a revenue source and to which no statutory obligations apply is low. This alternative would prejudice the health and well-being of occupiers of prescribed accommodation and the community generally.

9.9 Conclusion

The requirement that certain premises be registered and to observe certain standards is a barrier to entry into the market, thus constituting a restriction on competition which must be reviewed under the requirements of the national competition policy. However, it is argued that the benefits of the regulations outweigh the costs, an outcome that can only be achieved with this restriction on competition. These benefits (many of which are difficult to quantify as they represent the non-transmission of diseases) include the reduction in the risk of transmission of communicable diseases to the wider community and higher standards of Victorian residential accommodation.

9.10 Recommendations

9.10.1 That the Health Act continue to require the registration of prescribed accommodation.

9.10.2 That Regulation 7 of the *Health (Prescribed Accommodation) Regulations* 1990 be amended to bring the room size requirement in line with NSW and South Australian requirements (one person for every two square metres) and to amend the short stay accommodation exclusion from 14 to 31days or less.

9.10.3 That Regulation 15 of the *Health (Prescribed Accommodation) Regulations* 1990 be amended to bring the toilet, bath and shower facilities requirement in line with the BCA requirement of one per 10 persons.

10 Part 14 - Drugs, Substances and Articles

10.1 Background

Part 14 of the Act relating to Drugs, Substances and Articles covers the mixing, sale, advertising and labelling of drugs. There are also some miscellaneous provisions which deal with other potentially harmful items such as lead in toys. Part 14 also deals with offences and legal proceedings relating to these matters.

"Drug" is defined in the Act as "any substance used as medicine or in the composition or preparation of medicines whether for external or internal use and without limiting the generality of the foregoing includes a drug that is listed or registered as a therapeutic good within the meaning of the Therapeutic Goods (Victoria) Act 1994 or the Therapeutic Goods Act 1989 of the Commonwealth.

"Substance" includes any article or compound.

"Appliance" is defined in the Act as "any instrument or contrivance which is advertised exhibited or offered for sale as of use for the prevention cure or relief of any human ailment or physical defect".

The restrictions on competition in this Part of the Act are as follows:

- Prohibition on the sale and mixing of injurious ingredients in drugs (section 230);
- Prohibition on the sale of any drug which is not of the substance or quality demanded by the purchaser (section 231);
- Prohibition on the sale of any adulterated or improperly packed articles (section 238);
- Prohibition on the sale of disinfectants, germicides, antiseptics, preservatives or household insecticides (section 242);
- Prohibition on the manufacture or sale of toys, wall papers, and serviettes containing substances exceeding a prescribed quantity (section 245);
- Prohibition on the manufacture or sale of textiles or leather containing specified substances in greater than prescribed quantity (section 246);
- Prohibition on false advertising of drugs, medicines and appliances (section 249);
- Requirement that specified formularies be used when preparing medicines (section 270A);
- Labelling requirements for drugs (section 271); and
- Requirement that only approved drug analysts be permitted to make analysis (section 274).

These requirements are barriers to entry into, and restrict conduct within, the market for these services, and are therefore restrictions on competition.

10.2 Description of the Market

The market for "drugs, articles and substances" dealt with under Part 14 of the Act is very broad as an enormous diversity of products come within the definition of drugs, articles and substances. Additionally Part 14 specifically deals with other potentially harmful items such as disinfectants, germicides, antiseptics, preservatives, household insecticides, lead in toys, etc. "Drugs, substances and articles" are used widely in the community and the costs and benefits of the restrictions impact on a wide range of stakeholders, including:

- Manufacturers;
- Wholesalers;
- Suppliers;
- Importers;
- Exporters;
- Pharmacists;

- Allied health professionals;
- Naturopaths;
- Herbalists;
- Homeopaths;
- Practitioners; of traditional Chinese medicine;
- Medical practitioners;
- Dentists;
- Hospitals;
- State, Territory and Commonwealth governments; and
- Consumers.

An appreciation of the size of the market for “drugs, substances and articles” within Australia is indicated in the following publications:

- TGA documentation produced in 1998 which stated that there were approximately 16,000 medicines and 25,000 medical devices on the market in Australia at that time;
- *TGA Corporate Plan 1997/1998 to 1999/2000* which stated that the TGA has responsibility for regulating 10,000,000 therapeutic goods with a gross market value of over 5 billion dollars; and
- A press release by Senator Christopher Ellison in 1997 which stated that 57% of Australians currently use complementary or alternative medicines.

10.3 Market Failure

The principle market failures associated with the “drugs, substances and articles” relate to externalities and information asymmetries. “Drugs, substances and articles” which are not developed, manufactured, stored, supplied or used appropriately have the potential to seriously harm or kill users and their unborn children. The “drugs, substances and articles” market does not bear all the costs of harmful goods. A high proportion of attributable costs from harmful “drugs, substances and articles” are external costs, including:

- Direct costs to the health system and the welfare system which are ultimately borne by Australian taxpayers;
- Indirect costs to the Australian economy in lost production; and
- Intangible costs of pain, suffering, lost years of life, anxiety and bereavement.

There are enormous information asymmetries between producers of “drugs, substances and articles” and consumers of “drugs, substances and articles” as:

- Specialised technical expertise is necessary to understand the complexity of the manufacturing processes of many “ drugs, substances and articles”;
- Information about production processes for “drugs, substances and articles” is not freely available as manufacturers jealously guard the secrecy of their processes;
- Assessment of the quality, safety and efficacy of “drugs, substances, and articles“ requires knowledge of internationally recognised good manufacturing principles, international best practice and adverse reactions experienced overseas;
- Assessment of the quality, safety and efficacy of “drugs, substances and articles” is a very time consuming and costly exercise;
- Consumers do not have the technical expertise, information, time or resources to evaluate the quality, safety, and efficacy of “drugs, substances and articles“; and
- Advertising and public information campaigns can not redress the imbalance of information between producers and consumers of “drugs, substances and articles“.

10.4 Effect of Other Legislation and the Common Law on these Market Failures

10.4.1 Commonwealth Therapeutic Goods Act

The *Therapeutic Goods Act* 1989 (Cth) regulates the supply of therapeutic goods in Australia with the intention of protecting health care workers and the Australian public by ensuring the safety, quality and efficacy of therapeutic goods. To meet this objective, the Act places a number of major controls and restrictions on the importation, export, manufacture and supply of therapeutic goods. The principle control measures provided in the Act may be summarised as follows:

Powers to declare goods to be therapeutic goods and obtain information

The Secretary of the Department of Health and Aged Care (DHAC) has the power to declare that certain goods are, or are not, therapeutic goods within the meaning of the Act (section 7). The DHAC has power to obtain information concerning the composition, indications, directions for use, labelling, or advertising of therapeutic goods imported into, or supplied within, Australia (section 8).

Standards

The Minister has the power to determine standards that apply to therapeutic goods or classes of therapeutic goods. Standards can relate to the quality or quantity of therapeutic goods to be supplied, standards for the manufacture, labelling, and storage of therapeutic goods, or can relate to such other matters as the Minister thinks fit (section 10). A person may not import therapeutic goods into, or supply therapeutic goods within, Australia if the goods do no confirm to the relevant standards (section 14).

Australian Therapeutic Goods Register

Division 1, Part 3 of the Act provides for the establishment of the Australian Register of Therapeutic Goods (ARTG) to hold information in relation to, and to provide for the evaluation of, therapeutic goods for use in humans. Relevantly, this Part provides that:

- The import into, export from, manufacture in, or supply in, Australia of therapeutic goods for use in humans is prohibited unless the goods are:
    - registered or listed on the ARTG; or
    - exempt goods; or
    - the subject of specific approvals (section 20).
- The wholesale supply in Australia of therapeutic goods for use in humans is prohibited unless the goods are registered or listed on the ARTG or are exempt goods or the subject of specific approvals (section 21).

Registration and listing on the Australian Therapeutic Goods Register

Division 2, Part 3 of the Act establishes a scheme for the registration or listing of therapeutic goods on the ATGR. The *Therapeutic Goods Regulations* identify the classes of therapeutic goods that must be registered and those that must be listed[122]. Relevantly, section 25 provides for the evaluation of therapeutic goods before they may become registered. Evaluation includes consideration of:

- Whether the quality, safety and efficacy of the goods for the purposes for which they are to be used have been satisfactorily established; and
- Whether the presentation of the goods is acceptable; and

[122] Registered products are generally required for more serious conditions or require special care in their use. These are assessed for safety, quality and efficacy and comprise prescription and pharmaceutical products, and some complementary medicines. Listed products are assessed for safety and quality but not for efficacy.

- Whether the goods conform to any standard applicable to the goods, or any requirements relating to advertising applicable under the regulations; and
- If a step in the manufacture of the goods has been carried out outside Australia – whether the manufacturing and quality control procedures used in the manufacture of the goods are acceptable; and
- If the goods have been manufactured in Australia – whether the goods have been manufactured in accordance with Part 4 [of the Act]; and
- Whether the goods contain substances that are prohibited imports for the purposes of the Customs Act 1901; and
- Such other matters (if any) as the Secretary considers relevant.[123]

Section 26 provides for the listing of therapeutic goods on the ARTG. Section 28 provides that conditions or restrictions may be imposed on the registration or listing of goods on the ARTG. Section 30 provides that the Secretary of the DHAC may cancel the registration or listing of a therapeutic good in certain circumstances, including for the avoidance of death, serious illness or injury or if the quality, safety and efficacy of the goods is unacceptable. The Secretary of the DHAC may also require the sponsors of therapeutic goods which have been supplied but which:

- are not registered or listed on the ARTG, nor are they exempt goods or subject to specific approval; or
- are registered or listed on the ARTG, or are exempt goods or subject to specific approval, but which do not confirm to the relevant standards;

to inform the public as necessary, and/or require steps to be taken to recover the goods (section 30A and 30B). Section 33 provides that the list of therapeutic goods included on the ARTG must be published at least once every 12 months.

In relation to advertising, section 22 provides that:

- A person must not intentionally or recklessly:
    - Represent therapeutic goods that are not included in the Register as being so included; or
    - Represent therapeutic goods that are not exempt goods as being exempt goods; or
    - Represent therapeutic goods that are included in one part of the Register as being included in the other part of the Register; or
    - Represent therapeutic goods that are not the subject of an approval or authority under section 19 as being the subject of such an approval or authority; or
    - Represent therapeutic goods that are not the subject of an approval under section 19A as being the subject of such an approval (section 22(4)).
- A person, being the sponsor of therapeutic goods that are included in the Register, must not, by any means, intentionally of recklessly advertise the goods for an indication other than those accepted in relation to the inclusion of the goods in the Register (section 22(5)).
- A person must not intentionally or recklessly make a claim, by any means, that the person or another person can arrange the supply of therapeutic goods (not being exempt goods) that are not registered or listed goods (section 22(6)).

Controls on the manufacture of therapeutic goods

Part 4 of the Act imposes controls on the manufacture of therapeutic goods. These controls include:

- A prohibition on any step in the manufacture of therapeutic goods being undertaken other than by the holder of a valid licence, except if the goods or the person are exempt (section 35);
- Requirement for the manufacture of therapeutic goods to comply with manufacturing principles that may from time to time be determined by the Minister (section 36);

[123] s.25(d) – (k), *Therapeutic Goods Act* 1989 (Cth)

- Provision for licences permitting the manufacture of therapeutic goods to be issued subject to conditions (section 40);
- Provision licences to be suspended or revoked if:
    - the holder of the licence has been convicted of an offence against the *Therapeutic Goods Act* 1989;
    - the holder has breached a condition of the licence;
    - the holder has failed to observe the manufacturing principles;
    - the holder requests in writing that the licence be revoked or suspended;
    - the holder ceases to carry on the business of manufacturing the goods to which the licence relates;
    - the annual licensing charge, or any applicable prescribed inspection fees, have not been paid within 28 days (section 41).

Payment of charges

Part 5 of the Act provides for the payment of annual charge for the registration or listing of a therapeutic good on the ARTG, and in respect of licences issued to permit the manufacture of therapeutic goods.

Powers of entry, search and the issue of warrants

Part 5A of the Act grants powers to authorised persons[124] to conduct searches to monitor compliance with the Act. These include power:

- To enter and search premises either with the consent of the occupier of under the authority of a warrant;
- To make seizures on public health grounds (section 46B);
- To make seizures of evidence to be used in prosecutions for offences against the Act.

Regulations

Section 63 provides for the making of regulations by the Governor-General. Generally, the *Therapeutic Goods Regulations* expand upon the principal control measures created by the Act. Part 2 of the Regulations create restrictions on the advertising of therapeutic goods, but do not apply to:

- Advertisements directed at health professionals (regulation 4);
- Advertisements for therapeutic goods not for use in humans (regulation 5); and
- Advertisements for export goods (regulation 5A).

Subject to these exemptions, the Regulations prohibit any advertisement about therapeutic goods that:

- Contains a prohibited representation[125];
- Does not contain a required representation[126];
- Contravenes a notice issued under Regulation 7 or Regulation 9[127];
- Contains a statement suggesting or implying that the goods have been recommended or approved by or on behalf of a government or government authority[128] other than a statement of their availability as a pharmaceutical benefit or statement authorised or required by a government or government authority;

[124] Meaning any person authorised by the Secretary of the DHFS to exercise power under the relevant provision, or a member of the Australian Federal Police,

[125] Prohibited representations are defined in Schedule 2 to the Regulations, which is used to give statutory force to requirements set out in the Therapeutic Goods Advertising Code (TGAC).

[126] Required representation are defined in Schedule 2 to the Regulations.

[127] Regulation 7 allows the Secretary of the DHFS to issue a notice to any person apparently responsible for publishing an advertisement which contains a representation that is false or misleading to prevent the person from publishing or causing to be published the advertisement. Regulation 9 allows the Secretary of the DHFS to publish a notice in the *Gazette* permitting a prohibited representation to be included in the label of therapeutic goods, or in information included in the package in which the therapeutic goods are contained, if the representation is necessary for the appropriate use of the goods.

[128] Including a foreign government or foreign government authority.

- Refers to goods in Schedules 3, 4 or 8 to the Poisons Standard;
- Refers to goods that are not registered or listed on the ARTG, unless the goods are exempt goods;
- Refers to goods that are exempt from the requirements of Part 3 of the *Therapeutic Goods Act* 1989 (requiring therapeutic goods for human use to be registered or listed on the ARTG); or goods that are specified in Schedule 5[129] to the Regulations.

The penalty for contravening the above restriction on advertising is the imposition of a fine of up to $1,000.

10.4.2 Therapeutic Goods Advertising Code and the Therapeutic Goods Advertising Code Council

The Therapeutic Goods Advertising Code (TGAC), originally developed by the Media Council of Australia (MCA), is administered by the Therapeutic Goods Advertising Code Council (TGACC) which comprises representatives of government, industry, advertisers, media professional organisations and consumer organisations. The TGAC applies only to the content of advertisements submitted for publication or broadcast by constituent members of the MCA and members of constituent and associate organizations of the MCA. Advertising controls do not apply to advertising directed at health professionals on the basis that health professionals are considered to be capable of making informed judgements about therapeutic claims.

The object of this Code is to ensure responsible advertising in promoting the sale of therapeutic goods which may be purchased by the public without prescription and for which therapeutic claims are made. The Code contains general principles and lists prohibitions relating to claims which make reference directly or by implication to a range of procedures or diagnoses. Substances are identified which have restrictions against them for advertising and there are specific restrictions relating to vitamins, claims, testimonials and samples.
The following clauses of the Code are adopted by reference into the Therapeutic Goods Regulations:

- Prohibited claims relating to goods for therapeutic use (clause 4);
- Prohibited claims in relation to analgesics (clause 5.3);
- Prohibited claims in relation to vitamins (clause 6.1); and
- Prohibited claims (clause 7).

The Code is more prescriptive than the Commonwealth Legislation or Regulations. It sets out the prohibited claims for therapeutic goods advertising directed to the public. It also requires certain statements to be included in advertisements in respect of particular types of therapeutic goods (e.g. “use only as directed” or “vitamin supplements can be of assistance only if the dietary vitamin intake is inadequate”).

The TGAC also sets out a complaints mechanism whereby any person or organization may complain about advertisements believed to be in breach of the TGAC by writing to the Advertising Standards Council (ASC).

10.4.3 Commonwealth Agricultural and Veterinary Chemical Code Act

The Agvet Code[130] establishes a national system for the registration of chemical products and approval of container labels. Section 14 of the Code requires that the National Registration Authority (NRA) for Agricultural and Veterinary Chemicals must satisfy itself of a number of matters before granting

[129] Schedule 5 identifies therapeutic goods that are exempt from the operation of Part 3 of the *Therapeutic Goods Act.*
[130] As explained in fn.3, this Code is a Schedule to the Commonwealth’s *Agricultural and Veterinary Chemicals Code Act* 1994, and is part of the law of Victoria by virtue of s.5 of the *Agricultural and Veterinary Chemicals (Victoria) Act* 1994.

registration of a chemical product, including that the proposed use would not cause an undue hazard in respect of:

- Occupational health and safety;
- Public health;
- Unintended environmental impacts;
- Trade and commerce.

Registered products are required to be supplied with labels which are also approved under the Code as containing adequate information regarding their safe and effective application (section 19(3)(g)). Under section 19 of the Agricultural and Veterinary Chemicals (Control of Use) Act it is an offence to use a chemical product other than in accordance with the information contained on these labels without a permit.

The NRA is responsible for a compliance program involving inspections of chemical products to ensure that they comply with the registered formulations, and that the labels on them are as approved.

10.4.4 Victorian Therapeutic Goods Act

The Commonwealth has no constitutional power to regulate unincorporated bodies within the therapeutic goods industry who only operate intrastate. In order to overcome this gap in the constitutional power of the Commonwealth, all States and Territories made a commitment to introduce complementary legislation to the Commonwealth Act. The *Therapeutic Goods Act* 1994 (Vic.), Victoria's complementary legislation, is largely a transcription of the Commonwealth Act.

The Act brings unincorporated Victorian manufacturers and suppliers of therapeutic goods, who only operate within Victoria, into the national scheme for the regulation of therapeutic goods which is administered by the TGA under the Commonwealth Therapeutic Goods Act. It is an offence to import, export, manufacture or distribute " therapeutic goods" which do not comply with relevant standards unless the consent of the Secretary to DHS has been obtained. Standards relate to the quality, quantity, manufacturing, packaging and labelling of " therapeutic goods".

The Act regulates three areas which are not covered by the Commonwealth Act:

- The supply of therapeutic goods via vending machines;
- The hawking of therapeutic goods; and
- The licensing of wholesalers of therapeutic goods.

10.4.5 Drugs, Poisons and Controlled Substances Act and Regulations

The *Drugs, Poisons and Controlled Substances Act* 1981 and the *Drugs, Poisons and Controlled Substances Regulations* 1995 have been developed to control substances which may cause injury, ill-health, or death to humans or (through veterinary preparations) animals, by reason of their toxic, corrosive, irritant, strongly sensitising or flammable nature.

The controls provided in the Drugs, Poisons and Controlled Substances legislation flow from the Schedule in which a substance is included. Scheduling is conducted at the national level by the National Drugs and Poisons Scheduling Committee (NDPSC) under the auspices of Australian Health Ministers Advisory Council (AHMAC). NDPSC is composed of representatives from the various States and Territories, New Zealand, the Commonwealth, as well as representatives from industry and the pharmacy profession and relevant experts. The Commonwealth provides the secretariat. The Schedules and recommendations for the controls that should apply to them are published in a document entitled the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). In Victoria, the parts of the SUSDP which are suitable for adoption by reference are adopted by means of a Poisons Code. Other parts of the SUSDP are implemented by regulation.

The Schedules fall into two broad categories - those that relate to medicines (Schedules 2, 3, 4 and 8) and those that relate to poisons (Schedules 5, 6 and 7). In addition, Schedule 9 covers substances that are prohibited. Division into schedules in this way enables a different set of controls to apply to each. The legislation is the means of implementing the degree of control implied by the schedules.

Legislative controls include limiting possession and activity to persons who have some general or specific authorisation (licence, permit, warrant, authorisation) under the Act. Controls cover such activities as manufacture, supply, use (including administration), storage, purpose of possession, labelling and packaging, personnel and security.

Finally, the Drugs, Poisons and Controlled Substances Act gives authorised officers extensive powers to investigate possible contravention of the Act, and allows for the seizure of any poison or controlled substance whose sale or use is prohibited (section 42).

10.4.6 Agricultural and Veterinary Chemicals (Control of Use) Act and Regulations

The *Agricultural and Veterinary Chemicals (Control of Use) Act* 1992 (Vic.) includes among its purposes protection of the health of the general public, the users of chemical products and the environment. In furtherance of these objectives, the Act creates a number of offences including:

- Use of a chemical product that is not registered under the Agricultural and Veterinary Chemicals Code ("the Agvet Code") (section 6).[131]
- Use of a chemical product other than in accordance with its labelling instructions (section 19).
- Sale or use of a chemical product in contravention of an Order made by the Governor in Council (sections 25 and 25A).[132]

Finally, the Agricultural Chemicals (Control of Use) Act gives authorised officers extensive powers to investigate possible misuse of chemical products, and allows for the seizure and destruction of chemical products whose sale or use is prohibited (Part 8).

The *Agricultural Chemicals (Control of Use) Regulations* 1996 also contain a number of provisions designed to protect people from the dangers of chemical products, including: business, consumers and the environment from the dangers of pesticides. These include:

- A prohibition on the possession of certain agricultural chemical products (regulation 5);
- Labelling requirements in respect of veterinary chemical products (regulation 12);

10.4.7 Professional practice legislation

Standards that health professionals are expected to meet are managed through the State legislation regulating professional practice (e.g. medical practitioner registration legislation, and pharmacy acts, veterinarian registration legislation etc.) and the relevant professional practice boards established in each jurisdiction. In relation to "drugs, articles and substances" health professionals exercise their skills and knowledge to redress consumers' information deficit thereby enabling the consumer to use the products safely and effectively.

10.4.8 Food Act and standards

The *Food Act* 1984, with it associated standards also plays a role in the framework of public health protection in this area. For example, the amount of a particular substance, such as selenium that can be included in a food product.

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[131] This Code appears as a Schedule to the Commonwealth's *Agricultural and Veterinary Chemicals Code Act* 1994. It is adopted in Victoria by s.5 of the *Agricultural and Veterinary Chemicals (Victoria) Act* 1994.

[132] The only Order made under s.25A appears in the *Victoria Government Gazette* No. S 86, dated 31 July 1997; the most recent Order made under s.25 appears in the *Victorian Government Gazette* No.41, dated 12 October 2000.

10.4.9 Consumer protection legislation and civil litigation

Trade practices legislation, fair trading legislation or the common law may be used when consumers suffer harm as a result of harmful "drugs, substances and articles".

The *Trade Practices Act* 1974 (Cth) and the *Fair Trading* Act 1985 (Vic.) provide for:

- Prosecutions to be instituted in respect of false representations or misleading conduct in relation to the supply of goods or services; and
- Proceedings to be taken in relation to the supply of defective products in contravention of those Acts.

The common law of negligence allows civil proceedings to be instituted to compensate consumers who suffer damage as a result of a breach of a duty of care by manufacturers or suppliers of "drugs, substances and articles".

Court procedures allow class actions to be instituted against manufacturers or suppliers of defective "drugs, substances and articles" on behalf of all persons who suffered injury, loss or damage as a result of a defective product.

10.5 Objectives of the Legislation

There are no stated objectives in the Act. However it can be inferred that the objective of the legislation is to protect public health (see section 2) by ensuring that "drugs, substances and articles" are:

- High quality (in compliance with appropriate international and national standards and truth in labelling);
- Safe to consumers and their unborn children; and
- Effective in performing the function they are intended for.

10.6 The Rationale for Legislative Intervention

Medicines, household pesticides and other household chemicals have made an immeasurable difference to our lives. While these substances deliver a number of benefits they can also cause harm. Market forces alone do not offer an adequate level of public health and safety protection in relation to "drugs, substance and articles". The legislative controls are intended to minimise the risk of these harms occurring, while enhancing the benefits to be gained.

The public health risk of misuse of drugs, substances and articles can be demonstrated in three articles[133,134,135] published by the Victorian Injury Surveillance Unit (VISU) group at Monash University Accident Research Unit, quoted in the recent National Competition Policy review of drugs, poisons and controlled substances. [136] As stated in that review, the articles report:

> *…that there were over 600 admissions of childhood poisonings per year in Victoria where it was the second major cause of hospital admissions in the age group, after falls. Of the emergency department attendances, 71 per cent were due to medications and 45 per cent of these cases were admitted. Deaths were very rare. Chemical poisoning of children accounted for 26 per cent of poisoning admissions and 29 per cent of presentations. Nearly 90 per cent occurred in the home, mostly by gaining access to things in cupboards, eg. mothballs, rat bait, or dishwasher detergent [alkaline salts] from the dishwasher (VISU data).*

[133] Routley V, Ozanne-Smith J, Ashby K. Poisonings in early childhood. *Hazard,* 1996; 27:1–13.
[134] Ashby K, Routley V. Childhood domestic chemical and plant poisonings. *Hazard,* 1996;28:1–7.
[135] Routley V, Ashby K, Lough J. Adult poisoning overview - Victoria. *Hazard,* 1999; 39:1–17.
[136] Review of Drugs, Poisons and Controlled Substances Legislation, Draft Final Report, September 2000.

Restrictions on the conduct of business with respect to manufacturing, handling and sale of drugs, substances and articles aim to ensuring the quality, safety and efficacy of these products used by community.

Packaging restrictions are intended to ensure safe and effective use of drug, articles or substances in the community by:

- Reducing accidental poisoning by medicines and poisons from packaging which falsely describes contents; and
- Reducing accidental poisoning by medicines and poisons, where packages have been tampered with.

The rationale for restricting advertising of drugs, medicines and appliances relate to concerns that consumers – and particularly those in a very vulnerable position because of serious health conditions – would not be in a position to assess the sort of claims that might be expected to appear in advertisements for therapeutic drugs or substances.

Labelling controls mandate the information for inclusion on the label of a package of any drug. Labelling provides the consumer with information to assist in its safe use, eg. name of the drug and quantity, etc, in the package.

The Act specifies that every analysis made under the Act must be made by an approved analyst. The Secretary may approve as analysts persons possessing competent skills and experience.
The assumption that underlies these controls on “drugs, articles and substances” is that it is difficult for consumers to gain independently an adequate knowledge and understanding of:

- The risks associated with a particular substances;
- The way in which products containing the substances need to be used safely and to achieve optimal health benefits; and
- Poisonous substances that may be very dangerous if they are used inappropriately.

Use of many substances covered by drugs, substances and articles legislation by consumers without this knowledge could have serious and, in some cases, fatal consequences.

With the increase in the range of “drugs, substances and articles” used by the community and the expansion of their use, a range of legislative controls have been enacted in the last decade or more to address the market failure in relation to these substances. The provisions in the Health Act appear to have been superseded by the introduction of specific legislation relating to therapeutic goods and more general fair trading and consumer protection legislation and therefore may be suitable for repeal.

10.7 Costs and Benefits of the Restrictions

The Health Act Review Discussion Paper sought comments on the costs and benefits of the restrictions, whether the costs outweigh the benefits and whether there are any less restrictive means of achieving the objective of the registration. The majority of submissions to the Discussion Paper stated that it would be appropriate to repeal Part 14 of the Health Act as other Commonwealth and State legislation adequately cover regulation of “drugs, substances and articles”.

10.7.1 Costs

The restrictions on business conduct through controls on manufacturing, handling, packaging, and labelling impose costs on manufacturers, distributors and suppliers in the form of compliance costs in adhering to standards and requirements in respect of “drugs, substance and articles”. The additional costs to industry may, especially for some smaller companies, be such as to prevent market entry where the costs of compliance make it uneconomic for a firm to operate in that market. However, many of these costs may be minimal, eg. labelling is a one-off cost. Furthermore, the costs involved in

compliance with provisions of the Health Act in relation to "drugs, substances and articles" are minimal in comparison to costs imposed through the broader and more prescriptive controls on "drugs, substances and articles" under other relevant Commonwealth and State legislation.

The recent National Competition Policy Review of drugs, poisons and controlled substances legislation[137] noted that the major costs to industry appear to be associated with the complexity and confusion of the raft of legislative controls on medicines, household chemicals and agricultural and veterinary products. Industry needs to identify, and then comply with, the various requirements imposed by a number of different legislative instruments at the State and Territory and Commonwealth levels. This adds to industry costs and ultimately, to the cost to consumers and government (for subsidised medicines).

The requirements may impose a cost on consumers as a result of business compliance costs with manufacturing, handling, packaging, and labeling requirements being reflected in the ultimate price of products purchased by consumers.

The requirement that analysts be approved potentially imposes costs on analysts in relation to the making of applications to DHS establishing that they are appropriately skilled and experienced to be approved. For DHS the potential administrative costs include processing of applications for approval of analysts to ensure that applicants are appropriately skilled and experienced. However, the superceding of the provisions under the Health Act by Commonwealth and State statutory regulation of "therapeutic goods" (see sections 10.4 and 10.8) has meant that no analysts have been approved by DHS since the introduction and operation of Therapeutic Goods Acts.

10.7.2 Benefits

The restrictions provide significant unquantifiable benefits to public health, to consumers, to industry, to the Australian economy and the public purse. The benefits of the restrictions include the following:

- The reduction of the risks to public health by the reduction of fatalities, illness, injury, pain, suffering and anxiety associated with "drugs, substances and articles" use. The adverse effects prevented relate not only to the users of the goods but to their unborn children. Relatives and friends of the users of the goods also indirectly benefit from reduced bereavement and anxiety;
- The reduction of health expenditure as the need for medical interventions and the length of medical interventions are reduced;
- The reduction of reliance on the welfare system because of a higher standard of user wellbeing;
- The reduction of lost productivity in the Australian economy because of a higher standard of public health;
- The adherence of Australian industry to high standards and international best practice in relation to "drugs, substances and articles";
- Increased public confidence in the quality and safety of and consequently increased use of "drugs, substances and articles";
- The good reputation of the Australian "drugs, substances and articles" industry internationally which maintains and strengthens export markets for Australian "drugs, substances and articles"; and
- The reduction of fraudulent and opportunistic behaviour by backyard operators, who have no commitment to the long term benefit of the industry and who are able to play on the vulnerability of users of "drugs, substances and articles" and the enormous information asymmetries between producers and users of "drugs, substances and articles".

[137] ibid, p.xi

An estimate of the benefits to the community in the form of prevention of deaths from drugs, poisons or articles can be gained from the report by the National Competition Policy review of drugs, poisons and controlled substances[138], which stated that:

- The harm that can result from poisoning and medicinal misadventure is estimated at $600 million annually[139];
- It is estimated that as many as 40 000 hospital admissions annually related to medicinal misadventures may be avoidable[140] ; and
- The National Drug Strategy Household Survey[141] identified that 4% of those surveyed had recently used medicines for non-medical purposes.

The approval of analysts is an important element in ensuring enforcement of the Act. For example, a certificate by an approved analyst is more likely to be taken as conclusive evidence of the matters stated in the certificate in relation to proceedings for offences under the Act. For business the approval of independent persons to conduct analyses offers a measure of procedural fairness in the administration of the Act by allowing for independent testing to be conducted. For consumers, testing procedures help to ensure that the objectives of the Act to protect public health and safety can be achieved right through to legal proceedings for breaches of the Act.

10.7.2 Analysis of costs of restrictions against benefits

The Federal Government and the TGA have both acknowledged the significant benefits to industry, consumers, the Australian economy and the public purse of regulation therapeutic goods.

The Federal Government in a document published in April 1997 titled *Medicinal Products: Standards, Safety & Security- A Government Statement On The Regulation Of Medicinal Products* stated that:

> *A regulatory system which ensures that medicinal products are of a high quality bestows significant advantages on industry. Australia's regulatory system has helped industry to foster the well founded public confidence in products approved for sale in this country. In addition, Australia is highly regarded by importing countries as a source of quality medicinal products.*

The TGA in its *Corporate Plan 1997/1998 to 1999/2000* stated that:

> *Any regulatory system which ensures standards and safety has far reaching consequences. It means increased industry and community involvement, greater choice, more effective self medication and fewer adverse reactions. For the health system it means freeing up resources through shorter hospital stays and fewer visits to the doctor. The tangible results include improved health, fewer work absences and increased productivity.*

The removal of all controls on "drugs, substance and articles" will not provide a net benefit for consumers, as these controls are a key mechanism for overcoming the information asymmetry to enable consumers to select and use "drugs, substances and articles" safely and effectively. Restrictions on the market in relation to manufacturing, handling, labeling and advertising helps to ensure the availability of high quality and safe products. The prevention of harm from "drugs, substance and articles" can lead to substantial savings in medical, hospital and social costs.

Whilst the removal of all controls on "drugs, articles and substances" is not in the public interest, the provisions in the Health Act appear to have been superseded by the introduction of specific legislation

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[138] ibid, p.26
[139] Moller J. *Cost of Injury in Australi*a, National Injury Surveillance Unit, Flinders, University, South Australia, 1998.
[140] Roughead EE. The nature and extent of drug related hospitalisations in Australia. *Journal of Quality in Clinical Practice*, 1999;19:19–22.
[141] Australian Bureau of Statistics, *1995 National Health Survey: Summary of results Australi*a, Catalogue No. 4364.0, ABS, Canberra, 1997

relating to therapeutic goods and more general fair trading and consumer protection legislation and therefore may be suitable for repeal (see section 10.8.2).

The repeal of Part 14 of the Health Act was supported by the majority of submissions, including the submission received by the Australian Pharmaceutical manufacturers Association, which stated that:

> *APMA considers that it would be appropriate to repeal Part 14 of the Victorian Health Act as the Therapeutic Goods (Victoria) Act adequately covers matters relating to Therapeutic Goods. Further, rationalising the legislation relating to Therapeutic goods in this way would facilitate a uniform national approach to the regulation of therapeutic goods under the Commonwealth Therapeutic Goods Act 1989 and complementary State therapeutic goods legislation, such as the Therapeutic Goods (Victoria) Act 1994.*

Two submissions recommended maintaining the controls under the Health Act, those of the Society of Hospital Pharmacists of Australia and Victorian Health Care Association, as they were of the view that controls were required to address areas which fall outside the Pharmacists Act, Drugs, Poisons and Controlled Substances Act and Complementary Medicines Regulations. The gaps identified in these submissions however, are adequately covered by specific legislation relating to therapeutic goods, agricultural and veterinary chemicals and more general fair trading and consumer protection legislation. For example, the submissions proposed that protection of the public from inappropriately labeled preparations be maintained in the Health Act to protect the public from labeling of drugs and preparations by persons who are not registered pharmacists. Product labelling is covered by requirements in State and Territory drugs, poisons and controlled substances legislation, Commonwealth legislation (the *Therapeutic Goods Act,1989* and the *Agricultural and Veterinary Chemical Code Act, 1994* and associated instruments). The requirements for dispensing labels are covered by State and Territory drugs, poisons and controlled substances legislation. Many of the product labeling requirements are set out in the *SUSDP* and these are adopted in varying degrees by States, Territories and the Commonwealth.

Furthermore, controls under other Commonwealth and State legislation may be more effective and appropriate as evidenced by submissions received from the Society of Hospital Pharmacists of Australia and Victorian Health care Association, which stated that:

> *While it is agreed that there are certain lawful formularies for preparation of medicines, as presented in section 270(1), there are times when reference to another formulary can provide more appropriate information. Publications such as the Royal Children's Hospital Pharmocopoeia provide dosages and recommendations for drugs in the paediatric setting, and this is a recognized authority on paediatric dosing in Australia.*

10.8 Alternatives to these Restrictions

10.8.1 No Regulation

Total deregulation of the "drugs, substances and articles" market would give rise to too many points of possible failure in the health system for the public interest to be served. The precise probabilities of harm of arising out of a deregulated market are often unclear, but there are so many hazards that the overall likelihood of harm is high.

10.8.2 Reliance upon the existing law

As can be seen from earlier discussion (see section 10.4), the "drugs, substances and articles" provisions in the Health Act are not the only laws which operate to achieve the objectives of protecting public health by ensuring that "drugs, substances and articles" are:

- High quality (in compliance with appropriate international and national standards and truth in labelling);
- Safe to consumers and their unborn children; and
- Effective in performing the function they are intended for.

Other laws which operate in this area include:

- Commonwealth Therapeutic Goods Act and Regulations, which regulate the supply of therapeutic goods in Australia through a number of controls on the importation, export, manufacture and supply of therapeutic goods, including registration, specification of quality or quantity of therapeutic goods to be supplied, standards for manufacture, labelling and advertising;
- Commonwealth Therapeutic Goods Advertising Code which ensures responsible advertising in promoting the sale of therapeutic goods which may be purchased may be purchased by the public without prescription and for which therapeutic claims are made;
- Commonwealth Agricultural and Veterinary Chemical Code Act which established the Agvet Code, a national system for registration of chemical products and approval of container labels;
- Victorian Therapeutic Goods Act which brings unincorporated Victorian manufacturers and suppliers into the national scheme for the regulation of therapeutic goods;
- Victorian Drugs, Poisons and Controlled Substances Act and Regulations which regulate the supply of drugs (human and animal medicines) and poisons (including household chemicals) through a number of controls including limiting possession and activity to persons who have some general of specific authorization (licence, permit, warrant, authorization) and activities, eg. manufacture, supply, use (including administration), storage, labeling and packaging;
- Victorian Agricultural and Veterinary Chemicals (Control of Use) Act and Regulations, which regulates the use and labeling of chemical products;
- General laws relating to consumer protection and duty of care, which also deter unsafe practice by giving persons affected by such practice the right to recover their loss.

These controls are complementary to each other (in parts overlapping) but overall provide a comprehensive and sufficient means for achieving the objectives of the restrictions under the Health Act in relation to “drugs, substances and articles”.

An analysis of how those other laws would by themselves offer sufficient protection against the risks inherent in the use of “drugs, substances and articles” which the restrictions seek to address follows. This should not be taken as a comprehensive analysis of the areas of other overlapping legislation in relation to these restrictions, but rather provides examples of where other legislative controls are in place.

Mixing and sale of drugs (sections 230 and 231)

Other legislation concerned with public health and safety in the use of drugs includes the Commonwealth’s *Therapeutic Goods Act* 1989, the *Agricultural and Veterinary Chemical Code Act* 1994*,* both of which control supply of products by a registration process. Therapeutic goods legislation places additional controls on the manufacture of drugs though imposing a licensing system. There are also series of controls provided by drugs, poisons and controlled substances legislation on the administration and manufacture of medicines, including a variety of licensing requirements: licences for individuals; licences for manufacturers of therapeutic goods; retail licences; and wholesale licences.

The objective of the licensing requirements is generally to ensure that only those who have demonstrated the necessary competencies in dealing with drugs, who meet other requirements such as secure storage, and who supply these substances in accordance with relevant controls are given a legal right to do so, for a specified range of medicines. For manufacturing licences, the objective is to ensure that the quality of the product is such that it will not be contaminated or sub-standard thereby making it unsafe or ineffective.

General laws relating to consumer protection and duty of care also operate in this area to reduce the incidence of harmful events.

Packaging (section 238)

For medicines for human use, packaging controls are imposed under the *Therapeutic Goods Act* 1989*.* Further controls relating to the packaging of household chemicals and agricultural and veterinary products are contained in drugs and poisons legislation.

Drugs and poisons legislation places additional controls at the wholesale level that seek to ensure that the quality of the products is maintained during storage and handling.

Sale and labelling of disinfectants, germicides, antiseptics, preservatives or household insecticides (section 242)

All medicinal and Agvet products are regulated under Commonwealth legislation which requires the products to be assessed for safety. This is generally based on the toxicological assessment of the substance(s) in the products. There is no comparable national registration scheme for household chemicals, although all new chemicals must be assessed for safety under the National Industrial Chemicals Notification Assessment Scheme (NICNAS) before being introduced in a product marketed in Australia.

Commonwealth and State therapeutic goods legislation imposes restrictions related to the end-use safety, quality and efficacy of medicinal products (human and animal) and Agvet chemicals permitted to be supplied in Australia.

State drugs, poisons and controlled substances legislation provides restrictions intended to prevent, or reduce unsafe or harmful use of medicines and Agvet chemicals throughout the supply chain and use in the community, and with all aspects of the safety of household poisons.

Drugs, poisons and controlled substances legislation also includes labeling requirements in the case of Schedules 5 and 6 poisons, household products, veterinary and agricultural chemicals.

Manufacture of items such as toys which contain substances that when present in such quantities may be potentially harmful (sections 245 and 246)

Poisons that pose a potential risk to public health (e.g. household and industrial chemicals, cosmetics, paints etc) are 'scheduled' by the NDPSC. The intrinsic hazard (toxicity), purpose of use, potential for abuse, safety in use and the need for the substance are all considered when substances are classified into schedules. The scheduling of substances, and the corresponding controls, are consolidated by the inclusion of the scheduling decision of the NDPSC in the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP). The processes of the NDPSC were recently codified in amendments to the *Therapeutic Goods Act* 1989, proclaimed in April 1999.

As well as general controls, for example, on labelling, packaging and advertising, controls that are specific to a substance in a particular presentation and quantity are set out in the appendices of the SUSDP.

This regulatory system as outlined provides sufficient redress in relation to the information asymmetry between consumers and industry in the market for toys, textiles, etc that may contain quantities of substances that would be expected to be harmful.

Advertising (section 249)

Specific advertising controls are included in drugs, poisons and controlled substances legislation for Schedule 4 and Schedule 8 as well as many Schedule 3 substances. The ban on advertising Schedule 4 products includes those used for veterinary purposes.

Similar controls in advertising medicines in these Schedules are contained in the Commonwealth Therapeutic Goods Regulations. Regulation 6(1) states:

> *A person must not publish an advertisement about goods for therapeutic use...*
> *(d) that refers to goods included in Schedule 3, 4 or 8 to the Poisons Standard, except goods mentioned in Appendix H of the Standard.*

Apart from the above regulation, there are also disease-based controls on advertising, including controls which affect, inter alia, Schedule 4 products, under the Therapeutic Goods Advertising Code (TGAC), which is adopted, in part, by the Therapeutic Goods Regulations. The TGAC restricts the advertising of a range of serious medical conditions whether or not a medicine is approved for that condition. The *Therapeutic Goods Act* 1989 also prohibits advertising of therapeutic goods which are not included in the ARTG for that purpose.

Generic measures such as Trade Practices legislation also attempts to ensure that the information is balanced and truthful.

Labelling (section 271)

Product labelling is covered by requirements in State and Territory drugs, poisons and controlled substances legislation, Commonwealth legislation (the *Therapeutic Goods Act* 1989 and the *Agricultural and Veterinary Chemical Code Act* 1994 and associated instruments). The requirements for dispensing labels are covered by State and Territory drugs, poisons and controlled substances legislation. Many of the product labelling requirements are set out in the *SUSDP* and these are adopted in varying degrees by State and Commonwealth legislation.

Labelling controls mandate the information for inclusion on the label of the primary pack and sometimes other labels. The labelling provisions in these various legislative instruments adequately address information asymmetries by providing the consumer with information to assist in the safe use of “drugs, substances and articles” and provides handlers, professional workers and consumers with guidance for compliance with the appropriate controls, such as on access and storage.

Formularies (section 270A)

Prescribed formularies are no longer relevant as all therapeutic goods are required to be registered by the TGA.

Drug analysts (section 274)

Therapeutic goods legislation, agricultural and veterinary chemicals legislation and drugs, poisons and controlled substances legislation all provide extensive powers to authorized officers to investigate, seize and destroy substances whose sale or use is prohibited.

10.9 Conclusion

Controls on “drugs, substance and articles” provide a net benefit for consumers, as these controls are a key mechanism for overcoming the information asymmetry to enable consumers to select and use “drugs, substances and articles” safely and effectively. Restrictions on the market in relation to manufacturing, handling, labeling and advertising helps to ensure the availability of high quality and safe products. The prevention of harm from “drugs, substance and articles” can lead to substantial savings in medical, hospital and social costs.

Restrictive provisions related to “drugs, articles and substances” in the Health Act are adequately covered and the objectives able to be met by specific legislation relating to therapeutic goods, agricultural and veterinary chemicals and more general fair trading and consumer protection legislation and are therefore suitable for repeal.

It is worth noting that the National Competition Policy Review on drugs, poisons and controlled substances[142] concluded that there would be considerable savings to industry, government and consumers if there were a much more consistent national/uniform approach taken to the regulation of drugs, poisons and controlled substances in Australia. Based on its analysis, the Review determined that there are sound reasons on public interest grounds for Australia to have a comprehensive system of legislative controls that regulates drugs, poisons and controlled substances - notwithstanding the fact that many of these controls restrict competition – but that the efficiency of the regulatory system of controls and their administration across a significant number of areas should be improved by ensuring that the interface between the various pieces of legislation is rational and avoids duplication and overlap.

In this context, the broader review of the Health Act should address whether the remaining provisions under Part 14 of the Health Act are suitable for repeal. These provisions appear to have been superseded by the introduction of specific legislation relating to therapeutic goods and more general fair trading and consumer protection legislation.

10.10 Recommendation

10.10.1 That sections 230, 231, 238, 242, 245, 246, 270A, 271 and 274 of the Health Act be repealed.

[142] ibid, p.111.

11 Part 15 - Meat Supervision

11.1 Background

The provisions relating to meat supervision have largely been superseded by specific food legislation and the *Meat Industry Act* 1993 (particularly the amendments which were made to that Act by the *Food (Amendment) Act* 1997).

There are now only eight sections relating to meat remaining in the *Health Act.* These restrict slaughter and sale of certain meat and storage of certain meat from premises where food is sold or prepared for human consumption. The *Meat Industry Act* 1993 and the *Food Act* 1984 regulate food that is to be sold for human consumption. Some of these provisions in the *Health Act* are therefore now clearly obsolete.

Section 305 of the Act prohibits the slaughter of any animal or dressing of any carcass except at a meat processing facility licensed under the *Meat Industry Act* 1993.

Section 309 of the Act prohibits the sale of a prohibited animal or any food or article containing the flesh of a prohibited animal and the preparation of the flesh of a prohibited animal or preparation or manufacture of any food or article containing (whether in whole of in part) the flesh of a prohibited animal.

These requirements are barriers to entry into, and restrict conduct within, the market for these services, and are therefore restrictions on competition.

11.2 Description of the Market

The Meat Industry is comprised of the beef, sheep, pork and poultry industries each of which have production and processing sectors. Meat and Livestock Australia (MLA), the peak industry representative body for Australian-based companies involved with the processing and marketing of red meat, has summarised the characteristics of the Australian Beef industry[143]. Estimates put the industry's gross value at $4-5 billion. More than 17% of Australian farm production value, and 14% of rural export earnings are directly attributable to the beef industry. The Australian industry remains largely based on grassfed cattle, although feedlots are becoming increasingly important. There are approximately 70,000 farms involved in the production of livestock; around 1,000 feedlots account for 16% of total beef production. The beef processing sector is comprised of approximately 215 licensed meat processing companies, processing 2 million tonnes of beef each year which is retailed by 7,600 butchers and supermarkets (35% of total market for beef). The 65% of Australia's beef production not consumed domestically is exported to over 100 countries, earning $3 billion annually. Beef for the export market is processed by an accredited export processor and exported by a licensed meat exporter.

Meat and Livestock Australia (MLA) has summarised the characteristics of the Australian Sheep industry[144]. Estimates put the Australian sheepmeat industry's gross value at $2 billion. This represents about 4% of the value of Australian farm production and farm exports. The domestic market is the major market for all sheepmeat, taking an estimated 209,000 tonnes (cw) of lamb and 108,000 tonnes of mutton in 1998/99. Australia exports only 35% of all sheepmeat produced. Australia sends sheepmeat to over 70 countries, earning around $600 million each year, and accounting for 42% of total world sheepmeat exports. Like beef, sheepmeat for the export market is processed by an AUS-MEAT accredited export processor and exported by a AQIS licensed meat exporter.

[143] MLA Market Information Services website. www.mla.com.au/mis/industry/beefoverview.cfm
[144] MLA Market Information Services website. www.mla.com.au/mis/industry/sheepoverview.cfm

DNRE has reported[145] that Victoria accounts for approximately 25 per cent of the nation's beef, veal, sheep meat, pig meat and poultry production and employing more people than any other industry in the State's food processing sector. In 1996-97, Victoria accounted for 21 per cent of national beef and veal production and 29 per cent of national sheep meat production. Improved pastures provide the feed-base for 90% of beef cattle and sheep on 16,000 farms, however in recent years beef feedlots have expanded in Victoria. The State's beef and sheep meat industries have gross values of production of $664 million and $347 million respectively. The gross value of pig meat (pork, bacon and smallgoods) production in Victoria is about $185 million. In 1995-96, Victoria's share of national pig meat production was 27 per cent. Although historically Australia has only exported about three per cent of its pig meat, exports increased by 60 per cent in 1997. Australia's largest pork exporter is located in Victoria. In 1996-97, the gross value of Victoria's chicken meat industry was $250 million, with the egg industry contributing a further $90 million. Victoria contributes about 23 per cent of the total gross value of Australian poultry production. Exports of chicken meat and egg products are low and under increasing pressure from imports.

Stakeholders in the meat industry include:

- Meat industry production and processing sectors, suppliers and wholesalers;
- Employees of those businesses who are required to slaughter and process meat as part of their work;
- Importers and exporters;
- Consumers who purchase meat for consumption, including households and businesses;
- Members of the public who live or work close to areas where animals are slaughtered and poultry and game processed;
- Government regulatory authorities, in particular DHS and DNRE;
- The community generally which may have to bear the costs to the public health system if prohibited meat is sold and consumed.

11.3 Market failure

The restrictions on slaughtering of any animal, and prohibition on sale or preparation of the flesh of prohibited animals are intended to address two possibilities for market failure in respect of the meat industry. The first of these are the costs which the slaughter of animals and sale of meat unfit for human consumption may impose on persons other than the meat business and the consumer who entered into the contract for the purchase of meat product (negative externalities). These persons might be:

- Businesses supplying safe food who may be adversely affected by other businesses supplying contaminated or sub-standard food, due to the reluctance or inability of (domestic and international) consumers to distinguish between providers of similar food items;
- Meat workers who are called upon by their employer to slaughter and process meat from contaminated animals;
- Members of the community who may be called upon to pay for the direct cost to the public health budget as a result of unsafe meat being made available for human consumption;
- Indirect costs to the Australian economy in lost production; and
- Intangible costs of pain, suffering, lost years of life, anxiety and bereavement.

The second potential source of market failure in the meat industry is the knowledge disparity which tends to exist between the provider of meat products and the consumer of the services (information asymmetries). Consumers have insufficient knowledge, skill, time, opportunity, or financial resources to verify the standard of an important part of the food which they purchase and use food which, potentially at least, might pose a serious threat to health.

[145] DNRE website, www.nre.vic.gov.au

11.4 Effects of other Legislation and the Common Law on these Market Failures

11.4.1 Meat Industry Act

The *Meat Industry Act* 1993 sets standards for meat production and transport, and establishes the Victorian Meat Authority. The Meat Industry Act sets up a licensing and inspection system and a mechanism for adopting and implementing quality assurance programs to help to ensure standards are maintained. In furtherance of these purposes, the Act creates a number of offences including:

- Acceptance for delivery at a meat processing facility a consumable animal that is suffering from a disease or condition or is otherwise unfit for consumption (section 32);
- Sale of meat for human consumption that is not from a consumable animal (section 35 (1));
- Sale of meat in contravention of an Order made by the Governor in Council (section 35(5))[146];
- Slaughter or sale for human consumption meat from a horse, donkey (section 35(6)) or other prescribed meat (section 35 (7));
- Sale or disposal of a carcass for human consumption from a knackery or boiling down works (section 36);
- Sale from a butcher shop of any meat that is unfit for human consumption, regardless of whether the meat is intended for human consumption (section 37A);
- Slaughter or dressing the carcass of a consumable animal for human consumption or processing game or poultry at a place that is not a meat processing facility licensed for that purpose (section 38);
- Operation of a meat processing facility without a licence (section 40).

The offences listed above carry a first offence penalty of $5,000 and second offence penalty of $10,000 or 12 months imprisonment or both.

The Meat Industry Act gives authorised officers extensive powers to investigate whether provisions of the Act, Regulations, conditions of a licence or quality assurance program are being complied with, inspect any place not occupied as a place of residence where meat is thought to be processed or sold; search any place believed to be used as a place of slaughter of animals; and allows for the seizure, treatment or disposal of any meat (Part 7).

The Meat Industry Act does not apply to the following:

- Meat from a consumable animal in a dwelling;
- Slaughter of an animal on a farm or poultry on a property if it is slaughtered for consumption on that farm or property, not slaughtered for sale or use in the preparation of food for sale and is not removed from that farm or property;
- Preparation of certain animals for human consumption where the meat is not intended for sale.

11.4.2 Food Act and standards

The *Food Act* 1984 sets out to among other things, make provisions for securing the wholesomeness and purity of food and fix standards for food. [147] In furtherance of these purposes, the Act:

- Prohibits the sale, preparation and packing of food that is adulterated or not fit for human consumption (section 8);
- Protects purchasers of food (section 9);
- Prohibits the sale of food not complying with prescribed food standards (section 10);
- Prohibits false labelling (section 11) and false advertising (section 12); and

[146] There are currently no orders made section 35 (5).
[147] see Long Title of the *Food Act* 1984 (Vic).

- Requires the registration of food premises/food vehicles with relevant municipalities (section 36).

Penalties under the Food Act are sizeable. For example, a person convicted of a breach of section 8: 'Prohibition on sale, preparation for sale or packing of certain food', faces a maximum penalty of $10,000 for a first offence, $20,000 for a subsequent offence, or imprisonment for six months, or both.

The surveillance and monitoring of food production processes and premises is the responsibility of the 78 local government authorities in Victoria. Local councils have been given extensive legislative responsibilities and powers in regard to monitoring and controlling the hygiene and safety standards of food preparation in their individual municipality. Under the Food Act, local councils are responsible for:

- Registration and inspection of all food premises and food vehicles;
- Procuring food samples for analysis and investigating non-compliance with standards;
- Monitoring commercial food preparation hygiene, and safety standards, and taking preventive and remedial action in the event of non-compliance with the legislation.

A range of strategies are open to councils and their authorised officers, including food handler training and education, accreditation and incentive programs, microbiological assay of sanitation practices, premises and process design improvements, seizure of food, and if necessary, prosecution.

In addition, supermarkets are not required to be licensed under the Meat Industry Act. The responsibility for the maintenance of standards at these premises continue to be dealt with under the *Food Act* 1984. Given the potential overlap in jurisdictional activities, DHS and VMA have signed a Memorandum of Understanding providing that at any point in time clarification will be sought by these agencies as to the agency authorised to take action in any particular case.

The ANZFA Food Standards Code Standard C1 defines meat, game meat and associated products, and provides standards for the composition, labelling and, in some instances, microbiological specifications for such foods. This Standard specifically relates to mammalian and avian meat. Meat pies and meat and vegetable pies are regulated in Standard C4. The Food Standards Code is adopted by reference into the *Food Act* 1984.

11.4.3 Occupational Health and Safety Act

Provisions of the *Occupational Health and Safety Act* 1995 (Vic.) which are of particular relevance in protecting meat workers and consumers from the dangers of unsafe practice are as follows:

- Employers shall make arrangements for ensuring so far as is practicable safety and absence of risks to health in connexion with the use, handling, storage and transport of substances (section 21(2)(b));
- Employers shall provide such information, instruction, training and supervision to employees as are necessary to enable the employees to perform their work in a manner that is safe and without risks to health (section 21(2)(e));
- Employers and self-employed persons shall ensure so far as is practicable that persons (other than the employees of the employer or self-employed person) are not exposed to risks to their health or safety arising from the conduct of the undertaking of the employer or self-employed person (section 22);
- Employees shall, while at work, take reasonable care for their own health and safety and that of anyone else who may be affected by their acts or omissions at the workplace (section 25).

11.4.4 Nuisance provisions in the Health Act

The provisions in the *Health Act* 1958 which allow municipal councils to investigate and deal with nuisances which are occurring in their districts could be used to respond to the dangers and nuisance to neighbours caused by animals being slaughtered on premises which are not licensed for that purpose and dangers caused by preparation of unsafe meat for human consumption.

11.4.5 Consumer protection legislation and civil litigation

Trade practices legislation, fair trading legislation or the common law may be used when consumers suffer harm as a result of harmful products.

The *Trade Practices Act* 1974 (Cth) and the *Fair Trading* Act 1985 (Vic.) provide for:

- Prosecutions to be instituted in respect of false representations or misleading conduct in relation to the supply of goods or services; and
- Proceedings to be taken in relation to the supply of defective products in contravention of those Acts.

The common law of negligence allows civil proceedings to be instituted to compensate consumers who suffer damage as a result of a breach of a duty of care by manufacturers or suppliers of meat.

11.5 Objectives of the Legislation

The specific objectives of regulatory intervention by Government in relation to meat are not stated in the Act but may be taken to include:

- Protecting public health and safety;
- Protecting consumers from deception; and
- Providing consumer information.[148]

11.6 The Rationale for Legislative Intervention

There are a large number of foodborne pathogens including pathogenic bacteria, viruses, trematodes, protozoa, cestodes, nematodes; chemical contaminants including natural toxins, pesticides, toxic metals, polychlorinated biphenyls and radionucleotides and physical contaminants, both chemical and microbiological which cause food poisoning.[149] There are also a range of nutrients and food additives (such as Vitamin A, zinc, sodium nitrate) which are potentially toxic. Prevention measures can help food businesses minimise potential contamination which can contribute to an increased risk of foodborne illness.

In 1995, Commonwealth and State and Territory Primary Industry Ministers agreed to develop national food safety standards for the domestic meat market: these have been implemented through the State and Territory Meat Acts (in Western Australia, the Health Act).[150]

11.7 Costs and Benefits of the Restrictions

The Health Act Review Discussion Paper sought comments on the costs and benefits of the restrictions, whether the costs outweigh the benefits and whether there are any less restrictive means of achieving the objective of the registration. The majority of submissions to the Discussion Paper commented on the provisions in Part 15 which deal with meat not for sale which are not relevant for the

[148] Commonwealth Business Regulation Review Unit and Victorian Regulation Review Unit, *Report of an Inquiry into Food Regulation in Australia,* (2 vols) BRRU and VRRU, Canberra, November 1988.
[149] WHO draft, Guidelines for the investigation and control of foodborne disease outbreaks.
[150] Food Regulation Review Committee. *Food: a growth industry, Report of the Food Regulation Review*, August 1998.

purposes of an NCP analysis, but will be dealt with in the broader review of the Health Act. The majority of submissions commenting on the provisions of the Health Act dealing with meat for sale stated that it would be appropriate to repeal these sections from the Health Act as they are adequately dealt with under other legislation which regulate the production and preparation of meat for sale.

11.7.1 Costs

The restrictions on business conduct through controls on production and sale of meat on producers, processors, manufacturers, distributors and suppliers impose costs on industry in the form of compliance costs in adhering to standards and requirements. The additional costs to industry may, especially for some smaller companies, be such as to prevent market entry where the costs of compliance make it uneconomic for a firm to operate in that market. It should be noted that these costs are incurred indirectly by industry complying with their other legal obligations in relation to the slaughter, manufacture, and preparation of meat under both the Meat Industry and Food Acts.

Local council and DHS would potentially incur the costs of inspection where compliance with the Act was questioned. However, licensed meat processing facilities and other places where meat is sold for human consumption (eg. butchers) under the Meat Industry Act are inspected by officers authorised by the Victorian Meat Association under that Act. The maintenance of standards at mixed retail premises, but where meat is sold, eg. supermarkets, are the responsibility of authorised officers under the Food Act. The responsibility for routine inspection of premises where animals are slaughtered, meat manufactured or processed for sale has therefore moved to these agencies, and as a consequence EHOs have not used the enforcement provisions under the Health Act in relation to meat for sale for some time.

The requirements may impose a cost on consumers as a result of business compliance costs with manufacturing, handling, packaging, and labeling requirements being reflected in the ultimate price of products purchased by consumers.

11.7.2 Benefits

Benefits of the regulation of the meat industry come from a reduced incidence of food-borne illnesses in terms of less human suffering, lower costs for medical services and work absenteeism, more leisure time, improved general nutrition, increased life expectancy, and reduced morbidity and mortality.[151]

Some of the risks involved in meat production and processing in causing foodborne illness were reported by the Australia New Zealand Food Authority (ANZFA) as part of the regulatory impact statement for proposed national food safety reforms.[152] ANZFA identified these risks as follows:

- Modern intense farming practices such as animal husbandry, introduced to maximise production, have led to the emergence of zoonotic Salmonella serovars and campylobacter spp. as the most often reported causes of foodborne illness in Australia.[153] The main reservoirs of these bacteria are the gastro-intestinal tract of animals and birds – both domestic and wild.[154,155]

- Hazards in the food chain which are introduced at the animal production stage and have been shown to be spread during slaughter and processing.[156]

[151] See Victorian Food (Amendment) Bill 1997 - Second Reading Speech.
[152] ANZFA, *Food Safety Standards Costs and Benefits: An analysis of the regulatory impact of the proposed national food safety reforms*, Commonwealth of Australia, 1999.
[153] Crerar SK, Dalton CB, Longbottom HM, Kraa E. Foodborne disease: Current trends and future surveillance needs in Australia, *Med J Aust*, 1996;165:672-675.
[154] Baird-Parker AC. Foodborne salmonellosis, *Lancet*, 1990;336;1231-1235.
[155] Mulder RWAW. Impact of transport on the human pathogens in poultry, *World Poultry-Misset*, 1996;12:18-19.
[156] Ahl AS, Buntain B. Risk and the food safety chain: animal health, public health and the environment, *Review of Science Technology*, 1997;16:322-330.

- Faecal contamination of meat during slaughtering from farm animals carrying pathogens such as Salmonella and enterohaemorrhagic *Eschericia coli* (EHEC) in their gut.[157]

- An outbreak of *E.coli* 0157:H7 from contaminated meat in Scotland in 1996 affected 496 people and killed 18.[158]

- An outbreak of *E.coli* 0111 from contaminated mettwurst in South Australia affected approximately 150. 23 children were diagnosed as suffering from haemolytic uraemic syndrome, and one child died.[159]

- The main risk factors for contracting *Campylobacter jejuni*, the most commonly reported bacterial cause of foodborne illness and can also lead to long-term effects including reactive arthritis and Guillain-Barre syndrome, are handling raw poultry and eating undercooked poultry.[160]

In addition, the disease brucellosis is widely recognised as an occupational hazard for workers in meat-processing plants where contact with infected carcases and infected discharges is possible.[161] Of all the zoonoses that have public health and economic implications, brucellosis is the most widespread, especially in countries where infection in animals has not been brought under control and standards of animal husbandry are low.[162] Following the success of the National Brucellosis and Tuberculosis Eradication Campaign, Australia, Australian cattle have been free from brucellosis since 1989, however, breakdowns in the system have occurred.[163] Twelve cases of human brucellosis have been reported in Victoria between 1990 and 1995, however, the major risk factor in recently acquired infection in Australia is exposure to *Brucella sui*s in feral pigs.[164]

Australia regularly experiences food-borne illness and its associated costs. The 1995 outbreak in South Australia from contaminated mettwurst received high level media attention but the real problem is far less obvious. Every day across Australia, thousands of people succumb to a variety of food-borne illnesses which are not mentioned in the media or other outlets.

The incidence of food-borne disease in Australia is estimated to be 4.2 million cases per annum or approximately a ten to twenty percent chance every year of an individual in Australia being affected by food-borne illness.[165] Every day another 11,500 people are afflicted with food poisoning.[166] Although not all of these cases of food-borne illness are caused by meat contaminated in slaughtering and processing, it does illustrate the huge impact of foodborne illnesses in Australia.

The principal benefit of regulating the meat industry is in the form of costs saved from food poisoning which would otherwise be borne directly and indirectly by government, industry and consumers alike. There are no Victorian, or Australian, data which accurately quantify the total cost of illness associated with consumption of unsafe meat. Overseas data reported in by ANZFA show that the average cost per case of foodborne illness is between A$1,000 and A$2,000 in these countries which takes into account direct socio-economic costs including losses incurred by society, either as economic costs through

[157] Vanderlinde PB, Shay B, Murray J. Microbiology quality of Australian beef carcass meat and frozen bulk packed beef, *Journal of Food Protection*, 1998;61:437-443.
[158] Pennington Group. *Report on the circumstances leading to the 1996 outbreak of infection with E,coli 0157 in Central Scotland: The implications for food safety and the lessons to be learned*, The Stationary Office, Edinburgh.
[159] Chivell WC. *Finding of inquest: Inquest into death of Nikki Dearne Robinson*, State Coroner's Report, Adelaide, South Australia,1995.
[160] Altekruse SF, Stern NJ, Fields PI, Swerdlow DL. *Campylobacter jeyjuni* – an emerging food borne pathogen. *Emerging Infectious Disease*, 1999;5:28-35.
[161] Neville G, Pearce M. Brucellosis – almost eradicated. *AVA News*, 1992;March:14.
[162] Cosivi, Ottorino, Seimenis, Aristarhos. Brucellosis: A widespread public health problem. *World Health*, 1998;51(4):14-15.
[163] Neville G, Pearce M. Brucellosis – almost eradicated. *AVA News*, 1992;March:14.
[164] Surveillance of notifiable diseases in Victoria 1996, DHS Report.
[165] ANZFA, *Food Safety Standards Costs and Benefits: An analysis of the regulatory impact of the proposed national food safety reforms*, Commonwealth of Australia, 1999.
[166] ibid, p.32.

production losses resulting from sickness related absenteeism or costs to the affected individual and his/her family from illness-related expense.[167]

Benefits for industry include enhancement of opportunities for the sale of meat into export markets through the generation of higher levels of buyer confidence in Australian meat. Studies have also pointed to the general confidence building which arises from an enhanced administration and enforcement of food standards and regulations and the effect this has on Australia's sales of food products particularly into export markets.[168] In addition, industry benefits from reduced costs associated with independent audits, insurance, product recalls, volumes of spoiled goods through effective enforcement of existing meat standards and regulations reducing the risk of meat contamination. The National Meat Industry association has estimated that sales of mettwurst were reduced by more than 20 percent for several years after the contamination incident in South Australia.[169]

Meat workers benefit from reduced occupational exposure to zoonoses, including brucellosis.

Consumers benefit from lower search costs by enhancing public confidence in the safety of meat and allowing consumers to source their requirements from more than one location without the need to test all products.

11.7.3 Analysis of the costs of the restrictions against the benefits

Some businesses may be disadvantaged by the restrictions as a result of compliance requirements but benefit in the longer term through this contributing to food safety, stimulating consumer demand for their products and lowering business insurance and other risk management costs.

Similarly, governments may be disadvantaged by having to monitor business activity. However, they may benefit over time through legislation deterring business from engaging in more extreme forms of proscribed conduct which are among the most costly for regulatory authorities to address. Consumers benefit from meat safe for consumption by meat suppliers compliance with the regulatory provisions. However, they may be disadvantaged over the longer term if businesses raise their prices to cover higher regulatory compliance costs and if legislation reinforces regulations which are high enough to raise barriers to market entry by new suppliers, limit competition and restrict product innovation.

The community at large may be expected to benefit from the removal of barriers to the entry into the meat industry from the expected increase in activity within that industry, at least in the short term, which would benefit the economy generally. However, by reducing the risks to public health from foodborne illness, the economic and social benefits to the community are likely to be more lasting than the benefits which would flow from a short-lived increase in activity.

11.8 Alternatives to these Restrictions

11.8.1 Non-legislative regulation

At least two factors suggest that non-legislative regulation of the meat industry is not a viable alternative. Firstly, legislation is necessary to support aspects of regulatory enforcement by Government authorities such as the power of entry, the power of seizure, the power to demand and receive information, the power to apply pecuniary and other penalties, the power to exempt food items and the power to approve auditors. Secondly, non-legislation measures may fail to adequately reflect:

- The high and increasing priority placed by society on access to safe food;

[167] ANZFA, *Food Safety Standards Costs and Benefits: An analysis of the regulatory impact of the proposed national food safety reforms, Commonwealth of Australia*, 1999.
[168] Victorian Food (Amendment) Bill 1997 - Second Reading Speech.
[169] Commonwealth Department of Health and Aged Care. *The National Environmental Health Strategy*, Commonwealth of Australia, 1999.

- The emergence of new food-borne diseases;
- Public concern to protect groups within the community especially vulnerable to food-borne illnesses such as the elderly, children and those with immune deficiencies; and
- The need for a regulatory approach which supports the desire to pre-empt food-borne diseases rather than react after outbreaks have occurred.

11.8.2 Reliance on the existing law

Other laws which operate to protect public health by ensuring meat for sale is fit for human consumption include:

- The *Meat Industry Act* 1993 sets standards for meat production and transport by establishing a licensing and inspection system and a mechanism for adopting and implementing quality assurance programs to help to ensure standards are maintained;
- The *Food Act* 1984 minimises the risk of contracting food-borne illnesses by ensuring that food for sale is safe for human consumption, and establishing a registration and inspection system and a mechanism for adopting and implementing food safety programs to help to ensure standards are maintained;
- Various criminal offences in the Occupational Health and Safety Act which all operate to deter unsafe practice;
- Nuisance provisions under the Health Act, which allow municipal councils to make orders with respect to nuisances in their districts which are, or a liable to be, dangerous to health or offensive, including nuisances arising from any building or structure and which create an offence of causing or allowing a nuisance to exist;
- Consumer protection legislation and civil litigation, which also deter safe practice by giving persons affected by such practice the right to recover their loss.

The majority of submissions submitted that these sections are adequately dealt with under other legislation. The submission received from Manningham City Council stated that:

> *Local government no longer deals with meat for human consumption, this is the responsibility of the VMA. It should be removed and referred to the Vic Meat Act for VMA officers to respond to.*

The submission received from DNRE stated that:

> *The current regulatory arrangements are considered to be adequate, particularly following the recent changes to the Meat Industry Act 1993 which expanded the coverage of the Act across almost all aspects of meat processing…Section 305, which relates to the slaughtering and dressing at licensed facilities is adequately addressed in the Meat industry Act 1993… Section 309 relate[s] to the sale of food comprised of [comprised of meat from a prohibited animal] for human consumption and should be retained.*

The submission received from the Australian Institute of Environmental Health (Vic.) stated that:

> *Diseases transmitted through meat consumption have not been eliminated and are currently managed by inspection at slaughter, public education and brand inspection at the retail level. The Health Act provisions relating to the sale of unbranded meat are currently used by EHO's in rural municipalities to deal with problems that come to their attention. It would seem logical that these provisions be transferred to the Meat Industry Act along with the current transfer of retail meat from the Food Act. Our concern however is that the enforcement regime employed by the VMA is not suitable for the detection and prevention of the intentional sale of unbranded meat…If it can be established that an effective level of control of unbranded meat exists through this regime then the meat supervision provisions of the Health Act be transferred to the Meat Industry Act.*

The controls provided by Food Laws (Meat Industry Act and Food Act) are complementary to each other but overall provide a comprehensive and sufficient means for achieving the objectives of the restrictions under the Health Act in relation to “meat supervision”.

An analysis of how those other laws would by themselves offer sufficient protection against the risks involved in the consumption of unsafe meat which the restrictions seek to address follows. This should not be taken as a comprehensive analysis of the areas of other overlapping legislation in relation to these restrictions, but rather provides examples of where other legislative controls are in place.

Prohibition on slaughtering

The prohibition on the slaughter of any animal or dressing of any carcass except at a meat processing facility licensed under the Meat Industry Act 1993 is adequately provided for by that Act. Slaughter or dressing the carcass of a consumable animal for human consumption or processing game or poultry at a place that is not a meat processing facility licensed for that purpose is an offence under section 38 of the Meat Industry Act.

Prohibition on manufacturing, preparation and sale of the flesh of a prohibited animal

“Prohibited animal” is defined in the Health Act as a “mammal which is not a consumable animal within the meaning of the Meat Industry Act 1993”. Under section 34(1) of the *Meat Industry Act* 1993 it is an offence to sell or dispose of meat for human consumption unless it is from a consumable animal slaughtered and processed at a meat processing facility licensed for that purpose.

Under section 39(1) of the *Meat Industry Act* 1993 it is an offence to supply meat or to remove meat from a meat processing facility unless the meat is a carcass or comes from a carcass branded in accordance with the regulations as fit for human consumption.

Penalties for these offences are sizable: $5,000 for a first offence, and penalty of $10,000 or 12 months imprisonment or both for a second offence.

Under section 8 of the *Food Act* 1984 it is an offence to sell, prepare or pack food that is adulterated or not fit for human consumption. Meat not from a consumable animal slaughtered and processed at a meat processing facility would be expected to be unfit for human consumption. A person convicted of a breach of section 8 faces a maximum penalty of $10,000 for a first offence, and $20,000 for a subsequent offence, or imprisonment for six months, or both.

Consumer protection legislation and civil litigation

Common law (both civil and criminal) and other consumer protection legislation (such as *Trade Practices Act* 1974, State fair trading and sale of goods laws) also deter unsafe practice by giving persons affected by such practice the right to take action to recover their loss.

11.9 Conclusion

There is scope to lessen regulatory burdens on business while at the same time providing for acceptable levels of consumer information and protection of health and safety standards in Australia by relying upon existing food law. All meat processing chains [production, processing and retail sectors (eg. butchers)] come within the ambit of the *Meat Industry Act* 1993, which is where the principal expertise regarding meat safety lies. The *Food Act* 1984 covers preparation of meat for sale, eg. restaurants, etc.
Restrictive provisions related to “meat supervision” in the Health Act are adequately covered and the objectives able to be met by specific food legislation.

11.10 Recommendation

11.10.1 That sections 305 and 309 of the Heath Act be repealed.

12 Part 19 – Registrations

12.1 Background

Part 19 of the *Health Act* 1958 requires that premises to which it applies must be registered with the local council. Currently the premises that must be registered are those where a person is conducting a business of:

- Hairdressing;
- A beauty parlour or other similar business;
- Tattooing, ear piercing, acupuncture or any other process involving the penetration of the skin in a living human being.

The Act also provides for the form and fee for registration of premises and gives power to the Secretary to grant or refuse registration. The Secretary has the power to inspect premises that are seeking registration and to require any alterations or improvements to premises to ensure that they comply with the requirements of the Act. There are a number of regulation making powers enabling regulations to be made in relation to all the procedural aspects of registration and also other matters such as the cleanliness of the premises, inspection of premises and matters necessary to safeguard the health of persons likely to be using the premises. The *Health (Infectious Diseases) Regulations* 1990 currently regulate the cleanliness of the premises, the cleanliness of equipment and standards of hygiene for persons performing skin penetration procedures.

The Act also provides a regulation making power to exempt certain businesses from complying with the registration requirements. The *Health (Exempt Business) Regulations* 2000 prescribe the following businesses as exempt: the practices of registered medical practitioners; registered dentists; registered nurses; registered podiatrists and accredited pathology services. Also exempted are mobile hairdressers and beauty therapists where the mobile premises are not the principal place of business. Further, the practices of chiropractors, optometrists, osteopaths and physiotherapists, which involve acupuncture in the normal course of the practice of the respective professions, are also exempt.

The requirement that certain premises be registered is a restriction on competition because it creates a barrier to entry to the market for those services. In addition, the power to require alterations or improvements to premises prior to registration could act as a barrier to entry into the market, by potentially imposing additional costs on some participants in the market. Further, the requirement to observe certain standards on those premises places constraints on the way in which proprietors conduct those businesses potentially adding to their operating costs.

12.2 Description of the market

As stated in section 12.1, premises are registered by local councils. To obtain some information about the effect of these provisions, during the review, a survey was sent to all 78 Local Government Authorities to obtain information on the registered premises within each municipality. Responses to the survey were obtained from 64 of the 78 Local Government Authorities, consisting of 39 out of 47 rural councils and 25 out of 31 metropolitan councils (see section 9.2 for further discussion).

Results of the Survey are shown in the following tables.

The number of each type of premise as at August 2000 registered with local councils under these provisions are as follows:

Type of Premise	**Metropolitan**		**Rural**		**Total**	
Hairdressing	2451	(70%)	1055	(30%)	3506	**(68%)**
Beauty Therapist	589	(73%)	220	(27%)	809	**(16%)**
Ear Piercing	311	(68%)	146	(32%)	457	**(9%)**
Tattooist	56	(65%)	30	(35%)	86	**(2%)**
Body Piercing	68	(72%)	27	(28%)	95	**(2%)**
Acupuncturist*	155	(84%)	30	(16%)	185	**(3%)**
Total	3630	(71%)	1508	(29%)	5138	**(100%)**

*****Many of these acupuncturists will no longer be required to register with local councils as a result of the *Chinese Medicine Registration Act* 2000 (see section 12.5.3)

The distribution of registered premises as at August 2000 by DHS Regions in rural Victoria was as follows:

Region	**Type of Premise**						**Total**
	Hair-dressing	Beauty Therapist	Ear Piercing	Tattooist	Body Piercing	Acupuncturist	
Barwon South Western	319	104	50	7	10	14	504 (33%)
Gippsland	174	21	32	3	4	4	238 (16%)
Grampians	126	20	8	7	3	1	165 (4%)
Hume	237	49	23	7	6	6	328 (22%)
Loddon Mallee	199	26	33	6	4	5	273 (18%)
Total	1055	220	146	30	27	30	1508 100%)

The distribution of registered premises as at August 2000 by DHS Regions in metropolitan Victoria was as follows:

Region	**Type of Premise**						**Total**
	Hair-dressing	Beauty Therapist	Ear Piercing	Tattooist	Body Piercing	Acupuncturist	
Eastern	694	217	74	14	7	73	1079 (30%)
Northern	521	107	90	16	10	23	767 (21%)
Southern	829	196	108	13	34	37	1217 (33%)
Western	407	69	39	13	17	22	567 (16%)
Total	2451	589	311	56	68	155	3630 (100%)

Stakeholders in the hairdressing, beauty therapy and skin penetration services market include:

- Hairdressing, beauty therapy, body piercing, ear piercing, tattooing businesses;
- Businesses that provide these services as part of their business, eg. department stores, pharmacies;
- Employees of those businesses;
- Consumers who purchase hairdressing, beauty therapy and skin penetration services;

- Government regulatory authorities, in particular DHS and Local Government; and
- The community generally which has to bear the costs to the public health system if services are provided unsafely so increasing the risk of transmission of infectious diseases.

12.3 Market Failure

The requirement for these premises to be registered addresses two potential areas of market failure. The first is the costs that may be imposed on people not involved in the provision or consumption of one of these services (negative externalities). If any adverse outcomes occur and disease is transmitted as a result of dirty premises, inadequate sterilisation of equipment or infection of an operator performing the service, costs to third parties include:

- Direct costs to the health system and welfare system which are ultimately borne by Australian taxpayers;
- Indirect costs to the Australian economy in lost production; and
- Intangible costs of pain, suffering, lost years of life, anxiety and bereavement where the nature of the disease is serious.

The second potential source of market failure is the knowledge disparity which tends to exist between the provider of the particular service being performed and the consumer of the services (information asymmetries). To prevent the transmission of disease through provision of these services, operators must be informed about infection control procedures and adequate sterilisation of equipment. For example, in the provision of tattooing services there are numerous aspects of the procedure which could result in the transmission of disease. Consumers, whilst they can observe the cleanliness or otherwise of premises would not necessarily be aware of the nature of infection that can be spread via these services or the manner in which to prevent such diseases. Consumers do not have the technical expertise, information, time or resources to evaluate the quality of sterilisation of equipment. As stated earlier in this paper, government regulation is generally accepted as warranted where the relevant decision making is distributed asymmetrically between market participants (that is, consumers and providers) and there is a clear public interest.

12.4 Effects of Other Legislation and the Common Law on these Market Failures

12.4.1 Occupational Health and Safety Act

Provisions of the *Occupational Health and Safety Act* 1995 (Vic.) which are of particular relevance in protecting hairdressers, beauty therapists, skin penetration technicians and consumers from the dangers of unsafe practice are as follows:

- Employers shall make arrangements for ensuring so far as is practicable safety and absence of risks to health in connexion with the use, handling, storage and transport of substances (section 21(2)(b));
- Employers shall provide such information, instruction, training and supervision to employees as are necessary to enable the employees to perform their work in a manner that is safe and without risks to health (section 21(2)(e));
- Employers and self-employed persons shall ensure so far as is practicable that persons (other than the employees of the employer or self-employed person) are not exposed to risks to their health or safety arising from the conduct of the undertaking of the employer or self-employed person (section 22);
- Employees shall, while at work, take reasonable care for their own health and safety and that of anyone else who may be affected by their acts or omissions at the workplace (section 25).

Offences against these provisions carry a maximum penalty of $250,000 for a body corporate and $50,000 for a natural person (section 47).

12.4.2 General provisions in the Health Act

Regulation 14 of the *Health (Infectious Diseases) Regulations* 1990 provides the Secretary with powers during an outbreak or suspected outbreak of infectious disease. It empowers the Secretary to:

- Require compliance with any procedure relating to infectious disease;
- Require compliance with the provisions of Part 4 of the Infectious Diseases Handbook;
- Enter and search without warrant;
- Require the provision of information to trace the source and prevent the further spread of the disease;
- Inspect premises where the disease may be spread;
- Require cleaning or disinfection of premises where the disease may be spread;
- Require disposal or destruction of any infected article;
- Direct the proprietor of a business or the person in charge of premises to take any action necessary to prevent the spread of the disease on or from those premises;
- Direct any person to take any other action that the Chief General Manager considers necessary to prevent the spread of the infectious disease.

Failure to comply with a direction of the Secretary issued under Regulation 14 is an offence.

12.4.3 Chinese Medicine Registration Act

The *Chinese Medicine Registration Act* 2000 includes among its purposes the protection of the public by providing for the registration of practitioners of Chinese medicine and investigations into the professional conduct and fitness to practise of registered practitioners of Chinese medicine and to establish the Chinese Medicine Registration Board of Victoria. A person may apply to the Board for registration as an acupuncturist (section 4(1)(b)). The Act creates a number of offences including:

- Using the title of registered acupuncturist unless a registered practitioner (section 61(1)(a));
- Falsely claiming to be a registered practitioner (section 61(1)(b));
- Carrying out any act which is required to be carried out by a registered practitioner (section 61(1)(c));
- Claiming to be qualified to practice as an acupuncturist unless a registered practitioner (section 61(1)(d));
- Using the title of acupuncturist unless registered as an acupuncturist (section 61(2));
- Failing to comply with a condition, limitation or restriction attached to registration (section 61 (8)).

Offences against these provisions carry a maximum penalty of $5,000.

Section 108 of the Act Chinese Medicine Registration Act amends the Health Act so as to exempt from the requirement to register premises under section 366C of that Act any person who is registered as an acupuncturist under the *Chinese Medicine Registration Act* 2000 or who is authorised in accordance with section 61(11) of that Act with respect to the practice of acupuncture.

Finally, the Chinese Medicine Registration Act gives the Chinese Medicine Registration Board extensive powers to investigate, either in response to a complaint or of its own motion, the professional conduct of a registered practitioner.

12.4.4 Consumer protection legislation and civil litigation

Trade practices legislation, fair trading legislation or the common law may be used when consumers suffer harm as a result of harmful products.

The *Trade Practices Act* 1974 (Cth) and the *Fair Trading* Act 1985 (Vic.) provide for:

- Prosecutions to be instituted in respect of false representations or misleading conduct in relation to the supply of goods or services; and
- Proceedings to be taken in relation to the supply of defective products in contravention of those Acts.

The common law of negligence allows civil proceedings to be instituted to compensate consumers who suffer damage as a result of a breach of a duty of care by hairdressers, beauty therapists and person providing skin penetration services.

12.5 Objectives of the Legislation

Regulation 2 of the *Health (Infectious Diseases) Regulations* 1990 states that:

- The objective of these Regulations is to protect the public health by preventing, or containing, outbreaks of infectious disease.

As stated earlier in this report, there are no stated objectives in the Act however it can be inferred that the objective of the legislation is also to protect public health.

The objective of registering the premises where certain businesses are conducted is to facilitate the protection of public health by minimising the risk of infection and the transmission of disease when businesses undertake the activities of hairdressing, beauty therapy and skin penetration.

12.6 The Rationale for Legislative Intervention

There are a number of potential risks arising from activities undertaken during the course of hairdressing, beauty therapy or skin penetration procedures. The skin provides a barrier against infection and the penetration of that barrier whether deliberately or accidentally creates a risk of infection. Skin penetration procedures or the penetration of any bodily part result in the emission of fluids thereby giving rise to a risk of blood borne viruses such as HIV, Hepatitis B (HBV), Hepatitis C (HCV) as well as other strains of Hepatitis. There have been several documented cases of HBV[170,171,172,173] and HCV[174,175,176,177] attributed to tattooing. Infectious complications of body piercing (including ear piercing and acupuncture) have been shown to involve HBV, HCV, Hepatitis D (HDV), HIV, staphylococcus, streptococcus, endocarditis, impetigo and human papillomavirus.[178,179]

While the risk is clearly higher where skin penetration is an ordinary part of the procedure, the use of equipment that has potential to penetrate the skin also poses risk of infection. In the submissions to the Review of the Health Act Discussion Paper there was universal support for registration of skin penetration premises but significant diversion of opinion on the need to register hairdressers and beauty therapists. When questioning the need for continued registration in these areas, many local councils raised the fact that there were perhaps other activities for which there was a greater need for registration. The difficulty with these services is that whilst many activities may pose very little risk for disease transmission, activities such as electrolysis, waxing, the use of razors or other shaving equipment and hair and nail cutting do have a moderate level of risk of disease transmission attached

[170] Pavli P, Bayliss J, Dent O, Lunzer M. The prevalence of serological markers for hepatitis B virus infection in Australian Naval Personnel. *Med J Aust,* 1989;151:71-75.
[171] Harrison M, Noah N. Hepatitis B from tattooing. *Lancet,* 1980;2:644.
[172] Limentani A, Elliott L, Noah N, Lamborn J. An outbreak of Hepatitis B from tattooing. *Lancet,* 1979;2:86-88.
[173] Reed BE, Barrett AP, Smith MW. The relationship of tattooing to Hepatitis B virus exposure. *ANZ J Med,* 1985;15:769.
[174] Davis A. Tattoo parlours and hepatitis C virus infection, *Med J Aust,* 1995;163:556-557.
[175] Abildgaard N, Peterslund N. Hepatitis C virus transmitted by tattooing needle. *Lancet,* 1991;338:460.
[176] Thompson S, Hernberger F, Wale E, Crofts N. Hepatitis C transmission through tattooing: a case report. *Australian New Zealand Journal of Public Health* 1996;20(3):317-318.
[177] Ko Y-C. Ho M-S. Chiang T.A et al. Tattooing as a risk of Hepatitis C virus infection. *J Med Virology,* 1992;38:285-291.
[178] Long G, Rickman L. Infectious Complications of Tattoos. *Clinical Infectious Diseases,* 1994;18:610-619.
[179] Samantha S, Tweeten M, Rickman L. Infectious complications of body piercing. *Clinical Infectious Diseases*,1998;26:735-740.

to them. For example, electrolysis has been linked to a case of diphtheroid endocarditis[180] and associated with the spread of flat warts.[181] Hairdressing or beauty therapy services may not be intended to be skin penetration, but scissors may accidentally penetrate the skin, razors and/or waxing may scrape the skin. Waxing can result in bleeding at the site of hair follicles which provides potential entry points for infection.

Furthermore, infections that may be transmitted by non-skin penetrating hair and beauty procedures include herpes, impetigo, cellulitis, head lice, conjunctivitis, and fungal, bacterial and viral skin and nail infections. For example, eye infections may occur from contaminated makeup, folliculitis from inadequately cleaned hairdressing equipment, and nail infections (bacterial, fungal or viral) can be introduced by contaminated equipment. Whilst these conditions range from relatively minor through to quite serious or fatal, even mild complications may give rise to treatment costs and discomfort which could be avoided through proper infection control procedures being observed.

Ensuring that these procedures are undertaken in accordance with correct infection control procedures, that there is proper cleaning and sterilisation of equipment and that the environment in which the activities are undertaken is appropriate minimises the risk of disease being transmitted as a result of these practices.

Hairdressing is subject to occupational licensing or registration in other States including: New South Wales, South Australia, Tasmania and Western Australia; and the Northern Territory, and remains subject to public health regulation by most health departments through premises' licensing or registration, and/or regulations about health related standards. For example, the *Local Government (Orders) Regulation* 1997 pursuant to the *Local Government Act* 1993 (NSW) establishes *Standards for Hairdressers Shops* and *Standards for Beauty Parlours*. It is an offence to not comply with the Standards. Skin penetration premises are subject to regulation in other States: NSW, TAS, WA; ACT and NT. For example, the *Public Health Act* 1997 (ACT) provides for any activity/procedure to be declared to be "public health risk activity". Skin penetration is declared to be a licensable public health risk activity under that Act. Operators are thus required to be licensed as well as to comply with relevant Codes of Practice.

12.7 Costs and Benefits of the Restrictions

The Health Act Review Discussion Paper sought comments on the costs and benefits of the restrictions, whether the costs outweigh the benefits and whether there are any less restrictive means of achieving the objective of registration. Additional information on the costs involved in registration of prescribed accommodation was collected in the survey of Local Government Authorities in Victoria, conducted by DHS in August 2000.

12.7.1 Costs

The cost to proprietors to register the prescribed accommodation will vary according to the council involved. Councils have the discretion to set their own fees. The methods for determining fees vary between councils, including: standard fees across all categories of registered premises; different fees for premises conducting skin penetration, that is fee rates dependent on the risk of contamination associated with the activity; and different rates for new registration and annual renewal of registration. Some councils combine the fees for registration of premises where more than one of the activities of hairdressing, beauty therapy and skin penetration are carried out.

In rural Victoria, the average fee charged for registration of premises was $93 (range $84 to $100). The average fee charged by type of business was as follows: $84 for hairdressing; $88 for beauty therapist; $90 for ear piercing; $99 for tattooist; $98 for body piercing; and $100 for acupuncturist.

[180] Cookson W, Harris A. Diphtheroid endocarditis after electrolysis. *Brit Med J,* 1981;282: 1513-1514.
[181] Petrozzi J. Verrucae Planae spread by electrolysis. *Cutis,* 1980; 26: 85.

The average and range in fees charged by rural councils within each DHS region by class of registered premise are shown in the table below:

Region	Type of Registered Premise	Average	Range
Barwon South Western	Hairdressing	$73	$30 - $140
	Beauty therapist	$73	$30 - $140
	ear piercing	$73	$35 - $140
	Tattooists	$88	$50 - $140
	Body piercers	$76	$30 - $140
	Acupuncturists	$70	$30 - $140
Gippsland	Hairdressing	$89	$70 - $120
	Beauty therapist	$89	$70 - $120
	ear piercing	$93	$70 - $120
	Tattooists	$94	$70 - $120
	Body piercers	$102	$85 - $120
	Acupuncturists	$99	$85 - $120
Grampians	Hairdressing	$115	$60 -$166
	Beauty therapist	$124	$60 -$166
	ear piercing	$122	$60 -$166
	Tattooists	$153	$140 - $166
	Body piercers	$145	$130 - $166
	Acupuncturists	$153	$140 - $166
Hume	Hairdressing	$69	$30 - $110
	Beauty therapist	$71	$50 - $110
	ear piercing	$75	$60- $110
	Tattooists	$70	$65 - $75
	Body piercers	$70	$65 - $75
	Acupuncturists	$77	$65 - $110
Loddon Mallee	Hairdressing	$75	$40 - $120
	Beauty therapist	$81	$40 - $120
	ear piercing	$89	$50 - $120
	Tattooists	$90	$50 - $120
	Body piercers	$98	$80 - $120
	Acupuncturists	$102	$60 - $120

In metropolitan Victoria, the average fee charged for registration of premises was $90 (range $87 to $93). The average fee charged by type of business was as follows: $90 for hairdressing; $88 for beauty therapist; $87 for ear piercing; $90 for tattooist; $90 for body piercing; and $93 for acupuncturist.

The range in fees charged by metropolitan councils within each DHS region by class of prescribed accommodation are shown in the table below:

Region	Class of Accommodation	Average	Range
Eastern	Hairdressing	$71	$60 - $85
	Beauty therapist	$71	$60 - $85
	ear piercing	$67	$60 - $82
	Tattooists	$62	$60 - $105
	body piercers	$73	$60 - $105
	Acupuncturists	$72	$60 - $105
Northern	Hairdressing	$81	$55 - $100
	Beauty therapist	$81	$55 - $100
	ear piercing	$81	$55 - $100
	Tattooists	$90	$55 - $150
	body piercers	$90	$55 - $150
	Acupuncturists	$90	$55 - $150
Southern	Hairdressing	$87	$60 - $100
	Beauty therapist	$87	$60 - $100
	ear piercing	$87	$60 - $100
	Tattooists	$90	$60 - $100
	body piercers	$87	$60 - $100
	Acupuncturists	$90	$60 - $100
Western	Hairdressing	$117	$77 - $166
	Beauty therapist	$111	$77 - $166
	ear piercing	$113	$77 - $166
	Tattooists	$117	$77 - $166
	body piercers	$111	$77 - $166
	Acupuncturists	$120	$77 - $166

The cost to businesses of these provisions is not a significant portion of overall operating costs of these businesses. Registration fees range from $30 - $166 per annum depending on the location of the business. Councils set these registration fees. The lower level of risk associated with hairdressing in comparison to tattooing or body piercing is often reflected in the fees councils charge with many charging higher registration fees for skin penetration premises. Modifications that may be required to premises before registration is granted are generally costs that a business would have to incur anyway for practical reasons such as the requirement to install a suitable hand washing facility.

The provisions are administered at a local council level by EHOs. These officers also perform many other functions such as monitoring of food premises and investigation of nuisances. In the response to the survey conducted, most EHOs indicated that the administration of these provisions constituted a relatively small percentage of their time. The cost of administration is offset to some degree by the registration fees charged.

In 1999/2000, a total of 1259 inspections of registered premises were conducted by local councils in rural Victoria (333 in Barwon South Western Region; 217 in Gippsland Region; 154 in Grampians Region; 315 in Hume Region; and 261 in Loddon Mallee Region) and 4947 inspections were conducted in metropolitan Victoria (1240 in Eastern Region; 826 in Northern Region; 1830 in Southern Region; and 572 in Western Region). On average premises were inspected one to two times per year and inspections took 25 to 45 minutes.

12.7.2 Benefits

There are documented cases of disease transmission from these types of activities (see section 12.6) and whilst the frequency may not be high, the potential consequences are significant and easily preventable through the observance of infection control procedures. The benefits of the restrictions are the minimisation of the spread of infectious diseases through education of operators of these services and regular monitoring of hygiene standards.

An evaluation of infection control in registered tattooing premises in Victoria was conducted in 1994.[182] Enquiries made by the authors of health departments and EHOs in other States suggest that the standards and arrangements for the supervision of tattooing in Victoria are comparable to or better than those of the other States or Territories. The results of this study indicated that:

> *All the tattooists were aware of the need to protect themselves and their clients against blood-borne infectious diseases, although there were deficiencies in tattooist's understanding and knowledge of infection control, and their preventative actions varied considerably.*

None of the study participants used instruments that were cleaned or sterilised according to the Victorian *Standards of practice for tattooing*, adopted by reference under the *Health (Infectious Disease Regulations)* 1990. 73 per cent of observed tattooists used reusable razors. Two observed tattooists used only reusable containers for dyes, and over half added dye during tattooing, contrary to standards. In addition, over half of the tattooists observed did not wash their hands before tattooing or after attending to a client.

This study shows that even registered operators do not follow recognised infection-control procedures, and this is likely to be more frequent for unregulated, unregistered backyard operators, concluding that:

> *Registered tattooists need the support of health authorities in ensuring that all tattooing meets acceptable infection control practices and that the public understands the potential dangers of improperly supervised tattooing.*

This finding, and similar views in relation to other registered activities, was supported by a number of submissions to the Health Act Discussion paper. The submission received from the Australian Podiatry Association stated that:

> *…the Government must ensure that the public is adequately protected through appropriate regulations…It is therefore necessary that tight regulations and vigilant monitoring occur for such premises where skin penetration may occur including basic therapists, hairdressers and other businesses involving skin penetration procedures to ensure that practices are carried out within the limits of the individual's training and in accordance with the Health (Infectious Diseases) Regulations.*

The submission received from the Australian and New Zealand Association of Nurses in AIDS Care stated that:

> *There is a continuing need to safeguard consumers and provide education to any operators whose work may expose them and/or clients to blood or body fluids. Once standards have been breached it is often too late; that is, a potentially fatal infection may have been transmitted. It is also not clear how breaches would come to the attention of public health authorities if premises were not registered.*

[182] Goudey RE, Thompson SC. Evaluation of infection control in registered tattooing premises in Victoria. ANZ J Public Health, 21(1);1997:22-28.

The Maribyrnong City Council submission stated that:

> *Registration enables location of premises, regular monitoring, targeted education, and where requirements are not met registration can be revoked by councils. It also allows for the recovery of costs of the service from the industry by Local Government via registration fees.*

The South Gippsland Shire Council submission stated that:

> *…the likelihood of council's applying scarce resources to businesses which are not a revenue source and to which no statutory obligations apply is reduced [without registration and associated fees].*

Preventing the spread of infectious diseases will result in significant cost reductions to the community as a result of:

- The prevention of unnecessary morbidity and mortality;
- The avoidance of lost work hours; and
- Savings in health costs.

An indication of the extent of the costs saved by the prevention of transmission of infectious diseases by these regulations is indicated by the costs associated with HCV. Treatment protocols and associated costs to Medicare for disease sequelae of chronic HCV infection are shown in the table[183] below:

i. Chronic hepatitis	
Specialist visits (2)	$145
Pathology services (full blood examination, liver function Tests, α-fetoprotein, ultrasound)	$79
Total cost (*per patient year*)	**$224**
ii. Asymptomatic cirrhosis	
Specialist visits (2)	$145
Pathology services (anti-HCV, liver function tests, α-fetoprotein, ultrasound, biopsy)	$270
Total cost (*per patient year*)	**$415**
iii. Liver failure[a]	
Without transplant, cost per patient	$164,340
With transplant, cost of transplant	$75,000
Expected cost *per episode*	**$128,639**
iv. Hepatocellular carcinoma[b]	
Without surgery, cost per patient	$117,895
With surgery, cost per patient	$28,290
Expected cost *per episode*	**$88,325**

Notes:
(a) 40% of patients can be expected to have a transplant.
(b) 33% of patients can be expected to have surgery.

For every 1,000 new HCV infections, there is an estimated $14.32 million (in 1994 dollar terms) added to Australia's health care budget per year as sequelae develop.[184] In addition to these direct costs, incurred as a result of action to respond to the disease, including expenditure on research, surveillance, prevention, diagnosis and treatment, there are the indirect costs relating to productivity

[183] Taken from Brown K, Crofts N. Health care costs of a continuing epidemic of hepatitis C virus among injecting drug users. *Australia & New Zealand Journal of Public Health,* 1998*;* 22:384-8.
[184] Ibid, p.386

losses including days lost because of treatment and premature mortality, and changes in employment participation.

12.7.3 Analysis of the costs of restriction against benefits

If the Health Act did not seek to regulate businesses which conduct the activities of hairdressing, beauty therapy or skin penetration, they would benefit from not having to pay registration fees or meeting the registration requirements. However, the costs borne by proprietors attendant to the maintenance of appropriate sanitation and hygiene to minimise the risk of infection and the transmission of disease would be the requirement of an appropriately operated business, whether or not regulations were imposed. Although some businesses may be disadvantaged by the restrictions as a result of compliance requirements, they benefit in the longer term through stimulating consumer confidence and hence demand for their services and lowering business insurance and other risk management costs.

Local governments may be disadvantaged by having to monitor business activity. However, fees recovered through registration to some degree cover the cost of administering the registration system.

Consumers may benefit from lower prices in the short term by the removal of the requirement to be registered, as the numbers in that industry would be expected to increase. However, this needs to be balanced against the significant benefits which consumers derive from the regulation of these businesses under the Health Act in terms of protection against increased risk of transmission of infectious diseases.

Removal of the barriers to entry into the hairdressing, beauty therapy and skin penetration services industries would be expected to lead to some increase in activity within those industries, at least in the short term, which would benefit the economy generally. However, by reducing risks to public health, registration confers economic and social benefits to the community which are likely to outweigh any benefits that may flow from an increase in economic activity within those industries.

12.8 Alternatives Means of achieving the Objective

12.8.1 No Regulation

The objective of the Regulations is to prevent or contain outbreaks of infectious disease. As stated earlier, public health aims at preventative measures and intervention to minimise potential health problems and risks.

The existence of legislation requiring registration of businesses undertaking activities which have potential health risks enables monitoring of these activities and intervention strategies to take place which assist in preventing the transmission of disease.

The businesses that are required to register do not generally have strong industry bodies that would be able to provide the education and information about infection control that occurs as part of the registration process. Further, whilst industry bodies exist, there would be a significant proportion of operators who do not belong to any such organization.

Information from Local Government Authorities about the enforcement of these provisions indicate that many businesses have had infection control procedures explained to them during the course of inspections of these premises. In the case of tattooing there are no accredited courses through which important infection control procedures are learnt. The registration requirements provide a mechanism through which education of operators can occur and also enables monitoring of how effectively those procedures are put into practice.

If there is no regulation, the objectives of the legislation to minimise the risk of transmission of disease simply cannot be fulfilled.

12.8.2 Self-Regulation

Self regulation in these industries is also not a viable option. As discussed above, the industries in question do not have strong industry bodies which are in a position to develop appropriate standards for operators. Nor would any such requirements be enforceable given that many operators do not belong to industry associations. Further the nature of many of these industries is transient and particularly in the areas of tattooing and body piercing, many backyard operators exist creating problems for the industry.

12.8.3 Negative Registration/Licensing

Public Health is by its very nature proactive and attempts to minimise the impact of disease, the transmission of disease and the effect of disease. The objectives of these provisions are to minimise the risk of disease transmission in these settings. The objectives cannot be met through a system of negative registration because by its nature it waits for a problem to exist before action occurs. It does not facilitate to the same degree the education of operators or the taking of action before a problem has arisen. It also does not provide local councils with a revenue base through which they can fund the inspection of these services. As such, the cost to the health care system in treating a case of disease will have been incurred before action is taken against the person conducting the activity in a risky manner.

Also, as stated above, because of the transient nature of some of these businesses, it would be open to operators to shift to a location where registration would not be imposed if difficulties were encountered with a particular local government. The new local council would not know of the operator because there is no registration requirement.

12.8.4 Reliance upon the existing law

The regulation of registered premises under the Health Act are not the only laws which operate to ensure a reasonable standard of hygiene, sanitation and safety are maintained. Other laws which operate in this area include:

- Various criminal offences in the Occupational Health and Safety Act which all operate to deter unsafe practice;
- General provisions of the *Health Act* 1958 which help to ensure reasonable standards of hygiene, sanitation and safety and minimises the risk of airborne and infectious diseases.
- The common law and consumer protection legislation, which also deter unsafe practice by giving persons affected by such practice the right to take action to recover their loss.

Occupational Health and Safety Act

The requirements established by the Occupational Health and Safety Act have a different focus, and whilst important in protecting hairdressers, beauty therapists, skin penetration practitioners and the public from the risk of unsafe practice, they are not specifically aimed at ensuring that the people who conduct or work in these businesses use appropriate precautionary measures to prevent the transmission of infectious diseases. Therefore, repeal of the provisions in the Health Act in favour of reliance upon laws which impose criminal and civil penalties for unsafe practice would involve an unacceptable risk to the public health.

Health Act

More vigorous enforcement of public health standards in the Health Act, the Health (Infectious Diseases) Regulations and the Health (Prescribed Accommodation) Regulations with respect to those premises is an alternative to the requirement for registration. However, registration fees are the revenue source which supports local councils maintaining their inspection role. The likelihood of local council applying scarce resources to businesses which are not a revenue source and to which no statutory obligations apply is low. This alternative would prejudice the health and well-being of occupiers of prescribed accommodation and the community generally.

Consumer protection legislation and civil litigation

Trade practices legislation, fair trading legislation and the common law are not sufficient to correct market failures in the hairdressing, beauty therapy and skin penetration markets. This is principally because these Acts and the common law are reactive to adverse events as a result of unsafe practices rather than preventative.

12.9 Conclusion

The requirement that premises from which certain businesses are conducted be registered is one of the numerous ways through which the Health Act attempts to control the spread of infectious disease. Whilst the degree of risk associated with each activity varies significantly, hairdressing, beauty therapy and skin penetration all pose risks to the community of the spread of infectious diseases. The range of those diseases varies from the very treatable but inconvenient case of head-lice through to blood borne viruses such as Hepatitis and HIV. The cost to business is not high but the benefits from having clean and hygienic establishments are significant. These benefits are not only to the broader community in the reduction of potential health care costs but also to the businesses which benefit from the education they receive in this area and the establishment of a level playing field where all those involved in the same business are required to observe the same standards of sterilisation and hygiene. Those that do go to the cost of ensuring compliance with proper hygiene standards are therefore not disadvantaged through competition with those who may place the health of clients at risk.

12.10 Recommendation

12.10.1 That the Health Act continue to register premises from which the activities of hairdressing, beauty therapy and skin penetration procedures are conducted.

Appendix I

Terms of Reference for the National Competition Review of the Health Act 1958

Government of Victoria
National Competition Policy Review of Legislative Restrictions on Competition

Review of the Health Act

Terms of Reference

The review of the HEALTH ACT 1958 has been commissioned by the Minister for Health in accordance with the Victorian Government *Timetable for the Review and Reform of Legislation that Restricts Competition,* determined in accordance with National Competition Policy.

Legislation to be reviewed

The review will examine the case for reform of legislative restrictions on competition contained in the Health Act and Health (Infectious Diseases) regulations, Health (Prescribed Accommodation) regulations and Health (Pest Control) Operators regulations, in accordance with the Victorian Government's *Guidelines for the Review of Legislative Restrictions on Competition.*

In particular the review panel will:

- Clarify the objectives of the legislation;
- Consider the general efficiency and effectiveness of the legislation;
- Identify the nature of the restrictions on competition;
- Analyse the likely effect of the restriction on competition and on the economy in general;
- Assess and balance the costs and benefits of the restriction; and
- Consider alternative means of achieving the same result including non-legislative means.

Reform Options

Without limiting the scope of the review, the review should specifically address the appropriateness of regulating premises where certain activities are conducted, and regulating miscellaneous matters pertaining to public health while continuing to ensure a high standard of public health is maintained. The review should also consider the harmonisation of public health controls to maximise efficiency where regulation is considered necessary.

Review Arrangements

This review is to be established and conducted in accordance with the In-House Review model contained in the Guidelines.

Key Dates

The review will report its findings and recommendations to the Minister by **May 1999.**

Secretariat

The review secretariat will be located in DHS. The Secretariat can be contacted on:

Phone	9637 5509
Facsimile	9637 5510
Address	Level 18, 120 Spencer Street Melbourne
Postal	NCP Legislative Review Public Health Division DHS GPO Box 1670N Melbourne Vic 3001

Appendix II

Review Panel

Dr Jacqueline Goodall - Chair

Dr Goodall is employed as a Legislation Officer with DHS. Dr Goodall has previously been employed as Senior Legislation Officer with the Health Department of Western. Responsibilities in this position included detailed research, development and review of Health legislation. Dr Goodall is currently on secondment to the Public Health Division to assist in the review of the Health Act for the purpose of National Competition Policy and as part of the broader framework of review of that Act.

Dr Goodall is not, at present, engaged in the operation or regulation of the matters regulated under the Health Act or its regulations and therefore satisfies the independence requirements of the In-House Review model contained in the Guidelines.

Ms Carmel Benham

Ms Benham is a Barrister and Solicitor of the Supreme Court of Victoria and has been employed as a Legal Officer with DHS since 1992. Ms Benham's responsibilities have included the provision of advice to the Department on a wide range of matters and the amendment of a number of pieces of legislation administered by the Department. Ms Benham is currently on secondment to the Public Health Division to assist in the reviews of a number of Public Health Acts for the purpose of National Competition Policy and as part of the broader framework of review under the National Public Health Partnership Legislative Reform Working Group.

Ms Benham is not, at present, engaged in the operation or regulation of the matters regulated under the Health Act or its regulations and therefore satisfies the independence requirements of the In-House Review model contained in the Guidelines.

Ms Lucy Middleton

Ms Lucy Middleton is the Team Leader, Legislation and Cemeteries Unit in the Public Health Division and has been employed by DHS since 1989. Ms Middleton has worked in a number of different Divisions within the Department and has extensive program experience within the Health and Community Services portfolios, including experience in the amendment of legislation administered by the Department.

Ms Middleton is not, at present, engaged in the operation or regulation of the matters regulated under the Health Act or its regulations and therefore satisfies the independence requirements of the In-House Review model contained in the guidelines.