Executive Summary

I. Overview of the Report

This report reviews current regulatory approaches relevant to "safe design", that is, a strategic approach concerned with eliminating hazards and controlling risks to health and safety "at the source", as early as possible in the life cycle of designed-products. This review is a basis for exploring possible future directions for regulation and enforcement, to lead and encourage safe design.

In **Parts One to Four**, the report discusses regulatory approaches and strategies to safe design that are currently used in Australia and in some overseas jurisdictions. The regimes reviewed include: the Australian OHS statutes and subordinate legislation; the regulation of machinery safety and construction site safety in the European Union; the product safety provisions of Australian trade practices law; building safety requirements; and the regulation of electrical equipment safety in Australia. The application of common law principles of negligence to designed-products is also discussed. While examples were sought from other countries, the European regimes provide the most developed examples of regulation relevant to safe design.

The report presents some detail about each of the regulatory regimes, for readers who would like to understand how specific regimes operate. To the extent relevant to a particular regime, the discussion of that regime is structured to cover: (1) the relevant legal instrument(s), (2) the area of law and its administration (3) scope and application of the law; (4) who has responsibility; (5) the core provisions and elements of the legislation; (6) whether, and if so how, the duties are qualified; and (6) enforcement matters. However, for readers who prefer a shorter summary, "Progressive Summaries" are presented throughout the report to provide an overview of key information.

The report is structured to address regulation relevant to four types of designed-products: (1) plant; (2) buildings, structures and other construction projects; (3) business systems; and (4) substances. This is not an exhaustive set of designed-products. However, these are key sources of risks at work and some of the principal examples of regulation relevant to safe design are represented by these products.

Parts Five and Six of the report draw together the preceding discussion of regulatory regimes to consider possible future directions for regulation and enforcement of safe design. Some broad principles and elements are canvassed. These principles and elements are not presented as a "blueprint" but rather as the basis for discussion of possible features of safe design regulation and enforcement policy. It is proposed that they be considered in relation to each of the designed-products to determine approaches suitable for each. They can also be applied to other designed-products, as appropriate.

II. Key Insights from the Review of Regulatory Regimes for Safe Design

(i) Plant - Machinery, Equipment, Appliances and Tools

The Australian OHS statutes and regulations expect upstream parties to address OHS matters in relation to plant. In broad terms there are duties to ensure that plant is designed and constructed so that it does not present risks to safety or health. There are also requirements to apply a risk management process, to test or examine plant, to provide information, and for design verification for certain high risk plant. Australian OHS law creates somewhat different responsibilities in each Commonwealth, state and territory jurisdiction. There is variation both in regard to which upstream parties have responsibilities and the nature of the duties. These differences are compounded by differences in OHS regulations and evidentiary standards. This variable regime is problematic, especially in relation to the upstream duties, as plant is supplied between jurisdictions within Australia, as well as into and out of this country. If regulation is to encourage and enable safe design of plant, consistency and clarity about what is required are essential characteristics. The features and sources of variation in the Australian OHS regulation of plant are discussed in **Section 3**. There is scope both to address the issue of national consistency and also to consider the nature of provisions, to establish provisions that effectively lead and support upstream parties to ensure safe design.

In the European Union, the *Machinery Directive* is concerned with the safe design of plant as well as critical safety components of plant. This regime is reviewed in **Section 4** of the report. An interesting feature of this regime is the requirement to address "essential health and safety requirements" which draw attention to a comprehensive range of hazards and problems that could arise with plant. However, manufacturers (or others responsible) may choose to apply relevant harmonised standards. These are an important source of technical guidance about safe design and construction for particular types of plant or safety components, as well as for particular aspects of OHS, for example ergonomic aspects, and for processes such as risk management. There is a “presumption of conformity” for machinery and components that comply with relevant standards. Most plant is subject to a process of self-assessment by the manufacturer who maintains a technical construction file with details of the design and how OHS has been addressed. However, third party technical assessment, by an independent and competent, “notified body” is required for some types of plant. This is the “EC type examination”. Before plant can be placed on the market or put into service the CE mark must be applied and a “declaration of conformity” is made by manufacturer, declaring that the plant complies with relevant essential health and safety requirements. There are elements of the European Union's regime that are worth considering in Australia.

Unlike Australian OHS law or the European Union's *Machinery Directive*, which have a preventive focus, the Australian *Trade Practices Act 1974* (TPA) focuses principally on the kind of action that can be taken against a corporation (manufacturer or importer) for supply of goods in an unsafe or defective condition. There is less focus on preventive health and safety requirements. Nonetheless, as discussed in **Section 5**, action can be taken to restrict or prohibit supply of unsafe goods. There is provision for gazettal of warning notices, restrictions on supply, a permanent ban or compulsory recall of unsafe goods. Voluntary recalls of defective goods are encouraged and must

be notified. A range of sanctions are also established by the TPA including fines, Court imposed injunctions to prevent specific conduct, Court orders to disclose information in a public advertisement and enforcement of undertakings entered into with the regulatory authority. There may be opportunities for cooperation between OHS inspectorates and the Australian Competition and Consumer Commission (or its state/territory counterparts). Some of the TPA's strategies to remedy product safety problems are also worth considering as part of an OHS regulatory regime for safe design.

Some items of equipment that are electrically powered are subject to specific regulation by electrical regulatory authorities in Australia, as discussed in **Section 6**. A uniform approvals scheme, is administered by state/territory authorities. This involves testing by an accredited testing facility, approval and application of an approval number before the equipment can be placed on the market. The system aims to regulate both locally made and imported electrical equipment, with a focus on pre-sale compliance and compliance checks by enforcement officers at sale outlets. The requirement for an approval number on designated items provides enforcement officers and purchasers with a means to check compliance. A national register is maintained (by the Queensland authority) of recalled electrical equipment.

In summary, the review of Australian OHS law in relation to plant as well the regulatory regimes for machinery safety in Europe, and the regimes for product safety and electrical equipment in Australia, highlights some potential problem areas as well as some opportunities to enhance the regulation of safe design in Australia. These ideas are developed in Part Two of the report and summarised in the 'Conclusions About Regulation for the Safe Design of Plant'.

(ii) Buildings, Structures and Other Construction Projects

Traditionally, the Australian OHS statutes have not regulated safe design in relation to buildings and structures. They have focused on the construction phase, where the responsible parties are the principal contractor or sub-contractors, with responsibilities under the duties of care of employers and self-employed persons. However, the South Australian OHSW Act and regulations, and the Western Australian OSH Act do address this. The South Australian legislation is the most developed as it quite comprehensively identifies a range of OHS matters to be addressed by duty holders from designers and owners of buildings, to designers of structures, manufacturers, importers and suppliers of structural materials and those who erect structures. The SA regulations provide a useful model for identifying a range of OHS matters to be addressed by upstream parties. This approach is discussed in **Section 7**.

The *Building Code of Australia* (BCA) is the principal instrument for regulating the activities of architects, engineers and others involved in the design of buildings and some structures. This is discussed in **Section 8**. The BCA does cover a range of health and safety matters but a number of OHS matters relevant to design are not addressed. In particular the BCA is not concerned with safe design to minimise risks to those involved in the construction phase. The approach taken by the BCA may be a useful model for safe design regulation. It allows designers flexibility to select materials, components, forms of construction and designs that suit a particular building or

structure. In particular, it does this by a mix of mandatory performance-outcome provisions that establish the required level of performance, and building solutions that set out a means of complying with the performance requirements. (See Section 2.5 for an explanation of types of provisions). As the primary reference point for building designers the BCA is arguably the most logical place to incorporate requirements for safe design, to address OHS for those involved in the construction phase as well as end use and occupancy. However, this would involve a change in the scope of the BCA. An alternative approach would be to adopt the BCA approach, with which designers are familiar, but to apply this approach under the OHS statutes.

In the European Union, a rather different approach has been taken through the *Construction Site Directive* which has now been transposed into national legislation by all Member states. The Directive is outlined in **Section 9**. It is concerned with improving planning and coordination in the design and the construction phases of building and civil engineering construction projects. The “client” (the person for whom a project is carried out) or the “project supervisor” (a person acting on behalf of the client) have primary responsibility. Employers and self-employed persons are also responsible during the construction (project execution) phase. In most Member states, designers do not have specific obligations although they do have a role to play. Coordinators appointed by the client are expected to work with designers to facilitate attention to OHS issues in the design phase. Some countries take this further by designating specific responsibilities for designers. Key requirements are the development of a “safety and health plan” and a “safety and health file”. Construction projects must also be notified to the relevant competent authority.

An aspect of the *Construction Site Directive* that is of particular interest is the emphasis on safe design to address OHS risks to those involved in construction as well as maintenance, repair and cleaning of the finished structure. However, the evidence so far about the effectiveness of this Directive and the associated law of member states is at best equivocal. There are grounds to consider whether a regulatory regime based on coordination and development of documentation, in the form of OHS plans and OHS files, is the appropriate approach for an industry in which small business is predominant. There is also concern that designers of construction projects may need more assistance in identifying construction methods, components and materials that meet traditional design criteria of fitness for purpose and aesthetics, as well as the OHS aspects of constructability. In this regard, designers may be assisted by development of OHS performance-outcomes and design solutions (an approach similar to the BCA).

In summary, the review of Australian OHS law in relation to buildings, structures and other construction projects, as well the regulatory regimes for building safety in Australia and construction site safety in Europe, highlights some gaps in the regulation of safe design in this area, as well as some opportunities to enhance regulation in Australia. These ideas are developed in Part Three of the report and summarised in the 'Conclusions About Regulation for Safe Design of Buildings, Structures and other Construction Projects'.

(iii) Business Franchising Systems

The blueprint for operating a business franchising system developed by a franchisor may specify the form of work premises, machinery and equipment, substances and work methods (or some combination of these) to be used by the franchisee and his/her employees. The system design and plans developed by the franchisor may significantly influence the OHS of those working to the blueprint, in business franchises downstream. While a well-designed system can enhance health and safety, a poorly designed one can impose risks on others that may be difficult for the franchisee (as the employer) to address in the context of the binding contractual agreement of the franchise. As discussed in **Section 10**, some of the duties under the Australian OHS statutes may apply to franchisors, subject to specific contractual arrangements. However, none of them specifically apply to business franchising systems. Some starting points for regulation in this area are the duties of employers and self-employed persons to others under the Victorian and Queensland OHS statutes, which require attention to risks arising from the "conduct of the undertaking". However, this is a very broad duty. It would be helpful to clarify the kinds of risks that a franchisor should address.

(iv) Workplace Substances

Internationally, the established approach to regulating workplace substances begins with the testing and evaluation of substances in order to classify their toxicological as well as physico-chemical properties. This information then provides the basis for producing labels and material safety data sheets. As discussed in **Section 11**, the Australian regime for regulating workplace "hazardous substances" is consistent with this and applies European directives on classifying substances. The Australian regime for "dangerous goods" is also consistent with international requirements. Arguably there is scope to place greater emphasis on safe design in the development of workplace substances by emphasising: (1) elimination of particularly hazardous ingredients or substances; (2) modification of substances, for example, by changing chemical composition of composite materials, mixtures and formulations; (3) designing packaging to minimise risk of hazardous exposure; and (4) elimination or control of risks in the design of processes for the manufacture of substances (controlling risks at source for workers exposed to substances in production). In this regard, it is noteworthy that the Australian OHS statutes typically require upstream parties to ensure that substances are "safe and without risks to health". It is doubtful whether this could be satisfied, in the case of particularly hazardous or dangerous substances, by classification and information provision alone.

III. Principles and Elements of Regulation for Safe Design

In **Part Five, Section 12** we outline some principles and elements to be considered in developing possible future directions of regulation to promote safe design. The principles and elements are not necessarily exhaustive, nor are they all necessarily applicable to each type of designed-product. It is suggested that they provide a basis for determining regulatory approaches most applicable to particular types of designed-products, as it is likely that they will require somewhat different approaches.

The following matters are discussed in this part of the report:

(i) Options for achieving **a nationally consistent regulatory regime** including: (1) template OHS legislation adopted in an identical form by each jurisdiction; (2) national OHS legislation adopted by the Commonwealth government using a relevant Constitutional "head of power"; or (3) integration of OHS requirements for safe design into another national or nationally coordinated regulatory regime, for example the *Building Code of Australia 1996* or the *Industrial Chemicals (Notification and Assessment) Act 1989*.

(ii) Approaches to assigning **responsibility** by either: (1) assigning the same duties to any person responsible for procurement, design, manufacture, construction, import, supply, installation, erection, commissioning (as appropriate to each designed-product), requiring that OHS is addressed as far as “practicable”, and to the extent of the person's control; or (2) assigning different duties to different parties, for example, so that a person who designs has different duties to a person who supplies.

(iii) Core **processes for systematic management** of safe design, that is: (1) risk management; (2) testing and examination; and (3) information provision. For each of these core processes we discuss the importance of guiding and focusing the activities of those involved in safe design by defining OHS performance outcomes and/or providing guidance in the form of evidentiary standards.

(iv) Use of **performance-outcome provisions** to define OHS outcomes to be achieved while leaving open the means for achieving them.

(v) Use of **evidentiary standards**, including technical standards, to describe acceptable methods or ways of achieving OHS outcomes.

(vi) **Technical assessment or design verification** as a means of ensuring that OHS matters have been addressed with high risk products before they are placed on the market. This requires the involvement of independent and technically competent persons and agreed technical criteria or standards.

(vii) Forms of **documentation** to record action taken to address OHS, for example, by technical files and OHS plans, to assist inspectors, procurers and third party assessors to evaluate safe design.

(viii) Application of a **safe design mark** and **declaration of conformity** to signal that action has been taken to address safe design matters.

(ix) **Notification** as a process of alerting relevant authorities to particular designed-products, early in the life cycle, to enable a strategic response.

(x) Definition of **OHS competencies** for safe design as a strategy to ensure that those involved in safe design functions are equipped with relevant OHS knowledge and skills.

(xi) Use of the expression "**practicability**" (as applied in each jurisdiction) to provide the necessary qualification of duties, and removal of the expression "when properly used" as it gives a false impression about reliance on warnings rather than ensuring that a designed-product is inherently safe, as far as "practicable", and conflicts with the common law.

IV. Principles and Elements of Enforcement Policy for Safe Design

In **Part Six, Section 14** we outline some principles and elements to be considered in developing possible future directions for enforcement policy tailored to safe design. As with the discussion of regulatory provisions for safe design discussed in Part Five. The principles and elements of enforcement policy are not necessarily exhaustive, nor are they all necessarily applicable to each type of designed-product. It is suggested that they provide a basis for determining enforcement responses most applicable to particular types of designed-products.

The following matters are discussed in this part of the report:

(i) The need for enforcement policy to make an explicit **commitment** to address safe design in the enforcement activities of OHS authorities.

(ii) **Consistent enforcement policy and practice** across jurisdictions and for equivalent circumstances, so that the same response is applied to contraventions of a similar type, wherever they occur in Australia, and whether they arise in relation to "Australian-made" or imported products. A consistent approach to enforcement requires a cooperative and coordinated approach by enforcement agencies, applying a consistent range of enforcement strategies and sanctions.

(iii) **Strategic enforcement** which emphasises a proactive, targeted approach to enforcement. The most suitable enforcement measures may not be the same as those used for regulating the actions of employers or workers. In particular, enforcement should be aimed at preventing unsafe designed-products from entering the market, or being put into use, or being constructed (in the case of buildings and structures). Measures are also required to deal with unsafe products that are identified, that ensures that the relevant upstream parties take appropriate action to remedy the situation.

(iv) **Responsive enforcement** which involves tailoring the response to the nature of non-compliance and taking into account compliance history. It begins with efforts to inform and persuade responsible parties and provides for an escalation of response when this is warranted. Duty holders have the opportunity to comply voluntarily with advice and guidance, but a range of alternative action might be taken if non-compliance persists.

(v) **Measures to persuade** and promote voluntary compliance including:
   (a) *engaging* with upstream duty holders to discuss how OHS performance-outcome provisions have been addressed and/or how relevant evidentiary standards applied;
   (b) *auditing safe design management practices*, focusing on the core processes and arrangements for risk management, testing and examination of products; and information provision;
   (b) *voluntary third party technical assessment* to enable confirmation, from a competent authority, that hazards have been adequately identified and eliminated or controlled;
   (c) *auditing of procurement practices* in employers' OHS management systems to ensure that purchasing procedures, contracts procuring specific items, design briefs and tender documents specify OHS requirements;
   (d) *voluntary notification of unsafe products* to OHS inspectorates (by procurers) where the purchaser's efforts to have problems rectified by the "supplier" are unsuccessful;
   (e) voluntary implementation of a "*safe design compliance program*" which involves establishing systems to manage safe design requirements. Such an agreement could also be the basis of an agreed undertaking with the OHS authority (that is, an "enforceable undertaking", see (vi)(c) and (viii (d) below);
   (f) v*oluntary recall* of hazardous products (or components) and notification to the relevant authority.

(vi) Measures to give **formal direction** to duty holders:
   (a) *targeted inspections and audits* with follow up direction;
   (b) issue of *improvement and prohibition notices* to give formal direction in relation to contraventions (which would require amendment of the OHS statutes in some jurisdictions);
   (c) requirement to enter into an *enforceable undertaking* with the relevant authority, for example, to establish a "safe design compliance program" or to review and improve a design to the satisfaction of the regulator (breach of such an undertaking would be enforceable by the court).

(vii) Measures to **warn and protect procurers** of designed-products:
   (a) investigation of hazardous designed-products and publication of a Ministerial *warning notice* in the relevant government *Gazette* advising of specific product risks and action taken to restrict supply or use;
   (b) investigation of hazardous designed-products and publication of a Ministerial notice advising of *mandatory product recall* and/or *restrictions on sale* and/or *advice* to procurers.

(viii) Measures to **deter non-compliance**:
   (a) *penalty or infringement notices* ("on-the-spot" fines) for specific safe design offences;
   (b) refusal of *design registration* (eg high risk plant) or *approval* of a new development (eg construction projects or hazardous substances);
   (c) investigation of a hazardous designed-product and *prohibition of supply* by publication of a Ministerial notice in the relevant government *Gazette*;

(d) e*nforcement of undertakings* entered into with the relevant authority, where the undertaking has been breached - if the inspectorate considers that the person who gave the undertaking has breached any of its terms, it may apply to the Court for an order to direct the person to comply, to pay a fine, or to make another order ;

(e) application by the relevant authority to the court to grant an *injunction* in relation to particular conduct;

(f) investigation and *prosecution* of serious and/or persistent breaches (amendments are required to most OHS statutes so that the time period for initiating a prosecution commences from the time the alleged offence is detected, for example, 18 months from detection of the alleged offence); and

(g) penalties imposed by a court if a prosecution is successful to include:
- *fines* (set at the same level in all jurisdictions);
- *court order* to disclose information and/or publish an advertisement; and
- other forms of *corporate probation* such as an order to implement arrangements to manage safe design processes.

V. Summary

In summary, there is a range of possible futures for regulation to promote safe design and for enforcement policy to persuade, direct, warn and deter. The regulatory regimes reviewed in this report provide considerable food for thought. They are presented in some detail to enable readers of this report to draw on different sources in developing proposals. The key principles and elements discussed in Parts Five and Six of the report are designed to give some focus to discussion of possible future regulation and enforcement of safe design. In determining the best "mix" of regulatory provisions and enforcement strategies it should be kept in mind that behavioural change occurs with the right balance of elements to develop knowledge, capacity and motivation to comply.