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The analysis and regulation of safety risk

A survey of the practices of National and Commonwealth regulatory agencies

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A survey of the practices of National/Commonwealth regulatory agencies

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CONTENTS

ABBREVIATIONS

ABS	anti-lock braking system
ADI	acceptable daily intake
ADR	Australian design rule (for road vehicles)
ARL	Australian Radiation Laboratory
ARTG	Australian register of therapeutic goods
BASI	Bureau of Air Safety Investigation
CAA	Civil Aviation Authority
CAR	civil aviation regulation
CSU	Chemicals Safety Unit
EC	European Community
EIA	economic impact assessment
EPA	Environment Protection Agency
EWG	expert working group
FAA	Federal Aviation Administration (US)
FBCA	Federal Bureau of Consumer Affairs
FDA	Food and Drug Administration (US)
FORS	Federal Office of Road Safety
GMP	good manufacturing practice
ICAO	International Civil Aviation Organisation
ICRP	International Commission for Radiological Protection
IPCS	International Programme on Chemical Safety
ISO	International Standards Organisation
NFA	National Food Authority
NHMRC	National Health and Medical Research Council
NOEL	no observable effect level
NOHSC	National Occupational Health and Safety Commission
NRA	National Registration Authority for Agricultural and Veterinary Chemicals
NRTC	National Road Transport Commission

OECD	Organisation for Economic Co-operation and Development
OHS	occupational health and safety
ORR	Office of Regulation Review
RIS	regulation impact statement
TGA	Therapeutic Goods Administration
TGC	Therapeutic Goods Committee
US	United States of America
VMD	vehicle monitoring device
WHO	World Health Organisation

INTRODUCTION

People encounter many types of risk in daily life, and governments face pressures to act to moderate the likelihood and consequences of adverse events. For example, governments are often called on to regulate to limit risks taken by certain financial institutions, to help cover losses from certain investments, to subsidise insurance against common occurrences such as the risk of illness, or to provide financial and material support in case of events such as droughts and floods.

Safety risk is a generic class of risk which is extensively regulated by governments, but some policy analysts have questioned the efficacy of safety regulation. This is partly because high economic costs are involved, but mostly because of the problems which can arise due to the range of pressures regulatory agencies face when dealing with particular safety issues.[1]

In May 1993, the Office of Regulation Review (ORR)[2] commenced a survey of National and Commonwealth regulatory agencies to ascertain how they currently develop and implement regulation to reduce safety risk in Australia. After receiving the agencies' responses, the ORR sent out follow-up questions and met with some of the agencies to discuss their responses. Delays in receiving responses from some key agencies, both to the initial survey and follow-up questions (last responses received February and July 1994 respectively), delayed the project. In September 1994, the ORR sent a draft of this paper to the agencies for comments and corrections. A further draft was distributed for final comments in December 1994.

The agencies which responded to the survey are:

- Australian Radiation Laboratory (ARL);
- Civil Aviation Authority (CAA);
- Chemicals Safety Unit (CSU);
- Federal Bureau of Consumer Affairs (FBCA);
- Federal Office of Road Safety (FORS);
- National Food Authority (NFA);
- National Occupational Health and Safety Commission (NOHSC);
- National Road Transport Commission (NRTC); and
- Therapeutic Goods Administration (TGA).

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1 See Industry Commission, *Annual Report 1991-92*, AGPS, Canberra, 1992, pp. 179-182.

2 The ORR — located within the Industry Commission — provides advice on the Commonwealth Government's regulation review policy. Amongst other things, the ORR advises Cabinet on regulatory proposals affecting business, liaises with departments and agencies in the development of regulation, and comments publicly on regulatory issues.

In addition to these nine agencies, the ORR sought responses to the survey from another four, namely: the Australian Maritime Safety Authority, the Australian Quarantine and Inspection Service, the Environment Protection Agency (EPA), and the National Registration Authority for Agricultural and Veterinary Chemicals (NRA).

Despite follow-up contacts with these agencies, no responses were forthcoming. EPA did not submit a response because it has limited involvement in direct safety risk regulation. In the case of NRA, it indicated that it was unable to respond due to work loads on the agency during its establishment.

In this paper, the ORR documents the responses received. The paper follows the format of the survey itself. Each question is followed by an overview of the agencies' responses which draws out key points and common themes, and then the specific response of each agency is generally set out. In some cases, the agencies' responses have been augmented with other publicly available information. A summary and digest of the agencies' approaches to analysing and regulating safety is presented towards the end of the paper. The paper has been compiled by Tom Nankivell. The ORR records its appreciation for the contribution of the agencies which responded to this survey.

ABOUT THE AGENCIES

Question 1:
Agencies' structures, functions, staffing and funding

What is your agency's main function? How many people does it employ? What are their main areas of expertise (for example, scientific, engineering, medical, economic, legal, humanities)? What is your agency's level of funding?

Question 2:
Risk categories and regulatory responses

What are the main types of safety risk that your agency seeks to regulate against (for example, hazardous chemicals, road safety, health/environmental risks)? Give some examples of regulations developed by your agency to reduce safety risks.

The agencies which responded to this survey take three main institutional forms:

- the three national agencies (NFA, NOHSC, NRTC) are constituted under Commonwealth Acts of Parliament. Their powers are exercised by members or commissioners who are statutory appointees. Attached to these agencies are offices which provide technical and administrative support. The office attached to NOHSC has been given a separate identity — Worksafe Australia[3];
- CAA, while falling within the Commonwealth's Transport portfolio, is constituted under its own Act and operates as a government business enterprise. CAA's statutory safety regulation functions are carried out by the Directorate of Aviation Safety Regulation which reports directly to CAA's Chief Executive Officer[4]; and
- the other agencies are divisions or branches within the relevant Commonwealth Government departments.[5]

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3 As well as servicing NOHSC, Worksafe Australia also has prime responsibility for the administration of the National Industrial Chemicals Notification and Assessment Scheme.

4 The Commonwealth Government announced in October 1994 that the Directorate of Aviation Safety Regulation will be reconstituted as a separate and independent statutory authority called the Aviation Safety Agency. Brereton, L. (Minister for Transport and Industrial Relations), 'New Aviation Safety Arrangements',*News Release*, 12 October 1994.

5 FBCA is a division of the Attorney General's Department; FORS is a division of the Department of Transport; and TGA is a division of the Department of Human Services and Health. ARL is a branch of the Office of the NHMRC, and CSU is a branch of the Health Advancement Division, both located within the Department of Human Services and Health.

The main regulatory functions undertaken by the agencies are:

- *researching problems* which may require regulation;
- *promulgating standards* that products, processes or personnel of a certain type are legally required to meet. (Technically, the agencies themselves do not enact legislation or enable regulations. Rather, as discussed in question 3, they make recommendations to Ministers or Ministerial Councils on these matters);
- *authorising products* (or processes or personnel): this involves testing and/or certifying that particular products, processes or personnel meet requisite safety standards, before they can be sold or deployed;
- *excluding products* (or processes or personnel): this involves banning or recalling particular products, processes or personnel, normally after safety problems become apparent;
- *monitoring compliance* with regulations; and
- *enforcing regulations.*

Table 1 shows the functions undertaken by the different agencies. CAA, FBCA, FORS and TGA have the greatest spread of functions.

Some of the agencies, whilst not undertaking a particular function themselves, provide advice or have input into the regulatory functions of other agencies. For example, CSU provides technical advice to the NRA, NFA, the National Drugs and Poisons Scheduling Committee, and certain National Health and Medical Research Council (NHMRC) committees — in areas such as toxicology, water quality and air quality. ARL provides logistics support and the secretariat for the NHMRC's Radiation Health Standing Committee, and the head of ARL chairs the Committee. In practice, ARL is the principal drafting source for NHMRC codes of practice dealing with radiation. FORS has input into road transport regulations developed by NRTC.

In addition to these main regulatory functions, some agencies also have other functions. For example, some undertake public education or provide policy advice to Ministers. Of the agencies surveyed, however, CAA alone is required to supply commercial services to the industry it regulates.

Table 1: Main regulatory functions, by agency

Agency	*Research problems*	*Promulgate standards*	*Authorise products etc*	*Exclude products etc*	*Monitor &/ or enforce*
ARL	✓	☑		☑	
CAA	✓	✓	✓	✓	✓
CSU	✓	✓	☑	☑	
FBCA	✓	✓		✓	✓
FORS	✓	☑	✓	✓	✓
NFA	✓	✓	☒	✓	
NOHSC	✓	✓			
NRTC	✓	✓			
TGA	✓	✓	✓	✓	✓

☑ ARL, CSU and FORS do not formally undertake these functions themselves. Rather, th provide advice to, or operate on behalf of, other agencies that do (see text

☒ While variations to the Food Standards Code act in some respects like a pre-marke assessment scheme, products do not need individual authorisation prior to being marketed See question 4 for more detail

The main areas of safety risk covered by the agencies surveyed are set out in Table 2, and are reflected in the names of the agencies.

The risks regulated against vary in terms of their time frame. Some of the risks are immediate or acute, as in the risk of death or injury from motor vehicle accidents. Others, such as the risk of contracting cancers from ongoing exposure to low levels of radiation, are of a longer term or chronic nature.

Two types of trade-offs arise in the safety matters examined by the agencies:

- *risk-cost trade-offs:* these occur where action to reduce the level of safety risk increases the cost (or reduces the usefulness) of the product or process that causes the risk; and
- *risk-risk trade-offs:* these occur where action to reduce the level of safety risk associated with one aspect of a product or process may increase other types of safety risk.

Most of the safety problems addressed by the agencies surveyed involve risk-cost trade-offs. One example is the vehicle safety issues confronting FORS and NRTC. Action to improve the safety of vehicles, such as mandating improved occupant protection standards, will generally increase the costs of vehicles. In the area of food standards, the longer and more detailed is the scrutiny of new food products (to increase the level of confidence in their safety), the greater are the costs incurred by both the firm and the regulatory authority.

Only two agencies (NFA, TGA) appear to deal with safety problems involving largely risk-risk trade-offs. TGA deals with drugs and devices which are essentially intended to have therapeutic benefits, but which also carry the risk of adverse side-effects.[6] Actions to reduce the risk of side-effects, such as lowering the active ingredients in drugs, will generally increase the health risk associated with the drugs not working. Further, the longer and more detailed are drug testing procedures to ensure their safety, the greater will be the delay before new drugs (which could save or improve lives) are supplied to the market. Some issues falling within NFA's purview, particularly those relating to food additives, also involve these types of trade-offs. For example, the use of preservatives and anti-oxidants can reduce the health risk (and, indeed, the cost) of food spoilage while increasing the health risks which may be associated with chemical additives.

As well as the types of safety risks covered, Table 2 lists and provides examples of the main regulatory instruments used by the agencies. They include standards, codes of practice, forms of certification and licensing, and product bans and recalls.

Information on the agencies' staffing and funding levels is set out in Tables 3 and 4 respectively. The data give a reasonable indication of the size of the agencies and their main areas of expertise, although in some cases they are not directly comparable and should be treated accordingly.

6 TGA pointed out that, in the field of therapeutic goods, it is more common to speak of 'risk-benefit' ratios than 'risk-risk' trade-offs. TGA indicated that the aim of work in this field is to increase the 'therapeutic index' by increasing the benefit of a drug whilst minimising the risk.

Table 2: Safety risks and regulatory responses, by agency

Agency	*Safety risk*	*Types of regulation*	*Comment/Examples*
ARL	occupational, public and medical exposure to ionising and non-ionising radiation	• standards	Australian radiation protection standards relating to ionising radiations, power lines, micro-wave, and ultra-violet light.
		• mandatory codes	Codes of practice for the above standards, which are usually attached as mandatory conditions to State and Territory licences.
		• permits	ARL advises Customs regarding the need for permits for the import of radioactive material for use in medicine, industry and research.
CAA	air safety risks	• standards	Civil Aviation Regulations (CARs) for the design, operation and maintenance of aircraft, aerodromes, air routes, airway facilities and for related personnel, eg CAR 214: Training of maintenance personnel CAR 218: Route qualifications of pilots in command of regular public transport aircraft CAR 221: Facilities and safety devices for the public.
		• registration/certification licensing/permits	To apply the above standards, CAA issues pilots' licences, air worthiness certificates, flight permits etc, eg: certification of new air service operators to ensure that they comply with CARs.
CSU	health hazards arising from chemicals	• standards	Poison scheduling of chemicals, environmental health standards (eg: air, water, soil), and standards for labels and warning statements regarding safety and first-aid directions.
		• registration	CSU provides advice to bodies such as NRA regarding chemicals for registration.

Table 2 cont'd

Agency	*Safety risk*	*Types of regulation*	*Comment/Examples*
FBCA	unsafe consumer products	• standards	Mandatory standards for children's toys, motorcycle helmets, motor vehicle child restraints, bean bags and cosmetics labelling.
		• product bans and recalls	Bans on smokeless tobacco products, glucomannan in tablet form and 'Diveman' underwater breathing apparatus.
FORS	road safety and health/ environmental risks	• standards	ADR 37: Emission control for light vehicles ADR 68: Occupant protection in buses ADR 69: Full frontal impact occupant protection.
		• certification	Certification of new vehicles to ensure compliance with ADRs.
		• voluntary codes	Codes of practice for industry relating to particular matters.
		• product recalls	FORS may request the Minister for Consumer Affairs to recall certain products.
NFA	public health risks associated with diet and the food supply	• standards	Food Standards Code: A1: Labelling and advertising A3-A9: Food additives A14: Residues in foods.
		• product recalls	NFA may request the Minister for Consumer Affairs to recall certain products. To date, NFA has mainly negotiated 'voluntary' recalls relating, for example, to certain smoked salmon.
		• voluntary codes	Codes of practice relating, for example, to hygiene matters.

Table 2 cont'd

Agency	*Safety risk*	*Types of regulation*	*Comment/Examples*
NOHSC	workplace health and safety matters	• model standards	National Standards for Occupational Noise National Health and Safety Standard for Plant Model Regulations for the Control of Workplace Hazardous Substances.
		• voluntary codes	Codes of practice for meeting the above standards. Currently, these codes formally confer 'deemed to comply' status for these standards in two States.
NRTC	road accidents and health/environmental risks	• standards	Standards/regulations for vehicle design, construction and use Mass and loading regulations for gross vehicle and axle weight loading dimensions etc Regulations for movement of very large or heavy vehicles/loads Transport of dangerous goods legislation Vehicle emission standards.
		• voluntary codes	Codes of practice which augment or, in some cases, confer 'deemed to comply' status for some of the above standards.
TGA	side-effects from therapeutic goods	• standards	Standards for drugs/medical devices, and manufacturing processes.
		• registration/listing	Registrable devices include heart valves and intra-ocular lenses; listable items include medicated throat lozenges and sun screens.
		• licensing	Licences are required for the manufacturing of therapeutic goods.
		• product recalls	TGA may request the Minister for Consumer Affairs to recall certain products.

Table 3: Agencies' staffing

Agency	*Numbers*	*Comments/Main areas of expertise*
ARL	87	Mainly scientific.
CAA	500	This is the Australia-wide figure for the CAA's Directorate of Aviation Safety Regulation. Approximately 33 officers are engaged in standards setting, comprising 2 aerodrome engineers, 1 aerodrome inspector, 4 airworthiness engineers/ inspectors, 16 flying operations inspectors, 2 operations inspectors, 2 research officers and 6 lawyers. These officers also draw on the expertise of the other staff of the Directorate and/or external consultants.
CSU	45	Sixty percent are technical/scientific experts, including expert toxicologists, pharmacologists, immunologists, veterinarians, pharmacists, environmental health experts, pathologists, biochemists and geneticists.
FBCA	54	Mainly public administration, with some qualifications in accounting, arts, economics, engineering, law and science.
FORS	82	Engineering, humanities, science and statistics disciplines.
NFA	66	Scientific, public health, legal and humanities.
NOHSC	225	Professional/medical, technical/paramedical and administrative.
NRTC	20	Engineering, economic, legal and regulation/administration.
TGA	360	Medicine, pharmacy, science, bio-engineering and administration.

Table 4: Agencies' funding, for 1993-94

Agency	*Amount*	*Comments*
ARL	≈ $8m	ARL and CSU were funded jointly under sub-program No. 1.2 — Environmental Health Standards — of the Department of Human Services and Health. Of the approximately $12m allocated to these agencies, around two thirds was allocated to ARL, one third to CSU.
CAA	$60.3m	This figure applies to the Australia-wide operations of the CAA's Directorate of Aviation Safety Regulation. $2.3m of this was allocated to the standards setting function.
CSU	≈ $4m	See comments on ARL.
FBCA	$6.5m	Relates to the FBCA's overall budget. Received from Parliamentary Appropriations.
FORS	$11.4m	Of this, $4.25m was committed to public education activities. The balance covered policy development, provision of the secretariat to several consultative committees, and activities involving research, statistics, safety, environmental and dangerous goods standards development, vehicle certification approvals, audit of vehicles manufacturing plants, inspection of test facilities and vehicle recalls. $1.33m was expended on research activities examining such matters as vehicles crash-worthiness, driver fatigue, drink driving and young driver crash risk. Summary figures are: salaries $3.81m, administration $1.97m, research $1.33m, and public education $4.25m.
NFA	$7.8m	Received mainly from Parliamentary Appropriations. NFA's actual expenses for the year were $7.0m.
NOHSC	$20.5m	Received from Parliamentary Appropriations.
NRTC	$3.3m	35% of NRTC funding is provided by the Commonwealth Government. The remaining 65% is paid by State and Territory road authorities and/or transport departments in proportion to the number of motor vehicles registered in each State/Territory.
TGA	$36.1m	Of this, $22.9m was obtained from Parliamentary Appropriations. The balance came from fees and charges.

PROCESSES FOR DEVELOPING AND PROMULGATING REGULATIONS

Question 3: Processes for formulating regulations

Describe in broad terms the process your agency uses in formulating regulations to deal with safety risks.

Most of the agencies have formal step-by-step procedures for developing regulations. In some cases (FBCA, NFA, TGA), these procedures are specified in legislation. In other cases (CAA), the agencies themselves have promulgated these procedures. FORS and NRTC have agreed to a Memorandum of Understanding which has been endorsed by the Ministerial Council for Road Transport. The Memorandum establishes procedures for developing and promulgating relevant road safety regulations.

The agencies use one or more of three broad approaches in assessing regulations:

- *Technical research:* all the agencies utilise technical/scientific research and information in assessing the merits or necessary stringency of particular regulations;
- *Consultation:* apart from CSU[7], all of the agencies consult affected parties or interest groups to elicit information, including in some cases views on the 'acceptability' of a regulation; and
- *Economic assessment:* forms of cost-benefit or cost-effectiveness analysis are used by ARL, CAA (occasionally), FBCA, FORS, NOHSC and NRTC.

There is a range of processes by which the agencies' regulatory proposals are adopted into law:

- NFA and NRTC recommendations are considered by the relevant joint Commonwealth-State Ministerial Council and then implemented via forms of parallel legislation[8];

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7 While CSU does not undertake public consultation, its advice feeds into the regulatory processes of other agencies (including NFA, NRA and NHMRC) which do consult.

8 NRTC operates on a 'template legislation' model. Under this approach, an Act containing the regulation is passed in one jurisdiction and the other jurisdictions adopt its provisions in their own law. Regarding NFA regulations, the Food Standards Code has been adopted 'by reference' in State and Territory legislation.

- ARL and NOHSC are purely advisory bodies and have no formal channel for ensuring that their standards are adopted. Rather, they must rely on State and Territory governments to adopt their recommendations in State/Territory legislation on a case-by-case basis[9]; and
- the other agencies generally operate through their Minister or processes prescribed in Commonwealth legislation.

Specific responses to this question are presented below. In general, they relate to the processes the agencies use in setting standards. The FBCA response also outlines its process for banning or recalling goods. As indicated in Table 2, other agencies formally seeking to take such measures (including FORS, NFA and TGA) must do so through the FBCA process. The response prepared for TGA is a more comprehensive statement of its regulatory activities than the other responses. It is included in full here for information — it provides an example of many of the other aspects of safety regulation undertaken by the agencies surveyed.

ARL: The staff of ARL work in scientific groups which specialise in specific areas of interest such as microwave radiation or radioactive material in the environment. These groups are familiar with current international recommendations in their area with regard to risk and control, and propagate these views in their dealings with regulatory authorities. Regulatory documents usually in the form of NHMRC Recommendations are developed by consensus with the States and Territories.

There is no direct relationship between ARL and the NHMRC. In practice, though, interaction is fairly close. This comes about because the NHMRC has a standing committee known as the Radiation Health Standing Committee to advise it on matters related to the regulation of radiation in Australia. The Standing Committee has representatives from all of the States and Territories, is chaired by ARL, and ARL also provides full secretariat functions and logistic support. It is fair to say that ARL is the principal drafting source for codes of practice which are promulgated by the NHMRC and, in many cases, act as mandatory conditions of licence within the States and Territories. Ultimately, responsibility for health resides with State/Territory jurisdictions rather than the Commonwealth.

9 The Council of Australian Governments agreed in 1992 to implement uniform OHS standards based on NOHSC proposals.

CAA: The Directorate of Aviation Safety Regulation has set down a consultation process, known as the Aviation Regulatory Proposal process, for the amendment or development of aviation standards. It generally involves the following steps:

- advertise intent;
- seek input from all interested parties;
- formulate proposal;
- reflect best international practice;
- harmonise with overseas standards where practical, and differ only where there are publicly justified reasons;
- undertake risk analysis, as required;
- circulate proposals to all interested parties;
- receive comment;
- summarise input and amend proposal as necessary;
- advise industry about the new proposal, and the reasons for change and non-acceptance of specific suggestions;
- make decision in final form; and
- promulgate (including internal and external training, education, etc, as necessary).

CSU: In determining safety risks of chemicals, CSU undertakes analysis and assessment of technical data (including studies on animals, published literature, international activities of organisations such as World Health Organisation (WHO), International Program on Chemical Safety (IPCS) and the Organisation for Economic Co-operation and Development (OECD), and information on human exposures) to:

- identify potential hazards;
- determine estimates of human exposure; and
- manage identified risks by regulating the availability of products and determining measures to minimise exposure.

The above processes involve skills in data analysis and in data extrapolation (from findings in animals to potential hazards for humans). Advice on public health aspects of chemicals are provided to relevant agencies including NFA, NRA, Worksafe Australia, NHMRC, and State and Territory governments who administer relevant legislation.

FBCA: Identified unsafe products are regulated by the Minister for Consumer Affairs using powers under the *Trade Practices Act 1974* relating to recalls, bans, information standards and product safety standards.

In broad terms, the process for banning or recalling a specific product is:

- an alleged hazardous product is identified through notifications from State, Territory or New Zealand consumer affairs agencies, other government departments, or through consumer complaints;
- the Bureau tests the product and/or seeks expert advice to confirm that the hazard exists;
- if a hazard exists, the Bureau consults suppliers to determine whether voluntary action by suppliers can remove the hazard;
- if a supplier's response to the hazard is satisfactory, the Bureau undertakes no further action other than surveillance to ensure that the supplier's response is carried out;
- if a supplier's response is not satisfactory, the Bureau advises the Minister on a course of action;
- the Minister proposes a ban or recall by signing a Gazette notice that outlines reasons for the proposed action;
- the supplier may request a conference chaired by the Trade Practices Commission to discuss the intended action;
- the Commission recommends to the Minister whether the proposed action should proceed, be modified or be abandoned; and
- the Minister takes final action.

For standards setting, the broad process used is:

- the alleged hazardous product class is identified;
- the Bureau considers what standard it can make and/or evaluates existing standards. Standards may be set by regulation or may adopt a Standards Australia standard. If an overseas standard is adopted, it must be assessed rigorously beforehand;
- consultation with all known suppliers occurs;
- the market is examined in order to set a minimum standard that has least impact on market functioning;
- when agreement has been reached, a date is set for the commencement of the standard; and
- an announcement outlining the requirements of the standard and the date of introduction is published in the Gazette.

Both the standards setting process and the enactment of bans or recalls involve the preparation of Justification Papers (although these are more important when developing standards).

FORS: Development of Australian Design Rules (ADRs) is through a consultative process involving Federal, State and Territory governments, industry, consumer groups and vehicle safety experts. ADR development is jointly managed by NRTC and FORS [see NRTC response below].

NFA: The *NFA Act 1991* sets out a process whereby any person or body may apply to develop or vary a standard in the Food Standards Code:

- when an application is received, NFA makes a preliminary assessment as to whether the standard or variation is warranted;
- if NFA accepts the application, it advises the applicant and relevant government agencies in writing; advises State and Territory authorities and the general public by publishing a notification of its acceptance in the Gazette and newspapers; and it invites public submissions on matters relevant to the application;
- NFA then proceeds to make a full assessment of the application;
- if at this stage NFA rejects the application, it notifies the applicant and relevant bodies directly, and publishes a notice in the Gazette and newspapers;
- alternatively, if at this stage it accepts the application, NFA prepares a draft standard or a draft variation to a standard;
- a draft standard or variation is notified publicly, to those who made submissions and to State and Territory authorities, and further comment is invited;
- NFA holds an inquiry to take into account comment received;
- NFA then notifies the applicant, relevant agencies and the public of the outcome of the inquiry;
- NFA also makes a recommendation to the National Food Standards Council, which comprises Commonwealth, State and Territory Ministers responsible for food standards, with a New Zealand representative as an observer; and
- The Council must then accept, reject, amend or return the recommendation to NFA for reconsideration. It may also request further information on the matter.

A similar process is set out in the Act for proposals to develop or vary standards which NFA may make on its own initiative.

NOHSC: The process for the priority issues dealt with by NOHSC is:

- a brief is prepared by a tripartite committee;
- a tripartite expert working group (EWG) is established to develop the standard in line with the brief. The work of this EWG is oversighted by an expert review group;
- once agreement has been reached by the EWG and the review group, the draft standard is submitted to the tripartite committee for approval and released for a 3 month public comment period;
- following public comment, the EWG is reconvened to revise the document;
- the finalised document is then submitted to the tripartite National Commission for final approval;
- at this stage, NOHSC has in several instances determined that an 'economic impact assessment' (EIA) be made of the regulation; and
- once endorsed by NOHSC, individual jurisdictions work with their own Parliamentary Counsel to incorporate the intent of the key mandatory requirements into their legislative structures under the parent OHS Act.

NRTC: The general process followed by NRTC is:

- policy proposals are developed;
- research is initiated where necessary;
- an issues/discussion paper is prepared and circulated for public comment;
- wide ranging public discussion is undertaken and feedback is incorporated in policy proposals;
- a publicly accessible 'regulation impact statement' (RIS), which includes cost-benefit analysis where appropriate, is prepared;
- legislation, codes or guidelines are prepared as appropriate;
- NRTC recommends proposed legislation, codes or guidelines;
- proposals including legislation etc, accompanied by a RIS are submitted to the Ministerial Council for Road Transport for final approval;
- legislation must be passed by the Commonwealth Parliament for implementation in the Australian Capital Territory; and
- the States and the Northern Territory set aside any conflicting legislation and adopt the national legislation.

TGA: The process TGA uses in formulating regulations to deal with safety risks depends on experience, the advice received from international agencies, and consultation with interested parties. A number of key committees carry responsibilities related to regulation. These include the Therapeutic Goods Committee, the Australian Drug Evaluation Committee, the Therapeutic Devices Evaluation Committee, and the Traditional Medicines Evaluation Committee. Matters are also discussed at the Industry/Government Consultative Committee.

To ensure the quality, safety and efficacy of therapeutic products, TGA employs a four-pronged approach which involves:

- standards for therapeutic goods;
- pre-market assessment of products;
- manufacturing controls; and
- post-market monitoring.

Standards

The British Pharmacopoeia and the British Pharmacopoeia Veterinary are the main sources for standards under the Act. The Minister for Health and Human Services also has the authority to amend or replace a monograph of the British Pharmacopoeia and the British Pharmacopoeia Veterinary or create new standards by issuing a Therapeutic Goods Order on the advice of the Therapeutic Goods Committee (TGC). Standards from sources like other pharmacopoeia or standards published by Standards Australia can also be adopted by reference in a Therapeutic Goods Order.

In formulating regulations to deal with safety risks, the following process is set in place:

- a safety-related issue is identified by TGA, or brought to the attention of TGA by industry, consumers, health professionals etc;
- TGA prepares a briefing paper on the issue;
- the brief is presented to the TGC which refers it to a Sub-Committee with membership representation and expertise to cover the interested parties;
- if required, a draft standard is prepared and referred back to TGC;
- TGC may make additions and amendments to the draft;
- the draft is distributed for public comment;
- comments are reviewed by the Sub-Committee and a final report is prepared for TGC;

- TGC recommends a new standard to the Minister; and
- if the Minister accepts the recommendation, the new standard is published as a Therapeutic Goods Order in the Commonwealth Gazette.

Pre-market assessment

All therapeutic goods must be registered or listed in the Australian Register of Therapeutic Goods (ARTG), unless they are exempt or given special approval. To obtain a Certificate of Registration or Certificate of Listing for the ARTG, goods are evaluated by TGA or an approved assessor.

Certificates of Registration or Listing remain valid (provided the sponsor pays an annual fee) until they are cancelled or new conditions are imposed. Registration or listing may be cancelled in cases where:

- products create an imminent risk of death, serious injury or illness;
- products become exempt;
- the sponsor requests cancellation in writing; or
- the goods fail to comply with the conditions applying to registered and listed goods.

Manufacturing controls

A licence must be obtained to manufacture most therapeutic goods that appear on the ARTG. Once an application for a licence has been lodged, the manufacturer's premises are audited for compliance with a code of 'good manufacturing practice' (GMP). Regular audits of premises are also conducted. If a manufacturer does not comply with the GMP principles, a licence may be refused, cancelled or suspended. Imported therapeutic products must meet similar GMP standards to products produced locally. A sponsor must provide certification that GMP standards applying in the place of manufacture have been met.

Post-market monitoring

TGA conducts selective testing of therapeutic products. This testing forms a significant part of post-market monitoring of therapeutic products. Post-market monitoring by sponsors is also a condition of registering or listing in the ARTG: sponsors must report all adverse reactions, serious injuries or deaths that arise from, or are related to the use of, registered or listed products. Similarly, a sponsor must notify

TGA immediately if a regulatory action, such as a recall, is taken by an authority overseas against a product that has also been used within Australia.

Selection for testing of products is based on history, therapeutic importance, consumer complaints or advice from GMP auditors. Samples are obtained from manufacturers, sponsors, distributors or retailers' premises and may be tested by procedures/processes employed by TGA or by alternative methods suggested by sponsors.

If a sample does not meet official standards, the sponsor is notified and given 21 days to respond (unless the failure is significant enough to justify immediate recall of the product). If a sponsor disagrees with a TGA assessment, an independent analyst may be appointed to re-test a sample.

As a result of consumer complaints and/or product testing, recalls may be required for certain goods. Recalls are voluntarily undertaken by the sponsor of the goods but the *Trade Practices Act* allows the Minister for Consumer Affairs to intervene if a consumer hazard exists and the sponsor fails to take the appropriate action.

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IDENTIFYING PROBLEMS/ SETTING OBJECTIVES

Question 4: Basis for investigating potential safety problems

On what basis does your agency decide to investigate whether a safety problem may require regulation? For example, does your agency identify problems itself, does it respond to requests and submissions from individuals and community groups, does it respond to directives from government, or are producers required to submit new products/technologies to you for approval before they can release them onto the market?

Most agencies have several sources for identifying potential safety problems which may require them to make or revise a regulation.

All the agencies surveyed rely at least in part on external sources to trigger an investigation or evaluation. Four specific external triggers were mentioned:

- *government directives:* all of the agencies may be required to respond to problems raised by the Government or by the responsible Minister;
- *requests from other government agencies:* ARL, CSU, FBCA, NFA and NOHSC stated that they respond to requests from other agencies to examine a safety-related issue;
- *non-government requests:* all the agencies surveyed indicated that they can respond to representations from community groups, the public and industry; and
- *overseas regulatory developments:* CAA, CSU, FORS, NFA and TGA indicated that changes in relevant overseas safety standards may trigger an examination of standards in Australia.

As well as responding to external requests, several agencies (ARL, CAA, FBCA, FORS, NOHSC, TGA) indicated that they undertake their own investigations to identify safety problems. ARL monitors the international literature and undertakes its own field studies. FORS reviews Australian and international accident statistics to identify potential problem areas and undertakes or commissions its own road safety research, including the crash-testing of vehicles. FBCA sometimes undertakes internal research on a product where notifications from other Consumer Affairs agencies or consumer complaints suggest it may be hazardous. TGA identifies some unsafe drugs by undertaking random samples of drugs on sale (although this is more to check for compliance with existing regulations than to

identify new safety problems). CAA also undertakes its own surveillance activities and responds to analyses of air accidents prepared by the Bureau of Air Safety Investigation (BASI).

Five agencies (CAA, CSU/NRA, NFA, NOHSC, NRTC) are undertaking a systematic review of existing regulations. CAA's review is intended to consolidate and validate current regulations and to harmonise Australian regulations with international regulations where appropriate. NFA has been directed by government to review the complete Food Standards Code. NRTC is currently examining road transport regulations with a view to harmonising and streamlining them. CSU noted that NRA — a body to which CSU provides technical input — is to undertake a systematic re-evaluation of existing agricultural and veterinary chemicals as a result of a government initiative arising from public concern about chemicals. NOHSC has been directed to achieve national uniformity in OHS regulations and is reviewing several areas accordingly.

Three agencies (CSU/NRA, FORS, TGA) operate pre-market assessment programs. These involve the examination of goods before they can be sold, rather than after a problem is identified with them.[10] In the case of TGA, the manufacturer must submit detailed information about a drug or device for examination before it can be marketed. FORS noted that all motor vehicles supplied to the Australian market are subject to an approval process in which manufacturers provide evidence of compliance with ADR requirements. The CSU/NRA scheme involves the evaluation of technical information on new chemicals submitted for registration.

Specific responses to this question included:

CAA: CAA responds to many forms of input as a trigger for the development of a new standard or the overhaul of an existing one. All of the points listed in the question (other than pre-market product assessment) are sources, that is: requests from individuals, groups etc; directives from government; technological change; and changing attitudes. Additional to the above are the traditional aviation triggers: international Airworthiness Directives from either manufacturers or government agencies; major defect reporting systems; BASI reports; international safety practices specified by the International Civil Aviation Organisation (ICAO); and results of CAA's own surveillance activities. CAA's surveillance activities now include the recently introduced

10 Regarding the NFA, many applications to vary the Food Standards Code are made by firms seeking to market new products which do not meet the existing Code requirements. In this sense, the NFA's Code variation process acts to some extent like a pre-market assessment scheme. However, new products which meet existing Code requirements do not need to be assessed prior to being marketed.

Aviation Safety Surveillance Program which enables inspectors of the Directorate of Aviation Safety Regulation to plan, conduct, record, report and analyse surveillance activities.

CAA does not conduct accident investigation (similar to BASI) on any regular basis. Occasionally, where the Authority believes that there may have been a serious breach of regulations, it conducts its own investigation. This is so because the evidence collected by BASI cannot be used in any prosecution by the Authority.

CAA is also undertaking a systematic review of its regulations. The 'Regulatory Structure Validation Project' was set up to consolidate and validate current regulatory material. The 'Harmonisation' project will more closely align Australian regulatory requirements with international standards.

CSU: CSU undertakes the majority of its work in response to legislative requirements. Activities relating to agricultural and veterinary chemicals involve the evaluation of technical information on new products submitted under legislative requirements for the purposes of registration. In addition, CSU undertakes public health review of chemicals and/or issues of concern arising from requests from the public, consumer groups, State governments or other agencies such as NRA and NFA. As a result of a government initiative arising from public concern about chemicals, a formalised review program aimed at systematic re-evaluation of existing chemicals is to be implemented by the NRA.

The public health implications involved in the use of industrial chemicals are assessed prior to their introduction in Australia. In addition, CSU actively participates in international fora on chemical safety including the assessment and other programs of the IPCS and the OECD, and participates in programs aimed at the harmonisation of chemicals regulation.

FBCA: Unsafe products can be identified by internal research, requests and submissions from individuals and organisations, the media and injury data. Some requests are made by other government agencies. However, the Bureau does not serve as an agency to certify goods as safe or otherwise.

FORS: Through FORS statistics and research activities, risk levels and effective countermeasures are identified. The development of ADRs involves a consultative process involving Federal, State and Territory governments, industry, consumer groups and vehicle safety experts. Therefore, proposals for new regulations can come from many sources. Acknowledgment is made of international developments and, where appropriate to Australian conditions, vehicle safety standards developed in international fora are adopted as regulations. All vehicles supplied to the Australian market are subject to an approval process in which manufacturers provide evidence of compliance with ADR requirements. There is no impediment on new products/technologies, only the need to demonstrate compliance with existing regulations applicable to all vehicles.

NFA: In essence, a person or body, or the Authority, may seek to vary or develop a standard in the Food Standards Code where necessary. Information on the potential safety problem may come from a variety of sources, including local industry, government authorities, consumers, and overseas authorities. Government directives are limited to a formal direction from the Minister. Where a new product does not conform to the Code, a producer would normally make an application to develop a standard or vary an existing standard. This would also apply for new processes, such as irradiation and the use of genetically modified organisms, which may result in new types of food.

NOHSC: NOHSC responds to directives from government and from the tripartite membership of its National Commission in setting its work priorities. However, in addition NOHSC has developed a framework to assign priority status for standards development. Under this framework, priority status is assigned in accordance with the following criteria:

- areas of most pressing need, including those having a major impact on the severity of injuries/disease;
- capacity to enhance productivity and efficiency of industry; and
- significance in terms of achieving national uniformity, taking into account the effects of mutual recognition on OHS regulation.

It is estimated that regulatory reform in the seven priority OHS areas will address between 65% and 80% of all compensible occupational injuries and diseases currently occurring in Australia.

NRTC: One of the requirements of the *NRTC Act* is to achieve national uniformity or consistency in road transport regulation. Much of the work to date has therefore been concerned with harmonising *existing* regulations rather than investigating the need for new regulations.

TGA: Drugs and devices by their very nature have safety problems. It is important to ensure the quality, safety and efficacy of drugs and devices and this is done through the evaluation of detailed submissions from manufacturing and sponsor companies. It is also important to determine the most appropriate usage guidelines for each individual drug or device.

TGA Laboratories carries out testing in a random sampling program and also examines complaints which are brought to its attention. These complaints can come from the TGA's own inspectors, the general public, other government agencies, or the pharmaceutical and allied industries.

Question 5:
Trigger risk levels

In addressing a problem that involves risk, what level of risk does your agency consider justifies a regulatory response? For example, if a device was likely to cause severe injury or death to one user in every ten million users, would your agency seek to regulate it to improve its safety? What if the device was likely to cause death to one in every one million users, or one in one hundred thousand users, etc?

ARL and CAA were the only agencies to nominate a threshold risk level below which they would generally not seek to regulate. CAA said that, in terms of airworthiness, the likelihood of any failure which would prevent the continued safe flight and landing of an aeroplane must not exceed one in 1000 million. Overall however, on the basis of reality, CAA accepts an accident rate of one in 10 million in certain operations. ARL advises regulatory control if the individual risk of contracting fatal cancer from exposure to radiation at work were to exceed about one in 25 000, although average occupational exposures in the radiation industry lead to a risk level of around one in 10 000. These risk levels are based on an international consensus derived from 'optimisation' measurements.

Agencies which undertake some form of cost-benefit analysis (for example, NRTC, FORS) noted that this procedure involves an assessment of the level of risk in the determination of the net benefits of a safety regulation. This approach does not aim to reduce risk to some pre-specified level, but to ensure that the benefits of a proposed measure exceed the costs. Under this approach, the level of risk can vary (up/down) as the costs of an accident vary (down/up) or the costs of a regulatory measure vary (up/down) in a cost-benefit analysis. Hence, the acceptable level of risk is simply any level which generates a benefit/cost result greater than one.

Most of the remaining agencies did not specify or consider a target level of risk, but indicated that their aim was simply to reduce the level of risk as far as possible or practicable.

CSU stated that its primary concern is to establish "appropriate health measures that *avoid* morbidity and/or mortality related to chemical exposures."

FBCA and NOHSC, while also having a strong safety focus, indicated that they are required to balance risks against other considerations, rather than seeking to eliminate risks completely. FBCA stated that "...just one death or injury in the country may be sufficient to justify regulation should the probability of recurrence remain and there are safe alternatives available." NOHSC pointed out that, even with the noise level specified in its National Standard for Occupational Noise, up to 2% of the exposed population will continue to suffer hearing loss.

Reflecting the 'risk-risk' aspects of the safety problems they deal with (see question 2), both NFA and TGA indicated that they need to balance different aspects of risk, the overall goal being to minimise total health risk (or, its equivalent, to maximise total health benefit). NFA said any risk associated with food additives needed to be balanced against the benefits to health of those additives. TGA indicated that all therapeutic goods have the potential to cause toxicity or side-effects and that, in appraising them, the aim is to maximise the 'therapeutic index' by increasing the therapeutic benefits of drugs whilst minimising the risks.

Specific responses to this question included:

ARL: For ionizing radiations, recommendations are usually framed on the philosophy that risk of immediate injury (deterministic effects) are not possible and that risk of induction of a fatal cancer over a lifetime is not intolerable. Annual occupational dose limits coupled with the further requirement that doses should be kept as low as reasonably achievable, leads to an average risk for radiation workers of the order of 10^{-4}. The annual limit (20 mSv/y averaged over any consecutive five years) corresponds to a risk of about 8×10^{-4}. In other areas of the electromagnetic spectrum, where risks are not as well quantified, limits based on acute but non-fatal effects are applied.

Traditionally, the risk level for radiation has considered only the probability of inducing fatal cancer; however, in the most recent recommendations of the International Commission for Radiological Protection (ICRP), other non-fatal detriments are factored in and the risk of detriment is increased accordingly by about 20 percent.

CAA: The use of explicit risk levels varies depending on which area is affected by the legislation. Airworthiness being a traditional engineering discipline follows the concept that aeroplane systems and associated components, considered separately and in relation to other systems, must be so designed so that the occurrence of any failure condition which would prevent the continued safe flight and landing of the aeroplane is extremely remote (10^{-9}). In the past, in non-engineering disciplines the Authority did not normally conduct a safety analysis but relied on comparisons with best international practice, the subjective judgment of experts in the appropriate field and exhaustive consultation with industry. However, it is now starting to use risk modelling techniques and is relying more on empirical data.

Overall, while the Authority has an objective of achieving the least number of accidents possible, on the basis of reality it accepts an accident rate of 10^{-7} in many circumstances (see response to question 7).

CSU: As CSU's charter is to protect public health, it is primarily concerned with establishing appropriate measures that avoid morbidity and/or mortality related to chemical exposures. As the primary aim is to regulate to avoid or minimise risk, the level of risk to justify a regulatory response is not quantified. It would be contrary to acceptable public health regulatory processes to use mortality or morbidity as risk indicators which would trigger a regulatory action.

FORS: FORS does not base decisions on any particular 'target risk level'. In fact, there would be major problems in attempting to apply any such target. First, there are a number of different methods of measuring risk levels; all have their uses, but none is uniquely and universally appropriate. For example, risk levels of different transport modes can be expressed in terms of risks per vehicle kilometre, person kilometre or hour of travel, with different measures providing different relative risk levels. More importantly, a focus on any single target level of absolute risk (however expressed) would be inconsistent with a focus on promoting cost-effective measures.

In a broad sense, it would be true to say that the acceptability of a risk is implicitly considered as part of the process of cost-benefit evaluation. Strictly speaking, of course, cost-benefit calculations provide information about the desirability of introducing particular countermeasures, rather than the acceptability of a particular risk. This may seem like hair-splitting, but it does underline the difference between cost-benefit approach and the concept of 'target risk level'. Under a cost-benefit approach, the 'acceptability' of a risk depends on the acceptability and effectiveness of the alternatives available for reducing that risk, rather than on the absolute level of risk.

Finally, while cost-benefit estimates are an important part of a RIS , they are of course used as a guide to decision making, rather than the sole criterion for determining which countermeasures are implemented. This is not necessarily a matter of other factors over-riding the cost-benefit principle: there is an important distinction between calculated cost-benefit estimates and 'true' cost-benefit. For example, a particular measure might be ostensibly cost-effective but likely to be extremely unpopular with the bulk of the community. While a decision not to

implement such a measure could be seen as a matter of political factors over-riding economic considerations, the same result might be arrived at by extending the cost-benefit analysis to impute a cost (beyond the direct market cost) reflecting the disutility of the countermeasure to the community. Evaluation of indirect or intangible costs and benefits inevitably involves a process of judgment: whether these are incorporated in the cost-benefit analysis or considered as part of the broader decision making process.

NFA: Underlying NFA's use of risk assessment is the concept that there is no such thing as absolute safety in respect of food.

For a substance which is added to food to perform functions which are not themselves nutritional, the material must generally be demonstrated to present no appreciable risk and, in the case of food additives and pesticides, must be demonstrated to have a technological or agricultural function before their use is permitted. In cases where there is an identified risk, this must be balanced against a benefit (for example, the risk inherent in not using the substance). In the case of whole foods, any risks arising from consumption of a food are deemed to be acceptable unless there is evidence to the contrary.

NOHSC: In OHS it is mostly not possible to directly and precisely quantify the level of risk. While it is possible to use available data as a guide to decision making, the data available in Australia are not able to produce relative risks for alternative hazards. The relative burden of suffering, that is the numbers developing a particular disorder, is known in many cases and can be used as an indication of risk. But the risk, that is the proportion of the people who could potentially get any problem who actually do get it, is mostly unknown. To estimate the relative risk of disease and injury due to exposure to a hazard, it is necessary to know the relative risk due to exposure, compared to the relative risk of the non-exposed population. These data are often unavailable because there is a poor linkage between cancers, diseases and any occupational cause. Additionally, data are also not readily available to establish either exposure levels, or to identify the non-exposed population.

In the recent EIA for the National Model Regulations for the Control of Workplace Hazardous Substances, it was not possible to accurately judge the level of risk reduction the regulations would achieve. To allow for this, three scenarios were built into the model to cover the possible impact of the regulations on occupational injury and disease.

There are additional problems in assessing OHS risks because safety has many characteristics of a public good.

NRTC: The level of risk is not subject to explicit trade-off in the evaluation of costs and benefits of regulations. Increases in risk would be costed (using historical accident rates and average accident costs) and compared with the benefits of regulation (for example, lower fuel use) to determine whether the regulation is justified.

TGA: All therapeutic goods have the capacity to be dangerous. The use of a therapeutic good depends on the specific disease state for which it is designed, and the seriousness of the illness. Safety is to a degree controlled by dose, route of administration, patient monitoring, etc. TGA itself carries out a different level of evaluation depending on the type of therapeutic good which is being evaluated. For example, a prescription medicine involving a new chemical entity or for a new form of treatment is evaluated at a higher level of detail than a non-prescription medicine where the active ingredients and therapeutic use are already well known. It is difficult to identify actual risk ratios for any individual drug or device as there are too many parameters to consider for each individual case.

[Also see TGA response to question 8].

Question 6:
Official guidance on acceptability of risk levels

Does your agency seek specific guidance from elected officials about the acceptability of particular risk levels? If so, in what form is the guidance given (guidelines, case-by-case consideration of regulatory proposals)?

All the agencies indicated that they have not been given, nor have they sought, specific guidance from elected officials on the acceptability of particular risk levels.

However, some agencies advising Ministers pointed out that, in making a decision on a particular proposal, the Minister makes an implicit evaluation about the acceptability of the risk levels that the proposed measure aims to address.

Some agencies also pointed out that, while not seeking guidance from elected officials, they consult widely with experts and community groups about their proposals. This may provide an opportunity to gauge the acceptability of particular risk levels.

Specific answers included:

ARL: No. International recommendations offered by the ICRP and the International Radiation Protection Association are used as the basis for setting Australian standards. Codes of practice are based on Australian experience.

CAA: The Authority seeks guidance via the consultation process with all interested parties, for example, unions, industry, its own staff, and overseas agencies.

CSU: CSU operates under chemicals legislation and regulation which aims to establish guidelines or approvals for specific chemicals use and therefore does not seek endorsement from elected officials.

FBCA: Not specifically. The Bureau attempts to consult as wide a range of affected persons as possible as well as obtaining expert and overseas advice if necessary. Because of the wide range of consumer goods available and differing safety requirements, the Bureau tends to examine issues case-by-case. Submissions to the Minister for Consumer Affairs

inform her of the safety issues and arguments for and against regulation, and generally make a specific recommendation.

NFA: NFA does not seek guidance from elected officials regarding risk levels. There is wide public consultation regarding proposed standards which gauges public acceptance of particular risks.

NOHSC: NOHSC does not seek specific advice from elected officials about the acceptability of particular risk levels. Acceptability is determined within the tripartite process. This is compatible with the total quality management approach where the 'client' determines the level of acceptability.

NRTC: Individual proposals are put to the Ministerial Council for Road Transport on a case-by-case basis. After a period for consideration, these proposals must be rejected by a majority of Ministers, otherwise they are adopted. All proposals involving regulations or other legislation must be accompanied by a RIS. At this stage, the Commission has not sought guidance from the Ministerial Council on acceptability of specific risk levels.

The Ministerial Council recently made a decision on the fitting of anti-lock braking systems (ABS) to B-Double vehicles that was not in accordance with cost-benefit analysis contained in the RIS. This may indicate that politicians place different (higher) values on the cost of accidents.

Question 7:
Specification of regulatory objectives

In formulating regulations, does your agency specify an objective that the regulation is meant to achieve and, if so, in what terms (for example, a reduction in head injuries from motor vehicle accidents in Australia of 270 per year; or a fall in the number of cases of food-poisoning caused by substance X of 25 percent)?

Most agencies have overall policy objectives but do not normally specify objectives for particular regulations. The overall objectives are generally couched in qualitative terms, such as "the protection of public health and safety" (NFA) or "to reduce community exposure to environmental health hazards" (CSU). Only two agencies (ARL, CAA) have quantified risk levels for some groups of regulations or regulated activities. ARL said that, in terms of the likelihood of radiation workers incurring a fatal cancer, its annual radiation dose limits taken over a lifetime give rise to an average risk in the order of one in ten thousand. However, this risk level is the outcome of a consensus based on 'optimisation' measurements rather than a pre-determined objective. CAA said that, while it seeks the least number of accidents possible, in practice it will accept an accident rate of one in ten million in many circumstances.

The only agencies that specify objectives for particular regulations are FBCA, FORS/NRTC and NOHSC, although these are also couched in general, qualitative terms. FORS/NRTC stated that specifying objectives for individual regulations was part and parcel of preparing a Vehicle Standards Proposal. However, the level of specificity rarely gets down to a measurable level, such as that in the question. Likewise, FBCA and NOHSC objectives are simply to reduce the risk or incidence of injuries associated with a particular product, process or problem.

CSU considered that it would be inappropriate to specify a target such as "...to reduce the incidence of food poisoning caused by a substance by 25 percent." In its view, any level of food poisoning would be unacceptable.

Specific responses included:

ARL: The philosophy of setting limits is discussed in the answer to question 5.

CAA: The Authority has an objective of achieving the least number of accidents possible but, on the basis of reality, it will accept an accident rate of one in 10^7 in many circumstances. For example, it uses the ICAO aircraft approach procedures which should ensure a collision with

terrain or obstacles no more frequently than one in 10^7. In setting standards the Authority has adopted a policy of setting the requirement at the minimum acceptable level, such that any operation conducted below that is unacceptable and will not be condoned. For example, it accepts an accident rate in the order of one in 10^4 hours for light aircraft because, in reality, that has long been the accepted rate.

It is quite simple to achieve a perfect safety level in aviation, however, no-one would be able to afford to fly and there would be no industry. In other words, the standard would be so high that nothing flies. The most difficult task in aviation standards development is achieving that minimum standard which allows the industry to operate and still provides the public with an acceptable level of safety.

CSU: CSU's objective, which is "to reduce community exposure to environmental health hazards", is carried out in a qualitative, not quantitative, manner. Involuntary exposure to chemicals means that the public have an understandably high expectation that they will not be affected by chemicals in their food, air, water or environment. To address the suggested example of a measure being "a fall in the number of cases of food poisoning caused by a substance of 25 percent", it would be unacceptable from a public health, and political, point of view to adopt such an approach given the current public expectation. Clearly, food poisoning due to any chemical contamination, at any level, is unacceptable.

FBCA: Product safety regulation does attempt to remove identified risks, but outcomes or objectives tend to be treated in general terms only and not in specific numbers of injury reductions. For example, in a discussion paper about the safety of baby walkers, the Bureau provided detail on the number (according to type) of injuries related to the use of baby walkers but did not specify a quantitative objective for regulation or other measures to achieve. Rather, the paper's purpose was simply to examine the options available "to reduce the incidence of these injuries."

FORS: Proposed regulations are summarised in 'Vehicle Standards Proposals' which are widely circulated. The Proposals set out the aim of the proposed regulation, development process, time frame, implementation process, implications for industry and the consumer, etc. Quantitative assessments of likely benefits and costs are developed in the RIS.

NFA: NFA does not set objectives for specific regulations. The objectives specified in section 10 of the *NFA Act* are taken into account when developing standards, although they may have different degrees of relevance for a particular standard.[11]

NOHSC: Parent OHS legislation in each State/Territory jurisdiction generally contains the provision that control of risks can only be to the level that is reasonably practicable. Therefore, regulations developed by NOHSC generally specify the objective of minimising risk.

For example, the National Standard for Manual Handling seeks to "... prevent the occurrence of injury and/or reduce the severity of injuries resulting from manual handling tasks in workplaces; and to require employers to identify, assess and control risks arising from manual handling activities in the workplace." Likewise, the objective of the National Standard for Occupational Noise is "...to reduce significantly the incidence and severity of occupational noise-induced hearing loss."

NRTC: The road transport regulations are aimed at achieving general objectives, but not specific objectives similar to those indicated by the examples in the question. One exception to this may be vehicle emissions where the Commonwealth Government has signed international agreements to reduce greenhouse gas emissions to specific levels.

Although specific objectives are not set for individual regulations, they are for sets of regulations, such as those relating to in-service vehicle standards. These objectives tend to be fairly general in nature and are set out in the RIS. The objectives are qualitative, not quantitative. The purpose of an Act and associated regulations are also spelt out at the beginning of each piece of legislation.

TGA: The objectives of quality, safety, efficacy and availability of therapeutic goods can only be qualitative.

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[11] In developing standards and variations to standards, under section 10 of the *NFA Act*, the Authority must take into account the following objectives in descending order of priority:
a) the protection of public health and safety;
b) the provision of adequate information to enable consumers to make informed choices;
c) the promotion of fair trading in food;
d) the promotion of trade and commerce in the food industry; and
e) the promotion of consistency between domestic and international food standards where they are at a variance, providing it does not lower the Australian standard.

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ASSESSING RISK LEVELS, BENEFITS AND COSTS

Question 8: Calculation of risk factors

How does your agency calculate the 'risk factor' (or the probability of an accident or other outcome occurring if the safety problem is not addressed)?

Most of the agencies attempt to account for risk in developing or assessing regulatory proposals, although not necessarily by calculating a risk factor as described in the question.

Several agencies use historical data to determine risk factors, although differences in the availability of data affect the robustness of the calculations. FORS and NRTC are able to draw on detailed road-crash databases to determine the proportion of accidents attributable to different causes. They are thus able to make reasonable estimates of the risk factor associated with each particular cause. However, NRTC noted that, for some issues, data are unavailable and 'guesstimates' are made. NOHSC also pointed to data limitation problems. In the absence of specific injury data, it has used individual state workers' compensation statistics to determine the major causes of workplace injuries and thus the areas of regulation most in need of review. NOHSC has recently established a national data set of workers' compensation statistics. FBCA also makes use of historical data regarding product-related injury, obtained from the National Injury Surveillance Unit. However, as FBCA considers the data to be insufficiently detailed, it supplements this information with product testing and specialist advice when assigning an 'overall risk factor' to potentially hazardous products.

As part of its optimisation process, ARL calculates the risks of contracting fatal cancers and selected non-fatal ailments associated with different levels of exposure to radiation. These risk factors are based on epidemiological evidence from high exposure groups, extrapolated to lower exposure levels.

The approach taken by CSU and NFA is quite different. Like ARL, these agencies develop regulations relating to substances which may cause harm to humans exposed to them. However, rather than seeking to determine what level of risk would result from a particular level of exposure to a particular substance, they seek to determine what level of exposure would result in no appreciable risk. Data are gathered by exposing test animals to different levels of the substance to determine

the maximum level of exposure for which there is 'no observable effect'. This level is then used to calculate allowable exposure levels for humans.

TGA indicated that risk factors are taken into account in the drug evaluation process. A dose is determined to give the desired therapeutic effect with minimum side effects. TGA said this can only be determined on a case-by-case basis and must be considered against the disease state which is being treated. However, TGA did not indicate how risk factors are calculated within this process.

Specific responses included:

ARL: Risk factors adopted are those accepted internationally as best estimates in the light of current scientific knowledge. These are based on epidemiological studies of highly exposed groups such as the Japanese A-bomb survivors, extrapolated to the much lower occupational exposures relevant to radiobiological models. For non-ionizing radiations exposure limits are based on prevention of serious injury, as indicated in animal studies. The risk factor is expressed in terms of risk per unit dose, and the risk is considered to be directly proportional to the dose.

CAA: In seeking to achieve specified risk levels, the Authority uses standard aeronautical practices such as fault and failure mode analysis, and reliability theory applied to aircraft design. It is now using risk modelling techniques such as Cause-Consequence models, along with empirical data where available, in such areas as collision risk probabilities in airspace design.

CSU: Potential public health hazards from chemicals are scientifically assessed on the basis of data. CSU does not possess data that allow calculation of 'the risk factor'. However, in comparing the public health regulation of chemicals in Australia to countries where such chemicals are not adequately regulated, the cost in terms of mortality and morbidity and environmental contamination would be expected to be high.

In general, CSU uses a qualitative approach to scientifically assess chemical risk. The overall 'no observable effect level' (NOEL) for a chemical is taken as the lowest NOEL in the most sensitive species tested and this is used to establish an 'acceptable daily intake' (ADI) level of a chemical. The determination of safety/uncertainty factors for use in the allocation of ADIs needs to reflect the complexity of

biological data interpretation, the need for professional judgment and a flexible approach when assessing the public health risk of a chemical. The uncertainty inherent in extrapolation between and within species has generally been overcome by the use of a safety factor. Allocation of a safety factor can range from 10 to 2000 depending on the source and quality of the data, the biological relevance of the end point and the hazard assessment (case by case). Safety factors are not rigidly applied. The usual safety factor is 100, derived by having a factor of 10 for species extrapolation and a factor of 10 for individual variation in humans. In general terms only, a safety factor of 10 would apply when appropriate human data were available and a safety factor of 1000 to 2000 may apply if lifetime studies are unavailable, for example. The ADI is calculated by dividing the NOEL by the safety factor. This assumes that exposure up to the ADI is without appreciable risk, but there is no attempt to estimate the actual level of risk at exposures equivalent to the ADI.

FBCA: The Bureau prepares a 'product safety analysis' of products which have been identified as potentially hazardous. This analysis involves using a scale of one to ten to rate products in terms of three attributes. These are: potential hazard severity; probability of occurrence; and probability of hazard recognition. An 'overall risk factor' is then derived by multiplying the ratings given for each attribute. Risk factors are derived for products both in the case where the safety problem is not addressed and in the case where a measure to deal with the safety problem is introduced. The comparison of these risk factors is one issue considered when determining whether a particular measure to remove a safety risk should be introduced.

FORS: FORS maintains national databases on fatal road crashes and crashes resulting in the hospitalisation of at least one person ('serious injury' crashes). The fatality database is extremely detailed, with up to several hundred items of information collected on each crash. Because of this detail, it is often possible to obtain a reasonable estimate of the number and proportion of fatalities or fatal crashes likely to be affected by a particular regulation. The serious injury database is less detailed, but can still be useful for estimation purposes. This information is supplemented by data from other sources, where appropriate. For example, estimates of the benefits of occupant protection measures relevant to ADR 69/00 drew on detailed crash studies, insurance data, and overseas research.

NFA: Risks arising from chemicals in food are assessed on the basis of an evaluation of toxicological tests in animals and, where available, humans. The studies are normally undertaken according to internationally accepted protocols.

The objective of the evaluation is to establish a 'no observed effect level' (NOEL) which is the level of consumption at which no adverse effects are observed. Normally the NOEL is established from long-term (or lifetime) studies, although in specific cases it may be from special studies on, for example, reproduction and development.

For food additives, the NOEL is used to determine the ADI by application of a suitable safety factor. For animal studies this is normally 100 (10 fold for the difference between humans and animals and 10 fold for variation with the human population).

The ADI is defined as the amount of the substance, expressed on a bodyweight basis, which can be ingested daily, for an entire lifetime, without appreciable risk. Consumption at or below the ADI is considered to be 'safe'.

For food contaminants there are two possible end points. The 'provisional maximum tolerable daily intake' for contaminants with no cumulative properties and the 'provisional tolerable weekly intake' for contaminants which are cumulative. Because much of our knowledge of the adverse effects of contaminants comes from direct human observation, and because there may be less scope for control over the presence of a contaminant in our food, the margins of safety from the NOEL are often less than the 100 fold used to set the ADI.

Decisions are made on the basis of the best available data at the time. Thus, there is always scope for re-evaluation in light of new data.

NOHSC: [See NOHSC responses to questions 4 and 5].

NRTC: Historical data on the incidence and severity of road crashes is used, where it is available. If data is not available, some judgment of likely outcomes is made based on similar situations. For example, analyses indicated that the fitting of ABS to B-Doubles could not be justified based on historical accident rates and average accident costs. The fitting of ABS to B-Double tankers hauling dangerous goods was, however, recommended. NRTC made the assessment that the average accident cost would be significantly higher in cases where dangerous goods were

the cargo. There was nothing terribly scientific about that assessment, but it was generally thought that the severe potential consequences of an accident involving dangerous goods justified the cost of requiring ABS to be fitted in these circumstances.

TGA: The major risk factor in the use of therapeutic goods is determined by the dose and/or the method of administration or use. In the case of a drug, a dose is determined to give the desired therapeutic effect with minimum side effects. This can only be determined on a case-by-case basis and must be considered against the disease state which is being treated.

In this context, TGA's approach differs from that followed by CSU and NFA. A consumer does not have to eat a specific food or use a particular household chemical; there is generally choice available. However, when a person is ill, they usually must use a drug or therapeutic device under medical supervision. The fact that drugs and devices must be used is taken into account in the evaluation process. The emphasis on safety is paramount in attempting to determine the appropriate risk-benefit ratio for the particular product while considering the illness which is being treated. A higher risk could be considered in the treatment of very serious disease states.

Question 9:
Actual versus perceived risk levels

Does your agency base its calculations and judgments on actual risk levels (that is, the level of risk that would be derived from accident statistics if they were available) or the risk perceived by individuals?

All agencies using accident data or scientific experiments indicated that they base their decisions on the best available scientific data.

Only FORS undertakes analysis which (indirectly) incorporates consumers' risk perceptions as opposed to actual risk levels, through its 'willingness to pay' studies.[12] However, FORS pointed out that this analysis was undertaken as a supplement to conventional analysis based solely on objective risk levels.

While NFA bases its risk assessment on actual risk levels, its risk management strategy also takes into account community perceptions of risk. As community perceptions sometimes do not align closely with real risk levels, this can result in regulation to overcome ill-based community concerns. NFA noted that the case of irradiation is an example of where a lack of community confidence led to a ban being imposed, even though there is a general consensus amongst the scientific community that food irradiation is safe.

Specific responses included:

ARL: Exposure limits are based on the best available scientific evidence together with a judgment about what level of risk is acceptable.

CAA: Both, depending on the discipline. Normally, risk levels are determined by CAA experts. However, if the majority of the industry is advocating a higher standard than the Authority considers necessary then, in the spirit of consultation, the Authority will probably accede to their desires.

In other instances, such as air traffic control towers that are not cost beneficial, CAA has retained the facility at the request of the local community, where that community has agreed to pay the difference between the cost of maintaining the facility and its estimated benefit.

12 NRTC indicated that, while it has not undertaken any 'willingness to pay' studies, it is intending to examine the implications of this type of study for deriving values of saving life. The work will be undertaken jointly by NRTC, FORS, the Bureau of Transport and Communications Economics and the Australian Road Research Board.

CSU: Potential public health hazards from chemicals are critically assessed on the basis of scientific data.

FBCA: Risk levels are derived from a number of sources such as State consumer agencies, coroners' courts, and the National Injury Surveillance Unit.

FORS: FORS has conducted research on car buyers' willingness to pay for vehicle safety features, but has not attempted to relate this to estimates of perceived risk. It was assumed that 'objective' assessments of cost-effectiveness might bear little relationship to car buyers' willingness to pay for vehicle safety features, and results of research tend to bear this out: willingness to pay tends to be higher than objective risk estimates and standard 'human capital' crash costings would suggest. The fact that car buyers want better occupant protection, and a majority are willing to pay more than the expected costs, is of course a relevant policy consideration.

NFA: Matters regarding perceived risk raised by consumers (or anyone else) will be assessed according to the *NFA Act* but, in the absence of evidence of actual risk, will not result in regulatory action. By virtue of the requirement imposed by the *NFA Act* that all applications to amend food standards are accepted with no prioritisation, much of NFA's work is responsive to community perceptions.

The risk management solutions expressed in food standards take account of the risk assessment but also of community perceptions. In principle, the less confidence the community has in a technology or substance the greater will be the perceived risks. NFA therefore responds by providing an appropriate risk management strategy (for example, in a food standard which must be approved by a Ministerial Council) to support community confidence in the food supply.

Unnecessary exposure, due to inappropriate use of an additive or pesticide, is not necessarily 'unsafe' but may be socially unacceptable. The implication is that society puts a different (undefined) level of acceptable risk on exposure resulting from unnecessary exposure to the additive or pesticide. Hence food additives and pesticides are subject to pre-market approval; contaminants and natural toxins are not.

Clearly, the concept of 'no appreciable risk' in respect of food additives and contaminants is also open to subjective interpretation. A conservative interpretation is that the risk inherent in lifetime exposure at the ADI is deemed to be acceptable providing that exposure to the additive is the result of an application consistent with 'good manufacturing practice' (GMP) or 'good agricultural practice'. This issue is, however, also confused by the concept of technological need or benefit and issues of deception and of the ability of the consumer to determine how or why a food additive or pesticide has been used.

Essentially, where dietary estimates indicate that the use of a food additive in line with GMP will not result in consumption exceeding the ADI, NFA has supported broad ranging approvals, leaving the consumer, through labelling information, to decide whether its presence is justified. Where benefits are not obvious to consumers (for example, pesticides), where there is a high probability of deception or where the chance of consumption exceeding the ADI is higher, specific foodstuffs and levels of use may be prescribed (based upon an assessment of the technology) in regulations. If necessary the ADI can be rationed across a small number of food categories. It is also apparent that NFA has inherited a substantial volume of regulations developed by the NHMRC which appear inconsistent, and often overly conservative, in this regard. These inconsistencies will be addressed in the standards review.

The case of irradiation is an example of a situation where a lack of community confidence led to a political solution being imposed — the moratorium on irradiation. This was despite the fact that the NHMRC had prepared a standard for irradiated food. There would appear to be general consensus amongst the scientific community that, by the criteria applied to establish food additive safety, food irradiation is safe. Providing that irradiated food is so labelled consumers can clearly make food choices about it and the market will respond. Nonetheless, there is likely to be considerable debate about technological justification, re-irradiation of spoilt food and other subjective quality issues before NFA is able to propose to governments a draft standard which is politically acceptable.

NOHSC: Wherever possible NOHSC bases its decisions on actual risk data. However, there are gaps in the available data. In an effort to address this problem, NOHSC has recently established a 'national data set' for workers' compensation statistics. In future this data base will be able to be used to ascertain more accurate risk levels for injuries. However it is expected the data base will not provide accurate information on the level

of occupationally related disease due to time lags between exposure and occurrence, inadequate diagnosis and reporting systems. Presently the expertise of the Epidemiology Unit is utilised to ascertain best possible estimates of the incidence of injuries and diseases.

NRTC: Accident statistics are generally used, not the risk perceived by individuals.

An approach has also been adopted of estimating the number of crashes that would need to be avoided in order to warrant a specific proposal. This means the impact of the proposal on crash risk is not directly estimated.

Question 10:
Analysis of benefits and costs

To what extent are costs and benefits of the proposed regulation identified and quantified? What are included as costs and what are included as benefits? How are they measured? If your agency makes calculations about the benefits and costs, do these calculations involve placing a quantitative value on human life? If so, how does your agency do this? Are the costs of delaying the introduction of new products or technologies (which could save or improve lives) also factored into these calculations?

Three agencies (ARL, FORS and NRTC) undertake 'full valuation' cost-benefit analysis as part and parcel of their regulation-making functions. The FORS/NRTC cost-benefit analyses are conventional and involve discrete assessments of specific regulations. NRTC indicated that the degree of analysis undertaken in its studies varies between regulations. For some, NRTC undertakes discrete analyses of the benefits and costs of a range of regulatory options. The 'optimisation' process used by ARL is more complex and effectively involves a series of analyses of different standards to determine which one minimises total costs (that is, the cost of injuries and fatalities plus the cost of avoiding them).

These analyses have several standard elements of cost-benefit analysis in common. Each involves the identification and valuation of monetary and non-monetary costs and benefits, allowance for different probabilities that particular costs and benefits will accrue, and discounting of future costs and benefits.

However, they also have some methodological differences, particularly in the way non-monetary costs and benefits are valued. For example, the agencies use values for life derived by different methods. The ARL figure of $1 million, borrowed from the United States of America (US), is calculated from an amalgam of court judgments, insurance assessments, and the value which people place on their own time. The figure of $625 000 used by FORS and NRTC is derived from work undertaken by the Bureau of Transport and Communications Economics and is based on expected future earnings discounted to present values, with an allowance for unremunerated family and community services. NRTC noted that it is re-examining its approach to the valuation of life.

Three agencies (CAA occasionally, FBCA, NOHSC) undertake 'partial valuation' cost-benefit analyses. These are similar conceptually to the FORS/NRTC approach but omit to place a value on human life. Hence, these analyses do not provide a common (dollar) basis for comparing the costs of a regulation with its benefits. The FBCA approach in some cases involves a simple listing of the main costs and benefits with little quantification. NOHSC sometimes undertakes cost-effectiveness

analysis rather than cost-benefit analysis. This approach yields results in terms of dollars per life saved or level of safety attained.

Agencies undertaking forms of cost-benefit analysis pointed to the difficulties involved. Some problems in attributing a monetary value to life have been alluded to above. FORS also mentioned the difficulties of including the value of 'community angst' in cost-benefit analyses (see FORS answer to question 5). In addition, NOHSC noted that its recent analysis of regulation to control hazardous substances had been inconclusive because of substantial data deficiencies. In the absence of reliable data on risk levels, it had to explore three quite different scenarios. The result was a range of outcomes from positive to negative values.

Three agencies (CSU, NFA, TGA) indicated that they do not undertake nor require cost-benefit analysis when assessing regulations.

Specific responses included:

ARL: In determining whether doses have been reduced to 'as low as reasonably achievable' a complex cost-benefit process is used, where the monetary 'value' of human life is set at about $1 million, and the cost of exposure avoidance is balanced against the notional cost of the risk of fatality. This formal process is part of the ICRP system of radiation protection where it is known as 'optimisation'.

The costs are the real cost of radiation protection measures and the benefits are the dollar value of the risks avoided. The costs are accounted in the normal way and the benefit is calculated by assessing the exposure which has been avoided by incurring these costs. The balance point occurs where these are equal.

In terms of valuing life, there is considerable literature discussing this issue. For western societies the figure is an amalgam of court judgments, insurance assessments, and the value which people place on their own time. For example, the point at which an individual chooses not to work extra hours (for a given recompense) is an index of the value which he/she places on leisure time. There is no real consensus about the figure to be used and the value of $1m which ARL uses is that used in the US.

The costs of delaying the introduction of new products and technologies are allowed as social and economic factors to be taken into account in assessing whether exposures are as low as reasonably achievable.

CAA: The Authority does not normally conduct a detailed cost-benefit analysis in the development of a standard, although such techniques are used from time to time to assist decision making: for example, to determine establishment/disestablishment criteria for control towers. Costs are certainly weighed up and the more the cost to the industry the more consultation and education of the industry is undertaken prior to adoption. The Authority has not placed a quantitative value on human life, except in the control tower study where the US Federal Aviation Administration (FAA) figure of $A1.9 million was used. It also used FAA figures for the cost of injuries and loss of time.

Generally, the Authority only has power under the Act to regulate for safety, so the issue of safety is addressed first. Having done that, the Authority would look for options to give the desired level of safety for the particular issue. If one of those options is cheaper for the industry than the others and still provides an acceptable level of safety, then that is the option chosen.

Only occasionally are CAA safety-related decisions exposed to a cost-benefit analysis. Matters such as airspace, towers review, firefighting services have been subject to cost-benefit studies with the costs identified in dollars.

CSU: CSU does not conduct cost-benefit analysis and does not regard this as a practical approach in terms of public expectation or political realities associated with the regulation of potential public health hazards from chemicals. CSU does have a mechanism for prioritisation of regulatory activity based on justifiable needs within the regulatory framework. For example, requests for expedited considerations have been undertaken when needs have been identified and justified on agreed State agricultural needs. Such priority is not related to commercial interest.

FBCA: The Bureau usually makes an assessment of cost/benefits in a substantive justification paper. Some monetary value can be attributed to injury reduction. However, the value of human life is not quantified. Injury costs are usually quantified on the basis of hospital and medical costs of injuries and lost productivity costs. Production and marketing costs associated with compliance with the regulation are also assessed. Regulatory action taken generally establishes minimum safety standards only and such standards do not delay the introduction of new products or technologies. In any event, new product developments are monitored

and standards regularly reviewed to help ensure safety standards do not inhibit product development.

However, while the Bureau seeks to identify and where possible quantify benefits and costs, practical constraints sometimes limit the degree of analysis. For example, in its discussion paper on baby walkers, the Bureau presented only a general qualitative outline of the potential costs and benefits of regulating any activity. The conclusion of this analysis was thus heavily qualified: "...a mandatory warning label requirement and/or education campaign could have some merit and may reduce these injuries, [but] this may not be as effective (in terms of cost and achieving a favourable result) as a ban."[13]

FORS: Estimation of costs and benefits is a standard component of the RIS prepared for new ADRs. The level of detail and precision depends on the scope of the regulation, data availability, and other practical considerations.

As a general summary of recent FORS analyses, cost factors considered have included:

- effects on costs of new vehicles;
- effects on vehicle operating costs (maintenance, fuel consumption, etc); and
- effects on road maintenance costs (where increases to the mass of heavy vehicles are involved).

Full quantification of all costs may not be attempted: for example, order of magnitude estimates may indicate that one particular cost factor predominates.

Figures representing 'costs' of loss of life are based on expected future earnings discounted to present value, with an allowance for unremunerated family and community services. This results in a more conservative figure than the 'willing to pay' estimates used by a number of other developed countries in their costings of road crashes.

The issue of costs of delaying beneficial technologies is not relevant as manufacturers are free to introduce design improvements before they are mandated.

Benefit estimates of reducing accidents are usually based on crash costs prepared by the Bureau of Transport and Communications Economics.

13 FBCA, *Need for Mandatory Action: Baby Walkers,* Discussion Paper, August 1993, p. 14.

These include estimates of property damage, emergency services, medical treatment costs, insurance overheads, traffic delays, pain and suffering, and loss of human productivity associated with death and injury.

It should be noted that FORS' practice is to discount the flow of expected costs and benefits from design rule changes to present values. This approach contrasts with the 'steady state' models used by US authorities, which estimate the balance of benefits and costs expected if the change applied to the whole vehicle fleet. Because the bulk of costs tend to be 'up front', while benefits accrue over the service life of the vehicle, FORS' approach gives significantly more conservative results.

NOHSC: NOHSC's approach to measuring costs and benefits of proposed regulations has been evolving rapidly as the national OHS environment changes. Legislation in three States — Tasmania, Victoria and NSW — now requires a RIS as part of the regulatory development process. Other States have similar but non-mandatory requirements.

NOHSC has not undertaken cost-benefit analysis for all NOHSC standards. Until recently, EIAs have been undertaken for NOHSC standards only in isolated cases, including for the regulation of occupational noise and manual handling.

NOHSC decided that cost-benefit assessment was necessary for the draft manual handling standard because it proposed a change from a prescriptive weight limits based approach to a hierarchy of risk control strategies. The standard was performance based thus allowing individual enterprises to adopt the least costly control mechanisms to suit their situation.

As a result of a report entitled "Economic Impact of Draft Safe Manual Handling Code of Practice", together with the volume of public comment received, NOHSC decided not to go ahead with the development of the standard. Instead, a less complex performance based standard was developed.

In July 1992, 'Guidelines for the Application of Cost Effectiveness Analysis to NOHSC Instruments' were endorsed by NOHSC. These guidelines provide for a regulatory impact assessment to be conducted for "new standards and those that are significantly different from the status quo." The guidelines propose cost-effectiveness analysis as the preferred methodology for evaluating national regulatory models based

on the 1991 Commonwealth Department of Finance report 'Handbook of Cost-Benefit Analysis'.

The approach taken varies in each cost-benefit analysis. In the case of the draft manual handling standard, analysis was carried out for only one level, being compliance with the standard. This was chosen because the standard provides for a nonprescriptive approach. On the other hand, the draft noise exposure standard represented a change from one set point to another. Thus the analysis was conducted assuming compliance at each set point.

The EIA for regulations to control hazardous substances was conducted by a consultant with extensive experience in conducting EIA, as Worksafe has insufficient in-house expertise to conduct modelling aspects of an EIA. Worksafe staff from epidemiology, statistics, standards development and the library provided extensive assistance with data gathering and interpretation. Despite this intense effort there were extensive gaps in the available data, particularly data relating to the cost of the regulations.

On the benefit side of the model, epidemiological information was used to calculate the number of injuries, illnesses and deaths caused by hazardous substances covered by the regulation.

It was not possible to accurately judge the level of risk reduction the regulations would achieve. To allow for this three scenarios were built into the model to cover the possible impact of the regulations on occupational injury and disease.

As a result of the modelling work a range of positive to negative values was obtained for the cost-benefit. Within the model, no value was used for human life. Instead a value was calculated for cost per life saved for each negative cost-benefit outcome. The results were presented to NOHSC as an aid to the decision making process.

NRTC: Costs and benefits are identified and quantified to the greatest extent possible. An example of costs and benefits used to evaluate fitting vehicle monitoring devices (VMDs) follows:

- purchase and installation costs of VMDs;
- costs to vehicle operators of collecting and storing records from VMDs;
- costs to enforcement authorities of auditing the records from VMDs;

- the equivalent number of crashes required to be saved to justify the above expenditure was calculated using average accident costs for rigid and articulated trucks for: all crashes; crashes involving casualties; and crashes involving fatalities or serious injuries;
- the accident costs were based on analyses in two studies (each included/excluded items that the other excluded/included). The component costs were person costs, vehicle damage, cargo loss, emergency services, insurance administration and vehicle replacement. The person costs included loss of life or quality of life, medical, ambulance and funeral services; and
- the cost of loss of life and quality of life estimates using an ex-post approach based on losses in earnings. The value of life is $625 000 using the ex-post approach.

None of the evaluations undertaken to date has included the costs of delaying introduction of new products or technologies. The timing of costs and benefits in specific circumstances is important in calculating present values in some cases. For example, there may be staged implementation of a regulation as it only applies to new vehicles, while the existing fleet is not required to retrofit the device, etc. Alternatively, a specific proposal may only involve retrospective requirements.

TGA: In the case of cost and benefit analysis, there are two levels to be considered: one related to the activities of TGA itself, and the other related to the activities of manufacturing companies in the pharmaceutical and allied industries.

In the case of TGA, the costs are the annual budget compared to the outcome of high quality medicines and therapeutic devices. For TGA this is measured through the Industry/Government Consultative Committee which discusses TGA's budget, sets performance indicators for performance monitoring, and reviews strategic planning. These activities are not related to placing a quantitative value on human life.

Regulation and control of the availability and marketing of drugs and devices also has a cost-benefit analysis which must be undertaken by the pharmaceutical and allied industries. In the case of pharmaceuticals which are included in the Pharmaceutical Benefits Scheme, a cost-benefit analysis must be submitted by the applicant company when products are considered for listing under the Scheme.

However, TGA does not undertake cost-benefit analysis of allowing particular pharmaceutical products onto the market, nor are such analyses considered in the TGA approval process.

Question 11: Margins of error

Are 'margins of error' built into your risk calculations? If so, is this done explicitly and transparently? How large are they?

Most agencies indicated that they use margins of error in examining the efficacy of particular regulations. CSU and NFA use explicit margins in risk considerations. ARL, FORS, NOHSC and NRTC explicitly make conservative judgments about certain variables and/or undertake sensitivity analysis of key variables to test the robustness of their cost-benefit analyses. CAA and FBCA also incorporate conservative assumptions into their analyses, but this is not always done explicitly.

The size of the margins of error is highly variable. CSU noted that its safety factor can range from 10 to 2000 depending on the source and quality of the data, the biological relevance of the endpoint and the hazard assessment. CSU also noted that safety factors are not rigidly applied. CAA indicated that its safety margins are arrived at partly by subjective judgment of the expert involved and partly by the consultation process with the industry.

TGA said it did not use margins of error *per se*, but rather made decisions on the basis of minimising the risks of side-effects from using drugs while maintaining their therapeutic effect.

Specific responses included:

ARL: Yes. Through the introduction of conservative assumptions in the assessment of exposures. This is generally done explicitly. How large they are varies with circumstance. For example, in assuming risks to Aborigines living near Maralinga (to define exclusion boundaries), the assumption of 100 percent occupancy was made. In practice, it is unlikely that they would spend more than one tenth of their time in the affected areas.

'Sensitivity analyses' in the optimisation process are generally not relevant since the models used are linear. In determining the risk co-efficient (risk per unit dose), there are quite complicated uncertainties related to non-linear effects but for the purpose of radiation control at the low doses normally encountered, these are not relevant.

CAA: When setting a minimum standard it is obvious that a margin for error has to be built in. This margin is arrived at partly by subjective judgment of the expert involved and partly by the consultation process with the industry.

In some cases, CAA 'inherits' safety margins built into international design standards. For example, accuracy of navigational equipment and route width tolerances are based on a 95% probability of staying within tolerances. The airspace design and risk assessment models that CAA now uses are amenable to sensitivity analysis.

FBCA: Error margins are taken into account in risk calculations but are not necessarily explicit as any calculation is usually of a general nature.

FORS: Margins of error are made explicit.

NFA: The safety factors reflect the normal ranges of observed metabolic and physiological differences between the test animals and humans and the observed variation within the human genotype (both around 10 fold, hence the 100 fold overall safety factor normally applied).

NOHSC: For the most recent EIA on Hazardous Substances, margins of error were transparently built into the calculations in two ways. Firstly, a range of values was incorporated for each variable. Secondly, separate scenarios were built to allow for sensitivity analysis. They were: discount rate (at 4, 6, 8 and 10%); impact of the regulations (high, medium and low impact); and the number of employees affected by the regulations (25 and 65 %). In cases where NOHSC has conducted cost-benefit studies, explicit sensitivity analysis has been carried out.

NRTC: Margins of error are not specifically included. There is a natural degree of imprecision associated with measuring the effects of regulations. Due to uncertainties a conservative approach is generally taken in estimating effects and their valuation. (Perhaps this is not the case with the value of life where an *ex-ante* approach could have been adopted. New Zealand and the United Kingdom road authorities now use *ex-ante* values of about double those used in our analyses.)

Confidence in the estimates and overall results is also assessed by undertaking sensitivity analyses on specific parameters. This gives some guide to the overall robustness of the cost-benefit calculations. No probability analysis of parameters or results has been undertaken to date.

TGA: Margins of error are not built into any risk considerations undertaken by TGA. The accent is on the minimisation of unwanted side effects while maintaining maximum therapeutic effect.

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ALTERNATIVE SOLUTIONS

Question 12: Consideration of alternatives

Before recommending/promulgating a particular regulation, does your agency consider alternative solutions to the problem the regulation is intended to fix? If so, what types of alternatives has the agency considered, and how has it compared them with the regulation? Does your agency prefer regulatory controls or market-based measures to enhance safety?

Most of the agencies consider alternatives to a particular regulation, although the range of alternatives considered depends on the agency. At one extreme, FBCA considers a wide range of options including: no action; education; publicity; voluntary actions by suppliers; and mandatory requirements. At the other, in relation to its agricultural and veterinary chemicals functions, CSU indicated that only product labelling and product availability regulation are considered.

Some of the agencies indicated that they generally use direct regulation rather than market-based measures to address safety matters. CSU indicated that it is "...bound by regulation...to support chemical registration schemes mandated by law." CAA said that "As the body charged under the *Civil Aviation Act [1988]* with the responsibility of safety regulation of civil air operations...we do adopt the regulatory approach." Likewise, TGA uses only regulation.

However, often agencies use less prescriptive intermediate measures. For example, ARL and NFA indicated a leaning towards industry codes of practice in some circumstances. NOHSC is moving towards the use of performance standards, rather than prescriptive standards, for new OHS regulation. NOHSC also develops codes of practice as an adjunct to its performance standards. FORS already uses performance standards. FBCA indicated a preference to overcome safety problems using market-augmenting measures and/or negotiations with product suppliers, with direct regulation of products as a last resort.

Specific responses included:

ARL: Sometimes it is not possible to use a regulatory approach. For example, the application of ionizing radiation in diagnostic medicine is not amenable to regulation as the benefit in the form of improved patient management goes to the individual who is exposed. It is a matter of

judgment for the physician whether the benefit outweighs the risk and all we can do is offer a Code of Practice for the minimisation of patient exposure. That is, the process is one of education. On the other hand, exposures to volunteers for medical research is and should be regulated. Regarding the types of measures, regulatory controls are generally necessary.

CAA: Often the Authority will propose a number of options to the industry together with the pros and cons of the options. These options include industry education and provision of information through CAA publications.

As the body charged under the *Civil Aviation Act* with the responsibility of safety regulation of civil air operations in Australian Territory, and the Australian aircraft outside Australian Territory, we do adopt the regulatory approach.

CSU: The chemicals regulation role carried out by CSU is bound by legislation and as such CSU's primary function is to support chemicals registration systems mandated by law. Mechanisms at CSU's disposal to ensure safe use of chemicals include the regulation of product availability and labelling.

Regarding CSU's environmental health responsibilities, they are implemented through co-operative initiatives and guidance with the States and Territories.

FBCA: As far as possible product related safety problems are examined as broadly as possible to ensure as many alternative resolutions are canvassed. The Bureau prefers market based measures to enhance consumer product safety, however, regulatory action will be taken if unnecessary safety risks remain.

Once a hazardous product has been identified, FBCA considers several options to deal with the safety risks that the product imposes. These options are outlined below:

- no action;
- educating users about product use;
- publicising potential product hazards;

- allowing industry to undertake voluntary action to remove the hazard (for example, by providing detailed instructions on product use, altering a product's design, setting a code of practice, or conducting a product recall); and
- regulating (for example, establishing labelling requirements, information or product standards, product recalls and/or bans).

It is possible that some of these options might be combined to remove a safety risk. For example, a ban on all future sales of a particular product might be applied in combination with an educational campaign directed at existing owners of the product.

FORS: The standards development process ensures that alternative solutions are considered in the RIS. Some solutions might be to do nothing, or develop voluntary codes of practice for industry on a particular matter. Regulatory controls are preferred, but market-based measures can be used in concert with regulations to achieve a better overall result than regulations alone.

ADRs are performance-based standards with a few exceptions related to the fitment of identity plates, labels, dimensions related to interchange-ability and road space etc.

NFA: Yes. Development of codes of practice for industry on any matter that may be included in a standard are a statutory function of the Authority. The NFA Policy Review published in May 1993 points to the Authority's awareness of the benefits of codes of practice in particular circumstances, and a code of practice is always canvassed as an option when developing or varying a standard.

NOHSC: Regulations are only one integral component of an effective OHS strategy. Other components include the provision of information and advice and the application of sound management principles in the workplace.

The standards developed by NOHSC are performance based, not prescriptive. Thus they allow employers flexibility in determining the least cost method to achieve control of a workplace hazard. Where a hierarchy of control measures is prescribed, the "as far as is reasonably practicable" phrase in the parent act allows the employer flexibility.

NRTC: The Commission is operating in an area characterised by extensive prescriptive regulation. One of the Commission's major functions is to achieve national uniformity or consistency in this regulation. As each set of regulations is examined, the Regulatory Impact Statement process requires a consideration of alternative means of achieving the objectives of the proposed regulations. Where appropriate, the removal of regulation is one option considered.

The Commission does sympathise with the use of non-regulatory mechanisms or the abolition of regulations where they do not appear to be justified. For example, in achieving uniformity for the operation of oversize/overmass vehicles there will be no requirement for vehicles up to 49.5 tonne gross vehicle mass to obtain permits for individual trips.

TGA: Within the Regulations to the *Therapeutic Goods Act 1989* there are already alternatives available *within* the regulation process, these alternatives are directly related to the risks involved and the type of product being evaluated.

In the case of pharmaceutical products and medical devices, regulatory control is the preferred mechanism of control rather than any market-based measure.

INFORMATION SOURCES

Question 13: Information/consultation

What sources of information does your agency use in formulating regulations? Does your agency consult with interested parties during the regulation formulation process?

The agencies use various information sources, including:

- regulatory assessment documents, recommendations and advice from international regulatory bodies;
- the practical experience of Australian regulators;
- scientific literature;
- accident research and test results;
- injury statistics;
- general statistical data; and
- input from industry, interest groups and the public.

Virtually all the agencies undertake public consultation during the regulation formulation process.[14] This often involves the release of a draft regulatory proposal and/or justification paper for public comment.

Additionally, four other forms of consultation are undertaken:

- NRTC convenes working groups and holds workshops on specific areas of road transport regulation;
- NFA holds public hearings into certain food standards proposals;
- producers likely to be subject to an FBCA product ban or recall can opt to have the Trade Practices Commission convene a conference to examine the matter; and
- NOHSC makes extensive use of tripartite working groups in developing regulatory proposals.

14 In the case of ARL and CSU, consultation is mainly undertaken by bodies further along the regulation formulation chain (such as NHMRC and NRA).

Specific responses included:

ARL: Information sources are international recommendations, scientific literature, the practical experience of State and Territory regulators and input from the industries affected. Informed public comment is routinely sought before final promulgation.

The Radiation Health Safety Committee of the NHMRC does not have formal procedures regarding public consultation. For most issues, drafts are sent to everyone who is known or thought to be likely to have an interest in the outcome. For some more contentious issues — for example, recommended radiation protection standards — the final committee draft is advertised in the press and made available to anyone who requests it.

CAA: Yes, via our Aviation Regulatory Proposal process (see question 3).

CSU: In framing regulatory policy on chemicals, the activities of national and international bodies are taken into consideration. As such Australia often utilises regulatory and assessment documents from the IPCS, OECD, WHO, United Nations, Food and Agricultural Organisation and their joint organisations. CSU uses a regulatory system for public health assessment, in part framed by NHMRC and in consideration of international standards. Consultation on public health regulation of chemicals is undertaken by the NHMRC via a legislative requirement to do so. With the planned introduction of legislation by the NRA, further public and special interest group consultation mechanisms will be introduced.

FBCA: As far as possible, all interested parties are consulted before and during the regulation formulation process. Specific sources of information include available injury statistics, and relevant Australian and overseas safety standards.

FORS: Consultative arrangements have been developed with NRTC which involve all interested parties.

NFA: In addition to public comment, the Authority would normally seek advice from other food standards regulators, for example in the US, the European Community (EC), Canada and Japan, as appropriate.

NOHSC: In formulating national common essential requirements and standards, a wide range of information is drawn upon. Existing regulation in the States and Territories is reviewed and inconsistencies and similarities are identified. International OHS is also used where appropriate. NOHSC relies on the expertise of the tripartite EWG and expert review group in developing common essential requirements and standards. Members of these groups also consult with their constituents as appropriate. All new NOHSC standards are subjected to a period of public comment during the drafting stage.

The development process for national common essential requirements and standards by NOHSC involves the full participation of interested parties, including unions and employers, who are represented on the National Commission and the EWG. Individual draft common essential requirements and standards are also released for public comment, and this comment is reviewed and incorporated into the final regulatory models where appropriate.

All new NOHSC standards are subjected to a period of public comment during the drafting stage. In addition, States/Territories undertake their own regulatory review process of each standard prior to adoption. It is believed that conducting a national EIA during development of each standard will eliminate the need for separate state assessments.

NRTC: Information is obtained from a variety of published and unpublished sources including historical data from road authorities, analyses of accident data to determine their average costs, vehicle manufacturers, vehicle operators, enforcement authorities, and the Australian Bureau of Statistics (vehicle registration and usage data). Consultation is a requirement of the *NRTC Act* and an important part of the process to develop national regulations. Many rounds of consultations have been held to develop regulations to date.

TGA: In formulating regulation, TGA uses its own assessment of an issue, international literature, the advice from international regulatory authorities, and consultation with the pharmaceutical and allied industries. There are no formal procedures to seek input from industry.

However, as indicated in question 3, the TGC seeks advice from industry when any new draft standard has been prepared and industry is represented on the Committee. Industry is also represented on a number of committees established to advise TGA in areas which can have an impact on regulation. The same applies to the public — consumer representatives are members of some of the TGA committees, and in particular are represented on the TGC.

Question 14:
Feedback mechanisms

What feedback mechanisms does the agency have in place to determine the impact of a regulation once introduced? Does the agency have any systematic means of assessing the impact of individual safety regulation and/or the cumulative impact of all regulation directed towards achieving some safety objective?

The agencies have a range of mechanisms for receiving feedback on their regulations, including:

- feedback from State and Territory authorities;
- feedback from staff;
- surveys;
- applications from the general public; and
- reporting practices put in place to detect adverse events.

Systematic means of assessing the impact of safety regulations are more limited. FORS conducts research into the effects of regulations on overall safety. However, most of the other agencies appear to concentrate on detection of adverse events or compliance with standards, rather than systematic analysis of safety outcomes.

Specific responses included:

ARL: Good communications via State/Territory authorities.

CAA: The Authority receives feedback from its own staff in the district offices, from the industry representative bodies, from its regular consultative meetings with the industry, and from the Aviation Safety Surveillance Program, BASI and the media.

CSU: CSU routinely monitors poisoning statistics from Australian Poisons Information Centres and monitors published literature and overseas regulatory agencies for reports and activities concerning public health aspects of chemicals. Food consumption data used in dietary risk assessment is available via the Australian Dietary Survey and the Market Basket Survey. As part of a surveillance program, Australia conducts a National Residue Survey which examines food commodities (at the farm gate) for a wide range of pesticide residues, heavy metals and

contaminants of natural and industrial origin. Both the Market Basket Survey and the National Residue Survey act as feedback mechanisms on the impact of chemicals regulation. To date, both have shown a high degree of compliance with chemicals standards. In addition, the continued acceptability of Australian produce overseas is a further indicator of the success of chemical regulation in Australia.

Whilst much of the regulatory activity of CSU is initiated by applications from the chemicals industry, there are evolving mechanisms to review the public health implications of previous decisions in light of contemporary information.

FBCA: The main feedback mechanisms come through compliance surveys and ongoing consultations with suppliers. Any adverse reports are quickly identified and the subject regulation is reviewed.

FORS: Monitoring the effectiveness of mandatory occupant protection devices is difficult for a number of reasons. Despite these problems, there is a considerable body of research evidence available about the efficacy of major occupant protection devices, such as seat belts and air bags. Attempts in the early 1980s to evaluate the effects of other ADRs, such as head supports and side impact protection, were limited by methodological problems and limits on the level of detail available in statistical databases. The prospect for future evaluation studies is somewhat better, because of improvements in statistical databases. Moreover, FORS is currently sponsoring research aimed at the development of more sophisticated and powerful statistical techniques.

NFA: The Authority coordinates the Australian Market Basket Survey which analyses for pesticides and contaminants in the Australian diet.

Testing for compliance with food standards is a responsibility carried out under the appropriate State/Territory Food Act by each jurisdiction. The Authority also has a function in the coordination of such activities.

A second feedback mechanism is that anybody may make an application to the Authority for a variation to a standard, for review of an existing standard or development of a new standard, and therefore has the opportunity to identify where existing standards do not meet the objectives prescribed in the *NFA Act*.

NOHSC: Jurisdictional representatives on NOHSC can facilitate feedback on the impact of National model regulations that have been adopted in their jurisdiction.

Occupational injury and disease reporting and surveillance systems, which have been recently introduced, will serve to provide data on national trends. A national recording system for compensation claims has been established by NOHSC which will assist in the assessment of national regulatory models.

NOHSC's overall approach is to establish standards that provide for a systematic process for the improvement of safety.

NRTC: It is too early in the life of the Commission to answer this question. The Commission's responsibilities include review of regulatory authority performance and implementation. There are also requirements to monitor road safety and to make comparative assessments of the performance of road systems (for example, by State).

TGA: The most important mechanism is related to the Adverse Drug Reaction Reporting Scheme for drugs and the Problem Reporting Scheme for medical devices. The regulations themselves set up reporting practices which must be completed if any sponsor is advised of an adverse reaction to any therapeutic good included in the ARTG. Special requirements have been developed for areas such as clinical trials, use of unapproved drugs, etc.

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OTHER ISSUES

Question 15:
Replication of overseas testing procedures and regulations

To what extent do your agency's analytical/testing processes replicate processes conducted by regulatory regimes overseas? To what extent does your agency consider/adopt overseas standards to deal with the safety risks? Does your agency allow products/technologies that meet certain overseas requirements to be marketed in Australia without meeting specific Australian testing/approval requirements?

Most of the agencies do repeat overseas testing to some extent. Only FBCA and NFA indicated that they do not replicate any tests that are carried out overseas. FORS said that it accepts overseas testing in cases where standards are fully harmonised.

Most of the agencies consider overseas standards and adopt them to varying degrees. ARL and TGA normally adopt overseas standards, FORS harmonises standards where possible and NOHSC tends to adopt overseas standards, modified where necessary for local characteristics. CAA, which adopts several overseas standards and recognises certain overseas certification procedures, stated "Because of the restricted size of the Australian aviation industry and the small population, it is simply not cost effective for Australia to develop its own standards in [many] instances."

None of the agencies indicated that their regulatory regime allows for the 'mutual recognition' of overseas standards in cases where they differ from Australian standards, although FORS indicated that it is actively pursuing this option.

Specific responses included:

ARL: In the case of radiopharmaceuticals, a detailed Australian assessment of clinical evidence is required though the evidence preferred may be from overseas studies. For radiation emitting devices, test results from reputable overseas agencies are accepted.

Generally speaking, equipment performance standards are set in Australia through Standards Australia, and ARL has a significant input to them. It is probably fair to say that overseas standards are re-evaluated in Australia but ARL understands that their policy is to adopt

internationally agreed standards (International Electrotechnical Commission and International Standards Organisation (ISO) standards for example) without significant variation. ARL routinely provides advice to Standards Australia when it votes on the acceptance or not of these international standards.

CAA: CAA follows recognised overseas practice and seeks to harmonise Australian standards with overseas standards where practical. Variances are only made where there are publicly justified reasons.

The Authority recognises 'Aircraft First of Type Certification' from the US, Canada, United Kingdom, France and Holland. Furthermore, CAA recognises and adopts 'Aircraft airworthiness standards' such as US Federal Aviation Regulations without alteration. Similarly, CAA accepts the US Technical Standard Order system for aviation equipment. Because of the restricted size of the Australian aviation industry, the small population and a lack of resources and experimental data, it is simply not cost effective for Australia to develop its own standards in these instances.

CSU: CSU takes into account, when available, regulatory activity and decisions made overseas but this does not obviate the need for Australian regulatory requirements, such as toxicological data, to be independently assessed. CSU considers all available data when determining the potential public health hazard of a chemical.

CSU sees harmonisation of assessment and the exchange of assessment reports as an important part of chemicals regulation. Attempts to exchange evaluation reports with overseas agencies have, to date, been frustrated by legislation relating to the confidentiality of data. CSU is optimistic that the pending new legislation for agricultural and veterinary chemicals will enhance the exchange process.

FBCA: The Bureau does not undertake testing of products itself and normally seeks the expertise of suitable approved organisations for the testing of products if necessary. Where applicable, overseas studies are adopted in the analytical stage. The Bureau usually adopts Australian standards for regulation purposes and Standards Australia would normally adopt international (ISO) standards. The Bureau allows many products meeting overseas standards to be marketed without regulation.

FORS: It is FORS' policy to harmonise, wherever possible, with international standards unless there are significant safety grounds to do otherwise. At present, over 60% of the ADRs are aligned with international standards, predominantly the United Nations Economic Commission for Europe regulations. Further, FORS is currently pursuing formal mutual recognition agreements with a number of countries and economic groups, including the EC. Where overseas standards are totally harmonised with an ADR, approvals issued by the relevant authorities are accepted. In cases of partial harmonisation with an ADR, the overseas approval can be supported with additional testing to demonstrate compliance with requirements.

NFA: NFA does not undertake any testing itself. It evaluates the raw data of toxicological studies which are submitted to it. All testing is the responsibility of an applicant for approval of a chemical. It is normally conducted by an applicant, in their own labs, or under contract. As a result of a number of scandals in the mid-1970s involving toxicity testing, there are strict national and international guidelines and protocols which must be complied with. These include quality assurance certifications. Furthermore, the lab may be audited by government agencies. Since no testing is undertaken in Australia, NFA does not operate an audit team. All national food regulatory agencies in developed countries require all studies undertaken to be submitted, thus the data presented in Australia will be identical to that presented in US, Canada and the EC. Each agency carries out its own evaluation of the data. Public processes and professional networks provide a route for comparison.

In effect all national regulatory agencies review the same raw data. Since many of the effects observed in toxicological studies are novel there can be significant scientific debate about their interpretation. In addition certain countries or agencies may have particular areas of interest or regulatory restriction. For example, the US Delaney clause prohibits the addition to food of any substance shown to be carcinogenic, regardless of the mechanism. The US food legislation also places a more demanding duty of care on the US Food and Drug Administration (FDA) to ensure that food is safe than Australian legislation places on NFA. As a result NFA can proceed to approval of a new food additive once it has satisfied all reasonable safety criteria; whereas the FDA interpretation is that it must be absolutely certain of safety before approval. NFA can achieve its 12 month statutory deadline for approval of additives, the FDA process is currently running at 8-10 years.

It should be noted that where NFA has access to evaluations of reputable national and international bodies, these will be taken into account. However, given NFA's 12 month statutory deadline, Australia (along with Canada) is becoming a very desirable country in which to seek first approval so Australian evaluations normally lead the pack.

NOHSC: When EWGs are developing standards, they collate all relevant material including, where necessary, information and standards from Australia's major trading partners. Where international standards exist they are adapted to suit Australian conditions.

For example, in developing the National Standard for the Control of Major Hazard Facilities, existing standards from the International Labour Office and EC were considered. Advice from the EWG was that Australian factories are on a different scale to those in Europe and thus the standard should not be adopted unchanged. Advice from the EC regarding the facilities covered under their standard was that some had been included for political rather than safety reasons. The EWG thus advised that overseas standards should not be adopted but rather modified to suit Australia. This was done so that provisions in the Australian standard harmonise with all international provisions.

NRTC: Analysis and testing of the technical performance of vehicles and their components undertaken overseas is frequently utilised by both the Commission and FORS. The Commission works closely with FORS in the development of ADRs. ADRs pick up overseas standards where appropriate.

TGA: The analytical and testing process carried out by TGA Laboratories does replicate processes conducted by regulatory regimes overseas. TGA does adopt overseas standards in dealing with matters related to the safety and quality of medical products. Australia adopts the standards of the British Pharmacopoeia, and ISO standards.

All therapeutic goods which are imported into Australia need TGA approval prior to marketing. In a small number of cases, applications for products already approved in advanced overseas countries have been rejected by TGA. Rejections are referred to the Australian Drug Evaluation Committee for further advice and are generally endorsed. Rejections can be due to one or more factors related to the quality, safety or efficacy of the Australian product.

Question 16:
Capability to undertake economic analysis

Would your agency be able to undertake formal cost-benefit or cost-effectiveness analyses of regulations given its current financial and staff resources?

Three agencies currently undertake substantive cost-benefit analyses of their regulations (ARL, FORS, NRTC). ARL noted, however, that the optimisation process is particular to the radiation protection field. NOHSC has commissioned some cost-benefit and cost-effectiveness analyses as part of the EIAs of its standards. Apart from CAA, the other agencies indicated that they do not presently have the capability to undertake substantive cost-benefit analyses.

Specific responses included:

CSU: Given our brief to protect public health, CSU does not believe such undertakings are practicable.

FBCA: Essentially no, however, should such cost-benefit or cost-effectiveness analyses be required, for example, in a review of a regulation, a general analysis can be made.

NOHSC: The conduct of single national EIAs is seen by the tripartite membership of NOHSC to be very important.

The national perspective allows consideration of national effects. In addition it will avoid duplication of effort in each jurisdiction. Most importantly, it avoids different standards being developed in different jurisdictions as a result of a partial equilibrium analysis conducted by a single state.

Worksafe has finalised an EIA for Plant, is currently finalising an EIA for Major Hazard Facilities, and initiating an EIA for Dangerous Goods. Worksafe does not have the economic modelling expertise in house to conduct EIA of regulations. However, Worksafe does have staff with expertise in all OHS fields, epidemiology and standards development who can assist in gathering and interpreting data for EIAs.

Question 17: Cost-recovery

Does your agency seek to recover the costs of its risk regulation activities? If so, who do you see as the beneficiaries of your activities and what proportion of your total costs do they pay?

Of the agencies surveyed, two agencies are specifically required to recover part of the cost of their standards-setting function. CAA is required to recoup half the cost of this function (and its compliance function) from industry. Regarding NFA, the Government has recently determined that, from 1995, it will be required to recover ten percent of the cost of processing applications to vary the Food Standards Code.

None of the other agencies are required to cost-recover for their standards setting activities, although some of the agencies (for example CAA, NFA, FORS, TGA) charge for various non-regulatory services, publications or discrete regulatory activities such as licensing and certification. In the case of TGA, the Government requires that it recover 50 percent of its annual operating costs.

Most of the agencies that nominated beneficiaries of their regulatory activities included broad groupings such as "the general public" (CAA), "all consumers" (FBCA), and "the entire community, both consumers and industry" (NFA). Only a few nominated a specific and easily identifiable sub-group. NFA pointed out that the problems of identifying specific beneficiaries of general regulations such as standards reduced the feasibility of undertaking cost-recovery for them.

Specific responses included:

CAA: Regulatory services, such as licences, are 100% cost recoverable. Until recently, regulatory standards setting and compliance activities were fully funded by Government. The Government has now introduced a policy of funding up to 50% of the cost of these activities, expecting cost recovery of the remainder from the aviation industry. The main beneficiaries of aviation regulations are the general public, safety wise, and the aviation industry.

CSU: CSU participates in cost recovery programs where this has been mandated by the appropriate legislation, for example, industrial chemicals under National Industrial Chemicals Notification and Assessment Scheme (50% cost recovered) and, from 1994-95, the National Registration Scheme for Agricultural and Veterinary Chemicals (up to 100%).

FBCA: No. The Bureau views its activities as benefiting all consumers, however, children and other possibly disadvantaged population groups are also specifically targeted to benefit.

FORS: The costs of regulation development are not recovered. Other FORS activities, import and certification approvals, vehicle inspections, test facility inspections and conformity of production assessments are cost recovered through a schedule of fees published in the Motor Vehicle Standards Regulations.

NFA: At present, no. The Authority, discussing the issue of cost recovery in its Review of Policy, concluded that it was not feasible to identify a beneficiary. In effect, the entire community, both consumers and industry, benefited from food standards which served as the basis of a safe food supply system, and accordingly it was not feasible to recover costs from a particular industry, consumer sector or individual on the basis of an identifiable service provided or benefit received. Costs were best recovered through the taxation system; that is, consolidated revenue.[15]

NOHSC: NOHSC only produces and declares national regulatory models. It is then up to the individual jurisdictions to adopt the regulatory models through their OHS agencies and enforce them. Consequently, NOHSC does not have any direct risk regulation functions and has no ability to recover costs.[16]

NRTC: NRTC is funded by the Commonwealth, State and Territory road and transport agencies. It prepares regulatory policy and legislation for approval by Ministers. The operating authorities in each jurisdiction are responsible for the cost of implementation.

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15 In December 1994, the Government determined that NFA will be required to recoup 10 percent of the cost of processing applications to vary the Food Standards Code. In making this determination, the Government decided that a 90 percent reduction on full cost-recovery is warranted to allow for the 'public good' and 'free rider' characteristics of applications to vary the Code.

16 Worksafe Australia, the body which services NOHSC, also has prime responsibility for the operation of the National Industrial Chemicals Notification and Assessment Scheme. As mentioned in CSU's response, 50 percent cost-recovery fees apply under this scheme.

TGA: It is government policy for TGA to generate 50% of its operating costs through revenue collection. Cost-recovery is through annual charges, inspection fees, evaluation fees, and other charges.

The beneficiaries of the cost-recovery system are the government in pure revenue terms, and the consumer and pharmaceutical industry in that the drugs available on the Australian market have been evaluated for quality, safety, and efficacy. The consumer can take the medicine in confidence and the industry can supply the medicine with an element of reduced liability because the safety of the particular medicine has been evaluated.

SUMMARY/DIGEST

About the agencies

The agencies which responded to this survey have the following characteristics:

- three are Commonwealth statutory bodies, one is a government business enterprise, and the others are divisions and branches of Commonwealth departments;
- the size of the agencies, measured by funding levels for 1993-94 and staff numbers, ranges from $3.3m and 20 staff (NRTC) to $60.3m and 500 staff (CAA's Directorate of Aviation Safety Regulation);
- staff expertise ranges from mainly technical/scientific (ARL) to general administration (FBCA);
- functions undertaken by the agencies include researching problems which may require regulation, promulgating standards, undertaking pre-market assessments of products, excluding products from the market after safety problems become apparent, monitoring compliance with regulations and enforcing regulations; and
- most of the agencies undertake several regulatory functions.

Processes for formulating regulations

In terms of the processes the agencies use to formulate regulation, the following points emerge:

- most of the agencies have transparent, step-by-step procedures for developing regulations;
- none of the agencies has the power to formally 'make' regulations — rather, they generally recommend regulations to Ministers or Ministerial Councils;
- all the agencies use technical or scientific information and most consult publicly, but only a subset use economic analysis in developing regulations;
- most of the agencies have broad, qualitative objectives, but few specify objectives for individual regulations; and
- only two agencies (ARL and CAA) specify quantitative risk levels for their regulations.

To gain greater insights into the way the agencies develop regulations, it is helpful to break down the processes they use into the following two stages:

- in the first stage, the objectives of a regulation or regulations are determined. This may involve, for example, specifying a target risk level; and
- in the second stage, the mechanism or instrument to be used to achieve these objectives is determined. This may involve choosing between general product standards and pre-market assessments to ensure that products do not exceed the target risk level.

Regulatory objectives

In terms of setting regulatory objectives, two distinct groups of agencies emerge.

The first group have as their target an 'arbitrary' level of risk. This target level of risk might be implicitly set in legislation or in an agency's charter. These 'risk-targeting' agencies do not use cost-benefit analysis or any other formal analytical techniques when setting objectives. Once the arbitrary level of risk has been set, these agencies attempt to formulate regulations and controls that keep safety risk at or below this predetermined level. CAA, CSU, NFA and TGA all appear to fall into this category.

The other agencies (ARL, FBCA, FORS, NOHSC and NRTC) do not specifically set out to achieve a target level of risk. Rather, the level of risk that these agencies are prepared to tolerate arises from other considerations. For example, in the case of FORS and NRTC, the level of risk that will be tolerated arises out of a process of weighing up the costs and benefits of a given regulation. Regulations that have a favourable cost-benefit ratio will generally be approved, whilst regulations with an unfavourable cost-benefit ratio generally will not be endorsed. Under this approach, a variety of risk levels may be accepted. In the case of NOHSC, the allowable level of risk arises primarily out of a process of consultation which implicitly measures the strength of any support or opposition to a regulatory standard. Standards that are acceptable to a tripartite group are generally endorsed. Again, there is substantial scope for divergent allowable risk levels for different NOHSC standards, because the risk level associated with a given regulation is not predetermined but arises out of the consultation process.

The agencies in this second group adopt varying degrees of formal economic analysis of regulations. ARL, FORS and NRTC often use fully quantified cost-benefit analysis. These agencies use approaches that have several standard elements of cost-benefit analysis in common. Each involves the identification and valuation of monetary and non-monetary costs and benefits, allowance for different probabilities that particular costs and benefits will accrue, and discounting of future costs and benefits. However, they also have some methodological differences,

particularly in the way non-monetary costs and benefits are valued. Other agencies in this group undertake 'partial valuation' cost-benefit analyses which omit to place a value on human life. In this spirit, NOHSC sometimes undertakes cost-effectiveness analysis rather than cost-benefit analysis as an input into the tripartite decision making process. This analysis yields results in terms of dollars per life saved and thereby avoids the contentious value-of-life debate. FBCA occasionally adopts some qualitative economic evaluation techniques.

Regardless of the method they use to determine the level of safety risk, the agencies' actions promote an environment in which there is a wide range of safety risk levels, some much higher than others.

There are substantial difficulties in attempting to precisely rank the agencies in order of the level of risk that they tolerate. For example, difficulties arise because few of the agencies actually quantify risk levels and, amongst those that do, there are differences in the way risk is measured and denominated.

Nevertheless, a rough approximation of the agencies' relative acceptance of risk can be made. At the low-risk end of the spectrum are CSU, NFA and TGA which can all be categorised as aiming for minimum or no appreciable risk. That said, for certain applications of pharmaceuticals, TGA's approach of minimising overall health risks means that it will tolerate a higher risk of side-effects to achieve a higher therapeutic benefit. CAA also appears to have a slightly higher risk target than CSU and NFA, but its target of an aircraft accident risk of, at most, one in ten million is significantly lower than the risk allowed by other agencies. In the intermediate range of risk levels are ARL, FBCA and NOHSC, although the latter two agencies are very difficult to place. At the higher end of the risk spectrum are FORS and NRTC.

There are at least four possible explanations for the spread of agencies along this spectrum. Some of these explanations are clearly borne out by the survey data; others remain speculative. There may also be some overlap in these explanations.

First, there is a strong link between the processes used to set target risk levels and the size of those risk levels. Agencies clustered at the low end of the risk spectrum are those that set arbitrary risk targets. Agencies that primarily derive the appropriate level of risk from other considerations such as cost-benefit analyses and community consultations tend to tolerate higher levels of risk.

Second, the level of risk tolerated by the agencies appears to be related to the number of people who may be involved in a particular safety incident. For example, one air accident can imperil several hundred people, and a safety problem associated with a particular chemical, food or therapeutic drug is likely to affect a large number of people. Agencies dealing with these safety risks (CAA, CSU, NFA

and TGA) are clustered at the low end of the risk spectrum. On the other hand, accidents associated with particular consumer products are rarely likely to affect more than a few people, as is also the case with individual motor vehicle accidents. The agencies dealing with these risks (FBCA and FORS/NRTC) lie in the middle or at the upper end of the risk spectrum.

Third, there is some evidence of a link between the level of risk tolerated by the agencies and the extent to which the related safety risks can be influenced by the person who bears the risk. At the low-risk end of the spectrum, risks associated with chemicals (CSU), food (NFA) or therapeutic drugs (TGA) are arguably difficult for individuals to understand, and therefore influence, because detailed technical issues are involved. In the case of air travel (CAA), beyond choosing airlines with safer aviation records, travellers have little personal influence over the safety of a flight they take. At the higher-risk end of the spectrum, users of everyday products (FBCA), workers and employers (NOHSC) and drivers (FORS/NRTC) arguably can generally exert more control on the probability of an accident occurring or, at least, on the magnitude of its adverse effects. Indeed, because significant human input is involved in using everyday products, working and driving, there is limited scope for regulation to reduce risk to negligible levels in these activities.

Fourth, the level of risk tolerated by the agencies may be related to the cost or disutility of reducing the relevant safety risks. For example, for FORS/NRTC to achieve the extremely low risk levels pursued by some agencies, they might need to mandate very low speed limiters in vehicles or, at the theoretical extreme, ban vehicles altogether.

Regulatory mechanisms

The agencies use three broad types of mechanisms to address safety issues:

- promulgation of general safety standards;
- pre-market assessment of products, processes or personnel to ensure they meet desired safety standards; and
- post-market exclusion of products — after a safety problem becomes apparent.

All the agencies promulgate general safety standards or advise other bodies that do.

In addition, most of the agencies that regulate the safety of products, whether those products be aircraft[17], chemicals, motor vehicles, drugs or food[18], undertake or require pre-market vetting of those products.

[17] While CAA does not pre-vet aircraft itself, it requires aircraft flying in Australia to have gained 'Aircraft First of Type Certification' from certain overseas countries (see question 15).

Of the agencies regulating product safety, only FBCA does not conduct any form of pre-market vetting. This may be because, whereas the other agencies have been established to deal with specific classes of products which are inherently dangerous, FBCA deals with the large remainder of products, only a small proportion of which are likely to be hazardous. As it would not be sensible to pre-market vet all the products which fall within FBCA's purview, this agency is instead involved in general standard-setting and post-market exclusion of products.

A form of pre-market vetting also applies to personnel in aviation, road travel and transport, and certain occupations. CAA administers a licensing scheme for pilots, car drivers and heavy vehicle operators are required to obtain licences from State and Territory road safety agencies, radiation workers require licences from State and Territory health authorities, and operator licensing or certification in some types of work is required under State/Territory OHS legislation.[19]

The agencies (ARL, NOHSC and NRTC[20]) which are primarily concerned with practices, rather than products or personnel, do not undertake pre-market vetting. Rather, these agencies seek to promote safe practices mainly through the specification of standards and codes of conduct.

Outside these three broad regulatory approaches, the range of options the agencies employ to address safety issues is limited. Apart from FBCA, non-regulatory options are largely peripheral to the agencies' activities. In some cases, this reflects legislative constraints on the approaches that agencies can adopt. In others, it reflects a view that safety issues inherently require regulatory solutions.

The agencies with the most flexible approaches appear to be FBCA, FORS, NOHSC, and, increasingly, NFA. FBCA uses a form of 'enforcement pyramid' to deal with unsafe consumer products. Its possible actions range from no action through negotiated solutions, education campaigns and, at the top of the pyramid, product recalls or outright bans. If initial actions fail to bring desired safety

18 As discussed in question 4, while NFA's assessment of applications to vary the Food Standards Code acts in some respects like a pre-market assessment scheme, new products which meet existing Code requirements do not receive specific vetting by NFA. That said, responsibility for the enforcement of food laws is primarily a State and local government responsibility. One aspect of the enforcement approach adopted is the inspection/surveillance of foods on the market to ensure that they meet the requirements of the Code.

19 Examples include licensing for operators of cranes and rigging, scaffolding and hoists, pressure equipment (eg boilers), welding equipment and fork lifts.

20 Much of NRTC's workload is related to the regulation of driving practices. It is also responsible, together with FORS, for new ADRs relating to vehicle safety. NRTC does not pre-market vet vehicles for compliance with ADRs. This function is undertaken by FORS.

outcomes, FBCA escalates up to the next level of the pyramid.[21] NOHSC generally promulgates performance standards rather than prescriptive standards. These are designed to give firms the flexibility to meet workplace safety objectives in the most cost-effective manner. Most FORS regulations are also performance standards. NFA has adopted the broad objective of reducing the prescriptiveness of Australian food standards, although its progress to date has been limited.

There appears to be a link between the level of safety risk tolerated by agencies and the flexibility of the approach they take. The agencies utilising the most rigid approaches to product safety issues are those towards the lower end of the risk spectrum, while those using more flexible approaches tend to lie towards the middle or upper end of the risk spectrum.

Other findings

Other information arising from the survey includes:

- the agencies investigate safety problems in response to a range of internal and external triggers;
- the agencies have not sought, nor been given, explicit official guidance on the acceptability of particular risk levels. In many cases, the agencies effectively form their own judgments about risk acceptability;
- the agencies base their calculations on actual risk levels as measured by scientific data rather than the level of risk perceived by individuals. However, community (mis)perceptions and political considerations can in some instances influence the regulations adopted;
- the agencies use a wide range of margins of error;
- in some cases, data limitations make it difficult or impossible for agencies to calculate risk levels and/or undertake comprehensive cost-benefit analyses;
- several agencies indicated that they do not have the capability to conduct substantive cost-benefit analyses;
- some agencies replicate overseas testing procedures;
- many agencies adopt, completely or in modified form, overseas regulations. However, none of the regulatory regimes currently allows for the 'mutual recognition' of overseas regulations where they differ from Australian standards;

[21] For a discussion of enforcement pyramids, see Chapter 2 of Ayres, I. and Braithwaite, J., *Responsive Regulation: Transcending the Deregulation Debate*, Oxford University Press, 1992.

- the agencies have a range of mechanisms for receiving feedback on their regulations. However, systematic means for assessing the impact of regulations on safety outcomes are more limited; and
- two agencies are required to undertake partial cost recovery for their standards setting functions, and several charge for other activities, including publications, certification and licensing. No consistent principles for the attribution of costs are apparent.