SPECIAL FEATURE

What makes regulation work?

Bruce J Farquhar

Intervention in injury control

Rivara described regulation and legislation as having become part of the Holy Trinity of injury control along with education and product or environmental modification.¹ I hope to demonstrate that the kinds of regulation that are effective relate not only to demanding or encouraging behavioural changes but also that they contribute greatly to modification of the product and environment.

Why regulate?

Why regulate at all? Free marketers find regulation abhorrent and argue that the market will find the most efficient level of safety, balancing marginal costs and benefits. However, this hypothesis has to be measured against the expectations of society.

PUBLIC PROTECTION

Safety is often claimed to be a right of the individual. John F Kennedy's four consumer rights, which have served as the basis of the United Nations Consumer Protection Guidelines and the consumer policy of the European Union, include the right to safety. This accepted right is often used as justification in itself for regulatory intervention in the marketplace. However, in many ways the market mechanism may be more efficient than many safety advocates wish to admit. Regulatory intervention is not always necessary, although Asch asserts that government safety regulation may be vastly preferable to a purely private system of safety decisions.² There are in any event instances where we can talk of a market failure that entirely justifies regulatory action. We can identify three principle cases in relation to injury control issues; these are listed below.

(1) Public good and externalities

These present some of the clearest cases of market failure and thus the strongest arguments for collective intervention. Public good relates to consumption by society in general, for example the use of public services and interventions such as safe highway design or enhancements to public buildings. Externalities is a term economists use to describe spill-overs, knock-on effects, or side effects. We could describe this as the protection of society at large from the consequences of the actions of certain individuals or groups. In relation to injury control we can think of drunk-driving and exploding soda bottles. Another external-

ties condition concerns the strain put upon public services. For example, the economic costs of injury in relation to the burden on public health and social security systems. These costs are after all, in the main, borne by third parties.

(2) Information

Sometimes consumers are unable to make the correct choice with respect to safety due to a complete lack of information or the provision of insufficient information. An example is car safety. In Europe, especially in the past few years, there has been a much greater emphasis in car advertising on safety as a result of growing interest among consumers. However, the information provided has not allowed consumers to choose intelligently between different cars as to their relative safety. Swedish research has shown that there can be significant differences in the relative safety performance of cars even in the same size and weight class.³ Injuries, and even the risk of death, can be substantially reduced according to the vehicle chosen. Independent information is now being made available through the EURO-NCAP programme and this has already resulted in one instance where the sales of a car that scored badly in the tests fell by 30% over six months.

(3) Human failure

Another cause for market failure is actually human failure. Although information is available to the consumer, the consumer still behaves irrationally or incompetently. For example, driver error is often cited as responsible for over 90% of auto accidents. Yet interventions aimed at driver education have not been particularly successful. Also very important are varied perceptions of risk and the "it can't happen to me" syndrome, which results from a common illusion of having control over truly chance events.

In general, Asch concludes by stating that²:

- In some instances people are unable to process information about risk accurately.
- There are situations in which apparent irrelevancies, such as the context in which the alternatives are viewed, may affect choice.

Forms of regulation

Berger and Mohan identify two levels at which regulatory action can be taken.⁴ The first is the macro level, such as requiring manufacturers to construct their products in certain ways—

ANEC—European Association for the Co-ordination of Consumer Representation in Standardisation

Correspondence to:
Bruce J Farquhar,
Secretary-General, ANEC,
Tervurenlaan 36-4, 1040
Brussels, Belgium.

introducing safety features into building regulations, etc. The second level is that of the individual and includes laws requiring car occupants to wear seat belts or motorcyclists to wear helmets. We should note, however, that there is often more than a casual link between the two levels. Laws requiring the use of some form of personal protective equipment, for example, will be undermined if the law or standard governing the performance of the protective equipment is in itself deficient. Consider the centre rear seating position in a motor vehicle: it is accepted that seat belt use reduces greatly the risk of serious injury and death in the event of an accident and accordingly is mandated by law in many jurisdictions. In Europe, however, at present there is no requirement for three point belts to be fitted in the centre rear position in motor vehicles, even though this is technically feasible. If we examine the injury data, however, we see lumbar spine and internal injuries to the abdomen that would be eliminated if three point belts were fitted. The effect of the requirement to wear seat belts is undermined then by the failure to require three point belts.

What regulations work?

Some examples of successful regulations are cited by Berger and Mohan: the introduction of inflammable fabric standards for sleepwear for children reduced related hospital admissions from 17 to one in five years at a burns unit in Boston; 10 years after safety packaging of aspirin was required in the US deaths from aspirin poisoning declined almost 90%; and helmets are successful, with over 50% of motorcyclists in the US wearing helmets, where they are required by law, but the figure drops to a 50% wearing rate in states where the laws have been weakened or repealed. In New Delhi a law requires motorcycle drivers to wear helmets but not passengers and not surprisingly a study found 90% of drivers wearing helmets but that only 3% of passengers did so. Similarly, in Victoria, Australia bicycle helmet regulation resulted in a reduction of head injuries of between 37%–51%. Child restraint laws in the US are another example. In the 1970s about 10% of children were restrained but in the space of eight years several states passed laws after the pioneering efforts of Sanders and rates rapidly rose. Another excellent example is the relationship between accidents and traffic speed limits which has been demonstrated with the lowering and raising of speed limits in Denmark and the US.^{5 6} Other effective regulations have been targeted at modifications to the construction of power tools, toys, sports equipment, and motor vehicles.

What regulations don't work?

From examples of regulations that do not work we can try to draw some conclusions.

Berger and Mohan identify some injury control approaches that perform well in high income but not in low income countries. This suggests that the interventions proposed must

relate to the particular circumstances of the country to which they are to be applied. This doesn't only involve differences between countries in different stages of economic development but also between otherwise similar countries due to local use. It has for example been argued by industry that the current problems posed by airbags in the US are partly caused by different assumptions made in the drafting of the crash worthiness tests with respect to the relative proportion of belt wearing.

The airbag example could be characterised as an unforeseen side effect of the introduction of the regulation. In Sweden bike helmet successes led to some deaths when children were hung by their helmet straps when playing in trees or in playground equipment, but a simple solution for this problem was an amendment to the helmet standard to allow for a quick release buckle.⁷ This demonstrates the interdependence of laws seeking to alter behaviour by mandating the use of personal protective equipment and the regulations or standards governing the specifications of the equipment itself.

The desired effect of regulations can also be undermined due to compensatory behaviour that was not envisaged when the regulation was drafted. For example, in Europe there is no requirement to evaluate whether child resistant packaging can be opened by the elderly and infirm. This can result in dangerous prescription drugs and other harmful substances being decanted into non-child resistant packaging. Another example is the industry that has grown up around marketing a tool aimed at disabling the child resistant feature in cigarette lighters, which was recently required by federal regulation in the US.

Regulation can also stifle design innovation if it is unnecessarily design restrictive and not based on performance criteria.

It could also be argued that care should be taken to ensure that regulation is targeted at the underlying problem and not at certain symptoms. We return to our example of passive versus active restraints in the US where industry representatives are claiming that the terms of a federal regulation mandating passive restraint reduce their options in tackling the problems that have arisen from the potentially fatal interaction between airbags and children or out of position occupants.

Why do regulations work?

Berger and Mohan suggest that the most effective regulations are those based on environmental and engineering approaches that might not be voluntarily implemented because of cost or inconvenience. If we return to the reasons for regulating in the first place the most obvious reason to regulate is to remedy a market failure.

Market forces can be stimulated through the provision of information such as is the case cited above with crash tests in Europe. Regulation can attempt to reduce the effect on third parties by attempting to influence behaviour which can result in injury, for example

drink-driving laws, speed limits. As we have also already seen regulation can also support other forms of action, for example regulation can help promote the spread of “best practice” in dealing with a particular issue. This can also lead to problems being anticipated and resolved before they arise in another jurisdiction. A regulation concerning beanbags was introduced in the US as a result of 13 deaths. Extrapolating these figures to a country say the size of Australia would result in one death every three years, which may result in the problem not being identified so easily (I Scott, unpublished data).

Consolidation

Regulation also serves to enshrine advances that have been made, especially in product development. We can avoid new generations of product designers repeating the mistakes of their forerunners. One such example is the conditioning of seat belts. An expensive recall resulted in a change in the regulation outlawing the use of certain defective materials. A failure to change the regulation would have left the door open for the mistake to be repeated.

Enforcement

Finally probably the most important reason that regulations fail to work is due to a lack of enforcement. Differences in helmet wearing rates between Australian states with real enforcement and those with no enforcement or those who used voluntary measures or bribes to kick start helmet wearing are revealing. The best regulatory framework is useless if there is no active enforcement. This will become a more important issue as trade becomes more liberalised and more and more countries enter into mutual recognition agreements that reduce the number of border checks.

Barriers to implementing injury control regulations and how do we get round them?

Some common arguments against regulations, according to Berger and Mohan, include:

- The problem is not all that important.
- The proposed law won't work.
- It will cost too much.
- It is not legal (or constitutional).
- It is an undue burden on personal freedom.
- It is not feasible or enforceable.
- It is not popular with most citizens.
- If people would only take care of themselves and their families—by wearing seat belts, supervising their children, etc—there would not be a problem.

To this list, we can add industry reluctance. The original proposal for the universal child restraint ISO-Fix gives an example. Agreement had almost been reached in the standards committee on a four point system. Then at the last moment, car manufacturers, who had not taken such an active role in the drafting of the proposal up until then, were able to defeat the proposal. This was not done on grounds of

safety but to try to reduce the amount of modification the car manufacturers would have to do to their vehicles to accommodate the universal child restraints. Similarly, a proposal to amend the European standard on lighters to introduce a requirement for child resistance such as is mandated in the US was defeated due to concentrated industry lobbying. The goal was to delay any such development because industry would have had difficulty adapting their production for two large markets in a short timescale.

How do we overcome these barriers?

Berger and Mohan recommend the following actions before moving along the legislative route:

- Choose a problem that is important, consider the number and severity of injuries, the economic costs, and community concern about the issue.
- Have a goal that is well defined and feasible.
- Gather the facts before recommending any action.
- Anticipate sources of opposition.

There needs to be a broad array of supporting evidence to support the planned intervention including data, surveys, and scientific articles. In addition, a broad base of support should be assembled. This can come from politicians, government agencies, consumer groups, and single issue citizen action groups, for example MADD (Mothers against Drunk-Driving) and BUSK (Belt-Up School-Kids). The important role of advocacy needs to be stressed. If injury control professionals do not have the resources to take the lead in advocacy then they are at least in the best position to provide the necessary evidence to support the proposals of advocates in the regulatory or standards setting process.

Free trade and injury control—a challenge for the future?

Up until now I have attempted to try to identify why legislation is needed. But it is important to be aware that the nature of regulation is changing fundamentally. In the future a greater priority will be placed on free trade and this may undermine improving consumer safety. The first results of dispute resolution panels set up by the World Trade Organisation indicate a tendency to assign a higher priority to trade than to environmental or health issues. There is also at least one example of a well thought out proposal for an improved product standard being vetoed by a national administration on trade grounds. Not because of a conflict with an international standard but with another country's national standard.

These examples reveal the dangers that lie ahead if too much emphasis is placed by governments on trade liberalisation and not enough on consumer safety. An explicit requirement to balance trade and health and safety in national and regional legislation and the right of individual nations to take unilateral action in support of health and safety, is

enshrined in the General Agreement on Tariffs and Trade (GATT). The difficulty arises if little political priority is given to safety.

Before rushing to condemn developments taking place as a result of attempts to liberalise trade, it should be noted that international standardisation can foster safety. For example, best practice has been spread around Europe much quicker due to the harmonisation of standards and in general, many national standards have been improved through input from other countries as a result of the need to revise the standards to conform primarily with trade obligations.

Recommendations

I have demonstrated that regulation is an important tool underpinning many injury control interventions even where regulation is in itself not the main instrument of the intervention. To ensure the optimum chance of regulatory success the ideas advocated by Berger and Mohan and outlined above should be followed.

In trying to identify other important factors we can usefully make a distinction between regulations aimed at product modifications and those aimed at modifying behaviour or the local environment. The former will increasingly be influenced by international developments. With the GATT treaty the right to challenge national legislation has been established and the first results of the dispute panels indicate that the emphasis will be placed on trade to the disadvantage of safety and environmental concerns. If injury control professionals want to ensure that improvements they have achieved to date are preserved, they must be willing to either participate in the standards setting process themselves or collaborate internationally with consumer groups or government agencies who are active participants.

For regulations that relate to behavioural changes or changes in the local environment the initiative will probably continue to rest at local regional or national level depending on the particular jurisdiction. In these instances there is still the need for international collaboration. Here, however, we will be more concerned with the exchange of information leading to the spread of best practices.

Lastly, it is important that the best drafted regulation is only as good as the enforcement applied. Injury control professionals need to remain vigilant in their analysis of injury rates to ensure that regulations are properly applied and with the growing emphasis being placed on the removal of border controls careful attention will have to be given to international collaboration in enforcement.

6 US Department of Transportation. *Report to Congress: the effect of increased speed limits in the post-NMSL era*. Washington, DC: US Department of Transportation, February 1998.

7 Andersson T. Chin strap forces in bicycle helmets. *International Journal of Consumer Safety* 1995;2:1-11.

Commentaries

Editor's note: The sections that follow reflect my desire to have some additional perspectives on the general issue being addressed by Bruce Farquhar in his Special Feature. This could have evolved into a broad forum with many countries represented. For the sake of time and space I chose to ask only for the four contributions published here. The writers were not asked to comment specifically on the Special Feature. Instead, I simply asked them to describe how their respective agencies decided a product was dangerous and how they then decided what action to take. After reading these contributions, I found them highly informative but similar in tone. Each balances safety with realities of the marketplace and politics. For me the balance is too even; not enough emphasis is placed on what some would view as heavy handed solutions to the problem, that is, through regulation and enforcement. To add to my ever shrinking 2 cents worth, I wonder what health department officials think about all this, or, indeed, whether they think about it all? They, and other readers, are urged to contribute their points of view.

How the UK decides a product is a problem and whether to use regulation or voluntary compliance

Product safety in the UK is the responsibility of the Department of Trade and Industry (DTI). The UK has traditionally taken a multidimensional approach to controlling product safety using information from a variety of sources. The first classification of these approaches can be considered to be into reactive and proactive. The reactive category includes all those approaches where problems with products, including details of accidents caused, are monitored, the proactive category covers the situations where action is taken to promote product safety before specific problems have been identified.

The ideal is clearly to move towards a proactive approach, anticipating problems and taking pre-emptive action before they are allowed to become serious, possibly even preventing any injuries arising from a particular product. In practice, it is accepted that epidemiological analysis of accidents and injuries will always be necessary.

The reactive category includes the careful collection of information from a variety of sources. The UK introduced the Home Accident Surveillance System (HASS) in 1976, and to this day this system, which has been updated and redeveloped several times, remains an important source of information linking products to the accidents and injuries associated with them. HASS has always included cases where there has been an injury, but the use of the word "accident" in the title

1 Rivara FP. Injury prevention in practice. *Inj Prev* 1998;4:4-5.

2 Asch P. *Consumer safety regulation*. New York: Oxford University Press, 1988.

3 Gustafsson H, Nygren A, Olofsson B, et al. *Safety standards in private cars; risk of injury in different car models*. Folksam: Traffic Safety Group, 1988.

4 Berger LR, Mohan D. *Injury control: a global view*. Delhi: Oxford University Press, 1996.

5 Insurance Institute of Highway Safety. *Status Report* 1997;32(8): Oct 11.

was deliberate as from the outset HASS was designed to include cases of suspected injury and fatalities (fatalities are contained in the closely related Home Accident Deaths Database, HADD), as well as studying injuries in the context of the sequence of events leading up to and proceeding from the injury itself.

In the late 1980s and early 1990s HASS was developed and modified to enable it to conform to the European Home and Leisure Accident Surveillance System (EHLASS), which now operates in 12 of the 15 member states of the European Union. The main changes to HASS to enable this were to introduce full coverage of all "leisure" accidents and to extend the coverage to include Scotland and Northern Ireland—these two parts of the UK were originally omitted because HASS had been set up in the Home Office for England and Wales. It is now run by the DTI, which covers the whole of the UK.

However, while the EHLASS data for the UK are extracted from data collected for HASS, the UK's EHLASS data are based on a subset of HASS hospitals—and are thus a different sample. Because EHLASS uses a different set of codes for classifying accidents and injuries, HASS data are recoded before being submitted to the European Commission as the UK's EHLASS data, and there are thus slight differences between accident statistics presented in HASS and those derived from the UK's EHLASS data. While these differences are not serious, it does mean that decisions on product safety taken in the UK based on HASS data may not reflect all the characteristics of the epidemiology of accidents identified by EHLASS data on which others in Europe may be making comparisons and taking or advocating decisions. To date, this has not caused serious difficulties, probably because EHLASS is not being used as actively across the European Union as HASS is used in the UK. It is likely that when the next redevelopment of the EHLASS coding system occurs, the UK will take steps to move the HASS classification nearer to EHLASS and possibly use the same hospital sample for each system.

Policy decisions on product safety and the appropriate balance between mandatory and voluntary standards are not taken by the DTI using HASS data alone. HASS data are supplemented by information from a variety of other sources, including enforcement bodies' databases of product safety problems and concerns, representations made by members of the public, information from standards bodies, consumer organisations, health and safety professionals, and any other relevant sources including the media; this includes both reporting and investigative journalism. And, of course, the UK takes full account of the views of its European Union partners to ensure that member states work effectively together to improve product safety. It is always helpful if another member state has already tackled and solved a product safety problem before it arrives on the UK's shores, and where the UK is the first to identify a problem we are always

quick to pass on details of our solutions to assist others to take pre-emptive action.

The proactive approach to product safety is more difficult to adopt. Wherever possible, the DTI monitors new product development, and carries out detailed research aimed at anticipating problems before they arise. While much of this research draws heavily on the use of HASS data, it should be distinguished from the reactive research responding to problems identified by HASS. HASS differs somewhat from EHLASS in that HASS is designed primarily along the lines of an epidemiological surveillance system, where the aim is to observe rather than form judgments of causality, while EHLASS (despite the use of the word "surveillance" in its title) tends to go beyond the strict epidemiological use of the word surveillance, to include the concept of identifying causal factors where possible.

The UK has a long tradition of introducing well thought through product safety standards, particularly through the work of the British Standards Institution. There has always been a strong technical input, together with comprehensive consultation processes, usually supported by appropriate research with all relevant interested parties. There is little doubt that the protection of UK consumers from product related injuries, through effective standards, has been highly developed, and this is reflected in one of the lowest rates of home accidents and injuries in the world. However, all attempts to date to establish a scientifically valid link between the effectiveness of standards for specific products and the injury rates associated with those products have been unsuccessful.

The UK's approach to moving ahead with the further development of product safety standards has generally been to secure what has been achieved, through a robust participation in negotiations within the European Union on securing harmonised European Union standards, and where the UK has wished to move ahead to strengthen or enhance existing UK standards the aim has similarly been to promote the UK position on the basis of its invariably strong merits. However, with 15 member states needing to agree on harmonised standards, negotiations within the European Union have always involved an element of compromise from all parties. In such a diverse and complex subject, it is difficult to generalise about what has been achieved, but most observers and participants would probably agree that there have been many considerable successes and few disappointments.

The UK took a major initiative on product safety with the Consumer Protection Act of 1987. This introduced the UK's first general safety requirement for consumer products, and also provided for a system of standards approval whereby regulations could be made to call up selected standards. The purpose of standards approval was to provide statutory backing for the most crucial product safety standards, while the idea of a general safety requirement is to provide a catch-all safety provision to apply to all those products not covered by such specific safety provisions. A

general safety requirement requires all products not covered by specific provisions to be reasonably safe, and has been described as “mopping up” legislation since it covers all those cases that have been left out of regulation, whether by design or default.

The process of standards approval through regulation was actively carried forward in the UK until the appearance of the European Union’s General Product Safety Directive in 1992 (the GPSD). The GPSD brought its own general safety requirement, intended to apply across the whole of the European Union, and it was intended to work without any system of standards approval. The standards approval processes of the Consumer Protection Act in the UK were thus swept completely away by the GPSD, and very few of the approved standards thereby lost have been replaced by regulation.

The Consumer Protection Act’s general safety requirement has now been largely superseded by the conceptually similar general safety requirement of the GPSD, although the Consumer Protection Act’s general safety requirement still has effect in limited areas (where specific over-riding European Union directives apply). In the UK, therefore, there has accordingly been a shift from mandatory to voluntary standards for product safety, strongly supported by the GPSD’s article 4 paragraph 2 which states that:

“...in the absence of specific rules...the conformity of a product to the general safety requirement shall be assessed having regard to voluntary national standards giving effect to a European standard or, where they exist, to Community [that is European Union] technical specifications or failing these, to standards drawn up in the Member State in which the product is in circulation, or to the codes of good practice in respect of health and safety in the sector concerned or to the state of the art and technology and to the safety which consumers may reasonably expect”.

The current situation in the UK is that specific regulations are made only where there is an element of doubt in the likely effect of the general safety requirement of the GPSD, or where there are any other grounds for presuming that there is a lack of clarity or agreement on how a particular product may be made safe. Experience suggests that this is a considerable improvement over the situation where regulated standards sometimes ended up being enforced by the issue of prohibition notices.

In the UK product safety is thus now covered by a mix of a small number of mandatory standards, together with a much larger number of voluntary standards subject to the general safety requirement of the GPSD. The standards include both harmonised European Union standards now accepted as British standards, and some standards unique to the UK, with most products being subject to the general safety requirement of the GPSD. After many years of consultation between consumers and suppliers, it is likely that the current mix of mandatory and voluntary standards reflects the wish of both sides to have an appropriate degree of regulation only where there is an

explicit need for clear guidance, so that everyone knows where they stand, but without regulation in those areas where it can possibly be avoided.

Successive UK governments have been concerned not to regulate where regulation cannot be justified, for example, in the area of product recall there is a strong view that a voluntary approach is to be preferred. However, in this as in other areas, it is likely that the views of the European Union will carry increasing weight in future. It remains to be seen how the European Union will balance the principle of subsidiarity—European Union jargon for the principle that wherever possible, decisions regarding member states should be taken by the member states themselves rather than by the European Commission—with the need to ensure the continued development of the common standards regime across the 15 member states required to enable the Single Market to function effectively.

Some have mourned the UK’s loss of approved standards under the Consumer Protection Act, but there is no indication that the new emphasis on voluntary standards, codes of practice and state of the art, has given a lower level of protection—although there has yet been no formal scientific evaluation of the change. This may soon change, since the European Union has just commenced the process of carrying out a wide ranging review of the experience gained with the GPSD. It will be interesting to see if the shift from mandatory to voluntary standards in the UK has been associated with any measurable improvements in product safety. It is understood that a large number of ideas for developing and improving the GPSD have already been put to the European Commission, and it may well be that a new chapter in the development of consumer product safety provision in Europe will soon be written.

Note: the opinions expressed by the author represent his views and are not necessarily those of the DTI.

MALCOLM R BARROW
34 Heath Drive,
Potters Bar,
Herts EN6 1EH, UK

Saving lives and keeping families safe: US Consumer Product Safety Commission

Helping to keep families—especially children—safe in their homes, schools, and recreation areas is the job of the US Consumer Product Safety Commission (CPSC). This is done by reducing unreasonable risks of death and injury associated with 15 000 types of consumer products which this federal independent agency oversees. By so doing the CPSC seeks to reduce annual losses of 22 000 deaths; 29.5 million injuries; and \$400 billion in societal costs.

The commission staff first determines which products are hurting people. Death certificates referencing consumer products are forwarded to the commission from each of the 50 states. Injury data are received daily from a statistical

sample of 101 hospital emergency rooms scattered throughout the US. The statistical sample enables extrapolation of estimated losses to the nation as a whole. A free consumer telephone hotline handles 160 000 calls annually and newspaper and other media sources provide additional information. Serious problems are investigated by the CPSC's field offices' personnel.

Having identified the consumer products associated with the deaths and injuries, the commission responds in various ways to reduce the losses including: (a) working with industry to develop non-governmental, voluntary safety standards addressing performance requirements, warnings, and instructions for safe use of the product; (b) issuing and enforcing mandatory standards, where appropriate; (c) obtaining the recall or repair of products that fail to comply with mandatory standards or that present substantial hazards or imminent hazards to consumers; (d) conducting research on potential hazards; and (e) conducting information and education programs.

The decision on which of the above responses is appropriate in a specific case is made by three CPSC commissioners who are appointed by the President of the United States and confirmed by the US Senate. Decisions take into account staff recommendations and requirements of the laws which the CPSC administers. For example, the commission shall rely upon voluntary consumer product safety standards, rather than promulgate a consumer product safety standard prescribing requirements, whenever compliance with such voluntary standards would eliminate or adequately reduce the risk of injury addressed and it is likely that there will be substantial compliance with such voluntary standards.

Additional CPSC information is available via the internet from its web site whose address is: <http://www.cpsc.gov> or by writing the Office of the Secretary, US Consumer Product Safety Commission, at the address below.

Note: the comments above are those of the author and do not necessarily reflect the views of the CPSC or its staff.

COLIN B CHURCH
Voluntary Standards Coordinator,
US Consumer Product Safety Commission,
Room 604C, Washington, DC 20207, USA

Criteria used by Health Canada's Product Safety Bureau to determine whether or not regulations are needed to address the hazards associated with a given consumer product

Health Canada's Product Safety Program administers the Hazardous Products Act which provides the authority to control, restrict (regulate), or prohibit (ban) certain hazardous materials, as well as the sale, importation, and advertisement of other dangerous or potentially dangerous consumer and industrial products. Under the Act, consumer products can be scheduled as prohibited or restricted and workplace hazardous products can be classified as controlled. The scope of the Hazardous

Products Act includes consumer products which pose or are likely to pose a hazard to public health and safety because of their design, construction, or contents; and workplace hazardous materials.

In the regulatory process, federal authorities must follow Regulatory Process Management Standards. The decisional process through which the Product Safety Program determines whether or not a product should be regulated or an existing regulation revised is based on an assessment of the risk presented by the product. Regulatory authorities proposing new regulatory requirements or changes to regulations must have evidence that a problem has arisen, that the risks posed are such that intervention is required at the time, and that new regulatory requirements are necessary.

Several criteria are used to determine the most effective way to manage the risk. As a first step, the problem must be described, documented, and analysed. It should be demonstrated that new regulatory requirements will help solve the problem and that the benefits of regulatory requirements are greater than their costs. In the process, consultations with interested parties begin as early as possible in order to get stakeholder input on the definition of the problem, as well as on proposed solutions.

As part of the risk management process, regulatory authorities must consider several extrinsic factors, such as:

- Is there sufficient information (complaints, accident and injury data) to substantiate a need for action?
- How effective would an enforcement policy be in the advent that a regulation is put into place?
- How effectively can the organisation monitor the market place and enforce the regulations through inspections and market place sampling?
- How urgent is the need for action? Can a regulation, interpretation, and enforcement policy be developed rapidly to address the problem?
- How extensive and accurate would laboratory testing need to be to verify compliance?
- How willing is industry to collaborate towards the elimination of the problem at this time?
- Can total collaboration with industry be achieved and sustained in the future?
- Would stakeholders and interest groups support the regulatory initiative or would they favour an alternative solution?
- Have other strategies been tried and their effectiveness evaluated (education campaigns, information bulletins, etc)?
- How does the initiative rank among the other health and safety priorities of the organisation?

Answering these types of questions provides sound criteria to ensure that the most appropriate way to solve the problem is chosen by the regulatory authority.

YVES FORTIN
*Senior Project Officer,
 Product Safety Bureau, Health Canada,
 Statistics Canada Main Building, Wing 1000,
 Tunney's Pasture, address locator: 0301B2, Ottawa,
 Ontario, Canada K1A 0K9*

Evolving role of standards in child safety: a Canadian perspective

Standards have always made an important contribution to child safety. Whenever there has been a product or service with the potential for injury, child safety is taken into consideration when standards are developed. A standard is a document that provides requirements for the safety, performance, and/or quality of products, processes, and services.

With the strong movement to international trade liberalization and technological advancements, products are crossing borders more easily, and finding their way onto store shelves at a quicker pace than ever before. Further, with a growing trend to reduced government regulation and increased industry self regulation in many countries, there is some concern that child safety standards may be compromised. Regulators and standards writing organizations (SWOs) are facing challenges with this new reality and will need to adapt in order to continue playing an effective part in the prevention of childhood injuries.

Traditional standards approach

Voluntary, consensus based standards are developed by SWOs, such as Canadian Standards Association (CSA), using balanced committees of volunteers. These committees usually represent regulatory authorities, industry, and consumers. This is an approach to standards development employed by many SWOs worldwide. By involving many stakeholders, this approach helps to ensure that the standards meet the needs of the marketplace while providing a balance between diverse interests. Although standards are, in themselves, voluntary, consumer protection legislation in many countries makes reference to them when defining detailed technical requirements for products with particular hazards. For example, about one third of CSA's standards are referenced in legislation.

CSA helps to protect children from injury in many different environments through the application of these voluntary, consensus based standards and by certification programs. The standards cover a wide range of products from child resistant packaging to playgrounds. For the most part, standards have been developed on a product-by-product basis. Requests for standards work come from various stakeholders and often rise in response to specific injuries or fatalities. This reactive approach has

been customarily employed by most SWOs worldwide.

Recognition of the need to change

Canadian standards developers are now exploring the need to develop a more coordinated, proactive approach to child safety, one that can respond to the following factors:

- Globalization of markets and the shift to international standards.
- Changing public policy—downsizing of government and the shift from product specific regulations to voluntary standards and to hazard based regulations (which could be referenced by voluntary standards) that cover a range of standards.
- Downsizing of Canadian industry and the need to be competitive.
- Increasing public demand for safety.

The trend away from regulation concerns many child safety advocates. They feel that mandatory national standards, along with conformity assessment programs, would resolve many current safety issues related to procurement, liability, and public confidence. However, with reduced government resources, regulators will not be proactive in this area unless there is strong public pressure. Even where mandatory standards exist, enforcement activities may be more limited than many would wish them to be. Public education programs help increase compliance. Priority setting, based on sound research data and cost-benefit analysis and risk assessment analysis, is needed to determine if and where new or stronger mandatory standards are needed.

Global standards

In recognition of the need to change, the European Union's "New Approach" has led to a strong movement toward international and regional trade liberalization. General Agreement on Tariffs and Trade (GATT) makes specific reference to the use of international standards to promote competition and remove barriers to trade through the elimination of different rules for each country. Other regional trading blocs, such as NAFTA (North American Free Trade Agreement), APEC (Asia Pacific Economic Cooperation), and ASEAN (Association of South East Asian Nations) also recommend the harmonization of standards. As more and more products cross borders, harmonized and global standards become increasingly important. Although consumers benefit from greater competition among suppliers, there is growing concern that international harmonization could become an excuse for accepting less stringent consumer protection in some countries. Children remain among the most vulnerable consumers.

Hazard based safety criteria: new direction for standards development?

A trend that began in Europe has engendered interest and study throughout the world. That

trend is toward hazard based safety criteria (HBSC), or horizontal standards.

The hazard based approach focuses on hazards, which are constants, instead of products, which are ever changing and often improving due to advances in technology. Unlike the traditional "vertical" method of standardization, which takes a product-by-product approach, and specifies a set of design and performance criteria to address the hazards inherent in a product, in the "horizontal", hazard based approach safety criteria are formulated independent of specific products. Therefore, such criteria can be applied to a large spectrum of products. Presumably, this ensures consistency in the level of safety for a given hazard from one product to the other. For example, a safety criterion for sharp edges may be applied to any product, provided that sharp edges are not essential for the function of the product (for example, knives, scissors). Ergonomics play an important part in the formulation of safety criteria, because the main cause of hazards is often an incompatibility between a product and a human.

A senior official with the Product Safety Bureau, Health Canada, and the author of the 1997 paper *Hazard-Based Safety Criteria: A New Cost-Effective Generic Approach to Making Products Safer for Children*, envisions both horizontal and vertical standards working to complement each other (FPG Dignard, personal communication, 1998). He says HBSC identify the essential elements that are needed in a general safety directive. Then standards may be written for specific products by organizations, such as CSA, referencing the general safety directive as its basis. The involvement of many different stakeholders would still be crucial to the process, and federal regulations may mandate hazard based criteria under a national general safety code or directive, such as ISO/IEC Guide 50 (see next paragraph). However, the pace of HBSC development is slow, and widespread acceptance of the hazard based approach could be a long way off.

CSA, Guide 50, and HBSC

CSA is helping to facilitate Canadian input to the revision of an International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) draft document, Guide 50 *Safety aspects—Specific guidelines to take child safety into account in standards* which is now being revised. This international policy document acts as a guideline based on implementing a hazard based approach when developing safety standards for children. Although the document is primarily directed toward standards writers, it also could be useful for designers, service providers, manufacturers, retailers, and regulators. Once published, the guide could be implemented in various ways:

- Adopted as a CSA or national standard/guide.

- Be used as a requirement for the approval for national product standards used by or for children.
- Act as a guidance tool for manufacturers/designers.
- Referenced in legislation as a general safety directive.

At a CSA roundtable held in 1997,¹ participants felt that there is a need for both a hazard based approach as well as product specific standards and regulations. European officials feel that Guide 50 will be helpful in speeding up the process of developing new standards and in improving the consistency of standards. With Guide 50 used as the basis for product specific standards, standards writers need only address the peculiar requirements for the product not covered by this general safety directive. Using Guide 50 as the basis for safety criteria would not only expedite standards development, but would ensure a level of consistency among those standards which do likewise.

Guide 50 covers the following topics:

- Child safety *v* safety in general.
- The need to take child development, behaviour, and psychosocial factors/environment into account.
- Preventing and reducing injury.
- Hazards relevant for children, including mechanical, thermal, chemical, electrical, radiation, biological, fire, explosion, psychological/behavioural hazard, noise and vibration hazard.
- Principles for addressing the hazards in requirements.
- Checklist.
- Bibliography.

Finally...

With the international trend toward reduced government regulation and increased industry self regulation, along with the trend to global standards and global competition, standards developers must look to new marketing strategies aimed at industry to adopt standards voluntarily—perhaps a strategy that promotes adopting a standard to gain a competitive advantage along the lines of the prestigious, sought after ISO 9000 series of quality standards. We must be alert to the challenges ahead of us, and see to it that they do not create additional risks to the most vulnerable in our society, our children.

The box on the next page looks at child safety standards for bicycle helmets and draw-strings on children's clothing.

JEANNE BANK
Canadian Standards Association,
178 Rexdale boulevard,
Etobicoke, Ontario
Canada M9W 1R3
(e-mail: bankj@csa.ca)

¹ Canadian Standards Association. *CSA's role in child safety*. (Published proceedings.) Etobicoke, Ontario: CSA, 1997.

A look at child safety standards: bicycle helmets and drawstrings on children's clothing

Let's look at two areas of concern for child safety and the role of standardization and ensuing legislation in different jurisdictions.

Bicycle helmets

Bicycles are associated with more childhood injuries than any other consumer product except the automobile. Head injury is the leading cause of death in bicycle crashes and is the most important determinant of bicycle related death and permanent disability. The single most effective safety device available to reduce head injury and death is a bicycle helmet. A number of bicycle education programs in many jurisdictions help to disseminate information about the importance of wearing a certified bike helmet. A certified helmet carries the mark of an accredited certification organization which tells the buyer/user that the helmet meets the applicable requirements of a standard.

Both CSA and, in the US, the American Society for Testing and Materials (ASTM) bicycle helmet standards were developed with multistakeholder input which included, among others, manufacturers, regulators, academics, researchers, and consumer representatives. Similar requirements are covered in each, with one major difference. CSA has gone on to develop a child helmet standard that requires lower *g* levels and lighter test headforms similar to a child's head weight.

In the past few years, some 15 states and more than 30 localities (municipalities) in the US have enacted some form of bicycle helmet legislation (mostly covering only young riders). Several standards are referenced, including ASTM, Snell Foundation, and CSA. New Jersey, the first state in 1992 to enact legislation for children under 14, has had a 60% decrease in fatalities (the number of bicycle related fatalities for those 14 and over remains stagnant).

The US government Consumer Product Safety Commission (CPSC) has developed a mandatory federal safety standard for bicycle helmets which will come into effect next year. This means that helmets sold in the US will have to meet the standard's requirements by law. It does not make the wearing of a helmet mandatory—that remains a state's prerogative.

In Canada, Ontario (1995) and British Columbia (1996), as well as some municipalities, have passed legislation mandating that helmets be worn—in British Columbia, by all ages, and in Ontario, by those under 18. CSA's and ASTM's bicycle helmet standards are among those referenced in legislation. Statistics are not yet available on the impact of this new legislation.

Clearly, bicycle education programs and mandatory bicycle helmet legislation are proving to be effective at increasing helmet use and, therefore, reducing bicycle related death and injury.

Drawstrings on children's clothing

Drawstrings on children's clothing are a hidden hazard that can lead to deaths and injuries when they catch on such items as playground equipment, bus doors, or cribs. Typically, as a child descends a slide, the toggle or knot on the drawstring gets caught in a small space or gap at the top of the slide. As the child hangs by the drawstring, suspended part way down the slide, the drawstring pulls the garment up taut to the neck, strangling the child.

Britain banned drawstrings from children's clothing more than 25 years ago. The number of deaths from drawstring strangulation fell significantly. There still exists a strangulation hazard, however, for children who wear necklaces and makeshift drawstrings affixed by well meaning but unaware parents.

Both Health Canada (drawstrings are not within the purview of CSA) and the US CPSC have used voluntary efforts to this point to educate manufacturers and consumers. In the last few years, in both countries, the number of fatalities has gone down, resulting perhaps from consumer information campaigns and from voluntary guidelines for manufacturers to develop alternative closures to replace drawstrings. Many retailers don't carry children's clothing with drawstrings anymore. However, this type of clothing is still available to consumers. Parents should take drawstrings off the hoods and necks of children's jackets and sweatshirts, and they should substantially shorten the drawstrings around the bottom of coats and jackets.

This year, Health Canada will be conducting a comprehensive market survey to determine the proportion of children's garments that still have drawstrings. Based on the analysis of the survey outcome, Health Canada will take appropriate corrective measures if industry compliance is insufficient. This could mean regulation will be enacted. Public education efforts will remain an integral part of Health Canada's response to this hazard.