

Analysis of Relative Risks and Levels of Risk in Canada

Ron Law

Juderon Associates

- 1. INTRODUCTION2**
- 2. METHOD.....6**
 - DATA SOURCES6
 - Fatalities in Canada*.....6
 - Levels of Risk*.....7
 - NEEDED TO HAVE ENOUGH DATA TO PROVE THE BENEFIT OF THE DECISION). VALIDATION OF DATA.....10
 - ACCESSIBILITY TO DATA.....11
 - MISSING DATA11
- 3. POLICY14**
 - CANADIAN GOVERNMENT14
 - HEALTH CANADA14
 - POLICY VACUUM.....15
- 4. KEY FINDINGS.....15**
 - POLICY DEVELOPED IN EVIDENCE VACUUM15
 - Missing data*.....15
 - Flow on effects*16
 - FILLING THE GAPS16
 - EVERY DAY RISKS IS CANADA17

5.	RISK ANALYSIS	17
	WHAT IS AN ACCEPTABLE LEVEL OF RISK?	18
6.	RISK CRITERIA : FUNDAMENTALS	19
•	INDIVIDUAL ACCEPTABLE LEVEL OF RISK	19
7.	INDIVIDUAL ACCEPTABLE LEVEL OF RISK.....	19
•	THE PROBABILITY OF LOSING ONES LIFE IN NORMAL DAILY ACTIVITIES SUCH AS DRIVING A CAR OR WORKING IN A FACTORY IS ONE OR TWO ORDERS OF MAGNITUDE LOWER THAN THE OVERALL PROBABILITY OF DYING.	19
•	ONLY PURELY VOLUNTARY ACTIVITIES (SUCH AS MOUNTAINEERING) HAS A HIGHER RISK (SEE FIGURE).	19
8.	ECONOMIC OPTIMAL LEVEL OF RISK.....	27
•	THE PROBLEM OF THE ACCEPTABLE LEVEL OF RISK CAN ALSO BE FORMULATED AS AN ECONOMIC DECISION PROBLEM.	27
•	THE EXPENDITURE I FOR A SAFER SYSTEM IS EQUATED WITH THE GAIN MADE BY THE DECREASING PRESENT VALUE OF THE RISK (.....	27
•	NATIONAL ACCEPTABLE LEVEL OF RISK	20
	AS AN UNTENABLE—INDEED, UNREALISTIC—POSITION.NEED FOR INTERVENTION	21
	<i>Foreseeable or not?</i>	<i>Error! Bookmark not defined.</i>
	<i>Voluntary or involuntary?</i>	<i>Error! Bookmark not defined.</i>
	<i>Significant potential harm or not?</i>	<i>Error! Bookmark not defined.</i>
	<i>Reversible or irreversible?</i>	<i>Error! Bookmark not defined.</i>
	<i>Likelihood of harm highly probable or not?</i>	<i>Error! Bookmark not defined.</i>
	<i>Planned intervention practicable or not?</i>	<i>Error! Bookmark not defined.</i>
	<i>The risk is an involuntary one. “Acceptable Level of Risk?”</i>	21
	<i>Proposed description of Acceptable Level of Risk</i>	24
	<i>De Minimis Provision</i>	25
	<i>As Low As Reasonably Practicable (ALARP)</i>	26
	<i>Establishing the Factual Basis for Comparative Risks</i>	26
	Standard of proof	26
	<i>Discussion</i>	28
	CANADIAN EVERY DAY BENCHMARKS	28
	DISCUSSION	35
	<i>Bright lines or guidelines?</i>	35
	<i>Precautionary principle and science</i>	37
9.	FINDINGS OF COMPARATIVE RISK ANALYSIS.....	38
	RELATIVE RISK COMPARATOR	39
	<i>Air travel</i>	39
	IS ABSENCE OF EVIDENCE, EVIDENCE OF ABSENCE?.....	39
	PUBLIC HEALTH RICHTER SCALE	40
10.	PROPOSED FRAMEWORK FOR CLASSIFICATION OF RISKS.....	43

1. Definitions

1. Canadian Government Definitions¹

Incidence	means the number of new cases or outbreaks of a disease that occur in a population at risk in a particular geographic area within a defined time interval.
Risk	the likelihood of the occurrence and the likely magnitude of the consequences of an adverse event to animal or human health in the importing country during a specified time.
Risk Analysis	the process composed of hazard identification, risk assessment, risk management and risk communication.
Risk Assessment	a scientifically based process consisting of the following steps (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment and (iv) risk characterization.
Risk Communication	the interactive exchange of information on the risk among assessors, risk managers and other interested parties.
Risk Management	the process of identifying, selecting and implementing measures that can be applied to reduce the level of risk.

2. Webster's dictionary has the following definitions:

Safe:	free from harm or risk.
Risk:	1- possibility of loss or injury. 2- expose to hazard or danger.
Adventure:	an undertaking usually involving danger and unknown risks.

“Without risk there is no progress. In fact, the only way to avoid risk is to do nothing, and even that has risks.”²

2. Introduction

3. This paper has been requested by Tuck's Professional Services Belleville.
4. The brief was to assess identifiable hazards that Canadians are exposed to, to determine the exposure rate of individuals to those risks, and determine the magnitude of harm through that exposure, calculate relative risks based on that data and to provide analysis and opinion on same.
5. This paper uses death as a marker for harm, but in doing so acknowledges that serious non fatal harm can occur. The basis for using death as a marker is that it has proven to be a very sensitive marker, is used every day to measure concerns

¹ Canadian Food Inspection Agency,
<http://www.inspection.gc.ca/english/fssa/polstrat/import/appence.shtml>

² Ultralight Pilots Association of Canada, President's Message January 2003
<http://www.upac.ca/modules.php?name=News&file=article&sid=94>

such as traffic fatalities, suicides, drowning, and monitoring diseases such as meningitis and SARS.

6. As an example, death was the marker that identified both the 2003 SARS outbreak and the more recent avian flu incident. Put in to context, the World Health Organisation estimates that annual epidemics of influenza result in between three and five million cases of severe illness and between 250 000 and 500 000 deaths every year around the world.³ There have to date been approximately 20 deaths due to avian flu during a time when approximately 50,000 to 100,000 people have died from influenza. In other words, the sensitivity of using death as a marker for avian flu in humans is of the order of 0.0004 to 0.0002 or 1:2,500 to 1:5,000.
7. It is universally accepted that there is an iceberg effect whereby for every death there will be several cases of serious harm and many more of moderate and insignificant harm. The following “Facts about Injury in Canada”⁴ and poisoning in the USA highlight the iceberg effect.



Injury statistics are alarming:

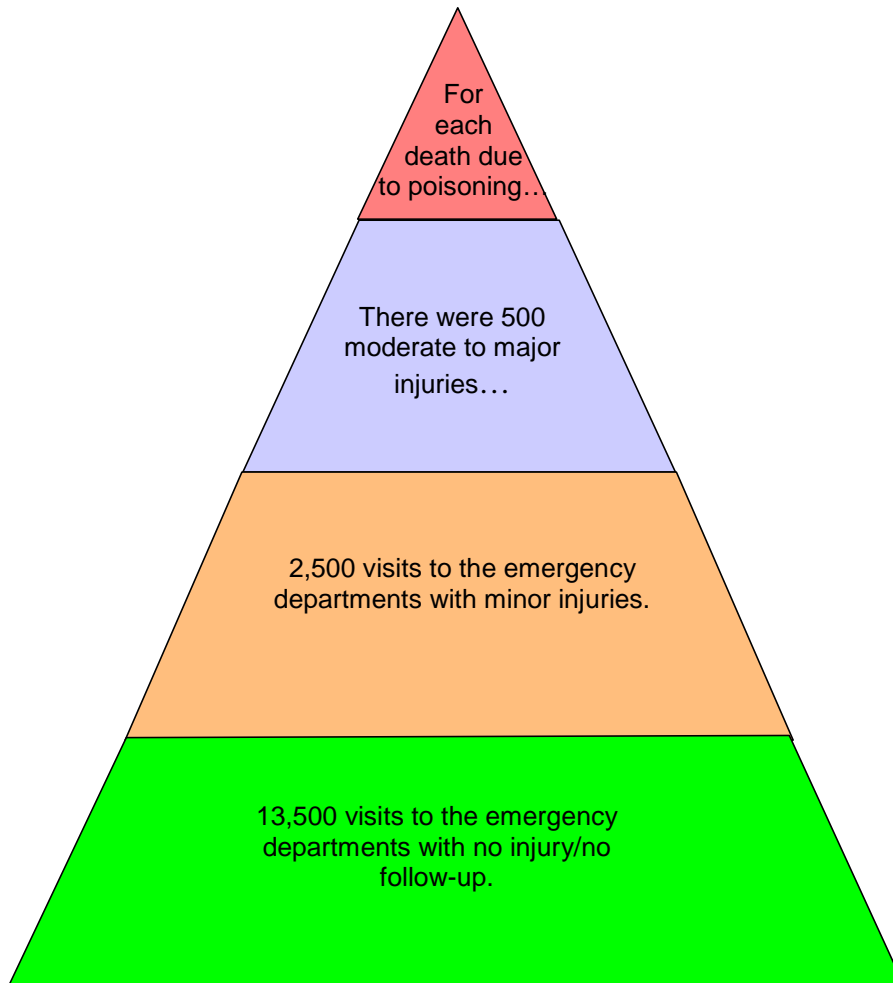
- **Injury is the *leading* killer** of persons 1-44 years of age.
- **It is estimated that 90%** of these injuries could have been prevented.
- **Motor vehicle collisions kill 3,000 Canadians** and 40% of these incidents involved alcohol
- **20-25% of children** sustain sufficient injuries to require medical attention, miss school, or require bed-rest
- **Farm worker fatalities** represent 13% of all occupational deaths in Canada

Figure 1: Iceberg effect – Canadian Injuries

8. What is not said in these statements is that preventable medical injury is excluded from these stats and there are more deaths in 1-44 year olds than other forms of injury; **preventable medical injury is therefore the leading killer of persons 1-44 years of age in Canada.**

³ <http://www.who.int/mediacentre/factsheets/2003/fs211/en/>

⁴ <http://www.injuryprevention.ca/facts.htm>



Unintentional poisoning: USA 1999. Source: Litovitz et al, American Journal of Emergency Medicine, Vol 18, No 5, Sept 2,000

Figure 2: Iceberg effect – USA Poisonings

9. Of more than 2 million visits to USA emergency departments due to poisoning, less than 10 (0.000005) were related to fatalities associated with natural health products whilst 78% of the fatal poisoning cases were associated with pharmaceutical products.
10. In Canada, about 3,000 people die from motor vehicle accidents – over 10,000 Canadian's die from preventable medical injury in acute care hospital's only – research in similar healthcare environments suggests that perhaps three times that number are killed by preventable medical injury in all healthcare settings in Canada.

11. As part of the brief was to determine relative risks associated with everyday activities, it is reasonably assumed that the lesser forms of harm will be proportional to the most severe form; death.
12. The paper examines Canadian government and Health Canada policy regarding risk management and good regulatory practice and in doing so defines a quantitative model of assessing various levels of risk and proposes descriptors to assist in the development of evidence based and proportionate policy.
13. Risk management options that enable individuals freedom of choice regarding exposure to risk as well as providing the state with guidelines regarding the provision of an acceptable level of protection within society are discussed.
14. In assessing the risk to society, it is important that the emphasis is on ensuring that all reliable information is considered provided it has not been obtained improperly. The evidence, discussion and opinion expressed in this report provides "beyond a reasonable doubt" standard of proof mandated by *R vs Gardiner*, that natural health products are extremely safe products by any standard, and pose a de minimis level of risk to both society and individuals. As such, it is proposed that classifying them as a subset of products proven to expose society and individuals to dangerously very high level of risk is inconsistent with the cornerstone of good regulatory practice, namely the Proportionality Principle.
15. Risk is the likelihood of the occurrence and the likely magnitude of the consequences of an adverse event to human health during a specified time.⁵
16. A full risk assessment should aim to achieve hazard identification, hazard characterisation, appraisal of exposure and risk characterisation. It may not always be possible to complete every stage systematically, owing to insufficient relevant scientific evidence and the nature or urgency of the risk.
17. This is when the precautionary principle may come into play being particularly relevant where the possibility of harmful effects on health or the environment has been identified, and preliminary scientific evaluation, based on available data, proves inconclusive for assessing the level of risk.⁶
18. Health Canada believes that good evidence of health benefits is not always sufficient justification for recommending that Canadians be allowed to be exposed of higher levels of potential hazards, whether voluntary or not.⁷ Health Canada believes that there must also be good evidence of a lack of adverse health effects, not only among the population subgroups expected to experience the documented health benefits but among all other population subgroups as well.
19. In developing its framework for undertaking risk assessments of nutrients, Health Canada therefore acknowledges that lack of evidence of harm is **evidence** of lack of harm. This is not the same as saying that lack of evidence of harm is **proof** of lack of harm, but simply acknowledges that absence of evidence is evidence of

⁵ Codex Alimentarius quoted in Canadian Food Inspection Agency,
<http://www.inspection.gc.ca/english/fssa/polstrat/import/appence.shtml>

⁶ Precaution in the WTO - EC position paper July 2001,
<http://europa.eu.int/comm/trade/miti/envir/prec.htm>

⁷ http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/nq-qn/e_executive_summary_risk.html

absence, especially following a systematic review of evidence databases that might contain evidence of harm.

20. As such, this paper provides a framework for using available publicly available information to identify a number of causes of death in Canada to determine exposure rates for each of the hazards identified to determine relative risks for a wide range of activities and to establish a model for classifying risk according to levels of risk to assist choosing risk management options.

3. Method

Data sources

Fatalities in Canada

21. This report analyses the number of deaths in Canada related to various activities [hazards] and then calculates the number of people exposed to each hazard.
22. It provides a best estimate of the risks associated with each activity expressed as fatalities per million people at risk.
23. Relative risk is then determined using a common Data are extracted from a wide variety of sources including from Statistics Canada⁸, Health Canada^{9,10,11} to Transport Canada¹², Environment Canada, various research groups such as the Canadian Agricultural Injury Surveillance Program¹³, Canadian Institute for Health Information (CIHI)¹⁴, Canadian Institutes of Health Research (CIHR), Safe Kids Canada¹⁵, university and hospital research centres^{16,17} including the Injury Prevention Research Office¹⁸, sports and recreation related organisations such as the Canadian Safe Boating Council¹⁹, work and industry related accident reports and websites such as <http://airsafe.com/airline.htm>, ministerial speeches,

⁸ eg; <http://www.statcan.ca/start.html>

⁹ eg; http://www.hc-sc.gc.ca/hpb/lcdc/pub4_e.html

¹⁰ eg; <http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/chirpp-schirpt/index.html>

¹¹ eg; http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/lcd-pcd97/hsp_mf_e.html

¹² eg; http://www.tc.gc.ca/roadsafety/Stats/statsi_e.htm

¹³ eg; <http://meds.queensu.ca/~emresrch/caisp/>

¹⁴ eg; <http://www.cihi.com/index.htm>

¹⁵ eg; www.safekidscanada.ca/English/Media/mediarelease_skweek2001.html

¹⁶ An example report; Scanlan, A., MacKay, M., et al, (2001) Sports and Recreation Injury Prevention Strategies: Systematic Review and Best Practices BC Injury Research and Prevention Unit, Plan-it Safe, Children's Hospital of Eastern Ontario

¹⁷ <http://www.med.ualberta.ca/acicr/pages/data.html>

¹⁸ <http://www.injuryprevention.ca/default.htm>

¹⁹ <http://www.csbc.ca/text/91bbsmartriskpresentationb.ppt> and http://www.csbc.ca/PDFfiles/Will_it_Float_PFD_report.pdf

parliamentary speeches²⁰, standing committee reports, and provincial government databases.

24. The causes of death table is not comprehensive, but is representative of a wide range of activities. For example, the data available enables fatalities to be sub classified in to many smaller groups which was not necessary for the brief given.

Levels of Risk

25. Amalberti refers to three categories of risk.²¹ The first category he refers to corresponds to non professional systems. The safety level remains below $1:10^{-3}$ (one catastrophic accident per thousand trials). Whilst most of the situations fitting this category are related to individual experience of risk management, such as high altitude mountain climbing. Amalberti believes that the safety of these systems cannot go much beyond 1×10^{-3} because of the absence of formal regulations about risk taking, education, and practice.
26. Risk is managed exclusively on individual basis. However, Harvard researcher, Lucian Leape,²² notes that medical practice within acute-care hospitals fits this risk category with risk of death related to highly preventable medical injury being approximately 3×10^{-3} making being a patient in the Canadian Health System this one of the most hazardous activities in Canada.
27. Amalberti notes that his second category includes regulated industries such as chartered flights, the chemical industry, road transport, and anaesthesiology have catastrophic events that taper off at levels approaching 1×10^{-4} to 1×10^{-5} . He then refers to 'ultra-safe' activities with safety records in excess of 1×10^{-6} catastrophic events per million units of exposure to risk. These ultra safe systems have several major characteristics that can be referred to as "Ultra Safe Paradoxes."
28. These paradoxes include the fact that as accidents become increasingly and extremely rare, ie they are much safer, the greater the irrational consequences of remaining accidents/incidents leading to over reaction of the commercial market (possibly leading to rapid bankruptcy), growing intolerance of media and public opinion, and over-reactivity within the company.
29. There is a tendency for management to over prescribe remedies to an already saturated 'shop floor', and to over regulate due to the irrational public (and therefore political) perception of risk.
30. There is a good argument that such a paradoxical response to perceived risks associated with natural health products has resulted in natural health products being shifted from a relatively 'safe' regulatory paradigm such as that used to regulate foods to a relatively 'unsafe' regulatory paradigm such as that used to regulate pharmaceutical medicines.

²⁰ eg; http://www.parl.gc.ca/37/2/parlbus/chambus/house/debates/002_2002-10-01/han002_1445...

²¹ Amalberti, R. (2001) Revisiting safety and human factors paradigms to meet the safety challenges of ultra complex and safe systems, In B. Willpert, & B. Falhbruch, Challenges and pitfalls of safety interventions, Elsevier : North Holland.

²² Leape, L., cited in Patient Safety in the Canadian Health Care System What are the issues? What is happening? Peter Norton Professor and Head Department of Family Medicine University of Calgary

31. Amalberti argues that there is a propensity to introduce reporting systems on incidents, and near incidents, as priorities, because accidents are so rare. Because incidents are so rare, any distortion of actual reporting due to biases can result in remedy focus being channelled in to politically motivated areas. He notes that the use of the reporting systems in such cases can easily be manipulated management and workforce at all levels to take certain actions as part of a hidden political agenda. Whilst reports of certain types of incidents might be reported by workers or communicated by managers, for example, the actual number of incidents may not have changed as an intentional means to communicate problems to the management and regulatory level, or conversely to pass a safety message back to end users. Risks can be amplified or attenuated by the risk communication process.
32. The feedback time to prove the effectiveness of a given safety action in ultra-safe activities can be 6 years or more and even then is very difficult to measure.
33. A skeptic has described the term, "Act of God" as; "a useful construct invented by religious apologists to explain away anomalies within the natural environment and by devious insurance companies to get them off the hook for huge claims."²³
34. Forces of Nature are legally defined, such as freezing or hot weather, avalanches, floods, drought and may be foreseen or unforeseen.
35. An Act of God is legally defined as an unforeseen act of nature such as lightning or a flash flood.²⁴
36. In *R. v. B.C. Hydro, Hallcraft Construction Ltd., and Ralston's Excavating Ltd.* BC Provincial Court (1986) the court explained that an "act of God" is an extraordinary operation of nature to which no man contributed; and an event that could not foresee or guarded against.²⁵
37. Insurance companies define an Act of God as 'An accident or event which happens independently of human intervention and due to natural causes such as storm earthquake etc, which no human foresight can provide against.'²⁶
38. The Canadian legal glossary of Federal statutes defines an Act of God²⁷ in terms of *loss or damage acte de Dieu* (R.S., c. C-27.01; Sch. I IV 2.(d)) *act of God or Queen's enemies (not covered by an insurance) cas de force majeure ou acte d'ennemis de Sa Majesté* R.S., c. C-24; 52(4) *Act of God or other unforeseen circumstance cas de force majeure ou autre circonstance fortuite* R.S., c. N-26; Sch. I, 12(ii).
39. An act of God is an unusual, extraordinary and unexpected manifestation of the forces of nature, or a misfortune or accident arising from inevitable necessity

²³ http://www.skeptic.ca/acts_of_god.htm

²⁴ *R. v. Byron Creek Collieries Ltd* BC Provincial Court (1977) & Appeal BC County Court (1982) viewed an Act of God as something that could not be foreseen.

²⁵ http://www.dfo-mpo.gc.ca/canwaters-eauxcan/infocentre/publications/bulletins/habitat-bulletin-11_e.asp

²⁶ <http://www.travel-insurance-uk.org.uk/definitions.html>

²⁷ Legal Glossary of Federal Statutes, University of Ottawa,
http://www.uottawa.ca/associations/ctdj/lexfed/defa_a.htm#act of God

which cannot be prevented by reasonable human foresight and care. If a plaintiff's injuries were caused by such an event without any negligence on the part of a defendant, the defendant is not liable.

40. However, if a defendant has been guilty of negligence which was an efficient and cooperative cause of the mishap, so that the accident was caused by both the forces of nature and the defendant's negligence, the defendant is not excused from responsibility.
41. In other words, if a defendant was negligent and his/her negligence contributed as an efficient and cooperating cause to the happening of the mishap and the injuries which proximately resulted, it is immaterial that an act of God was also a concurring cause.
42. It is a well established principle that where a defendant has been guilty of negligence which is an efficient and cooperating cause of the mishap, the defendant is not exonerated from liability by proof that an "act of God" was a concurring cause. *Cora v. Trowbridge Outdoor Adv. Corp.*, 18 N.J. Super. 1 (App. Div. 1952).
43. When there has been a finding of wrongdoing which is an efficient and cooperative cause of the mishap, the wrongdoer is not relieved from liability by proof that an "act of God" was a concurring cause. *Hopler v. Morris Hills Regional District*, 45 N.J. Super. 409 (App. Div. 1957). Reducing this principle to the terseness of a maxim, "he whose negligence joins with an 'act of God' in producing injury is liable therefor." 38 *Am. Jur. Negligence. Sec. 65*, 719; *Cora v. Trowbridge Outdoor Adv. Corp.*, *supra*, p. 4.
44. **Foreseeability (As Affecting Negligence)** In determining whether reasonable care has been exercised, consideration as to whether the defendant ought to have foreseen, under the attending circumstances, that the natural and probable consequence of his/her act or omission to act would have been some injury. It is not necessary that the defendant have anticipated the very occurrence which resulted from his/her wrongdoing but it is sufficient that it was within the realm of foreseeability that some harm might occur thereby. The test is the probable and foreseeable consequences that may reasonably be anticipated from the performance, or the failure to perform, a particular act. If an ordinary person, under similar circumstances and by the use of ordinary care could have foreseen the result, [*i.e.*, that some injury or damage would probably result] and either would not have acted or, if he/she did act, would have taken precaution to avoid the result, then the performance of the act or the failure to take such precautions would constitute negligence.
45. **This differentiation is important in the context of foreseeable risk whether in the manufacture and supply of natural health care products, playing sport, flying an aeroplane, or undertaking some form of medical intervention.**
46. For example, continuing to play golf in bare feet with steel handled golf clubs in the middle of a thunder storm is stupidity – death is avoidable – therefore if one were struck by lightning, that would not be an act of God.
47. Likewise, a merchant of a very common commodity that results in severe harm for the first time due to unforeseen circumstances such, as when aflatoxin in peanuts was first noted as being a problem, could be seen as being an unavoidable act of God and therefore one would have a strong legal defence in a court of law...

however if one continues to sell such contaminated product knowing that it is likely to cause harm then one would rightfully be deemed to be negligent and therefore criminal.

48. Two common risk management principles in such a circumstance is for voluntary or mandatory standards to be developed setting maximum permitted levels of aflatoxin. Businesses would also apply the principle known as the “As Low As Reasonably Practicable” (ALARP) or “As Low As Reasonably Achievable” (ALARA) principle.
49. Risk management options such as codes of best practice, education, testing for certain contaminants, maximum levels of contaminant, or ingredient thresholds that invoke labelling, restriction of access to supply above certain levels, etc are all practicable ways of reducing risk to acceptable levels.
50. In every day life such methods are used to reduce risk. Sometimes the hazard remains the same, but risk is reduced [likelihood of harm] by such things as wearing life-jackets or safety harnesses, or even by simple education methods such as warning signs.
51. The very few cases of harm due to deviant manufacture in the natural healthcare product industry have been when a hitherto unknown problem has arisen. In nearly all cases simple education, labelling or manufacturing standards have reduced such risks to acceptable levels. Where adulteration, or substitution continues to occur then an ‘Act of God can not be used as a defence.
52. Based on the risks determined from fatalities and exposure, and based on a selection of risk management literature, the following levels of risk are proposed depending as to whether exposure to hazards is voluntary or involuntary, informed or uninformed, @ @ @ @ @
53. Ultra Safe
Very safe - De minimis / acceptable
Relatively Safe / Tolerable / ALARA
Unacceptable
Dangerous
Very Dangerous

needed to have enough data to prove the benefit of the decision).

Validation of data

54. In all cases data has been cross checked and discrepancies harmonised utilising commonsense or simply averaging data where multiple data sources exist. In some cases data was smoothed over several years. In some cases, there is overlap between categories. For example, deaths resulting from pharmaceutical use are also included in total medical injury deaths where these occur within the hospital setting.
55. In the case of natural healthcare & therapeutic products, only a single reference to a ‘possible’ death was found relating to ephedra use. This Health Canada data was

accepted at face value as a death was required to include natural healthcare & therapeutic products in the comparative risk analysis. The Canadian Parliamentary Health Standing Committee found no evidence of any deaths in Canada as at 1998, so that death was averaged over a four year period. If it had been taken as a whole unit it would have made no material difference to this analysis.

Accessibility to data

56. A key frustration in this research was the fact that Health Canada does not directly collate hospitalisation and mortality data. This task is the domain of the Canadian Institute for Health Information (CIHI) and most data is available on a pay per view basis. Apart from access issues for such important data, several attempts to purchase access to these databases were thwarted by errors preventing transactions to occur. nevertheless, sufficient data became available for the purposes of this report.
57. It is always difficult to compare apples with oranges. In this case, what should be used as a unit of exposure to a given hazard? For example, when analysing risks associated with travel, does one calculate the number of deaths per kilometre or thousand or million kilometres travelled, the length of roading available to drive on, the number of registered vehicles, number of licensed drivers, or the number of passengers? Does one calculate it per trip, or per year of exposure?
58. For planes, does one use the number of passengers, knowing that many people fly often and some people do not fly at all and therefore it is impossible to calculate the number of Canadians that actually fly, or does one use per million passenger flights based on global statistics.
59. In the case of car travel, several options have been used. In the case of air travel, there are so few fatalities on scheduled airlines that global statistics have been used as well. Data for other forms of air travel such as helicopters and ultra light planes are available for Canada.
60. It should also be noted that there are significant differences in risk between scheduled flights and chartered flights, hence these have been separated. A table is included to show units of risk exposure used.

Missing data

61. It is acknowledged by Canadian officials and researchers that there are no baseline data on adverse events in Canada and that there are no systems in place to routinely collect data that would be necessary for ongoing monitoring.²⁸ Systems need to be developed to capture data not only in hospitals, but also in community-based settings, nursing homes, mental institutions and in the home.
62. Despite there being an acknowledged “urgent need to develop indicators, data definitions, standards and systems to expand and improve on the data currently collected on these events,” what limited data is available is systematically removed from most publicly available sources of information by Health Canada.²⁹

²⁸ http://secure.cihi.ca/cihiweb/en/downloads/adevents_bulletin_e.rtf

²⁹ As an example; Canadian Injury Data Mortality – 1997, and Hospitalizations - 1996-97 Prepared by Child Injury Division, Bureau of Reproductive and Child Health, Laboratory Centre for Disease Control,

This is at odds with good regulatory practice as removing such data from reports that simply collate data, but which are then used to collate ranked lists of “10 leading causes of death in Canada”³⁰ leads to a flow-on effect of distorted risk management policy, research and strategies.

63. For example, one injury prevention in children research centre³¹ notes the top 5 causes of “Unintentional Injury Resulting in Hospitalization of Children in Canada:
1. Unintentional falls (47%)
 2. Motor vehicle collisions (10%)
 3. Struck by objects, persons, or flying objects (9%)
 4. Cycling (8%)
 5. Natural and environmental factors (3%)
64. The above percentages refer to the Canadian Institute for Health Information (CIHI) National Trauma Registry Hospital Injury Admissions Report, and are for children under the age of 15 years (CIHI).
65. Top 5 causes of Unintentional Injury Related deaths of Children in Ontario:
1. Motor vehicle collisions (36%)
 2. Drowning and Suffocation (22%)
 3. Fire and flames (7%)
 4. Cycling (5%)
 5. Unintentional falls (3%)”
66. It is noted that the above specifically mentions the Canadian Institute for Health Information (CIHI) National Trauma Registry Hospital Injury Admissions Report. The actual CIHI report is not freely available for verification, but the executive summary is and it explicitly notes that the data is not actually related to injury per se, but a subset of injury – namely trauma. It defines trauma as ‘injuries resulting

Health Protection Branch, Health Canada October, 1999. “Events associated with injuries are classified using the codes for external cause of injury and poisoning (E-codes). Adverse events occurring in medical treatment, which are included in the injury chapter of the ICD-9, are excluded from the injuries considered in this document*.” The asterisk refers to a footnote which says, “Three groups of events that are assigned E-codes in the ICD-9 are excluded from the report. They are very different from most injuries, both in their nature and in the types of preventive measures that might be considered appropriate.

ICD-9 codes Description

E870-E876 Misadventures to patients during medical and surgical care.

E878-E879 Surgical and medical procedures as the cause of abnormal reaction of patient or later complication, without mention of misadventure at time of procedure.

E930-E949 Drugs, medicinal and biological substances causing adverse effects in therapeutic use.

³⁰ <http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/lcd-pcd97/index.html>

³¹ <http://www.injuryprevention.ca/frameTargetOC.htm>

from a transfer of energy’ but does not define what it means by energy. Note that it explicitly excludes three classes of injury from the report;

“Trauma or injury cases were included if their External Cause of Injury codes (E Codes) met the NTR definition of trauma; generally, these are injuries resulting from a transfer of energy. Examples of cases that are *excluded* from this definition are cases hospitalized because of poisonings by drugs or gases, adverse effects of drugs or medicine, and late effects...”³²

67. Having redefined injury as trauma involving transfer of energy, the report proceeds to use the common term ‘injury’ which is used by others in subsequent reports.
68. This redefining of the term injury is incongruous with good policy. Health Canada and the Canadian Adverse Event researchers’ operational definition of an adverse effect is;
 - The patient experiences injury,
 - The injury results in death or prolonged length of stay, disability at discharge or prolonged length of stay, and
 - The injury is caused by healthcare management³³
69. Data is published grossly understates the known regarding medical injury. When comparing hospital researched data with data collected via the WHO ICD 9 or 10 protocol, it is likely that at least 95% of medical injury related fatalities are coded as being due to something else. This in turn throws in to doubt official data regarding mortality of other causes.
70. Research is currently being undertaken in Canadian acute hospital to provide a Canadian evidence base for estimating the extent of medical injury in Canada. International researchers have documented preventable injuries and deaths in every setting where measurement was attempted. There is no reason to believe that the Canadian health-care system would be dramatically different.³⁴ As such, in the absence of Canadian specific data it is reasonable to assume that data from comparable countries can be used as a legitimate substitute.
71. The assessment includes a range of data using research from the US, Australia and New Zealand. Data from France, the UK and Denmark are all within a similar narrow range and are well within a fraction of an order of magnitude of each other. Statements made by the former Health Minister and senior researchers which are on public record have also been used as evidence for this report.
72. As noted, research of visible medical injury within the public acute hospital system is due to be published in 2004. It is unlikely to be materially different to that presented in this report.

³² http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=AR8_2001sum_e

³³ http://secure.cihi.ca/cihiweb/en/downloads/AdverseEvents_v2.pdf

³⁴ National [Canadian] Steering Committee on Patient Safety. (2002) Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care

4. Policy

73. The first essential step of developing new legislation generally is to define and state the policy objectives. In other words, what is the problem or ‘mischief’ that is being addressed? Only after there is clarity about the problem can we determine an appropriate solution.

Canadian Government

74. The Canadian Government has committed to good regulatory practice and as such is committed to the least amount of regulation required to manage defined levels of risk. Principles of GRP include transparency, objectivity and proportionality. Whilst GRP is discussed more fully in the paper, it is noted here that there does not appear to be a government wide policy defining the terms ‘acceptable level of risk,’ ‘acceptable level of protection’ or ‘acceptable level of safety,’ all of which are used by policy makers.
75. There is a framework regarding risk management

Health Canada³⁵

76. In launching a consultation process, Health Protection for the 21st Century, the then minister of health said, “Health Canada plays a leadership role in protecting and improving the health of Canadians. One important part of this role is managing the risks posed by diseases and products.”
77. This and other statement imply that Health Canada’s role is to permit an acceptable level of risk, rather than control an acceptable level of safety. There is a subtle difference.
78. Health Canada states that the following factors would be considered to determine whether a product represents an undue risk: the guiding principles for risk decision making mentioned above the nature and function of the product the level of safety that may reasonably be expected.³⁶
79. In Canada, as in most countries of the world, the recommendations of the International Commission on Radiological Protection (ICRP) form the basis for risk management involving regulated practices.³⁷ However, despite the ICRP indicated that a risk in the range of one in a million (10^{-6}) to one in one hundred thousand (10^{-5}) per year would likely be acceptable to any individual member of the public Health Canada states that regulatory authorities in Canada do not recommend any single legal dose limit or level of *acceptable* [original emphasis] risk at which to regulate chemical carcinogens. Risk management decisions

³⁵ http://www.hc-sc.gc.ca/hpfb-dgpsa/ocapi-bpcp/health_protection_21c_01_e.html

³⁶ General Safety Requirement, <http://www2.itssti.hc-sc.gc.ca/HPCB/Policy/LegislativeRenewal.nsf/vwProposalWeb/B8071087A98BCD0685256D25006EA20A>

³⁷ Assessment And Management Of Cancer Risks From Radiological And Chemical Hazards, ISBN 0-662-26624-2

<http://www.hc-sc.gc.ca/hecs-sesc/ccrpb/publication/98ehd216/print.htm>

concerning control are made following consultation with affected parties, and involve judicious balancing of the estimated risks against the associated costs, feasibility of controls, and benefits to society.³⁸

80. Health Canada uses the term Acceptable Level of Risk in its risk management policy statements which supports the minister's focus on managing risk rather than controlling safety.
81. Whilst analysing Health Canada's application of its own policy, it soon became apparent that a part from managing risks associated with pesticide residues in foods there is very little evidence of this policy being objectified in its implementation.

Policy vacuum

5. Key findings

Policy developed in evidence vacuum

Missing data

82. In the case of medical injury, it is normal practice for Health Canada to remove what fragments of data relating to medical injury from key statistics prior to publication of freely available statistical data.³⁹ This is at odds with good regulatory practice as removing such data from reports that simply collate data, but which are then used to collate ranked lists of "10 leading causes of death in Canada"⁴⁰ leads to a flow-on effect of distorted risk management policy and strategies.

³⁸ Assessment And Management Of Cancer Risks From Radiological And Chemical Hazards, ISBN 0-662-26624-2

<http://www.hc-sc.gc.ca/hecs-sesc/ccrpb/publication/98ehd216/print.htm>

³⁹ As an example; Canadian Injury Data Mortality – 1997, and Hospitalizations - 1996-97 Prepared by Child Injury Division, Bureau of Reproductive and Child Health, Laboratory Centre for Disease Control, Health Protection Branch, Health Canada October, 1999. "Events associated with injuries are classified using the codes for external cause of injury and poisoning (E-codes). Adverse events occurring in medical treatment, which are included in the injury chapter of the ICD-9, are excluded from the injuries considered in this document*." The asterisk refers to a footnote which says, "Three groups of events that are assigned E-codes in the ICD-9 are excluded from the report. They are very different from most injuries, both in their nature and in the types of preventive measures that might be considered appropriate.

ICD-9 codes Description

E870-E876 Misadventures to patients during medical and surgical care.

E878-E879 Surgical and medical procedures as the cause of abnormal reaction of patient or later complication, without mention of misadventure at time of procedure.

E930-E949 Drugs, medicinal and biological substances causing adverse effects in therapeutic use.

⁴⁰ <http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/lcd-pcd97/index.html>

Flow on effects

83. This failure to include a major cause of preventable death in Health Canada statistics flows in to a series of publications including the “Economic Burden of Illness in Canada.”⁴¹ It and others omit medical injury as a major cause of death demonstrating an ongoing and systematic removal of such important data. The executive summary of the above report states;
- “Comprehensive and authoritative estimates of the cost of illness in Canada are vital to setting priorities for allocating limited health resources. However, many conceptual and methodological difficulties arise when attempting to quantify, in economic terms, the impact of illness and injury. The authors of this report have chosen the prevalence-based human capital approach to translate morbidity and premature mortality into direct and indirect costs to affected individuals and society.”
84. The report notes, “Cardiovascular diseases, the largest diagnostic category, accounted for 15.3% of the total cost of illness classifiable by diagnostic category, \$7.4 billion in direct costs and \$12.4 billion in indirect costs. Musculoskeletal disorders and injuries ranked second and third with total costs of \$17.8 billion and \$14.3 billion, respectively.” Cancer came fourth on this ranking system.
85. If medical injury was included, then it would easily compete with cardiovascular disease as the largest drain on financial resources. This is evidenced by a small comment made by a previous Minister of Health in a speech when she commented that, “healthcare costs due to adverse drug reactions were upwards of \$10 billion annually.”⁴²
86. Two 1998 reports uses the above report extensively with not a single mention of medical injury.^{43,44} The report, “The Economic Burden of Unintentional Injury in Canada” ignores the largest cause of unintentional injury in Canada – that being medical injury.
87. What data is published grossly understates the known regarding medical injury. When comparing hospital researched data with data collected via the WHO ICD 9 or 10 protocol, it is likely that at least 95% of medical injury related fatalities are coded as being due to something else. This in turn throws in to doubt official data regarding mortality of other causes.

Filling the gaps

88. Research is currently being undertaken in Canadian acute hospital to provide a Canadian evidence base for estimating the extent of medical injury in Canada. In the absence of that Canadian specific data it is reasonable to assume that data from comparable countries can be used as a legitimate substitute. The assessment

⁴¹ http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/ebic-femc93/excsum_e.html

⁴² McLellan, Minister of Health speaking notes for speech presented to the Canadian Pharmacists Association, Vancouver , June 2003. <http://www.annemclellan.ca/speeches/1june2003.html>

⁴³ http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/chirpp-schirpt/13mar98/iss13h_e.html

⁴⁴ <http://www.hc-sc.gc.ca/pphb-dgspsp/injury-bles/ebuic-febnc/>

includes a range of data using research from the US, Australia and New Zealand. Data from France, the UK and Denmark are all within a similar narrow range and are well within a fraction of an order of magnitude of each other. Statements made by the former Health Minister and senior researchers which are on public record have also used as evidence for this report.

89. As noted, research of visible medical injury within the public acute hospital system is due to be published in the spring of 2004. It is unlikely to be materially different to that presented in this report.

Every day risks is Canada

90. Chart xx contains a range of causes of death in Canada.
91. It is not comprehensive, simply because of space limitations. It does, however, contain a wide range of everyday activities and common and not so common recorded fatalities.
92. These have been divided by the number of Canadian citizens exposed to each to provide a fatality rate per million citizens exposed. These standardised figures were then compared to a common hazard that is generally accepted as safe – flying on a Boeing 747. The risk of death on a Boeing 747 flight is approaching the universally accepted de minimis figure of 1×10^{-6} . Activities are grouped in orders of magnitude of risk ranging from $<1 \times 10^{-3}$ to $>1:10^{-7}$.
93. There is an exceptionally increased risk of trauma and death due to highly preventable medical injury, including pharmaceutical drugs, compared to every day activities such as horse riding, swimming, skiing, playing sport and even driving motor vehicles.
94. In spite of the high death rates due to preventable medical injury, regulators and health professionals seem to have become complacent about severe injuries and tend to accept them as a fact of life.
95. Unfortunately, medical injury seems to have been interpreted as some natural act, some act of God, some unpreventable problem. Nothing could be further from the truth. Medical injury can, to a large extent, be predicted, injury can be avoided through safe systems and safe workplace culture, and people can be conditioned to avoid injury in the future.

6. Risk analysis

96. Risk analysis consists of three separate stages – risk assessment, risk management and risk communication. All three should be iterative, and open to new information. Risk management is increasingly viewed as a process that should be separate from risk assessment so that researcher/analyst bias and ‘buy-in’ don’t cloud risk management judgements. Health Canada states that risk assessment is a key part of the decision-making process, not only because it provides an estimate of the level of risk, but because it can help to identify possible options for risk management.⁴⁵ Given that risk management decisions are predicated on what society deems to be acceptable risk, the process tends to be more political.

⁴⁵ http://www.hc-sc.gc.ca/hpfb-dgpsa/hcrisk_e.pdf

97. Safety and wholesomeness are related to a level of risk that society regards as reasonable in the context, and in comparison with other risks in everyday life. In this context, it is the risk assessor who determines the level of risk that exists, and risk manager who decides whether the level of risk is acceptable or not, and if not, what options exist for minimising, or mitigating the risk.
98. Risk communication is the process of communicating risk to the public and may occur in the early stage of the process when uncertainty is high, or later in the process when knowledge about the actual risk is clearer.
99. Every human activity involves risk in some form or another. It is often difficult, if not impossible, for individuals to accurately assess the impact of a given risk on their lives, or to realistically compare risky alternatives. We therefore tend to address risks by making qualitative judgments regarding their gravity and impacts on our lives. These assessments are based on a variety of criteria, some of which are rational, self-interested value judgments, and others that are based on societal practices and beliefs, or life-style choices and personal habits.⁴⁶
100. Risk has been defined as a measure of human injury, environmental damage or economic loss expressed in terms both of the incident likelihood and the magnitude of the injury, damage or loss. Risk can therefore be considered to be a function of the existence of a hazard, the frequency of occurrence of an incident associated with the hazard and the consequence or impact of the incident should it occur:
- Risk = f (hazard, frequency, consequence)
- A cynic might define risk as a measure of a potential hazard and the associated outrage. Risk = Hazard x Outrage.
101. It is therefore almost inevitable that questions about whether or not a numerically estimated risk is acceptable or unacceptable will arise. The findings of this Canadian research are very similar to those of the New Zealand environment which gives some reassurance regarding certainty of this research. For many risks, the findings would need to be wrong by several orders of magnitude to make any substantive difference – that is highly unlikely.
102. This report is primarily approached from a risk assessment point of view, but does develop a pragmatic model for risk management policy and resource allocation purposes. This model provides a useful tool for not only looking forward, but also in monitoring past actions to determine whether they were appropriate given current evidence that may not have been available when the original decision was made.

What is an acceptable level of risk?

103. If the Canadian government, and Health Canada permit an ‘acceptable level of risk’ for both the individual and society, then an obvious question that needs answering is ‘what is an acceptable level of risk?’ Viewing it from the opposite paradigm, one could ask the question, “How safe is safe enough?” Despite the best endeavours of ordinary citizens to try to live and operate businesses safely, for the

⁴⁶ http://www.bayer-bioethics.org/documents/Plasma_Product_Safety.pdf

sake of themselves, their families, their neighbours, their customers and society at large, in some cases miscalculations are made, oversights committed, and in others "acts of god" occur. Innocent people get hurt. Risk management is about minimising significant risk without becoming a "kill-joy" and without stifling innovation. Acceptable levels of risk are socially determined.

104. The term "safe" is a value judgement and is difficult to define. Some people consider safe to mean no risk, while others consider safe to carry risks that they consider negligible, but that others would consider unacceptable.
105. The World Trade Organisation requires that "once a government has determined its appropriate level of ... protection," it should not choose a risk management measure that is more stringent and trade-restrictive than necessary.⁴⁷ the World Trade Organisation provides a framework for managing biosecurity risks in imported agricultural products, under which the application of risk management measures must be justified by a scientific assessment of risks.
106. Individual
107. Society as a whole

7. Risk criteria : fundamentals

108. Individual acceptable level of risk

8. Individual acceptable level of risk

109. The probability of losing ones life in normal daily activities such as driving a car or working in a factory is one or two orders of magnitude lower than the overall probability of dying.
110. Only purely voluntary activities such as high altitude mountaineering and being exposed to medical practice have a higher risk (see Figure 3).

⁴⁷ http://www.wto.org/english/thewto_e/whatis_e/eol/e/wto03/wto3_28.htm

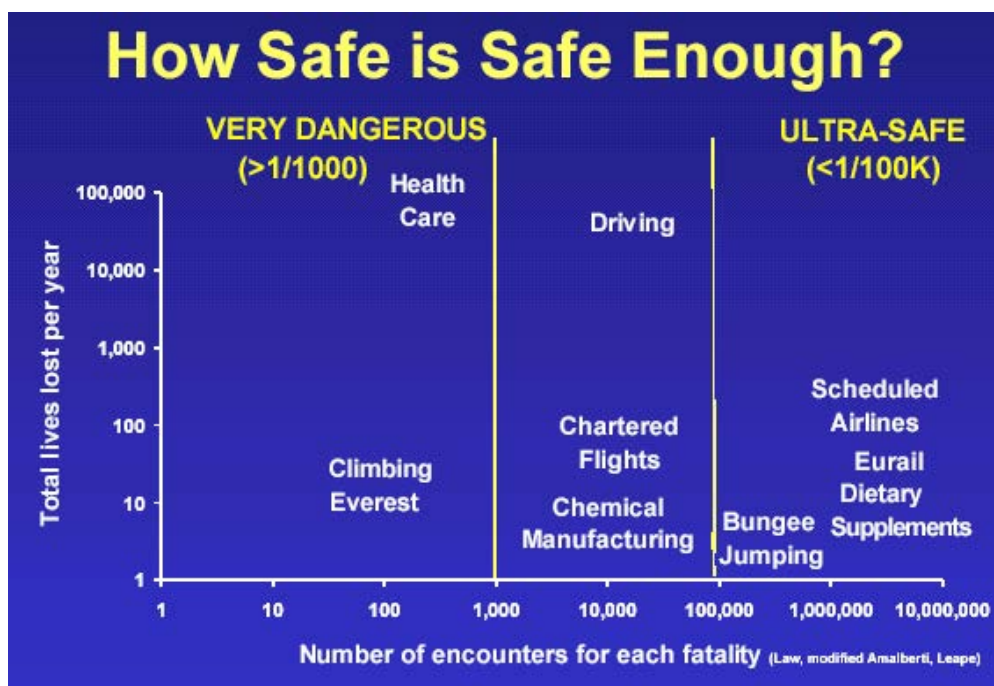


Figure 3: Comparison total fatalities vs exposure to each hazard of a selection of hazards.

- **National acceptable level of risk**

111. an appropriate level of protection or acceptable level of risk have been viewed as being synonyms,⁴⁸ but are they?
112. Pharo's examination of societal risk perception suggests that there are fundamental issues of democracy at stake if the assessment of risk and the judgement of acceptable levels of risk are left entirely to technical experts.
113. Wagner⁴⁹ refers to appropriate levels of protection "against risk."

"negligible risk" and "manageable risk"

114. 'No level of risk is acceptable'. That position has been clearly considered by governments, ministers and indeed Senate committees in various Commonwealth countries over the years as an untenable—indeed, unrealistic—position.⁵⁰

⁴⁸ <http://www.maf.govt.nz/mafnet/publications/primarysource/september-2003/primary-source-0903-9.htm>

⁴⁹ <http://www.law.georgetown.edu/journals/lpib/symp00/documents/wagner.pdf>

⁵⁰ <http://www.aph.gov.au/hansard/senate/commttee/s8961724.pdf>

Need for Intervention

115. The need for intervention, and if so, the type of intervention, depends upon the nature of the risk. An intervention framework can be developed by answering six basic questions.⁵¹:
- Is an event **foreseeable or not**?
 - Is the exposure to the potential hazard **voluntary or involuntary**?
 - Is the potential harm **significant or not**?
 - Is the potential harm **reversible or irreversible**?
 - Is the likelihood of harm **highly probable or not**?
 - Is any planned intervention **practicable or not**?
116. There is a possible case for intervention when the risk of significant harm is highly probable, whether the risk is voluntary or involuntary and whether the harm is reversible or irreversible.
117. Significant harm has been defined as covering significant harm to one person or moderate harm to a large number. Significant and moderate harm were not defined. Harm to a large number might arise from a high risk single event, or a lower risk ongoing exposure.⁵² Serious harm has been defined for health safety in the work place purposes.⁵³ WHO defines a serious adverse event is any event that:⁵⁴
- Is fatal;
 - Is life-threatening;
 - Is permanently/significantly disabling;
 - Requires or prolongs hospitalization;
 - Causes a congenital anomaly; or
 - Requires intervention to prevent permanent impairment or damage.

The risk is an involuntary one. “Acceptable Level of Risk?”

118. In the context of legislation or regulation introduced under the mandate of managing risk, the threshold of ‘acceptable level of risk’ needs to have been breached; in other words, there must be an unacceptable level of risk.
119. The term, Acceptable Level of Risk (ALOR) is often used but rarely defined in measurable terms. As an example to illustrate this point, following the Commission of Inquiry on the Blood System in Canada (Krever Commission) an interim report was released in 1995, and a final report in November 1997.⁵⁵ In

⁵¹ Synthesised from http://www.med.govt.nz/buslt/bus_pol/policyframework/policyframework-01.html;

⁵² Synthesised from http://www.med.govt.nz/buslt/bus_pol/policyframework/policyframework-01.html;

⁵³ <http://www.osh.dol.govt.nz/report/harm.shtml>

⁵⁴ WHO (2002) Safety of Medicines: A guide to detecting and reporting adverse drug reactions -- Why health professionals need to take action

http://www.who.int/medicines/library/qsm/who-edm-qsm-2002-2/esd_safety.pdf

⁵⁵ <http://www.hc-sc.gc.ca/english/protection/krever/index.html>

response to the inquiry, the government established a National Blood Safety Council to advise it on policy regarding blood supply. Within a month of Krever's final report, in Toronto in December 1997 Bayer [one of two Canadian based suppliers of blood products] announced the formation of an Advisory Council on Bioethics via press release under the headline, "The Ethics of the Blood System - Protecting the Public Interest." Bayer stated that this was the first of its kind in the World, that it would be independent and that;

"The Council will debate issues such as the benefit versus risk in using blood products; **the definition of acceptable risk**; the public's need right to be informed about blood products; and, side effects related to blood products... Most importantly, Council will help ensure our blood products are safe, effective and of the highest quality... The Council's findings will be widely published so that all participants in the blood system, both in Canada and around the world, will have access to its reports and recommendations."⁵⁶

120. Interestingly the subsequent terms of reference for the council⁵⁷ made no mention of the term 'acceptable risk' let alone defining it, and very little evidence of it having been quantified or defined can be found on the Council's website.⁵⁸
121. One example of discussion, however, is worth repeating; [this report's emphasis]

"It is also a product of the Krever Report, which emphasizes that "[s]afety of the blood supply system is paramount." (9) But this still begs the question of '**how safe is safe enough?**' because, as the Krever Report also states, 'Safety implies the absence of risk and because risk is inherent in the use of blood and blood products, it can never be said that their use is absolutely without risk and therefore perfectly safe.' (9)

The literature on risk reveals three competing concepts.

5.2.1 Minimal Risk

Minimal risk incorporates ambient risk as its benchmark. In the context of medical research in Canada, it is defined as follows:

[I]f potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research can be regarded within the range of minimal risk...

In the United States, minimal **risk** is defined somewhat differently: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those **ordinarily encountered in daily life** or during

⁵⁶ The Ethics of the Blood System - Protecting the Public Interest: Bayer Advisory Council on Bioethics First of its Kind in the World, <http://www.bayerhealth.com/news/misc/?aID=367>

⁵⁷ <http://www.bayer-bioethics.org/termsOfReference.html>

⁵⁸ eg; http://www.bayer-bioethics.org/documents/Plasma_Supply.pdf

the performance of routine physical or psychological examinations or tests.”⁵⁹

122. Are these competing concepts or variations on a theme? In all three cases, risks ordinarily encountered and accepted in daily life are defined as minimal, and therefore, acceptable risks. The variant relating to research must be broader than every day risks as research may expose subjects to harm via unknown adverse effects, or may actually deprive subjects of benefits if, for example, a new drug is found to be ineffective.
123. Health Canada seems to be acknowledging that it has no objective policy guidelines regarding defining ‘acceptable level of risk’ in the following discussion of what it calls ‘Key Considerations’ in managing risk;⁶⁰

“Some Key Considerations

One key consideration when analysing options is that the same measures can affect different populations in different ways depending on a range of risk factors such as gender, age, ethnic origin, social situation, economic conditions, education, culture or personal convictions. It may be necessary to tailor options to meet the needs of specific groups or to use different options for different groups. For example: advisory information could be provided at different reading levels, through different types of news media, and in different languages; recommended daily intakes of specific chemical contaminants in food could be different for general and sensitive populations.

A second consideration is Health Canada's difficult but necessary responsibility to balance the rights of individuals and groups with the needs and interests of society. Related to this is the importance of ensuring that societal and group rights do not unnecessarily override the rights of the individual. In principle, when the rights of an individual and society are in conflict, precedence should be given to the latter; in practice this may be a challenge to achieve.

A third consideration is the difficulty in determining what constitutes an “*acceptable*” level of risk. **An acceptable risk is one that is so small, whose consequences are so slight or whose associated benefits (perceived or real) are so great, that persons or groups in society are willing to take or be subjected to that risk. The acceptability of risk, from both an individual and social perspective, is influenced by risk perception, values, judgments and other factors, such as the trade-offs people make between potential risks and benefits. The level of trust in the person or agency responsible for managing the risk is also a factor.**

⁵⁹ Practical Limits To Plasma Product Safety: The Case Of Parvo B19 Virus A Bioethical Analysis Working Paper, Bayer Advisory Council on Bioethics, March 2002

⁶⁰ Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks - August 1, 2000 http://www.hc-sc.gc.ca/hpfb-dgpsa/hcrisk_5_e.html

Although individuals may hold opinions about what is acceptable, there are often no objective measures for determining acceptability. What is acceptable to one group or individual may be unacceptable to another. Given this, attempts need to be made to determine acceptability from the perspectives of a range of interested and affected parties (e.g. women, cultural minorities, seniors, children and other groups).

124. A closer look at the third consideration is revealing from four aspects. Firstly, the consideration of acceptable risk embraces both perception and reality. Secondly, it embraces a relationship between perceived and real risks and benefit. Thirdly it relates to individuals or groups in society, and fourthly, it acknowledges that the level of trust in the person or agency for managing the risk is a factor. This would appear on first glance to imply that the person exposed to potential risks plays little role in the risk management process, yet educating consumers so that they can make informed choices is a very real part of good regulatory practice.
125. That aside, it is proposed to embrace the essence of all of these nuances of acceptable levels of risk to derive a proposed definition for policy and risk management purposes.

Proposed Description of Acceptable Level of Risk

126. A generic description of Acceptable Level of Risk can therefore be described as;

“An acceptable level of risk is a level of risk that incorporates ambient risk as its benchmark, and such risk is no greater than those encountered in everyday life and considers whether;

the exposure to the potential hazard is voluntary or involuntary,

an event is foreseeable or not,

the potential harm is significant or not,

the potential harm is reversible or irreversible,

the likelihood of harm is highly probable or not, and

whether any planned intervention practicable or not?”

127. It will be noted that these discussions imply that an ALOR will vary between individuals and societal perspectives. On the other hand, it could be argued that there is a tension that needs to be maintained between the need to protect the freedom of choice of the individual and the need to protect them from harming themselves or others. Again, circumstances will vary. An individual who is mountain biking poses less risk to others than a drunk driver. No quantitative risk assessment evidence was found to help resolve a conflict between the need to protect the individual and the need to protect society other than comparing total fatality rates and standardised rates.
128. As noted, one concept often used to help delineate an ALOR is to use every day risks as a benchmark – especially natural ones. This has been termed a “Natural

standard: A Risk from naturally occurring events serve as a benchmark for created events.”⁶¹

129. There are some examples where ALOR has been defined at least semi-quantitatively. Euphemisms such as ‘more likely to be killed by lightning’ and ‘1 in a million’ have been considered as societal norms, if not benchmarks. The latter, especially so in the setting of acceptable daily intakes for food additives.
130. The 1:1,000,000 is used in the context of contributing an extra case of cancer per million consumers of food per year and is predicated on the basis of an involuntary activity, where people have no choice, rather than a voluntary one where people have choice.

De Minimis Provision

131. The *de minimis* threshold embraces that point at which risk would normally be determined negligible.⁶² Examples of its legal application globally include, international trade law,⁶³ takeover law,⁶⁶ food law,⁶⁷ genetically modified content of food exempt from labelling,⁶⁸ tax law,^{69,70,71} resource management law,⁷² telecommunications regulations,⁷³ and computer sales.⁷⁴ The EC has even ruled on

⁶¹ WHO/IPCS, From a synopsis of selected criteria used in the USA for regulating public, occupational and environmental exposure as used by the WHO/IPCS, http://www.who.int/pes/training_material/module4/section6.2.htm

⁶² <http://www.executive.govt.nz/minister/sutton/singapore/analysis.pdf>

⁶³ NAFTA Rules of Origin: The De Minimis Provision, <http://infoserv2.ita.doc.gov/ticwebsite/naftaweb.nsf/3c5a68c244d2af1a85256691006d7add/197b7bc5e58aef65852566fe0070be24!OpenDocument>

⁶⁴ <http://www.maf.govt.nz/mafnet/issues/sustain/owg-report.pdf>

⁶⁵ <http://www.ejil.org/journal/curdevs/sr17.rtf>

⁶⁶ <http://www.takeovers.gov.au/Content/Resources/CASAC/CorporateGroupsMay2000.asp>

⁶⁷ [http://www.moh.govt.nz/moh.nsf/bbedab58c53332744c2566740013148d/4bfbc7660fe2d8d44c25695f007efbda/\\$FILE/cagmff99jan00.pdf](http://www.moh.govt.nz/moh.nsf/bbedab58c53332744c2566740013148d/4bfbc7660fe2d8d44c25695f007efbda/$FILE/cagmff99jan00.pdf)

⁶⁸ http://www.nfpa-food.org/members/international/Biotechchart9_6.pdf

⁶⁹ <http://www.inlandrevenue.gov.uk/budget2001/revbn17.htm>

⁷⁰ http://www.taxreform.ato.gov.au/general/expla_statement.htm

⁷¹ <http://www.deloitte.co.nz/default.cfm?pageID=1026>

⁷² *Bayley v Manukau City Council; Barrett v Wellington City Council* [2000] NZRMA 481

⁷³ <http://www.fplc.edu/risk/vol9/spring/Claycamp.pdf>

⁷⁴ <http://www.bxa.doc.gov/factsheets/ExportGuidance.html>

Formula for <i>de minimis</i> percentage for software	=	Value of U.S. code commingled with or incorporated into foreign software	
		Total selling price of all foreign-software units already sold	+ Total selling price of all foreign-software units estimated for future sales

the application of Articles 87 and 88 of the EC Treaty to de minimis aid [subsidy].⁷⁵

132. Health Canada acknowledges that there are instances where benefit assessment is not necessary such as where the level of risk is deemed to be minimal or “de minimus.”⁷⁶

As Low As Reasonably Practicable (ALARP)

133. The regulation of safety in most countries including the United Kingdom, Australia, Canada, the USA and New Zealand is based upon the principle that risks must be reduced to a level that is "As Low As Reasonably Practicable" (the so called ALARP principle) or As Low As Reasonably Achievable (ALARA).

134. The meaning of "reasonably practicable" is well established in case law:⁷⁷

"Reasonably practicable" is a narrower term than "physically possible" and seems to me to imply that a computation must be made by the owner in which the quantum of risk is placed on one scale and the sacrifice involved in the measures necessary for averting the risk (whether in money, time or trouble) is placed in the other, and that, if it be shown that there is a gross disproportion between them -- the risk being insignificant in relation to the sacrifice -- the defendants discharge the onus on them. "

(Judge Asquith, *Edwards v. National Coal Board*, All England Law Reports Vol. 1, p. 747 (1949)).

Establishing the Factual Basis for Comparative Risks

Standard of proof

135. In criminal law, where the sentence to be imposed is discretionary, the sentence which the judge imposes must fairly reflect how serious the offence is and how culpable the offender. It must recognise and reconcile contrasting, even contending, public and private values or interests. It must be consistent with sentences imposed on like offenders and for like offences.⁷⁸ One of the hardest tasks confronting a trial judge is sentencing. The stakes are high for society and for the individual. Sentencing is the critical stage of the criminal justice system, and it is manifest that the judge should not be denied an opportunity to obtain relevant information by the imposition of all the restrictive evidential rules common to a trial. Yet the obtaining and weighing of such evidence should be fair. A substantial

⁷⁵ Commission Regulation (EC)No 69/2001 of 12 January 2001 on the application of Article s 87 and 88 of the EC Treaty to de minimis aid. Official Journal of the European Communities 13.1.2001.

⁷⁶ http://www.hc-sc.gc.ca/hpfb-dgpsa/hcrisk_e.pdf

⁷⁷ Geyer, T.A.W. Chapman, C.P. and Morris, M.I." Improving Passenger Safety at Platforms," Paper presented at The 1996 Annual Meeting of the Society for Risk Analysis-Europe accessed from <http://www.riskworld.com/Abstract/1996/sraeurop/ab6ad054.htm>

⁷⁸ Law Commission Report 76 Proof of Disputed Facts on Sentence, November 2001, Wellington, New Zealand, www.lawcom.govt.nz

liberty interest of the offender is involved and the information obtained should be accurate and reliable.

136. In the risk assessment function, the factors which predominate are those which concern the protection of society whilst at the same time protecting the rights of individuals. The risk assessment process is, very much like a trial and the risk management process is akin to the sentencing process. As stated by Dickson J., in *R. v. Gardiner*, [1982] 2 S.C.R. 368, at p. 414, in relation to sentencing proceedings:

“One of the hardest tasks confronting a trial judge is sentencing. The stakes are high for society and for the individual. Sentencing is the critical stage of the criminal justice system, and it is manifest that the judge should not be denied an opportunity to obtain relevant information by the imposition of all the restrictive evidential rules common to a trial. Yet the obtaining and weighing of such evidence should be fair. A substantial liberty interest of the offender is involved and the information obtained should be accurate and reliable.”

137. The above case law has become an integral part of Canadian law,⁷⁹ and applied in other countries.⁸⁰ Where facts are contested the issue should be resolved by ordinary legal principles including resolving relevant doubt in favour of the offender.
138. Once challenged, a trial judge must not accept the Crown's version of the unproven facts as related at an informal hearing. Thus, in this case, if the trial judge was of the opinion that the matter should have been resolved, his choice was to 'so far as possible accept' the version of the accused and sentence him on that version of the facts, or, if he was not of the opinion that he could resolve the matter on that basis, he would hear the sworn evidence, resolve the dispute, and then sentence the accused." (at 370-71)

9. Economic optimal level of risk

139. The problem of the acceptable level of risk can also be formulated as an economic decision problem where the expenditure for a safer system is equated with the gain made by the decreasing present value of the risk. A common means of determining such economic impact is by use of the Willingness to Pay.
140. Health Canada employs age-adjusted VSL estimates in its economic assessments, applying a VSL of C\$5 million (or US\$4 million) to exposed populations under 65

⁷⁹ for example, see;

Mooring v. Canada (National Parole Board), [1996] 1 S.C.R. 75
<http://www.canlii.org/ca/cas/scc/1996/1996scc9.html>

Criminal Lawyers Association May 1998 Newsletter which referred to *R. v. Gardiner* [1982] 2 S.C.R. 368 extensively. <http://www.criminallawyers.ca/newslett/19-1/significant.htm>

⁸⁰ Law Commission Report 76 Proof of Disputed Facts on Sentence, November 2001, Wellington, New Zealand, www.lawcom.govt.nz

years of age and using an adjustment factor of 0.75 for populations 65 years and older.⁸¹

Discussion

141. ALARP and de minimis risk considerations need to be evaluated for all risk reduction measures:

“The basis for ALARP is that risks are acceptable only if reasonable practical measures have been taken to reduce risks. In practice this is commonly taken to mean that risks have been reduced to the point where it is no longer cost effective to reduce them further. The cost effectiveness of improving life safety [i.e. cost-per- (statistical) life -saved, CPLS] can be used to assess the degree of ALARP justification for a risk reduction measure.”⁸²

Canadian Every Day Benchmarks

142. On average, the chances of being killed by lightening in Canada are approximately 1 in 4 million persons per year. This is a level of risk deemed ‘ultra safe’ among risk management experts.⁸³ Using this figure as a benchmark would perhaps mean adding an excessive safety factor in to any risk management decision making process.

143. In its training manual for its international program on chemical safety (IPCS) the WHO states;

“...the actual level of risk considered "acceptable" must be a **societal** and **political** judgement taking into account such factors as benefit of the chemical or process, and the cost of its replacement or removal.”⁸⁴ [This reports emphasis]

144. In its discussion about the management of toxic chemicals in foods, the WHO says that individual risk can be defined as [This report’s emphasis];

“...**the chance that someone from a certain (sub) group runs during an established period (e.g. a year or lifetime)** of suffering health effects from exposure to a toxicant(s). The distinction made between individual risks for persons from a critical group and that for persons from the whole population is important because the acceptability of a certain individual risk varies according to the size of the group running the risk. An individual risk can be considered

⁸¹ Alberini, A., Cropper, M., Krupnick, and Simon, N. (2002) Does the Value of a Statistical Life Vary with Age and Health Status? Evidence from the United States and Canada. Discussion Paper 02-19, <http://www.rff.org>

⁸² Bowles, D.S., L.R. Anderson, and T.F. Glover. 1998. The Practice of Dam Safety Risk Assessment and Management: its Roots, its Branches, and its Fruit. Proceedings of USCOLD 1998 Annual Lecture, Buffalo, New York.

⁸³ Amalberti, R. (2001) Revisiting safety and human factors paradigms to meet the safety challenges of ultra complex and safe systems, In B. Willpert, & B. Falhbruch, Challenges and pitfalls of safety interventions, Elsevier

⁸⁴ http://www.who.int/pcs/training_material/module4/section6.1.htm

when effects are involved for which no threshold value exists (stochastic effects), e.g., carcinogens or when exposures are involved which are higher than existing threshold values for non-stochastic effects.

In some cases an individual risk equal to or less than 10^{-6} (generally considered an insignificant risk) cannot be realized, e.g., because natural background levels already cause a high risk or the agent or activities fulfils an essential societal function from which a given exposure is unavoidable and/or which may be difficult to reduce through utilization of alternatives.

Frequently, individual risks are calculated for some or all of the persons in the population being studied and are then put into the context of where they fall in the distribution of risks for the entire population. Key questions often asked when considering strategies for dealing with individual risk include: to what risk levels are the persons at the highest risk subjected?; can individuals with a high degree of susceptibility be identified?; what is the average individual risk?; and **what is the estimate of the probability that an individual will suffer an adverse effect given a specific set of exposure circumstances?**⁸⁵

145. In other words, the WHO acknowledges a 1:1,000,000 risk as being a threshold below which it is **generally considered an insignificant risk**.
146. This is termed a de minimis level of risk which is a legal definition of the term trivial and by any standard “acceptable.” In other words, it is considered unreasonable to force further safety margins unless there are extenuating circumstances. Such circumstances might include, say, a nuclear reactor where the magnitude of potential harm is so large that any failure could potentially expose millions of people to harm before any action could be taken to get out of harms way. There would be no warning – the consequences would likely be catastrophic.
147. Not surprisingly, this figure of 1:1,000,000 features in other discussion on acceptable risk such as in New Zealand,⁸⁶ Australia, USA, the UK and Canada.^{87,88}
148. It must also be noted that the discussion here relates to involuntary activities – it must be assumed that voluntary activities would pass the ‘acceptable level of risk’ benchmark at higher levels of risk – perhaps one or two orders of magnitude.
149. Other examples of approaches taken to regulate risk include,
 - “notional zero-risk” approaches e.g. safety evaluations for chemical hazards based on acceptable-daily-intake (ADI)
 - balancing approaches e.g. benefit/cost, “as-low-as-reasonably-achievable” (ALARA also known as ALARP(practicable))

⁸⁵ http://www.who.int/pcs/training_material/module4/section6.1.htm

⁸⁶ <http://www.nzfsa.govt.nz/policy-law/harmonisation/rmgmtpr.pdf>

⁸⁷ Note: Not all references are provided. In some cases, such as here, examples are given.

⁸⁸ <http://www.hc-sc.gc.ca/pmra-arla/english/pdf/spn/spn2000-01-e.pdf>

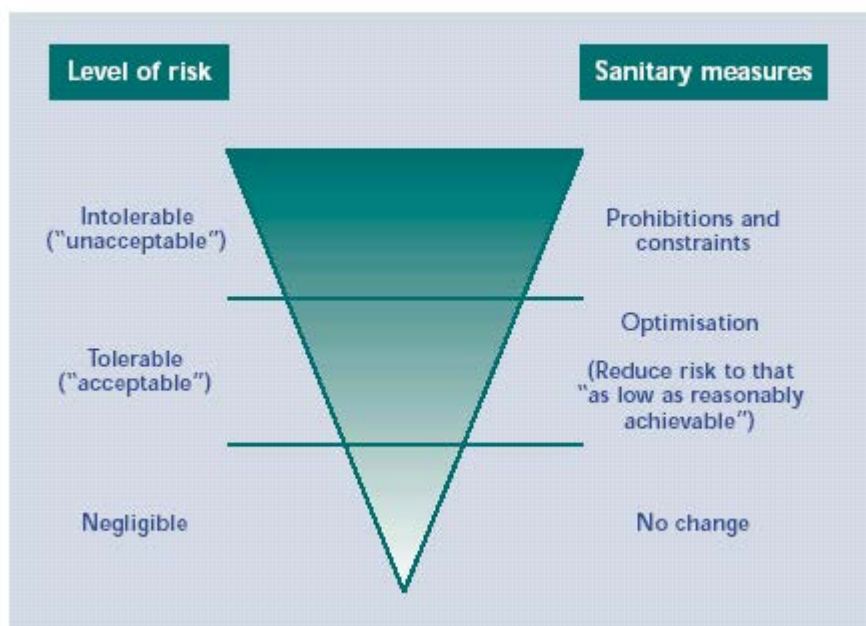
- procedural approaches, where the level of consumer protection is determined by precedent, negotiation or other social processes.
150. To declare that an individual life-time excess risk of one in ten thousand, one in one hundred thousand, or one in one million is high enough to warrant regulatory attention is a policy choice rather than an attribute of scientific methodology, and should have dichotomies such as voluntary/involuntary risk factored in. Nevertheless, there is a world wide move towards the adoption of objective standards set by transparent means that can be defend via legal means at the WTO if required.
151. Renshaw (Table 1) defines acceptable risk as being < 1:100,000 probability for the death of an individual in a given year, and < 1:100,000 for 10 people per year. He does not seem to define what total population would absorb those ten deaths.

**Table 1: Risk Guidelines
(Renshaw, 1990)**

Risk Measure	Units	Unacceptable Risk	Negligible Risk
Individual Risk at the location of a potential resident	Probability of fatality, per year	$> 1 \times 10^{-5}$	$< 1 \times 10^{-7}$
Societal risk of 10 or more fatalities	Probability of an incident causing 10 or more potential fatalities, per year	$> 1 \times 10^{-5}$	$< 1 \times 10^{-7}$

152. The New Zealand Food Safety Authority proposes levels of risk labelled 'Intolerable' (unacceptable), Tolerable (acceptable) and Negligible without defining intolerable and tolerable; it does, however, refer to 1:1,000,000 as being negligible.

Figure 1: Management of risk



- **Canada**

153. Health Canada argues that “a *de minimis* or *essentially negligible* risk is one that is so small that no action needs to be taken. If a risk is judged to be *insignificant* or *acceptable*, however, this does not necessarily mean that it is *de minimis* or *negligible*”⁸⁹

154. The Canadian Government’s “Integrated Risk Management Framework” notes;⁹⁰

“Risk management is a systematic approach to setting the best course of action under uncertainty by **identifying, assessing, understanding, acting on and communicating risk issues.**

In order to apply risk management effectively, **it is vital that a risk management culture be developed...** Limits and boundaries are established and communicated concerning what are acceptable risk practices and outcomes... In establishing the strategic risk management direction, internal and external concerns, perceptions and risk tolerances are taken into account. **It is also imperative to identify acceptable risk tolerance levels** so those unfavourable outcomes can be remedied promptly and effectively.”

155. The Framework does not define what ‘acceptable risk tolerance levels’ might be.

⁸⁹ Assessment And Management Of Cancer Risks From Radiological And Chemical Hazards, ISBN 0-662-26624-2

<http://www.hc-sc.gc.ca/hecs-sesc/ccrpb/publication/98ehd216/print.htm>

⁹⁰ http://www.tbs-sct.gc.ca/pubs_pol/dcgpubs/RiskManagement/dwnld/rmf-cgr_e.rtf;

156. Higher levels of risk might be deemed acceptable where that risk is related to individuals, is voluntary and is known. As more members of society become exposed to the hazard, especially when they have no choice and even more so when the risks are unknown, the precautionary principle becomes increasingly operative as a means of managing uncertainty.
157. Based on this concept, individuals are not prevented from climbing high altitude mountains, even though the fatality rate of successfully climbers of Mt Everest, for example, is 33%. In other words, 1:3 of all mountaineers who have successfully climbed Mt Everest have died climbing.
158. **A semi-quantitative definition an Acceptable Level of Risk can therefore be described in a continuum;**

1.	An Ultra Safe activity is one that poses less than 1 chance of death per million exposures to that risk. This is deemed to be a de minimis level of risk.
2.	A tolerable or acceptable level of risk is one that poses 1 chance of death between 100,000 and 1,000,000 exposures.

159. Based on the findings of this report, it is proposed that as a rule of thumb, a figure of 1 death per million total population be deemed a de minimis risk and that 1:100,000 be a tolerable level of risk where proactive ALARP risk management is required to reduce risk further. In the context of the Canadian society as a whole, this would mean, given a population of 31 million, that 31 deaths per year would be deemed de minimis – although it would be tragic for the individuals and their families, and up to 300 deaths would be tolerable. Most activities with total death numbers less than 300 could be classified as ‘every day activities.’ (see table 2)

160. Table 2: Total fatalities in Canada (not a complete list)

Causes of death in Canada (*)	Fatalities
Smoking	45,000
Cardiovascular disease	40,493
Associated with medical injury in acute hospitals only	31,665
Lung cancer	15,439
Adverse drug reaction (all)	15,000
Cerebrovascular disease	14,493
Preventable medical injury - (Acute Hospitals - NZ/AUS/USA adj)	12,500
Adverse effects of pharmaceutical drugs - all (USA adj)	11,571
Preventable medical injury - (Acute Hospitals only Minister's est)	10,000
Diabetes	5,756
Preventable adverse drug reaction - acute hospitals (NZ adj)	5,250
Alcohol related (Liver disease + direct)	4,900
Breast cancer	4,873

Suicide	3,688
Prostate cancer	3,664
Traffic accidents	3,032
Accidental falls	1,727
Accidental Poisoning - Medicines	1,440
Workplace accidents	850
Firearms - total	827
Influenza	763
Food (est - USA/Aus)	600
Homicide	467
Suicide - Pharmaceutical drugs	456
Pedestrians	393
Choking on food/other objects	252
Fire	243
Food - Highly preventable (est - USA/Aus)	240
Drowning - accidental (male)	231
Water transport	217
Motorcycle accidents	148
All Terrain Vehicles	141
Forces of nature	124
Railway (total)	119
Tuberculosis	101
Farm work	100
Snowmobiles	84
Horse riding	83
Pedal cyclist	73
Air accidents (All Canada - Per flight)	62
Air accidents (all passengers - Canada)	62
Sport & recreation	59
Menningitis	54
Acceptable risk for cancer (food additives)	31
Railway -- Pedestrian	30
Firearms - accidental	28
Electrocution	27
School bus accidents	20
Avalanche	16
Air - corporate/private/clubs (Per hour Canada)	13
Ultralight aircraft	12
Lightning	8
War operations	4
Bee/wasp/hornet sting	2
Commercial airliners (per hour - Canada)	1
Natural healthcare & therapeutic products	0.25
Meteorite	0.0002

161. Table 3 lists fatalities per activity (hazard), the number of people exposed to each of those activities, and a calculation of the number of fatalities per million people exposed to any given hazard.

Causes of death in Canada (*)	Fatalities	Population at risk	Fatalities per year per million at risk
Associated with medical injury in acute hospitals only	31,665	3,000,000	10,555
Smoking	45,000	7,000,000	6,429
Preventable medical injury - (Acute Hospitals - NZ/AUS/USA adj)	12,500	3,000,000	4,167
Preventable medical injury - (Acute Hospitals only Minister's est)	10,000	3,000,000	3,333
Preventable adverse drug reaction - acute hospitals (NZ adj)	5,250	3,000,000	1,750
Cardiovascular disease	40,493	30,770,000	1,316
Adverse drug reaction (all)	15,000	15,000,000	1,000
Adverse effects of pharmaceutical drugs - all (USA adj)	11,571	15,000,000	771
Lung cancer	15,439	30,770,000	502
Motorcycle accidents	148	308,333	480
Cerebrovascular disease	14,493	30,770,000	471
Breast cancer	4,873	15,385,000	317
Alcohol related (Liver disease + direct)	4,900	17,360,000	282
Firearms - total	827	3,000,000	276
Ultralight aircraft	12	50,000	240
Prostate cancer	3,664	15,385,000	238
Diabetes	5,756	30,770,000	187
Horse riding	83	500,000	166
Suicide	3,688	23,077,500	160
Farm work	100	851,405	117
Traffic accidents	3,032	30,770,000	99
All Terrain Vehicles	141	2,000,000	71
Workplace accidents	850	15,000,000	57
Accidental falls	1,727	30,770,000	56
Snowmobiles	84	1,518,658	55
Accidental Poisoning - Medicines	1,440	30,770,000	47
War operations	4	100,000	40
Influenza	763	30,770,000	25
Air - corporate/private/clubs (Per hour Canada)	13	560,000	23
Suicide - Pharmaceutical drugs	456	23,077,500	20
Food (est - USA/Aus)	600	30,770,000	19
Homicide	467	30,770,000	15
Drowning - accidental (male)	231	15,385,000	15
Pedestrians	393	30,770,000	13
School bus accidents	20	2,000,000	10
Firearms - accidental	28	3,000,000	9
Air accidents (All Canada - Per flight)	62	7,000,000	9
Choking on food/other objects	252	30,770,000	8
Fire	243	30,770,000	8
Food - Highly preventable (est - USA/Aus)	240	30,770,000	8
Water transport	217	30,770,000	7
Pedal cyclist	73	12,000,000	6
Avalanche	16	3,077,000	5

Forces of nature	124	30,770,000	4
Railway (total)	119	30,770,000	4
Tuberculosis	101	30,770,000	3
Sport & recreation	59	24,000,000	2.5
Menningitis	54	30,770,000	2
Acceptable risk for cancer (food additives)	31	30,770,000	1
Railway -- Pedestrian	30	30,770,000	1
Electrocution	27	30,770,000	1
Commercial airliners (per hour - Canada)	1	1,028,000	1
Air accidents (all passengers - Canada)	62	163,000,000	0.38
Lightning	8	30,770,000	0.26
Bee/wasp/hornet sting	2	30,770,000	0.1
Natural healthcare & therapeutic products	0.25	16,923,500	0.015
Meteorite	0.0002	30,770,000	0.000006

Discussion

Bright lines or guidelines?

162. Criteria should not be used as absolute bright lines but rather as guidelines recognizing that there is variability in experimental and observational data.
163. Where population-level (as compared with individual level) thresholds for adverse effects have not been shown to exist classification interfaces should not be interpreted as bright lines between ‘safe’ and ‘unsafe’ levels.⁹¹
164. Case law in the Canadian Supreme Court⁹² delineates significant risk and significant harm...

“135...The existence of fraud should not vitiate consent unless there is a significant risk of serious harm. Fraud which leads to consent to a sexual act but which does not have that significant risk might ground a civil action. However, it should not provide the foundation for a conviction for sexual assault. The fraud required to vitiate consent for that offence must carry with it the risk of serious harm....

137 It follows that in circumstances such as those presented in this case there must be a significant risk of serious harm if the fraud resulting from non-disclosure is to vitiate the consent to the act of intercourse. For the purposes of this case, it is not necessary to consider every set of circumstances which might come within the proposed guidelines. The standard is sufficient to encompass not only the risk of HIV infection but also other sexually transmitted

⁹¹ <http://www.bc.lung.ca/airquality.pdf>

⁹² R. v. Cuerrier, [1998] 2 S.C.R. 371 <http://www.canlii.org/ca/cas/scc/1998/1998scc66.html>

diseases which constitute a significant risk of serious harm. However, the test is not so broad as to trivialize a serious offence.

138 In summary, on facts presented in this case, it would be open to the trier of fact to conclude that the respondent's failure to disclose his HIV-positive status was dishonest; that it resulted in deprivation by putting the complainants at a **significant risk of suffering serious bodily harm**. If that conclusion is reached, the complainants' consent to sexual intercourse could properly be found to have been vitiated by fraud. It can be seen that applying the proposed standard effectively resolves the issue in this case. However, it is said that the test is too vague. Yet, it cannot be forgotten that **all tests or definitions are based on words. They are the building blocks of the law. ...**"

165. This research can find very little evidence that an acceptable level of risk has been defined by Health Canada in any meaningful way. As such, when the term is used, it would seem to be used loosely and hence tends to become a meaningless term and open to bias and subjective interpretation.
166. Using individual risk, we can see some variations when compared to societal risk. For example, only four deaths occur during war operations which could be deemed de minimus as a nation when compared to a de minimis threshold of 31 deaths. However, the individual risk is somewhat higher at 40 per million, or 1:25,000 of the total armed forces. Considering the folk killed were on duty in Afghanistan, and most of the armed force personnel were not on active duty, the actual individual risk would be somewhat higher and given the lack of public outrage at the casualties (a part from the fact that they were caused by 'friendly' fire), would seem to be an acceptable/tolerable risk to society.
167. On the other hand, if we look at fatalities in the airline industry, 62 deaths in total converts to less than 1:1,000,000 when considered as an individual risk. Further analysis of this data shows that scheduled air travel (zero deaths) is much safer than chartered air travel or flying an ultralight aircraft. Indeed, the later has a risk some 240 times that of the de minimis level of 1:1,000,000, and yet still seems to be acceptable to society and politicians based on the lack of outrage and regulation to manage the risk.
168. Indeed, even motorcycles have an individual risk of 480 times the 1:1,000,000 de minimis threshold, and still there is no pressure to make such activity more restrictive. Horse riding kills 83 individuals per year with an individual risk of as low as 1:6,000 and yet there are no calls for regulating horse riders.
169. On the other hand, consuming natural healthcare products appears to satisfy both the de minimis level of risk at a societal level (0.25 deaths per year on average; 1/120th the de minimis level) and an individual risk of 0.015 per million, or 1/67th of the de minimis risk level, and yet they have been reclassified via contentious regulation as a subset of drugs which appear to be some 250,000 times riskier. There appears to be no evidential basis for such regulation and regulating them in the same mindset as high risk substances may well produce risks of its own, especially regarding freedom of choice, and loss of benefits due to reduced product availability.

170. It is noted that during this research, it became apparent that Health Canada did not follow its own risk management guidelines regarding health warning when it came to natural health products. For example, in issuing public warning regarding the use of the herb Comfrey, Health Canada stated that whilst it was possible, they had no evidence of exposure to toxic alkaloids, nor did they have evidence of harm. Public warnings are supposed to be reserved for worst case scenarios. It is best practice that when there is no evidence of hazards nor evidence of harm then it can be assumed that the probability of there being an actual risk is very small in deed. Certainly not sufficient to issue a public warning – even under the guise of the precautionary principle.

Precautionary principle and science

171. To address the application of the precautionary principle by Canadian federal [science based] departments and agencies, the Government of Canada has developed “A Framework for the Application of Precaution in Science-Based Decision Making About Risk.”⁹³ The Framework outlines guiding principles for the application of precaution to science-based decision making in areas of federal regulatory activity, for the protection of health and safety, and the environment and natural resources. The Framework was developed through the efforts of a Government of Canada multi-departmental working group.
172. The framework itself states that it is legitimate that decisions be guided by society's chosen level of protection against risk,⁹⁴
- “To the extent possible, the level of protection should be established in advance through domestic policy instruments such as legislation and international agreements.
- While societal values and public willingness to accept risk are key in determining the level of protection, in all cases sound scientific evidence is a fundamental prerequisite to applying the precautionary approach...”
173. The framework also notes that assessing the efficiency of precautionary measures generally involves **comparing various policy instruments** to determine which options could most efficiently address the risk at least overall cost. The outcome of this process should result in any measures taken imposing the least cost or other negative impact **while reducing risks to an acceptable level**. It does not define what is an acceptable level.
174. According to the framework itself, “Ultimately, the Framework provides a lens to assess whether precautionary decision making is in keeping with Canadians’ social, environmental and economic values and priorities.”
175. If this is the case, then clearly acceptable levels of risk must be defined before legislation or regulation is implemented, otherwise how can there be any certainty as to whether the regulatory environment provides too much protection, thereby stifling commerce. This applies especially to Small and medium enterprises

⁹³ <http://www.inspection.gc.ca/english/reg/precaut/precaute.shtml>

⁹⁴ http://www.pco-bcp.gc.ca/default.asp?Language=E&Page=publications&Sub=precaution&Doc=precaution_e.htm

(SME). Conversely, not enough protection can be put in place, therefore exposing Canadian society to unacceptable risk of harm.

176. In light of the precautionary principle, if there is potential based on toxicity data or field data for "serious or irreversible damage", and the evidence that the substance meets the criteria is not conclusive then the substance should be proposed for risk profiling or full risk assessment. The precautionary principle is not a tool for regulators to use to remove ingredients from the market 'just in case' or when there is no evidence of harm. It is always a holding measure until more homework is undertaken. Perhaps a recent case where precaution was taken despite there being no evidence of harm relates to a recent public advisory on Comfrey use.⁹⁵
177. The news release included the statement, "Health Canada is advising Canadian consumers not to use the herb comfrey or any health products that contain comfrey because they might contain a compound called echimidine, which may cause liver damage. As a precaution, consumers are advised not to topically apply comfrey-containing products to broken skin. This advisory applies to both approved and unapproved products..."
178. The use of the words 'might contain' and 'may cause' provide no confidence of certainty. Use of the precautionary principle to extend the warning to topical use is not evidence based... there is no evidence to even suggest that topical use of comfrey causes liver damage. The advisory then says, "*What is Health Canada doing about this issue?* Health Canada has reviewed recent national and international research, as well as several reports associating the ingestion of comfrey (teas, capsules, leaves) with liver toxicity."
179. A search of Medline failed to identify any recent research, including case reports, that would have given Health Canada cause for issuing a public advisory, nor is there any evidence associating topical use of comfrey with adverse effects.
180. While the application of precaution primarily affects the development of options and the decision phases within science-based risk management, it is clearly linked to scientific analysis. The Framework says that even application of the precautionary principle cannot be done **without an appropriate assessment of scientific factors and consequent risks**.
181. Using the government's Framework as a "lens to assess whether precautionary decision making is in keeping with Canadians' social, environmental and economic values and priorities" begs the question as to the rationale of the public advisory.

10. Findings of comparative risk analysis

182. This report provides a comprehensive analysis of identifiable causes of death in Canada to enable a meaningful assessment of the level of risk various every day activities pose. It also provides a framework to assist determining whether those risks are acceptable or not in modern society, and to assist in determining risk management policy and allocating resources.

⁹⁵ Health Canada advises consumers not to use the herb comfrey or health products that contain comfrey
http://www.hc-sc.gc.ca/english/media/releases/2003/2003_101.htm

183. In doing so, it is clearly acknowledged that society accepts higher levels of risk in certain circumstances. For example, it is acceptable to society for search and rescue personnel to take normally unacceptable risks to rescue people in grave danger. Likewise, high risk brain surgery on a cancer patient might be acceptable given that the patient will certainly die without it, and has a 50/50 chance of success or fatal outcome. Other situations where different levels of risk are accepted by society, and therefore impact on policy and risk management choices such as legislation and regulation include whether the exposure to risk is involuntary (as in food additives or pesticide residual levels which are not identified on labels) or whether the exposure is voluntary, such as mountain climbing, horse riding or consumption of in natural healthcare & therapeutic products. In the case of the latter, actual exposure to any potential hazard is not only a voluntary action, but labelling the product with ingredient details is the main point of difference between products; therefore the ingredients are also known.

Relative risk comparator

Air travel

184. Air travel has become a widely recognised means of travel, and modern airliners are considered exceptionally, and acceptably safe.
185. The risks associated with an individual dying on any given flight of a Boeing 747 is 1.02 per million passenger flights based on comprehensive data recorded over the past 3 decades. In fact, risks are much less now than they were three decades ago; nevertheless, averages of all crashes and known flights have been used in this analysis.
186. The Airbus 300 is even safer at 0.7 deaths per million passenger flights. In part, this is because the A 300 is a more recently developed aircraft that utilised the latest computer controlled (safer) technology from conception.
187. On this basis, the risks associated with flying modern commercial Boeing 747 aircraft was used as a denominator for determining relative risk based on such activity being an every day risk that society deems to be acceptable – perhaps coincidentally, it also approaches the 1:1,000,000 level often referred to as a de minimis threshold.

Is absence of evidence, evidence of absence?

188. It is often argued that absence of evidence is not proof of absence of evidence. This statement is, of course, true unless all evidence is available and assessed. Bounded rationality, and the fact that only subsets of the whole [national census being a notable exception to the rule] are ever examined regarding harm emanating from exposure to hazards prevents absolute certainty of absence. However, if we take a hypothetical car accident, the first thing that people on the scene ask is, “Is anyone hurt?” If no-one is apparently hurt, everyone says no. On the face of it, that would suggest that absence of evidence of injury is evidence of absence of injury. Delayed concussion, internal injuries and the like may take some time to show up, so it is not proof of absence of injury. The longer the period of observation of no injury, the greater the certainty of there being no injury.

189. Likewise, the more sampling that is undertaken to determine whether significant risks or benefits are evident, the more certainty one can have regarding the fact. In medicine, for example, multi centred clinical studies have become the golden standard. If several study groups reach similar conclusions then the conclusions are deemed to be much more robust than if one study is undertaken.
190. It is common practice to use mortality data to analyse relative risk. Indeed, in medicine, mortality data is used to also determine benefit. If more patients live significantly longer with treatment A than with treatment B, then treatment A tends to become the new standard of care. Whilst it can be argued that serious harm should also be considered, analysing fatalities data is a very useful method for risk profiling and is used every day when measuring harm and progress in risk management strategies regarding exposure to everyday exposures to hazards such as motor vehicle accidents, work related accidents, drownings, cancer and heart disease.
191. This report examines the known causes of death utilising data primarily in public domain. It also analyses evidence to determine whether using fatalities is a sensitive measure of exposure to harm and the magnitude of that harm.
192. In doing so, the research concludes that whilst absence of evidence is not proof of absence of harm, it certainly is evidence of absence of harm and as such, can be used in determining a de minimus level of risk in everyday activities.
193. A detailed analysis of Health Canada, other Federal and Provincial government departments, and quasi government organisations' databases and published research – all in public domain – was undertaken

Public Health Richter Scale

194. In part, this question was answered in earlier discussion of the 1:1,000,000 threshold and the risks associated with flying on modern aircraft. This concept is now developed from another perspective, that being looking at harm caused by measurable hazards and determining if there is evidence to provide some degree of certainty regarding the use of acceptable levels of risk in modern society.
195. In the absence of any meaningful risk evaluation models in healthcare, this analysis begins by exploring the relationship between harm (effect) and the seismologists' use of the Richter scale (magnitude) to express the seismic energy released by each earthquake (hazard) as a model for providing an evidential basis for determining an appropriate level of regulation for the dietary supplement industry.
196. As a benchmark, all earthquakes in the world recorded in the past decade were analysed to determine if there was a relationship between magnitude of hazard (using the Richter scale) and the number of fatalities per earthquake. It is acknowledged that the risks associated with any particular earthquake is not only dependent on the magnitude of the earthquake, as recorded on Richter scales, but also dependent on how close to the surface the epi-centre was, how populated the area was, and the strength of any buildings exposed to the earthquake. Despite these variables, there are no recorded deaths in the past century associated with an earthquake of a magnitude of less than 4.0 on the Richter scale as shown in Figure 1.

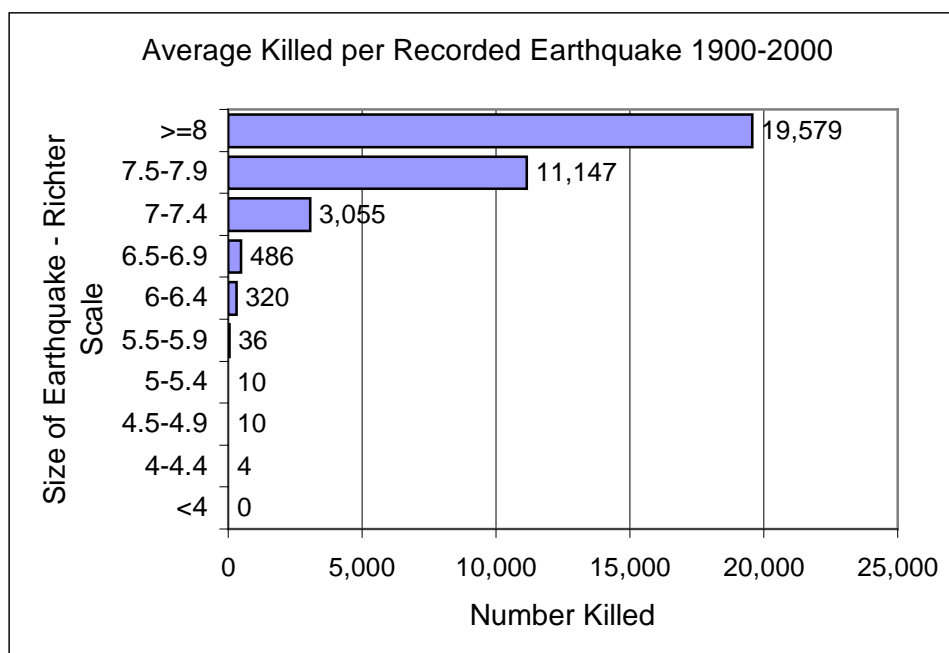


Figure 1: Number of fatalities vs magnitude of earthquake

Source:

197. The typical effects of earthquakes in various magnitude ranges are expressed in the following table:

Earthquake Severity Richter Magnitudes	Earthquake Effects
Less than 3.5	Generally not felt, but recorded.
3.5-5.4	Often felt, but rarely causes damage.
Under 6.0	At most slight damage to well-designed buildings. Can cause major damage to poorly constructed buildings over small regions.
6.1-6.9	Can be destructive in areas up to about 100 kilometres across here people live.
7.0-7.9	Major earthquake. Can cause serious damage over larger areas.
8 or greater	Great earthquake. Can cause serious damage in areas several hundred kilometres across.

198. In terms of earthquakes, analysis of earthquakes over the past century reveal a significant rise in fatalities compared to the magnitude of risk. The rare death due to earthquakes with a magnitude of less than 4.5 are primarily due to falling objects which are not able to be regulated easily – commonsense is about the only feasible risk management option. Fatalities are treated as unpreventable and deemed to be the result of bad luck or ‘mother nature.’.

199. Natural Resources Canada (NRCan) What is the "magnitude" of an earthquake? Magnitude is a measure of the amount of energy released during an earthquake. It

may be expressed using the Richter scale. It is very unlikely that an earthquake of magnitude less than 5 could cause any damage.⁹⁶

200. Just as building design for various earthquake loads is addressed in sections 4.1.9, 9.20.17 and 9.24.1.5 of the 1995 National Building Code of Canada, so there is a need for different risk management responses to various magnitudes of risk in everyday society.
201. Ground motion probability values are given in terms of probable exceedence, that is the likelihood of a given horizontal acceleration or velocity being exceeded during a particular period. The probability used in the National Building Code is 0.0021 per annum, equivalent to a 10-per-cent probability of exceedence over 50 years. This means that over a 50-year period there is a 10-per-cent chance of an earthquake causing ground motion greater than the given expected value.⁹⁷
- 202. No guarantees**
203. Seismic Hazard for the "Stable" Part of Canada. About half of the Canadian landmass has too few earthquakes to define reliable seismic source zones, and on prior maps the hazard computed for these regions came only from distant external sources. However, international examples suggest that large earthquakes might occur *anywhere* in Canada (albeit rarely).⁹⁸
204. The Richter scale is logarithmic which means that an earthquake measuring 7.0 is ten times more powerful than one of 6.0 and 1/10th that of an earthquake of magnitude 8.0.
205. This means that if adverse drug reactions measured, for arguments sake, 7.0, on a “public health” Richter scale, flying on a Boeing 747 would measure approximately 2.0. In geological terms, a figure of 2.0 would not result in significant harm and would not require special regulation or special building codes. In fact, areas where earthquakes are extremely rare have significantly lower factors of safety built into their building codes than areas prone to earthquakes.
206. The author is not aware of any evidence uncovered in any research of medical injury undertaken in several countries where natural healthcare & therapeutic products have been identified as being a significant source of harm. This does not mean that evidence it does not exist, it’s just that at a public health-risk magnitude reading of 2.0 on the healthcare Richter scale, there is no instrument sensitive enough to measure it – and if it there were able to, it would be of academic significance only, as the impact in terms of the totality of every day harm faced by Jo Citizen would be extremely insignificant.
207. Trying to take an overly prescriptive approach to regulating potential harm would be a bit like trying to regulate against the placement of ornaments on mantle-pieces – just-in-case they fell on granny’s head during a minor earthquake.

⁹⁶ http://www.seismo.nrcan.gc.ca/magnitudes/magnitude_e.php

⁹⁷ http://www.seismo.nrcan.gc.ca/hazards/zoning/haz_e.php

⁹⁸ **Lowering the Probability Level - Fourth Generation Seismic Hazard Results for Canada at the 2% in 50 year probability level Adams, John1, Weichert, Dieter2, and Halchuk, Stephen1** Earthquakes Canada, <http://www.seismo.nrcan.gc.ca/hazards/8ccee/8cceeawh.php>

208. An analysis of the frequency of earthquakes of differing magnitudes is also useful. Occurrence of earthquakes globally based on observations since 1900.⁹⁹

Descriptor	Magnitude	Average Annually
Great	8 and higher	1
Major	7 - 7.9	18
Strong	6 - 6.9	120
Moderate	5 - 5.9	800
Light	4 - 4.9	6,200 (estimated)
Minor	3 - 3.9	49,000 (estimated)
Very Minor	< 3.0	Magnitude 2 - 3: about 360,000 Magnitude 1 - 2: about 2,800,000

209. The decade of the 1990's resulted in an average of 5,924 deaths due to earthquakes globally and an average of 9,219 per year over the past century.¹⁰⁰ None of the top ten disasters, which ranged from 10,000 to 242,000 deaths occurred in what was a developed country at that time. As societies become more sophisticated, educated, and wealthy, they can afford less risky practices.
210. There are two terms used widely in international law that help delineate the threshold at which further effort to regulate trade or reduce risk are deemed either pointless or unnecessary.

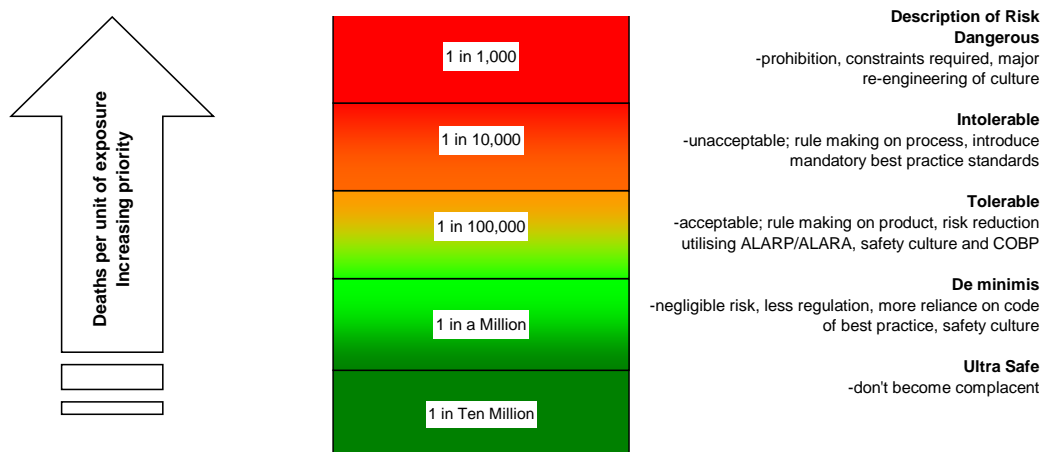
11. Proposed Framework for Classification of Risks

211. A 5-step framework for classification of risks is based on orders of magnitude is proposed.

⁹⁹ US Geological Survey National Earthquake Information Center, <http://earthquake.usgs.gov>

¹⁰⁰ <http://www.cred.be/emdat/intro.html>

A Model for Classifying Risk and Prioritising Risk Management Policy & Resources



Sources: Health Canada, Renshaw, Amalberti, Leape, NZFSA¹⁰¹

¹⁰¹ <http://www.hc-sc.gc.ca/pmra-arla/english/pdf/spn/spn2000-01-e.pdf>; Renshaw, F. M. (1990). "A Major Accident Prevention Program." *Plant/Operations Progress* 9, no. 3 (July), 194-197; Amalberti, R. (2001) Revisiting safety and human factors paradigms to meet the safety challenges of ultra complex and safe systems, In B. Willpert, & B. Falhbruch, Leape cited in Norton et al....Challenges and pitfalls of safety interventions, Elsevier; Leape, L., (2002) Safe Health Care: Are we up to it? <http://www.vipcs.org/conf2002/leape.pdf>; NZFSA (2000) A Risk Management Framework for Food Safety, <http://www.nzfsa.govt.nz/policy-law/harmonisation/rmgmtpr.pdf> © R Law 2004

12. Good regulatory practice

212. Good regulatory practice requires the need for regulation, and the most effective regime for it, to be periodically reviewed to ensure that the regime in place continues to meet its intended objectives with minimal negative impact on competition and consumer choice.
213. Therefore, evidence of good regulatory practice would include 'intended objectives' to be established. The importance of good regulatory practice was emphasised by the Canadian Government Commitment in the 2002 Speech from the Throne;
- “The government will move forward with a smart regulation strategy to accelerate reforms in key areas to promote health and sustainability, to contribute to innovation and economic growth, and to reduce the administrative burden on business”¹⁰¹
214. Regulators are obliged to provide regulatory impact assessments to establish an evidence based rationale for regulation that maintains a balance between cost of regulation and the benefit in the form of risk reduction.
215. The main elements of Canada's regulatory regime are stated as being Transparency and Instrument Choice. Transparency is defined as – knowing the rules and where to find them, and instrument choice is summarised as, 'regulate if necessary but don't necessarily regulate.'¹⁰² In other words, government agencies

¹⁰¹ <http://www.oecd.org/dataoecd/47/19/2505851.pdf>

¹⁰² <http://www.oecd.org/dataoecd/47/19/2505851.pdf>

are required to use the best tools to achieve public policy objectives; Intervention must be justified and there must be a favourable cost- benefit analysis.

216. Ultra safe systems ask for a different risk management strategies than high risk systems. To regulate disparate systems with the same mindset spells disaster for either innovation and free enterprise of public safety or both and is anathema to the concept of good regulatory practice.
217. One clear conclusion that this analysis of causes of death in Canada reaches is that regardless of the fact that natural healthcare and therapeutic products have recently been reclassified as drugs, the risks associated with pharmaceutical drugs and natural healthcare and therapeutic products are quite dissimilar – and therefore require quite different mindsets and systems regarding their respective management. As such, it is clearly evident that the risks associated with natural healthcare and therapeutic products are even somewhat less than common foods.
- | |
|--|
| 218. Health Canada asks, “Where should such acceptable risk benchmarks be set?” but doesn’t set them |
|--|
219. Individual risk can be defined as the chance that someone from a certain (sub) group runs during an established period (e.g. a year or lifetime) of suffering health effects from exposure to a toxicant(s). The distinction made between individual risks for persons from a critical group and that for persons from the whole population is important because the acceptability of a certain individual risk varies according to the size of the group running the risk. An individual risk can be considered when effects are involved for which no threshold value exists (stochastic effects), e.g., carcinogens or when exposures are involved which are higher than existing threshold values for non-stochastic effects.
220. In some cases an individual risk equal to or less than 10^{-6} (generally considered an insignificant risk) cannot be realized, e.g., because natural background levels already cause a high risk or the agent or activities fulfils an essential societal function from which a given exposure is unavoidable and/or which may be difficult to reduce through utilization of alternatives.
221. Frequently, individual risks are calculated for some or all of the persons in the population being studied and are then put into the context of where they fall in the distribution of risks for the entire population. Key questions often asked when considering strategies for dealing with individual risk include: to what risk levels are the persons at the highest risk subjected?; can individuals with a high degree of susceptibility be identified?; what is the average individual risk?; and what is the estimate of the probability that an individual will suffer an adverse effect given a specific set of exposure circumstances?

222. Perhaps as a comparison the following extract from the World Health Organisation's International Chemical Safety Programme training manual is worth using as a conclusion.

223. The WHO's ICSP states;¹⁰³

“6.1.4 Risk comparison

Risk implies uncertainty and subsequent risk evaluations and risk management decisions are concerned with the concept of probability. While high uncertainty may obscure the probability of a risk and the magnitude of harm, uncertainty does not eliminate risk. Unrecognized risks are still risks and derived risks are still risks. There is an apparent lack of consensus concerning the appropriate background risk with which to make comparisons. While many analysts would find it difficult to compare voluntary assumed risks to involuntarily assumed risks, proponents of risk comparisons strongly suggest that there should be consolidation and greater efforts by those engaged in risk evaluation to identify, assess, and compare risks to public health and the environment posed by the highest risk hazards. There is increasing recognition that in some cases it is useful to contrast risks in different ways in which they are treated in society. Comparisons should be seen as only one of a number of inputs to risk decisions, not as a primary determinant. It has been suggested that there is no conflict between comparative risk analysis and democracy since risk analysis gives citizens and elected representatives information to make sound choices about priorities. Regulatory agencies such as the US EPA support comparative risk analysis in order to help set the Agency's priorities.

Attempts have been made to measure health risks quantitatively and to give an upper limit on a risk where there is uncertainty. Table 12 lists a broad spectrum of risks estimated by Wilson (1990) that increase the chance of death by one in a million, which is often considered an acceptable risk, and may be a useful way to help people gain some sense of reality about very low probability events. However it is also suggested that many people do not perceive the various threats to health and wellbeing simply as matters of probability.

Smoking 1.4 cigarettes	Cancer, heart disease
Drinking ½ litre of wine	Cirrhosis of the liver
Spending 1 hour in a coal mine	Black lung disease
Spending 3 hours in a coal mine	Accident
Living 2 days in New York or Boston	Air pollution
Travelling 5 minutes by canoe	Accident
Travelling 10 miles by bicycle	Accident

¹⁰³ http://www.who.int/pes/training_material/module4/section6.1.htm

Travelling 300 miles by car	Accident
Flying 1000 miles by jet	Accident
Flying 6000 miles by jet	Cancer caused by cosmic radiation
Living 2 months in Denver on vacation from New York	Cancer caused by cosmic radiation
Living 2 months in average stone or brick building	Cancer caused by natural radioactivity
One chest X-ray taken in a good hospital	Cancer caused by radiation
Living 2 months with a cigarette smoker	Cancer, heart disease
Eating 40 tablespoons of peanut butter	Liver cancer caused by aflatoxin B
Drinking Miami drinking-water for 1 year	Cancer caused by chloroform
Drinking 30 12 oz. cans of diet soda	Cancer caused by saccharin
Living 5 years at site boundary of a typical nuclear power plant in the open	Cancer caused by radiation
Drinking 1000 24 oz. soft drinks from recently banned plastic bottles	Cancer from acrylonitrile monomer
Living 20 years near PVC plant	Cancer caused by vinyl chloride (1976 standard)
Living 150 years within 20 miles of a nuclear power plant	Cancer caused by radiation
Eating 100 charcoal broiled steaks	Cancer from benzopyrene
Risk of accident by living within 5 miles of a nuclear reactor for 50 years	Cancer caused by radiation
From: Wilson (1990) Technology Review, February, 1979 Analyzing the Daily Risks of Life by Richard. Wilson	

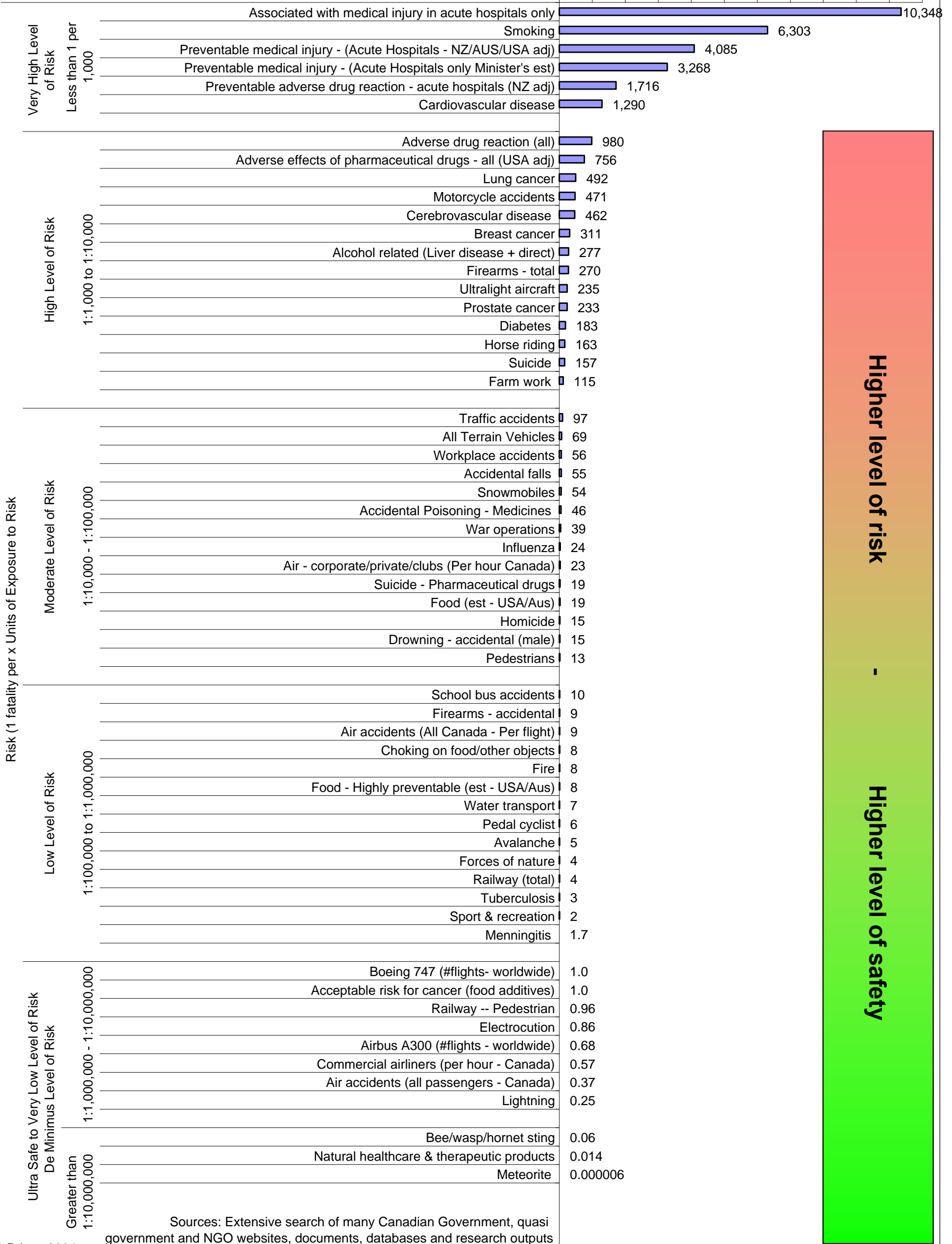
224. Do we regulate bike-riding coal miners who smoke 20 cigarettes a day, and whose partners do likewise, drink a couple of schooners [or diet soda if health conscious?], live in brick houses in suburbs downwind of a nuclear reactor and a PVC plant, and regularly eat steaks cooked on the outdoor Barbie, and does all the other stuff?

Risk of Dying Compared to Being Killed on a Boeing 747 Flight

(See separate table for units of risk used)

Relative risk

0 1,000 2,000 3,000 4,000 5,000 6,000 7,000 8,000 9,000 10,000 11,000



Higher level of risk

Higher level of safety

Sources: Extensive search of many Canadian Government, quasi government and NGO websites, documents, databases and research outputs