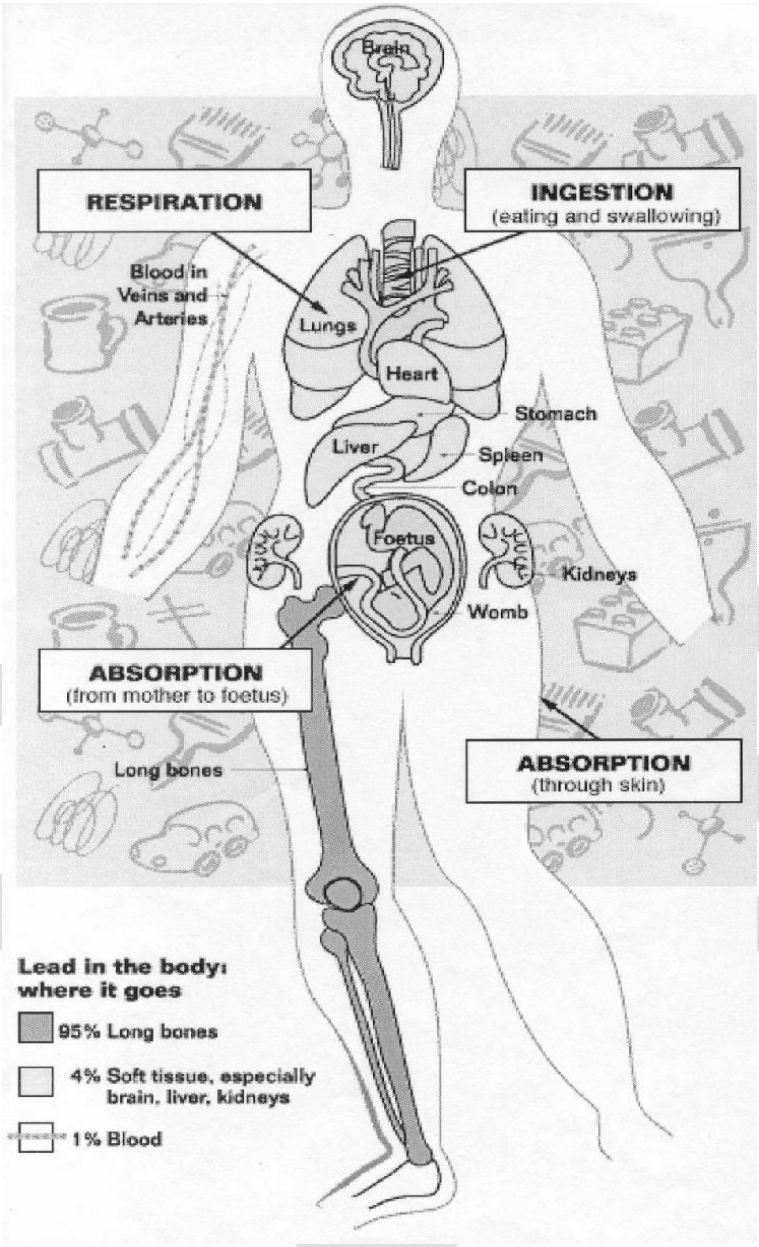

Figure 3. Lead in the Body (Used by permission of the Government of New South Wales, Australia)

2.4. Lead Exposure in Canada

Until the 1980's the two main sources of lead exposure for Canadians were leaded house paints and emissions from leaded gasoline. Under Health Canada's *Hazardous Products Act* the *Liquid Coating Materials Regulations* were enacted in 1976 to restrict the lead content of paints and other liquid coatings on furniture, household products, children's products, exterior and interior surfaces of any building frequented by children to 0.5% by weight. To reflect current scientific and medical knowledge, amendments to these *Regulations* which reduce the lead content of paints and other liquid coatings for these uses from 0.5% to 0.06 % by weight are currently being prepared.

In 1983 Canada initiated a phase-out of leaded gasoline and in 1990 the *Gasoline Regulation* under the *Canadian Environmental Protection Act* limited the use of leaded gasoline to competition vehicles, aircraft, farming equipment, boats and trucks of specific size. Lead concentration in urban air decreased from about 0.55 micrograms per cubic metre in 1975 to less than 0.05 in 1990, a drop of more than 90 percent (75). See **Figure 4** below.

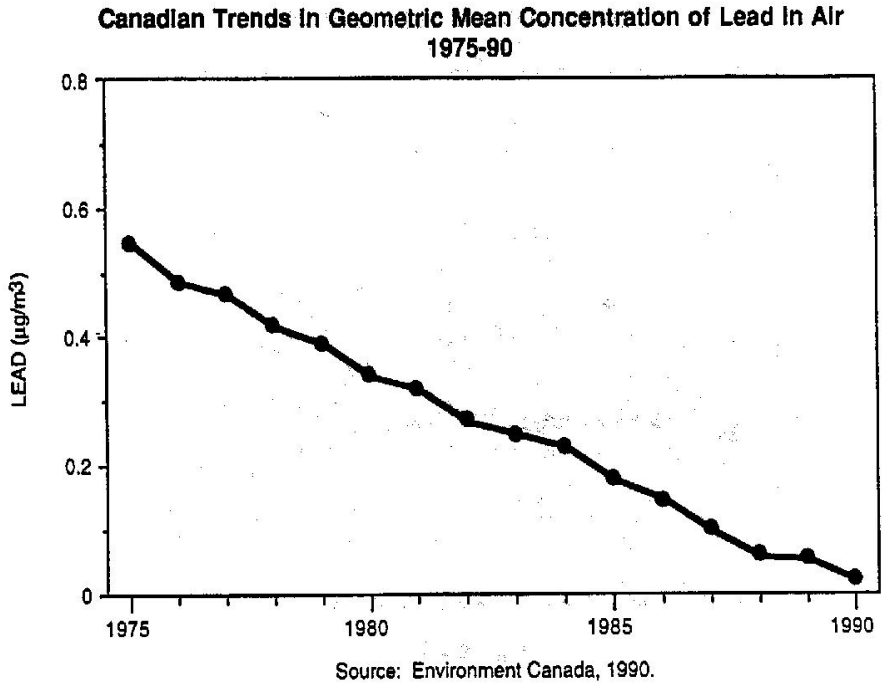

Figure 4. Canadian Trends in Concentration of Lead in Canadian air, 1975-1990. (75)

Before the late 1980's lead was widely used in soldering food can side seams. After Health Canada found high lead levels in canned baby food and evaporated milk in a 1986-87 survey, Canadian canners agreed to replace lead soldered can seams with welded seams. Production of lead-soldered food cans is illegal in the United States, and has ceased in most countries. While the import, advertisement or sale of lead soldered cans is not illegal in Canada, in practice lead soldered cans are no longer found on the Canadian marketplace, except, very rarely, in imported foods (20). The risks of lead exposure from other major sources such as ceramic glazes, drinking water distribution systems, cosmetics, and emissions from primary and secondary lead industries have been controlled through regulatory intervention and improved industry quality assurance programs. See Appendix D for an outline of federal legislation and guidelines related to control of lead exposure risks.

Today lead exposure in the Canadian population occurs mainly through handling of consumer products containing lead, through certain home-based occupations and hobbies, and through exposure to indoor leaded dust.

Evidence of pre-industrial exposure to lead suggests that human exposure to lead from natural sources is generally negligible (31). However, surveys of parent rock in Ontario and Quebec have found naturally occurring lead levels of up to 162 ppm, although the mean and medium values where much lower (56). While individuals living or working in these areas may occasionally be exposed through dust and soil to high natural levels of lead, the significance of natural sources on human exposure to lead is negligible compared to industrial sources.

3.0 HAZARDS ASSOCIATED WITH LEADED CONSUMER PRODUCTS

3.1. Introduction

Because lead is inexpensive, dense, easily molded, melts at low temperatures, and does not rust or corrode. it has many potential uses in consumer products. Because of lead's many uses, it is not possible to list all consumer products which may potentially contain lead. Products in which lead may be used include paints, pigments, frits (mixtures of sand and fluxes used in glassmaking), and other artists' supplies, lead crystal, protective/decorative coatings on a wide variety of products, jewellery, decorative figurines, fastenings and trim on clothing, lead shot, fishing sinkers and jigs, lead came used in panel and stained glass windows and doors, batteries, and lead vent and roof flashings. Activities which may expose both adults and children to lead-containing products and to lead-contaminated dust include pottery-making, where lead glazing or lead pigments may be used, manufacture of stained glass items, which may produce fumes from the soldering of lead and dust from sanding of leaded glass, and casting of fishing sinkers, lead shot or diving weights, which may produce fumes from melting lead.

The risk of lead exposure through consumer products depends not only on its total lead content, but also on the proportion of lead which is released from the product into the body under certain

conditions, such as chewing, sucking, or swallowing of the product. This proportion is called the migratable or leachable lead content. In this soluble form, lead is available for absorption into the body. Although higher total lead concentration in a product will generally result in a proportionately larger migratable lead concentration, there is no reliable correlation between the two. For the purposes of this Strategy, migratable lead is defined as the amount of lead that is leached out of a product when tested by the European Standard EN-71, Part 3 (9). This standard sets out maximum migratable levels of lead and other toxic metals for toys intended for children under six years of age. The EN-71 test method simulates the digestive process in the stomach.

Since trace amounts of lead are ubiquitous in the human environment, manufacturing a product with zero lead content is generally not feasible. For the same reason, it may be difficult to establish a link between exposure to a given consumer product and elevated blood lead levels.

3.2. Incidents Involving Lead in Children's Products

There have been a number of incidents in Canada involving lead in children's products over the past ten years:

- **March 5, 1999** - recall by NIKE of 110,000 pairs of children's shoes in the United States and 750 pairs in Canada because the red paint used to trim the shoes contained lead in excess of U.S. federal standards for children's products.

- **October 27, 1998** - recall by Universal Studios Canada Ltd. of a necklace included in a promotional package for Universal's "The Battle for Mount Olympus" video. The necklace had a ring and a sword pendant, which were found to contain 72% lead and 73% total lead respectively, with leachable lead of 104 mg/kg and 252 mg/kg respectively.

- **June 3, 1998** - GapKids of San Francisco, California, initiated a voluntary recall of children's anoraks, which had imported zipper tabs coated with paint containing an unacceptable level of lead.

- **April 22, 1998** - Health Canada issued a public warning respecting a lead Kids Klub children's pendant, which was associated with elevated blood lead levels in a five-year-old child in Calgary, Alberta. The pendant on this necklace was determined to be pure lead, of which 1,022 mg/kg was leachable.

- **March 1998** - Health Canada issued a letter to toy manufacturers and distributers requesting that lead not be used in game figurines. This action followed a 1977 survey conducted by Health Canada to determine the lead content figurines used in children's games such as Dungeons and Dragons. The average lead content of the 30 figurines analysed was 36.6%; the maximum lead content was 75.2%.

- **June 25, 1996** - Health Canada issued a press release concerning total lead levels of 0.5 - 1.4% (5,000 - 14,000 mg/kg) in some imported vinyl mini-blinds. Surface degradation of the blind slats resulting from exposure to UV rays from the sun caused release of lead as dust. Dust wipe samples taken from comparable mini-blinds were found to contain from 255 mg/kg to 2,874 mg/kg lead (86). The dust accumulated on the slate surfaces where it could pose an ingestion hazard to children.

- **In 1994** - Health Canada issued a Public Alert on lead in imported children's wax crayons. The Alert followed an extensive investigation which showed that roughly 29% of the wax crayons sampled contained lead in excess of 90 ppm. Some crayons contained up to 6,540 mg/kg total lead.

As a result of the Universal and Kids Klub pendants incidents outlined above, Health Canada issued a letter to 7,855 Canadian manufacturers, distributors, importers and retailers of jewellery products on April 9,1999. The letter requested compliance by January 31, 2000, with the following actions:

> (1) For jewellery intended for children under 15 years of age, obtain written confirmation from suppliers that lead has not been added to jewellery products, or the materials used to manufacture jewellery products, OR confirm, by laboratory analysis, that the concentration of total lead in the finished jewellery product does not exceed 65 mg/kg
>
> (2) For jewellery intended for adults or children older than 15 years of age, determine whether lead has been intentionally added to a jewellery product. If the total concentration of lead in the finished product exceeds 65 mg/kg, attach or display a warning to the effect that the product contains lead, may cause harm if chewed, mouthed, or ingested, and is not recommended for use by children under 15 years of age.

Health Canada carried out a national survey of lead content in 95 items of children's jewellery in May and June 2000 to determine compliance with the recommendations of the April 9, 1999 letter. Of the 95 items collected for the survey, 94 % contained lead in excess of 0.0065 %. Overall, sixty-nine percent of the jewellery samples had lead content of between 50% and 100% with the remaining thirty-one percent containing less than 10% total lead (48). These results prompted Health Canada to send a second letter to the jewellery industry on December 7, 2000, stressing Health Canada's concern at the continued use of lead in jewellery products and informing the industry of Health Canada's intent to regulate the lead content of jewellery products. It also reminded industry of its legal responsibilities relative to the potential toxicity of leaded jewellery. On January 8, 200l, Health Canada issued a public health advisory on lead in jewellery, informing consumers of the potential health risk to children who might chew or suck on inexpensive jewellery.

While the wicks of most candles are made entirely of cotton, some candle wicks, typically wicks of votives, pilfers, tealights and other novelty candles, may contain lead in their cores. These

cores are used to support the wicks and make them burn more slowly and evenly. As the combustible cotton portion of the wick burns down, the lead core melts and is volatilized as a mixture of elemental lead and its oxides. These lead vapours are hazardous if inhaled. Uninhaled vapours settle out as leaded dust on nearby surfaces. This leaded dust also represents a health hazard, particularly to young children.

Two national surveys of candles, carried out by Health Canada in 1999-2000 (52) and in 2001, found that lead-core candles are being sold on the Canadian marketplace. Approximately 71% of the candles had metal cores containing lead concentrations in excess of 600 mg/kg and of those almost all were roughly 100% lead. The January 2001 Public Health Advisory on lead in children's jewellery (49) also recommended that consumers not use candles having lead core wicks, especially in the presence of young children and pregnant women, because of the dangers of lead fumes released by these candles.

4.0 THE LEAD RISK REDUCTION STRATEGY

4.1 Health Canada's Lead Risk Management Policy

Lead exposure is recognized nationally and internationally as one of the most significant environmental threats to the health of children. The American Academy of Pediatrics (5) has concluded that lead remains a common, yet preventable, environmental health threat. The Environment Leaders' Summit of the Eight, (Canada, France, Germany, Italy, Japan, Russia, the United States, and the United Kingdom) on Children's Environmental Health held in May 1997 described lead poisoning as a major hazard and called for further action to reduce children's exposure to lead (24). The Organization for Economic Cooperation and Development (OECD) recognizes, through the Declaration on Risk Reduction for Lead and the OECD's Lead Risk Reduction Strategy, the need to reduce health risks, especially risks to children, related to lead exposure (76). Canada was a signatory to both the Summit of the Eight and the OECD documents. The Commission for Environmental Co-operation (CEC) established under the North American Agreement for Environmental Co-operation has identified lead exposure as a major environmental threat to children's health. The Dallas Declaration of 2000 commits Canada, Mexico, and the United States to a co-operative strategy for protecting children from exposure to environmental health hazards, including lead, through North American Regional Action Plans.

Regulatory controls for lead content in consumer products have been implemented in several of Canada's trading partners. The United States Consumer Product Safety Commission (CPSC) has, by regulation 16 C.F.R. Part 1303, required that "items intended for children" contain less than 0.06% lead by weight or 600 mg/kg total lead (97). Recently the CPSC issued a directive requesting that all "manufacturers eliminate the use of lead that may be accessible to children from products used in or around households, schools or in recreation" (98). In response to this directive, on August 20, 1998 the U.S. Toy Manufacturers of America "pledged that its members

will help to reduce children's exposure to hazardous lead levels...by eliminating lead from their products"(98). The European Community has adopted legislation limiting heavy metals in children's toys, under which toys may contain a maximum of 90 mg/kg leachable lead. This standard is the same as that found in the *British Standard Specification for the Safety of Toys - Part 3: Migration of certain elements*"(9). The 90 mg/kg limit is based upon the World Health Organization assessment of the tolerable weekly lead intake (32,34).

Health Canada is the Canadian federal agency with primary responsibility for the health of Canadians. As such, the Department, along with Environment Canada, plays a major role, both nationally and in international organizations, in initiatives aimed at controlling lead exposure. Within Health Canada, the Health Products and Food Branch is responsible, under the *Food & Drugs Act* and *Regulations*, for setting maximum lead limits for food products. The responsibility for monitoring lead contamination in foods is shared between Health Canada and the Canadian Food Inspection Agency. Under the *Canadian Environmental Protection Act*, Healthy Environments and Consumer Safety's (HECS) Safe Environments Programme shares with Environment Canada the responsibility for assessment of substances which may be harmful to human health and/or to the environment.

Health Canada's HECS Branch plays a major role in assessing and managing risks arising from exposure to lead in indoor and outdoor environments, in consumer products, and in drinking water and water used for recreational activities. The Consumer Product Safety Bureau (CBSB) of HECS is responsible for the control of toxic substances, including lead, in consumer products. The Consumer Product Safety Bureau supports the OECD and Summit of the Eight declarations and takes the position that any human health risk associated with the unnecessary addition of lead to consumer products is unacceptable.

4.2 The Need for a Lead Risk Reduction Strategy for Consumer Products

As noted above, while government regulations and industry initiatives have greatly reduced public exposure to lead, there are still risks, particularly to children, of lead exposure through use or handling of consumer products. Only a few consumer products are currently regulated for lead content under the *Hazardous Products Act* and *Regulations* administered by the Consumer Product Safety Bureau of Health Canada. These are:

(1) decorative coatings on pencils, and artists' brushes and on toys, children's furniture, and other articles intended for children. The current requirement stipulates that the coating on any of these products should not exceed 5,000 mg/kg total lead

(2) paints, enamels and other liquid coating materials on furniture, household products, children's products, exterior and interior surfaces of any building frequented by children to 0.5% by weight.

(3) toys, equipment, and other products "for use by a child in learning or play",

(4) glazes containing lead on ceramics and glassware. The regulation limits the amount of lead that may be released when the glazing is soaked in a solution of acetic acid.

(5) kettles. The regulation limits the amount of lead that may be released when water is boiled in the kettle.

Health Canada currently has no authority under the *Hazardous Products Act* to control the import, advertisement or sale of unregulated consumer products which may represent lead exposure risks. This regulatory deficiency leaves Health Canada unable to take proactive steps to reduce these risks. Instead the Department is forced to react on a case-by-case basis whenever instances of potentially hazardous lead in specific consumer products are brought to its attention and to rely on voluntary industry co-operation in controlling the associated risks. Evaluation of specific products or product groups can be lengthy and often requires dedication of considerable Health Canada resources.

Canadian regulations are required which will

(1) set lead content limits for consumer products which are based upon the most recent available scientific data and are in line with those of Canada's major trading partners, and
(2) regulate a broader spectrum of products which may potentially contain lead.

5.0 DEVELOPMENT OF THE LEAD RISK REDUCTION STRATEGY

5.1 Background

In May 1997, Health Canada began the process of developing a new strategy to reduce the lead content in consumer products to which children are likely to be exposed, and thereby minimize the risk to children of lead in consumer products (44,45,47). A series of consultations on a lead reduction policy for consumer products was held in Vancouver, Montreal and Toronto (see Appendix E for Report). Stakeholders consulted included consumers, health and environmental organizations, and industry groups. The consultations were completed in March 1998. The major outcome of these initial consultations was the agreement by all participating parties that the lead content of products intended for children should be federally regulated.

The Lead Risk Reduction Strategy document was developed to meet the need for a new approach to controlling lead exposure risks in consumer products. The document was submitted for review by Health Canada scientists and legal services in 2000.

5.2 Risk Management Options considered under the LRRS

5.2.1. Regulatory Controls on Lead Content of Consumer Products

Several risk management options for controlling the risks of lead exposure to children through unregulated consumer products were identified and evaluated before deciding that a regulatory approach would be most effective in controlling these risks. Regulations are equally applicable to all industry players and thus are fair. Regulations are a tool which would allow Health Canada to take measures when necessary to prevent the entry of hazardous products to the Canadian marketplace or remove them from it in a timely manner. The proposed regulations, by specifying lead content limits for various product categories, are proactive and thereby promote the distribution of safe products. Regulation of hazardous product categories would free up Health Canada resources which would otherwise be spent on case-by-case investigation of suspect products. Also, the threat of enforcement action provides a powerful deterrent.

The drawback of a regulatory approach is the length of time required to promulgate a major regulatory change like that proposed in this Strategy. Until the regulatory changes are implemented, the lead exposure risks to Canadian children would remain uncontrolled in the absence of any other risk management measures. Since regulations are not easily amended, thorough consultation is required to ensure that the proposed regulations will be effective and enforceable without imposing unnecessary costs and restrictions on industry. Therefore, sufficient resources must be made available to the Consumer Product Safety Program to monitor and evaluate the effectiveness of the proposed regulations. Another disadvantage of regulation is that any compliance costs to the industry will likely be passed on to consumers.

Regulatory action is Health Canada's preferred option for managing the risks to children associated with lead in certain categories of consumer products. While regulation is not without disadvantages it is the option most likely to produce adequate control of the risks. The regulations proposed under the LRRS will empower Health Canada to act swiftly and efficiently if necessary to remove hazardous products from the marketplace. Regulatory action for children's products was recommended by all stakeholders participating in the 1998 consultations on lead in consumer products. The specific regulatory standards proposed are outlined in Section 6 below.

Other risk management options considered include:

5.2.2. No Change in Current Management Practices

This option was considered inappropriate because it does not enable Health Canada to adequately fulfill its mandate under the *Department of Health Act* to protect and improve the health and safety of Canadians. As explained above, a number of unregulated products on the Canadian marketplace have been found to contain potentially hazardous

levels of lead, and current regulations on lead content in consumer products are not sufficiently broad in scope to encompass the wide variety of consumer products which may potentially contain lead.

5.2.3. Voluntary Compliance Program

A voluntary compliance program would require a formal commitment from the appropriate industry groups to establish and maintain voluntary restrictions on the use of lead in specific consumer product groups. Compliance would be monitored by industry, using recognized standards and test methods. The voluntary compliance program has been effective in virtually eliminating food cans sealed with lead solder from the Canadian marketplace. However, requests for industry to voluntarily refrain from marketing consumer products like lead-core candle wicks and leaded children's jewellery or to remove them from retail shelves have not been effective. Without regulatory tools, Health Canada's only effective risk management option when voluntary compliance is ineffective is to issue a Public Advisory or Public Warning.

Voluntary compliance arrangements often create an economic advantage for industry players who do not comply with them. The advantage of a voluntary compliance program is that it is relatively quick to implement and modify as required, and allows industry more flexibility in meeting the needs of the marketplace.

The March, 1995 *Policy Guidelines for Voluntary Compliance Programs* (42) state that a Voluntary Compliance Program (VCP) would not be a suitable risk management instrument under one or more of the following conditions:

1. The hazard is hidden or not easily known to consumers
2. Vulnerable populations, such as children and elderly are at risk
3. The risk is too high or the hazard is too severe
4. Even low levels of noncompliance may cause severe injury and death; and
5. Reasonable assurance cannot be established that the VCP will result in the removal or acceptable reduction of the hazard in a reasonable period of time.

In the case of leaded consumer products, the hazard is hidden in that it is generally difficult for a consumer to determine whether or not a product contains lead, a vulnerable population (children) is at risk, and the adverse health effects arising from exposure to lead may be severe. As noted above, industry response to Health Canada's requests for voluntary control of lead content in window coverings and jewellery has not been satisfactory. It is unlikely that the VCP would result in acceptable reduction of lead content in unregulated products within a reasonable period of time.

5.2.4. Combined Voluntary Compliance and Regulatory Program

Under this option, the lead content of consumer products which are determined to carry the greatest risk of lead exposure to children would be regulated. A voluntary industry compliance program would be introduced for lead content in consumer products for which the risk to children, while still significant, is lower than for the products to be regulated.

This option may be viewed as inequitable by industry. Because it is more complicated, it could be more confusing and difficult to administer.

(It should be noted that it is impossible to remove all risks of lead exposure through regulation. Health Canada recognizes the need for public education on the need to discourage behaviours which increase the risk of lead exposure, such as mouthing or ingestion of non-toy or non-food items.)

6.0. PROPOSED REGULATIONS UNDER THE LEAD RISK REDUCTION STRATEGY (LRRS) FOR CONSUMER PRODUCTS

The LRRS takes a precautionary stance by using a hazard-based rather than a product-based approach to regulating lead content in consumer products. This hazard based concept is analogous to the approach used by the Consumer Product Safety Bureau in developing the recently promulgated *Consumer Chemicals and Containers Regulations* amendments. Since the proposed measures are hazard-based rather than product-based, they will provide an effective means of controlling lead exposure from a wide range of consumer products rather than a few specific products. The advantage of a hazard-based approach is the broader regulatory coverage which it gives, addressing hazards which are common to many products. This approach places the responsibility of controlling the hazard on the manufacturer by limiting the lead content in regulated product categories.

6.1. General Considerations

The LRRS recognizes risk-based management by proposing regulations for five product categories. The groups are based on product description and use, and on the relative risk of lead exposure to children.

The risk was evaluated on the basis of two factors:

(1) the probability that product/child interaction would occur and would result in exposure to lead. The probability of interaction depends on accessibility of the product as

a whole to children, and on accessibility of lead-containing components of the product to children. For example, some toys contain batteries or electronic components which contain lead, but the toy is designed in such as way that these components are not accessible (taking into account the foreseeable actions of a child.)

(2) the expected level of exposure, which depends on factors such as the proportion of lead in the product which is migratable and the frequency of exposure to the product. Exposure to lead is affected by the form of lead, solubility of the lead, the chemical and mechanical properties of the substrate in which the lead is present, and how aging and/or wear and tear of the product will affect accessibility to lead.

The greatest risk was assigned to products for which both factors had a high magnitude. See Appendix F for a summary of the five Product Groups.

A total prohibition of lead in any form in all consumer products would be unrealistic since consumers, especially children, are constantly being exposed to very low baseline levels of lead in the environment.
To fairly reflect the reality of these low background lead levels as they affect Canadian and other industrial processes and to maintain a wide choice of consumer products on the Canadian marketplace, specific lead content standards and performance standards in the proposed regulations are in harmony with international standards and those of Canada's trading partners.

There are three groups of products which may contain lead and to which children may potentially be exposed which are not included in the current Strategy. These groups are:

1. Household Furnishings and Fittings with which Children are Likely to Interact, such as furniture and furniture and coverings, vent coverings, railings, windows and window covering products, carpeting, rugs, and other floor coverings, wall paper, doors and door trim, gift-wrapping paper, ribbons, bows and other gift-wrap items, Christmas tree ornaments, garlands, and other holiday trim.

2. Products Intended to be Used in Public Spaces, such as tools, nails, screws and other fasteners, scuba dive weights, exercise weights, caulking lead and casketing, and leaded greases.

These two categories contain a very broad range of products. Regulatory controls on the lead content of these products would affect a large number of industry sectors, and require extensive consultations. Since the risk of lead exposure to children is not as great for these products as for Groups 1-5, Health Canada has decided to develop a separate strategy at a later date to address the risks of lead exposure associated with these categories of product. This will allow Health Canada to proceed more quickly to control the greater risks of lead exposure associated with product groups 1-5.

3. Products used for Hunting, Target Shooting or Fishing, such as shot used for hunting or target shooting, and sinkers and jigs (weighted hooks) used for fishing and angling. A number of potential adverse effects for both the environment and for human health are associated with these products (see Appendix G for a fuller discussion of the environmental and health impacts of leaded hunting and fishing products). However, it is unclear whether or not Health Canada has the authority under the *Hazardous Products Act* to regulate the sale of these products. A legal opinion on this issue is being sought. Jurisdiction over the use of lead shot and lead sinkers and jigs is shared by a number of federal and provincial agencies, including Environment Canada and Parks Canada. Because of this jurisdictional complexity, it is considered that a separate Strategy should be developed for fishing and hunting products, with substantial input from all stakeholder agencies.

6.2 Proposed Regulations

The consumer products included in the proposed lead reduction regulations under this Strategy have been divided into five categories as follows:

Group 1:	**Products Likely to be Ingested in Significant Quantities**
Group 2:	**Products Intended to be or Likely to be Placed in the Mouth**
Group 3:	**Children's equipment, furniture, toys, and other products intended for used by a child in learning or play (Excludes Group 1 Products)**
Group 4:	**Products intended for use in eating, drinking, or for preparing, serving, or storing food and beverages (Excludes Group 1 or 2 Products)**
Group 5:	**Consumer Products Intended to be Melted or Burned in Enclosed Spaces**

The proposed regulations for each product category are outlined below:

6.2.1. Group 1: <u>Products Likely to be Ingested in Significant Quantities</u>

Examples of Group 1 Products

- children's crayons
- children's modelling clays
- children's paints, including finger paints and make-up paints
- chalk

Lead Limits:
For each individual component of Group 1 products which is likely to be ingested, total lead must not exceed 75 mg/kg. Migratable lead therefore can not exceed 75 mg/kg.

Intent:
The intent of the Group 1 lead content restrictions is to protect consumers, especially young children, from exposure to lead through ingestion of a Group 1 product.

Rationale:
Group 1 products are not only mouthed, but often ingested by young children. Most young children have ready access to these products, especially crayons**,** and over a period of time could ingest sufficient quantities to create a risk of exposure to harmful levels of lead. A 1994 risk assessment carried out by Health Canada demonstrated that levels of lead in crayons greater than 75 ppm would be sufficient to raise children's blood lead to harmful levels if it is assumed that one 14 g crayon is consumed per year.

The following exemptions apply to Group 1 products:

- food, beverages, medicines, or other products which are intended for human consumption (Lead contamination of these products is regulated under the federal *Food & Drug Act.*)

6.2.2 Group 2: <u>Products Intended to be or Likely to be Placed in or near the Mouth</u> (Excludes Products in Group 1)

Examples of Group 2 Products:

- plastic beverage straws (lead migration from straws is more likely to occur through contact with the saliva than with the beverage)
- mouthpieces used in sports such as snorkels, SCUBA mouthpieces, breath deflectors and mouthguards
- musical instruments with mouthpieces, such as tin or penny whistles, kazoos, flutes and recorders
- pacifiers, baby bottle nipples, teethers, rattles
- crib toys
- toys labelled by manufacturers as being suitable for children less than three years of age, or which are likely to be used by a child of less than three years of age

Lead Limits:
For each and every individual component of Group 2 products which is intended to be or likely to be mouthed, total lead must not exceed 90 mg/kg. By definition, therefore, migratable lead cannot exceed 90 mg/kg.

Intent:
The intent of the Group 2 lead content restrictions is to protect consumers from exposure to lead through use of products or product parts which are normally placed in or in close proximity to the mouth. The restrictions also protect children under 36 months of age, whose normal

behaviour entails mouthing objects in the course of exploring the world about them, by ensuring that the lead content of consumer products which they are most likely to mouth is reduced to the extent practicable.

Rationale:

Mouthing of objects containing lead results in lead-contaminated saliva which is absorbed from the digestive system into the body. In view of lead's deleterious effects on young children even at very low concentrations, it is essential to ensure that the risk of lead exposure associated with this group of products is negligible. This is achieved by limiting the total allowable lead content for each individual component of a Group 1 product to 90 mg lead per kg of product component. The 90 mg/kg standard is based on the European Committee for Standardization's European Standard EN-3, entitled "Safety of toys - Part 3: Migration of certain elements", issued in December 1994 (27) which limits leachable lead content in toys intended for children under six to 90 mg/kg.

There are two reasons for choosing this standard:

1. There is no known correlation between total and migratable lead that can be used to predict migratable lead from the total lead content of a specific product.

2. Mouthing new products which have protective coverings or coatings over the lead may not produce significant leaching of lead. However, mouthing may result in high exposure to lead when aging and wear have damaged the covering or coating, exposing the lead beneath. Mouthing itself has a wearing effect on coverings and coatings. As a result of a 1998 consumer complaint, Health Canada tested the two pendants of a child's necklace for migratable lead content. Both pendants had a core composed of approximately 75% lead, and both were covered with a decorative coating, When new, one pendant was found to contain non-detectable levels of migratable lead and the other contained 0.69 mg/kg migratable lead. However, when identical pendants that had been chewed by the complainant's child were tested, the migratable lead level of one was 251.6 mg/kg and of the other, 104.0 mg/kg. These levels considerably exceed the 90 mg/kg leachable lead limit set by the EN-3 standard. Once the thin protective coating was partially removed through the reasonable and foreseeable actions of a child, unacceptable levels of lead were released.

Restricting the total allowable lead to 90 mg/kg ensures that the maximum migratable lead limit will never be exceeded with time or use. It is intended to ensure that there will be no intentional use of lead in the manufacture of Group 2 products. While there should be no intentional use of lead in Group 1 products, it is impractical to establish a lead content limit at or near zero, because of the occurrence of trace amounts of lead everywhere in the natural and human environment.

6.2.3 Group 3: Children's Equipment, furniture, toys, and other items intended for used by a child in learning or play (Excludes Products in Groups 1 or 2)

Examples of Group 3 Products:

- baby carriers, carriages and strollers
- baby seats, high chairs and booster cushions
- cribs and cradles
- children's clothing, footwear, and accessories
- playpens
- interior and exterior play equipment

Lead Limits:
For each and every individual component of Group 3 products, total lead must not exceed 600 mg/kg and migratable lead must not exceed 90 mg/kg.

Intent:
The intent is to protect children from exposure to lead through mouthing of products which are intended for their use or for the use of those caring for them, and with which the child would reasonably be expected to be in frequent, often daily, contact. While mouthing and/or swallowing of inedible items ceases in the majority of children at or around 18 months, these behaviours, known as *pica*, persist beyond that age in 10% to 30% of children (62). The proposed lead limits would provide some protection against lead exposure for children exhibiting *pica*. The regulation would also protect young children from the effects of mouthing lead-contaminated dusts or other residues produced by children's products containing lead.

Rationale:
Group 3 products have a total lead limit which is higher than for Group 1 and Group 2 products. This reflects the fact that Group 3 products are not intended to be placed in the mouth nor intended for play by children under 36 months. As children grow older, the tendency to mouth objects is reduced. For the reasons set out for the Group 2 products, the maximum migratable lead concentration for Group 3 products is set at 90 mg/kg. The maximum total lead concentration for Group 3 products is 600 mg/kg. This standard offers manufacturers of Group 3 products a broader choice of materials, while ensuring the product is safe for children who may mouth it.

The 600 mg/kg maximum total lead standard is the same as that proposed for paints and other liquid coating materials used for furniture, household products, children's products, and exterior and interior surfaces of any building frequented by children, under the recent amendment to the *Hazardous Products Act Liquid Coating Materials Regulations*. It is also the same standard prescribed by the U.S. Consumer Product Safety Commission Regulation **16 CFR Part 1303**, for

paint and other liquid coatings for residential use, toys and furniture (97). This limit was determined by a risk assessment which calculated that 600 mg/kg of lead in paint was the threshold level, at or below which there would be no significant lead exposure if a child consumed a one square inch paint chip each day.

If a lead test demonstrates that the total lead content of a Group 3 product does not exceed 90 mg/kg, then it will not be necessary to perform a migratable lead test as, by definition, migratable lead in the product cannot exceed 90 mg/kg.

The following exclusions apply to Group 3 products:

- components of products that are required to store, generate or conduct an electrical current or to electrically insulate or shield an electrical conductor, provided that these components are not accessible to children. Such components include batteries, electrical solder and flux, wire and cable products including their insulation, and jacketing materials. *This exception does not apply to toys, hobby kits and other products of a similar type which are intended for children 36 months or older and which require assembly.* Examples of such toys are "build your own electrical or electronic device kits" and items requiring the use of solder.

- Solder and flux used to fuse or connect components of jewellery, crafts or artists' products. Though these products are of concern to Health Canada, no other viable substitutes are available at this time. A labelling requirement for solder, advising consumers of the lead content, is being considered.

- Artistic paints and pigments will be exempt from the requirement for total lead not to exceed 600 mg/kg, but they will be subject to a total migratable lead limit of 90 mg/kg because there is a reasonable probability that children will mouth these items. *A labelling requirement for these paints, advising consumers of the lead content, is being considered*. (Paints and pigments intended primarily for use by children are included under Group 1 or Group 2, depending upon whether or not they are marketed for use by children under 36 months.)

6.2.4 Group 4: Products that are intended for use in preparing, serving, eating, containing or storing food and beverages (Excludes Products in Groups 1, 2 or 3)

Examples of Group 4 Products:

- cutlery
- cooking utensils such as beaters, spatulas, cutting boards, pots, pans, and cooking trays
- serving utensils such as serving spoons and carving knives
- tableware such as plates, bowls, drinking glasses, and mugs

- food storage materials and containers such as plastic and foil wrap, sandwich bags, plastic containers, and juice jugs
- lead crystal decanters and other crystalware

Lead Limit:
Total lead in Group 4 products must not exceed 600 mg lead/kg. For glazes on hollowware, migratable lead must not exceed the levels specified for glazed hollowware under the *Glazed Ceramics and Glassware Regulations* of the *Hazardous Products Act*. Under these *Regulations*, hollowware is defined as a product having an internal depth greater than 25 mm, measured vertically from the lowest interior point to a horizontal plane passing through the point of overflow. For other types of foodware, migratable lead content must not exceed 90 ppm.

The concentration of migratable lead will be evaluated by Health Canada's test method: "Determination of Leachable Lead and Cadmium from Glazed Ceramics and Glassware" (46).

Intent:
The intent is to protect the Canadian public, especially children, from lead exposure associated with use of foodware products, by preventing migration of lead from such products into foods or beverages. A maximum lead concentration of 600 mg/kg for all components of Group 4 products is proposed to allow for potential increases in lead leachability over time due to erosion of the protective coating or alteration of the physical or chemical composition of the product with use. This limit ensures that migratable lead will never exceed 600 mg/kg with wear and time.

Rationale:
Products of this category are used regularly, often daily, by adults and by children. Under normal use, cooking and eating utensils may be subjected to intense heat, abrasion or other mechanical stress, chemical reactions from contact with such products as oils or acidic foods and beverages, or a combination of these effects. Examples of lead exposure from glazed ceramic products are quite numerous. However, lead poisoning can occur from the use of unglazed products as well. Clay used in the manufacture of plates have been found to contain as much as 16,504 mg/kg of lead (17). Hollowware is of particular concern because it is used to store foods and beverages, often for considerable periods of time. Alcoholic beverages such as wine and brandy, may be stored for very long periods of time, providing an opportunity for significant leaching of lead. Exposure from the leaching of lead from crystal decanters and glasses is still a concern, especially for antique crystal containing a high proportion of lead (38).

Adoption of the leachable lead limits specified in the *Glazed Ceramics and Glassware Regulations* ensures that the same standard is in force for all manufacturers and distributers of food contact products (53). Therefore, these regulations would not present an undue constraint to most of the lead crystal industry and would allow regulation of presently unregulated food contact products**.** Migratable limits for lead crystal products are stipulated by the ISO Standard 7086, "Glassware and Glass Ceramic Ware in Contact with Food - Release of lead and cadmium - Part 2: Permissible limits" (54) These limits are 1.5 mg/litre for small hollowware,

0.75 mg/litre for large hollowware, and 0.5 mg/litre for storage hollowware (defined as hollowware having a capacity of 3.0 litres or more). Member of the International Crystal Federation, which includes a large number of major lead crystal manufacturers, have reduced migratable lead from their products to levels below the ISO Standard 7086 permissible limits.

Products that are already covered under other legislation are exempt from Group 4 requirements: These include:

- products which are used for storing, preparing or serving food and which are "completely or partially covered with a coating, glaze or decoration that contains lead or cadmium." These products are covered under the *Glazed Ceramics and Glassware Regulations* of the *Hazardous Products Act.* Under these *Regulations*, maximum levels of leachable lead are 0.50 milligrams per litre for flatware, cups and mugs, and small hollow-ware, and 0.25 milligrams per litre for pitchers and large hollow-ware. (Small hollowware is defined as hollowware with a capacity of less than 1.1 litres, and large hollowware is defined as hollowware with a capacity of 1.1 litres or greater.)
- kettles, which are regulated under the *Hazardous Products (Kettles) Regulations*
- pre-packaged food items, which are regulated under the *Food and Drugs Act*

6.2.5 Group 5: <u>Consumer Products Intended to be Melted or Burned in Enclosed Spaces</u>

Examples of Group 5 Products:

- candles, including birthday, emergency, dinner, ceremonial and aromatherapy candles
- fuel for indoor lanterns
- incense
- metal moulding kits for craft making
- candles sold in glazed pottery containing lead flux and lead frits
- chemical fire logs

Lead Limits:
Total lead, in each component of Group 5 products which is intended to be burned or melted, must not exceed 600 mg/kg.

Intent:
To minimize the exposure to lead vapours and lead dusts created when any component of a Group 5 product is burned or melted.

Rationale:
Group 5 products which contain lead and which are intended to be melted or burned, may release lead vapours during use. Elemental lead has a relatively low melting point of 328 ^{o}C. When lead is heated to melting point, the lead vapourizes. This airborne vapourized lead quickly condenses to form a fume consisting of microscopic particles of lead suspended in air. The composition and toxicity of the fumes produced by melting or burning is dependent upon such factors as the product's composition, including impurities, its melting or vaporizing temperature, and the environment in which it is being used.

Lead fumes are readily inhaled into the lungs. Inhaled particles in the 0.003 - 5.0 micron size range are most likely to be retained in the lung. Lead fume particles are typically less than 1 micron (one millionth of a metre), so that there is considerable potential for them to remain in the lung. About 80% of inhaled lead is absorbed into the bloodstream (12,101), so that inhalation of lead fumes can result in a significant increase to the body lead burden. Larger inhaled particles that have impacted onto the mucous of the trachea or bronchial walls will be transported by ciliary action to the mouth. If they are swallowed, uptake may occur from the gastrointestinal system. Particles not inhaled will settle onto room surfaces where they become mixed with household dust to form a reservoir of lead-laden dust, which acts as a secondary source of lead exposure, particularly for young children.

Candles with lead-core wicks, discussed under 3.2 above, are an example of a Group 5 product which can emit lead vapours when burned (104).

There is little data on the production of lead vapours when consumer products are burned or melted. Experiments on lead-core wick candles carried out by the U.S. Consumer Product Safety Commission found no reliable correlation between the lead content of the wicks and the amount of lead vapour released when the candles are burned. However, the Commission found that no measurable amounts of lead fumes were produced when candles with metallic wicks containing 600 ppm or less of lead were burned. (100). In the light of these results, the Commission has proposed a ban on candles with more than 600 ppm lead in their wicks. The proposed lead content standard for Group 5 products is consistent with this standard.

The following exclusions apply to Group 5 products:

- untreated firewood to which lead has not been intentionally added.
- products covered under the *Explosives Act* administered by Natural Resources Canada.

7.0. IMPLEMENTATION OF THE LEAD RISK REDUCTION STRATEGY

The Lead Risk Reduction Strategy has been reviewed by experts within Health Canada and other federal Departments and has been finalized after incorporation of their input. After revision, the Strategy received senior management approval.

The next phase of the implementation process is stakeholder consultation. There is a large and diverse group of parties potentially affected by the recommendations of the Strategy. Health Canada has identified umbrella groups and other major stakeholders representing a diversity of interests. The Lead Risk Reduction Strategy will be sent to major stakeholders, including industry, public health organizations, consumer associations, and other non-government organizations with a request for comment in the form of a written submission or through attendance at a stakeholder meeting, which will be held in Ottawa in the spring of 2002.

The stakeholder feedback received will be compiled and issued as a stakeholder report. The next steps in the process will be determined by the stakeholder response received. If there is sufficient stakeholder acceptance of the proposals, the next step would be to initiate the regulatory process whereby the Strategy recommendations are promulgated as legislation under the *Hazardous Products Act.* Once the proposed regulations became law, they would be administered and enforced by CPSC as prescribed in Part III of the *Hazardous Products Act*. At the present time and during the interim period before such regulations come into force, the Consumer Product Safety Bureau of Health Canada will continue to work with industry and consumers to minimize the potential risks of lead exposure to children associated with unregulated consumer products.

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