APPENDIX A. Definitions

Component:	Any part of a product, its physical and chemical characteristics that can not be broken down into smaller components by mechanical means. For example, a solid plastic wheel on a toy car would be one component. A solid plastic wheel with a latex tire covered by a protective paint would consist of three components.
Consumer:	Any individual who purchases and/or uses consumer goods
Consumer Product:	Any goods used or intended to be purchased or used by consumers, rather than for further manufacture
Distributor:	Anyone who is involved in the import, storage, transport, or sale of a consumer product
Enclosed space:	Any wholly or partially contained space, including but not limited to a house or other building, a room in a building with or without exterior windows, a car, tent or lean-to, or other shelter
Hazard:	A danger to human health or safety
Hazardous Product:	Any consumer product which is potentially hazardous to human health
Hazardous Products	Canadian federal legislation which controls the advertising, import
Act & Regulations:	and sale of potentially hazardous products
Household Purposes:	Refers to any consumer product intended for use in and/or around the house or home, or for use on residential property.
Liquid Coating Materials:	Paints, enamels or other liquids used for or intended to be used for covering any consumer product or component of a consumer product with a decorative and/or protective coating
Mouthing:	The act of placing any object to the lips or into the mouth.
Risk:	The product of the magnitude of a hazard and the probability that exposure to that hazard will occur.

APPENDIX B. Products Currently Regulated for Lead Content Under the federal *Hazardous Products Act*

Prohibited Products - Schedule I, Part I

2. Furniture and other articles, intended for children, painted with a liquid coating material containing lead compounds of which the lead content is in excess of 0.50 per cent of the total weight of the contained solids, including pigments, film solids and driers.

9. Toys, equipment and other products for use by a child in learning or play that have applied to them a decorative or protective coating that contains any of the following substances:

(a) lead pigments;
(b) more than 0.5 per cent weight to weight of lead in the total solids contained in such coating;
(c) any compound of antimony, arsenic, cadmium, selenium or barium introduced as such if more than 0.1 per cent of such compound dissolves in five per cent hydrochloric acid after stirring for ten minutes at 20°C; or
(d) any compound of mercury introduced as such.

18. Pencils and artists' brushes that have applied to them a decorative or protective coating that, when dry, contains more than 0.5 per cent weight to weight of lead, as determined in accordance with test method 1-GP-500.1 of the Canadian Government Specifications Board, published in December, 1973.

Regulated Products - Schedule I, Part II

13. Toys, equipment and other products for use by a child in learning or play that

(p) contain a toxic substance other than a toxic substance named in item 8 of Part I of the Schedule;

20.1 Glazed ceramics and glassware.

28. Kettles for household use that release lead into water boiled therein.

31. Paints, enamels and other liquid coating materials
(a) for use on the interior or exterior surfaces of buildings, furniture or household products; and
(b) that contain more than 0.5 per cent weight to weight of lead as determined in accordance with test method 1-GP-500.1 of the Canadian Government Specifications Board, published December, 1973.

APPENDIX C. Lead Toxicity

Lead is a metal of high cumulative toxicity with no known biological role. It has been recognized for centuries that lead has detrimental effects on human health. Since lead disrupts essential enzyme systems mediated by metals such as calcium, iron, and zinc, it can produce adverse effects on virtually all body systems. It has been suggested that there is no minimum level of lead exposure which will not adversely affect human health (59). The potential risks associated with lead are increased by the fact that lead accumulates both in the environment and in the bones of exposed individuals. Once present in the skeleton, lead can be re-released into the blood under certain physiological conditions.

Evaluation of lead toxicity studies is complicated because differences in study population size, age, sex, health history, exposure to other health hazards, and lead exposure history often make it difficult to compare studies. There is little controversy about the multiple adverse effects of long-term exposures to high levels of lead on the human body. Although there are significant differences of opinion in the scientific and medical communities about the effects of low-level lead exposure, especially on learning and cognition in children (20,72,74,77), the debate is usually about the extent of effects rather than whether or not effects occur. The ubiquity of lead in the human environment makes it difficult to conclude causality when investigating the effects of exposure to low lead levels. At low blood lead levels, symptoms of lead poisoning are often subtle and non-specific and the condition may not be recognized or treated.

Lead poisoning can occur in acute or chronic form. Acute lead poisoning is rare today, especially in adults. It generally manifests itself by abdominal cramps and severe pain, followed by nausea and vomiting. Headaches, confusion, seizures, coma and other symptoms of brain dysfunction may follow. Very high exposure levels may result in kidney failure (71). Though it is an extremely rare occurrence today, blood lead levels above 80 ug/dL in children can cause coma, convulsions and even death. Chronic lead exposure at lower levels can cause a variety of non-specific symptoms including loss of appetite, nausea, constipation, anxiety, fatigue, weakness, irritability, headache, insomnia, pain or soreness in the joints and muscles, numbness, tremors and dizziness. Prolonged exposures can also cause severe impairment to the neurological, gastrointestinal, renal, reproductive and blood-forming systems.

Lead is known to inhibit enzymes involved in synthesis of heme (the pigmented, iron-containing portion of the hemoglobin molecule), resulting in decreased production of hemoglobin (red blood cells). This decrease may produce anemia and may affect hepatic function, particularly in children (105). Prolonged continuous exposure to even low dosages of lead may result in subclinical renal dysfunction (56). Nephropathy associated with elevated lead blood levels has been recorded in numerous studies, although some reports have found no correlation (102).

There is a clear link between high levels of lead exposure and adverse reproductive effects, including increased rates of miscarriage and stillbirths in exposed women (65).

Some studies suggest that exposure in childhood may cause reproductive difficulties in women (102). A large study in 1996 (3) found an association between sperm abnormalities and blood lead levels around or above 40 ug/dL. There is considerable debate on whether there is a significant link between lead exposure and hypertension. The correlation is greatest for men aged 40-59, even at very low blood lead levels (57). Some studies show an association between lead exposure and abnormal ECG tests or other heart effects (102).

A study by Rosen et al. (82) showed interference with conversion of vitamin D to its hormonal form in children, accompanied by lower blood calcium levels, in children with blood lead of 33-120 ug/dL. Lead exposure may also damage the male reproductive system and contribute to some miscarriages. Lead has been found to be a renal carcinogen at high doses in rats, but there is no definitive evidence for human carcinogenicity, although small, statistically non-significant increases in digestive and renal cancers have been recorded among occupationally exposed men, and a statistically significant link between rectal cancer and workers exposed to tetraethyl lead (27).

The best known and most studied effects of lead exposure are neurological effects. Fatigue, mood swings, apathy, dizziness, weakness, and subtle impairments in intellectual function are associated in adults with blood lead levels of 40-80 μg/dl (102). Increased exposure will result in such affects as insomnia, confusion, headaches, and memory problems as the central nervous system becomes more profoundly affected. Nausea and vomiting, diffuse abdominal pain, constipation or diarrhea, weight loss and decreased libido may also occur. Clinically, lead has been shown to affect nerve conduction at blood lead concentrations as low as 30 μg/dL (2,17,89,102). Prolonged exposure to lead degrades the nerves controlling the transmission of peripheral nerves, resulting in conditions like wrist drop and foot drop (83).

If blood lead levels are in excess of 100 ug/dL, toxic effects can progress to seizures, coma and death caused by lead encephalopathy (dysfunction of normal brain activities). Lead encephalopathy, though a relatively frequent occurrence prior to occupational heath legislations and lead controls for paint and gasoline, is extremely uncommon today (71).

Lead Toxicity in Children

Young children are more at risk from lead for a number of reasons:

1. The likelihood and level of exposure are greater (see **2.3 Exposure Routes**, below)
2. The level of gastro-intestinal absorption is greater in children
3. Children have a increased soft tissue lead burden because their smaller skeletons store less lead

4. Development of organs and systems is incomplete, making them less able to eliminate lead
5. Children have lower thresholds for the haematological and neurological effects of lead.

Because the organs, neurological, immune, and hematological systems of a child under age of six are still developing, the effects of lead exposure are potentially much more significant and harmful in fetuses, infants, and young children. The neurological effects in children arising from lead exposure have been intensively studied. Recent research indicates that even very low blood lead levels may be associated with adverse effects on children's intellectual development and behaviour (8, 11, 29, 73). For this reason, in 1991 the U.S. Centers for Disease Control lowered their blood lead intervention level for children from 25 ug/dL to 10 ug/dL. (15). In 1994, following the recommendation of the Federal-Provincial Committee on Environmental and Occupational Health (28), Health Canada followed suit.

Other possible neurotoxic effects of lead in children include short-term memory loss, reading and spelling difficulties, impaired visual-motor function, poor perceptual integration, and impaired reaction time. The CDC document "Preventing Lead Poisoning in Young Children" (15) concludes that other adverse effects, such as decreased stature or growth, decreased hearing acuity and a decreased ability to maintain a steady posture may occur at relatively low blood lead levels. Low-level lead poisoning in children produces no specific symptoms and the chances of diagnosis and treatment are
correspondingly reduced.

2.3 Exposure Routes

Lead may enter the body through ingestion, inhalation, dermal contact, or to the fetus via the placenta. In the Canadian general population the main exposure routes are the gastro-intestinal tract and respiration. Lead uptake by the fetus begins as early as the twelfth week and continues throughout development (36). The most common route of entry is ingestion, except in industrial environments where it is possible that inhalation plays a larger role (85). Dermal absorption of lead in the general population is rare, and generally results from exposure to organic lead compounds such as the gasoline additive tetraethyl lead, use of which has been severely curtailed in Canada by the *Gasoline Regulations* under the *Canadian Environmental Protection Act*.

Until the 1980's the two main sources of lead in the Canadian environment were house paints and emissions from leaded gasoline. 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). 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.

Before the late 1980's lead was widely used in soldering food can side seams. A voluntary compliance program by Canadian canners has virtually eliminated the use of lead in food cans - nearly all food can side seams in Canada today are welded. Other major sources of lead exposure, 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.

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. 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, 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 (40,44,45, 47,48, 79,80,108). 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 came and dust from sanding of leaded glass, and casting of fishing sinkers, lead shot or diving weights, which may produce fumes from melting lead (30,41).

Not only are the effects of lead toxicity more severe in young children, but they are also at greater risk of exposure to lead in consumer products because of their normal tendency to mouth or chew objects with which they come into contact. In addition, many children between one and six years also exhibit *pica*, an eating disorder described as a tendency to mouth or attempt to consume non-food objects such as paint chips, furniture, or toys.

Household dust and soil are significant sources of lead exposures for small children (25,93). The FDA estimated in 1990 that a two year old child received 16% of his or her total lead from food, 1% from soil and 75% from dust (102). Young children are most at risk from lead-containing dust because (i) their breathing zone is close to floor level (ii) their normal hand to mouth behaviour greatly increases the likelihood of ingesting dust, and (iii) they breathe in more air per unit body weight than do adults. A recent study has found the concentration of lead in house dust to be significantly greater than that of outdoor soil and dust from adjacent land (78). This was the case not only for pre-1970 homes, where the presence of lead-containing interior paints is to be expected, but also for recently built houses in areas with no industrial or commercial history - an indication that lead dust is being generated from within the home. Airborne lead dust settles onto food, water, clothing and other objects and may subsequently be transferred to the mouth. It has been estimated that the vast majority of dust particles that adhere to the hand

are < 10 μm in size (1) and therefore readily absorbed when ingested. Lanphear et al. (58) estimated that an increase in concentration of lead in dust from background to 200 μg/sq.ft (2.15 mg/m^2) would produce 23.3% increase in the number of children with blood lead level > 10 micrograms per decilitre. An increase in soil lead concentration from background to 400 μg/g was estimated to produce an increase of 11.6% of children having a blood lead level > 10 micrograms per decilitre.

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 (55). 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.

2.4. Absorption, Distribution, and Storage of Lead in the Body

In adults having a normal diet, 3-15% of ingested lead is generally absorbed by the intestine and less than 5% of absorbed lead is retained in the body (37). Pregnant women absorb greater levels of ingested lead, approximating absorption levels in children. Depending on such factors as particle size, solubility, and density, and the individual's ventilation rate, approximately 30% to 50% of the airborne lead particulates inhaled by an adult are retained, of which nearly all are absorbed (68,101). The EPA (67) and Cal/OSHA (12) estimate that 80% of the lead fumes and soluble lead dusts inhaled into the lungs are absorbed into the body.

Regardless of the route of entry into the body, lead is absorbed directly through the blood into soft tissue, including the kidney, liver, and brain. Distribution of lead in the soft organs is preferentially in the liver, followed by the kidneys, pancreas and lungs. Other than the intestine, the kidney is the major organ for lead excretion. A very high proportion of absorbed lead is transferred to bone, along with other minerals such as calcium, where it accumulates over time and remains for long periods. In adults, lead is partitioned between the skeleton and the soft tissues in a ratio of approximately 95% bone and 5% soft tissue (95). The half-life, or time required for the body to excrete half its accumulated lead, is about 25 years. Therefore, high lead concentrations can be maintained within the body for years after exposure to lead has ceased (6). The total amount of lead stored or accumulated in the body is the *body burden*.

Lead in the bone may contribute as much as 50% to total blood lead, but the relative effect of endogenous and exogenous lead sources on blood lead depends greatly on the amount of lead that has been accumulated in the skeleton over time. Because of lead's 25-year half-life, an individual may be at risk for release of stored lead into the bloodstream throughout a lifetime. During periods of physiological stress, the minerals stored in bones, including lead, can be mobilized back into the bloodstream, resulting in increased blood lead levels. In women, lead is released from the bone in significant amounts during pregnancy and lactation as the calcium is mobilized. Osteoporosis, common in the elderly, especially elderly women, causes deterioration

of the bone matrix and thus increases the rate of release of bone lead. In one report it was estimated that the total body burden of lead in 60 - 70 year old men may exceed 200 mg (85). In young children lead absorption and retention levels are thought to be much greater than in adults, but many uncertainties remain because of limited data. Fetuses and young children, especially those under the age of six, may be particularly susceptible (64). Children aged 2 weeks to 8 years absorb roughly 40 to 50% of ingested lead (4,108). One study found an infant's average net lead absorption to be 41.5% with a net retention of 31.8% when kept on a regular diet (65). The greater absorption and retention capacity found in young children has been linked to a higher metabolic rate and preferential absorption of calcium. The proportion of lead stored in soft tissues is also greater in children, because of the lesser storage capacity of their smaller skeletons. Newborns are especially affected by the toxicity of lead because of their high lead absorption rate and because their livers, which remove lead from blood, are not fully developed. (Lead is excreted into the bile in a concentration 100 times greater than the blood lead concentration.) These two factors produce an elevated blood lead concentration which increases the risk of neurological and other damage. Additionally, lead retention time in the child is protracted, thereby exacerbating the damage to the developing nervous system.

APPENDIX D. Federal Legislation and Guidelines related to Lead Exposure

1. FEDERAL ACTS AND REGULATIONS

Canadian Environmental Protection Act (CEPA) and Regulations
The intent of this *Act* is to prevent pollution of the Canadian environment and harm to human health by evaluating and managing potential environmental and human health risks posed by environmental pollutants and toxic substances. Under *CEPA* Environment Canada and Health Canada jointly operate a program of risk assessment and risk management of substances that are used commercially and are present in the environment. The Existing Substances Division of Health Canada evaluates substances on the Priority Substances List, which is composed of substances selected by provincial Ministries of Health or the Environment for priority toxicity assessment. Health Canada also provides risk assessment and risk management guidance on the health risks posed by *CEPA*-toxic substances.

Food and Drugs Act and Regulations
The Act applies to all food, drugs, cosmetics and medical devices sold in Canada, whether manufactured in Canada or imported. The *Act* and *Regulations* specify safety, compositional, nutritional and labelling requirements for food. The *Act* contains a general prohibition on the sale of any food "which has on it any harmful or poisonous substance...or, " is unfit for human consumption" which makes it illegal to sell foods containing harmful levels of lead. Maximum lead levels are specified for only a few foods, including tomato paste and fish protein. This *Act* is administered by Health Canada, in co-operation with the Canadian Food Inspection Agency, which monitors foods on the Canadian marketplace to ensure that they conform to the standards of the *Food and Drugs Act and Regulations.*

Hazardous Products Act and Regulations
This *Act* applies to products imported, advertised and/or sold in Canada which are "designed for household, garden or personal use, for use in sports or recreational activities, as life-saving equipment, or as a toy, plaything or equipment for use by children." Schedule I, Part I of the *Act* lists prohibited products, which may not be imported, advertised or sold in Canada. Schedule I, Part II lists controlled products, which may be imported, advertised or sold in Canada only if they meet certain standards of safety. There are a number of regulations under the *HPA*, such as the *Glazed Ceramics and Glassware Regulations,* the *Liquid Coatings Regulations* and the *Kettle Regulations*, which contain lead content standards for specific product groups (see Appendix B).

II. NATIONAL GUIDELINES

In addition to regulations, there are a number of national guidelines which are applicable to lead. These include:

1. *Guidelines for Canadian Drinking Water Quality*, prepared by the Federal-Provincial Subcommittee on Drinking Water. These Guidelines include Maximum Acceptable Concentrations of more than 85 chemical parameters, including lead.

2. *Exposure Guidelines for Residential Indoor Air Quality*. These Guidelines contain acceptable exposure limits for a number of indoor air pollutants, and suggest ways to control exposure to other pollutants, including lead vapours, for which formulation of acceptable exposure ranges is not feasible.

3. *National Plumbing Code of Canada 1995*. This is a Code issued by the Canadian Commission on Building and Fire Codes and the National Research Council of Canada (13). It includes prohibitions on the use of lead pipe and lead solders and fluxes in potable water systems. Most provinces and territories have adapted the National Plumbing Code.

APPENDIX E. The Lead Strategy - Results of the Public Consultation Process

The Lead Strategy - Summary Report
Results of the Public Consultation Process

The Delphi Group & Health Canada
November 1998

I. National Feedback Objectives

The Product Safety Bureau of Health Canada has been working diligently with key stakeholder groups to develop a Strategy to reduce the lead content of consumer products, especially those products intended for use by children.

The Product Safety Bureau utilized stakeholder feedback sessions in three Canadian cities: Vancouver, Montreal and Toronto, to develop an outline for the national Lead Strategy. The objectives of the feedback sessions were as follows:

- To communicate to the session participants the regulatory and non-regulatory options available to the Product Safety Bureau for the purpose of reducing the lead content of consumer products,
- To determine which options are supported by the stakeholders and the rationale for their support,
- To document any additional issues that will assist with the formation of the final draft of the Lead Strategy.
- To communicate to the stakeholders the next steps that the Product Safety Bureau will take to deal with this issue.

II. Feedback Session Activities and Attendance

- The evaluations conducted at each National Feedback Session suggested that there was a high degree of agreement amongst participants that the session's objectives had been achieved. (please see Appendix A for evaluation results).
- Vancouver attendance was low (10) in comparison to the number of invitations that were mailed. The Montreal session had better attendance (15) but several of the manufacturing representatives commented that attendance from the business sector was surprisingly poor given the importance of the agenda. Toronto had the largest turnout (28) with a good balance of business and health stakeholders.
- In all three cities, the following agenda items took place: presentations by Health Canada staff, question and answer periods and group discussions. Evaluations suggested that the group discussions added clarity and also assisted with the achievement of the session's stated objectives.

- The sessions were facilitated by:
  Vancouver: Diana Cartwright & Bruce Dudley
  Montreal: Christopher Duschenes & Bruce Dudley
  Toronto: Diana Cartwright & Bruce Dudley

- All facilities were well equipped and arranged in accordance with the room layouts provided. However, in retrospect, the Toronto session would have been improved by the use of a larger room in addition to a breakout room for the purpose of group discussions. Food was also available for each session and was of high quality. In Toronto, there was a minor problem with the visual aids (high resolution overhead did not work) however, this technical difficulty was minimized by utilizing back-up color overheads which Health Canada staff had prepared in advance.

- The sessions provided valuable insights on various aspects of the Lead Strategy . In addition, individuals who completed the evaluation forms indicated that the process was beneficial.

III. Session Themes from Discussion

The following points were developed from discussions during both the question and answer periods and group discussions:

- Several discussions were held concerning the degree of threat (risk) that lead poses to both children and adults. These discussions were commenced by both health and business stakeholders. Is the Lead Strategy directing resources to a low priority item? -This will be addressed by a cost/benefit analysis.

- Rationale for selecting extractable versus total lead as the basis for the lead strategy .

- Discussion regarding focused regulation (as opposed to a shotgun approach) was a recurring theme. The concept described a targeted approach to reduce the impact to business in areas with little or no concern while focusing Health Canada on problem "hot-spot" areas. , e.g. "adds value not cost" ,"results in a level playing field", "should not suppress business opportunities".

- Children need to be the focus of the effort as they are at greatest risk. Additionally, discussion supported the notion that regulation should be used to protect the vulnerable members of society. Voluntary mechanisms may be utilized to address other areas.

- The issue of lead dust surfaced in several discussions and it was agreed that this issue would be reviewed by the Product Safety Bureau of Health Canada.

The Lead Strategy -Results of The Public Consultation Process

- Representatives of business, health and consumers organizations raised concerns regarding voluntary mechanisms. It was suggested that limited knowledge of these mechanisms could cause problems.

- Defining a strategy that works (has the desired outcome) by the most efficient means possible was a goal that was stated by all participants.

- The issue of accountability surfaced across the country and was present regardless of the mechanism being discussed. All parties concerned should understand their role in addressing lead in consumer products. Additionally, all parties should be held accountable for that role.

- To ensure that benefits are being realized, the results of the Lead Strategy efforts must be monitored and made available.

- The Canadian Lead Strategy should interface with international efforts in other countries such as the US and Europe. Our efforts must complement these without creating trade barriers.

- Efforts are required to improve the Canadian response to situations wherein products are identified as a problem.

- Whether the approach is voluntary , regulated or a combination of both, clarity is essential to avoid confusion and to improve the effectiveness of the Lead Strategy -the "hot spots" need to be well defined.

- Efforts to address what may be “largely” an off-shore issue, must ensure that the Canadian strategy does not penalize domestic manufacturers.

- The issue of product review was discussed and on several occasions it was suggested that Health Canada should continue to act as a “watch-dog.” This includes both product testing and inspection. It was also suggested that product bans would be an effective means of getting dangerous products off the shelf.

- The need for consumer education was identified through several related discussions. Additionally, consumers have a need for information so they may make informed choices. Product labelling was also discussed.

- Concern was expressed regarding older products such as antiques. Concern was also expressed regarding new products which are constantly being introduced into the market.

- Discussion also took place on the subject of lead being present in a product to serve a purpose, versus being present for no apparent reason. There was strong support for the elimination of lead that serves no practical purpose.

- Self declaration, by industry, was discussed as a component of the voluntary mechanisms. This prompted additional discussion on the need for tougher penalties for businesses which take advantage of voluntary components.

- A long lead time on the implementation of the strategy was discussed. This would give the manufacturing, retail and importer sectors time to adjust.

IV. Thrust of Session Themes

Key themes were generated in all three cities; however, there were subtle differences which have been reflected in the discussion items and again in the evaluation feedback. The following points were present in all three exercises:

- That a regulatory approach be used for products designed specifically for use by children. This approach should also deal with the issue of lead dust where product application and total lead warrants.

- That voluntary mechanisms be used to reduce levels of extractable lead for products designed specifically for use by both children and adults

- That Health Canada continue to develop the Lead Strategy utilizing stakeholder input to create an efficient yet effective mechanism for the control of lead in consumer products.

The results of the tally regarding preference of regulations or voluntary mechanisms were as follows:

	Regulatory	*Voluntary*	**Combination*	*No Opinion*
Vancouver	0	0	10(100%)	0
Montreal	3(20%)	0	12(80.0%)	0
Toronto	8(28.6%)	0	15(53.6%)	5(17.9%)

*Support for the combination approach in Toronto was based on several modifications to the concept. This included the idea that problem areas or "product hot-spots" could be drawn into the regulation when deemed necessary. Additionally, efforts should be made to limit the impacts on products when little or no risk is identified.

V. Process Recommendations

The national feedback sessions have been a positive experience for many of the stakeholders. Health Canada should take action on the following general and specific recommendations.
This will facilitate the continued development of the Lead Strategy:

General Recommendations

- Communicate the results of these sessions to the participants as soon as possible and encourage feedback. This will ensure that there is agreement on the summary of the sessions. (This is required to ensure the integrity of the process).

- Prepare a press release to communicate the action that Health Canada has taken and is taking to deal with the issue of lead. This release should describe specific actions. (See specific recommendations).

- Develop a communication mechanism in order to keep stakeholders and other interested parties up to date on the development of the Lead Strategy .e.g. a fax server utilizing a group fax function would be an ideal communication tool for an update that could be sent every 2-3 months.

Specific Recommendations

- Develop a smaller working group made up of key stakeholders. (e.g. The Learning Disabilities Association of Canada and the Retail Council of Canada.) This working group may assist in the completion of the details of the Lead Strategy. **Participants who are not paid by an employer should be paid a stipend to cover expenses and travel costs.**

- Develop in-house expertise at the Product Safety Bureau regarding voluntary mechanisms.

- Finalize the Lead Strategy and proceed to implementation as soon as possible.

- Establish an evaluation group to not only review the results of the Lead Strategy efforts but also to discuss ongoing requirements. e.g. support/education.

Lead Strategy Framework Recommendations

The Lead Strategy's framework is of critical importance to the successful reduction of lead in Canadian consumer products. The Delphi Group recommends the following framework:

Regulatory

- The Product Safety Bureau will need to continue its role as monitor and enforcer . e.g. product testing and compliance monitoring. Health Canada should be seen visibly pursuing this role.

- Develop a "product banning mechanism" that may be used in extreme cases, where products are determined to pose imminent danger to Canadians.

- Regulations should target products intended for children (with a defined age range.) This encompasses products which are intended to be or likely to be mouthed by children.

- A mechanism to bring specific product lines within the purview of the regulations should also be defined and described for future “hot spot issues”.

Voluntary

- develop a supportive policy framework for the voluntary component of the Lead Strategy. Voluntary mechanisms which lack a legislative or policy support often have a minimal effect.

- Develop and describe the various components of a voluntary mechanism. These components should define the following:

    - Voluntary Covenants/partnerships - self management
    - Supply Chain Management
    - Pollution Prevention (lead elimination or replacement)
    - Labelling/education

- Develop the content of the voluntary mechanisms. This should include, as a minimum, the following:

    - clearly defined targets and objectives
    - the free loader clause
    - positive and negative incentives (links to reg's)
    - monitoring effectiveness and accountability
    - Define support for the development of this innovative and proactive approach to dealing with lead in consumer products.

The National Feedback Sessions demonstrated that there exists support for an innovative approach to dealing with the issue of lead in consumer products, provided the risks to Canadians and their children are managed.

Appendix A
Evaluation Responses

Fifty-three participants attended the National Feedback Sessions, of which 38 (71.1%) completed evaluation forms. The following is a sampling of the feedback received from the evaluations:

1. Do you feel the meeting accomplished its objectives

Poor	Acceptable	Good	Very Good	Excellent
0	0	4	29	5

Average = 4.02

2. What did you like best about the session?

- group discussion
- well represented by a wide range of players
- bilingual presentations
- open discussion with the various interest groups
- Health Canada officials much clearer and less defensive
- good opportunity for discussion
- frankness of information provided by presenters
- approach on extractable lead
- opportunity to be heard
- facilitators and presenters did a great job
- ample opportunity for input
- the need to take a step back to consider the strategies
- networking
- exchange between different people from different disciplines

3. What did you like least about the session?

- difficult to hear with 2 focus groups going on at once
- cramped meeting room
- too large a group
- Health Canada representatives did not speak enough French
- not enough time to ask questions
- no clear pathway left for us by Health Canada
- not enough background e.g. risk index

- too much attention to regulatory/voluntary
- not enough discussion about the benefits -how many children have been poisoned by lead
- constant focus on blind issue -consensus should be based on products intended &
- likely to be used by children
- presentation
- not enough technical discussions which I feel are relevant to the issue
- not enough representation from industry
- it was difficult to understand some of the English content
- nothing negative

4. Were there any unanswered questions or concerns that you would like follow-up?

- Is there any reason why Canada cannot be the leader in setting lower levels of lead for products?
- Off -shore products should be monitored, regulated and if they don't comply, penalized.
- timing of the final report from Health Canada?
- opportunity for further input into "final report"
- why didn't we go to the US TDI (15 mg/day) total for the risk assessment?
- I would hope that Canadian manufacturers will be informed now that Health Canada is moving to regulate lead.
- for persons without the background on the issue -needed more history
- issue of limits on total lead (not just leachable needs to be addressed, since disposal of consumer products (i.e. incineration) could permit entry of lead into environment
- Are there any plans to use research conducted by lead organizations such as ILMC & ILZRO in Europe?
- unavailable data regarding injuries caused by lead poisoning
- how will the data be gathered i.e. will physicians other than emergency and poison control be considered
- in your feasibility study, please consider the number of unreported cases of lead poisoning
- details on the assessment of risk: extractable lead and scenario of 8 mg
- details of the actual rules and regulations in place
- more information on disorders and symptoms caused by lead exposure
- I would like to receive complimentary information on the technical aspects of the lead toxicity.

5. Do you have any additional comments you would like to make?

- would like to continue to be involved
- thanks for the opportunity to be involved
- would like some Canadian and US data to indicate the need for a Lead Strategy
- there appears to be a need for baseline data on lead poisoning
- looking forward to follow-up
- well conducted session
- provide participants with proposal regarding all pathway/exposures to lead and how this will be incorporated into the lead strategy
- be proactive from the start with respect to reducing or eliminating the overall risk
- concerned primarily with regulations concerning imported products
- does Europe/US use regulatory or combination method
- all high risk products such as pacifiers should have lead component completely removed
- As a consumer I feel that this meeting has shown me I should always buy Canadian.
- re-emphasize harmonization with the N. American market, a regulatory approach that adds value not cost, looking at product groupings in terms of what other regulations apply to them e.g. Electrical Products and Electrical safety
- definitions of child's toy -a child of 8-9 is not likely to mouth a toy
- we need interim action
- relieved to hear that lead dust is being considered in terms of children's exposure pathway
- .you provided the best hot, fresh scones I have ever had at a meeting
- I am satisfied that my agency's concerns and interests have been fully addressed and will be reflected in the final decision.
- I look forward to the receiving "summary", I will fo11ow-up then if necessary .
- a very enriching experience

Appendix B
Session Participants

Vancouver, 26 March 1996

Jack Wandell	Consumer
Gillian Willis	B.C. Drug and Poison Centre
Karen Sharpe	Consumer
Richard Stanwick	Canadian Pediatric Society , Injury Prevention
Fran Thompson	Learning Disabilities Association Of Canada
Deidre Riley	Cominco Ltd, Environment & Corporate Affairs
Cassandra Caunce	Cominco Ltd, Environment & Corporate Affairs
Gillian Lockitch	Children's & Women's Health Centre OfB.C.
Jude Emnace	Stork Craft Manufacturing Inc.
David Roberts	Stork Craft Manufacturing Inc.
Hugh Davis	Product Safety Bureau, Health Canada
Jonathan Williams	Product Safety Bureau, Health Canada
Diana Cartwright	The Delphi Group
Bruce Dudley	The Delphi Group

.

Montreal, 25 mars 1998

Matthew Bramley	Toxics Campaigner, Greenpeace
Richard Shuller	Le Marche Oustore
Danielle Charbonneau	Association des Consommateurs du Quebec
Marie Claude Laroche	Association des Consommateurs du Quebec
Claude Ouellet	Association des Consommateurs du Quebec
Suzanne Lachance	Consommatrice
Catherine Myssyk	Consommatrice
Marielle Richer	Consommatrice
Claire Laviolette	Consommatrice
Michel Perreault	Consommatrice
Jocelyn Lavigne	Sante Publique
Warren Hertle	Hasbro Canada Inc
Patrick Levallois	Centre De Sante Publique De Quebec
Pat Tilli	Clariant (Canada) Inc.
Louise Vignault	Conseils et Verification
Hugh Davis	Product Safety Bureau, Health Canada
Jonathan Williams	Product Safety Bureau, Health Canada
Christopher Duschenes	The Delphi Group
Bruce Dudley	The Delphi Group

Toronto, 26 March 1998

Bob Stevenato	Consumer
Bernice Stevenato	Consumer
Larry Morris	Falkenbridge Ltd.
Stephen Kelly	Sears Canada Inc.
Sharon Landry	Sears Canada Inc.
Peter Woolford	Retail Council Of Canada
Judy Platt	Hudson's Bay
Stephen Lawson	Hudson' s Bay
Grant Caven	Canadian Tire
Eileen MacKinnon	Binney & Smith
Lesbia F. Smith	Ontario Ministry Of Health,-Public Health Branch
John Buhlman	Weir & Foulds
Joan M. Sayer	Consumers' Association Of Canada
Bernice Browne	Consumers' Association Of Canada
Monica Campbell	Toronto Public Health
Jeff Cox	Color Pigment Manufacturers Association
Catherine Clarke	Toronto Public Health
Suzanne Shaw	Toronto Public Health, East York Office
Dan Kartzalis	Ontario Public Health Association
Barbara McElgunn	Learning Disabilities Association Of Canada
Michael Hopkins	Electro Federation Of Canada
Jim McCarthy	Electro Federation Of Canada
Jeffrey Kowal	Brant County Health Unit
Wayne Glover	Juvenile Products Manufacturers Association
Dan Stapleton	Crossed Swords
Ann Watson	Wal-Mart Canada Inc.
(One participant missing)	
Hugh Davis	Product Safety Bureau, Health Canada
Jonathan Williams	Product Safety Bureau, Health Canada
Diana Cartwright	The Delphi Group
Bruce Dudley	The Delphi Group

Appendix F
Product Group Summary

Product Groups	Examples of Products	Proposed Lead Limits	Other Comments
Group 1: **Products Likely to be Ingested in Significant Amounts**	crayons, children's paints, chalk	Total lead content not to exceed 75 mg/kg for each and every individual component of the product.	Since total lead must not exceed 75 mg/kg, migratable lead will not exceed 75 mg/kg.
Group 2: **Products Intended to be or Likely to be Placed in the Mouth (Excludes Products in Group 1)**	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 beverage straws mouthpieces of musical instruments	Total lead not to exceed 90 mg/kg and migratable lead not to exceed 90 mg/kg for each and every individual component of the product.	If a lead test demonstrates that the total lead content of the product does not exceed 90 mg/kg, then it will not be necessary to determine the level of migratable lead.

Appendix F
Product Grouping Summary (continued)

Product Groups	Examples of Products	Proposed Lead Limits	Other Comments
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)**	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	Migratable lead not to exceed 90 mg/kg and total lead not to exceed 600 mg/kg, in all exposed, exterior surfaces of the product as well as in all components of the products to which it is likely that children will be exposed.	Artistic paints and pigments not intended for use by children 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.
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)**	cutlery cooking and serving utensils tableware food storage materials and containers such as plastic and foil wrap, sandwich bags, plastic containers, and juice jugs lead crystal decanters and other crystalware		

APPENDIX F
Product Grouping Summary (continued)

Product Group	Examples of Products	Proposed Lead Limits	Other Comments
Group 5 : **Consumer Products Intended to be Melted or Burned in Enclosed Spaces**	candles fuel for indoor lanterns incense metal moulding kits for craft making chemical fire logs	Maximum leachable lead limits are identical to those prescribed by the *Hazardous Products Act - Glazed Ceramics and Glassware Regulations*. Total lead must not exceed 600 mg lead/kg product for each and every individual component of the product.	There will be a crystal glassware limit of 90 mg/kg migratable lead; however, glassware will be exempt from maximum of 600 mg/kg total lead limit.

APPENDIX G
Human Health Risks Associated with Lead Shot, Sinkers, and Jigs

Exposure from Lead Shot, Jigs, and Sinkers

Lead sinkers and jigs (fishing hooks with lead attached) used in fishing represent a special category of consumer product that may contribute to environmental pollution and to human lead exposure. Lead shot, sinkers, and jigs lost to the environment create a lead reservoir that slowly leaches into soils, sediments, and water and may ultimately contaminate human environments, including the food chain. Lead concentration in surface water at a New York State target shooting range was from 60 to 2900 µg/L (100). The maximum acceptable concentration of lead in drinking water in Canada is 10 µg/L (43) and the recommended maximum in surface water is 1 µg/L to 7 µg/L (14). Surface water can migrate into the soil and find its way into groundwater reserves from which it may enter water courses that may be used as sources of potable water (10). Surface soil samples at an Ontario gun club contained leachable lead concentrations from 3.3 to 820 mg/L. Surface soil at a Michigan range contained 10-100 times as much lead as the background level of 25 mg/kg. (70).

In popular hunting areas, heavy buildups of lead pellets may occur on lake and marsh bottoms. A unknown number of loons, ducks, and other Canadian aquatic, wading and shore birds are killed annually in Canada by ingesting lead shot or lead sinkers and jigs deposited on the bottoms of water bodies. Non-waterfowl species may also ingest these products and develop lead poisoning. Predators such as the bald and golden eagles may accumulate lead and suffer lead poisoning through ingestion of lead shot, or fragments of shot, while eating birds or other animals killed with lead ammunition. About five or six shells are fired for every animal that is hit. It is estimated that about 1300 tonnnes of lead shot from upland game and small mammal hunting and about 266 tonnes from clay target shooting are discharged into the Canadian environment annually by hunters.

Lead shot and sinkers may expose humans to lead in a number of ways:

1. ***Direct mouthing or ingestion*** - There have been 92 reported cases of lead shot ingestion in humans in Canada (23). Lead poisoning has occurred in children who have deliberately swallowed accessible lead pellets and fishing sinkers (69). Cases of increased blood lead levels and deleterious health effects have been traced to the ingestion of lead shot (63,95). Depending on the density and size of the lead pellets, they may be retained in the gastrointestinal system. There are several cases in which lead shot was retained in the appendix (7,21,39,51,52,60,63,66,67,81,91). Radiographic evidence from randomly selected charts has shown that 15% of First Nation Cree examined in the western James Bay area had lead shot in their gastrointestinal tract (95).

2. ***Exposure to lead fumes and dust when lead shot, jigs, and sinkers are manufactured in home cottage industries***. In Canada, the manufacture of lead sinkers is primarily a cottage/hobby industry and it has been estimated that approximately 68% of sinkers made in Canada originate from small tackle companies and cottage industries (88). Lead is inexpensive, has a low melting point, and is easy to mold without specialized equipment. When lead is melted, fumes may be produced which are harmful to health of the worker or hobbyist as well as others in the household. A high proportion of inhaled lead fumes are absorbed into the body. Lead particles from uninhaled vapours can settle on clothing, floors, and other household surfaces and produce lead-contaminated dust. Young children, who typically occupy space close to the floor, may be exposed to such dust and ingest it in the course of their normal mouthing habits. Records of lead poisonings from this type of occupation are not readily available, because symptoms arising from low level exposures may remain undiagnosed, individual medical records are confidential, and there is no system for collecting and collating this type of data. A number of cases of elevated blood lead arising from home production of lead sinkers have been recorded in the northwestern United States. Some of the affected individuals were children.

3. ***Consumption of game contaminated with lead shot***. As a shot pellet collides with bone it produces fragments which become embedded in the tissue in its path. Consumption of game animals hunted with lead shot can produce exposure to lead through ingestion of whole pellets, fragments of lead left in the path of the pellet, and flesh in which lead has bioaccumulated. Normal bioaccumulation of lead in the tissue of game animals not killed or wounded with lead shot is not a major contributor to human lead exposure. However, investigations have shown that waterfowl killed by lead shot had lead tissue concentrations exceeding 100 mg/kg, resulting from the presence of lead fragments varying in size from fine dust to 2 mm (33,96). In the absence of a maximum lead limit for poultry flesh, the maximum lead concentration in fish protein of 0.5 mg/kg wet weight or approximately 2 mg/kg dry weight may be used to indicate the potential hazard associated with consuming game killed with lead shot (42). In both the Frank and Tsuji studies the lead tissue concentrations exceeded the maximum permitted in fish flesh by at least 50 times. Scheuhammer (87) collected pectoral muscle tissue from 190 game birds. None of the samples contained visually detectable pellets, but 21% had lead tissue concentrations averaging 211 mg/kg dry weight and ranging from 5.5 to 3,910 mg/kg. Ingestion of the flesh of game contaminated with lead thus may represent a significant contribution to dietary lead for game hunters and their families.

4.***Inhalation of fumes and dust in shooting ranges.***

Lead fumes are generated by friction when lead shot passes through the barrel of a gun and when lead styphnate, used as a primer, is ignited. (Exposure may also occur when lead shot is handled, and when firearms are cleaned.) Uninhaled lead fumes may settle out as dust on clothing, skin, and other nearby surfaces. Lead fumes are most likely to accumulate in indoor shooting ranges; however, elevated blood lead levels have been found in instructors at both indoor and outdoor firing ranges in the United States (35).

Regulation of Lead Products used in Hunting and Fishing

In 1997, under the *Canada Wildlife Act,* Environment Canada banned the use of fishing sinkers and jigs weighing less than 50 grams in National Wildlife Areas. Also in 1997, under the *National Parks Fishing Regulations* of the *Canada National Parks Act,* Parks Canada banned the use or possession of lead sinkers and jigs under 50 grams while fishing in National Parks. However, there are a few northern National Parks, such as those in Nunavit, in which First Nations lands claims take precedence over National Parks legislation. In these Parks aborginal peoples could legally use lead sinkers and jigs under 50 grams to carry out subsistence fishing.

Environment Canada has also banned some uses of lead shot in Canada. Effective September 1, 1999, the *Migratory Birds Regulations* under the *Migratory Birds Convention Act*, 1994 administered by Environment Canada stipulates that:

> "No person shall possess or use shot other than non-toxic shot, for the purpose of hunting a migratory game bird, except a woodcock, band-tailed pigeon,or mourning dove. Non-toxic shot is bismuth shot, steel shot, tin shot, tungsten-iron shot, tungsten-matrix shot or tungsten-polymer shot." (Migratory game birds include ducks, geese, brant, cranes, rails, gallinules, coots, murres and snipe.)

Non-toxic shot is defined as bismuth, steel, tin, tungsten-iron, tungsten-matrix or tungsten-polymer shot, in which the concentration of lead and other materials must not exceed one percent. This limit, which is the same as the limit for non-toxic shot under American federal wildlife legislation, permits the use of metals, such as tin, that normally have some lead content.

In 1996, an amendment to the *National Wildlife Area Regulations* under the *Canada Wildlife Act* prohibited the use of any shot other than non-toxic shot for **all** hunting, including small mammals and upland game birds, such as grouse, pheasant, and pigeons, within National Wildlife Areas and National Parks. (Hunting is banned in most National Parks, except for a few northern Parks where area residents, including First Nations peoples, are allowed to hunt. Most hunting within these Parks is big game hunting, in which lead shot is not used.) There are no other federal restrictions on the use of lead shot for hunting upland game birds or small mammals. Environment Canada has jurisdiction only over federal lands and over wildlife species which migrate interprovincially. First Nations land reserves are classified as federal lands; however, there are currently no bans on the use of lead shot on reserves. First Nations individuals are required to obey the bans on hunting migratory birds with lead shot and using lead shot or lead jigs or sinkers within federal parks and nature reserves. Provincial and territorial governments have jurisdiction over birds like pheasants and grouse, which are deemed to be resident within provincial or territorial boundaries. Currently there are no provincial restrictions on the use of lead for hunting upland birds and small mammals. Provincial legislation does not apply on federally owned lands.

The federal *Food & Drugs Act* administered by Health Canada provides that "No person shall sell an article of food that has in or on it any poisonous or harmful substance" but most game is consumed without ever being offered for sale. The *Food and Drug Regulations* limits the concentration of lead in fish protein to 0.5 mg/kg, but there are no lead limits for game or mammalian protein. The *Meat Inspection Act* administered by the Canadian Food Inspection Agency applies only to food animals processed at federally registered slaughterhouses. There is little detailed information about the manufacture of lead sinkers and jigs in home-based enterprises in Canada, and there are currently no legal restrictions on the manufacturing process for these cottage enterprises.

This was followed by a two-phase amendment of Environment Canada's *Migratory Birds Regulations* under the *Migratory Birds Convention Act*. This amendment banned the possession or use of lead shot for the purpose of hunting waterfowl and most other migratory game birds in Canada, except for woodcock, band-tailed pigeons, and mourning doves. It has been estimated that this intervention will result in reducing the deposition of lead shot into the environment by 800 to 1000 tonnes annually (22,23). Since 1997 the use of lead fishing sinkers weighing less than 50 grams has been banned in National Parks and National Wildlife Areas under the *Canada Wildlife Act* and *National Parks Act* (*National Parks Fishing Regulations*. These bans, however, do not address the problem of lead contamination of the environment arising from target shooting and from hunting of upland birds and small mammals. Lead deposition from these sources is estimated at 1,560 tonnes, which is greater than the 1,500 tonnes estimated to be released from industrial sources (23). It has been recommended that the ban on the use of lead shot be extended to all game hunting in order to safeguard the health of people who consume game in significant amounts (95).

The United States, in 1991, issued a total ban on the use of lead shot for waterfowl hunting and have proceeded to phase in lead shot bans for other game hunting in national wildlife refuge wetlands. Other countries where lead shot bans or restrictions have been established include Australia, Denmark, Finland, Mexico, Netherlands, Norway, Sweden, Switzerland, and the United Kingdom (22).