

Vol. 144, No. 25 — December 8, 2010

Registration

SOR/2010-272 November 26, 2010

HAZARDOUS PRODUCTS ACT

Order Amending Part II of Schedule I to the Hazardous Products Act (Consumer Products Containing Lead — Contact with Mouth)

P.C. 2010-1483 November 25, 2010

His Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to section 6 ([see footnote a](#)) of the *Hazardous Products Act* ([see footnote b](#)), hereby makes the annexed *Order Amending Part II of Schedule I to the Hazardous Products Act (Consumer Products Containing Lead – Contact with Mouth)*.

ORDER AMENDING PART II OF SCHEDULE I TO THE HAZARDOUS PRODUCTS ACT (CONSUMER PRODUCTS CONTAINING LEAD — CONTACT WITH MOUTH)

AMENDMENT

- 1. Part II of Schedule I to the *Hazardous Products Act* ([see footnote 1](#)) is amended by adding the following after item 4:**
- 5. Consumer products containing lead as defined in the *Consumer Products Containing Lead (Contact with Mouth) Regulations*.**

COMING INTO FORCE

- 2. This Order comes into force on the day on which it is registered.**

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Order or the Regulations.)

Executive summary

Issue: The adverse effects of lead on young children have been documented in numerous studies. Children absorb a much greater percentage of ingested lead than adults do, and their

developing organs and body systems are much more susceptible to the toxic effects of lead. In addition, young children are much more likely to be exposed to lead in consumer products because of their natural habit of mouthing objects. These Regulations give Health Canada the legal authority to prevent the import, advertisement or sale of affected products which contain hazardous levels of lead.

Description: The Regulations set a total lead limit of 90 milligrams of lead per kilogram of product (90 mg/kg) on the following categories of consumer products (also referred to as Group 1 in Health Canada's Lead Risk Reduction Strategy for Consumer Products):

- (1) products, other than kitchen utensils, that are brought into contact with the user's mouth in the course of normal use; and
- (2) products intended for use in play or learning by children under the age of three years.

Cost-benefit statement: Given that the anticipated economic costs from the present into perpetuity are low, and that over time, health benefits may reasonably be expected to result from limiting the lead content of Group 1 products, the economic benefits of the Regulations outweigh the economic costs.

Business and consumer impacts: Industry members who were consulted during the 2004 economic cost analysis on the Regulations commented that the economic impact to industry is likely to be negligible. Few North American manufacturers and importers use lead in the juvenile products they market, so most affected products marketed in Canada are already compliant with the proposed limit of 90 mg/kg total lead. Concerns raised by industry following pre-publication of the proposed Regulations have been addressed through further discussion and consultation. As a result, two key amendments have been made: a definition for accessible parts, and an exemption for accessible parts which do not present a lead exposure risk. Both amendments help to clarify Health Canada's original policy intent. Stakeholders were notified of these amendments in advance of the coming into force of the Regulations, and no concerns were raised.

Domestic and international coordination and cooperation: The lead content standards of these Regulations are consistent with international health and safety standards.

Issue

The *Hazardous Products Act* (HPA) prohibits or restricts the advertisement, sale and importation of products which are, or are likely to be, a danger to the health or safety of the public. These Regulations give Health Canada the authority to prevent the import, advertisement or sale of affected products which contain hazardous levels of lead, make it mandatory for all traders to comply with lead content standards, and allow Health Canada to remove any non-compliant affected products from the Canadian marketplace.

The adverse effects of lead on young children have been documented in numerous studies. Until recently, scientists believed that blood lead levels of less than 10 µg/dL (micrograms per

decilitre) in children did not represent a health hazard, but recent scientific studies ([see footnote 2](#)) suggest that even blood lead levels below 5 µg/dL may be associated with harmful effects on the behaviour and intellectual development of children.

Objectives

The purpose of these Regulations is to protect children against potential exposure to lead by placing a regulatory limit of 90 mg/kg total lead on the following categories of consumer products:

- (1) products, other than kitchen utensils, that are brought into contact with the user's mouth in the course of normal use; and
- (2) products intended for use in play or learning by children under the age of three years.

Description

The Regulations set a total lead limit of 90 mg/kg so that migratable lead will never exceed 90 mg/kg. Migratable lead is the amount of lead that is released from a product when it is brought into contact with a liquid solvent.

The products affected are categorized as Group 1 products under Health Canada's Lead Risk Reduction Strategy for Consumer Products. (Item 42 of Part I of Schedule I to the HPA covers all jewellery items intended for children under 15 years of age.)

Below is a table which outlines the product categories included in the Lead Risk Reduction Strategy for Consumer Products.

	Product Category	Examples of products (lists are not all-inclusive)
Group 1		
	(1) products, other than kitchen utensils, that are brought into contact with the user's mouth in the course of normal use;	— toys for children under 3 years of age — baby bottle nipples, soothers, baby bibs
	(2) products intended for use in learning or play by children under three years of age.	— beverage straws, drinking spouts, other drinking aids — mouthpieces of musical instruments — sports mouthpieces
Group 2		
	Products intended primarily for use in learning or play by	— strollers, cribs, carriages, high chairs

children aged 3–13 years	— children’s school supplies
Child care products	— toys for children aged 3–13 years
Children’s clothing and accessories (except jewellery, which is already regulated for lead content)	— children’s backpacks and lunch containers
Children’s furniture and equipment	— serving and eating utensils
Group 3	
Foodware (products intended for use in preparing, serving, or storing food)	— cookware
	— food storage containers
	— lead crystal glassware and decanters
Group 4	— candles
Products intended to be burned or melted in enclosed spaces	— fire logs

The term “affected products” will be used throughout this document in reference to Group 1 products. The Regulations make it illegal to import, advertise or sell in Canada affected products that contain more than 90 mg/kg total lead.

Regulatory and non-regulatory options considered

Lead has a sweetish taste which encourages children to mouth leaded items. Children under three years have a higher risk of lead exposure because of their natural exploratory behaviour which leads them to chew or suck on any objects within their reach. Their developing body organs and systems are also more susceptible to the toxic effects of lead.

In order to mitigate the risks to children of exposure to lead in consumer products, Health Canada developed a Lead Risk Reduction Strategy (LRRS) for Consumer Products which proposes lead content limits for several categories of consumer products to which children are likely to be exposed. Health Canada is implementing the LRRS in a phased manner, handling each consumer product category separately.

1. Status quo: No change in current risk management practices

There is broad agreement among stakeholders that lead content regulations, particularly for children’s products, are required to protect children against lead exposure, especially because it is difficult for consumers to tell whether or not the affected products contain lead.

While the majority of the affected products currently sold in Canada already meet the lead content limit of the Regulations, there is concern over the number of non-compliant products being imported. Reputable companies selling Group 1 products in Canada do their best to ensure

that there has been no intentional addition of lead to the products they market. However, because of complex supply chains and the very large volume of imported products, ensuring quality control of imported products is sometimes difficult. Affected products which do not meet the standards continue to be found on the Canadian marketplace. Also, the incidence of counterfeit goods is increasing on global markets, creating a significant risk that lead may be used in counterfeit children's products.

2. Voluntary industry standards

Most Canadian manufacturers voluntarily comply with international standards for juvenile products, which stipulate no intentional addition of lead. While compliance is voluntary, the non-complying sector may have an unfair economic advantage over the complying sector.

Voluntary standards are generally effective only when endorsed and enforced by industry, and when domestic manufacturing market share is greater than 50%. Given the number of manufacturers, suppliers, and distributors of Group 1 products, and the fact that most of them are based in foreign countries, it would be difficult to obtain commitment on a voluntary Canadian standard from the entire sector. Health Canada cannot enforce voluntary standards against non-compliant companies.

3. Mandatory lead content labelling

In this option, regulations under the *Hazardous Products Act* would make it mandatory for affected products containing lead to carry a lead content warning label. Mandatory labelling is inconsistent with international and Canadian policy and practice, which is to require or encourage the manufacture and sale of children's products which are lead-free. Since the majority of juvenile products sold in Canada are already manufactured with no intentional use of lead, permitting the sale of affected products which contain lead if they carry a lead content warning label would decrease the level of protection for Canadian children.

There is also a risk that labels on products or on their packaging will become separated from the product or will become worn to illegibility during product use.

4. Mandatory lead content limits

Lead is a naturally occurring mineral in the Earth's crust and has been very widely used in many industrial applications for centuries. As a result, trace amounts of lead occur everywhere in the natural and human environments. For this reason, it is not feasible to make products with zero lead content.

Canada currently has regulatory limits for migratable lead in glazed ceramics and glassware, in children's jewellery (in addition to a total lead limit of 600 mg/kg) and in kettles. International standards such as International Standards Organization (ISO) and EN:71: Part 3 limit migratable lead content of toys for children under six years of age to 90 mg/kg. Health Canada chose a total lead content limit of 90 mg/kg for the affected products rather than a migratable lead content limit for three reasons:

1. There is no known correlation between total and migratable lead that can be used to predict the amount of migratable lead released from the total lead content of a specific product.
2. The regulatory limit of 90 mg/kg total lead takes into account product wear and tear, which may greatly increase migration of lead from a product. Products containing high levels of lead may have protective or decorative coverings or coatings. In such cases children mouthing the product may not produce significant migration of lead when these products are new. However, once aging and wear have damaged the covering or coating, mouthing the product may cause extensive migration of lead, resulting in high levels of lead exposure. Mouthing itself has a wearing effect on coverings and coatings.
3. Calculations based on the World Health Organization Provisional Tolerable Daily Intake of 3.75 micrograms of lead per kilogram of body weight, developed in 1987 and reaffirmed in 2002, showed that a 90 mg/kg total lead limit would provide adequate protection to children against lead exposure through the affected products.

Economic costs

A survey of interested Canadian industry members (manufacturers, importers and distributors of affected products) was initiated in January of 2004 to identify two factors that contribute to potential regulatory impact:

1. the prevalence of lead in affected products; and
2. the projected cost to comply with the Regulations.

Industry members who were consulted received the survey in a positive manner, and provided very useful information. Many respondents from these industries commented that few North American manufacturers of juvenile products use lead in their products. All survey respondents indicated that the affected products they manufacture or import contain no intentionally added lead, or that any lead content is below the 90 mg/kg total lead limit mandated by the Regulations.

Respondents also mentioned that most Canadian companies were already compliant with international standard ISO 8124-3: 1997 or EN:71 standard (Part 3 — Migration of Certain Elements) for children's toys.

Canadian importers of affected products currently require that their suppliers meet the international lead content standard for 90 mg/kg migratable lead. To ensure compliance with a limit of 90 mg/kg migratable lead, the total lead content should not greatly exceed 90 mg/kg. As a result, survey respondents indicated that costs of complying with the Regulations would be at or near zero for manufacturers and importers of the vast majority of these products.

Recalls and other incidents in recent years involving imported consumer products highlight the difficulties for Canadian importers and distributors in monitoring the quality control systems of their offshore suppliers.

Both Canadian industry and government are working toward better quality control of imported products.

Government regulatory and enforcement costs

Health Canada identified a one-time cost of \$65,000 for dedication of a Health Canada analytical chemist's time to development or validation of test methods for the affected products. This cost will be covered within existing resources. No additional resources are required to implement and enforce this regulatory initiative.

Economic benefits

Given that the present economic costs into perpetuity are low, and that over time, benefits may reasonably be expected to result from limiting the lead content of affected products, the benefits of the Regulations outweigh the costs. An economic benefits study carried out for previous regulatory proposals to limit lead content in a consumer product found that the value of a single avoided case of childhood lead poisoning was between \$7,190 and \$11,985 (year 2009 CDN). The original figures of \$6,000 and \$10,000 were updated to 2009 values using the multiplier CPI_{2009}/CPI_{2000} . The CPI (Consumer Price Index) is a measure of changes in the cost of living over time and, therefore, of the value of money. Because of increases in the cost of living, a dollar was worth less in terms of purchasing power in 2009 than in 2000. Benefits include avoided direct medical costs, avoided special education costs, avoided juvenile justice expenditures, avoided loss of lifetime earnings, and avoided cases of mortality.

The Regulations would be economically efficient if one case of lead poisoning were avoided per year.

Rationale

The health and safety of young children is of great importance because they are a very vulnerable subgroup of the population and need the highest degree of protection against chemical hazards.

Lead is an inexpensive heavy metal. Its industrial properties have ensured that it has many potential uses in consumer products. However, lead is toxic, especially to children, even at very low levels of exposure. Lead accumulates in the body, so that continued exposure to even very low levels may increase the body burden of lead to harmful levels.

Children are especially vulnerable to the toxic effects of lead. They absorb a much greater percentage of ingested lead than adults do, and their developing organs and body systems are much more susceptible to the toxic effects of lead.

In addition, young children are much more likely to be exposed to lead in consumer products because of their natural habit of mouthing objects. Lead has a sweetish taste which encourages children to continue mouthing lead-containing items. Lead builds up in the body so that ongoing exposure to even very low levels of lead can eventually result in accumulation of toxic lead levels in the body.

Prior to the development of the Regulations, there were no Canadian lead content restrictions for many of the affected products. In addition, the maximum lead limits for affected products currently regulated under the HPA were too high to provide adequate protection for young children against lead exposure. The Regulations will protect the Canadian public, especially young children, by ensuring that products which are likely to be in close, prolonged contact with the mouth do not contain more than trace amounts of lead.

As a result of a 1998 consumer complaint, Health Canada tested 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 bought new by Health Canada, one pendant was found to contain non-detectable levels of migratable lead and the other contained 0.69 mg/kg migratable lead. However, when pendants of the same design that had been chewed by the complainant's child were tested, the migratable lead level of one was found to be 251.6 mg/kg and that of the other one was 104.0 mg/kg. These levels are considerably higher than the 90 mg/kg migratable lead limit set by international standards. Once the thin protective coating was partially removed through the reasonably foreseeable actions of a child, unacceptable levels of lead were released. These results indicated to Health Canada that a migratable lead limit would not give adequate protection against affected products, since some of them may also have protective or decorative coatings.

The migratable lead content of affected products can never exceed 90 mg/kg if the total lead content is 90 mg/kg or less.

The Regulations give Health Canada the authority to take enforcement action against any affected products imported, advertised or sold in Canada that contain more than 90 mg/kg total lead. Health Canada regularly monitors the Canadian marketplace to make sure that non-compliant products which are regulated under the *Hazardous Products Act* are not sold in Canada. Product removal and other appropriate enforcement measures are taken against any regulated products which are found to be non-compliant.

Consultation

Health Canada carried out several major stakeholder consultations on the Lead Risk Reduction Strategy for Consumer Products from which these Regulations are derived.

In 1997 approximately 600 stakeholders were sent a draft discussion paper, "Strategy for Reducing Lead in Children's and other Consumer Products," which included voluntary guidelines for reducing children's exposure to lead. The stakeholders included lead mining companies; toy manufacturers; paint and pigment manufacturers; manufacturers, importers, distributors, and retailers of lead-containing products; the Retail Council of Canada; the Canadian Pediatric Society; consumer groups; health units and ministries; and environmental groups. The guidelines asked for feedback in the form of an enclosed questionnaire on a variety of suggested lead content standards which ranged from less than or equal to 15 mg/kg total lead to 90 mg/kg migratable lead, in products accessible to children. There were 96 returned questionnaires, some accompanied by letters containing detailed and well-considered comments on the issue. While the 15 mg/kg standard was considered unrealistically low, no opposition to

the 90 mg/kg migratable lead standard was expressed by respondents who manufacture or sell children's products. The majority of health association and government respondents considered the 90 mg/kg migratable lead standard "just right," although a significant minority considered it too high.

In general, industry strongly supported alignment with international trading standards, pointing out that the Canadian market represents a very small proportion of the global market, and that many manufacturers would withdraw from the Canadian market rather than meet standards which differ from those of other, larger markets. Although trade issues were taken into consideration, the lead content standards of this proposal are aligned to international health and safety standards.

In 1998, Health Canada carried out stakeholder discussion meetings in Toronto, Montreal, and Vancouver on strategies for reducing the lead content of consumer products. Participants included manufacturers, distributors, consumers, public health agencies and societies, and an environmental non-governmental organization.

The majority of meeting participants agreed that children should be the focus of the lead risk reduction effort, that a regulatory approach should be used for products designed specifically for use by children, and that lead should not be present in consumer products where it serves no essential purpose.

In response to stakeholder input, Health Canada refined earlier proposals and finalized the Lead Risk Reduction Strategy for Consumer Products, which proposed lead content limits for categories of consumer products in which children are most likely to interact.

In December 2002, a consultation meeting was held to review the Lead Risk Reduction Strategy for Consumer Products. It was the consensus of industry, government, and non-government stakeholders attending this meeting that regulatory limits should be placed on the lead content of products intended or likely to be used by children. Stakeholders also expressed a strong desire for harmonization of lead content standards with the United States or with international standards.

The *Consumer Products Containing Lead (Contact with Mouth) Regulations* were prepublished for stakeholder comment on June 20, 2009. In response, Health Canada received comments from four industry stakeholders, including two major industry associations, one Canadian-based and one based outside Canada, one regional government, and one non-governmental organisation (NGO). Further discussions and consultations were carried out in August 2009 and May 2010 with the Canadian industry association in order to provide clarification where needed and to review the major issues raised by the industry associations. These issues, and Health Canada's responses, are outlined below.

1. A key industry request was for specific exemptions in the Regulations for product components that (1) are inaccessible under foreseeable conditions of use; or (2) cannot feasibly be made without lead for technical reasons and pose a low risk of lead exposure. Electrical components and certain metal alloys were identified as examples of this type of component.

In response, Health Canada added a definition for “accessible part” to the Regulations, as well as a clause exempting these two types of components from the 90 mg/kg total lead limit. However, accessible parts that cannot feasibly be made without lead are subject to a 90 mg/kg migratable lead limit. The responsible company must demonstrate that the use of lead is essential. Only parts of affected products that would be placed in regular and extended contact with the mouth or hands under reasonably foreseeable conditions of use pose a lead exposure risk. A few examples of accessible parts where regular and extended contact would not occur are wheel axles on toy cars/trucks, the heads of nuts, bolts, screws, and other fasteners, and the tips of inner tube valves on tricycle wheels. It was always Health Canada’s intent that only these components should be subject to the 90 mg/kg total lead limit. Therefore, the addition of the exemption clause is a clarification of regulatory intent rather than a change in regulatory policy.

Stakeholders who submitted comments and received the comprehensive report were informed of these additional changes by email. Health Canada also contacted several key NGO stakeholder groups representing child health advocacy and general consumer safety by phone to advise them of the potential exemption clause and its rationale. No concerns were raised with Health Canada.

2. Industry requested that a transition period be added, so that the Regulations would apply only to affected products manufactured or imported into Canada after the Regulations come into effect.

A transition period is not included in the Regulations. The Regulations have been under development for a number of years, and Health Canada believes that most companies should be in a position to comply. Information on date of manufacture or import is not usually found on affected products or their packaging. This means that it would not be easy for Health Canada inspectors sampling affected products to know whether a product was manufactured or imported into Canada before or after the introduction of the Regulations. If a non-compliant product is found on the Canadian market during the 12-month period following enactment of the Regulations and the responsible company can demonstrate that the product was manufactured or imported prior to enactment of the regulatory requirements, Health Canada will review the circumstances and take action on a case-by-case basis.

3. An industry association based outside Canada commented that the Regulations may represent an illegal barrier trade under Canada’s international trade obligations.

The World Trade Organization (WTO) was notified of the Regulations at the time of pre-publication as part of standard Government of Canada procedure. The Regulations are consistent with the Government of Canada’s obligations under the WTO Agreement on Technical Barriers to Trade.

All six stakeholders who submitted comments received a comprehensive report summarizing all comments received, as well as Health Canada’s responses. A summary report was also distributed by email to stakeholders to inform them of the potential amendments to the Regulations.

Implementation, enforcement and service standards

Compliance and enforcement of the Regulations will follow established departmental policy and procedures. Health Canada's Cyclical Enforcement (CE) policy for consumer products which are regulated under the *Hazardous Products Act* requires planned monitoring and enforcement surveys of all regulated products at regular intervals. Inspectors across the country visit a wide range of retail and distributor outlets, examine product lines, and sample those products which are suspected of non-compliance with the requirements of the *Hazardous Products Act* and its Regulations. The samples are tested according to publicly available test methods used by Health Canada's Product Safety Laboratory. The frequency of CE surveys is based on the degree of risk and hazard associated with the regulated products.

Health Canada also carries out ad hoc sampling and testing of regulated products and follows up on recalls and reports from other agencies, as well as consumer and industry complaints. Depending on the seriousness of the violation, action taken concerning non-compliant products will range from voluntary withdrawal of these products from the market to prosecution under the *Hazardous Products Act*.

The first CE survey for the products affected by these Regulations will be carried out within six months of the coming into force of the Regulations. The timing and scope of follow-up surveys will be determined by the results of the first survey.

Contact

Sarah Sheffield
Project Officer
Consumer Product Safety Bureau
Product Safety Directorate
Healthy Environments and Consumer Safety Branch
Health Canada
123 Slater Street, 3504D
Ottawa, Ontario
K1A 0K9
Fax: 613-952-9138
Email: Sarah.Sheffield@hc-sc.gc.ca

[Footnote a](#)

S.C. 1996, c. 8, s. 26

[Footnote b](#)

R.S., c. H-3

[Footnote 1](#)

R.S., c. H-3

[Footnote 2](#)

Lamphaer, B., et al. 2005. Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis. *Environmental Health Perspectives* 113(7):894-899

Lidski, T. and Schneider, J., 2004. Lead and public health; review of recent find-ings; re-evaluation of clinical risks. *Journal of Environmental Monitoring*. 6:(36-41)

Rossi, E., 2008. Low level environmental lead exposure - a continuing challenge. *Clinical Biochemist Reviews* 29(2):63-70.

NOTICE:

The format of the electronic version of this issue of the *Canada Gazette* was modified in order to be compatible with extensible hypertext markup language (XHTML 1.0 Strict).