

To the Editor:

This is an article from a series of monthly columns by Environmental Law Specialist Dianne Saxe, one of the top 25 environmental lawyers in the world, and Ms. Jackie Campbell. These articles are available for publishing at no charge, provided Dr. Saxe and Ms. Campbell are cited as the authors. Dr. Saxe can be contacted at (416) 962-5882 or admin@envirolaw.com. For more information, visit <http://envirolaw.com>.



Into the mouths of babes – *Phthalates Regulations* soon in force

Phthalates are chemicals used to make plastic toys, as well as soothers and other products, soft and flexible. Often these products end up in the mouths of infants, who may suck or chew on them for prolonged periods. Phthalates, which may enter the bloodstream via saliva in these infants, have been linked to reproductive and developmental toxicities in animals.

In 1998, Canadian industry voluntarily removed the two main phthalates used in teething rings and pacifiers, but as most of these products are manufactured off-shore, the impact has not been significant. As well, there are many other products that are likely to be mouthed by infants, bath toys (e.g., rubber ducks), squeeze and inflatable ones, which may contain phthalates.

New regulations restricting the concentration of phthalates in some products used by infants and children will soon be in place. These regulations are consistent with measures taken by the United States and European Union. This is a positive step in minimizing exposure to these chemicals in our most vulnerable population - infants and young children.

Below, we highlight some concerns about these chemicals, and briefly summarize the new regulations.

Health concerns - phthalates

The six phthalates that have been identified as potential concerns for human health are as follows:

- Di(2-ethylhexyl) Phthalate (DEHP)
- Dibutyl Phthalate (DBP)
- Benzyl Butyl Phthalate (BBP)
- Diisononyl Phthalate (DINP)
- Diisodecyl Phthalate (DIDP)
- Di-n-octyl Phthalate (DNOP)

DEHP, DBP and BBP have been linked to reproductive and developmental toxicity, as well as liver and kidney effects, in rodents. Of particular concern to regulators is that the estimated average daily intake of DEHP, by children under 4 years of age, may slightly exceed the tolerable daily intake. Assessments under the *Canadian Environmental Protection Act, 1999* (CEPA) concluded that the average daily intake of DBP and BBP will not cause adverse health effects in humans.

As for **DNOP**, data are insufficient to determine an appropriate tolerable daily intake or whether this agent affects human life or health. **DINP** and **DIDP** have not been assessed under CEPA. However, a 1998 Health Canada risk assessment (and recent re-calculation) of DINP-containing soft vinyl children's products concluded that there is a potential health risk for those under 3 years old who suck or chew on such products for prolonged periods. A 2001 US Consumer Product Safety Commission report also concluded that there may be a concern for children up to 18 months of age who mouth DINP-containing soft vinyl toys for 75 minutes or more per day. The US Center for the Evaluation of Risks to Human Reproduction has reported rodent studies showing the DINP and DIDP pose developmental hazards to rodents.

The Phthalates Regulations

The *Phthalates Regulations* under Canada's *Hazardous Products Act* (HPA) were registered on December 10 2010, and will come into force after 6 months, in June 2011. The regulations restrict advertising, sale and import of toys and child care articles made of vinyl that contains phthalates. "Toys" means products intended for use by children under 14 years of age in learning or play; "child care articles" are those intended to help a child under 4 years of age relax, sleep, feed, suck or teethe.

Soft vinyl products may contain up to 1000 mg/kg (0.1% w/w) of DEHP, DBP or BBP. As well, any part of a product containing vinyl that could "in a reasonably foreseeable manner" be placed in the mouth of a child under 4 years of age may contain up to 1000 mg/kg of DINP, DIDP or DNOP.

The regulations set out how one identifies if such a product can be "placed in the mouth" of a child: if any part of the product can be brought to the child's mouth to be sucked or chewed AND if one of its dimensions (in its deflated state, where applicable) is less than 5 centimetres. Vinyl-containing products that exceed 5 cm in all dimensions or that can only be licked, are not considered a concern, as these cannot be placed in the child's mouth, and licking is not a concern regarding phthalate absorption.

As of December 2010, toys and child care articles composed of phthalate-containing vinyl were added as restricted products under the HPA and the *Hazardous Products (Toys) Regulations* were amended - both as a consequence of the *Phthalates Regulations*. However until the *Phthalates Regulations* actually come into force later this year, it is doubtful that regulators will enforce these provisions. Enforcement will range from product recall to criminal prosecution, and those found guilty of contravening the HPA or its regulations are liable to significant fines and/or imprisonment.

Useful Links:

Phthalates Regulations - SOR/2010-298

<http://gazette.gc.ca/rp-pr/p2/2010/2010-12-22/html/sor-dors298-eng.html>

Regulatory Impact Analysis Statement

<http://gazette.gc.ca/rp-pr/p2/2010/2010-12-22/html/sor-dors297-eng.html>

Order amending Schedule I to the Hazardous Products Act (Phthalates)

<http://gazette.gc.ca/rp-pr/p2/2010/2010-12-22/html/sor-dors297-eng.html#REF2>

Health Canada. Preventing the use of six phthalates in soft vinyl children's toys and child-care articles. June 2009

http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/_2009/2009_96bk1-eng.php

A recent US report on chemical additives in toys highlights the concerns about hazardous substances in children's toys: See

Center for Health, Environment & Justice (CHEJ) and Teamsters Office of Consumer Affairs. Toxic Toys R Us: PVC toxic chemicals in toys and packaging. A Report to the National Commission of Inquiry into Toxic Toys. November 2010

http://www.toxictoysrus.com/documents/Toxic-Toys-Report_11.17.10.pdf