Environmental Effects of Phthalate Exposure on Development during Gestation, Infancy, and Early Childhood: United States and Canada

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ABSTRACT

This manuscript presents a review of the sources and pathways of phthalate exposures in home and community environments, followed by a description of the effects of phthalate exposure on prenatal, infant, and child development and health. An examination of policy responses over the past decade across the international landscape culminates in case descriptions of the recent statewide and nationwide policy changes implemented in the United States and Canada. The phthalate example sets the backdrop for a call to develop more timely and effective risk management investigations, regulations, and health education campaigns regarding chemical exposure to in our environment.

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Introduction

The process of recognizing and responding to the environmental contaminants that have adverse health effects is complex and varies by nation. Toxins such as DDT, lead (Rudel, 2010), thalidomide, and asbestos all have been recognized in connection with adverse perinatal and child outcomes, and subsequently banned in several countries including the United States (U.S.) and Canada. Often, animal studies indicate concerns, yet LOAEL/NOAELs (lowest or no observed adverse effects levels) are difficult to identify in humans due to research constraints (Tickner, 2001). National response to concerns depends upon a combination of research evidence, political pressures, and consumer advocacy. National organizations, public agencies, and the media all play a role in illuminating possible health concerns for the sake of policy response and also in communicating health information to the public. Because a number of known and currently banned contaminants remain in the environment, public awareness is essential. For example, polychlorinated biphenyls (PCBs), which were restricted in the U.S. in the 1970s, remain a major global pollutant (Rudel, 2010).

Some toxic substances remain freely available, including alcohol and tobacco, which have known adverse effects on health, particularly for pregnant women, fetuses, infants, and children. Concerns have been raised about many other exposures, including many of the 80,000 chemicals registered with the U.S. Environmental Protection Agency. Bisphenol A, food additives (artificial flavors and colors), and numerous pharmacological compounds (medications) may be further regulated in the future. The debate around perceived and actual risk rages daily in the academic literature as well as in the media.

One timely example of a group of chemicals that have been recognized and responded to internationally is phthalates. Phthalates are a family of eight chemical compounds used as a softener in polyvinyl plastics (Tickner, 2001). The prevalence of using phthalates as a manufacturing agent is high due to the low cost of production and the widespread use of plastics used in consumer products (Huedorf, 2007). The European Council for Plasticisers and Intermediates (ECPI) makes a distinction between "high phthalates" (DINP, DIDP, DPHP, DIUP, and DTDP), which they estimate represent 70% of phthalates currently being produced in Europe and "low phthalates" (DEHP, DBP, DIBP and BBP) which represent about 10% of the European market. The "low phthalates" have been most strongly linked to health concerns (European Council for Plasticisers and Intermediates [ECPI], n.d.).

Phthalates exist in a variety of consumer items such as children's toys, food products, personal care products, textiles, cleaning agents, building materials, and many more (Rudel & Perovich, 2010). In recent years, certain phthalates have been banned from plastics used for making children's toys and child-care products in Canada, the U.S., and the European Union. Eight phthalates have been examined, and six were identified by the U.S. and the European Union as having potential health

effects on humans. Depending on the type of phthalate compound, there are varying concentrations by environmental source, and differential health effects. Furthermore, the route and level of exposure, intake levels, and metabolization rates vary by age. Although phthalates do not bioaccumulate, they can migrate from primary sources into the surrounding environment, and because they are fairly ubiquitous, exposure can be relatively constant. Measurement of phthalate levels is accomplished using associated metabolites which are biomarkers for phthalate exposure (Table 1). For example, the phthalate DEHP is broken down to over 30 metabolites which are rapidly eliminated in urine (Centers for Disease Control and Prevention [CDC], 2009). It is this "characterization of exposure, sources, and pathways" (Rudel, 2009) that has guided public interest and policy responses, and can inform health education efforts.

Health Effects

The presence of phthalates existing in consumer products does not independently equate a health risk. The health risk occurs when the phthalates leach out of the plastic and are ingested, inhaled, or absorbed through the skin. Health effects of phthalates were first recognized in animal studies where rodents experienced adverse reproductive and developmental effects, such as reduced fertility and damage to the testes (Korpan, 2009). Phthalate concentrations can be measured in the external environment and concentrations of secondary metabolites in urine. Therefore, potential human exposures can be theoretically modeled from ambient data. It is through this plausibility framework, that recommendations have arisen.

Although exposure to phthalates within plastic products was found to be negligible when inhaled or through direct dermal contact (Korpan, 2009), phthalate exposure was of great concern when sucking or chewing of plastic products for prolonged periods of time occurred. This activity can lead to phthalates leaching out of the plastic and entering the body through the saliva (Korpan, 2009). Therefore, concern arose first among two groups; individuals (particularly infants and toddlers) exposed to phthalates in medical equipment and medications (Tickner, 2001) and children exposed to phthalates in toys (Heudorf, 2007).

Prenatal Issues

Kohn (2010) found higher concentrations of phthalates in women of childbearing age (20-40 years) and raised concerns about detrimental effects. Findings by Latini and colleagues (2003) suggested that phthalate exposure was significantly associated with shorter pregnancy duration. There is not an expected risk to fetal development from pregnant women using vinyl and other products containing phthalates, rather the levels of phthalates that can leach from materials containing phthalates through a mechanism beyond dermal contact, such as ingestion (Korpan, 2009).

Animal studies (and some cross-sectional human studies) have correlated phthalate exposures to testicular, ovarian, renal, pulmonary, cardiologic, hepatic, and developmental toxicity (Tickner, 2001). According to Tickner's review, the only study using human models was the pulmonary effect. Phthalates have been recognized as a potential endocrine disruptor, interfering with androgen production (Rudel & Perovich, 2010), potentially effecting sperm quality at the population level (Hauser et al., 2007), and producing higher anogenital index in males (Huang et al., 2009). Stahlhut and colleagues (2007) postulated that disruption of testosterone levels due to phthalate exposures could increase insulin resistance and prevalence of obesity and diabetes. Although the large study had several limitations, the authors did find in a cross-sectional study of adult men that high concentrations of phthalates were significantly correlated with abdominal obesity and insulin resistance and recommended further population based studies.

Lovekamp-Swan and Davis (2003) explored the pathways for phthalate toxicity within the female reproductive system and caution that effects even from *in utero* exposure may alter estradiol production within the ovaries. Other researchers have found prenatal exposure to phthalates associated with behavioral problems in children, including aggression, attention problems, conduct problems, depression and externalizing behaviors (Engel et al., 2010; Kim et al., 2009).

Infant and Child Issues

Children under three years of age have been identified as the group with the greatest risk of experiencing adverse health effects when exposed to DEHP (Health Canada, 2009). The low body weight, immature metabolic systems, high dosage per body surface, and rapid physical growth and development rates of young children place them at risk to the adverse effects of phthalate exposure (CDC, 2009; Sathyanarayana, et al., 2008). Of particular concern are infants receiving blood transfusions, ECMO, or respiratory therapy, all of which can be found in neonatal intensive care settings (Hillman et al., 1975; Karle et al., 1997; Rudel & Perovich, 2010; Tickner, 2001). In a follow-up study of 13 adolescents with

Table 1. Phthalates and Urinary Metabolites

Phthalate name (CAS number)	Abbreviation	Urinary metabolite (CAS number)	Abbreviation
Benzylbutyl phthalate (85-68-7)	BzBP	Mono-benzyl phthalate (2528-16-7) (some mono-n-butyl phthalate)	MBzP
Dibutyl phthalates (84-74-2)	DBP	Mono-isobutyl phthalate Mono-n-butyl phthalate (131-70-4)	MiBP MnBP
Dicyclohexyl phthalate (84-61-7)	DCHP	Mono-cyclohexyl phthalate (7517-36-4)	MCHP
Diethyl phthalate (84-66-2)	DEP	Mono-ethyl phthalate (2306-33-4)	MEP
Di-2-ethylhexyl phthalate (117-81-7)	DEHP	Mono-2-ethylhexyl phthalate (4376-20-9) Mono-(2-ethyl-5-hydroxyhexyl) phthalate Mono-(2-ethyl-5-oxohexyl) phthalate Mono-(2-ethyl-5-carboxypentyl) phthalate (40809-41-4)	MEHP MEHHP MEOHP MECPP
Di-isononyl phthalate (28553-12-0)	DiNP	Mono-isononyl phthalate	MiNP
Dimethyl phthalate (131-11-3)	DMP	Mono-methyl phthalate (4376-18-5)	MMP
Di-n-octyl phthalate (117-84-0) MOP	DOP	Mono-(3-carboxypropyl) phthalate Mono-n-octyl phthalate (5393-19-1)	MCPP MOP

Source: (CDC, 2009, p. 258)

Table 2. Environmental and Human Health, Inc.: Examples of National PVC Childcare Restrictions

Austria	1999	Ban on the sale of phthalate plasticizers in toys for children under age three.
Denmark	1999	Ban on phthalate plasticizers in toys and childcare articles for infants under age three.
Argentina	1999	Covers all toys and baby articles containing phthalates that could be chewed by children under three.
Greece	1999	Bans the import and sale of PVC toys containing phthalates for children under three years old.
Norway	1999	Bans production, distribution, import and export of toys and other products aimed at children under three years old and containing phthalate plasticizers.
European Union	1999	Ban on six toxic softeners found in soft PVC toys marketed for teething. In 2000 increased restriction to reduce maximum allowed concentration of phthalates in PVC to 0.05 percent instead of 0.1 percent, and bans any PVC toys containing perfumes, such as fruit flavors, which tempt children to suck them.
Cyprus	2000	Ban on baby toys made of PVC.
Fiji Islands	2000	Ban on the sale of children's items made of PVC, including soft PVC toys intended for children's mouths and other articles such as stroller covers and mattress covers.
Tunisia	2000	Ban on the importation, selling and distribution of all PVC toys and childcare articles intended for children under the age of three and which contain more than 0.1% of one of the six mentioned categories of phthalates (DINP, DEHP, DNOP, DIDP, BBP, DBP).
Czech Republic	2001	Ban on phthalates in PVC toys.
Japan	2001	Ordinance: In the production of resin toys, PVC containing DEHP should not be used.

Source: (Environment and Human Health, Incorporated, n.d.)

infant exposure to ECMO, Rais-Bahrami and colleagues (2004) found no significant adverse effects on health.

It is well understood, too, that frequent mouthing behaviors are a necessary exploratory activity amongst developing infants, and that DEHP can be leached out of soft vinyl children's toys as a response to prolonged sucking and chewing (Health Canada, 2009). Main and colleagues (2006) also found health effects in infants who received phthalates transmitted through breast milk. Baby care products, such as baby lotions, powders, and shampoos are also important sources of exposure (Sathyanarayana et al., 2008).

Phthalate concentrations in baby products and toys were first for regulation due to the sucking or chewing behaviors of infants and toddlers that maximize exposure and ingestion of phthalates (Heudorf, 2007). However, some researchers have pointed out that phthalates may be absorbed not only from toys, but from ambient sources such as dust (Kolarik et al., 2008). Bornehag and colleagues (2004) investigated correlations between phthalate particle exposure in dust and increased rates of asthma.

Adolescent Issues

Older children are considered a low risk for the effects of phthalate exposure. This reduced risk is due to their lowered sensitivity to phthalate effects, and because they are less likely to suck or chew on plastic products for long periods of time, thereby lowering their risk for ingestion of phthalates (Korpan, 2009). Lomenick and colleagues (2009) investigated the potential link between high phthalate levels and precocious puberty in females and did not find significant effects.

Policy Responses

Overview

The multiple sources of exposure, combined with recognized toxicity for several phthalate compounds, have raised concerns about the use of phthalates (National Industrial Chemicals Notification and Assessment Scheme [NICNAS], 2008). The challenges in identifying at what concentrations chemicals pose a risk is challenging given research limitations, and identifying pathways for exposure and populations most at risk is even more daunting. Furthermore, as these substances are in widespread use already- in the case of phthalates for building materials, food packaging, medical supplies, dental materials, personal care products, and numerous other products- alternatives must be identified (United States Environmental Protection Agency [U.S. EPA], 2009).

The international response appears to illustrate the interplay between major importers and exporters of consumer products in the global market. According to McGinn: "the chemical economy is one of the largest and most diverse industrial sectors in the world" (2002, p. 77). In 2001, the Convention on Persistent Organic Pollutants was signed; a treaty amongst over 60 countries banning pesticides and other pollutants, with the goal of implementing bans worldwide. Following the 1999 European Union (SCTEE, 2004), phthalate bans (listed in Table 2 by Environment and Human Health, Incorporated [EHHI]) have now been reported across the world, including Argentina and Brazil (Global Competencies Support Center, 2008), Austria, Cyprus, Czech Republic, Denmark, Fiji, Finland, Germany, Greece, Italy, Mexico, Norway, Sweden (Allen, 1999; Environment California, n.d.; Ackerman & Massey, 2003) and Japan (Société Generale de Surveillance [SGS), n.d.). Policy responses in Europe, Australia, the United States, and Canada are reflected upon below to describe the process of regulatory development and implementation.

In 2005, the European Commission extended the 1999 ban DEHP, DBP and BBP in all toys and childcare articles (Directive 2005/84/EC). As explained by ECPI, representing the eight major companies, involved in the production of plasticizers in Europe, "the inclusion of DEHP, DBP, BBP and DIBP on the "candidate list" means that any EU manufacturer or importer of an article containing more than 0.1% weight by weight (w/w) of these phthalates must notify ECHA as of June 2011, unless the articles manufacturer or importer can clearly demonstrate that their use has already been registered. In addition the article manufacturer or importer must now provide information to the recipient of that article…distributors and retailers to professional end-users… retailers also have an obligation to provide the same information to consumers, but only if a consumer requests it. A retailer has 45 days to provide the information." DINP, DIDP and DnOP were banned from use in toys and childcare articles, if they can be put in the mouth by children (Sathyanarayana, et al., 2008; U.S. EPA, 2009).

The Registration, Evaluation, and Authorization of Chemicals (REACH) European chemicals regulation collects all information from chemical producers and importers as well as safety information. REACH went into effect in 2007 (European Commission, n.d.). In 2011, the Danish Ministry of Environment issued a press release describing their intention to introduce a Danish ban on DEHP, DBP, DIBP and BBP for indoor use and products with which consumers are in direct contact (Danish Ministry, 2011). According to the report,

this is the first time that a ban is based on the cocktail-effect of chemicals.

In 2006 the Australian Government declared the phthalates DEHP, DIDP, DMP, DINP, DBP, BBP, DnOP, DEP and bis(2-methylethyl) phthalate as Priority Existing Chemicals; they were added to the NICNAS Candidate List and initiated public risk assessments for these phthalates. These risk assessments were underway throughout 2008 and 2009 (NICNAS, 2008; U.S. EPA, 2009). In 2010, products intended for use by children under 36 months of age containing greater than 1% DEHP by weight was banned in Australia beginning in 2011 (Commonwealth of Australia, 2011).

United States

Until 2008 phthalates were still allowed freely in the U.S., and listing of phthalate as an ingredient was voluntary. The concentration of phthalates in many products is still unknown (Sathyanarayana et al., 2008). At the state level, California, Vermont and Washington were the first states to establish restriction on phthalates in children's articles. Mirroring the European Union Ban, California and Vermont prohibited the manufacture, sale, or distribution in commerce of any toy or child-care article containing DEHP, DBP, or BBP at greater than 0.1% and of any toy or child-care article, intended for use by children under three years of age that can be mouthed, containing DINP, DIDP or DnOP at greater than 0.1% (U.S. EPA, 2009). As part of a statute concerning various chemicals in children's products, the State of Washington prohibits a manufacturer, wholesaler, or retailer from manufacturing, knowingly selling, offering for sale, or distributing for sale or for use in the state a children's product or product component containing phthalates (DEHP, DBP, BBP, DINP, DIDP, DnOP) "individually or in combination, at a concentration exceeding 0.1% by weight" (CRS, 2008). In 2009, Hawaii introduced legislation to prohibit the manufacture, sale, or distribution of certain toys and child care articles containing certain types of phthalates (U.S. EPA, 2009).

At the Federal level, the U.S. Consumer Product Safety Improvement Act of 2008 (CPSIA) banned the use of six phthalates in toys and child care articles at concentrations greater than 0.1 percent: DEHP, DBP, BBP, DINP, DIDP and DnOP (U.S. EPA, 2009), with the caveat that the use of three of these banned phthalates, DINP, DIDP, and DnOP may be reinstituted by CPSC pending review by the Chronic Hazard Advisory Panel, which is currently underway in 2011. Once the report is completed, the decision to lift the interim ban on the three phthalates, or to add additional phthalate compounds to the ban, will be determined (American Chemistry Council, n.d.; U.S. EPA, 2009). The Food and Drug Administration (FDA) also plays a role in phthalate regulation due to their presence in food contact substances (such as plastic wrap), cosmetics, pharmaceuticals and medical devices (U.S. EPA, 2009). Existing EPA Actions related to phthalates are listed in Table 3 (U.S. EPA, 2009). Although phthalates were banned in some products in 2009, those products produced before the bans remain in widespread use and distribution. The National Resources Defense Council sued the Consumer Product Safety to challenge the determination that a ban on phthalates in children's toys does not apply to items manufactured before the effective date of the ban in 2009 (U.S. District Court, 2008).

Canada

In June 2009 Canada proposed to harmonize their phthalate requirements with those already in effect in the European Union and U.S., ensuring the same level of protection as children in the U.S. and the EU (Canada Consumer Product Safety Act). (U.S. EPA, 2009) In January 2011 Canada passed the restrictions on phthalates under the *Phthalates Regulations*, effective June 10, 2011 (Health Canada, 2010). The regulation states the allowable concentrations of these following phthalates to be restricted to no more than 1,000 mg/kg (0.1%) in the vinyl of children's toys and child care products: di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP) and benzyl butyl phthalate (BBP) (Health Canada, 2010). Additionally, any vinyl products that can be reasonably foreseen to be mouthed by a child under the age of 48 months, are restricted to contain no more than the allowable concentrations of 1000 mg/kg (0.1%) of diisononyl phthalate (DINP), diisodecyl phthalate (DIDP) and di-n-octyl phthalate (DNOP). All children's toys and child care products that are not in compliance with the regulations will not be allowed to be sold, imported, or advertised in Canada (Health Canada, 2010). Previous to this new regulation, phthalates were asked to be voluntarily removed from products for use in children's toy or products, such as pacifiers, teethers, rattles, baby bottle nipples, and any other products that could be mouthed by babies or young children in Canada (Health Canada, 2010).

Risk Management Approach

Phthalates are used in products that are subject to EPA, FDA, and the CPSC. People may be exposed to phthalates from a variety of product uses, as well as from industrial releases and environmental exposures; these exposure pathways should be assessed together to appropriately characterize exposures and avoid underestimating risk. The assessment of combined exposure is important to determine the potential impacts of these chemicals.

Although one phthalate may act differently than another, focusing on restricting one individual

phthalate would likely underestimate their impact and undermine policy efforts, since they appear to produce similar adverse effects. Also, since many phthalates are interchangeable in their uses as plasticizers, restrictions on one could simply shift use to another of similar toxicity. Therefore, safe and affordable substitutes for phthalates are being identified, and will be an important consideration in any action that would restrict the use of these chemicals (McGinn, 2002; U.S. EPA, 2009).

Controversy

In 2005 the media highlighted a report by the National Toxicology Program, an expert panel convened by the U.S. government, which discounted previous studies, arguing that there was insufficient evidence of harmful effects on humans (Kaiser, 2005; NTP, 2005). Following the meeting, three members of the panel rescinded their position on the panel's recommendation to reduce level of concern regarding pregnant women "…because MEHP passes the placenta in free form where it may not be detoxified by the fetus, exposure throughout pregnancy is not necessary to cause damage in animal models, and current exposure estimates in women of child bearing age do not distinguish peak or episodic exposures from average exposures" (NTP, 2005).

When it comes to regulation of industry, pushback from chemical companies is inevitable. In fact, government agencies appear to collaborate with chemical companies for research and policy recommendations. For example, ECPI's stated aim is "to provide clear and concise information about the many applications of plasticizers and its safe use, supported by robust scientific research. Based on its extensive knowledge of the industry, many decades of experience, and its wealth of scientific data, the ECPI secretariat is able to provide valuable input to legislative and regulatory authorities, non-government organisations, consumer groups and all other stakeholders. It encourages an open dialogue between these groups and it actively supports research programmes." ECPI posts an online phthalate information center and has released a number of press releases challenging research findings that indicate concerns about exposure pathways and detrimental health effects from phthalates (ECPI b, n.d.). Similarly, in the U.S., the Chronic Hazard Advisory Panel of the American Chemistry Council was convened to make recommendations on whether the Consumer Product Safety Commission (CPSC) should address concerns regarding any phthalates (or combinations of phthalates) in addition to those identified in the CPSIA. The American Chemistry Council is comprised of chemical companies (American Chemistry Council, n.d.; U.S. EPA, 2009).

Additionally, major manufacturers of products containing phthalates that are exported to countries that now ban them must comply. In a 2007 media report, one Brazilian manufacturer was quoted, "We're shocked because we weren't even consulted on the decision and because recent studies show that there are no safety issues with the phthalates in question…Nothing from the scientific and toxic standpoint proves that these products are harmful. The image of these toy companies is being tarnished" (Carey, 2007). According to the article, the PVC institute would continue to lobby the government on behalf of the use of phthalates in plastics (Carey, 2007).

Health Education Campaigns

There are a number of sources for educating the public about potential environmental toxins in the environment, such as phthalates, including government reports and Websites, online search engines and special interest websites, the media, and targeted health education campaigns. Although Federal agencies compile comprehensive reports, such as those described in this review, the general public may not have access to these reports, or take the time to review them. The CDC (n.d.) has developed fact sheets to inform the public about common sources of phthalate exposure, to include updates on regulation. Additionally, public sites such as Wikipedia.com may chronicle research investigations and regulatory measures, and provide direct access to governmental reports, media reports, and other sources. However, the potential bias and inaccuracies are important considerations in an open access website.

Consumer interest websites are also important sources of information for the public. The *Trouble in Toyland* report is the 25th annual Public Interest Research Group (PIRG, 2010) survey of toy safety, which serves to educate consumers on safety guidelines and examples of toys that may pose potential safety hazards. The PIRG reports have contributed to recalls and regulatory actions, to address both mechanical and chemical hazards in children's toys and products. One common parenting website is babycenter.com which operates websites in 20 countries to provide health, safety, and developmental information and support to parents. The site has information available to parents regarding phthalate research findings and regulations (BabyCenter, n.d.) as well as tips on what types of baby bottles and other plastic items are recommended, how to reduce exposures during pregnancy, and opportunities to discuss the topic online with other parents. Websites such as safemama.com (Safemama, n.d.) offer consumers information regarding phthalate-free sources of food preparation and cleaning products, and children's

toys, as well as an online discussion forum for parents on the topic.

Government agencies, chemical companies, advocacy organizations, and research institutions all utilize media releases as a venue for getting consumer safety information out to the public. Media reports tend to illustrate tensions and debates among professionals and chemical companies, due to their orientation to drama and controversy. However, the media remains an important vehicle for public awareness. In our "crowded media environment' it is important that campaigns effectively reach the intended audience(s) with tailored messages that are theory-based (Randolph & Viswanath, 2004, p. 419). Unfortunately, without adequate support and funding, messages may not be effective in both increasing awareness and suggesting a potential solution (Randolph & Viswanath, 2004). In the case of phthalates, there has not been clear consensus on the risks or exposures, nor a collaborative approach towards informing the public, due to conflicting research, business, and policy interests.

Summary

In closing, we must concern ourselves with the fact that (1) over 80,000 chemicals are registered for use with the U.S. EPA alone, with minimum regulatory requirements for chemical safety testing (Rudel & Perovich, 2010); and (2) the global market facilitates widespread reach of experimental and banned chemicals; and many of these chemicals are both ubiquitous and persistent in the environment. In the future it is essential that researchers, policy makers, and consumers remain vigilant regarding possible ill-effects of these environmental exposures.

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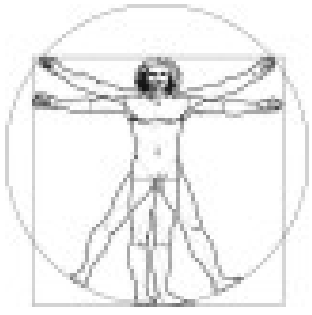

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