Food and Chemical Toxicology 58 (2013) 362–368

Contents lists available at SciVerse ScienceDirect

Food and Chemical Toxicology

journal homepage: www.elsevier.com/locate/foodchemtox

Taiwan food scandal: The illegal use of phthalates as a clouding agent and their contribution to maternal exposure

Justin Yang [a], Russ Hauser [a,b], Rose Hannah Goldman [a,b,c,d,*]

[a] Department of Environmental Health, Harvard School of Public Health, 677 Huntington Avenue, Boston, MA 02115, USA
[b] Harvard Medical School, 25 Shattuck Street, Boston, MA 02115, USA
[c] Cambridge Health Alliance, 1493 Cambridge Street, Cambridge, MA 02139, USA
[d] New England Pediatric Environmental Health Specialty Unit, Boston, MA 02115, USA

ARTICLE INFO

Article history:
Received 10 March 2013
Accepted 7 May 2013
Available online 16 May 2013

Keywords:
Clouding agent
Di(2-ethylhexyl) phthalate (DEHP)
Food contamination
Endocrine disruptor
Phthalate
Maternal exposure

ABSTRACT

In 2011 the Taiwan Food and Drug Administration reported that plasticizers di(2-ethylhexyl) phthalate (DEHP) and di-iso-nonyl phthalate (DiNP), endocrine disruptors, were illegally added to clouding agents used in foods and beverages. 965 products were found contaminated, of which 206 were exported to 22 countries. This study's purpose was to obtain English names for 28 contaminated products for which DEHP levels were reported, calculate estimated average daily intake (mg/kg/day) for a 50 kg woman consuming one portion, and compare to U.S. and E.U. guidelines for daily intake. We found that drinking just one bottle (500 ml) of sports drinks would result in an average DEHP intake of 0.14 mg/kg bw/day (range 0.091–0.341), which exceeds by several fold government guidelines (0.02–0.06 mg/kg bw/day). One (2 g) serving from 4/14 samples of contaminated dietary supplements exceeds the guideline of 0.02 mg/kg bw/day. In conclusion, consuming even one portion of tainted drinks and some powders would lead to daily intake of DEHP that greatly exceeds established safety guidelines, raising concerns about potential adverse effects, particularly reproductive tract development in the male fetus. Global distribution of DEHP-contaminated and other adulterated products should prompt governments to become proactive in food safety regulations and chemical testing.

1. Introduction

The food industry uses approved clouding agents (palm oil, gum arabic and other additives) in foods and beverages as emulsifiers to increase turbidity and to provide a more appealing natural appearance to the products (Wu et al., 2012; Yen et al., 2011). However, in May 2011, the illegal use of the industrial plasticizer di(2-ethylhexyl) phthalate (DEHP) as a food additive to replace palm oil in clouding agents was reported in Taiwan (TFDA, 2011c; Wu et al., 2012). On May 23rd, the Taiwan Food and Drug Administration (TFDA) reported that two companies substituted DEHP and di-iso-nonyl phthalate (DiNP) for palm oil in clouding agents and then distributed these agents to major food manufacturers in Taiwan, resulting in intentional and widespread use in foods and beverages that occurred over 15 years (TFDA, 2011c; Wu et al., 2012). A month after this initial report, TFDA released the names of 965 products that were contaminated with DEHP and comprised five food categories including sports drinks, concentrated juice beverages, tea drinks, jam or jelly, and food supplements in capsule- or powder-form (Lu, 2011; TFDA, 2011d). After releasing the list, all contaminated products were reportedly retrieved from the market by the manufacturers and destroyed by the Taiwanese government in June. This outbreak event is also known as the "2011 Taiwan Food Scandal" (Yen et al., 2011).

Phthalates are a family of chemicals used in a wide variety of consumer products, such as personal care products and plastics (Lyche et al., 2009). The long-chain high-molecular-weight phthalates DEHP, DiNP, di-iso-decyl phthalate (DiDP) and dipropylheptyl phthalate (DPHP) are primarily used as plasticizers in polyvinyl chloride (PVC) plastics, polyvinyl acetate, rubbers, cellulose plastics and polyurethane (U.S. Consumer Product Safety Commission, 2010; Wittassek et al., 2011). An estimated 97% of all DEHP is used in plastic productions (U.S. Consumer Product Safety Commission,

Abbreviations: ATSDR, Agency for Toxic Substances and Disease Registry; AGD, anogenital distance; CADIA, China Alcoholic Drinks Industry Association; DEHP, di(2-ethylhexyl) phthalate; DiNP, di-iso-nonyl phthalate; ECB/EU, European Chemicals Bureau; FSMA, Food Safety Modernization Act; MRL, minimal risk level; ppm, parts per million; PVC, polyvinyl chloride; RfD, reference dose; CSTEE, Scientific Committee on Toxicity, Ecotoxicity and the Environment; TBIA, Taiwan Beverage Industries Association; TFDA, Taiwan Food and Drug Administration; TDI, tolerable daily intake; US-EPA, US Environmental Protection Agency.

* Corresponding author. Address: Cambridge Hospital, Macht Building Room 427, Cambridge, MA 02139, USA. Tel.: +1 617 665 1580; fax: +1 617 665 1672.
E-mail address: rgoldman@challiance.org (R.H. Goldman).

0278-6915/$ - see front matter © 2013 Elsevier Ltd. All rights reserved.
http://dx.doi.org/10.1016/j.fct.2013.05.010

2010). The utilization of DEHP in plastic products is diverse, ranging from clothing (footwear, raincoats), food packaging materials, child products, floorings and pharmaceutical products and medical devices (Fromme et al., 2007; Huang et al., 2009; Lyche et al., 2009; Tsumura et al., 2001). Phthalates have no approved use as a food additive (Lu, 2011; TFDA, 2011c).

In rodents, the reproductive and developmental effects of DEHP have been well studied (U.S. Consumer Product Safety Commission, 2010). Phthalates are anti-androgenic and disrupt the development of androgen-dependent structures by inhibiting fetal testicular testosterone biosynthesis (Yen et al., 2011). Studies have suggested gestational exposure alters development of the reproductive tract, including the Wolffian duct and prostate, with adverse outcomes that include hypospadias, cryptorchidism, female-like areolae, nipple retention and reduced anogenital distance (AGD) (Foster, 2006; Gray et al., 2009). This collection of abnormalities has been termed the 'Phthalate Syndrome' (Foster, 2006; Swan et al., 2010).

Results from animal studies were used by the US Environmental Protection Agency (US-EPA) to propose a DEHP reference dose (RfD) of 0.02 mg/kg bw/day, and the European Chemicals Bureau (ECB/EU) to recommend a 0.02 mg/kg bw/day tolerable daily intake (TDI) for newborns <3 months and women of childbearing age (Heudorf et al., 2007).

The announcement of the Taiwan Food Scandal raised public concerns about the potential adverse health outcomes from high DEHP exposure, especially on male reproductive tract development following in utero exposure. In news reports released in Taiwan, the TFDA published DEHP levels found in some of the food and drink products. To our knowledge, only limited information about the concentrations of the contamination has been released to the international community (Lu, 2011; Wu et al., 2012). The purpose of our study was to: (1) obtain the English names of the contaminated products and the levels of contamination for dissemination to the international community, (2) estimate potential average daily intake for an average weight woman of reproductive age and compare this intake to previous studies and current guidelines, and (3) discuss the potential prenatal sexual development effects that might be caused by such high chronic exposures to DEHP during the years when products were in circulation.

2. Material and methods

We reviewed related news reports written in Chinese that listed the products presumed to be contaminated, and then obtained preliminary DEHP concentration reports of contaminated foods and beverages through announcements written in Chinese on the TFDA website. A preliminary report published on May 27th, 2011 by the TFDA included the names (in Chinese) of 28 products (4 brands of sports drinks and 13 different brands of powders and capsules containing digestive enzymes marketed as food supplements) with the measurements of DEHP concentrations in parts per million (ppm). The TFDA subsequently published a list of 965 products with their Chinese names and English translations but without concentrations of DEHP (Lu, 2011; TFDA, 2011a). We searched this list for the 28 Chinese names for which we had DEHP concentrations in order to obtain the names in English, which we then used in our tables. Concentrations on the website were reported in parts per million (ppm) and we changed to mg/kg to facilitate comparisons to toxicology reports, reference guidelines and other studies. Conversion methods were adopted from the DEHP informational booklet published by the Taiwan Department of Health (Wu et al., 2011). In the sports drinks and juice category, further assumptions were made in order to facilitate conversion. The volume of a typical beverage container in Taiwan is about 500 ml. Therefore, from the original TFDA document with concentration reported in parts per million (ppm), we calculated DEHP concentration in one portion (500 ml) and converted to mg/500 ml assuming the density in sports drinks and juice to be approximately the same as water. Previous research indicated the average weight for women of childbearing age was 53.6 kg in Taiwan (Yang, 2004). In our study, calculations of DEHP in mg/kg bw/day were based on the assumptions that a woman of childbearing age weighed about 50 kg and drank one bottle of the contaminated drink per day.

In calculating daily DEHP intake for the capsules and powders category, because all products were recalled and destroyed right after the announcements, we were not able to obtain information on the specific suggested daily intake amount of each product, which is usually listed on the packaging. However, internet research of recommended daily amounts of similar food supplements being sold in the United States (GNC, 2012) noted that the usual recommended daily amount is 2 g. Therefore we used the assumption of a 2 g daily amount to calculate the DEHP content of the similar Taiwanese tainted products, and to calculate the DEHP intake in mg/kg bw/day.

Emails and phone calls were made to the Director-General's office of TFDA in an attempt to gather additional information about DEHP concentrations on all contaminated products (965 items). Data of beverage sales in Taiwan (in Chinese) were obtained through reviewing the Taiwan Beverage Industries Association (TBIA) website (TBIA, 2012a,b).

Statistics of human background DEHP exposures in food were acquired from the Handbook of Environmental Chemistry by Clark et al. (2003), as extracted, presented and cited in the article by Lyche et al. (2009). DEHP human risk assessments conducted by US-EPA, Agency for Toxic Substances and Disease Registry (ATSDR), Health Canada, Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) and ECB/EU were reviewed from previous published articles (Heudorf et al., 2007; U.S. Consumer Product Safety Commission, 2010; Yen et al., 2011).

A qualitative review of studies on DEHP exposure and prenatal sexual development was conducted by searching relevant terms on PubMed: exposure, phthalates, di(2-ethylhexyl) phthalate, DEHP, reproductive outcome, prenatal sexual development, clouding agents, and/or penile length. Descriptions of animal studies and results on prenatal sexual development were obtained from the Toxicity Review of di(2-ethylhexyl) phthalate (DEHP) done by the United States Consumer Product Safety Commission (U.S. Consumer Product Safety Commission, 2010) and from a review article on phthalates (Lyche et al., 2009). Data analyses were conducted by Microsoft Excel 2007 and STATA 11.0.

3. Results

3.1. Categories of contaminated products

From the TFDA website, information was provided on categories of contaminated products (TFDA, 2011b,d). Table 1 is our translation of a similar table provided in Chinese on the TFDA website and demonstrates the breadth of DEHP contamination in this incident. Since a clouding agent is one of the ingredients included in powders, most of the products in Table 1 are foods and beverages that are reconstituted from powders.

Many processed products derive from materials listed in this table. For example, B(P)oba milk tea (also known as pearl milk tea or tapioca tea) is a well-known Taiwanese beverage made of black tea powder, tapioca pearls, milk powder and sweetener which normally comes in a 500 ml cup. With more than 40,000 tea shops nationally, consumption of this beverage is very prevalent in Taiwan (Huang, 2012).

3.2. DEHP concentrations and exposure calculations

Table 2 lists DEHP concentrations in sports drinks and juice that were in the TFDA report (TFDA, 2011e) as well as converted data calculated according to assumptions described in Section 2. As indicated in the table, a 50 kg pregnant woman would ingest as much as 0.341 mg/kg bw/day by drinking one bottle of a tainted sports drink, which is 17 times higher than the RfD or TDI set by US-EPA and ECB/EU (0.02 mg/kg bw/day) (Heudorf et al., 2007). With an average consumption of 0.14 mg/kg bw/day, drinking any bottle of the listed sports drinks would result in the intake of 7 times the recommended safety guidelines. Even after consumption of one of the least contaminated drinks (4.55 mg/bottle), the DEHP intake from one drink would still be 4.5 times higher than the suggested maximum daily intake. In the juice samples, the level of contamination would also contribute to an intake that also surpassed 0.02 mg/kg bw/day. If we assume a woman weighs 60 kg in her pregnancy, the average daily (mg/kg bw/day) consumption of DEHP by drinking one tainted sample would still greatly surpass the safety guidelines by several folds.

Table 3 describes the DEHP concentrations in contaminated capsules and powders. Products listed in Table 3 are mostly digestive enzyme supplements that contain probiotics such as