Original Article

Dietary Exposure to Benzyl Butyl Phthalate in China*

ZHANG Lei[1], JIANG Ding Guo[1], SUI Hai Xia[1], WU Ping Gu[2], LIU Ai Dong[1], YANG Da Jin[1], LIU Zhao Ping[1], SONG Yan[1,#], and LI Ning[1]

1. Key Laboratory of Food Safety Risk Assessment, National Health and Family Planning Commission of the People's Republic of China (China National Center for Food Safety Risk Assessment), Beijing 100022, China; 2. Zhejiang Provincial Center for Disease Control and Prevention, Hangzhou 310051, Zhejiang, China

Abstract

Objective Benzyl butyl phthalate (BBP) is a plasticizer used in food contact materials. Dietary exposure to BBP might lead to reproduction and developmental damages to human. The present paper was aimed to assess the health risk of BBP dietary exposure in Chinese population.

Methods The BBP contents were detected in 7409 food samples from 25 food categories by gas chromatography-mass spectrometry operated in selected ion monitoring (SIM) mode. The dietary exposures of BBP in different age and sex groups were estimated by combining the content data with food consumption data derived from 2002 China National Nutrient and Health Survey, and evaluated according to the tolerable daily intake (TDI) of BBP established by European Food safety Agency.

Results It was found that BBP was undetectable in most samples and the highest level was 1.69 mg/kg detected in a vegetable oil sample. The average dietary exposure of BBP in people aged ≥2 years was 1.03 μg/kg bw per day and the highest average exposure was found in 2-6 years old children (1.98 μg/kg bw per day). The BBP exposure in 7-12 months old children excessed 10% of tolerable daily intake (TDI) in worst scenario.

Conclusion The health risk of BBP dietary exposure in Chinese population is low and, considering BBP alone, there is no safety concern.

Key words: Benzyl butyl phthalate; Dietary exposure; Risk assessment; China

Biomed Environ Sci, 2016; 29(5): 365-373 *doi: 10.3967/bes2016.047* *ISSN: 0895-3988*

www.besjournal.com (full text) *CN: 11-2816/Q*

INTRODUCTION

Benzyl butyl phthalate (BBP) is an ester of phthalic acid, benzyl alcohol and n-butanol, mainly used as plasticizer in polyvinyl chloride and other polymers used in adhesives, paints and pigments[1-2]. Its largest use is in vinyl tiles. BBP is also present in food conveyor belts, artificial leather, toy and food packaging[1,3]. As a plasticizer, BBP is not tightly bound to plastic, and tends to leach from plastic products to the environment. It has been found in food, water, air, and soil[2,4]. Human could expose to BBP through oral, inhalation and skin contact.

Studies in rat and mice have shown that BBP might have reproduction and developmental toxicity[4-8]. These effects have been also observed in several human studies[9-12]. Generally, males are more susceptible than females to adverse developmental effects on the reproductive tract. Young children are considered a potentially susceptible population[13]. Recent epidemiological

*This work was partially supported by China's Ministry of Science & Technology (No.2014ZX09304307).

#Correspondence should be addressed to SONG Yan, E-mail: songyan@cfsa.net.cn

Biographical note of the first author: ZHANG Lei, male, born in 1973, PhD, Associated Researcher, majoring in food safety risk assessment.

studies suggested childhood exposure to BBP might increase the risk of allergic diseases, such as asthma and eczema[14]. There is no sufficient evidence to suggest the genotoxic and carcinogenic effects of BBP in animals and human[15-16].

Several tolerable dietary intakes (TDI) have been estabilished based on different toxicological end-points in experimental animals. In 1988, the United States Environmental Protection Agency (USEPA) established a TDI of 0.2 mg/kg bw per day based on a significant increase of liver-body ratio and liver-brain ratio of rat with the no-observed-adverse-effect-level (NOAEL) of 159 mg/kg bw and an uncertainty factor of 1000[17]. In 1995, the European Commission's Scientific Committee on Food (SCF) set a temporary TDI of 0.1 mg/kg bw per day based on the end-point of peroxisome proliferation in rodent liver[18]. However, the international agency for research on cancer (IARC) has reported that liver peroxisome proliferation in rodents is not relevant for human risk assessment[19]. Based on the scientific consensus and newly available toxicological evidence, the European Food Safety Authority (EFSA) concluded that the effects on reproduction and development are the most sensitive end-points for assessing of the effect of BBP through dietary exposure. Based on testicular toxicity and on the presence of reduced anogenital distance (AGD) in F1 and F2 males at birth, EFSA set a TDI of 0.5 mg/kg bw per day in 2005, derived from a NOAEL of 50 mg/kg bw with an uncertainty factor of 100[8,20].

Although humans may be exposed to BBP through the oral, inhalation and dermal routes, food is still the most important source of BBP exposure[3,20]. As the biggest producer and consumer in the world, China is also facing the environmental and food contamination of BBP[21-23]. However, there has been no comprehensive study on the content levels of BBP in most food categories and dietary BBP exposure in the Chinese population. This paper reports the contents of BBP in food (including drinking water) and age/sex specific dietary exposure levels in the Chinese population.

MATERIALS AND METHODS

BBP Contents of Food

Food samples in 25 food categories, including rice, wheat flour, leafy vegetable, cucurbit & fruiting vegetable, root & stalk vegetable, livestock, poultry, packaged meat products, freshwater fish, seawater fish, shrimp, egg, fruit, milk, instant noodle, seasoning oil for instant noodle, soft drink, drinking water, distilled spirit, yellow wine, vegetable oil, jelly, jam, infant formula and child food, were collected from supermarkets and local markets in all of 31 provinces, autonomous regions and municipalities of China from 2012 to 2013. The total sample size was 7409, and the sample size in each province, or autonomous region and municipality ranged from 30 to 1114. All the samples were collected by using glass containers and segregated from plastic materials to avoid contamination with phthalates.

Food samples of vegetable oil, soft drink, alcohol, drinking water, jam and jelly were analyzed according to China national standard (GB/T 21911-2008: Determination of phthalate esters in foods)[24]. Other food samples were also analyzed according to China national standard (GB/T 21911-2008) with minor modifications developed by an expert committee on the analysis of phthalate acid esters[25]. In brief, about 0.4-2.0 g samples were spiked with deuterated phthalates and homogenized. BBP in fat free food samples, such as soft drink, alcohol and drinking water, were extracted with n-hexane and centrifuged at 4000 rpm for 5 min. BBP in vegetable oil was extracted with ethyl acetate: cyclohexane (1:1) and were cleaned up by using gel permeation chromatography system. Other food samples were added with petroleum ether for the extraction of fat first, then the fat were extracted with acetonitrile and cleaned up by using silica/PSA - mixed SPE. After concentration, the extracts were analyzed with gas chromatography-mass spectrometry (GC-MS) fitted with DB-5ms capillary column (30 m long, 0.25 mm in diameter, and with a 0.25 μm film thickness) and operated in selected ion monitoring (SIM) mode.

In the analysis, special attention was paid to sources of contamination. All laboratory glassware was washed carefully and heated at 300 °C or rinsed with redistilled n-hexane before use. Blank test sample were analyzed following same procedure for each batch of samples. Only when the BBP content of the blank sample was lower than 0.02 mg/kg (conversion according sample weight), the analysis results were accepted. To ensure the accuracy of analysis, a recovery test sample spiked with 0.2 mg/kg BBP were analyzed for each batch of samples and the recovery should be in 70%-120%. All the data were vertified by an expert panel of analysts before the use for exposure estimation.