

Commerce, Industry and Tourism Branch
Commerce and Economic Development Bureau

Proposal to impose concentration limits of phthalates in toys
and child care products

This consultation note can be found on the internet at
<http://www.cedb.gov.hk/citb>

November 2012

SECTION ONE

INTRODUCTION

1.1 The Toys and Children's Products Safety Ordinance (Cap. 424) ("the Ordinance") regulates the safety of toys and specified children's products that are supplied in Hong Kong.

1.2 Under the Ordinance, three sets of safety standards (the International Standard series, the European Standard series and the American Society for Testing and Materials Standard)¹ are prescribed for toys. A toy that complies with all the applicable requirements contained in any one set of the standards is regarded as safe under the Ordinance. The safety of 12 types of children's products² is also regulated by the Ordinance, which prescribes applicable safety standards³ for each of these 12 types of products. A children's product subject to the regulation of the Ordinance is regarded as safe if it complies with all the requirements contained in any one set of the standards specified for it.

1.3 The safety standards specified in the Ordinance (which are standards adopted internationally or in major jurisdictions) prescribe detailed physical, mechanical and chemical requirements on applicable articles and corresponding test procedures. In addition, the Ordinance provides⁴ that regulations may be made to establish additional safety standards for toys and children's products. Products which fail to comply with any additional applicable standards established by regulations are regarded as unsafe under the Ordinance.

¹ ISO 8124 series (and IEC 62115 for electric toys), BS EN 71 series (and EN 62115 for electric toys), and ASTM F963.

² Babies' dummies, Baby walking frames, Bottle teats, Bunk beds for domestic use, Carry cots and similar handled products and stands, Child safety barriers for domestic use, Children's cots for domestic use, Children's high chairs and multi-purpose high chairs for domestic use, Children's paints, Children's safety harnesses, Playpens and Wheeled child conveyances.

³ Schedule 2 to the Ordinance.

⁴ Section 35 of the Ordinance.

1.4 Any person who manufactures, imports or supplies an unsafe toy or an unsafe children's product in Hong Kong commits an offence, and is liable, on first conviction, to a fine at Level 6 (which is currently \$100,000) and to imprisonment for one year, and on subsequent conviction, to a fine at \$500,000 and imprisonment for two years⁵.

1.5 The Customs and Excise Department is the agency responsible for enforcing the Ordinance. In addition to taking out prosecutions, the Department is empowered under the Ordinance to issue "notices to warn", prohibition notices and recall notices⁶ if the Department believes that an unsafe article is supplied in Hong Kong. Apart from acting on complaints, the Department conducts regular inspections at wholesale and retail premises and takes samples for laboratory testing to ascertain their compliance or otherwise with the requirements laid down by the Ordinance. The Department also takes note of product recalls and warnings issued in other advanced jurisdictions and relevant markets. In the first eight months of 2012, the Department conducted 1,033 inspections and took 836 articles for testing.

Phthalates

1.6 Phthalates are a class of chemicals which are commonly added to materials such as hard plastics to improve their flexibility and durability. Called plasticizers when used this way, they are used in many consumer products, primarily in polyvinyl chloride (PVC) products. Various quarters of the public have expressed concerns over the health hazards posed to young children by phthalates and, in the light of tightened regulations in other jurisdictions, suggested that Hong Kong should follow suit and impose phthalates limits on toys and children's products.

1.7 We have reviewed the phthalates limits that have been imposed by selected overseas jurisdictions and the scope of

⁵ Section 31 of the Ordinance.

⁶ Sections 10, 11 and 12 of the Ordinance.

products to which the limits are applicable. We present our findings in section 2 of this note. In the light of the findings, and to ensure that our regime is on par with those in advanced economies, we propose, in section 3, to impose concentration limits in respect of six types of phthalates in toys and child care products that are susceptible to “mouthing” by young children. We welcome views from the public on the proposal. The public may find in section 4 how they can respond to this consultation note.

SECTION TWO

CONTROLS OVER PHTHALATES IN OTHER JURISDICTIONS

2.1 Phthalates are a type of plasticizers that are commonly used in PVC consumer products and consumer products that contain plastic components.

2.2 Human exposure to phthalates is mainly through the oral route. Phthalates have a very low acute toxicity in humans⁷. The main concern is over chronic exposure. Overseas authorities have conducted comprehensive scientific reviews⁸ of animal studies on phthalates and revealed that chronic exposure to phthalates might result in a number of adverse effects, including toxicity in the liver and kidney. Certain phthalates, such as diethylhexyl phthalate, have been found to cause reproductive and

⁷ Opinions on phthalates migration from soft PVC toys and child care articles by the European Commission's Scientific Committee on Toxicity, Ecotoxicity and the Environment expressed at its fourth plenary meeting on 16 June 1998, http://ec.europa.eu/health/scientific_committees/environmental_risks/opinions/sctee/sct_out15_en.htm, and its sixth plenary meeting on 26 and 27 November 1998 in Brussels on phthalate migration from soft PVC toys and child care articles, http://ec.europa.eu/health/scientific_committees/environmental_risks/opinions/sctee/sct_out19_en.htm.

⁸ Environmental Health Criteria 131 for Diethylhexyl Phthalate, <http://www.inchem.org/documents/ehc/ehc/ehc131.htm>, Environmental Health Criteria 189 for Di-n-butyl Phthalate, <http://www.inchem.org/documents/ehc/ehc/ehc189.htm>, and Concise International Chemical Assessment Document 17 for Butyl Benzyl Phthalate, <http://www.inchem.org/documents/cicads/cicads/cicads17.htm> conducted by the World Health Organization, European Union Risk Assessment Report for Di-isononyl Phthalate, <http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/5395/1/EUR%2020784%20EN.pdf>, and European Union Risk Assessment Report for Di-isodecyl Phthalate, <http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/5459/1/EUR%2020785%20EN.pdf>, conducted by the Institute for Health and Consumer Protection, European Chemicals Bureau, and Toxicological Profile for Di-n-octyl Phthalate conducted by the US Agency for Toxic Substances and Disease Registry, <http://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=973&tid=204>.

developmental toxicity in experimental animals.

2.3 Advanced economies such as the European Union, the United States of America, Australia, Canada and Singapore have given particular attention to six types of phthalates, i.e. diethylhexyl phthalate (DEHP)⁹, dibutyl phthalate (DBP)¹⁰, benzyl butyl phthalate (BBP)¹¹, di-isononyl phthalate (DINP)¹², di-isodecyl phthalate (DIDP)¹³ and di-n-octyl phthalate (DNOP)¹⁴ and imposed varying concentration limits. We set out in the following paragraphs the controls that have been imposed.

European Union

2.4 In December 1999, having regard to the advice of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE)¹⁵, the European Commission decided to impose a renewable temporary ban on the use of six phthalates (DEHP, DBP, BBP, DINP, DIDP and DNOP) in soft PVC toys and child care articles¹⁶. The decision was made having regard to the SCTEE's confirmation that, on the basis of the "adverse effects of DINP for liver and kidney and testicular damage caused by DEHP observed in laboratory tests"¹⁷, there were grounds for concern with the low safety margins as regards the exposure of children to the phthalates DEHP and DINP. The Commission also considered that there would be increased exposure by children to and hence

⁹ Also known as bis (2-ethylhexyl) phthalate, Chemical Abstracts Service (CAS) no. 117-81-7.

¹⁰ CAS no. 84-74-2.

¹¹ CAS no. 85-68-7.

¹² CAS no. 28553-12-0 and 68515-48-0.

¹³ CAS no. 26761-40-0 and 68515-49-1.

¹⁴ CAS no. 117-84-0.

¹⁵ A committee established pursuant to the Commission Decision of 23 July 1997 setting up Scientific Committees in the field of consumer health and food safety, No. 97/579/EC.

¹⁶ Commission Decision of 7 December 1999 adopting measures prohibiting the placing on the market of toys and child care articles intended to be placed in the mouth by children under three years of age made of soft PVC containing one or more of the substances DINP, DEHP, DBP, DIDP, DNOP and BBP, No. 1999/815/EC.

¹⁷ Recital (18).

increased health risks posed by DNOP, DIDP, BBP and DBP when they might be more frequently used as substitutes for DEHP and DINP if the latter two were banned¹⁸.

2.5 The temporary ban was made permanent in early 2006¹⁹. Toys and child care articles²⁰ containing an aggregate weight of DEHP, DBP and BBP which is greater than 0.1% of the plasticized material are prohibited from being placed on the market. Toys and child care articles that can be placed in the mouth by children and contain an aggregate weight of DINP, DIDP and DNOP which is greater than 0.1% are also banned.

United States

2.6 In the United States, similar restrictions have also been imposed since 2008, with the enactment of the Consumer Product Safety Improvement Act. Under the Act, children's toys and child care articles²¹ that contain more than 0.1% by weight of DEHP, DBP or BBP are permanently banned. Pending further examination by an advisory Panel²², the Act also puts in place (as an interim measure) a ban on children's toys that can be placed in a child's mouth and child care articles, if they contain more than 0.1% DINP, DIDP or DNOP by weight.

Australia

2.7 As of date, among the various phthalates, only DEHP concentration in toys and children's product is regulated in Australia. An interim ban²³ was imposed with effect from 2 March 2010 on toys, child care articles and eating vessels and utensils that:

¹⁸ Recital (21).

¹⁹ Directive 2005/84/EC of the European Parliament and of the Council of 14 December 2005.

²⁰ Defined as products intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.

²¹ Defined as consumer products designed or intended by the manufacturer to facilitate sleep or the feeding of children aged three and younger or to help such children with sucking or teething.

²² The Chronic Hazard Advisory Panel formed under section 108(2) of the Act.

²³ Consumer Protection Notice No. 6 of 2010.

- (a) contain, or have a component that contains, more than 1% by weight DEHP;
- (b) are intended for use by children up to and including 36 months of age; and
- (c) can readily be sucked and/or chewed.

This ban was made permanent with effect from 1 February 2011²⁴, in recognition of the risk of reproductive toxicity that DEHP may pose to young children who may extensively mouth objects on a recurrent basis for substantial periods of time²⁵.

Canada

2.8 In Canada, limits of phthalates in toys and child care articles have been imposed since mid-2011²⁶. Any plasticized material of a toy or child care article²⁷ must contain not more than 0.1% by weight DEHP, DBP or BBP. The plasticized material of any part of a toy or child care article that can, in a reasonably foreseeable manner, be placed in the mouth of a child under four years of age must contain not more than 0.1% by weight DINP, DIDP or DNOP.

2.9 The limits are imposed in the light of similar restrictions placed in the United States of America and the European Union and also on health and precautionary grounds²⁸. DEHP is

²⁴ Consumer Protection Notice No. 11 of 2011.

²⁵ Priority Existing Chemical Assessment Report No. 32 (on DEHP), prepared by the Department of Health and Ageing of the Australian Government under the National Industrial Chemicals Notification and Assessment Scheme in July 2010 (referred to in the Explanatory Statement of the Consumer Protection Notice No. 11 of 2011), http://www.nicnas.gov.au/Publications/CAR/PEC/PEC32/PEC_32_Full_Report_PDF.pdf

²⁶ Phthalates Regulations and Order amending Schedule I to the Hazardous Products Act (Phthalates).

²⁷ Defined as a product that is intended to facilitate the relaxation, sleep, hygiene, feeding, sucking or teething of a child under four years of age.

²⁸ Regulatory Impact Analysis Statement of December 2010 accompanying

restricted because of its inherent potential to cause adverse effects on reproduction and development and because exposure estimates for infants and toddlers who mouth on soft vinyl children's products containing DEHP approach levels at which adverse effects on reproduction and development are likely to occur. As regards DBP and BBP, while exposure has the potential to be hazardous to reproduction and development, exposure estimates are within acceptable levels. That said, limits of DBP and BBP are still imposed because the two may be used as substitutes for DEHP after the latter is banned, and will therefore raise exposure to levels which may cause adverse effects on development or fertility problems (or both) later on in life. For DINP and DIDP, having regard to researches done in the European Union and Australia, the competent authorities find it reasonable to conclude that exposure to the two substances by young children who mouth on soft vinyl children's toys containing them is likely to cause adverse effects on reproduction and development. As for DNOP, although data were inadequate, and despite some uncertainties in the then available scientific knowledge, the authorities consider it prudent to subject DNOP to the same restrictions as DINP and DIDP.

Singapore

2.10 In Singapore, toys and children's products have to meet safety standards adopted in either the European Union or the United States of America or the international standards (ISO and IEC).

2.11 The restrictions against the use of phthalates in toys and children's products are benchmarked on those adopted in the jurisdictions referred to in the preceding paragraphs. Plasticized materials in toys and child care articles²⁹ shall contain not more

the legislative instruments imposing the limits.

²⁹ Defined as product intended to facilitate sleep, relaxation, hygiene, feeding of children or sucking on the part of children (see Appendix F to the Consumer Protection (Consumer Goods Safety Requirements) Regulations 2011 Information Booklet (Edition 1.3), http://www.spring.gov.sg/QualityStandards/CPS/Documents/CGSR_InfoBooklet.pdf).

than 0.1% by weight DEHP, DBP or BBP. Further, plasticized materials in toys and child care articles that can be placed in the mouth shall contain not more than 0.1% by weight DIDP, DINP or DNOP.

SECTION THREE

PROPOSED ALIGNMENT WITH RESTRICTIONS ADOPTED IN EUROPEAN UNION, UNITED STATES, CANADA AND SINGAPORE

3.1 In section two, we have reviewed the restrictions adopted in the European Union, the United States, Australia, Canada and Singapore. Except Australia, all these jurisdictions have put into effect restrictions against the use of DEHP, DBP and BBP in plasticized parts of all toys and of child care products that are in close contact with toddlers, and also the use of DINP, DIDP and DNOP in plasticized parts of toys and child care products that can be mouthed by toddlers.

3.2 We propose that we impose similar restrictions in alignment with the restrictions adopted in the European Union, the United States, Canada and Singapore. We have considered, in addition to the health risks as identified by the jurisdictions, the following factors before coming to this proposal:

- (a) alignment with restrictions adopted in the European Union, the United States, Canada and Singapore will mean that the young generation in Hong Kong will have the same level of protection from exposure to phthalates as children in those jurisdictions. This is in line with the current regulatory approach of benchmarking on the safety standards adopted in advanced economies;
- (b) alignment will also prevent us from becoming a possible dumping ground for non-compliant products rejected by those jurisdictions the markets of which are of a much greater size; and
- (c) the comparatively small size of the market in Hong Kong means that products supplied in Hong Kong are likely to be supplied in other places too. Imposing

restrictions that are stricter than those in the larger markets will reduce choices available to consumers in Hong Kong.

Proposed Concentration Limits

3.3 Specifically, we propose that the following phthalates concentration limits be imposed:

- (a) the plasticized parts of a toy or child care article (defined as a product that is intended to facilitate the relaxation, sleep, hygiene, feeding, sucking or teething of a child under 48 months of age) should not contain an aggregate weight of DEHP, DBP and BBP which is more than 0.1% (equivalent to 1,000mg/kg); and
- (b) the plasticized parts of a toy or child care article that can be placed in the mouth of a child under 48 months of age should not contain an aggregate weight of DINP, DIDP and DNOP which is more than 0.1% (equivalent to 1,000mg/kg).

3.4 Products that contain phthalates in excess of any of the prescribed limits will be deemed to be unsafe under the Ordinance. Offence provisions and enforcement actions under the Ordinance (paragraphs 1.4 and 1.5 of section 1) will apply.

3.5 To implement the above proposals, we will need to amend the Ordinance.

SECTION FOUR

COMMENTS WELCOMED

4.1 We welcome views from the public on the proposal set out in section three. Please send us your views on or before 19 January 2013 by mail, facsimile or email to the following address:

Address : Special Duties Division
Commerce, Industry and Tourism Branch
Commerce and Economic Development Bureau
23/F, West Wing, Central Government Offices,
2 Tim Mei Avenue, Tamar, Hong Kong
Fax number : 2869 4420
Email address : tcpso_phthalates_2012@cedb.gov.hk

4.2 It is voluntary for members of the public to supply their personal data when providing views on this consultation document. Any personal data provided with a submission will only be used for the purpose of this public consultation exercise. The submissions and personal data collected may be passed to relevant Government bureaux and departments for purposes directly related to this consultation exercise.

4.3 We may publish the submissions made in response to this consultation note for public viewing after the conclusion of the public consultation exercise. If you do not wish your name or your affiliation (or both) to be disclosed, please state so when making your submission.

4.4 Any sender providing personal data to us in the submission will have the rights of access and correction with respect to such personal data. Any requests for data access or correction of personal data should be made in writing to:

Address : Special Duties Division
Commerce, Industry and Tourism Branch
Commerce and Economic Development Bureau
23/F, West Wing, Central Government Offices,
2 Tim Mei Avenue, Tamar, Hong Kong

Fax number : 2869 4420

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