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# Safety Issues of Baby Bottles and Children's Tableware

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Centre for Food Safety
Food and Environmental Hygiene Department
The Government of the Hong Kong Special Administrative Region

Correspondence:
Risk Assessment Section
Centre for Food Safety,
Food and Environmental Hygiene Department,
43/F, Queensway Government Offices,
66 Queensway, Hong Kong.
Email: enquiries@fehd.gov.hk

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## EXECUTIVE SUMMARY


The Centre for Food Safety (CFS) has conducted a literature review on the safety issues on baby bottles and children's tableware and discussed the health concerns of the potential migration of chemicals from these products. On the basis of the review, advice to the public on safe use of baby bottles and children's tableware and to the trade on the good manufacturing practices was formulated.

2. The safety of baby bottles and children's tableware is important because infants and children are more susceptible to the potential adverse effects caused by chemical contaminants. Of all materials, plastics are the most common materials used for children's tableware because they do not break easily and are economical. Therefore, people are concerned more about the chemicals in plastic tableware in generally.

<u>The study</u>

3. This study discussed the properties, uses, safety and regulatory control on different food contact materials commonly used in baby bottles and children's tableware. The study focused on the two plastic materials, polycarbonate (PC) and melamine because the potential health risks associated with bisphenol A (BPA) from polycarbonate (PC) baby bottles and formaldehyde from melamine-ware have recently received high attention not only from scientists but also regulatory bodies and the public around the world. The study also briefly discussed other plastic and non-plastic materials.

4. Migration of chemicals including raw materials, additives, reaction products and contaminants originating from different food contact materials may migrate into foods at various stages of processing of the products. Whether a chemical would pose health risks to consumer depends on its toxicity and amount of the chemical migrated into the foodstuff. Therefore only inert materials can be used for food contact. In general, migration of chemicals from food contact materials increases with temperature, contact time, fat content and acidity of the food that they come into contact with. Plastic materials are particularly sensitive to the fat content and temperature of the food since many of the components in these materials are oil soluble and plastics have relatively low heat resistance compare to some non-plastic materials such as metals and ceramics. On the other hand, the major concern on metals and ceramics is the migration of heavy metals such as lead and cadmium. The migration of heavy metals in metal-ware may increase when the article comes into contact with highly acidic foods.

5. For BPA, some recent studies in experimental animals suggested that low levels (i.e. doses below the no-observable-adverse -effect level (NOAEL) found in animal studies) of BPA may have adverse effects on brain and behaviour during the developmental period and on reproductive system while other studies indicated no such effect. The Joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Expert Meeting in 2010 considered that, based on current knowledge of BPA, it was premature to use study results of low-dose of BPA in experimental animal to realistically assess the human health risk.

6. However, risk assessment by major national food safety authorities showed

that migration of BPA from PC baby bottles under typical conditions of use was extremely low and many samples had migration levels below the limit of detection and exposure levels to BPA of infants and young children were well below the safety reference dose. Nevertheless, regulatory authorities from Mainland China, European Union (EU) and Canada have taken precautionary measure to ban the use of BPA in baby bottles while authorities from the US and Australia have encouraged a voluntary phase out of BPA in baby bottles by the industry. The CFS supports the industry's actions to stop producing and selling BPA-containing baby bottles and infant feeding cups.

7. Regarding formaldehyde, improperly processed melamine-ware may result in excessive migration of formaldehyde. Formaldehyde can also be found naturally in food including fruits and vegetables (e.g. pear, apple, green onion), meats, fish (e.g., Bombay-duck, cod fish), crustacean and dried mushroom, etc. with levels up to 400 mg/kg. Ingestion of a small amount of formaldehyde is unlikely to cause any acute effect. The Mainland China and European Union have set specific migration limits for chemicals including formaldehyde from melamine-ware. The compliance of these standards indicates that the products are safe for food use.

8. Nowadays, many "BPA" free plastic materials have become available including polypropylene (PP) with nano-silver, polyethersulfone (PES), Tritan copolyester (PCTG), polylactic acid (PLA), etc. However, data on the safety of these plastic materials are limited. The Joint FAO/WHO Expert Panel considered that any new or existing materials would need to be assessed for functionality and

safety.

Summary and Recommendations

9. Baby bottles and children’s tableware that comply with safety standards are not supposed to pose health risk to consumers. The responsibility to ensure safety compliance of food contact materials rests with the manufacturers and they must ensure that their products will not release any substance in an amount that causes food safety or quality problems under normal use.

10. When choosing baby bottles and tableware for children, parents should consider the conditions of use of the article such as whether the article is intended to hold hot, fatty or acidic foods, or be used in microwave oven, etc. Parents should always follow manufacturer’s instruction and not to misuse the food contact materials.

**Risk Assessment Studies –**

## *Safety Issues of Baby Bottles and Children's Tableware*

### OBJECTIVES

This study aims to review the safety issues on baby bottles and tableware for infants and young children and discuss the health concerns of the potential migration of chemicals from food contact materials commonly used in these products.

### BACKGROUND

2. With the growing public interest in health, people not only concern about food safety but also the safety of tableware especially those intended for infants and young children. Young children have higher exposure to chemical hazards because they consume more food per kilogram of body weight than adults and the food contact material area to food mass ratio is higher due to smaller containers they used. They are also more vulnerable to the adverse effects of chemical hazard due to the immaturity of their physiological systems.[1] Therefore, food safety issues on baby bottles and children tableware draw public attention.

3. Of all materials, plastics are the most common materials used for children's tableware because they do not break easily and are economical. However, there are concerns over migration of chemicals in plastic tableware. For examples, bisphenol A (BPA) in baby bottles and plasticisers such as di (2-ethylhexyl) phthalate (DEHP) in food packaging materials have been under spotlight in recent years. In fact, chemicals originating from different food contact materials might migrate into food at various stages of processing of the products. For instance, the major concern on metals and ceramics is the migration of heavy metals such as lead and cadmium.

Furthermore, the migration of heavy metals in metal-ware is increased when the article comes into contact with highly acidic food.[2] The chemical nature of the food and the conditions of contact, particularly the time and temperature, will influence the type and amount of substances that migrate from the material into the foodstuff. In general, migration increases with temperature, fat content and acidity of the food and contact time.[3] Whether a chemical would pose health risk to consumer depends on its toxicity and the amount migrated into the foodstuff. Therefore, only inert materials, regardless of whether they are natural or synthetic, should be used for food contact.

***Baby bottles***

4. Ever since the invention of plastic bottles, they have become popular alternatives to glass bottles due to their durability, high impact resistance and low cost. Over the past several decades, polycarbonate (PC), a hard and clear plastic, bottles dominated the market. However, there have been reports in recent years saying that BPA, the monomer (building block) of PC, may cause adverse health effects in human. The safety of BPA has been the subject of much debate and attracted much media and public attention. Consequently, PC bottles are becoming less popular and many "BPA-free" baby bottles emerged in response to consumer preference.

5. "BPA-free" plastic baby bottles currently available locally include polypropylene (PP), polyethersulfone (PES), polyphenylsulfone (PPSU) and polyamide (PA) bottles. On the other hand there is a growing number of consumers who opt for non-plastic materials and embrace the return of traditional glass baby bottles. In addition, stainless-steel and silicon baby bottles are other alternatives although they are not as common as glass and plastic bottles in local market.

***Children's tableware***

6. Melamine-ware is the most common type of plastic tableware. Due to its durability, high heat resistance and low cost, it is widely used in household and food premises. Since the outbreak of melamine-tainted milk incident in the Mainland in 2008 that caused renal stones in infants and children, some people began to worry that melamine from melamine-ware can also get into foods and drinks and caused safety problems. With media reporting leaching out of melamine from melamine-ware every now and then, food safety issues surrounding melamine-ware have continued to attract public attention. Besides melamine, materials commonly used in children tableware are polypropylene (PP), acrylonitrile butadiene styrene (ABS), ceramic, stainless steel, etc.

## Regulatory Control

International perspective

7. The only available international reference from Codex for packaging materials is a guideline level of 1.0 mg/kg set for vinyl chloride monomer. Codex has also established guideline levels for two food contact substances, vinyl chloride monomer (0.01 mg/kg) and acrylonitrile (0.02 mg/kg), in food.[4] For other chemicals in food packaging materials, there are no Codex standards. For individual countries, the degree of control of food contact materials varies significantly among them.

8. Both the United States (US) and the European Union (EU) have very complex regulations covering the raw materials and additives that can be used in the manufacture of food contact materials. When necessary, these regulations also establish restrictions such as migration limits and residue limits of chemical substances. The US Food and Drug Administration (FDA) has required pre-market

approval for all food additives since 1958. Food contact materials are classified as indirect food additives. The regulations for indirect food additives laid down positive lists of permitted substances, which were published in Title 21 of the US Code of Federal Regulations. Conditions for use of an additive may include temperature, food type, use level in a material, and whether the food contact article is single use or repeated contact as in food processing equipment. Essentially, the regulations prescribe the levels of exposure to the additive which is considered to be safe. Manufacturers of food contact materials or new additives are required to demonstrate the safety of the material for use under appropriate contact conditions.[5]

9. In EU, food contact materials and articles are regulated by (i) Framework Regulation EC 1935/2004 which set out general requirements for all food contact materials. (ii) Legislation on specific materials which contains groups of materials and articles namely plastics, ceramics, regenerated cellulose film, elastomers and rubbers in the Framework Regulation, (iii) Directives on Individual Substances or groups of substances used in the manufacture of materials and articles intended for food contact such as vinyl and nitrosamines, and (iv) National legislation covering groups of materials and articles for which EU legislation is not yet in place.[6]

10. In Mainland China, there are regulations for the control of specific types of food contact materials such as plastic, paper, ceramics and stainless steel. The China National standard (GB 9685-2008) “Hygienic standards for uses of additives in food containers and packaging materials” made reference to the standards of the US and the EU.[7] For chemicals in food contact materials that have potential adverse effects (e.g. BPA and phthalates), particularly on infants and young children, both Mainland China and EU have set some specific restrictions on their usage. [7,8,9,10]

11. The standards of US and EU are also referenced by other countries such as Australia and New Zealand.[11,12] The New Zealand Food Safety Authority considered that the compliance with internationally recognised standards such as those of the EU and US, and the Australian standards is reasonable evidence that materials are suitable for food use.[12] Although there is not a set of harmonised food contact legislation worldwide, the general principle is that the chemical migration from food contact materials and articles into foodstuffs should not endanger human health.

<u>Local situation</u>

12. The safety of consumer goods, including baby bottles and tableware intended for young infants and children ordinarily supplied for private use in Hong Kong are controlled under the Consumer Goods Safety Ordinance (CGSO), Cap 456, which is enforced by the Customs and Excise Department (C&ED).

13. Under CGSO, it is an offence for any person to manufacture, import or supply consumer goods which fail to comply with the general safety requirement. The requirement imposes a duty on manufacturers, importers and suppliers of consumer goods to ensure that the consumer goods they supply are reasonably safe, having regards to all the circumstances including: (a) the manner in which and the purposes for which the goods are sold; (b) the use of marks, instructions or warnings on the goods in connection with their keeping, use or consumption; (c) compliance with reasonable safety standards published by a standards institute; and (d) the existence of reasonable means to make the goods safer. C&ED regularily monitor the safety of food contact materials such as baby bottles and tableware supplied on the

local markets. Product failing to comply with the general safety requirement should not be supplied on the local market.

14. On the other hand, the safety of food utensils used by local food businesses is overseen by Food and Environmental Hygiene Department (FEHD) according to the Public Health and Municipal Services Ordinance (PHMSO). Under the Food Business Regulation of the PHMSO, every person who carries on any food business shall ensure that all equipment and utensils are kept clean and free from noxious matters.

## SCOPE OF STUDY

15. The study discussed the safety issue on chemical safety of baby bottles, teats and children's tableware for repeated use including sippy cups, cups, bowls, plates, divided food plates, meal boxes, water bottles, chopsticks, knives, forks, spoons, drinking straws, etc. Food contact materials and the potential migrants from these materials are numerous. The study focused on the two plastic materials, polycarbonate (PC) and melamine that have recently received high attention not only by scientists but also regulatory bodies and the public around the world. The study also briefly discussed the safety issues of the specific components, additives and/or contaminants in other plastic materials (i.e polypropylene (PP), polyethersulfone (PES)/polyphenylsulfone (PPSU), polyamide (PA), polystyrene (PS), acrylonitrile butadiene styrene (ABS), polyvinylchloride (PVC), polyethylene (PE), polyethylene terephthalate (PET) polypropylene (PP) with nano-silver, Tritan copolyester (PCTG), and polylactic acid (PLA)) and non-plastic materials (i.e. glass, ceramics, rubber, silicon, stainless steel, aluminum, wood and bamboo).

**Literature Search Strategy and Sources of Information**

16. To identify literature relevant to the research questions, multiple database searches were conducted using internet search engines. Academic resources were obtained via google scholar, EBSCO databases, informaworld database and Wanfang data. Searches for internet resources were conducted through the search engine Google.

17. The major key words used including “baby bottles and safety”, “tableware and safety”, “children’s tableware and safety”, “bisphenol A”, “polycarbonate”, “formaldehyde” and melamine-ware”, etc. All search terms were limited to publication dates ranging from 1980-2011 (inclusive) and with English or Chinese versions available.

18. In addition, references were also made to relevant publications from international and national food safety authorities such as the World Health Organization (WHO), Food and Agriculture Organization of the United nation (FAO), European Food Safety Authorities (EFSA), US Food and Drug Administration (FDA), Food Standards Australia New Zealand (FSANZ), Health Canada, UK Food Standards Agency (FSA) and Federal Institute for Risk Assessment (BfR) of Germany. General information of different food contact materials were searched from the websites the International Life Science Institute (ILSI) and some trade associations such as Plastics New Zealand, British Plastics Federation, PlasticsEurope, British Stainless Steel Association, the American Ceramic Society, and the Aluminum association. Reference lists of the retrieved documents were hand searched to identify additional publications. Items that have been quoted or made direct reference to were listed in the reference section.

# FOOD CONTACT MATERIALS

## I. Polycarbonate (PC)

19. Polycarbonate (PC) is a light weight and high-performance plastic commonly used in a variety of plastic products including baby bottles food containers.[13] PC is commonly formed with the reaction of BPA (produced through the condensation of phenol with acetone under acidic conditions) with carbonyl chloride in an interfacial process. PC falls into the polyester family of plastics. PC plastics are strong, stiff, hard, tough, transparent engineering thermoplastics that can maintain rigidity up to 140$^{o}$C and toughness down to -20$^{o}$C or even lower for some special grades.[14] The durability, shatter resistance, high heat resistance and glass-like appearance of PC make it an ideal replacement for glass. PC does not have a specific plastic identification code and are identified as "other" or number "7".[15]

20. The monomer (building block) of PC, bisphenol A (BPA), has been used in food contact materials for more than 40 years. However, some recent studies in experimental animals suggested that low levels (i.e. dose below the no-observable-adverse-effect levels found in animal studies) of bisphenol A (BPA) might have adverse effects on nervous system and behaviour during the developmental period and on reproductive system while other studies indicated no such effect. This has led to controversy within the scientific community about the safety of BPA, as well as considerable media attention.[16]

### Bisphenol A (BPA)

21. BPA is also known by its proper chemical name, 2,2-bis(4-hydroxyphenyl)

propane. It is a high-production-volume industrial chemical that is widely used in the production of PC and epoxy resins, as well as other applications.[17] BPA may migrate from food packaging, such as plastic containers (including baby bottles) and coated food cans, into the food. Food is a major source of human exposure to BPA. Other less important sources of BPA are house dust, soil or toys, dental treatments and thermal papers (e.g. cash register receipts).[16]

**Toxicity of BPA**

22. There are major species differences in toxicokinetics of BPA between rodents and humans in the way that BPA handled in the body.[18] In rats, orally administered BPA is eliminated slowly, with terminal elimination half-lives between 20 and 80 hours.[19] In primates, including humans, orally administrated BPA is rapidly absorbed from the gastrointestinal tract and readily metabolised primarily into BPA-glucuronide in the gut and liver. BPA-glucuronide is rapidly eliminated by urinary excretion within 6 hours.[16] Recent human data and data in young monkeys revealed that even human premature infants can metabolise and excrete BPA efficiently.[17]

23. BPA has low acute toxicity. There are no indications of any genotoxic or carcinogenic effects. However, BPA belongs to a group of substances which can act in a similar way to oestrogen and as such are described as “endocrine disrupters”. The major concerns on BPA are its low-dose effects on reproductive system and neurobehaviour during the developmental period in experimental animals.[17]

*Developmental and reproductive toxicity*

24. The low-dose effects of BPA effects on fertility and reproduction and the

endocrine system in rodents have been subject to much scientific debate. The effects of BPA reported in some studies at low doses in sensitive animal system included developmental toxicity to the prostate, urinary tract and early onset of puberty in females. The National Toxicological Program (NTP) of the US considered that the possibility that BPA may alter human development cannot be dismissed, based on the fact that the estimated exposures in pregnant women and fetuses, infants, and children are similar to levels of BPA associated with several "low" dose experimental animal findings of effects on the brain and behavior, prostate and mammary gland development, and early onset of puberty in females.[20]

25. However, a recent two-generation reproductive toxicity study in mice performed under Good Laboratory Practice did not confirm the presence of low-dose effects. BPA administration in the low-dose range did not result in changes in reproductive organs or performance and gave an overall NOAEL of 5 mg/kg bw/day, with liver toxicity as the most sensitive endpoint.[21] The European Food Safety Authority (EFSA) in 2010 considered that valid studies do not raise concern regarding reproductive and developmental toxicity of BPA at doses lower than 5 mg/kg bw/day.[17] The Joint FAO/WHO Expert Meeting in 2010 considered the "new" studies since 2008 and a recent draft review of BPA and integrated these with the existing data to provide an overall summary of the potential low-dose effects (below 1 mg/kg bw/day) of BPA that may be relevant to human health. However, the Expert Meeting concluded that there was considerable uncertainty as to whether BPA has any effect in rodents on conventional reproductive and developmental endpoints at dose below 1 mg/kg bw per day by the oral or subcutaneous route.[16]

*Developmental neurotoxicity*

26. Several studies in rodents have investigated neurotoxic endpoints and suggested that at dietary exposure to BPA below 5 mg/kg bw/day during development can cause alterations in brain development and behaviour. These doses were relevant to human exposure. The Joint FAO/WHO Expert Meeting in 2010 considered the methodological limitations of these low-dose studies introduced uncertainty in interpretation of the findings. Therefore, further investigation was necessary to address the uncertainty.[16]

*Other chronic effects*

27. Several studies demonstrated immunotoxicity, cardiovascular effects and effects on metabolism of BPA in experimental animals. The Joint FAO/WHO Expert Meeting and EFSA in 2010 considered the currently available data are not sufficient to conclude these effects of BPA.[16,17]

*Human studies*

28. Some recent epidemiological studies have suggested associations of BPA exposure and adverse health effects (i.e. increase incidence of cardiovascular disease and diabetes, enhanced liver enzymes, reduced semen quality, caused male sexual dysfunction in adults and behavioural changes (aggression and hyperactivity) in young girls. Some of these studies have shortcomings in the design such as the use of data from self-reported diagnosis of pre-existing chronic diseases and incomplete assessment of occupational co-exposure of other chemicals. The Joint FAO/WHO expert meeting in 2010 commented it was difficult to draw any conclusions from these studies.[16] EFSA in 2010 also identified some limitations in these studies. It commented that it could not draw any relevant conclusion for risk assessment from

those studies.[17]

*Safety Reference value of BPA*

29. EFSA adopted an opinion on BPA on 29 November 2006 and re-established a tolerable daily intake (TDI) of 0.05 mg/kg bw for BPA. The TDI is established based on an NOAEL of 5 mg/kg bw/day of a comprehensive three-generation study in the rat and in a recent two-generation reproductive toxicity of BPA in mice and an uncertainty factor of 100. EFSA considered that the application of the uncertainty factor of 100 as conservative since there was a low level of free BPA in humans compared with rats.[18] This TDI was reconfirmed by EFSA in 2008 and 2010.[17,19]

**Migration limit for BPA**

30. According to the European Commission Regulation (EU) No 10/2011, the specific migration limit of BPA from food contact materials is 0.6 mg/ kg food.[22]

**Migration of BPA from polycarbonate baby bottles**

31. The potential for traces of BPA to migrate from PC baby bottles has been extensively studied by researchers around the world. It is generally agreed that migration of BPA from PC baby bottles under typical conditions of use is extremely low and many samples had migration levels below the limit of detection. The maximum migration level of BPA under worst-case realistic uses was defined as 15 µg/L by the Joint FAO/WHO Expert Meeting in 2010 for exposure estimation.[16] Some recent studies have explored the migration potential of BPA from old PC baby bottles and under elevated temperatures. These studies suggested that migration of bisphenol A from PC bottles increased with contact temperature and time but the overall levels were still well below safety limits.[23,24,25]

**Estimates of exposure to BPA**

32. The Food Standard Australia and New Zealand (FSANZ) has evaluated the safety of BPA in food, including that consumed by infants and concluded that levels of intake of BPA are very low and do not pose a significant human health risk for any age group. It found that extremely large amounts of foods and beverages would need to be consumed to reach the TDI for BPA. For example, to reach the safe level (TDI) for BPA: a nine month old baby weighing 9 kg would have to eat more than 1 kg of canned baby custard containing BPA everyday, assuming that the custard contained the highest level of BPA found (420 parts per billion) in a recent survey by CHOICE, a consumer group in Austraila.[26]

33. The Joint FAO/WHO Expert Meeting in 2010 estimated the international exposure to BPA. It considered a variety of possible scenarios of model diets, combining consumption from the worst-case scenario (100% of consumption from packaged food) to the best-case scenario (25% of consumption from packaged food) with concentration data reported from selected literatures. Consequently, a number of exposure estimates were derived.[16] The international estimates of exposure of all age groups by the Joint FAO/WHO Expert Meeting were well below the TDI of 0.05 mg/kg bw/day established by EFSA. This indicated health risk of all age groups due to current exposure of BPA is unlikely. The dietary exposure estimates for the four population groups are summarised in Table 1.

Table 1. Estimates of exposure of BPA

| Population | Source of exposure | Dietary exposure estimate (µg/kg bw/day) Mean | 95th percentile |
|---|---|---|---|
| Infant, 0-6 months | Exclusively breastfed | 0.3 | 1.3 |
| | PC bottles and formula[a] (powder-liquid) | 2.0-2.4 | 2.7-4.5 |
| | Formula, no PC bottles[a] (powder-liquid) | 0.01-0.5 | 0.1-1.9 |
| Infants, 6-36 months | Breastfed + solid food (best case-worst case)[b] | 0.1 | 0.3-0.6[c] |
| | PC bottles and formula + solid food (best case-worst case)[b] | 0.5-0.6 | 1.6-3.0[c] |
| | Formula only, no PC bottles[a] + solid food (best case-worst case)[b] | 0.01-0.1 | 0.1-1.5[c] |
| Children, 3+ years | Fruits, desserts, vegetables, meat, soups, seafood, carbonated drinks (best case-worst case)[b] | 0.2-0.7 | 0.5-1.9[c] |
| Adults | Fruits, vegetables, grains, meat, soups, seafood, desserts, carbonated drinks, tea, coffee, alcoholic beverages (best case-worst case)[b] | 0.4-1.4 | 1.0-4.2 [c] |

[a] Assumes formula only, no breast milk.

[b] Worst case is assuming the daily consumption of 100% packaged food and beverages, and the best case is assuming the daily consumption of 25% packaged food and beverages.

[c] Because of the use of the budget method model, maximum consumption is reported in these upper range of exposure estimates.

*TDI=50 µg/kg bw/day

**International perspectives**

34. The Joint FAO/WHO Expert Meeting in 2010 considered that it would be premature to conclude that animal studies on low-dose effects provide a realistic estimate of the human health risk, given the uncertainties of these studies.[16]

35. However, some countries have taken precautionary measures to reduce BPA exposure of the public. Canadian government added BPA to toxic substances list in the Canada Gazette in September 2010.[27] The listing allows it to develop regulations to manage the risks posed by the chemical. In Canada the prohibition of PC baby bottles that contain BPA was proposed in 2008 and came into force in 2010.[28]

36. The EU banned the manufacture of PC baby bottles with BPA in member states in March 2011 and products were banned from the EU marketplace, including imports in June 2011.[29] Before EU came to the decision to ban BPA in baby bottles, two of its member states France and Denmark had taken action to ban the manufacturing, the import, the export and the placing on the market of all baby bottles made with BPA. In addition, the French Food Safety Agency (AFSSA, now ANSES) recommended that any household containers and utensils that contain BPA must be labelled with appropriate warnings, indicating the risks to health by heating over certain temperatures and for too long.[30]

37. On Mainland China, the manufacture of PC baby bottles and other BPA containing baby bottles was banned from 1 June 2011. The importation and sales of polycarbonate baby bottles and other BPA containing baby bottles were banned from 1 September 2011.[31]

38. However, other countries such as the US, Japan, and Australia have not banned BPA in baby bottles. In the US, several states have banned or moved to ban BPA on children's products to different extent but BPA has not been banned at federal level. The current position of the USFDA is to support voluntary phase out of BPA in baby bottles and infant feeding cups in the US market by industries. Meanwhile, it is doing further studies to address the safety of BPA.[32]

39. In Japan, almost all domestic industries related to food containers have voluntarily taken measures to prevent BPA exposure since the 1990's, when the issue of low dose effects of BPA became public. Since then, high levels of exposure have not been reported from the containers in Japan. However, from the standpoint of pubic health, the Ministry of Health, Labour and Welfare (MHLW) of Japan stated that it would be appropriate to reduce BPA exposure as much as possible, and therefore urged related industries to promote further voluntary efforts. For consumers, MHLW created a FAQ document, including advice for pregnant women and infant care-takers, about diet and breast-feeding, in order to deepen their understanding of BPA.[33,34]

40. In Australia, the Parliamentary Secretary for Health announced the phase out of BPA in baby bottles by major retailers. The voluntary phase out is the result of months of constructive discussions between the Australian government and retailers. The phase out was effective on July 2010.[35] The FSANZ stated that the voluntary phase out of BPA in baby bottles is in response to consumer preference and demand and not an issue about product safety.[26]

41. Since PC baby bottles were either banned or phased out voluntarily in some

countries, consumers in these countries mainly use BPA-free plastic bottles or glass bottles. The Joint FAO/WHO Expert Panel noted some alternatives to PC bottles and containers are available on the market. However, at present, there appears to be no single replacement for BPA for all food contact applications. Furthermore, data on the safety of some of these replacement materials are limited or non-existent. For PC, replacement materials include those polymers that are currently used to make bottles and containers for food packaging applications, including glass, PP, PES, PET, HDPE, PVC, PA and silicone. An example of a new alternative to PC is Tritan copolyester (PCTG). It is important to note that any of these new or existing alternative materials would need to be assessed for appropriate functionality and safety using state of the art methodology and scientific knowledge.[16]

**Local situation**

42. The safety of consumer goods, including baby bottles ordinarily supplied for private use in Hong Kong is enforced by C&ED under the CGSO. Over the past three years (from January 2009 to October 2011), all samples of plastic baby bottles, drawn by the C&ED from the market for safety testing by the Government Laboratory were found to comply with the standard for BPA migration. CFS supports the industry's actions to stop producing and selling BPA-containing baby bottles and infant feeding cups and make efforts to replace BPA or minimise BPA levels in food can lining.

## II. Melamine

43. As a food contact material, melamine is commonly referred to melamine-formaldehyde (MF) resin. Melamine-ware is the most common type of plastic tableware. Due to its strong durability, good chemical and heat resistance

and low cost, it is widely used in household and food premises. Like ceramic tableware, melamine-ware has smooth and glossy surface that can be decorated with colourful patterns such as cartoon figures.[36] These properties made melamine-ware especially popular among children.

44. Melamine-ware is made by compression-moulding MF resin from powder or granular form. The heat and the pressure of the moulding process cure the resin to provide a thermoset plastic.[37] MF resin was found by a Swiss scientist in 1938 and patented by an US company in 1939. Since the 60s, China has started to produce melamine-ware and is now the world biggest producer of melamine-ware.[38] Tableware made of MF has good heat resistance. Most manufacturers specify a temperature of -30°C to +120°C while some specify a temperature of up to +140°C.

45. However, some tableware products sold as melamine-ware are made of urea-formaldehyde (UF) resin totally or are UF resin products with surface coating of MF resin powder.[38,39,40,41] UF resin is produced by a non-transparent thermosetting resin or plastic, made from urea and formaldehyde. According to the USFDA, urea-formaldehyde resin can be safely used as the food-contact surface of molded articles intended for use in contact with food under specified conditions.[42] In addition, urea, melamine, and formaldehyde are authorised substances for use as monomers and other starting substances in plastic in EU.[43] Urea-formaldehyde resin is a very hard, scratch-resistant material but it has lower heat resistance than melamine-formaldehyde resin. Tableware made of urea-formaldehyde resin usually has heat resistance up to +80°C only.[39]

**Release of formaldehyde from melamine-ware**

46. The migration of excessive formaldehyde is a major food safety concern of melamine-ware. The use of UF resin to replace MF resin for making melamine-ware is one of the causes of the inferior quality of the final products that released excessive formaldehyde.[37,39,44,45] UF resin is less stable than melamine-formaldehyde resin. The reactions leading to the formation of the urea-formaldehyde products formed during urea-formaldehyde resin synthesis and cure are reversible. Therefore UF products may leach out more formaldehyde than MF products..[39,46]

47. In addition, the migration of monomers from a polymer could be caused by residual monomers remain in the articles after the manufacture or break down of the polymer.[47] It was also suggested that a possible cause of the high formaldehyde migration but with no detectable melamine monomer migration could be due to use of an excess of formaldehyde precursor hexamethylenetetramine (HMTA) in the manufacture of the polymer. Hydrolysis of the excess HMTA residue in the article would result in the formation of formaldehyde and ammonia.[37] Therefore, melamine resin must be formulated precisely in order to minimize excessive and unreacted formaldehyde. Moreover, the moulding conditions have to be well controlled to ensure the complete polycondensation of monomers.[41]

***Formaldehyde***

48. Formaldehyde is used mainly in the production of phenolic, urea, melamine and polyacetal resins. These materials have wide uses as adhesives and binders for the wood products, pulp and paper, and synthetic vitreous fibre industries and in the production of plastics and coatings as well as in textile finishing.[48,49]

49. Formaldehyde can also be found naturally in food including fruits and vegetables (e.g. pear, apple, green onion), meats, fish (e.g., Bombay-duck, cod fish), crustacean and dried mushroom, etc. with levels up to 400 mg/kg.[50]

Toxicity of formaldehyde

50. Following ingestion, formaldehyde is readily absorbed from the gastrointestinal tract and converted to formate, which is further oxidised to carbon dioxide or incorporated into nucleic acids and amino acids. Excretion of formate in the urine is the other major route of elimination of formaldehyde. Formaldehyde has medium oral acute toxicity in experimental animals. Ingestion of a small amount of formaldehyde is unlikely to cause any acute effect. Acute toxicity after ingestion of large amount can cause severe abdominal pain, vomiting, coma, renal injury and possible death.[48,49]

51. The main health concern of formaldehyde is its cancer causing potential. The International Agency for Research for Cancer (IARC) in 2004 concluded that formaldehyde is genotoxic and is a human carcinogen (Group 1), based mainly on epidemiological evidence from occupational exposures via inhalation in industrial workers.[49] On the other hand, WHO in 2005 when setting its Drinking Water Guidelines considered that there was no definitive evidence for carcinogenicity upon ingestion. Animal studies showed that long-term exposure to high dose of formaldehyde in drinking-water might lead to pathological changes in the stomach and increase in kidney weights.[51]

52. The US Agency for Toxic Substances and Disease Registry has established the intermediate and chronic oral minimal risk level for formaldehyde at 0.3 mg/kg

bw/day and 0.2 mg/kg bw/day, respectively. Minimal risk level is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse non-cancer health effects over a specified duration of exposure, intermediate being 14-36 days and chronic being 365 days and longer.[52]

***Melamine***

53. Melamine (also known as 2,4,6-triamino-1,3,5-triazine) is an industrial chemical mainly used for the production of melamine resins, typically by reaction with formaldehyde.[53]

Toxicity of melamine

54. A study in rats showed that melamine is not metabolised and is rapidly eliminated via urine, with an elimination half-life in plasma of about 3 hours. Melamine is of low acute toxicity. The most commonly observed chronic effects in animal experiments where melamine was administered orally include reduced food consumption, body weight loss, bladder stones, crystalluria, epithelial hyperplasia of urinary bladder and lowered survival rate.[54,55] With reference to the data from the 2008 Chinese incident, it showed that infant formula contaminated mainly with melamine can result in stone formation if sufficient concentrations are present.[56] The IARC in 1999 noted that melamine was not genotoxic in experimental system and also classified melamine in Group 3, not classifiable as to its carcinogenicity to humans.[57]

55. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has not evaluated the safety of melamine and its structural analogues. Little human data on oral exposure to melamine were available before the 2008 outbreak of the infant

kidney stone cases in Mainland China. The WHO convened an expert meeting in collaboration with FAO supported by Health Canada in December 2008 to review the toxicological aspects of melamine and cyanuric acid. A TDI of 0.2 mg/ kg bw was established for melamine.[56]

**Migration limit of formaldehyde and melamine**

56. In Mainland China, the migration limits for melamine and formaldehyde is 0.2 mg/dm$^2$ and 2.5 mg/dm$^2$, respectively.[58] In the EU, formaldehyde and urea are approved for use as monomers or additives in plastics with a specific migration limit of 30 mg/kg (5.0 mg/dm$^2$) food for melamine and 15 mg/kg (2.5 mg/dm$^2$) food for formaldehyde. But there is no specific migration limit for urea.[42] In the US, it is specified that the moulded melamine-formaldehyde and urea-formaldehyde food-contacting articles when extracted with the solvent(s) characterising the type of food in contact and under the conditions as specified in 21 CFR 177, shall yield net chloroform-soluble extracts not to exceed 0.5 mg/in$^2$ (~7.8 mg/dm$^2$) of food-contact surface.[42,59]

**Migration studies on melamine-ware**

57. Some recent studies from Hong Kong and overseas countries including the UK, US, Thailand showed that melamine migration from melamine-ware in general was very low and unlikely to pose any health risk. However, leaching of excessive formaldehyde was found in some samples.[60,61,62,63,64] In 2008, the UK FSA commented that although sustained exposure to formaldehyde would probably have been necessary for health to be at risk, formaldehyde is a carcinogen by inhalation and a sensitiser, which may produce allergic dermatitis and transient irritation of the mouth. Therefore, non-compliant melamine-ware should not be sold in the market.[62]

**Estimates of exposure of melamine from melamine-ware**

58. The WHO/FAO Expert meeting in 2008 reviewed the available migration data of melamine-ware and agreed that concentrations of melamine in food are likely to be <1 mg/kg. Although there are some limited data on concentrations above 1 mg/kg, it was noted that the assays used harsh migration conditions (typically 3% acetic acid, 70$^{o}$C for 2h) that would not be encountered in practice.[56]

**Estimates of potential inhalative exposure of formaldehyde from melamine-ware**

59. The Federal Institute for Risk Assessment (BfR) of Germany in 2011 estimated the potential inhalative exposure of formaldehyde from melamine-ware and derived a tolerable air concentration as so-called “safe level” from animal testing data on cell proliferation as well as human data on sensory irritation of the upper respiratory tract of 0.1 ppm, which was 0.124 mg/m$^3$. This “safe level” was exceeded under the assumed conditions. BfR considered there was a potential consumer health hazard through inhalation exposure to formaldehyde even taking into account the relatively short exposure time. According to BfR, consumer goods made of melamine resins should not be used for cooking or in microwave ovens. However, the use of melamine resins at room temperatures and at temperatures of up to 70$^{o}$C (i.e. conditions such as those when hot beverages or foods are filled into cups, bowl, or onto plates) could be considered safe for human health.[65]

**International Perspective**

60. The Rapid Alert System for Food and Feed of the European Commission showed that some melamine-ware products originating in or consigned from

Mainland China and Hong Kong were found to have excessive migration of formaldehyde on several occasions in the past few years. As a result the EU has imposed import control of these melamine-ware. The requirements set out by the EC regulation include documentary checks on all consignments as well as identity and physical checks (including analysis of 10% of consignments). The regulation entered into force on 1 July 2011.[66]

**Local situation**

61. In Hong Kong, the safety of tableware including melamine-ware ordinarily supplied for private use is enforced by C&ED under the CGSO. Furthermore, the CFS conducted a study on the safety of melamine-ware available for use in local food premises in 2010. A total of 61 melamine-ware samples covering seven melamine-ware categories and nine brands were collected and analysed. Results showed that migration levels of both melamine and formaldehyde were all below the respective GB and EU limits. Proper use of these products is not expected to pose health risk to consumers.[67]

## III. Other Materials

62. There are other plastic and non-plastic materials commonly used in baby bottles and children's tableware. For plastic materials, PP is a very popular food contact materials nowadays. It is well-suited as a material for packaging and containers designed for use from freezer to microware.[68] Therefore, prior to the BPA issue, polypropylene bottles and plastic disposable bag liners have long been used as alternatives to PC nursing bottles.[69] PP is basically an inert material and does not present a health hazard to the consumer in either handling the plastics or consuming foodstuffs with which they have come into contact in general.

63. Currently, there are PP microwaveable containers incorporated with nano-silver particles for enhancing the anti-microbial properties of the material sold in local market. Some of these containers may be used as snack boxes for children. Nano particles in general refer to particles sized between approximately 1 and 100 nanometer in at least one dimension.

64. The BfR in 2009 commented the silver ions released from various silver compounds can damage living cells in different ways. The antimicrobial effect of silver is based on this mechanism. Nano-silver presents a particular situation. While the antibacterial effect of nano-silver is also based on the release of silver ions, due to the considerable surface-volume ratio and their special behaviour in the human body, they may also include other mechanisms of action. The nano-formulation of silver may cross biological barriers into the cell. These intracellular nano-silver particles constitute a deposit that continually releases silver ions. Hence, BfR recommended manufacturers to avoid the use of nanoscale silver or nanoscale silver compounds in foods and everyday products until such time that the data are comprehensive enough to allow a conclusive risk assessment which would ensure that products are safe for consumer health.[70] At present, nanoscale silver has not been authorised to be used in plastic for direct food contact at EU level. The only authorised nano-material for direct food contact by the EU is nanoscale titanium nitride which was shown to be chemically inert and would not migrate. It was restricted to be used in PET bottles up to 20 mg/kg.[10]

65. The WHO in 2008 considered that as for all new materials used in food and food processing, the potential health and environmental risks for nanoscale materials

need to be assessed before they are introduced into food.[71] Since there is no tenable evidence that food contact materials derived from nanotechnology is any safer or more dangerous than their conventional counterparts, no general conclusion can be made on the safety of food contact materials incorporated with nano-materials. As a precautionary approach, traders should not sell nano food contact materials that have not undergone safety assessment.

66. Regarding alternatives to PC baby bottles, polysulfone polymers, including PES and PPSU are very popular in local market. Their properties are very similar to that of PC. Although polysulfone polymers were approved food contact materials by the USFDA[72] and their monomers such as 4,4'-dichlorodiphenyl sulphone and 4,4'-dihydroxydiphenol sulphone were authorised by EU[73], they have undergone far fewer tests than BPA. In fact, 4,4'-dihydroxydiphenol sulphone known as Bisphenol S is a BPA-like material. The French Food Safety Agency (AFSSA) in 2010 stressed the importance of a rigorous risk assessment process for any products being considered as substitutes for bisphenol A. AFSSA in 2010 opined that the use of bisphenol S (the PES monomer) in baby bottles was assessed in 2000 by the Scientific Committee for Food (SCF) based on only four toxicity studies only and considered it important to reassess the alternative products to BPA/PC currently on the market and the relevance of such reassessment should be soon discussed at the European Community.[74]

67. A relative new replacement of PC that has been mentioned by the Joint FAO/WHO expert meeting in 2010 was Tritan copolyester (PCTG). Nowadays, PCTG water bottles especially those intended for children are very common in local market. The toxicity data related to this copolyester and its monomers were mainly

provided by its developer, Eastman Chemical Company. Based on available data, FDA has approved this copolyester be used as repeated use food contact articles for contacting all type of foods at temperature up to 100$^{o}$C.[75]

68. Another relatively new plastic material currently used in children's tableware is polylactic acid (PLA). PLA tableware is marketed as biodegradable plastic. The monomer lactic acid is derived from renewable resources such as corn starch. Lactic acid does not present any health risk to consumers.[76]. However, PLA tableware has relatively low heat resistance and is not suitable for contact hot food at temperature above 80$^{o}$C according to the product specification provided by manufacturers. Otherwise, excessive migration might occur and that can affect the organoleptic characteristics of foods.

69. The Joint FAO/WHO Experts Meeting in 2010 opined that data on the safety of some plastic materials are limited or non-existent and it was important to note that any of these new or existing alternative materials to PC would need to be assessed for appropriate functionality and safety.[16] In fact, other than PC alternatives mentioned above, there are a wide variety of materials used in baby bottles and children's tableware that worth further study. It should be noted that although chemicals originating from different food contact materials may migrate into foodstuffs, it is not necessarily mean that there would be a health risk. In general, inert food contact materials that have chemical migration comply with safety standards are unlikely to pose health risk to consumers. The properties, uses, major chemicals of concern of these materials are summarised in Annex I and Annex II, respectively.

## SUMMARY AND RECOMMENDATIONS

70. Baby bottles and children's tableware that comply with safety standards are not supposed to not pose health risk to consumers. The responsibility to ensure safety compliance of food contact materials rests with the manufacturers and they must ensure that their products will not release any substance in an amount that causes food safety or quality problems under normal use.

71. When choosing baby bottles and tableware for children, parents may consider various factors such as safety, durability, the ease of cleaning and handling, price and environmental criteria. However, for safety, parents should consider the conditions of use of the article, for example, whether the article is suitable for holding hot, fatty or acidic foods, or microwave cooking, etc. Parents should always follow manufacturer's instruction and not to misuse the food contact materials as this may result in greater amounts of chemical migration than would otherwise be expected.

### Advice to Public

*General advice*

Purchase

- Obtain baby bottles and children's tableware from reliable retailers.
- For plastic baby bottles and tableware, choose those with product specifications and user instructions.

Use

- Avoid using tableware that is broken or damaged on its surface.
- Use tableware according to manufacturer's instructions especially on the temperature limitation and instructions on microwave and freezer uses.

- Avoid using plastic tableware to hold hot fatty food or highly acidic foods for long period of time.
- Avoid using metal tableware to hold highly acidic foods for long period time.

<u>Cleaning</u>

- Do not use abrasive detergents and cleaning tools or strong chemicals which will damage the surface of tableware.
- Only use tableware that is labelled as dishwasher-safe and steamer-safe for dishwasher cleaning and steam sterilization, respectively.

*Baby bottles*

When using baby bottles, parents should always follow the instructions on the infant formula for preparation and use. The following advice applies to all baby bottles or cups, whatever type of plastic they are made from:

- Discard any scratched bottles or feeding cups as they may harbour germs. However, there is no need to replace old bottles unless they are damaged or scratched.
- Try to avoid putting boiling or very hot water, infant formula, or other liquids into bottles while preparing them for your child. However, water used to reconstitute powdered infant formula for infant no more than 12 months should be boiled and left for no more than 30 minutes, to ensure it is still hot enough (no less than 70ºC) to kill harmful bacteria potentially inherent in the powder.
- Do not heat baby bottles of any kind in the microwave - the liquid may heat unevenly and burn your baby.
- Sterilise and clean bottles according to instructions on infant formula labels and

they should be left to cool to room temperature before adding infant formula.

- Parents who are concerned with BPA exposure can choose to use alternatives to PC baby bottles such as glass bottles.

**Advice to Manufacturers and Retailers of Tableware**

- Manufacturers should adopt good manufacturing practices and make sure baby bottles and tableware comply with recognised standards such as those of the EU, the USFDA, and Mainland China.
- Manufacturers should provide product specifications and user instructions including temperature limitations and any restrictions on use.
- Retailers should obtain baby bottles and tableware from reliable manufacturers and ensure the products are of suitable quality for food use.
- CFS supports the industry’s actions to stop producing and selling BPA-containing baby bottles and infant feeding cups.

**Advice to Food Businesses**

- Obtain tableware from reliable manufacturers and suppliers and use tableware of suitable quality to serve food to customers.
- Use tableware according to the product specifications and user instructions

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**ANNEX I**

## Overview of Other Common Plastic Materials Used in Baby Bottles and Children's Tableware

| Materials | Symbol[a] | Uses | General Properties[b] | Major migrant(s) of concern | Adverse Health Effects of the concerned migrants | Relevant Regulations[c] |
|---|---|---|---|---|---|---|
| Polyethylene Terephthalate (PET) | 1 PET<br>or<br>1 PETE | Water bottles | Clear, good chemical resistance, barrier to gas, withstand temperature up to ~80°C | Antimony (catalyst) | Chronic, occupational exposure to antimony led to myocardial effect.[1] IARC (1989) classified antimony trioxide in Group 2B (possibly carcinogenic to humans).[2] | -(EU) No 10/2011<br>-21CFR 177.1630<br>-GB 13113-1991<br>-GB 9685-2008 |
| High Density Polyethylene (HDPE)<br><br>Low Density Polyethylene (LDPE) | 2 HDPE<br><br>4 LDPE | Flexible cup lids | Hard to semi-flexible, opaque, good chemical resistance, withstand temperature up to ~75°C | Octadecyl 3- (3 5-di-tert-butyl-4-hydroxyphenyl) propionate/ Iganox 1076 (antioxidant) | Chronic exposure to high doses affected liver of experimental animals.[3] | -(EU) No 10/2011,<br>-21CFR177.1520,<br>-GB 9687-1988<br>-GB 9685-2008 |

| Materials | Symbol[a] | Uses | General Properties[b] | Major migrant(s) of concern | Adverse Health Effects of the concerned migrants | Relevant Regulations[c] |
|---|---|---|---|---|---|---|
| Polyvinyl Chloride (PVC) |  or  | Drinking straws | Unplasticised PVC: hard, brittle withstand temperature up to ~80°C<br>Plasticised PVC: flexible and elastic | Vinyl chloride (monomer) | Occupational exposure to high doses is associated with significant increases in the incidence of cancer at multiple organ sites.[4] IARC (in prep)* classified it in Group 1 (carcinogenic to humans).[2] | -CAC/GL 6-1991<br>-(EU) No 10/2011,<br>-GB 9681-1988<br>-GB 9685-2008 |
| | | | | DEHP (additive: plasticiser) | Chronic exposure to high doses affected liver, kidney, reproduction and development in experimental animals.[5] IARC (in prep) classified it in Group 2B.[2] | |

* In prep denotes the publication of the IARC classification is in preparation of as at 17 June 2011.

| Materials | Symbol[a] | Uses | General Properties[b] | Major migrant(s) of concern | Adverse Health Effects of the concerned migrants | Relevant Regulations[c] |
|---|---|---|---|---|---|---|
| Polypropylene (PP) | 5 PP | Baby bottles, drinking straws, tableware, microwavable ware | Hard to semi-flexible, opaque, chemicals resistance,withstand temperature up to ~140$^{o}$C | Octadecyl 3- (3 5-di-tert-butyl-4-hydroxyphenyl) propionate/ Iganox 1076 (antioxidant) | Chronic exposure to high doses affected liver in experimental animals.[3] | -(EU) No 10/2011,<br>-21CFR177.1520,<br>-GB 9688-1988<br>-GB 9685-2008 |
| Polystyrene (PS) | 6 PS | Sippy cups | Clear, glassy, rigid, brittle, affected by fats and solvents. withstand temperature up to ~95$^{o}$C | Styrene (monomer) | Toxic to central nervous system in humans through inhalation.[6] IARC (2002) classified it in Group 2B.[2] | -(EU) No 10/2011,<br>-21CFR177.1640<br>-GB 9689-1988<br>-GB 9685-2008 |

| Materials | Symbol[a] | Uses | General Properties[b] | Major migrant(s) of concern | Adverse Health Effects of the concerned migrants | Relevant Regulations[c] |
|---|---|---|---|---|---|---|
| Polyamide (PA) |  | Baby bottles | Clear, amber, hard, good chemical resistance, withstand temperature up to ~170$^{o}$C | Caprolactam (monomer) | Chronic exposure to large dose caused developmental toxicity in experimental animals.[7] IARC (1999) classified it in Group 4 (probably not carcinogenic to humans).[2] | -(EU) No 10/2011, -21CFR177.1500 -GB 16332-1996 -GB 9685-2008 |
| Polysulfone (PES, PPSU) | PES, PPSU | Baby bottles | Clear, amber in colour, hard, good chemical resistance, good withstand temperature up to ~200$^{o}$C | 4,4'-dichloro-diphenylsulphone (monomer) | Chronic exposure affected liver, kidney, and CNS in animal studies.[8] | -(EU) No 10/2011, -21CFR177.2440 -GB 9685-2008 |
| | | | | 4,4'-dihydroxydi-phenol sulphone/ bisphenol S (monomer) | Potent inducer of methaemoglobinemia in rats and human.[9] | |

| Materials | Symbol[a] | Uses | General Properties[b] | Major migrant(s) of concern | Adverse Health Effects of the concerned migrants | Relevant Regulations[c] |
|---|---|---|---|---|---|---|
| Polylactic acid (PLA) | 7 PLA | Bio-degradable tableware | Opaque, hard, brittle, withstand temperature up to ~80°C | lactic acid, lactide (monomer) | Adverse effect is not expected since lactic acid is a safe food substance.[10] | -(EU) No 10/2011,<br>-GB 9685-2008 |
| Tritan Copolyester (PCTG) | 7 PCTG | Reusable water bottles | Clear, hard, good chemical resistance, withstand temperature up to ~100°C | 2,2,4,4-tetramethyl-cyclobutane-1,3-diol (TMCD) (monomer) | Exposure to high doses affected adrenal gland and development in experimental animals.[11] | -(EU) No 10/2011,<br>-USFDA FCN No. 1041<br>-GB 9685-2008 |
| Acrylonitrile Butadiene Styrene (ABS) | ABS | Chopsticks and other tableware | Opaque, high impact resistance, good chemical resistance, withstand temperature up to ~80°C | Acrylonitrile | Chronic exposure of pregnant animals to acrylonitrile results in developmental toxicity, including malformations. IARC (1999) classified it in Group 2B.[2] | -CAC/GL 6-1991<br>-(EU) No 10/2011,<br>-21CFR177.1020<br>-GB 17327-1998<br>-GB 9685-2008 |

Notes: [a] Plastic identification codes or symbols marked on the articles. [b] Information are based on plastic associations from different countries (i.e. Plastics New Zealand, British Plastics Federation and PlasticsEurope), and specifications of products provided by manufacturers. Properties of food contact articles made of each plastic material may vary due to differences in formula, processing methods, technologies, etc. [c] Refer to regulations or standards stipulated by the Codex, European Commission, USFDA, and Ministry of Health of the People's Republic of China.

**ANNEX II**

## Overview of Common Non Plastics Materials Used in Baby bottles and Children's Tableware

| Materials | Uses | General Properties [a] | Major migrant(s) of concern | Adverse Health Effects | Relevant Regulations [b] |
|---|---|---|---|---|---|
| Glass and Ceramic | Baby bottles, tableware, microwaveable ware | Good heat and chemical resistance, low impact resistance, withstand temperature up to $\sim 400^{o}$C | Lead (contaminant from glaze or colour decoration) | Chronic exposure caused developmental neurotoxic effects in humans.[12] IARC (2006) classified inorganic lead compounds in Group 2A agent (probably carcinogenic to humans). [2] | -Directive 84/500/EEC 2005/31/EC<br>- USFDA CPG Sec. 545.450<br>- USFDA CPG Sec.545.400<br>- GB 13121-91<br>-GB 9685-2008 |
| | | | Cadmium (contaminant from glaze colour decoration) | Chronic exposure affected affect kidney in humans.[13] IARC (in prep) classified cadmium and cadmium compounds in Group 1.[2] | |

| Materials | Uses | General Properties [a] | Major migrant(s) of concern | Adverse Health Effects | Relevant Regulations [b] |
|---|---|---|---|---|---|
| Stainless steels | Baby bottles, tableware, thermoflasks | High heat and chemical resistance, high impact resistance, durable, melt at ~1300°C | Nickel (component) | Not poisonous in small quantities but can provoke a reaction in people allergic to nickel.[14] IARC (in prep) classified nickel compounds in Group 1 agents and in 1990 classified metallic nickel in Group 2B.[2] | -GB 9684-2011<br>-GB 9685-2008 |
| | | | Chromium (component) | Chronic excessive exposure to chromium (VI) caused development toxicity in experimental animals. Some people are allergic to chromium (VI) and (III).[15] IARC (in prep) and classified chromium (VI) in Group 1 and in 1990 classified metallic chromium and chromium (III) compounds in Group 3.[2] | |
| Aluminium | Drinking bottles | High impact and heat resistance, durable, melt at ~660°C | Aluminium (component) | Chronic exposure affected the reproductive system and developing nervous system in experimental animals.[16] | -GB11333-1989<br>-GB 9685-2008 |

| Materials | Uses | General Properties [a] | Major migrant(s) of concern | Adverse Health Effects | Relevant Regulations [b] |
|---|---|---|---|---|---|
| Rubbers | Feeding teats and soothers | Flexible, withstands temperature up to ~100$^{o}$C | Nitrosamines | Associated with increase cancer risk in humans.[17] IARC classified some nitrosamines compounds in Group 2A or 2B.[2] | -Directive 93/11/EEC,<br>-21CFR177.2600<br>-GB 4806.2-1994<br>-GB 9685-2008 |
| Silicone | Baby bottles, feeding teats and soothers, tableware, straws | Flexible, high heat resistance, withstand temperature up to ~200$^{o}$C | Volatile organic compounds (VOC), e.g. Silioxanes (monomers) | Chronic exposure to high doses affected liver in experimental animals.[18] | -21CFR177.2600 |
| Wood and bamboo | Chopsticks and other tableware | High impact and heat resistance, burn at ~300$^{o}$C | Formaldehyde (contaminant from lacquer and binder) | Animal studies showed that long-term exposure of high dose in drinking-water might lead to pathological changes in the stomach and increase in kidney weights.[19] The IARC (in prep) classified formaldehyde by inhalation in Group 1.[2] | -GB 19790.1-2005<br>-GB 19790.2-2005<br>-GB 9685-2008 |

Notes: [a] Based on information from British Stainless Steel Association, the American Ceramic Society, the Aluminum Association and specifications of food contact articles provided by manufacturers. Properties of food contact articles made of each material may vary due to differences in raw materials, formula, processing methods, technologies, etc. [b] Refer to regulations or standards stipulated by the European Commission, USFDA, and Ministry of Health of the People's Republic of China.

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**ANNEX III**

## Illustrations of Baby Bottles and Children's Tableware Made of Different Materials

| | | |
|---|---|---|
|  |  |  |
| Polycarbonate (PC) | Melamine | Polypropylene (PP) |
|  |  |  |
| Polyethylene Terephthalate (PET) | Polyethersulfone (PES) | Polyphenylsulfone (PPSU) |

| | | |
|---|---|---|
|  |  |  |
| Tritan Copolyster (PCTG) | Polylactic Acid (PLA) | Polystyrene (PS) |
|  |  |  |
| Polyamide (PA) | Acrylonitrile Butadiene Styrene (ABS) | Polyvinyl Chloride (PVC) |

| | | |
|---|---|---|
|  |  |  |
| Wood and bamboo | Ceramic and glass | Stainless steel |
|  |  |  |
| Aluminium | Silicone | Rubber |