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Evaluation of the potential health risks of substances migrating from polycarbonate replacement baby bottles

Birgit Mertens [a, *, 1], Els Van Hoeck [a, 1], Marie-Noëlle Blaude [a], Coraline Simon [b], Matthias Onghena [c], Tara Vandermarken [d], Kersten Van Langenhove [d], Heidi Demaegdt [e], Karin Vandermeiren [e], Adrian Covaci [c], Marie-Louise Scippo [b], Marc Elskens [d], Joris Van Loco [a]

[a] Department of Food, Medicines and Consumer Safety, Scientific Institute of Public Health (Site Elsene), J. Wytsmanstraat 14, Brussels, Belgium
[b] Department of Food Science, University of Liège - FARAH-Veterinary Public Health, Quartier Vallée 2, Avenue de Cureghem 10, Sart Tilman B43bis, Liège, Belgium
[c] Toxicological Center, Department of Pharmaceutical Sciences, University of Antwerp, Universiteitplein 1, Wilrijk, Belgium
[d] Department of Analytical, Environmental and Geo-Chemistry, Vrije Universiteit Brussel, Bd de la plaine 2, Ixelles, Belgium
[e] CODA-CERVA, Department of Chemical Safety of the Food Chain, Leuvensesteenweg, 17, Tervuren, Belgium

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ABSTRACT

Since the European Commission prohibited the use of bisphenol A in the production of polycarbonate (PC) baby bottles, many other materials have replaced PC for the manufacture of this type of food contact materials. In the present study, the potential migration risks associated with these alternative materials were investigated. First, all substances were evaluated for endocrine disruptive (ED) activity by using different existing lists of (suspected) ED chemicals. Next, the potential non-ED risks were assessed. A distinction was made between migrants listed in Annex I of European Regulation 10/2011 and the unlisted substances (e.g. non-intentionally added substances). For the listed substances, concentrations in the migration solutions were compared to their respective specific migration limits (SML) (when applicable). Migration of all substances was shown to be below their SML. The unlisted substances were evaluated using toxicological information from previous evaluations, or if not available, by applying the Threshold of Toxicological Concern (TTC) approach. In case the estimated exposure to the unlisted substance exceeded the human exposure TTC value, a more indepth risk assessment was performed. Based on the results of both parts of the study, four baby bottles were considered of high concern because of the potential toxicity of migrating compounds.

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1. Introduction

Bisphenol A (BPA) has been used for many years as a starting product to manufacture polycarbonate (PC) food contact materials (FCMs) including infant feeding (baby) bottles. Over the last years, studies identifying BPA as an endocrine disruptor (ED) have however been published (Alonso-Magdalena et al., 2012; Hass et al., 2016; Mandrup et al., 2016; Palanza et al., 2008; Talsness et al., 2009). Together with the observation that BPA can migrate into the food (Nam et al., 2010), these reports have raised worldwide concern about the application of BPA in FCMs. To address these concerns, the European Food Safety Authority (EFSA) re-evaluated BPA exposure and toxicity and concluded that BPA poses no health risk to consumers of any age group at current exposure levels (EFSA, 2015). Nevertheless, controversy over BPA remains. In 2011, the European Commission (EC) had already decided to prohibit the use of BPA in the manufacture of PC baby bottles in the European Union on the basis of the precautionary principle (European Union, 2011a). Consequently, PC has been replaced by a wide variety of other materials, such as polypropylene, polyamide, polyethersulfone, silicone, and glass. Compared to PC baby bottles, release of substances from replacement products has been relatively poorly studied. Recently, results of migration studies with baby bottles used as substitutes for PC have however become

* Corresponding author.
E-mail address: birgit.mertens@wiv-isp.be (B. Mertens).
[1] Both authors equally contributed to the manuscript.

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Abbreviation

AFC	Scientific Panel on food additives, flavourings, processing aids and materials in contact with food
BMDL10	benchmark dose level 10
BPA	bisphenol A
Bw	bodyweight
CMR	carcinogenic, mutagenic or toxic to reproduction
CoE	Council of Europe
EC	European Commission
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
ED	endocrine disruptor
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
FCM	food contact materials
IRIS	Integrated Risk Information System
LOAEL	lowest observed adverse effect level
MOE	margin of exposure
MOS	margin of safety
NIAS	non-intentionally added substances
NOAEL	no observed adverse effect level
PBT	persistent, bioaccumulative and toxic
PC	polycarbonate
QSAR	quantitative structure-activity relationship
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SA	structural alert
SCF	Scientific Committee on Food
SML	specific migration limit
TDI	tolerable daily intake
TTC	threshold of toxicological concern
TXIB	2,2,4-trimethyl-1,3-pentanediol diisobutyrate
vPvB	very persistent and very bioaccumulative

available (Onghena et al., 2014, 2015; Simoneau et al., 2012). These studies showed that only part of the substances migrating from PC replacement products are included in the positive list (Annex I) of commission regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. In Europe, only substances included in this Annex I of Regulation 10/2011 can be used as starting product for the manufacture of plastic FCMs and migration should be below the specific migration limit (SML), if available (European Union, 2011b). Other substances that were found to migrate from PC replacement products included non-intentionally added substances (NIAS) migrating from plastics (e.g. degradation and reaction products with unknown chemical identity) or substances migrating from non-plastic FCMs, such as silicones. Although no specific regulation exists for these substances, they should be in accordance with Regulation (EC) No 1935/2004 stating that migration of FCM constituents should not negatively affect consumer health (European Union, 2004). Furthermore, for substances migrating from plastic FCM, any potential health risk should be assessed by the manufacturer in accordance with internationally recognized scientific principles (European Union, 2011b).

One possibility to investigate the potential risks associated with the migration of substances not included in Annex I of Regulation 10/2011 is to use the threshold of toxicological concern (TTC) approach (EFSA, 2016). Within the TTC approach, a threshold value is identified for a chemical below which there is a very low probability of adverse effects to human health following daily ingestion. Since this approach is solely based on the structural chemical characteristics and estimated exposure, it can be used to assess health concerns of chemicals with limited or no specific toxicity data (EFSA, 2012). Both in the US and Europe, the usefulness of the TTC approach as a pragmatic risk assessment or prioritisation tool has been established in different domains, including that of FCMs (US FDA, 1993; EFSA, 2016). Importantly, the TTC approach cannot be applied when there is a requirement to submit toxicity data or when the available toxicity data allow a chemical-specific hazard assessment (Brüschweiler, 2014). So whereas the TTC approach might be an interesting tool to preliminary assess the risks associated with NIAS migrating from FCMs, it cannot be used for starting products for the manufacture of plastic FCMs.

In the present study, a strategy was developed to assess the potential health risks associated with substances for which migration from PC replacement products has been quantified (Onghena et al., 2016). First, it was evaluated whether these substances are included in lists of (suspected) EDs. Baby bottles releasing EDs may be of concern as suspected ED activity at low doses was the reason why BPA was prohibited to be used in PC baby bottles. Next, the other potential risks associated with the migration of substances from the PC replacement products were assessed. Depending whether or not a substance is present in Annex I of Regulation 10/2011, a different approach was used. Indeed, for substances included in Annex I of Regulation 10/2011, a risk assessment has already been performed by the EFSA or by its predecessor, the Scientific Committee on Food (SCF), based on the toxicological information submitted in the application dossier (Barlow, 2009; EFSA, 2008). For these substances, migration values were compared with the corresponding SML, if available. For substances not included in Annex I of Regulation 10/2011, a literature search was performed to check whether the substance had been evaluated in another context than for its use in plastic FCM. In case adequate toxicological information could be retrieved from these evaluations, the risk assessment was performed using these data. For the other substances, the TTC approach was applied.

2. Materials and methods

2.1. Chemicals

The 17 substances included in the present study were selected based on the publication of Onghena et al. (2016) (Table 1). For these 17 substances, migration was shown to be above the detection limit in the third migration solution of at least one of the 24 PC replacement baby bottles that had been investigated. An overview of the baby bottles is provided in Table 2.

2.2. Evaluation of the potential ED activity of all substances

For all 17 selected substances, the presence in different existing lists of (suspected) ED chemicals was verified.

2.2.1. EU priority list

The EU priority list has been assembled by DG Environment of the EC. In a first step, a 'candidate' list was compiled containing 553 substances identified as 'suspected' ED. Based on scientific literature and quantitative structure-activity relationship (QSAR) tools substances included in this list were given a first score (I, II or III). In a second step, the substances of the candidate list were prioritized based on their persistence in the environment and on the

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