Supplementary Material

Phthalates and substitute plasticizers: Main achievements from the European Human Biomonitoring Initiative HBM4EU

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Table S1: Phthalates and the substitutes DINCH and DEHTP (analyzed in time trend studies, Vogel et al., 2023a) sorted by HBM4EU categories A-C according to the availability of HBM and toxicology data (HBM4EU 2022a; Vogel et al., 2023b). Acronyms, names of parent compounds, chemical abstract service (CAS) numbers, metabolites and corresponding studies investigating exposure, derived HBM-GVs and investigating exposure - effect associations (details on the individual studies are provided in section 2.3 of the main text). It should be noted that abbreviations might differ from abbreviations in other studies (a compilation is given in e.g., Koch and Calafat, 2009). Abbreviations used in the US NHANES are given in brackets.

Parent compound (acronym)	Full name of parent compound	CAS-Number	Metabolite(s) investigated (acronym)	Metabolite(s) Full Name	[a]Existing studies	[b]Aligned Studies	[c]Time trend study	[d]time pattern study	[e] E-waste study	[f]exposure determinants	[g]derivation of HBM-GVs	exposure-effect investigation					
												[h]neurode-velopment	[i]Sexual maturaion	[j]BMI	[k]thyroid hormones	[l]kissepti n & sex	[m]astma and allergy
Orthophthalates																	
HBM4EU Category A																	
BBzP	Butyl benzyl phthalate	85-68-7	MBzP	Mono-benzyl phthalate	X	X	X	X	X	X	X	X	X	X	X	X	X
DEHP	Diethylhexyl phthalate	117-81-7	5cx-MEPP (MECPP)	Mono(2-ethyl-5-carboxypentyl) phthalate	X	X	X	X	X	X	X[2]	X	X	X[4]	X	X	X
			5OH-MEHP (MEHHP)	Mono(2-ethyl-5-hydroxyhexyl) phthalate	X	X	X	X	X	X	X[2]	X	X	X[4]	X	X	X
			5oxo-MEHP (MEOHP)	Mono(2-ethyl-5-oxohexyl) phthalate	X	X	X	X	X	X	X[2]	X	X	X[4]	X	X	X
			MEHP	Mono(2-ethylhexyl) phthalate	X	X	X	X	X	X	-	-	X	X[4]	X	X	X
DEP	Diethyl phthalate	84-66-2	MEP	Mono-ethyl phthalate	X	X	X	X	X	X	-	X	X	X	X	X	X
DiBP	Diisobutyl phthalate	84-69-5	MiBP	Mono-isobutyl phthalate	X	X	X	X	X	X	X	X	-	X	X	X	X
			OH-MiBP (MHiBP)	Mono-hydroxy-iso-butylphthalate	X	-	X	-	-	-	-	-	-	-	-		

Parent compound (acronym)	Full name of parent compound	CAS-Number	Metabolite(s) investigated (acronym)	Metabolite(s) Full Name	[a]Existing studies	[b]Aligned Studies	[c]Time trend study	[d]time pattern study	[e]E-waste study	[f]exposure determinants	[g]derivation of HBM-GVs	exposure-effect investigation					
												[h]neurode-velopment	[i]Sexual maturaion	[j]BMI	[k]thyroid hormones	[l]kisspeptin & sex	[m]astma and allergy
DiNP	Diisononyl phthalate	28553-12-0	MiNP	Mono-methyl-octyl phthalate	X	-	-	X	-	-	-	-	-	-	-		
			cx-MiNP (MCOP)	Mono(4-methyl-7-carboxyheptyl) phthalate	X	X	X	X	X	X	X[3]	-	X	X[4]	X	X	X
			OH-MiNP (MHNP)	Mono(4-methyl-7-hydroxyoctyl) phthalate	X	X	X	X	-	X	X[3]	-	X	X[4]	X	X	X
			oxo-MiNP	Mono-oxo-isononyl phthalate	X	-	X	X	-	-	-	-	-	-	-		-
DnBP	Di-n-butyl phthalate	84-74-2	MnBP	Mono-n-butyl phthalate	X	X	X	X	X	X	X	X	-	X	X	X	X
			3OH-MnBP (MHBP)	3OH-mono-n-butylphthalate	X	-	X	-	-	-	-	-	-	-	-	-	-
HBM4EU Category B																	
DCHP	Dicyclohexyl phthalate	84-61-7	MCHP	Mono-cyclohexyl phthalate	X	X	X	-	-	-	-	-	-	-	-	-	X
DiDP	Di-isodecyl phthalate (all C10 phthalates including DPHP)	26761-40-0; 68515-49-1	MiDP	Mono- -isodecyl phthalate	X	-	-	-	-	-	-	-	-	-	-	-	-
			cx-MiDP (MCNP)	Mono(2,7-methyl-7-carboxy-heptyl) phthalate	X	X	X[1]	X	X	X	-	-	-	X[4]	-	-	X
			OH-MiDP	Mono-hydroxy-isodecyl phthalate	X	X	X[1]	-	X	X	-	-	-	X[4]	-	-	X
			oxo-MiDP	6-Oxo-Mono-propyl-heptyl phthalate	X	-	X[1]		-	-	-	-	-	-	-	-	-
DMP	Dimethyl phthalate	131-11-3	MMP	Monomethyl phthalate	X	-	X	-	-	-	-	-	-	-	-	-	

Parent compound (acronym)	Full name of parent compound	CAS-Number	Metabolite(s) investigated (acronym)	Metabolite(s) Full Name	[a]Existing studies	[b]Aligned Studies	[c]Time trend study	[d]time pattern study	[e]E-waste study	[f]exposure determinants	[g]derivation of HBM-GVs	exposure-effect investigation					
												[h]neurode-velopment	[i]Sexual maturaion	[j]BMI	[k]thyroid hormones	[l]kisspeptin & sex	[m]astma and allergy
DnOP	Di-n-octyl phthalate	117-84-0	MnOP	Mono-n-octyl phthalate	X	X	X	X	-	-	-	-	-	-	-	-	X
			MCPP	Mono-(3-carboxypropyl) phthalate	-	-	X	-	-	-	-	-	-	-	-	-	-
DnPeP	Di-n-pentyl phthalate	131-18-0	MnPeP	Mono-n-pentylphthalate	X	X	X	-	-	-	-	-	-	-	-	-	X
DPHP	Di(2-propylheptyl) phthalate	53306-54-0	cx-MPHP	Mono-2-(propyl-6-carboxy-hexyl)-phthalate	X	-	X	-	-	X	-	-	-	-	-	-	-
			OH-MPHP	Mono-(propyl-6-hydroxyheptyl) phthalate	X	-	X	-	-	X	X^2	-	-	-	-	-	-
			oxo-MPHP	Mono-cyclohexyl phthalate	X	-	X	-	-	-	X^2	-	-	-	-	-	-
HBM4EU Category C																	
DiPeP	Di-isopentyl phthalate	605-50-5	MiPeP	Mono-isopentyl Phthalate	-	-	-	-	-	-	-	-	-	-	-	-	-
DHNUP	Di-C7-11-(linear and branched)-alkyl phthalate	68515-42-4	n.a.	n.a.	-	-	-	-	-	-	-	-	-	-	-	-	-
DMEP	Di(methoxyethyl)phthalate	117-82-8	n.a.	n.a.	-	-	-	-	-	-	-	-	-	-	-	-	-
DnHP	Di-n-hexyl phthalate	84-75-3	MnHP	Mono-n-hexyl phthalate	-	-	-	-	-	-	-	-	-	-	-	-	-
Substitute plasticizers																	
HBM4EU Category B																	

Parent compound (acronym)	Full name of parent compound	CAS-Number	Metabolite(s) investigated (acronym)	Metabolite(s) Full Name	[a]Existing studies	[b]Aligned Studies	[c]Time trend study	[d]time pattern study	[e] E-waste study	[f]exposure determinants	[g]derivation of HBM-GVs	exposure-effect investigation					
												[h]neurode-velopment	[i]Sexual maturaion	[j]BMI	[k]thyroid hormones	[l]kisspeptin & sex	[m]astma and allergy
DINCH	Di-isononyl cyclohexane-1,2-dicarboxylate	166412-78-8	cx-MINCH (MCOCH)	Cyclohexane-1,2-dicarboxylate-mono-(7-carboxylate-4-methyl)heptyl ester	X	X	X	X	X	X	X[2]	X	X	X[4]	X	X	X
			OH-MINCH (MHNCH)	Cyclohexane-1,2-dicarboxylate-mono-(7-hydroxy-4-methyl)octyl ester	X	X	X	X	X	X	X[2]	X	X	X[4]	X	X	X
			oxo-MINCH	Cyclohexane-1,2-dicarboxylate-mono-(7-oxo-4-methyl)octyl ester	X	-	X	-	-	-	-	-	-	-	-	-	-
Non-categorized within HBM4EU																	
DEHTP	Di-2-ethylhexyl terephthalate	6422-86-2	2cx-MMHTP	1-mono-(2-carboxyl-methyl-hexyl) benzene-1,4-dicarboxylate	-	-	X	-	-	-	-	-	-	-	-	-	-
			5cx- MEPTP (MECPTP)	1-mono-(2-ethyl-5-carboxyl-pentyl) benzene-1,4-dicarboxylate	-	-	X	-	-	-	-	-	-	-	-	-	-
			5OH-MEHTP (MEHHTP)	1-mono-(2-ethyl-5-hydroxy-hexyl) benzene-1,4-dicarboxylate	-	-	X	-	-	-	-	-	-	-	-	-	-
			5oxo-MEHTP	1-mono-(2-ethyl-5-oxo-hexyl) benzene-1,4-dicarboxylate	-	-	X	-	-	-	-	-	-	-	-	-	-

n.a. = not applicable,

[1]DiDP/DPHP sum method: OH-MiDP/OH-MPHP; oxo-MiDP/oxp-MPHP; cx-MiDP/cx-MPHP; sum of DiDP/DPHP metabolites

[2]HBM-GVs for the general and working population derived for: DEHP ∑5oxo-MEHP + 5OH-MEHP; DEHP ∑5cx-MEPP + 5OH-MEHP; DINCH: ∑cx-MINCH + OH-MINCH; HBM-GVs derived for the working population only: DPHP: DPHP ∑oxo-MPHP + OH-MPHP; oxo-MPHP; OH-MPHP (Lange et al., 2021)

[3]a provisional HMB-GV was derived for the purpose of the mixture risk assessment for DiNP (Lange et al., 2022) for cx-MiNP and ∑cx-MiNP and OH-MiNP (Lange et al., 2022)

[4]Molar sum of the metabolites was taken Exposure single pollutant models: i.e., ΣDEHP = Σ (MEHP + 5OH-MEHP + 5oxo-MEHP + 5cx-MEPP); ΣDiNP = Σ (OH-MiNP + cx-MiNP); ΣDiDP = Σ (OH-MiDP + cx-MiDP); ΣDINCH = Σ (OH-MINCH + cx-MINCH); for exposure multi-pollutant models this was the same, except for: DiDP, where only OH-MiDP was considered and DINCH, where OH-MINCH was considered.

[a] exposure data from existing HBM studies from 2005 to 2019 for the general population aged 3 to 60+ (Europe and Israel) (European HBM Dashboard (https://hbm.vito.be/eu-hbm-dashboard; see 2.3.7 of the main text) and Vogel et al., 2023b).

[b] HBM4EU Aligned Studies: pan-European harmonized exposure data for children (6-11 years) and teenagers (12-18 years) from HBM4EU Aligned Studies [d] (Vogel et al., 2023c; Govarts et al., 2023)

[c] exposure data from time trend studies (young adults) (Data from Denmark and Germany) (Vogel et al., 2023a)

[d] exposure data from time pattern studies (children), (three time points, whole of Europe) (Rodriguez Martin et al., 2023)

[e] occupational exposure from HMB4EU E-waste study (HBM4EU2022b, D8.13; Cleys et al., 2023)

[f] exposure sources and determinants (HBM4EU2022c, AD5.7; Martinsone et al., in preparation)

[g] derivation of HBM-GVs (Lange et al., 2021)

[h] neurodevelopment (Rosolen et al., 2022)

[I] sexual maturation (Cox et al., 2023)

[J] BMI (Desalegn et al., in preparation)

[k] thyroid hormones (Rodríguez-Carrillo et al., 2023)

[l] kisspeptin & sex hormones (Rodríguez-Carrillo et al., in preparation)

[m] asthma and allergy (Wauters et al., in preparation)

Category A comprises substances, for which HBM data are sufficient to provide an overall picture of exposure levels across Europe and where health risks assessments are possible. For these substances the focus of HBM4EU was on policy-relevant research questions and on the evaluation of the effectiveness of

existing regulation. **Category B** comprises substances for which HBM data exists, but the data is not sufficient to provide a clear picture across Europe. For substances of this category, the knowledge on exposure levels and impacts on human health were to be improved to provide policy makers with relevant and strategic data to a) establish appropriate regulations and b) improve chemical risk management. Furthermore, for these substances analytical methods and capacities were not fit for purpose. For substances grouped within **category C**, HBM data were scarce or non-existent, analytical methods not available, and knowledge on toxicological characteristics and effects on human health insufficient. Since HBM guidance values were not available, the interpretation of HBM data concerning health effects was not possible for this group of substances.

Table S2: Overview of biomonitoring data generated in HBM4EU for phthalates[a] and DINCH[b] from countries within Europe from the HBM4EU Aligned Studies in children (6-11 years) and teenagers (12-18 years) (Gilles et al., 2022; Govarts et al., 2023)

	Children (6-11 years)						Teenagers (12-18 years)					
Region	**Country**	**Study**	**Sampling Years**	**N**	**Age range**	**Sample type (urine)**	**Country**	**Study**	**Sampling years**	**N**	**Age range**	**Sample type (urine)**
North	Denmark (DK)	Odense Child Cohort	2018-2019	300	6-7	Spot	Sweden (SE)	Riksmaten	2016-2017	300	12-17	Spot
	Norway (NO)	NEB II	2016-2017	300	7-11	Spot	Norway (NO)	NEB II	2016-2017	181	12-14	Spot
East	Hungary (HU)	Indoor Air Quality	2017-2018	262	8-11	Spot	Czech Republic (CZ)	Pilot study in Czech school children	2019-2020	300	12-17	First Morning
	Poland (PL)	POLAES	2017	300	7-10	Spot	Poland (PL)	POLAES	2017	281	12-14	Spot
	Slovakia (SK)	PCB cohort	2014-2017	296	10-12	Spot	Slovakia (SK)	PCB cohort (follow-up)	2019-2020	287	15-17	Spot
South	Greece (GR)	CROME	2020-2021	161	6-11	First Morning	Greece (GR)	CROME	2020-2021	150	12-15	First Morning
	Italy (IT)	NAC II	2014-2016	299	6-8	Spot	Spain (ES)	BEA	2017-2018	300	13-17	First Morning
	Slovenia (SL)	SLO CRP	2018	149	7-10	First Morning	Slovenia (SL)	SLO CRP	2018	96	12-15	First Morning
West	Belgium (BE)	3xG	2019-2020	133	6-8	First Morning	Belgium (BE)	FLEHS IV	2017-2018	300	13-16	Spot
	France (FR)	ESTEBAN	2014-2016	286	6-12	First Morning	France (FR)	ESTEBAN	2014-2016	304	12-17	First Morning
	Germany (DE)	GerES V_sub	2015-2017	300	6-12	First Morning	Germany (DE)	GerES V_sub	2015-2017	300	12-18	First Morning
	The Netherlands (NL)	SPECIMEn-NL	2020	89	6-11	Spot						

N = number of participants;

[a,b]: parent compounds analyzed in the HBM4EU Aligned Studies are: BBzP, DiBP, DnBP, DEHP, DEP, DiNP, DiDP, DCHP, DnOP, DnPeP and DINCH (Gilles et al., 2022, Suppl. Material Tables S10 and S11). Please note that not all parent compounds were analyzed in all studies.

Exposure reconstruction via modelling

A methodology was developed and improved for exposure reconstruction to deliver external exposure estimates based on the summary statistics of HBM data available within the European HBM4EU Dashboard (see 2.3.7 of the main text) (HBM4EU, 2022d, D12.8). Aggregated HBM data from 13 different countries for different age groups including young children, young adults, seniors and (pregnant) mothers were used for the assessment. The exposure reconstruction approach is based on Georgopoulos et al. (2009). Exposure data are fed into an exposure model to provide input to a PBTK model. The result of this PBTK model simulation is then evaluated against the human biomonitoring data distributions, and the exposure model input parameters changed until convergence between the predicted and the actual biomonitored data is reached. Daily intake estimates could be established for DEHP, DiNP, BBzP, DnBP and DINCH (HBM4EU, 2022d, D12.8). The intake estimates were used to answer policy questions on current exposure and on health impact.

Human biomonitoring guidance values: Definition and Derivation

Within the framework of HBM4EU, a concept for deriving health-based human biomonitoring assessment values (named: human biomonitoring guidance values, HBM-GVs) was developed and agreed in the consortium (Apel et al., 2020), now enabling a harmonized assessment of HBM data. The HBM-GVs can be directly compared with the biomarker concentrations and allow an immediate toxicological interpretation. HBM-GVs were derived for the general population and for workers. HBM-GVs derived for the general population (HBM-GV_{GenPop}) represent the concentration of a substance or its specific metabolites at or below which, according to the current state of knowledge, no risk of adverse health effects is to be expected for the effect of the individual substance, assuming a life-long exposure and consequently there is no need for action at the individual substance level. The HBM- GVs correspond to the HBM-I values of the German Human Biomonitoring Commission (Angerer et al., 2011; Apel et al., 2017; Apel et al., 2020) and are similar to the biomonitoring equivalents (BE) used in the Canadian Health Measures Survey (Faure et al. 2020; Hays and Aylward 2009). The HBM-GVs derived for occupationally exposed adults (HBM-GV_{Worker}) represent a concentration of a substance or its relevant metabolite(s) in human biological media aiming to protect workers exposed to the respective substance regularly (each work day), and over the course of a working life from the adverse effects related to medium and long-term exposure (Apel et al., 2020).

The derivation of HBM-GVs is described in detail in Apel et al. (2020). Important steps in this process are: selection of relevant and reliable biomarker(s) of exposure, searching for information on toxicokinetics and toxicodynamics of the substance under consideration, identifying the most sensitive toxicological endpoint – preferably based on human data. The highest concentration without adverse effect for the selected endpoint is then used as point of departure (POD). Depending on the study used, assessment factors might be necessary to account for exposure duration, intra- and inter-species differences, etc. In a final step the value for internal exposure is calculated.

Within HBM4EU newly derived (or updated) HBM-GVs as well as the information underlying their derivation were shared with all participating countries as well as the EU Policy Board. National experts had the opportunity to provide comments on the derivation of the values.

Table S3: Human Biomonitoring Guidance Values for the general population (HBM-GV_{GenPop}) and the working population (HBM-GV_{Worker}) for selected phthalates and the substitute DINCH (modified from Lange et al., 2021)

	General population			Working population	
Parent compound	**Biomarker**	**HBM-GV_{GenPop} in µg/L[1]**		**Biomarker**	**HBM-GV_{Worker} in µg/L[1]**
		Children[2]	**Adults (incl. teenagers from 14 years onwards)[3*]**		**Adults[3]**
DEHP	∑ 5oxo-MEHP + 5OH-MEHP	340	500	5cx-MEPP	620
	∑ 5cx-MEPP + 5OH-MEHP	380	570	-	-
DnBP	MnBP	120	190	MnBP	3000
DiBP	MiBP	160	230	MiBP	3500
BBzP	MBzP	2000	3000	MBzP	3000
DPHP	∑ oxo-MPHP + OH-MPHP	330	500	∑ oxo-MPHP + OH-MPHP	700
	-	-	-	oxo-MPHP	400
	-	-	-	OH-MPHP	300
DINCH	∑ OH-MINCH + cx-MINCH	3000	4500	-	-

[1] rounded value; [2] including children 6-13 years of age; [3] including women of child-bearing age; ****currently the values for the adult population are under revision due to a higher urinary excretion volume applied for the derivation of the HBM-GVs (the adjusted values will be numerically identical both for children and adults);***

*5*oxo-MEHP: mono(2-ethyl-5-oxohexyl)phthalate); 5OH-MEHP: mono(2-ethyl-5-hydroxyhexyl) phthalate; 5cx-MEPP: mono (5-carboxy-2-ethylpentyl) phthalate; MnBP: monobutyl phthalate; MiBP: monoisobutyl phthalate ; MBzP: monobenzyl phthalate (CAS No.: 2528-16-7); oxo-MPHP: mono(propyl-6-oxo-heptyl) phthalate; OH-MPHP: hydroxy-mono-propylheptyl phthalate; OH-MINCH: cyclohexane-1,2-dicarboxylic acid-mono(hydroxyl-iso-nonyl) ester; cx-MINCH: cyclohexane-1,2-dicarboxylic acid-mono-(carboxy-iso-octyl) ester.

Table S4: Input into policy processes of HBM4EU results for phthalates

October 2020	European commission Public Consultation on the roadmap for the EU Action Plan Towards a Zero Pollution Ambition for air, water and soil	https://www.hbm4eu.eu/wp-content/uploads/2021/02/HBM4EU-input-to-Zero-Pollution-Final.pdf
June 2020	European commission Public consultation on the European Commission's roadmap for the chemicals strategy for sustainability	https://www.hbm4eu.eu/wp-content/uploads/2017/03/HBM4EU-input-on-chemicals-strategy-for-sustainability-roadmap.pdf
March 2020	European Commission Public consultation on the European Commission's roadmap for the farm to fork strategy	https://www.hbm4eu.eu/wp-content/uploads/2017/03/HBM4EU-input-on-farm-to-fork-strategy-roadmap.pdf
February 2020	European Food Safety Authority HBM4EU and EFSA on risk assessment, knowledge exchange and further collaboration	https://www.hbm4eu.eu/wp-content/uploads/2017/03/HBM4EU-visit-to-EFSA-12-13-Feb-2020-minutesDEF.pdf
April 2019	Scientific Committee on Health, Environmental and Emerging Risks Guidelines on the benefit-risk assessment of the presence of phthalates in medical devices	https://www.hbm4eu.eu/wp-content/uploads/2017/03/Input-on-phthalates-in-medical-devices.pdf
August 2018	European Chemicals Agency Public consultation on update to Annex XIV entries on four phthalates	https://www.hbm4eu.eu/wp-content/uploads/2017/03/Input-on-four-phthalates.pdf

Figure S1:

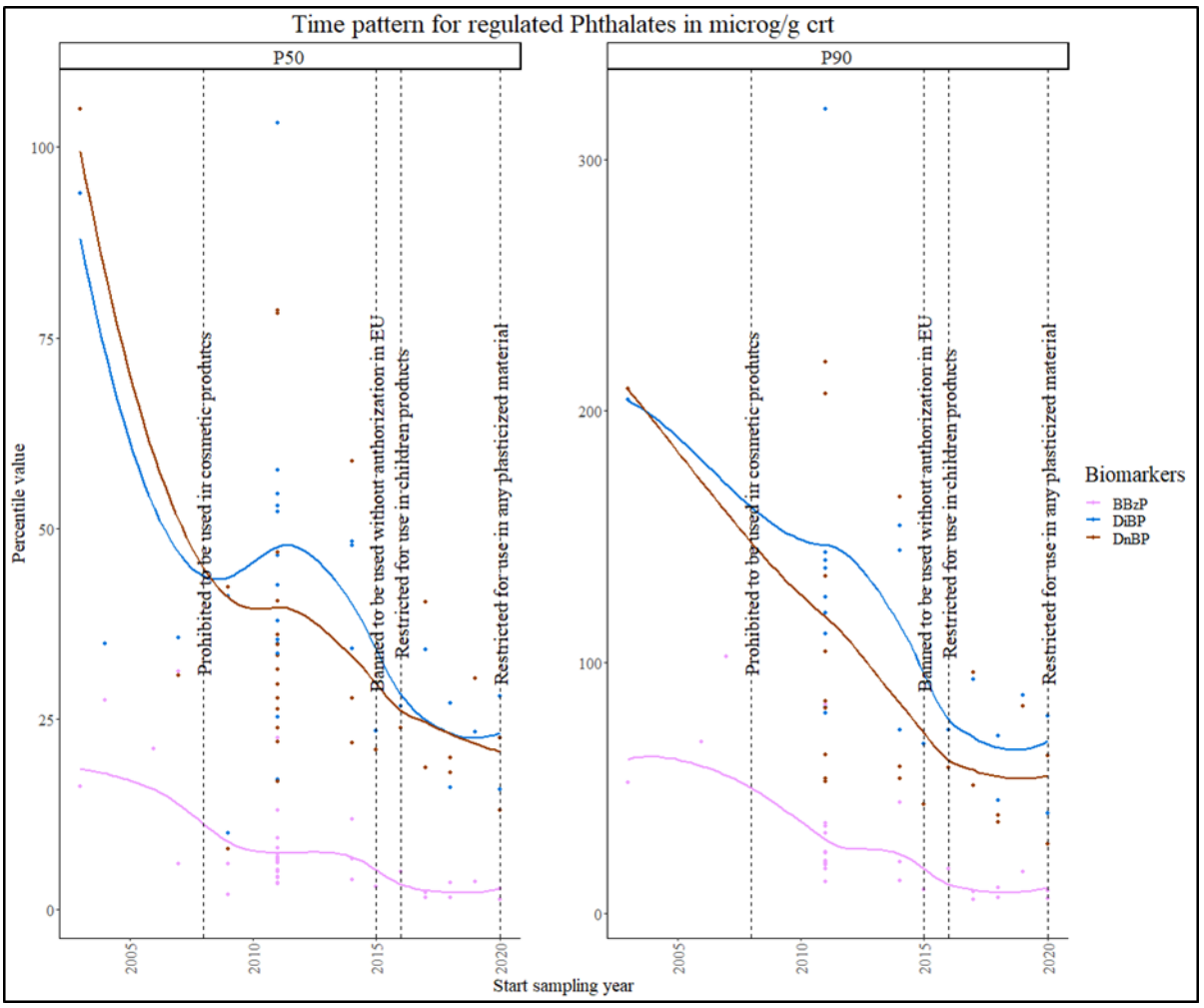

Figure S1: Time patterns for urinary levels of regulated phthalate metabolites in children from 5 to 12 years old exemplified for BBzP, DiBP and DnBP. Percentile value is shown in µg/g creatinine (modified after Rodriguez Martin et al., 2023).

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