ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAMES: FOUR PHTHALATES (DEHP, BBP, DBP, DIBP)

IUPAC NAMES: Bis(2-ethylhexyl) phthalate
Benzyl butyl phthalate
Dibutyl phthalate
Diisobutyl phthlalate

EC NUMBER(S): 204-211-0, 201-622-7, 201-557-4, 201-553-2

CAS NUMBER(S): 117-81-7, 85-68-7, 84-74-2, 84-69-5

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Preface

The preparation of this restriction dossier on Bis(2-ethylhexyl) phthalate (DEHP), Benzyl butyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP) (referred to as the four phthalates in this report) in articles was initiated on the basis of Article 69(2) of the REACH Regulation. [1] The scope of this proposal is limited to these four phthalates on Annex XIV whose sunset date has passed. [2]

The proposal has been prepared using version 2 of the Annex XV restriction report format and consists of a summary of the proposal, a report setting out the main evidence justifying the proposed restriction and a number of Annexes with more detailed information, analysis and detailed references that underpins the report.

A previous restriction report on the four phthalates was submitted by Denmark in 2011 and ECHA's Risk Assessment Committee and Socio-Economic Analysis Committee adopted opinions not supporting the proposal (ECHA 2012a). The four phthalates also were included in Annex XIV of REACH (the Authorisation List[3]). Applications for authorisation were received only for certain uses of DEHP and DBP (AfA 2013a,b,c).

The proposal from ECHA and Denmark builds on the previous restriction proposal and takes into account the applications for authorisation that have been submitted and granted. The new proposal presents: additional information and assessment covering the hazard, new information on exposure (especially DEMOCOPHES biomonitoring data), additional data on costs and trends in substitution, and a review of new information on benefits. Furthermore, the scope of the new proposal has taken into account comments made on better targeting of the proposal and the baseline has been adjusted to take account of the information available since the previous discussions.

This version of the report has been reviewed for confidential information and any such information has been redacted.

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1 Article 69(2) states that ECHA "shall consider whether the use of [the Annex XIV] substance in articles poses a risk to human health or the environment that is not adequately controlled. If ECHA considers that the risk is not adequately controlled, it shall prepare a dossier which conforms to the requirements of Annex XV".

2 The sunset date for DEHP, DBP, DIBP and BBP was 21 February 2015.

3 http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list?

Summary

The conclusion of the Dossier Submitter's examination of the risk from Bis(2-ethylhexyl) phthalate (DEHP), Benzyl butyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP) (referred to as the *four phthalates* in this report) is that their use in articles is not adequately controlled. Therefore, an analysis was conducted of diverse risk management options (RMOs), such as other REACH regulatory measures, existing EU legislation and other possible Union-wide RMOs, to identify the most appropriate measure to address these risks and to define the its scope and conditions.

On the basis of the analysis of the effectiveness, practicality and monitorability of these RMOs, the following restriction is proposed:

Proposed restriction

Brief title: Restriction on articles containing the four phthalates for: i) indoor use and ii) outdoor use, if in contact with human skin or mucous membranes

Table 1 gives the wording of the proposed restriction. It restricts the placing on the market of the following articles containing the four phthalates in a concentration, individually or in combination, in excess of 0.1% w/w of the plasticised material:

a) any (indoor or outdoor) articles whose phthalate containing material may be mouthed or is in prolonged contact with human skin or any contact with mucous membranes, and
b) any phthalate containing articles that are used (including stored) in an indoor environment where people are present under normal and reasonably foreseeable conditions and potentially exposed via inhalation. This does not apply to articles that are used only in industrial or agricultural workplaces by workers.

Both paragraph a) and b) do not apply to:

- articles placed on the EU market prior to the date of entry into force plus three years of transitional period (entry into force is assumed to take place in 2017);
- articles covered under existing legislation on food contact materials (Regulation (EC) No 1935/2004 and Regulation (EU) No 10/2011); immediate packaging of medicinal products (Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC); medical devices (Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC); toys and childcare articles containing DEHP, DBP and BBP (existing restriction entry 51 in Annex XVII of REACH);
- measuring devices for laboratory use.

The proposed restriction aims to restrict the placing on the market of articles containing the four phthalates which are shown to lead to human health risk to vulnerable groups but also the general population: this is seen as the primary concern related to the exposure to the four phthalates. These articles include mainly:

- flooring,
- coated fabrics and paper,
- recreational gear and equipment,
- mattresses,

- footwear,
- office supplies and equipment,
- wires and cables, and
- other articles moulded from or coated with plastic.

Summary of the justifications

Identified hazard and risk

The four phthalates covered in this report are considered as a group of substances and are all classified as toxic to reproduction in category 1B. The spectrum of effects in the male rat is known as the *phthalate syndrome*. It is well understood that the cause for the phthalate syndrome is suppression of foetal androgen action. The four phthalates inhibit foetal testosterone production, reduce male anogenital distance, decrease gene expression related to steroid biosynthesis, increase permanent nipple retention in male offspring, increase incidence of genital malformations (hypospadias and cryptorchidism), delay puberty onset, reduce semen quality and cause testicular changes including decreased testes and epididymides weight, tubular atrophy and Leydig cell hyperplasia in rats. The current scientific evidence in male animals and epidemiological studies shows that these effects are observed in and are relevant for male humans.

The DNELs proposed in the report are based on NOAELs for anti-androgenic effects seen in developmental studies, and are consistent with those previously agreed by RAC with the exception of DIBP. To appropriately reflect the anti-androgenic potency of DIBP, a new DNEL was derived based on read-across from its isomer DBP.

The uncertainty assessment suggests that the hazards and thus the risks from the four phthalates may be underestimated. The DNELs for DEHP and BBP may be lower than currently derived. A number of experimental and epidemiological studies have suggested possible effects on the immune system, the metabolic system and neurological development. Some of these studies indicate that reproductive toxicity may not be the most sensitive endpoint and that the selected DNELs may not be sufficiently protective against these other effects. Moreover, the Member State Committee (MSC) has confirmed that these four phthalates are endocrine disruptors related to human health and the Commission is considering to identify them as substances of equivalent concern under Article 57(f) of REACH. This raises additional uncertainties with the risk of these substances.

The general population is exposed to phthalates via different routes and from different sources. Oral exposure occurs from ingestion of food and dust, and from mouthing of articles. Exposure also occurs from inhalation of air and dust and from dermal contact with articles and dust. The main sources of exposure are considered to be food, indoor environment and direct contact with articles. The exposure to DEHP in women and infants appears to be driven by food consumption but exposure from articles is still a relevant source of exposure.

The exposure assessment has been based on DEMOCOPHES urinary biomonitoring samples taken in 2011-12. Based on the 95th percentile of combined exposure to the four phthalates in 2011, a risk was identified in 14 out of 15 Member States (93%) where the monitoring took place. Modelling estimates are generally consistent with the biomonitoring results for children (boys) and mothers (boys in utero), but appear to underestimate risks slightly in Member States with high exposure levels. It is estimated that in 2014 about 5% of new born boys

(130 000) in the EU28 were at risk through in utero exposure and about 15.5% boys (400 000) were at risk from direct exposure.

Based on these data, it is concluded that the identified risk to the general population is not adequately controlled and needs to be addressed. In addition, RAC concluded in 2013 that the limited exposure data in the applications for authorisation showed an occupational risk for the use of DEHP in formulation[4] and the production of articles. Moreover, the Member State Committee (MSC) has confirmed that DEHP is an endocrine disruptor in the environment and thus, there may also be risks to the environment from exposure to DEHP.

Justification that action is required on a Union-wide basis

The risks associated with EU manufactured or imported articles containing phthalates need to be addressed on a Union-wide basis for two reasons:

i. exposure takes place in all Member States, and
ii. the free movement of goods within the Union.

Effectiveness

The proposed restriction is targeted at those articles that present risks to human health, i.e., those that lead to exposure from direct contact (mouthing and contact with the skin or mucous membrane) and exposure via the indoor environment (inhalation and ingestion).

It can be concluded that the proposed restriction is capable of significantly reducing the risks to human health of combined exposure (RCRs are expected to be reduced to levels equal to or below 1 at the 95th percentile) within a reasonable period of time, starting from 2020, although some delay is caused by the service-life of articles in use. Considering the important contribution of food consumption to exposure to the four phthalates, in addition to the proposed restriction, the relevant authorities in the EU are encouraged take the necessary measures to reduce the risks relating to the four phthalates from food consumption. Any associated risks for the environment from the articles in scope would also be reduced as a result of the proposed restriction. The proposed restriction may furthermore reduce occupational risks due to substitution of DEHP in the production of articles in the EU.

If it is concluded that no threshold exists for the endocrine properties of the four phthalates, there would be a remaining risk following the entry into force of the proposed restriction. In this case, the restriction would contribute to reducing the exposure and thus the remaining risk.

The proposed restriction is considered to be a balanced measure as the benefits of risk reduction are estimated to outweigh its costs, in addition, it is cost-effective and is affordable for the impacted supply chains:

- the annual costs of the proposed restriction are estimated at €16.9 million (using 4% discount rate) or €19.1 million (using 2% discount rate);
- the annual benefits of the proposed restriction measured in terms of avoided social damage due to male infertility are estimated at €9.8 million (using 4% discount rate) or €19.6

[4] Including formulation of recycled soft PVC.

million (using 2% discount rate). As the benefits of the restriction occur far into the future, the sensitivity to the discount rate is evident.
- other potential benefits related to reduced cryptorchidism and hypospadias cases in the EU have been estimated to be over €23 million annually (using a 4% discount rate);
- the proposed restriction might also lead to other human health and environmental benefits. These have not been quantified but studies suggest that these benefits could be large;
- based on the uncertainty analysis it seems plausible that the benefits of reducing exposure to the four phthalates in the articles in scope are under- rather than overestimated;
- the proposed restriction is estimated to break-even by preventing a small number of negative human health impacts, for example 2 110 cases of male infertility plus 250 cases per year of cryptorchidism (or 420 cases of hypospadias). These avoided cases would represent less than 0.1% of the average annual male births projected in the EU28;
- the proposed restriction is estimated to cost €130 per tonne of the four phthalates replaced. This is nearly 20 times more cost-effective than the restrictions on phthalates in toys and childcare articles adopted earlier;
- the costs to transition to the alternatives are anticipated to be affordable for the majority of the impacted stakeholders: the proposed restriction is estimated to increase the price per tonne of imported articles in scope by about 2%.

It is concluded that the proposed restriction is effective because it is targeted to the exposures that cause the risks, is capable of reducing the identified risks within a reasonable period and its benefits exceed the costs of risk reduction.

Practicality

The proposed restriction is practical because it is implementable, enforceable and manageable:

Implementability

- There is a high degree of familiarity in the supply chains regarding many of the articles that may contain the four phthalates. Information is available to downstream users and consumers via provisions in REACH (e.g., Article 7).
- Technically feasible alternatives with lower risk are currently available at similar prices for all uses in the scope of this proposal.
- The proposed restriction gives sufficient time to the impacted supply chains to transition to alternatives.

Enforceability

- Enforcement authorities can set up efficient supervision mechanisms to monitor industry's compliance with the proposed restriction. Testing and sampling methods exist and both industry and enforcement authorities have experience applying them.
- The restriction clearly defines which articles are in its scope.
- The proposed restriction eliminates the possibility to replace the phthalates in the current restriction entry 51 with an equally hazardous substance: DIBP.

Manageability

Given the availability of information regarding which articles may contain the four phthalates and stakeholder experience with regulatory action on phthalates, the level of administrative burden for the actors concerned to implement the restriction is anticipated to be low.

Monitorability

For imported articles, the compliance control can be accomplished by border authorities and notifications of any violation of the restriction can be reported in the RAPEX system. For EU produced articles, the notification system for downstream users under Article 66 under Title VII – Authorisation of the REACH Regulation will also assist with monitoring the effectiveness and implementation of the proposed restriction. This monitoring can be done by ECHA and national enforcement authorities.

It is possible to monitor the result of the implementation and the effectiveness of the proposed restriction via biomonitoring studies similar to the COPHES and DEMOCOPHES projects.

Table 1. Proposed restriction

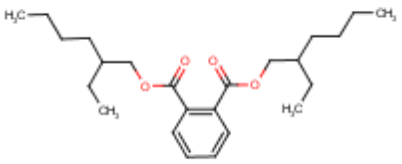
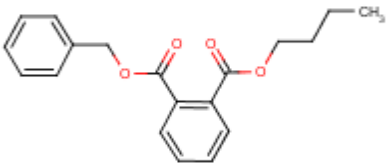
Bis(2-ethylhexyl) phthalate (DEHP) EC number: 204-211-0 CAS number: 117-81-7 Benzyl butyl phthalate (BBP) EC number: 201-622-7 CAS number: 85-68-7 Dibutyl phthalate (DBP) EC number: 201-557-4 CAS number: 84-74-2 Diisobutyl phthalate (DIBP) EC number: 201-553-2 CAS number: 84-69-5	1. Articles containing DEHP, DBP, DIBP, and BBP in a concentration, individually or in combination, greater than or equal to 0.1% by weight of the plasticised material shall not be placed on the market. 2. Paragraph 1 shall apply three years from the entry into force of the restriction. Paragraphs 1 and 2 shall not apply to: a. articles only for outdoor use where the phthalate-containing material is not in prolonged contact with human skin or any contact with human mucous membranes "Prolonged contact with human skin" should in this context be understood as covering a daily overall contact with skin of more than 10 minutes continuously or 30 minutes discontinuously. "Only for outdoor use" should in this context be understood as articles which are not used or stored in the interior of dwellings where humans are present under normal and reasonably foreseeable conditions. b. articles only for use in industrial or agricultural workplaces. This derogation does not apply to articles where the phthalate-containing material is in prolonged contact with human skin by workers. c. measuring devices for laboratory use d. articles placed on the market in the European Union prior to the date in paragraph 2. Paragraph 1 and 2 shall not apply to articles covered under existing legislation: i. Food contact materials covered by Regulation (EC) No 1935/2004 and Regulation (EU) No 10/2011 on plastic materials. ii. Immediate packaging of medicinal products covered by Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC, or to medical devices covered by Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC. iii. Toys and childcare articles containing DEHP, DBP and BBP covered by existing restriction entry 51 in Annex XVII of REACH 'Childcare article' is defined as in the existing restriction entry 51 in Annex XVII.

1. The problem identified

1.1. Hazard, exposure and risk

1.1.1. Identity of the substances and physical and chemical properties

This proposal concerns the following four phthalates:

Chemical Name: 1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester (**DEHP**) IUPAC Name: Bis(2-ethylhexyl) phthalate EC Number: 204-211-0 CAS Number: 117-81-7	Molecular weight: 390.6 g/mol Molecular formula: C24H38O4 Structural formula: 
Chemical Name: Benzyl butyl phthalate (**BBP**) IUPAC Name: Benzyl butyl phthalate EC Number: 201-622-7 CAS Number: 85-68-7	Molecular weight: 312.35 g/mol Molecular formula: C19H20O4 Structural formula: 
Chemical Name: Dibutyl phthalate **(DBP)** IUPAC Name: Dibutyl phthalate EC Number: 201-557-4 CAS Number: 84-74-2	Molecular weight: 278.34 g/mol Molecular formula: C16H22O4 Structural formula:

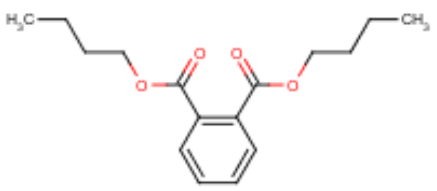
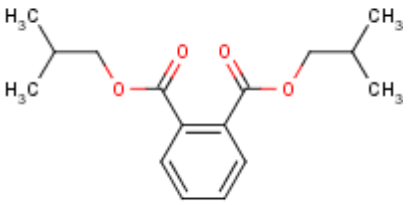
	
Chemical Name: Diisobutyl phthalate (**DIBP**) IUPAC Name: Diisobutyl phthalate EC Number: 201-553-2 CAS Number: 84-69-5	Molecular weight: 278.34 g/mol Molecular formula: C16H22O4 Structural formula: 

Table 2. Physicochemical properties of the four phthalates

Property	Substance	Value	Reference
Physical State	DEHP	Colourless oily liquid	EU RAR (2008a)
	BBP	Liquid	EU RAR (2008b)
	DBP	Oily liquid	EU RAR (2004)
	DIBP	Colourless liquid	Annex XV dossier (2009)
Melting point	DEHP	-55°C or -50°C	EU RAR (2008a)
	BBP	<-35°C	EU RAR (2008b)
	DBP	-69°C	EU RAR (2004)
	DIBP	-37°C at 1,013	Annex XV dossier (2009)
Boiling point	DEHP	385° C at 1 013 hPa	EU RAR (2008a)
	BBP	370° C at 10.10 hPa	EU RAR (2008b)
	DBP	340° C at 1 013 hPa	EU RAR (2004)
	DIBP	320° C	Annex XV dossier (2009)
Relative density	DEHP	0.98 g/cm^3 at 20°C	EU RAR (2008a)
	BBP	1.116 g/cm^3 at 20°C	EU RAR (2008b)
	DBP	1.045 g/cm^3 at 20°C	EU RAR (2004)
	DIBP		
Vapour pressure	DEHP	0.000034 Pa at 20° C	EU RAR (2008a)
	BBP	0.00112 Pa at 20° C	EU RAR (2008b)
	DBP	9.7±3.3 x 10^{-3} Pa at 25°C	EU RAR (2004)
	DIBP	0.01 Pa at 20°C	Annex XV dossier (2009)
Water solubility	DEHP	3 µg/l at 20°C	EU RAR (2008a)
	BBP	2.8 mg/L at 25 to 30°C	EU RAR (2008b)
	DBP	10 mg/L at 20°C	EU RAR (2004)
	DIBP	20 mg/L at 20°C	Annex XV dossier (2009)
Partition coefficient n-octanol/water (log value)	DEHP	7.5	EU RAR (2008a)
	BBP	4.84	EU RAR (2008b)
	DBP	4.57	EU RAR (2004)
	DIBP	4.11	Annex XV dossier (2009)

1.1.2. Justification for grouping

The four phthalates covered in this report are considered as a group of substances because:

- The structural and metabolic similarities of the four phthalates; all are ortho-phthalates with alkyl side chains, linear or branched, of length C4-C6 (Fabjan et al. 2006).
- The four phthalates are all anti-androgenic. They inhibit foetal testosterone production (Howdeshell et al. 2008; Hannas et al. 2011, 2012), reduce male anogenital distance (Saillenfait et al. 2008; Lee et al. 2006; Martino-Andrade et al. 2009; Mylchreest et al. 1999; Tyl et al. 2004; Gray et al. 2009); decrease gene expression related to steroid biosynthesis (Hannas et al 2012; Lehmann et al 2004) and increase nipple retention in male offspring (Christiansen et al 2010; Lee et al. 2004; Mylchreest et al 1999; Tyl et al 2004).
- DBP, DIBP and DEHP all induce changes in germ cell differentiation (multinucleated germ cells), which are considered to be independent of foetal testosterone reduction (Borch et al. 2006; Gaido et al. 2007; Lambrot et al. 2009).
- All four phthalates show effects on reproductive organs and fertility in experimental animals exposed prenatally, such as increased nipple retention, decreased anogenital distance, increased incidence of genital malformations (hypospadias and

cryptorchidism), delayed puberty onset (delayed prepubertal separation), reduced semen quality (reduced number of spermatocytes) and testicular changes including decreased testes and epididymides weight, tubular atrophy and Leydig cell hyperplasia in rats (EURAR 2004, 2008a, 2008b; ECHA 2009d).

- The spectrum of effects in the male rat is known as the "phthalate syndrome". It is well understood that the cause for the phthalate syndrome is suppression of foetal androgen action.

This grouping provides the basis for assessment of risks from combined exposure to the four phthalates. It has been concluded that the combined risks of anti-androgenic phthalates are adequately predicted with dose addition models (e.g., NCR 2008; CHAP 2014; Health Canada 2015a).

The hazard index (HI) method is the dose addition approach chosen in this assessment ($HI = \sum C_i/DNEL_i$[5]); the risk is not controlled if HI>1. This is supported by RAC (2012) and the Scientific Committees in their joint opinion on "Toxicity and assessment of chemical mixtures" (SCHER/SCENIHR/SCCS 2011). Both CHAP (2014) and Health Canada (2015) evaluated the combined risk of similar acting phthalates (including DEHP, DBP, DIBP and BBP) via the concept of dose addition through a HI approach.

1.1.3. Classification and labelling

Table 3. Harmonised classification and labelling of the four phthalates

Substance	**CAS no.**	**Classification and labelling according to Regulation 1272/2008**	
		Hazard class and category codes	**Hazard statement codes**
DEHP	117-81-7	Repr. 1B	H360-FD
BBP	85-68-7	Repr. 1B; Aquatic Acute 1; Aquatic Chronic 1	H360-Df; H400; H410
DBP	84-74-2	Repr. 1B; Aquatic Acute 1	H360-Df; H400
DIBP	84-69-5	Repr. 1B	H360-Df

[5] C_i is the concentration in the mixture or the estimated exposure for the included substance; and $DNEL_i$ is the DNEL of the included substance.

1.1.4. Hazard assessment

The four phthalates are all classified as toxic to reproduction in category 1B, and BBP and DBP as toxic to aquatic environment. In addition, the ECHA Member State Committee (MSC) has unanimously confirmed that these four phthalates are endocrine disruptors related to human health[6] and that DEHP is an endocrine disruptor in the environment. This report will focus primarily on the reproductive toxicity of these four phthalates as these effects form the basis of the N(L)OAELs and DNELs carried forward for the combined risk assessment.

1.1.4.1. Toxicity for reproduction

RAC previously recognised that multiple mechanisms of reproductive toxicity may occur at the same time following exposure to the four phthalates, leading to several effects (early marker effects, morphological and functional effects) caused by an anti-androgenic mode of action (RAC 2012).

The N(L)OAELs selected for risk assessment are based on developmental effects on male reproduction such as altered testicular development, delayed puberty onset, and increased incidence of hypospadias and cryptorchidism. Additionally, decreases in anogenital distance (AGD) and increases in nipple retention in male offspring are considered robust markers of anti-androgenic effects which are clearly related to adverse reproductive effects in offspring such as altered development of reproductive organs, impaired semen quality, and increased incidence of hypospadias and cryptorchidism (Christiansen et al. 2008; Hotchkiss et al. 2007; McIntyre et al. 2002).

Figure 1 illustrates the cellular targets, the associated changes in gene expression, and subsequent hormonal and organ responses following exposure to antiandrogenic phthalates. The spectrum of effects is known as the "phthalate syndrome" (Foster 2006; NRC 2008; Kortenkamp et al. 2011). It is well understood that the cause for the phthalate syndrome is suppression of foetal androgen action (Kortenkamp et al. 2011). It is hypothesized that these disorders may comprise a "testicular dysgenesis syndrome" (TDS) in humans with a common origin in fetal life. Testicular cancer may also be part of TDS in humans.

[6] However, the MSC did not reach unanimous agreement on whether this constitutes an equivalent level of concern to CMRs, as a minority of members were of the view that the concern related to endocrine disruption is already covered by the existing identification as SVHC due to toxicity to reproduction (ECHA 2014). As no unanimous agreement could be reached in the MSC, the Commission will take the final decision.

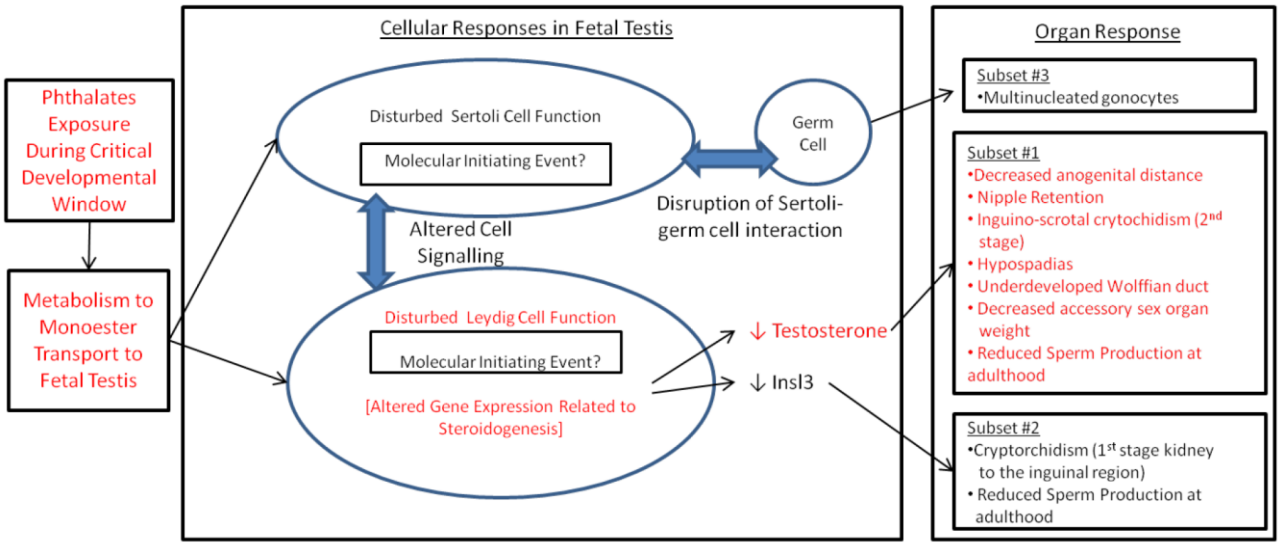


Figure 1. Representation of the cellular targets of the rat "phthalate syndrome", the associated changes in gene expression, and subsequent hormonal and organ responses. Source: Health Canada (2015a).

1.1.4.1.1. DEHP

Studies by Wolfe and Layton (2003), Christiansen et al. (2010) and Andrade et al. (2006) are critical for the selection of the starting point for DNEL derivation. From these studies, a **NOAEL of 4.8 mg/kg bw/day** based on testicular effects (germ cell depletion, reduced testis weight) in male offspring in Wolfe and Layton (2003) is selected for combined risk assessment. The effects can be attributed to an anti-androgenic mode of action. This study was used as a starting point in the EU RAR (2008) and by RAC (ECHA 2012,2013c).

Uncertainty

A more cautious starting point could be based on the findings of cryptorchidism in a few animals at 5 mg/kg bw/day in the study by Andrade et al. (2006) and the presence of mild dysgenesis of external genitalia at 3 mg/kg bw/day in the study by Christiansen et al. (2010). A LOAEL of 3 mg/kg bw/day can be derived as a starting point from Christiansen et al. (2010) and the NOAEL of 1.2 mg/kg bw/day from Andrade et al. (2006). Christensen et al. (2014) suggested to use a LOAEL of 3 mg/kg bw/day as an "alternate value" for deriving the reference dose. This starting point is similar to that of DBP which is in good agreement with the observation that DEHP and DBP have relatively similar potencies for effects on e.g., fetal testosterone production (Howdeshell et al. 2008).

1.1.4.1.2. DBP

Lee et al. (2004) observed delayed germ cell development and persistent male mammary gland changes[7] at 2mg/kg bw/day. A **LOAEL of 2 mg/kg bw/day** is selected from this study. The effects are considered to have an anti-androgenic mode of action. This selected starting point is consistent with EFSA (2005) and ECHA (2012, 2013d). Several newer studies were not considered critical.

Uncertainty

No NOAEL can be derived for DBP and thus uncertainty regarding the no-effect level exists for DBP.

As effects on the mammary gland and delayed germ cell development have only been investigated for DBP, it is not possible to compare DBP, DIBP, DEHP and BBP based on potency differences for these effects. The DNELs for DEHP and BBP do not therefore account for these effects, and may not be sufficiently protective for these endpoints.

1.1.4.1.3. DIBP

Derivation of the point of departure for DIBP in previous assessments

In the Background Document to the Opinion on the Annex XV dossier proposing restrictions on four phthalates (ECHA 2012), a LOAEL of 125 mg/kg bw/day from Saillenfait et al. (2008) was used as a starting point for DNEL derivation. RAC (ECHA 2012) noted that the LOAEL for histological effects of DIBP on the adult testes and epididymides can be considered "conservative" given the low incidences found at the LOAEL, but that a steep dose-response curve was seen in this study. Also the available registration dossier for DIBP used a LOAEL of 125 mg/kg bw/day for DIBP as a point of departure.

A starting point of 9.8 mg/kg bw/day was applied by US consumer product safety commission (CPSC) in their toxicity review of DIBP (CSPC 2011). This was based on a BMDL10 for effects on fetal testosterone in the study by Howdeshell et al. (2008).

Deriving a new point of departure for DIBP

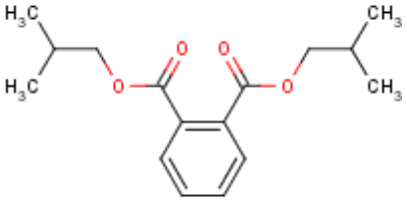
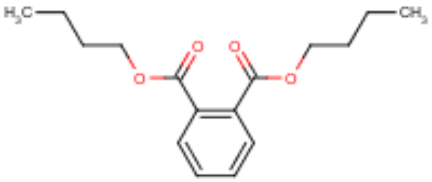
Few reproductive toxicity studies have been published on DIBP compared to the number of studies published on DEHP and DBP. No two-generation studies are available. The dose-response curve in Saillenfait et al. (2008) is steep with high incidences (up to 100%) of histological changes in testes and nipple retention at 500 and 625 mg/kg bw/day. Subtle effects are also seen at 125 mg/kg bw/day on anogenital distance, tubular degeneration, oligospermia/azoospermia, and prostate weight. The experimental data leaves a high degree of uncertainty when the selected point of departure is a LOAEL of 125 mg/kg bw/day as DIBP has not been tested below 100 mg/kg bw/day. Therefore it was considered important to evaluate the new mechanistic evidence regarding potency and to explore the potential to derive a new

[7] More specifically degeneration and atrophy of mammary gland alveoli. Alveolar atrophy may result from a decreased level of serum testosterone (OECD 2009).

point of departure using all the available evidence.

DIBP is structurally very similar to DBP. Indeed, DIBP is a branched isomer of DBP having the same molecular weight and physicochemical properties (see Table 4). Health Canada (2015b) grouped DIBP and DBP in the same subcategory, medium chain phthalate esters, with the longest carbon backbone length 3-7. Biomonitoring studies often assume that the molar urinary excretion fraction (FUE value) of DIBP is equal to that of DBP (e.g., UBA 2011; Fromme et al. 2013; Kasper-Sonnenberg et al. 2014).

Table 4. Comparison of structure and physicochemical properties of DIBP and DBP

Properties	**Diisobutyl phthalate (DIBP)**	**Dibutyl phthalate (DBP)**
Structure		
MW	278.34 g/mol	278.34 g/mol
Vapour pressure	0.01 Pa at 20°C	0.01 Pa at 25°C
Water solubility	20 mg/L at 20°C	10 mg/L at 20°C
Partition coefficient ($logP_{ow}$)	4.11	4.57

The structure activity relationship analysis found DBP to be more potent than DIBP with regard to reducing expression of 5 genes in the steroidogenic pathway (SR-B1, StAR, Cyp11a, 3bHSD, and Cyp17a1). DIBP was found to be slightly more potent than DBP in reducing fetal testosterone levels, and DIBP and DBP being equipotent in reducing AGD (all reviewed in Health Canada 2015b). Overall, DIBP and DBP affect similar mechanistic targets leading to similar adverse developmental effects as other phthalates within the medium chain phthalate esters group, and the mono ester of DBP is the closest structural analogue of the mono ester of DIBP.

The observed effects of DIBP at 500 mg/kg bw/day and 625 mg/kg bw/day in Saillenfait et al. (2008) on anogenital distance, nipple retention, reproductive organ weights, and puberty onset were comparable to the effects seen with 500 mg/kg bw/day of DBP. The potency difference between DIBP and DBP for these reproductive developmental endpoints thus appears to be minor.

Overall, the current data suggests that DIBP has similar potency to DBP, and thus the LOAEL of 125 mg/kg bw/day used previously as the starting point for DNEL derivation for DIBP does not seem to appropriately reflect this potency.

However, a possible potency difference between DIBP and DBP has been observed. Based on the available data from Saillenfait et al. (2008) an estimate based on the available data indicates that a 25% higher dose of DIBP would be required to illicit the same reproductive adverse effects as with DBP (anogenital distance, nipple retention, reproductive organ weights

and reproductive tract malformations and puberty onset).

If this potency difference of 25% between DBP and DIBP is extrapolated from the high dose area to the lower dose area, a new LOAEL for DIBP would be 25% higher than the current LOAEL of 2 mg/kg bw/day for DBP, leading to a LOAEL for DIBP of 2.5 mg/kg bw/day.

A **LOAEL for DIBP of 2.5 mg/kg bw/day** is used as the starting point for DNEL derivation.

1.1.4.1.4. BBP

The EU RAR (2007) used both a NOAEL of 50 mg/kg bw/day for developmental effects in the study by Tyl et al. (2004) and a NOAEL of 100 mg/kg bw/day for effects on fertility and reproductive organs in the study by Nagao et al. (2000). A NOAEL of 50 mg/kg bw/day is selected as this level is used for developmental effects in the EU risk assessment, and this is based on an anti-androgenic endpoint (reduced AGD). The registration dossier includes a two-generation study (Aso et al. 2005) that was not reported in the EU RAR (2007). This study revealed decreasing AGD in male offspring in all doses from 100 mg/kg bw/day of BBP (LOAEL) and no NOAEL was determined. Ahmad et al. (2014) found reduced reproductive organ weights and altered sperm counts and motility at 100 mg/kg bw/day in adult male rats exposed in utero. The corresponding NOAEL for these endpoints was 20 mg/kg bw/day. Combining the studies an overall **NOAEL of 50 mg/kg bw/day** can be determined with a LOAEL of 100 mg/kg bw/day. RAC supported this starting point for DNEL setting (ECHA 2012).

Uncertainty

For DBP and DEHP the lowest LOAELs were seen for endpoints including testicular histology, mammary histology of male adults and presence of mild dysgenesis of external genitalia. These endpoints have not been examined for BBP. The potency of BBP to reduce foetal testosterone production appears to be comparable to DEHP and DBP (Howdeshell et al. 2008), and it may be speculated that further studies on BBP including endocrine sensitive endpoints would reveal effects at lower doses than 50 mg/kg bw/day.

1.1.4.1.5. Epidemiology

A number of epidemiological studies are available showing associations with developmental effects on male reproduction, such as congenital malformations of the male reproductive organs, reduced semen quality, reduced male reproductive hormone levels, and changes in pubertal timing[8]. Epidemiological studies are generally associated with considerable uncertainties and it is therefore difficult to draw exact conclusions on these studies. However, they contribute to the overall evidence that effects seen in rats from exposure to the four phthalates are relevant in humans at exposure levels seen in the population.

[8] For example Main et al. (2006), Swan et al. (2005), Swan et al. (2015), Jensen et al. (2015), Axelsson et al. (2015a), Jørgensen et al. (2001) and Jørgensen et al. (2002), Main et al. (2006), Mendiola et al. (2011), Jørgensen et al. (2011), Aksglaede et al. (2009), Colon et al. (2000), Lomenick et al. (2010), Moral et al. (2011) and Jørgensen et al. (2011).

1.1.4.2. Derivation of DNELs

The DNELs are based on N(L)OAELs for anti-androgenic effects seen in developmental studies, i.e. where doses are administered to adult female rats during gestation and lactation. The DNELs are based on different endpoints assumed to have the same mode of action.

Table 5 lists the applied absorption fractions used in the calculation of internal exposure for humans and experimental animals to be able to estimate the risk from exposure by different routes (DNELs for internal dose).

Table 5. Absorption fractions for calculation of internal doses according to RAC (ECHA 2012a, 2013b,c).

	Absorption fraction, oral	**Absorption fraction, dermal**	**Absorption fraction, inhalation**
DEHP	70% rats, all ages 100% adult humans 100% infants/children	5% human, all ages	75% adults 100% infants/children
DBP and DiBP	100% (experimental animals and humans)	10% human, all ages	100% human, all ages
BBP	100% (experimental animals and humans)	5% human, all ages	100% human, all ages

The DNELs for consumers and the general public, including pregnant women and children are presented in Table 6 below. In accordance with ECHA guidance Chapter R.8, DNEL calculation uses an uncertainty factor of 2.5 for interspecies differences; an allometric scaling factor of 4 for rats and 7 for mice; a factor of 10 for intraspecies differences; and a factor of 3 for extrapolation from LOAEL to NAEL if no NOAEL is available.

No other assessment factors were considered relevant (e.g., for different duration/exposure time).

Table 6. Overview of DNEL derivation.

	NOAEL (mg/ kg bw/day)	LOAEL (mg/ kg bw/day)	Endpoint and study reference	AFs	Correction for absorption§	DNEL internal dose (mg/ kg bw/day)
DEHP	4.8	14	Small male reproductive organs (testes/epididymes/ seminal vesicles) and minimal testis atrophy in Wolfe and Layton (2003)	4*2.5*10 = 100	0.7	0.034
DBP	–	2	Reduced spermatocyte development at postnatal day 21, and mammary gland changes (vacuolar degeneration and alveolar atrophy) in adult male offspring in Lee et al. (2004)	4*2.5*10*3 = 300	1	0.0067
DIBP	-	2.5	Read-across from DBP	4*2.5*10*3 = 300	1	0.0083
BBP	50	100	Reduced anogenital distance in Aso et al. (2005), Tyl et al. (2004) and Nagao et al. (2000). Reduced reproductive organ weights and altered sperm counts and motility in Ahmad et al. (2014)	4*2.5*10 = 100	1	0.50

§oral absorption fraction=0.7 in rats for DEHP and 1 for other compounds.

1.1.4.3. Uncertainties

Uncertainties in the hazard characterisation of the four phthalates suggest that the current DNELs may underestimate the risk.

1.1.4.3.1. DNEL setting

In general, there is some uncertainty in the determination of DNELs, as N(L)OAELs are very dependent on dose selection, endpoint selection and the sensitivity of the critical endpoints. For each compound there are differences in study designs, doses and selected endpoints, and there are also likely to be inter-laboratory differences in the sensitivity of the methods to detect effects on certain endpoints.

The uncertainty to the N(L)OAEL selection discussed above for each of the four phthalates individually results in uncertainties to the DNEL derivation.

If Christiansen et al. (2010) or Andrade et al. (2006) are used for DNEL derivation for DEHP, the DNEL would be 0.007 or 0.008 mg/kg bw/day respectively. Such DNELs would be practically equal to the DNEL derived for DBP, which is in good agreement with their similar potency to reduce foetal testosterone production (Howdeshell et al. 2008). In the absence of conclusive experimental data, read-across from DBP has been performed to DIBP. The experimental evidence for concluding that DIBP is of similar anti-androgenic potency is considered robust, but the assumption of a potency difference of 25% is uncertain. The potency of BBP to reduce foetal testosterone production appears to be comparable to DEHP and DBP (Howdeshell et al. 2008), and it may be speculated that further studies on BBP including endocrine sensitive endpoints would reveal effects at lower doses than 50 mg/kg bw/day.

The DNELs are based on N(L)OAELs for anti-androgenic effects seen in developmental studies, i.e., where doses are administered to adult female rats during gestation and lactation. Therefore, the DNELs are especially relevant for pregnant women. Although the foetus is thought to be more sensitive to the effects of the four phthalates, children (boys) are considered to be among the sensitive population because their reproductive system is still developing (David 2006; Foster et al. 2001; den Hond and Schoeters 2006; Jacobson-Dickman and Lee 2009). The DNELs are therefore also considered valid for children (boys) albeit it is possible the DNELs for this age group would overestimate risks.

There are indications of species differences in metabolism and possibly in effects on fetal steroidogenesis, but the evidence is insufficient to deviate from the default assumption that humans are more sensitive than the test species (ECHA guidance Chapter R.8).

1.1.4.3.2. Threshold for phthalates

In December 2014 the Member State Committee (MSC) unanimously acknowledged that for DEHP, DBP, DIBP and BBP there is "*scientific evidence on the endocrine activity and on the link between this activity and the adverse effects to human health. However, the MSC did not reach unanimous agreement on whether this constitutes an equivalent level of concern to CMRs (majority view), as a minority of members were of the view that the concern related to endocrine disruption is already covered by the existing identification as SVHC due to toxicity to reproduction*" (ECHA 2014). As no unanimous agreement could be reached in the MSC, the Commission will take the final decision.

According to current policy, substances identified as having endocrine disruptive properties according to Article 57 (f) do not have a threshold, except where it can be demonstrated that a threshold exists (European Commission 2014). Even though RAC has previously established DNELs for reproductive toxicity for the four phthalates (ECHA 2012a, 2013c,d,e), these did not take into account the need to specifically assess and document the existence of a threshold if the phthalates are identified as having endocrine disruptive properties[9].

[9] In establishing the DNELs for reproductive toxicity, RAC acknowledged the endocrine mode of action. However, in

Thus, as the existence of a threshold has not yet been assessed and documented for DEHP, DBP, DIBP and BBP this leads to uncertainties regarding the appropriateness of the derived DNELs.

1.1.4.3.3. Toxicity other than toxicity for reproduction

In recent years, a number of experimental and epidemiological studies have examined the possible influence of phthalate exposure on the immune system, the metabolic system and neurological development. Some of these studies indicate that reproductive toxicity may not be the most sensitive endpoint and that the DNELs selected for the current combined risk assessment might not be sufficiently protective against other effects of phthalates.

Immunotoxicity

Several studies have proposed adverse effects of phthalate exposure on the immune system (allergy, asthma and eczema).

Braun et al. (2013), reviewed epidemiological data showing associations between exposure to DEHP, BBP and DBP and allergic diseases including asthma and eczema. It was found that children from homes with high concentrations of phthalates in dust had high incidences of allergy, asthma, rhinitis or eczema (Bornehag et al. 2004; Hsu et al. 2012; Kolarik et al. 2008). Higher maternal BBP exposure in pregnancy was associated with early-onset eczema in children (Just et al. 2012), but such studies do not clarify possible causative relationships.

Studies in mice and rats showed that DEHP could enhance the sensitisation to allergens (adjuvant effect), and this was suggested as an underlying risk factor in the increase in severity of asthma (Guo et al. 2012; You et al. 2014). Increased serum IgE responses were seen after 52 days exposure of adult mice to very low doses of DEHP (30 µg/kg bw/day) (Guo et al. 2012). Tonk et al. (2012), examined developmental and immunological effects of 1 to 1000 mg/kg bw/day of DEHP in juvenile and adult male rats, and found effects on immune parameters in juvenile males beginning from around 1 mg/kg bw/day, i.e. at lower doses than the doses affecting reproductive organ weights. Overall, there is a need for further robust data to perform a risk assessment regarding adverse effects of phthalates on the immune system.

These studies indicate that reproductive toxicity may not be the most sensitive endpoint for the effects of DEHP and that the DNELs selected for the current combined risk assessment may not be sufficiently protective against immunological effects of phthalates.

Effects on the metabolism

Associations between prenatal phthalate exposure and obesity or diabetes in adulthood have been investigated in epidemiological studies, and in vitro and animal studies have provided mechanistic knowledge indicating obesogenic effects of phthalates, e.g., by promoting differentiation of and accumulation of lipid in lipid cells (reviewed by Kim and Park 2014). The fetal period is considered critical to phthalate exposure, but few studies have been able to clarify the role of prenatal exposure to phthalates in the obesity epidemic.

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its opinions on the applications for authorisation for DEHP, RAC also recognised that DEHP was included in Annex XIV because of its reproductive effects and not as an Article 57 (f) substance, and stated that therefore a threshold approach was warranted.

Neurodevelopment

Altered neurodevelopment has been associated with high phthalate exposures in children, as reviewed by Miodovnik et al. (2014). Numerous behavioural disorders including autism spectrum disorders, ADHD, learning disabilities, and altered play behaviour have been associated with higher phthalate exposure in humans (reviewed by Braun et al. 2013). Animal studies examining behavioural effects of phthalate exposure have shown some effects that may be related to altered sex differentiation, whereas other behavioural effects are not clearly linked with disruption of sex hormones. Different modes of action for phthalate effects on neurodevelopment have been proposed, including interference with the thyroid hormone system, altered calcium signalling, relation to activation of peroxisome proliferator activated receptors (PPARs) in brain and altered lipid metabolism (Miodovnik et al. 2014).

Carcinogenicity

Although the findings of Leydig cell tumours in one study in rats was not confirmed in four other lifetime studies or in multigeneration studies with DEHP, the EU RAR (2008) considered the induction of Leydig cell tumours in rats to be relevant for humans. BBP tested negative for carcinogenicity in mice; in rats findings of mononuclear cell leukaemia, benign pancreas tumours and urinary bladder tumours were of doubtful significance. For DBP and DIBP, no carcinogenicity studies are available.

In rodent carcinogenicity studies, DEHP induced liver tumours in both rats and mice with peroxisome proliferation as one of the underlying mechanisms. Rusyn and Corton (2012) considered that activation of PPARα has an important role in DEHP carcinogenicity, but were of the opinion that the data suggest that multiple pathways in several cell types contribute to cancer in rats and mice. The authors concluded that the overall body of evidence on human cancer hazard of DEHP remains inconclusive. IARC reviewed the classification of DEHP in 2011 and changed their conclusion to 'possibly carcinogenic to humans (Group 2B)' (IARC 2012).

Repeated dose toxicity

In repeated dose toxicity studies with experimental animals, the main organs affected besides reproductive organs are the liver (lowest NOAELs for non-peroxisome related effects for DEHP, DBP, and BBP 28.9, 152, and 151 mg/kg bw/day, respectively) and the kidneys (lowest NOAELS for DEHP, DBP and BBP 28.9, 152, and 151 mg/kg bw/day, respectively). For DIBP only few, rather old repeated dose toxicity studies are available.

1.1.4.4. Conclusion

The spectrum of effects on male developmental and reproductive toxicity in the rat is known as the "phthalate syndrome". It is well understood that the cause for the phthalate syndrome is suppression of foetal androgen action. The four phthalates inhibit fetal testosterone production, reduce male anogenital distance, decrease gene expression related to steroid biosynthesis, increase permanent nipple retention in male offspring, increase incidence of genital malformations (hypospadias and cryptorchidism), delay puberty onset, reduce semen quality and cause testicular changes including decreased testes and epididymides weight, tubular atrophy and Leydig cell hyperplasia in rats.

The following uncertainties to the derived DNELs for reproductive toxicity were identified:

- DNELs of DEHP and BBP may be lower than assumed in the current risk assessment.
- The DNELs are relevant for pregnant women and for children, albeit it is possible that the DNELs for children would be higher.
- There are indications of species differences in metabolism and possibly in effects on fetal steroidogenesis, but the evidence is insufficient to deviate from the default assumption that humans are more sensitive than the test species.
- A number of experimental and epidemiological studies have suggested possible effects on the immune system, the metabolic system and neurological development. Some of these studies indicate that reproductive toxicity might not be the most sensitive endpoint and that the selected DNELs may not be sufficiently protective against these other effects.
- If it is decided that the four phthalates give rise to equivalent level of concern due to their endocrine disrupting properties for human health, it has to be determined whether a threshold for effects can be demonstrated if any applications for authorisation would be submitted in the future (European Commission 2014). The existence of a threshold has not yet been assessed and documented for DEHP, DBP, DIBP and BBP.

On balance, the uncertainties suggest that the derived DNELs for reproductive toxicity might underestimate the risks from exposure to the four phthalates.

1.1.5. Exposure assessment

1.1.5.1. Human exposure

The general population is exposed to phthalates via a range of different routes and sources. The exposure routes are ingestion, inhalation and dermal or mucous contact with articles.

The main sources of exposure are considered to be food, indoor environment and articles that have a high potential for direct contact. Articles that are used in food processing or packaging can contribute to exposure via food. Exposure occurs through exposure via the indoor environment (ingestion of dust and inhalation of air). Direct exposure from articles can arise from contact between articles and the skin or mucous membrane, or from infants mouthing articles.

Additionally, medicines and medical devices may contribute to exposure of the general population. Furthermore, articles release phthalates to the environment and thus contribute to exposure of humans via environment to phthalates (mainly via food). Finally, occupational exposure was considered.

The exposure assessment especially relies on biomonitoring. Whilst biomonitoring data integrates all exposures, biomonitoring studies have limited capability in identifying the sources of exposure. Therefore exposure modelling was performed to better characterise the contributing sources of exposure.

The population is divided into three age groups: (male) infants at the age of 6-12 months, (male) children at the age of 6-11 years and women. Infants at the age of 6-12 months are expected to mouth many articles and are being weaned onto "normal" food.

1.1.5.1.1. Exposure estimates based on biomonitoring data

A lot of urinary biomonitoring data is available for the four phthalates. The current assessment relies in particular on the urinary biomonitoring data generated by the EU-wide DEMOCOPHES project (largely unpublished). Morning urine samples were collected from mother-child pairs in 16 EU Member States and Switzerland from September 2011 until February 2012. Children were 6-11 years old and the median age of the mothers was 39 years.

Spot sample studies normalise urinary metabolite concentrations against creatinine or daily urinary volume reference values to estimate the amount excreted over a full day. Since individuals vary in the rate that they excrete urine, urinary biomonitoring data are often adjusted to the more constant creatinine excretion rate. However, normalisation of urinary metabolite levels against creatinine introduces some uncertainties related to the variability of creatinine excretion rates.

The creatinine corrected urinary concentration of metabolites was used to estimate the daily intake (µg/kg bw/day) from the spot samples gathered in the DEMOCOPHES project. Ideally, the data from the individual participants is used. No data on body weight, age, height, creatinine levels, and urinary metabolite levels for individual participants was made available to ECHA by the project members. This leads to some loss of precision or accuracy of the exposure estimates from the biomonitoring data.

It is considered appropriate to use the 95th percentile urinary exposure levels from

DEMOCOPHES as an estimate of the reasonable worst case of exposure. There are however indications that the selection of a 95th percentile may lead to an underestimation of the reasonable worst case exposure level[10].

1.1.5.1.1.1. Results

The median and 95th percentile intake estimates from DEMOCOPHES using creatinine corrected urinary metabolite concentrations are reported in Table 7.

Table 7. Intake estimates (µg/kg bw/day) from DEMOCOPHES based on creatinine corrected urinary metabolite concentrations

				intake			
				DEHP	DBP	BBP	DiBP
Country	N	Population		µg/kg/d	µg/kg/d	µg/kg/d	µg/kg/d
BE	125	Mother	P50	1.49	0.84	0.18	1.04
			P95	4.92	2.64	0.65	5.02
	125	Child	P50	2.11	0.98	0.23	1.43
			P95	12.06	2.90	0.92	8.60
CH	117	Mother	P50	1.15	0.46	0.10	0.50
			P95	5.83	1.82	0.43	1.61
	119	Child	P50	2.11	0.64	0.12	0.64
			P95	7.45	1.91	0.81	2.08
CY	59	Mother	P50	1.03	0.46	0.06	1.51
			P95	14.99	1.33	0.30	3.62
	60	Child	P50	1.42	0.57	0.09	1.54
			P95	7.77	1.51	0.41	3.60
CZ	117	Mother	P50	2.53	1.83	0.13	NA
			P95	8.05	4.98	1.30	NA
	120	Child	P50	4.41	3.10	0.19	NA
			P95	14.03	8.90	1.49	NA
DE	116	Mother	P50	1.39	0.86	0.12	0.68
			P95	3.82	2.28	0.54	1.89
	120	Child	P50	2.45	1.19	0.15	1.09
			P95	7.26	3.66	1.01	3.06
DK	143	Mother	P50	1.61	0.66	0.13	1.22
			P95	5.37	1.28	0.52	3.30
	142	Child	P50	2.84	0.93	0.21	1.73
			P95	7.75	2.03	1.00	4.92
ES	118	Mother	P50	3.17	1.00	0.24	1.25
			P95	8.70	2.25	0.96	2.67
	119	Child	P50	4.74	1.30	0.37	1.62
			P95	12.05	6.03	1.39	7.07
HU	115	Mother	P50	2.21	1.03	0.11	0.00
			P95	8.49	3.21	0.53	0.00
	117	Child	P50	3.47	1.49	0.17	0.00
			P95	12.86	4.57	0.78	0.00
IE	120	Mother	P50	2.05	0.56	0.08	0.71
			P95	6.58	1.58	0.54	3.00
	120	Child	P50	3.32	0.68	0.12	1.09
			P95	10.27	1.75	0.57	3.91
LU	58	Mother	P50	1.08	0.60	0.10	0.65
			P95	4.98	1.42	0.41	2.29
	60	Child	P50	1.63	0.77	0.12	1.09
			P95	3.84	1.69	0.58	5.98
PL	119	Mother	P50	2.89	1.37	0.11	1.51
			P95	12.39	5.59	0.71	5.94
	115	Child	P50	4.57	2.14	0.24	2.93
			P95	17.31	7.58	1.63	10.07
PT	117	Mother	P50	2.47	0.65	0.15	0.86
			P95	11.59	1.51	0.47	2.52
	116	Child	P50	2.82	0.81	0.20	1.05
			P95	8.91	2.25	1.05	3.41
RO	117	Mother	P50	3.13	0.72	0.07	1.01
			P95	34.60	1.70	0.32	2.79
	119	Child	P50	4.23	1.11	0.10	1.41
			P95	29.85	3.97	0.54	5.10
SE	96	Mother	P50	1.73	1.79	0.34	NA
			P95	5.84	4.96	2.25	NA
	97	Child	P50	3.21	2.27	0.60	NA
			P95	11.16	6.46	2.60	NA
SI	120	Mother	P50	NA	0.56	0.12	NA
			P95	NA	2.71	0.50	NA
	120	Child	P50	NA	0.84	0.16	NA
			P95	NA	2.70	0.75	NA
SK	125	Mother	P50	2.53	1.87	0.11	NA
			P95	7.11	5.32	0.44	NA
	127	Child	P50	4.90	2.70	0.18	NA
			P95	14.10	7.46	0.90	NA
UK	21	Mother	P50	1.00	0.42	0.06	0.47
			P95	2.69	0.95	0.14	2.20
	21	Child	P50	2.53	0.73	0.11	0.77
			P95	5.41	1.94	0.62	2.33

NA = not available

[10] Elements that indicate a 95th percentile may lead to underestimation of the reasonable worst case are: peak exposures may be indicative of certain reasonable foreseeable ways of behaviour or reasonable foreseeable circumstances that may be typical for some individuals or sub-populations; no biomonitoring is available for infants; even a short elevated exposure level within the 'critical windows of exposure' may be sufficient to cause adverse effects on the developing foetus which makes peak exposures particularly relevant in the case of the four phthalates; the sample sizes in the Member States participating in the DEMOCOPHES project are sufficiently large to even out some of the variability caused by taking spot samples (the actual 95th percentile exposure in the entire population may be lower or higher); it is possible that the spot morning urine samples systematically underestimate exposure to DEHP and possibly also the other four phthalates with a factor of 1.5 (CHAP 2015); further uncertainties result from the methods used in the current assessment.

1.1.5.1.2. Discussion

In addition to DEMOCOPHES, there are many other studies reporting urinary metabolite levels of the four phthalates in Germany and Denmark, and some information is available from other Member States (Austria, France and Spain). Data from samples taken after 2008 are available for infants (Denmark) and children (Austria, Germany and Denmark) and for adults (Austria and Denmark). The year 2008 was the year of entry into force of the food contact material legislation.

Comparisons between studies are difficult as a result of differences in sample period, age groups, geographical area of residence of the study population, size of the study population, and methodology used to estimate the intake. Therefore the attempts made below to draw conclusions need to be interpreted with caution and are not necessarily valid for other countries.

Age

The DEMOCOPHES biomonitoring exposure estimates clearly showed that the exposure of children is higher than that of mothers. This is generally the case also in other biomonitoring studies (Hartmann et al. 2015; Frederiksen et al. 2011; Becker et al. 2009; Geens et al. 2014). The higher food and dust intake or exposure through inhalation relative to body weight of children compared to adults might help to explain this difference. In addition, differences in exposure patterns in children and metabolism can be factors explaining the differences.

Exposure trend over time

It can be concluded that exposure to phthalates has declined over time when older biomonitoring studies are compare to the DEMOCOPHES data. The data presented in Table 8 indicates that a significant decline in exposure has taken place in Germany and Denmark over 2001-2011.

Table 8. Comparison of data from DEMOCOPHES (sample year 2011) and the literature to assess a trend in exposure

Study	Period	Member State	Population	Percentage decline			
				DEHP	BBP	DBP	DIBP
Wittassek et al. (2007a); Koch et al. (2007)	2001-2002 to 2011	DE	Children aged 6-11 years	50%	75%	60%	-
Wittassek et al. (2007b)	2001/2003 to 2011	DE	Adults	40-50%	30-45%	60-70%	55%
Frederiksen et al. (2011)	2007-2011	DK	Children aged 6-10 years	50-70%	80%		
		DK	Adults	30%	60%	75%	
		DK	Children			80%	

Co-exposure to multiple phthalates

Consistent results indicate that individuals exposed to high levels of one phthalate tend to be also highly exposed to other phthalates (Frederiksen et al. 2011, 2013; Becker et al. 2009).

Phthalate exposure via food intake

Several studies measured urinary levels of phthalates, and either the diet was changed (fasting or low-phthalate diet) or the content of phthalates in the diet was measured (Fromme et al. 2013a; Koch et al. 2013; Wittassek et al. 2011; Rudel et al. 2011; UBA 2011). Based on these studies, the current analysis assumed that 75% of the intake of DEHP is attributable to food (incl. drinks), whereas for DBP, DIBP and BBP it is assumed that 25% is attributable to food.

Medication and medical devices

DBP is used in enteric coatings in medications in concentrations up to 9000 µg per capsule (Seckin et al. 2009). There is likely to be an unknown proportion of the EU population where exposure to DBP via medicines results in a significantly higher exposure than estimated in the current restriction report. However, from 1 June 2018, medicines should only exceptionally contain DBP (EMA 2014)[11].

Medical devices may contribute to exposure to DEHP, for example in preterm neonates (SCENIHR 2016). Since the population in biomonitoring studies such as DEMOCOPHES does not include neonates, there may be additional risks from phthalates to infants not accounted for in the current risk assessment.

Exposure of women or children to DEHP from medical devices (e.g., used in blood transfusion) is of acute or short term nature. Patients with haemodialysis were not admissible to the DEMOCOPHES study but may be chronically exposed to DEHP from medical devices. It is highly unlikely that any patients with recent (within a day) exposure from medical devices would have been included in the study population. Medical procedures using PVC medical devices may lead to exposure that exceeds the daily intake in the general population by several orders of magnitude (Koch and Angerer 2012). Thus, for those children and women that regularly undergo medical treatment with DEHP containing medical devices, the risk as estimated in the current risk assessment is likely to be underestimated.

Indoor environment

Participants of DEMOCOPHES who reported to have PVC flooring or walls in their homes showed significantly higher BBP and DIBP metabolites in children as well as mothers and significantly higher DBP metabolite concentrations in children (Den Hond et al. 2015).

Fromme et al. (2013b) reported that the floor covering in 63 daycare centres from Bavaria, Berlin and North Rhine-Westfalia did not significantly correlate with excretion of phthalate metabolites. The authors however observed a significant correlation between phthalate concentrations in dust samples and urinary levels of DBP, BBP and to a lesser extent also DEHP metabolites.

Geens et al. (2014) observed significantly higher levels of DBP and BBP urinary metabolite levels in Flemish adolescents associated with the presence of wall paper in house (these phthalates are often present in adhesives and printing inks).

[11] Veterinary medicines seem not to be covered and potentially may contribute to human exposure via the food chain.

Socioeconomic position in society

Phthalate metabolites inversely correlated with educational level of the family in the DEMOCOPHES study. This might reflect associated lifestyle factors (Den Hond et al. 2015). One could also reason that lower educational level might be associated with lower incomes. This theory might be supported by the observation that in the diet of European low-income groups there is a higher contribution of fat to total energy intake and higher frequency of consumption of processed meat than for high-income groups (University of Leeds 2011). This is supported by other studies such as Geens et al. (2014) who observed a trend of increasing phthalate metabolites in Flemish adolescents with decreasing educational level of adolescents, but not with educational level of their parents.

1.1.5.1.3. Uncertainties in biomonitoring

Uncertainties to the exposure estimates from DEMOCOPHES data could be summarised as follows:

- There are uncertainties to the exposure estimates as a result of data availability issues.
- When using the volume based method of intake calculation from urinary biomonitoring data higher exposure estimates may be obtained (possibly by a factor of 2)[12].
- The exposure estimates are based on morning spot samples that may lead to systematic underestimation of exposure (possibly by a factor of 1.5)[13].
- The children in the study population of DEMOCOPHES were 6-11 years old. Younger children appear to be exposed at higher levels to the four phthalates and thus the estimates may underestimate exposure to children younger than 6.
- The FUEs[14] used for children are for adults and may result in underestimation of exposure to DBP and BBP.
- Due to the small sample size (n=21), the data from the UK is not considered representative for the exposure in the UK.

1.1.5.2. Exposure modelling

In an attempt to better characterise the sources of exposure to the four phthalates, the exposure from the different sources of the four phthalates DEHP, DBP, BBP and DIBP has been modelled. Exposure estimates were made for three main sources of exposure to the four phthalates: food, contact with articles and the indoor environment. Other sources contribute to

[12] Wittassek et al. (2007a) and Koch et al. (2007) found that values for children were on average about two times higher with the volume based-model in comparison with the creatinine-based model. The most recent publications showed a tendency to report volume based intake estimates rather than creatinine based intake estimates.

[13] Since phthalates are metabolised relatively rapidly there is both a diurnal and a day to day variation in the quantities of metabolites excreted in urine in response to the variation in intakes of these compounds over a 24 hour period. Following from the observation by Preau et al. (2010) that concentrations were significantly higher in the evening compared to the morning, spot samples taken in the morning may systematically underestimate exposure (CHAP 2015). The samples collected in DEMOCOPHES are spot morning urine samples and thus might underestimate exposure to DEHP and possibly also the other four phthalates with a factor of 1.5 (CHAP 2015).

[14] FUE = fraction of the phthalate diester excreted in urine.

the exposure to phthalates but were not modelled: exposure from medical devices and medicines and exposure of humans via the environment.

An estimate for a typical scenario and a reasonable worst case scenario was made to give an indication of the exposure for the average consumer and for the highly exposed consumer.

In addition to deterministic modelling, a probabilistic approach was used using Monte Carlo simulations. Specifically, probabilistic modelling was carried out to estimate exposure from contact with articles and to estimate combined exposure to the four phthalates. The probabilistic modelling assumed that there is no correlation between high exposure from one phthalate with high exposure from another phthalate and that distributions are normal.

Exposure from selected articles (erasers, sandals and sex toys) is also calculated to show that single articles in some cases can cause a high exposure.

The exposure estimates are converted to internal dose estimates (µg/kg bw/day) by using the absorption rate of the four phthalates for oral and dermal absorption.

1.1.5.2.1. Exposure from indoor environment

Phthalates are emitted as vapours from vinyl floor coverings, wall coverings and other PVC materials containing phthalates. The phthalate vapours then adsorb to suspended particles in indoor air but they also absorb to other surfaces like walls, carpets etc., from which they can be re-released as dust or vapours. In addition as PVC materials degrade during use, they will eventually start to release particles of PVC containing phthalates. Exposure to dust in indoor environments occurs through the inhalation of airborne dust, accidental ingestion of settled dust and dermal contact with settled dust. Small quantities of dust are present on most indoor surfaces, that is readily transferred to hands on contact with surfaces leading to a low level of dermal exposure and also accidental ingestion of settled dust via hand-mouth contact (both subconscious hand-face contact and also while eating, drinking or smoking; EA 2009).

Semivolatile organic compounds (SVOCs) such as the four phthalates tend to redistribute from their initial location (source) to all indoor surfaces, dust, and particles in the air. For DEHP, Xu et al. (2009) describes that after introduction of a phthalate containing source into a room, the air concentration reaches a steady level after about one and a half years. As long as the source of the phthalate is still available, release and steady-state will re-establish also after ventilation and vacuum cleaning.

The exposure modelling for dust uses measured phthalate concentrations in dust and assumptions on daily intake of dust. The estimated intake of dust is 0.1 g/day for infants and 0.05 g/day for children and women.

For indoor air two scenarios were simulated with DEHP (only): one children’s play room and one bathroom. The results for the two rooms gave similar results and the results from the children’s room were taken forward in the risk assessment.

The results are presented in Table 9.

Table 9. Internal exposure estimates (µg/kg bw/day) from dust ingestion, and for DEHP also inhalation of phthalates via air and particles in air[15]

	Infants		Children		Women	
	Typical case	**Reasonable worst case**	**Typical case**	**Reasonable worst case**	**Typical case**	**Reasonable worst case**
DEHP (dust)	3.94	20.42	0.57	3.68	0.31	1.65
DEHP (dust + air)	4.22	21.85	0.93	5.51	0.48	2.52
DBP	0.28	1.47	0.04	0.27	0.31	1.65
DIBP	0.27	1.41	0.04	0.25	0.02	0.11
BBP	0.08	0.42	0.01	0.08	0.01	0.03

The public could also be exposed dermally through dust and soil, but this was not further considered as the dermal exposure via dust and soil is expected to be relatively low.

1.1.5.2.2. Exposure from food

An important source of exposure to the four phthalates is via intake of food. Food may be contaminated via:

- Food contact materials (FCMs), such as food packaging and articles that are used during the processing of food;
- Non-FCM articles that may come into contact with food[16];
- Non-compliant FCMs; and
- The environment: environmental release of phthalates occurs from phthalate manufacturing plants (DEHP and DBP only), from downstream use of phthalates (DEHP and DBP only) and from the article service life (including the waste stage).

Since 2008, DEHP, DBP and BBP are authorised to be used in food contact materials with Specific Migration Limit (SML) of resp. 1.5, 0.3 and 30 mg/kg food and Limits of Quantifications (Qm) of resp. 0.1, 0.05 and 0.1% in the material.[17] The total SML is 60 mg/kg for DEHP, DBP, BBP, DINP, DIDP, and 15 other substances. DIBP is not authorised for use in FCMs. The SMLs for DEHP and DBP allocate 50% of the TDI to exposure from FCM since there are other sources contributing to the total exposure.

Market surveillance activities show the SML for especially DEHP and DBP is often exceeded (e.g., more than 1/3rd of FCMs were non-compliant in Danish Food Authority 2013).

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[15] The inhalation via air and particles in the air might be overestimated. However, inhalation of the other 3 phthalates might be underestimated.

[16] E.g., table mats and oilcloth for tables.

[17] Commission Regulation (EU) 10/2011 repealed Directives 80/766/EEC, 81/432/EEC, and 2002/72/EC from 1 May 2011. Commission Directive 2007/19/EC amended Directive 2002/72/EC and required Member States to adopt provisions to prohibit the manufacture and importation into the Community of plastic materials and articles intended to come into contact with food which do not comply with restrictions and specifications for phthalates from 1 June 2008.

No specific legal concentration limits exist for the four phthalates as contaminants in food. Member States may measure phthalates in food and may act on the basis of Article 14(8) in the general food law (Regulation (EC) No 178/2002)[18]. However, measurement of phthalates in food is technically complicated, no standardised methods exist, and there are no legal concentration limits to comply with. Studies show that phthalates are found in food samples and that the concentration varies in different samples.

A research project in Belgium reported in Fierens et al. (2012), Van Holderbeke et al. (2014) and Sioen et al. (2012) studied the concentration of phthalates in 400 food samples bought in Belgium in the period of May 2009 until June 2010. DEHP was the most detected phthalate, and the highest measured concentrations were for DEHP with several of the maxima above the SML for DEHP. High levels of DIBP were found in cereal products. Concentrations for other phthalates and food groups were generally below the SMLs.

Van Holderbeke et al. (2014) showed that there are several sources of contamination of food sold in Belgium. The contamination mainly took place during processing, either by the use of contaminated ingredients (e.g., flour) or by the use of contact materials containing phthalates (e.g., baking trays).

Other studies (Fromme et al. 2013 ; Sakhi et al. 2014; Serrano et al. 2014) also reported DEHP, BBP and DIBP were found in food samples tested. However, a study by the Danish Food Authority (Danish Food Authority 2014) did not find phthalates in the samples tested.

Exposure estimates from food

The exposure estimates from Sioen et al. (2012) and Fromme et al. (2013) were used to estimate exposure to the four phthalates via food in the current risk assessment. Sioen et al. (2012) provide estimates based on phthalate measurements in food samples taken between 2009 and 2011 combined with food consumption data from Belgian children of 2.5 to 6.5 years old. Fromme et al. (2013) estimated the exposure to phthalates via food for German children of 15-21 months based on measurements of duplicate diet samples collected over 7 consecutive days in Oct 2009 - Jan 2010. The sampling in these studies occurred after the entry into force of the legislation of phthalates in food contact materials. For exposure of infants to BBP, 30% of the exposure estimate of BBP from Fromme et al. (2007) is used[19]. Most of the data on exposure from phthalates in other studies are within the same range even though different methods are used to calculate the exposure. From the limited data on dietary exposure to phthalates in the literature, it is unclear whether the exposure to the four phthalates has decreased following the entry into force of food contact material legislation.

[18] *"8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe."*

[19] Exposure of adults to BBP in Sioen et al. (2012) is approximately 30 % of the exposure of adults estimated in Fromme et al. (2007).

Table 10. Intake estimates for phthalates from food (µg/kg bw/day).

	Infants**		Children*		Women*	
	Median daily intake	**95th p daily intake**	**Median daily intake**	**95th p daily intake**	**Median daily intake**	**95th p daily intake**
DEHP	4.66	7.09	3.50	5.38	1.49	2.86
DBP	0.70	1.24	0.20	0.30	0.08	0.16
DIBP	1.03	9.02	0.42	0.64	0.14	0.28
BBP	0.15	0.24	0.12	0.21	0.05	0.12

*Sioen et al. (2012)

**Fromme et al. (2013), except BBP where 30% of the estimate in Fromme et al. (2007) is used

1.1.5.3. Exposure from contact with articles

A very diverse range of articles containing soft PVC have been shown to contain phthalates. Examples include bicycle handles, covers for cell phones and tablets, children's wrist watches, gloves, school bags, garden hoses, PVC tape, rubber boots, rain coats, plastic sandals, bags, oilcloth and dinner mats, tools, synthetic leather furniture, floor coverings, wall paper, sex toys and erasers.

Phthalates are not covalently bound to the PVC matrix. Migration of phthalates depends on type of contact, contact duration, temperature, plasticiser concentration difference, plasticiser concentration level, molecular weight and molecular structure. Another element that seems important in determining the migration rate is the process conditions for PVC manufacturing. Phthalates are highly lipophilic, and therefore fatty simulants, such as olive oil, can produce significant migration in contrast with non-lipophilic media.

Because of the many factors determining migration, a relationship between the plasticiser content of PVC and the migration of plasticiser from PVC cannot be established based on published experimental data. An average of migration rates available in the literature is therefore used as summarised in Table 11. In comparison with these values, the average migration rates for DEHP and DBP reported by Wormuth et al. (2006) are slightly higher for DEHP and slightly lower for DBP.

Table 11. Average of migration rates for DEHP, DBP, DIBP and BBP are used in deterministic exposure modelling. Estimates in brackets are used in Monte Carlo analysis

Phthalate	**Min migration rate in µg/cm²/h**	**Average migration rate in µg/cm²/h**	**Max migration rate in µg/cm²/h**
DEHP	0.02 (0.1)	3.8	31.3 (15.2)
DBP	0.02 (0.2)	6.1	36.2 (17.2)
DIBP	0.9 (0.2)	5.4	17.9 (17.2)
BBP	0.3 (0.3)	2.5	6.5 (6.5)

Based on market information it is assumed that the proportion of PVC articles containing DEHP, DBP, DIBP and BBP is 74%, 8%, 8% and 10%, respectively.

Exposure to infants from mouthing of articles

The literature shows that children mouth many items other than dummies, teethers and toys. Particularly children under 1 year do mouth other articles due to teething and use mouthing as a method of exploring their environment. Examples of PVC articles that are not toys or childcare articles that infants could mouth are: covers for mobile phones and tablets, faux leather hand-bags, furniture with faux leather, oil cloth and dinner mats, shower curtains, balance balls and training balls as well as reflectors on jackets and straps on zippers on jackets.

The typical mouthing time for articles that are not toys or childcare articles is assumed to be approximately 1 min/day. ECHA (2013) assumed that the mean mouthing time for children in the age of 0-18 months can be estimated to be 30 min/day. This covers all articles made of various materials. Smith and Norris (2002) estimated that half of all mouthed articles are made of plastics, therefore mouthing of plastic articles is 15 minutes per day. It is expected that children will primarily mouth toys and childcare articles and therefore it is assumed that only 25% of the mouthing time for plastic articles is used to mouth articles not being toys and childcare articles (3.75 minute per day). It is then assumed that 25% of these plastic articles contain one or more of the four phthalates, thus resulting in a typical mouthing time of 1 min/day.

As a reasonable worst case scenario a mouthing time of 30 min/day is chosen for articles that are not toys or childcare articles. ECHA (2013) assumed two hours as the mouthing time in the reasonable worst case scenario for plastic articles (including toys and childcare articles). The 30 minutes reflects a situation where a child's favourite mouthing object is plasticised with one or more of the four phthalates.

The standard surface area of the mouthed articles is assumed to be 10 cm^2.

Exposure estimates of typical and reasonable worst case scenarios are given in Table 12.

Table 12. Exposure of infants from mouthing of articles (µg/kg bw/day)

	DEHP	**DBP**	**DIBP**	**BBP**
Typical*	0.05	0.01	0.01	0.00
Reasonable worst case*	1.53	0.27	0.23	0.14
Reasonable worst case**	2.76	0.37	0.36	0.18

* deterministic modelling, based on average migration rate

**Monte Carlo simulations related to variation of migration rate and mouthing time

Direct dermal exposure

The general public and employees may be dermally exposed to many kinds of PVC articles which might contain one or more of the four phthalates. Exposure could be from dermal contact with vinyl flooring, gloves for dishwashing or cleaning, bags and wallets, faux-leather sofas, handles of tools, steering wheels, sandals, oilcloths, dinner mats and other articles.

In the typical scenario for infants and children it is assumed that the daily dermal contact time with articles containing one or more of the four phthalates is 30 min. In the reasonable worst case scenario, the daily dermal contact time is assumed to be 1½ hour. This reflects that some articles are used for a short time, but frequently throughout a day and some are used for a longer period like furniture. The surface area in contact with articles containing one or more of the four phthalates is assumed to be 10% and 25% of the total body surface area respectively

in the typical case and reasonable worst case scenario.

Women can come into contact with the same type of articles as children but the exposure to for instance gloves, garden hoses, handles on tools, steering wheels is expected to be higher. Some of these articles might be used for most of the day. In the typical scenario for women, it is assumed that the dermal contact time with articles containing one or more of the four phthalates is ½ hour and in the reasonable worst case scenario 1½ hour. The contact surface is assumed to be 10% of the total body surface area in the typical scenario and 12% in the reasonable worst case scenario.

In comparison, Health Canada (2015c) assumed longer contact times and larger surface areas for both infants and women.

On this basis of the above parameters the dermal exposure is estimated for the three age groups. Exposure estimates of typical and reasonable worst case scenarios are given in Table 13.

Table 13. Internal exposure estimates from dermal exposure (µg/kg bw/d)

	DEHP			**DBP**			**DIBP**			**BBP**		
	TC	RWC	RWC MC	TC	RWC	RWC MC	TC	RWC	RWC MC	TC	RWC	RWC MC
Infants	3.44	25.79	24.91	1.19	8.95	6.10	1.06	7.92	6.39	0.31	2.29	1.57
Children	3.29	17.91	17.26	1.14	6.22	4.39	1.01	5.50	4.49	0.29	1.59	1.13
Women	2.13	7.63	12.06	0.74	2.65	3.17	0.65	2.34	3.09	0.19	0.68	0.77

TC = Typical case scenario
RWC = Reasonable worst case scenario. In this estimate, the reasonable worst case estimates for exposure time and contact area are used, while the typical case migration rate is used.
RWC MC = Monte Carlo simulation of the reasonable worst case scenario (variation of exposure time, contact area and migration rate).

1.1.5.4. Exposure from contact with selected articles

Contact with some specific articles might lead to high exposures. Erasers were identified as an example of an article that can be a possible source of high oral exposure. In the typical case mouthing by children during 60 min/day results in an estimated exposure level of 15.8 µg/kg bw/day. In the reasonable worst case scenario assuming in addition to the mouthing ingestion of 8 mg/day of eraser[20], results in an estimated exposure level of 176 µg/kg bw/day.

Some articles such as plastic sandals and sex toys that might lead to high exposures following contact with the skin or mucous membranes. The exposure to DEHP, DIBP and DBP in plastic sandals was estimated to be up to 5.45 µg/kg bw/day for DBP in women and over 3 µg/kg bw/day in infants and children (worst case). Exposure to DEHP from adult sex toys was estimated to be about 1 µg/kg bw/day (worst case).

In addition, DIBP is not restricted in childcare articles. Children could therefore be exposed dermally to DIBP from childcare articles as changing mats, bibs or car seats. If DIBP is used in a changing mat, the exposed dermal area could be as large as half of the body surface area.

[20] corresponding to approximately one sesame seed

1.1.5.5. Modelled estimates of aggregated exposure from indoor environment, food and contact with articles

The results from exposure modelling are summarised in Table 14.

Table 14. Aggregated exposure from indoor environment, food and contact with articles for each phthalate (µg/kg bw/day)

	Infants			**Children**			**Women**		
	Typical	RWC	MC RWC	Typical	RWC	MC RWC	Typical	RWC	MC RWC
DEHP									
Indoor	4.22	21.85	21.85	0.93	5.51	5.51	0.48	2.52	2.52
Food	4.66	7.09	7.09	3.50	5.38	5.38	1.49	2.86	2.86
Articles	3.49	27.32	27.67	2.39	17.91	17.26	2.12	7.63	12.06
Total	12.37	56.26	56.61	6.82	28.80	28.15	4.09	13.01	17.45
Monte Carlo			42.98			22.38			14.17
DBP									
Indoor	0.28	1.47	1.47	0.04	0.27	0.27	0.02	0.12	0.12
Food	0.70	1.24	1.24	0.20	0.30	0.30	0.08	0.16	0.16
Articles	1.20	9.22	6.48	0.83	6.22	4.39	0.74	2.65	3.17
Total	2.18	11.93	9.19	1.07	6.79	4.96	0.84	2.92	3.45
Monte Carlo			6.63			4.63			3.27
DIBP									
Indoor	0.27	1.41	1.41	0.04	0.25	0.25	0.02	0.11	0.11
Food	1.03	9.02	9.02	0.42	0.64	0.64	0.14	0.28	0.28
Articles	1.06	8.16	6.74	0.73	5.50	4.49	0.65	2.34	3.09
Total	2.37	18.59	17.18	1.19	6.40	5.39	0.82	2.74	3.48
Monte Carlo			12.19			4.94			3.28
BBP									
Indoor	0.08	0.42	0.42	0.01	0.08	0.08	0.01	0.03	0.03
Food	0.00	0.00	0.00	0.12	0.21	0.21	0.05	0.12	0.12
Articles	0.31	2.43	1.75	0.21	1.59	1.13	0.19	0.68	0.77
Total	0.39	2.85	2.17	0.34	1.87	1.41	0.25	0.83	0.92
Monte Carlo			1.90			1.25			0.83

Typical = Typical case scenario
RWC = Reasonable worst case scenario
RWC MC = Monte Carlo simulation of the reasonable worst case scenario

For DEHP, food is the dominant source for infants' and children's exposure in the typical case, while direct exposure (oral and dermal) to articles dominates for women. For the reasonable worst case exposure from contact with articles seems to be the main source for all age groups. Indoor environment contributes by 14% and 12% for children and women respectively, while for infants indoor environment count for 34%.

For DBP the main source seems to be direct exposure (oral and dermal) to articles for all three age groups.

The same applies for DIBP, even if the contribution from food seems to be higher, especially for infants and children.

1.1.5.6. Occupational exposure

All four substances are listed in Annex XIV of REACH, implying that the substances may not be used in the EU unless an authorisation is granted. Applications have been submitted for DEHP and DBP, only.

Workers are exposed to DEHP during manufacturing of DEHP, the formulation of DEHP (compounds, dry-blends and plastisol formulations) and the production of articles (polymer processing by calendering, spread coating, extrusion, injection moulding). Workers are furthermore exposed to the four substances during formulation of recycled soft PVC containing DEHP in compounds and dry-blends. During the service life stage of articles worker exposure may also occur (professional handling of PVC articles during installation of building materials and workers wearing PVC work clothes and footwear.

RAC confirmed that the risk assessment based on the limited exposure data in the applications for DEHP does not demonstrate adequate control of risks for workers from the use applied for. RAC's assessment based on these limited exposure data in the application showed a risk for the use applied for.

For DBP applications have been submitted for a number of narrowly defined uses. For all these applications, RAC confirmed that the exposure assessments in the applications demonstrated adequate control of risks from the use applied for provided that the risk management measures and operational conditions as described in the applications are adhered to.

1.1.6. Risk characterisation

Risk characterisation is only performed for the health of the general public. Risks related to manufacturing, formulation and use of the substances have been assessed by RAC under the authorisation process (AfA 2013a,b,c), see earlier.

1.1.6.1. Risk characterisation based on biomonitoring data

RCRs for 95th percentile exposure of children to DBP and DIBP are above or close to 1 in several Member States (Table 15). The RCR for 95th percentile exposure of children to DEHP is close to 1 in Romania and in mothers equal to 1. The geometric mean exposure values in Romania are also high compared to other countries (see Table 7).

In 13 out of 15 Member States (87%[21]) RCRs for combined 95th percentile exposure to DEHP, DBP, BBP and DIBP are at or above 1 for children. For 5 out of these countries RCRs are equal to or above 1 also for mothers, with a 6th country having an RCR above 1 in mothers but not in children (Cyprus).

[21] Excluding the UK (small sample size, n= 21) and Switzerland as it is not part of the EU.

In Polish children the geometric mean exposure values approach an RCR of 1 (RCR of 0.86). The RCR corresponding to the median and mean exposure values are 0.81 and 1.13 respectively in Polish children. The three countries with the highest 95th percentile combined exposure values (Poland, Spain and Romania), are also amongst the countries with highest geometric mean combined exposure values.

Approximately 5% of new born boys (130 000) were at risk through in utero exposure in 2014 and about 16% boys (400 000) were at risk from direct exposure in 2014[22]. In 2011, the percentages were 6% and 18%, respectively.

Table 15. RCRs for four phthalates as estimated from 95th percentile urinary biomonitoring exposure levels from DEMOCOPHES data from 2011-2012

		Mother						Child				
Country	**N**	**DEHP**	**DBP**	**BBP**	**DIBP**	**SUM**	**N**	**DEHP**	**DBP**	**BBP**	**DIBP**	**SUM**
SI	120	0.2	0.4	0.0	*NA*	0.6	120	0.2	0.4	0.0	*NA*	0.6
UK	21	0.1	0.1	0.0	0.3	0.5	21	0.2	0.3	0.0	0.3	0.7
CH	117	0.2	0.3	0.0	0.2	0.6	119	0.2	0.3	0.0	0.3	0.8
CY	59	0.4	0.2	0.0	0.4	1.1	60	0.2	0.2	0.0	0.4	0.9
PT	117	0.3	0.2	0.0	0.3	0.9	116	0.3	0.3	0.0	0.4	1.0
IE	120	0.2	0.2	0.0	0.4	0.8	120	0.3	0.3	0.0	0.5	1.0
HU	115	0.2	0.5	0.0	*NA*	0.7	117	0.4	0.7	0.0	*NA*	1.1
LU	60	0.1	0.2	0.0	0.3	0.6	60	0.1	0.3	0.0	0.7	1.1
DK	143	0.2	0.2	0.0	0.4	0.7	142	0.2	0.3	0.0	0.6	1.1
DE	116	0.1	0.3	0.0	0.2	0.7	120	0.2	0.5	0.0	0.4	1.1
SE	96	0.2	0.7	0.0	*NA*	0.9	97	0.3	1.0	0.0	*NA*	1.3
SK	125	0.2	0.8	0.0	*NA*	1.0	127	0.4	1.1	0.0	*NA*	1.5
CZ	117	0.2	0.7	0.0	*NA*	1.0	120	0.4	1.3	0.0	*NA*	1.7
BE	125	0.1	0.4	0.0	0.6	1.1	125	0.4	0.4	0.0	1.0	1.8
RO	117	1.0	0.3	0.0	0.3	1.6	119	0.9	0.6	0.0	0.6	2.1
ES	118	0.3	0.3	0.0	0.3	0.9	119	0.4	0.9	0.0	0.9	2.1
PL	119	0.4	0.8	0.0	0.7	1.9	115	0.5	1.1	0.0	1.2	2.9

NA = not available

[22] Based on the combined RCRs from DEMOCOPHES biomonitoring data, the population at risk in 2014 has been estimated as the percentage of mothers (boys exposed in utero) and children exceeding an RCR value of 1 for the individual 15 EU Member States (except UK). The overall percentage of the population at risk from these 15 Member States was used to extrapolate to the remaining 13 Member States. The estimations assume a lognormal distribution. The standard deviation of the lognormal distributions was derived per country from the natural logarithmic values of the measure 95th percentile and the geometric mean (2011 values projected to 2014).

Table 16. RCRs for four phthalates as estimated from geometric mean (GM) urinary biomonitoring values

		Mother						Child				
Country	N	DEHP	DBP	BBP	DIBP	SUM	N	DEHP	DBP	BBP	DIBP	SUM
SI	120	0.1	0.1	0.0	*NA*	0.2	120	0.1	0.1	0.0	*NA*	0.2
CH	117	0.0	0.1	0.0	0.1	0.2	119	0.1	0.1	0.0	0.1	0.2
CY	59	0.0	0.1	0.0	0.2	0.3	60	0.0	0.1	0.0	0.2	0.3
LU	58	0.0	0.1	0.0	0.1	0.2	60	0.0	0.1	0.0	0.1	0.3
UK	21	0.0	0.1	0.0	0.1	0.1	21	0.1	0.1	0.0	0.1	0.3
HU	115	0.1	0.2	0.0	*NA*	0.2	117	0.1	0.2	0.0	*NA*	0.3
IE	120	0.1	0.1	0.0	0.1	0.2	120	0.1	0.1	0.0	0.1	0.3
PT	117	0.1	0.1	0.0	0.1	0.3	116	0.1	0.1	0.0	0.1	0.4
DE	116	0.0	0.1	0.0	0.1	0.3	120	0.1	0.2	0.0	0.1	0.4
BE	125	0.0	0.1	0.0	0.1	0.3	125	0.1	0.2	0.0	0.2	0.4
DK	143	0.0	0.1	0.0	0.2	0.3	142	0.1	0.1	0.0	0.2	0.4
SE	96	0.1	0.3	0.0	*NA*	0.3	97	0.1	0.4	0.0	*NA*	0.5
RO	117	0.1	0.1	0.0	0.1	0.3	119	0.1	0.2	0.0	0.2	0.5
SK	125	0.1	0.3	0.0	*NA*	0.4	127	0.1	0.4	0.0	*NA*	0.6
ES	118	0.1	0.1	0.0	0.1	0.4	119	0.1	0.2	0.0	0.2	0.6
CZ	117	0.1	0.3	0.0	0.0	0.3	120	0.1	0.4	0.0	0.0	0.6
PL	119	0.1	0.2	0.0	0.2	0.5	115	0.1	0.4	0.0	0.4	0.9

NA = not available

1.1.6.2. Risk characterisation based on exposure modelling

Table 17 presents the RCRs for the typical case modelling exposure estimates for food, the indoor environment and contact with articles and the range of GM of biomonitoring exposure estimates from different countries. These RCRs are combined to obtain a total RCRs for aggregated exposure sources and combined exposure to the four phthalates for each of the age groups (deterministic modelling). The RCRs for combined exposure to the four phthalates in the typical scenario are 1 for infants but below one for children and women.

Table 17. Overview of RCRs for the typical case modelling exposure estimates (deterministic modelling) and the range of GM of biomonitoring exposure estimates from different countries

	Infants				**Children**					**Mothers**				
	Indoor	Food	Articles	Total	Indoor	Food	Articles	Total	GM BM	Indoor	Food	Articles	Total	GM BM
DEHP	0.12	0.14	0.10	0.36	0.03	0.10	0.07	0.20	0.04-0.14	0.01	0.04	0.06	0.12	0.03-0.10
DBP	0.04	0.10	0.18	0.33	0.01	0.03	0.12	0.16	0.08-0.46	0.00	0.01	0.11	0.13	0.07-0.30
DIBP	0.03	0.12	0.13	0.29	0.00	0.05	0.09	0.14	0.08-0.36	0.00	0.02	0.08	0.10	0.05-0.19
BBP	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00-0.00	0.00	0.00	0.00	0.00	0.00-0.00
Total	**0.20**	**0.37**	**0.41**	**0.98**	**0.04**	**0.18**	**0.28**	**0.50**	**0.23-0.89**	**0.02**	**0.07**	**0.25**	**0.34**	**0.16-0.49**

Table 18 presents the RCRs for the reasonable worst case modelling exposure estimates for food, the indoor environment and contact with articles and the range of 95th percentile of biomonitoring exposure estimates from different countries. These RCRs are combined to obtain a total RCRs for aggregated exposure sources and combined exposure to the four phthalates for each of the age groups by using Monte Carlo simulations. The RCRs for combined exposure to the four phthalates in the reasonable worst case scenario are 2.7 for infants, 1.3 for children and 0.9 for mothers.

Table 18. RCRs for the reasonable worst case modelling exposure estimates and the range of the 95th percentile of biomonitoring exposure estimates from different countries

	Indoor	**Food**	**Articles**	**Total**	**Aggregated RCR (MC)**	**95th percentile biomonitoring**	**Combined RCR (MC)**
Infants							
DEHP	0.64	0.21	0.81	1.67	1.26	NA	**2.63**
DBP	0.22	0.19	0.97	1.37	1.14	NA	
DIBP	0.17	1.09	0.81	2.07	1.47	NA	
BBP	0.00	0.00	0.00	0.00	0.00	NA	
Total	1.03	1.48	2.60	5.11		NA	
Combined RCR per source (MC)	0.76	1.34	1.69				
Combined RCR (MC)	2.69						
Children							
DEHP	0.16	0.16	0.51	0.83	0.66	0.16-0.88	**1.34**
DBP	0.04	0.04	0.65	0.74	0.69	0.28-1.21	
DIBP	0.03	0.08	0.54	0.65	0.60	0.25-1.21	
BBP	0.00	0.00	0.00	0.00	0.00	0.00-0.01	
Total	0.23	0.28	1.71	2.22		0.75-2.94	
Combined RCR per source (MC)	0.18	0.25	1.11				
Combined RCR (MC)	1.34						
Mothers							
DEHP	0.07	0.08	0.35	0.51	0.42	0.08-1.02	**0.90**
DBP	0.02	0.02	0.47	0.51	0.49	0.15-0.89	
DIBP	0.01	0.03	0.37	0.42	0.40	0.27-0.72	
BBP	0.00	0.00	0.00	0.00	0.00	0.00-0.00	
Total	0.11	0.14	1.20	1.45		0.50-1.98	
Combined RCR per source (MC)	0.08	0.12	0.81				
Combined RCR (MC)	0.91						

Total = simple sum of RCRs, i.e., not using Monte Carlo estimations
NA = Not available
MC = Monte Carlo

1.1.6.3. Overall conclusion

Based on the 95th percentile of combined exposure to the four phthalates a risk has been identified for children in 13 out of 15 Member States (87%) and in 6 out of 15 Member States in women (40%). Overall, in 14 out of 15 Member States (93%) more than 5 percent of the children were at risk.

Approximately 5% of new born boys (130 000) were at risk through in utero exposure in 2014 and about 16% boys (400 000) were at risk from direct exposure in 2014.

Based on modelling, the RCR for combined exposure to the four phthalates in the reasonable worst case scenarios are 2.7 for infants, 1.3 for children and 0.9 for mothers. These modelling estimates are generally consistent with the biomonitoring results for children and mothers, but appear to underestimate risks slightly in countries with high exposure levels. No biomonitoring estimates are available from DEMOCOPHES for infants but modelling suggests that the RCR for infants from combined exposure to the four phthalates may be twice that for children.

Regarding the contribution of sources to the exposure, the modelled exposure suggests the following:

- All exposure sources (contact with articles, food and indoor environment) contribute significantly to the risks.
- For infants, the reasonable worst case exposure to DEHP is dominated by exposure from contact with articles and via the indoor environment, while for DIBP the contribution of food explains 50% of the risk.
- For children, exposure from contact with articles explains in average about 77% of the RCR for combined exposure to the four phthalates in the reasonable worst case.
- For women, the reasonable worst case RCR for combined exposure to the four phthalates in the reasonable worst case is just below 1 (0.9). Also here exposure from contact with articles seems to be a major contributor, also for DEHP. It is noted that this is not in line with the common understanding that food is the main source of exposure to DEHP.
- Erasers were identified as an example of an article that can be a possible source of high oral exposure. RCRs for children are 0.5 in the typical scenario (mouthing) and 5.0 in the reasonable worst case scenario (mouthing and ingestion). Plastic sandals and sex toys that might lead to high exposures following contact with the skin or mucous membranes. Reasonable worst case exposure to sandals may lead to RCRs of 0.04-0.8. Exposure from sex toys may result in an RCR of 0.03 for reasonable worst case exposure.

Several studies show that food is an important source for the exposure of phthalates, in particular for exposure to DEHP. It can be concluded from these studies that the exposure of DEHP in women and infants is driven by food consumption while there seem to be additional important sources of exposure of DBP, DIBP and BBP. For the purposes of the current analysis it has been assumed that 75% of the intake of DEHP is attributable to food (incl. drinks), whereas for DBP, DIBP and BBP it is assumed that 25% is attributable to food. The modelling data is fairly consistent with this observation for the typical exposure case with DBP, DIBP and BBP. However, the modelling estimates for DEHP appear to underestimate to contribution of food to the typical exposure levels in the population of children and women. In the reasonable worst case, the contribution of food is very low for all phthalates. This may in part be explained by the fact that these are reasonable worst case exposure levels to which some

limited number of individuals may be exposed to. These cases may not be captured in the limited sample sizes in the 'fasting-urinary biomonitoring' or 'duplicated diet-urinary biomonitoring' studies.

It is concluded that a risk has been identified that is not adequately controlled and needs to be addressed.

1.1.6.4. Uncertainties in the RCR calculations

A summary of the main uncertainties and their implications for the RCR are listed in Table 19. Overall, uncertainties point in the direction of a possible underestimation of the risks.

Table 19. Overview of main sources of uncertainty in the phthalate risk assessment based on biomonitoring data and influence on RCRs (↓ towards lower RCR, ↑ towards higher RCR).

Source	Description	Effect on RCR
Hazard		
DNEL DEHP	Alternate DNELs of 0.007 and 0.008 mg/kg bw/day may be derived from Christiansen et al. (2010) and Andrade et al. (2006) (4.5 times lower).	↑
DNEL BBP	BBP appears to have comparable potency to DEHP and DBP on fetal testosterone production. It may be speculated that further studies on effects of BBP on endocrine sensitive endpoints would reveal effects at lower doses than 50 mg/kg bw/day, potentially leading to a lower DNEL (if similar to DEHP the DNEL for BBP would be a factor 10 lower)	↑
DNEL DIBP	In the absence of conclusive experimental data, read-across from DBP has been performed to DIBP. The experimental evidence for concluding that DIBP is of similar anti-androgenic potency is considered robust, but the assumption of potency difference (25%) is uncertain.	-
DNELs for children	The DNELs are relevant for both pregnant women and for children, albeit it is possible that the DNELs for children would be higher.	↓
Species differences	There are indications of species differences in metabolism and possibly in effects on fetal steroidogenesis, but the evidence is insufficient to deviate from the assumption that humans are more sensitive than the test species.	↓
Effects on the immune system, the metabolic system and neurological development	A number of experimental and epidemiological studies have suggested possible effects on the immune system, the metabolic system and neurological development. Some of these studies indicate that reproductive toxicity may not be the most sensitive endpoint for the effects and that the selected DNELs may not be sufficiently protective against these other effects	↑
Threshold	If it is decided that the four phthalates give rise to equivalent level of concern due to their endocrine disrupting properties for human health, it has to be determined whether a threshold for effects can be demonstrated if any applications for authorisation would be submitted in the future (European Commission 2014). The existence of a threshold has not yet been assessed and documented for DEHP, DBP, DIBP and BBP.	↑

Exposure		
Data availability	There are uncertainties to the estimates as a result of data availability issues. The effect appears to be minimal based on a comparison of our estimates and published estimates for DK.	-
Creatinine based method	When using volume based method of intake calculation from urinary biomonitoring data higher exposure estimates may be obtained (possibly by a factor of 2).	↑
Morning spot samples	The exposure estimates are based on morning spot samples that may lead to systematic underestimation of exposure (possibly by a factor of 1.5).	↑
Use of 95th percentile exposure and summation of 95th percentiles of several phthalates	The exposure estimates are derived from a fairly limited number of samples per country (around 120). This results in relatively high uncertainties to whether the actual 95th percentile exposure in the entire population is lower or higher: the sample might not be representative for highly exposed sub-populations. Risk assessment for consumers should assess risks to the reasonable worst case scenario. This scenario may correspond to a higher percentile of exposure of the population distribution than the 95th percentile (e.g., the 99th percentile, see RIVM 2014). Even a short elevated exposure level may be sufficient to cause adverse effects from exposure within the critical windows of exposure. On the other hand, maxima may arise from analytical and methodological errors or might result from non-representative exposure situations. Furthermore, adding RCRs based on 95th percentiles of several phthalates may lead to some overestimation of the RCRs, although consistent evidence indicates that individuals exposed to high levels of one of the four phthalates tend to be exposed at high levels to other phthalates as well.	↑↓
Selection of population	Patients with haemodialysis were not admissible to the DEMOCOPHES study (FPS 2013) and thus it is highly unlikely that any patients with recent (within a day) exposure from medical devices would have been included in the study population. These specific situations may lead to exposure that exceeds the daily intake in the general population by several orders of magnitude (Koch and Angerer 2012). Thus, for those children and women that regularly undergo medical treatment with DEHP containing medical devices, the risk as estimated in the current risk assessment is likely to be underestimated.	↑
Infants	The children in the study population of DEMOCOPHES were 6-11 years old. Younger children appear to be exposed at higher levels to the four phthalates and thus the estimates may underestimate exposure of younger children. In addition, medical devices may contribute to exposure to DEHP, for example in preterm neonates (SCENIHR 2016). Since the population in biomonitoring studies such as DEMOCOPHES does not include neonates, there may be additional risks from phthalates to infants not accounted for in the current risk assessment.	↑
FUEs used for children	The FUEs used for children are for adults and may result in underestimation of exposure to DBP and BBP.	↑
Estimates for specific Member States	The RCRs for combined exposure are underestimated for Slovenia since no measurement of DIBP metabolites was available. For the same reasons, the RCRs for the Slovak Republic, Sweden, Czech	↑

	Republic and Hungary may also be underestimated, although potential issues with chromatic separation may have compensated for the lack of a measurement value for DIBP. Due to the small sample size (n=21), the data from the UK is not considered representative for the exposure in the UK and might be underestimated.	
Present risk	Exposure is projected to decline and a projection was made to estimate the risk in 2014. Based on the projections no significant changes in the risk levels in 2014 can be expected to have occurred (RCRs may be about 10% lower).	↓
Other anti-androgenic substances may contribute significantly to the total risk	The combined risk assessment considers only DEHP, DBP, DIBP and BBP, but other substances may contribute to mixture effects on male reproductive development. Several substances are evaluated to be able to cause anti-androgenic effects. Exposure to other substances affecting male reproductive development can contribute significantly to the total risk. Therefore, the combined risk assessment of DEHP, DBP, DIBP and BBP alone is likely to be an underestimation of the risk for mixture effects on male reproductive development. Examples are other anti-androgenic phthalates such as DINP, DnHP, DIHepP, DnHepP (Health Canada 2015; ECHA 2013a) and other substances e.g., Vinclozolin, Prochloraz, Procymidone and p,p'-DDE (Kortenkamp and Faust 2010)	↑

1.2. Justification for an EU wide restriction measure

A Union-wide action to address the risks associated with EU manufactured or imported articles containing phthalates is needed to ensure a harmonised high level of protection of human health and the environment across the Union and to ensure the free movement of goods within the Union. In addition, the efficient functioning of the internal market for substances can be achieved only if requirements for substances do not differ significantly from Member State to Member State.

One of the primary reasons to act on a Union-wide basis is the cross-boundary human health problem: a risk was identified in 14 out of 15 Member States where biomonitoring took place. In fact, most children and women are in daily contact with some of the articles or are staying in indoor air exposing them to the four phthalates.

Furthermore, the fact that the articles containing the four phthalates, imported as well as produced in the EU, need to circulate freely once on the EU market and support the internal market of substances, stresses the importance of an EU-wide action rather than action by individual Member States. In addition, an EU-wide action would eliminate the distortion of competition on the European market between imported and domestically produced articles due to the authorisation procedure.

1.3. Baseline

Manufacturing and use

DEHP, DBP, DIBP, and BBP continue to be produced and used in the EU albeit at decreasing rate. Information from EuroStat shows that between 2004 and 2013 their consumption has declined by more than 10.5% annually on average, to about 95 000 tonnes. The regulatory changes which have been the driving force of this decline intensified it in recent years, leading to a faster rate of decline: 13% annually of consumption and close to 25% decrease in production between 2010 and 2013.[23]

DEHP, DBP, DIBP and BBP are commonly used plasticisers. They belong to the group of orthophthalates. Phthalates in general – covering orthophthalates and terephthalates - are the most commonly used plasticisers in the world. They accounted for just over 78% of the world consumption of plasticisers in 2012 (IHS 2013), while DEHP alone, for more than 50% of the phthalates used worldwide (ECPI 2012). China is the largest plasticiser market in the world, accounting for nearly 38% of world consumption in 2012; it also has the highest forecast growth rate between 2011 and 2018, spurred by increased plasticiser consumption in goods for both domestic and export markets. Other Asian countries taken together, including Japan, constitute the second-largest plasticiser consuming region, with nearly 21% in 2012, followed by Western Europe (16%) and North America (about 13%). (IHS 2013) In Europe, approximately 95% of produced orthophthalates are used in flexible PVC (ECPI 2015).

DEHP is a general purpose plasticiser, while the other three have particular advantages in some applications:

- DEHP has been used for more than 50 years in almost all soft/flexible PVC applications due to its recognised plasticising efficiency, fusion rate and viscosity. It is often used as the standard for PVC plasticisers due to being in the mid-range of plasticiser properties, at an attractive price. Largely, due to regulatory pressures, the use of DEHP in the EU, North America and Northeast Asia has been declining but elsewhere the plasticiser still holds a dominant market share, e.g., it represents 60% of all plasticisers used in China and its use is forecast to grow (TOC 2012, BASF 2011).
- DBP and DIBP exhibit low viscosity and good solvating properties but their high volatility has limited their use to that of a speciality plasticiser often used in combination with other plasticisers, including DEHP. DBP is essentially used for its viscosity reducing properties and compatibility with non-PVC mixtures (lacquers, printing inks, sealants, adhesives) or as processing aid for PVC (plastisols, compounds) (ECHA 2013a). Its soft PVC uses include flooring, packaging material, shoes, home furnishing, and clothing. DIBP has very similar application properties to DBP and may therefore be used to substitute DBP in most, if not all, of its applications.
- BBP is used mainly as a specialty plasticiser for PVC or other polymers. It is a fast fusing plasticiser, exhibiting lower volatility than DBP or DIBP but it is more volatile than DEHP and exhibits poor low temperature properties. Its high solvency results in poor plastisol shelf life, requiring the need to blend it with DEHP or DINP. BBP is used in some soft PVC products such as flooring, packaging, and artificial leather as well as car

[23] Statistics primarily reflect DEHP.

care products and together with other polymers in sealants, adhesives, paints, coatings and inks. (ECPI 2014)

DEHP, DBP, DIBP, and BBP are used as plasticisers in a wide range of articles many of which represent risk to human health and potentially to the environment. This restriction proposal focuses on those articles that present risks to human health via the critical routes of exposure:

i. oral (due to mouthing) and dermal or mucous membrane in an indoor or outdoor environment, as well as
ii. oral (due to ingestion of dust) or inhalation route in an indoor environment.

The following article groups fall in the scope:

- Flooring (and heavy wall covering)
- Film & sheets (& plates, foil, strip and other flat shapes) of plastics
- Bags
- Coated clothing
- Coated paper/wallpaper/tapestry
- Mattresses
- Balls for training and physical exercises
- Bathing equipment (swim-coats/wings/belts and pools - inflatable and others)
- Footwear
- Insulation on wires and cables
- Other moulded products (e.g., decorative items, office supplies, etc.)
- Miscellaneous: These are items not falling within the classification groups listed above such as: adult sex toys; handles of bicycles or garden tools; car interiors; other interior construction products, mixtures such as coating and finishes incorporated in the articles above, some hoses & tubes, etc.

The use of DEHP, DBP, DIBP, and BBP in production of articles in the EU is subject to authorisation requirements under Title VII of REACH. At the time of the writing of this report, there are pending authorisation decisions for two applications for authorisation for the use of DEHP in formulation of DEHP in compounds, dry-blends and plastisol formulations and in polymer processing by calendaring, spread coating, extrusion, injection moulding to produce polyvinyl chloride (PVC) articles.

Another application for authorisation with a pending decision is for formulation of recycled soft PVC in compounds and dry-blends and industrial use of recycled soft PVC in polymer processing by calendaring, extrusion, compression and injection moulding to produce PVC articles.

To date, there are no applications for authorisation for the use of the DBP, DIBP, and BBP in articles in the scope of this restriction proposal. Therefore, it can be assumed that the use of these three phthalates in the manufacturing of articles in the scope of this proposal was fully phased out in the EU28 as of 2015. No applications for the three phthalates have been received from recyclers which suggest that their content in the recycling waste stream does not exceed 0.3% w/w of the plasticised material.

Authorisation requirements do not apply to imported articles. These articles are produced outside Europe using the four phthalates and subsequently imported in the EU presenting risk to human health. The share of the tonnages of the four phthalates contained in imported articles has been growing. Between 2011 and 2014, their share is estimated to have grown

from 56.5% to 73% of the total tonnes the four phthalates in articles placed on the EU market (Table 20). The tonnage of the four phthalates in imported articles is anticipated to increase in the future primarily due to an increase in the import volume of articles.

Table 20. Estimated total tonnes of DEHP, DBP, DIBP and BBP contained in articles in the scope of this proposal placed on the EU28 market

in tonnes	**2011**	**2012**	**2013**	**2014**
Tonnes used in EU28 article manufacturing	92 403	84 259	73 458	62 612
Tonnes contained in Exported articles	14 438	14 924	15 755	15 722
Tonnes contained in Imported articles	101 256	100 015	122 822	124 245
Total tonnes in articles placed on the market	179 222	169 350	180 525	171 135
Share of tonnes imported of total placed on EU28 market	56.5%	59.1%	68.0%	72.6%

Notes: Estimates derived on the basis of EuroStat import, export, and manufacturing statistics; AFA 2013; Danish phthalate tax database, and market intelligence. See Annex C: Baseline for details.

Baseline

The "baseline" scenario describes the tonnages of DEHP, DBP, DIBP, and BBP estimated to be contained in articles placed on the EU28 market in the absence of the proposed restriction. The scenario reflects foreseen regulatory changes and employs a set of assumptions taking into account the main factors impacting the projections of the estimated tonnages in articles. These factors include the long term market forces influencing the use of the four phthalates in article manufacturing in EU28 and the import of articles containing the four phthalates to the EU.

The current use of DEHP, DBP, DIBP and BBP in the EU28 production of articles in the scope of this restriction proposal is estimated on the basis of EuroStat data, market intelligence and information from applications for authorisation. The tonnages of the four phthalates in imported and exported articles are derived from EuroStat data by CN (Combined nomenclature) code on the volume of imported and exported articles. These statistics are adjusted to estimate:

- first, what portion of the tonnes per CN code is the plasticised material;
- second, what portion of the tonnes plasticised material in the plasticiser itself;
- third, what portion of the plasticiser tonnes could in fact be DEHP, DBP/DIBP or BBP on the basis of historical use of the plasticisers in the geographic region they originate from.

Future tonnages of the four phthalates contained in articles placed on the EU market in the scope of this proposal are forecast taking into account the following regulatory and market forces:

- the impact of the authorisation requirements on the use of the four phthalates in EU production of articles;
- the amendments of the RoHS Directive on the use of the four phthalates in electrical and electronic equipment, such as wires, cables and moulded parts (to take effect in 2019 subject to possible exemptions) applicable to both EU manufactured and imported articles
- the forces impacting the future tonnages of the four phthalates in imported articles:
    - higher demand for consumer articles in the EU28 stimulated by population and income growth;

- outsourcing of manufacturing of lower profit margin products from EU28 to lower cost jurisdictions which would lead to higher imports (whose relative content of the four phthalates is anticipated to remain higher than the EU28 for the foreseeable future);
- substitution of the four phthalates as awareness of suitable alternatives increases.

Table 21 presents a summary of the main assumptions employed in the projection of the tonnages of the four phthalates contained in articles placed on the EU market in the scope of this restriction proposal.

Table 21. Baseline assumptions

Assumptions for:	Description of the assumptions under the Baseline scenario
DEHP	
Use in EU production of articles in scope	2011-2013: historical volumes estimated on the basis of EuroStat data, market intelligence and information from applications for authorisation. 2013-2019: approximately 13% annual decline of DEHP tonnages used in EU article manufacturing. All use in wires & cables will be phased out by 2019 – the year of entry into force of RoHS amendments. 2019 – end of scope (2039): 3.5% annual phase out of DEHP use in EU production due to substitution from 2019 onward; Authorisations are granted for the remaining volumes; Opposite but equal forces at work: increased use because of increased demand for end-products due to population & income growth, which is balanced out by decreased use of DEHP in EU article manufacturing due to relocating production outside the EU (outsourcing)
Tonnages in exported articles	2011-2014: Tonnages derived on the basis of historical volumes of exported articles. 2014- end of scope: similar assumptions to the use of DEHP in EU production of articles.
Tonnages in imported articles	2011-2014: Tonnages derived on the basis of historical volumes of imported articles. 2014-end of scope: 1% annual growth since 2014 explained with opposite but unequal forces: Increase of DEHP contained in imported articles because of increased demand for end-products due to population & income growth and due to higher outsourcing (to e.g., China). This force is larger than the decline in the DEHP in imports due to substitution as no further regulatory action in non-EU jurisdictions is anticipated.
DBP, DIBP and BBP	
Use in EU production of articles (including exports)	Full phase out of all uses in scope by 2015. No production and export of articles containing DBP, DIBP and BBP afterward.
Import	Same as DEHP

Notes: See Annex C: Baseline for further details.

As a result of the assumptions presented in Table 21, the tonnages contained in articles placed on the EU market are forecast to decline by close to 30% by 2020 as a result of pressures related to the authorisation requirements and the entry into force of the amendments of the RoHS Directive. More than half of this decline is anticipated to be recovered by the end of the study period in the absence of a restriction and other regulatory measures. This growth of more than 15% between 2020 and 2039 is projected due to increase in tonnages of the four phthalates contained in imports. This is seen as the result of growth in article import volumes which outpaces substitution of the four phthalates on many international markets where DEHP

in particular is anticipated to dominate for the foreseeable future. Table 22 shows that as a result of these forces, the tonnages contained in imported articles are anticipated to represent almost all of the tonnages of the four phthalates in articles placed on the EU market in the scope of this restriction proposal.

Table 22. Tonnes of DEHP, DBP, DIBP and BBP contained in articles in scope placed on the EU28 market – baseline projections

DEHP, DBP, DIBP and BBP content	**2014**	**2020**	**2039**	**% change****
Tonnes used in EU28 article manufacturing	62 612	13 828	9 663	-30%
Tonnes contained in Exported articles	15 722	5 952	3 025	-49%
Tonnes contained in Imported articles	124 245	112 965	136 474	21%
Tonnes contained in articles placed on EU28 market*	171 135	120 841	143 112	18%
Share of tonnes imported of total placed on EU28 market	72.6%	93.5%	95.4%	

Notes: * Tonnes contained in articles placed on EU28 market = Tonnes used in EU28 article manufacturing - Tonnes contained in Exported articles + Tonnes contained in Imported articles
** Percent change in tonnages between 2020 and 2039.

2. Impact assessment

2.1. Introduction

The impact assessment presented in this document employs a semi-quantitative approach to estimating the benefits and costs of the proposed restriction on DEHP, DBP, DIBP, and BBP. The analysis includes an examination of the compliance costs of the proposed restriction and its cost-effectiveness.

The boundaries of the assessment were defined to capture the main impacts of the proposed restriction, the actors impacted and the timeframe these impacts are likely to occur. Specifically, these were defined as follows:

- Geographic: The focus of the assessment is on EU28, as the final decision on whether or not to implement a restriction focuses mainly on weighting the costs and benefits for the EU society of the proposed measure. The impacts of the proposed restriction on actors in other jurisdictions are also considered, e.g., producers and suppliers of articles in the scope of the proposed restriction, insofar these result in impacts to EU actors, such as importers, wholesalers, retailers and consumers.
- Temporal: The majority of the costs and benefits of the restriction are anticipated to occur primarily during the first 20 years of its entry into force, assumed to be 2020 for the purpose of this analysis. This temporal scope was selected despite its limitations: while the costs of the restriction will likely begin to approach zero by 2040, many of the benefits of the restriction would continue further into the future. For the purpose of comparing the benefits and costs of the restriction, all monetised values are discounted with 4% social time preference rate) and CPI-adjusted (consumer price index) to 2014 values.[24]
- Supply chain: The focus of the analysis is on EU producers and importers of articles in the scope of this proposed restriction and their upstream and downstream supply chains, from substance manufacturers to end-users.

2.2. Risk Management Options

2.2.1. Proposed options for restriction

The preparation of this restriction dossier on DEHP, DBP, DIBP and BBP in articles was instigated by the legal requirement specified in Article 69(2) of the REACH Regulation to examine whether the use in articles of Annex XIV substances whose sunset date has passed poses a risk to human health or the environment that is not adequately controlled. The scope of the proposal is limited to the four phthalates on Annex XIV whose sunset date has passed. As shown in Annex B, the conclusion of this examination is that the risk of these four phthalates in articles is not adequately controlled. Therefore, ECHA conducted an analysis of diverse risk management options (RMOs) in order to identify the most appropriate to address these risks and to define its scope and conditions.

[24] 2% discount rate is used for sensitivity analysis.

As a first step, the possibility to address the risks to human health and the environment from the four phthalates (see Annex B) under other REACH regulatory measures, existing EU legislation and other possible Union-wide RMOs was examined. However, these were deemed inappropriate to address all article categories contributing to risk as presented in section D.1.3. Other Union-wide risk management options than restriction.

Therefore, the possibility to impose a restriction under REACH was investigated further and the following restriction options were considered:

- Restriction on the placing on the market of all articles containing the four phthalates
- Restriction on the placing on the market of articles for indoor use and for outdoor use when there is a potential for contact with human mucous membranes or prolonged contact with human skin. This option is herein referred to as "the proposed restriction". It includes selected derogations, on food contact materials (FCMs) being one of them.
- Proposed restriction without a derogation on FCMs
- Restriction on the placing of on the market of articles in the scope of the proposed restriction containing DEHP, DBP and DIBP only (i.e., excluding BBP from the scope of the proposed restriction)
- Proposed restriction with a derogation for DIBP in toys and childcare articles
- Restriction on EU production as well as placing on the market of all articles containing the four phthalates

Each of these options was succinctly assessed against the main criteria for restriction or other risk management measures: effectiveness, practicality and monitorability. As a result of this assessment, the restriction option below is proposed. The rational for not proposing the remaining restriction options is presented in Annex D, Section D.1.2. In summary, the proposed restriction was found to overall better meet the criteria for restriction in comparison to the other evaluated restriction options. Also, a special consideration on FCMs is of note. While FCMs contribute substantially to human health risks from the four phthalates, it was concluded that the best course of action is to derogate FCMs in the proposed restriction on the grounds that a sector-specific legislation would lead to a more efficient use of regulatory resources as well as improved clarity to stakeholders. However, this proposal highlights the need to take measures to reduce the risks of the four phthalates from food consumption.

Proposed restriction

Brief title: Restriction on articles containing the four phthalates for: i) indoor use and ii) outdoor use, if in contact with human skin or mucous membranes

The details of the proposed restriction are given in Table 1 (Summary section). It restricts the placing on the market of the following articles containing the four phthalates in a concentration, individually or in combination, in excess of 0.1% w/w of the plasticised material:

a) any (indoor or outdoor) articles whose phthalate containing material may be mouthed or is in prolonged contact with human skin or any contact with mucous membranes, and
b) any phthalate containing articles that are used (including stored) in an indoor environment where people are present under normal and reasonably foreseeable conditions and potentially exposed via inhalation. This does not apply to articles that are used only in industrial or agricultural workplaces by workers.

Both paragraph a) and b) do not apply to:

- articles placed on the EU market prior to the date of entry into force plus three years of transitional period (entry into force is assumed to take place in 2020);
- articles covered under existing legislation on food contact materials (Regulation (EC) No 1935/2004 and Regulation (EU) No 10/2011); immediate packaging of medicinal products (Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC); medical devices (Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC); toys and childcare articles containing DEHP, DBP and BBP (existing restriction entry 51 in Annex XVII of REACH);
- measuring devices for laboratory use.

Prolonged contact with human skin, outdoor use and childcare articles are defined for the for the purpose of the proposed restriction (see Table 1 in Summary).

As defined in Table 1, the proposed restriction includes in its scope toys and childcare articles containing DIBP in concentration greater than 0.1% w/w; the other three phthalates are excluded as there is an exemption for entry 51 of Annex XVII. The rationale for a restriction is that DIBP has very similar hazard and risk as DBP and DIBP can replace DBP in all its uses. Therefore, from a risk perspective, there is no reason to differentiate DIBP from DBP, which in combination with DEHP and BBP is restricted in entry 51 in toys and childcare articles. Furthermore, Annex D demonstrates that the proposed restriction, which includes in its scope DIBP in toys and childcare articles, is effective, practical and monitorable.[25] The most practical way of introducing such restriction is to revise the existing entry 51 of Annex XVII of REACH to include DIBP.[26] It is considered that the same restriction on all four phthalates in toys and childcare articles will ensure clarity for stakeholders in terms of requirements, type of articles covered, any testing or sampling methods, etc. The benefits and disadvantages of derogating DIBP in toys and childcare articles are further discussed in section D.1.2 in Annex D.

Justification for the selected scope of the proposed restriction

The proposed restriction aims to restrict the placing on the market of only those articles that present risks to human health via the critical routes of exposure.

Thus, the scope of the proposed restriction is aimed at restricting the placing on the market of:

a) any (indoor or outdoor) articles whose phthalate containing material may be mouthed or is in prolonged contact with human skin or any contact with mucous membranes, and
b) any phthalate containing articles that are used (including stored) in an indoor environment where people are present under normal and reasonably foreseen conditions and potentially exposed via inhalation regardless of whether there is a potential for exposure via the dermal or oral route.

[25] The restriction costs per tonne DIBP replaced (i.e., the cost effectiveness) are expected to be equivalent to other articles in the scope of the proposed restriction, but the exposure of infants through mouthing of toys and childcare articles is considered to be the highest, thus leading to an improved benefit-cost ratio.

[26] The intention is that the limit applies to toys and childcare articles that contain DIBP in a concentration, individually or in combination with DEHP, DBP and BBP, greater than or equal to 0.1% by weight of the plasticised material. This is consistent to current interpretation of the entry. See footnote to Table D1.

This means that, for example, articles whose phthalate containing material does not come in contact with skin and mucous membranes, such as phthalate containing plastic boots with inserts preventing contact with the skin of the foot, would be restricted as types of articles that lead to inhalation exposure in indoor environment. This is because they are present (i.e., stored) indoors and the phthalates from these articles are released to the indoor environment, thus contributing to air and dust levels of phthalates in the indoor environment (see Annex B, section B.9.4.2.).

However, the proposed restriction excludes (via specific derogations) articles whose use does not lead to high exposure situations under normal and reasonably foreseeable conditions for the general population and in particular for vulnerable groups (e.g., children). As these articles do not contribute to exposure to a significant extent, the costs of the substitution of the four phthalates in these articles would outweigh the benefits of the risk reduction. Examples of these are articles only for use in industrial or agricultural workplaces. Other examples are articles only present in building frames[27] or in (between) walls, which do not lead to contact with human skin nor contribute to phthalate levels in the indoor environment.

The proposed restriction also defines prolonged contact with skin for enforcement purposes.

> "Prolonged contact with human skin" should in this context be understood as covering a daily overall contact with skin of more than 10 minutes continuously or 30 minutes discontinuously.

The specified duration is intended to signal that for outdoor articles where only short intermittent dermal contact occurs, it could be reasonably expected that the exposure is low and the articles should fall outside the scope of this restriction proposal, e.g., window blinds or shutters which are installed on the exterior wall of a house. If such contact does not contribute significantly to the exposure; therefore, restricting these articles would not be necessary. At present, there is insufficient information available to set a specific contact limit for phthalates. Therefore, expert judgement was used to set the final value and should be seen in the context of the assumptions made in the exposure modelling where in the typical scenario for infants, children and women it is assumed that the daily dermal contact time with articles containing one or more of the four phthalates is 30 min.

The proposed restriction also introduces a derogation on articles placed on the EU market for the first time prior to the entry into force of the proposed restriction. This is deemed necessary due to the large existing stock of diverse articles containing the four phthalates. The reason for the exemption is that it was concluded disproportionate to replace articles currently in use in the EU whose phthalate content probably decreases with time as it volatilises and adheres to other articles, dust, etc. Some of the articles, such as flooring, have long useful lives (normally upgraded on average every 10-15 years) and can require several thousand euro per dwelling to replace. The majority of the articles in the scope are consumer articles with brief lifespan, which are anticipated to be progressively replaced within a few years of the proposed restriction. This will gradually reduce the risk and manage the costs of the proposed restriction.

[27] The main supporting structure of a building - often steel, concrete or wood.

In addition, a list of derogations is proposed for articles which fall under existing legislation. Due to the diverse list of articles in scope, it is unavoidable that the use of some of these articles is already governed by other European legislation, given the long-standing investigation of the risks of the four phthalates. The derogations are included as it is recognised that sector-specific legislation, e.g., medical devices, food contact materials, etc., have effective measures (or effective risk management systems) in place to assess and prevent risk to human health and the environment from these articles. The derogations are also included to further clarify to stakeholders which legislation governs the use of these articles.

With that said, these derogations were first evaluated to conclude whether they adequately address (or can address) the risks. This restriction proposal argues that in the majority of article types in the scope of this proposal, a combined concentration of DEHP, DBP, DIBP, and BBP of less than or equal to 0.1% is required in order to adequately manage the risk to human health. This concentration limit is seen to effectively discourage any intentional use in articles within scope. Therefore, in cases where other EU legislation imposes a higher limit or where the scope of the limits do not align sufficiently, e.g., DIBP use regulated under the Toy Safety Directive, a proposal for restriction is included (see discarded restriction option on a derogation of DIBP in section D.1.2. of Annex D). Similarly, while the changes in RoHS entering into force in mid-2019 will impose concentration limits of 0.1% w/w, to ensure that no exemptions[28] are granted and to align REACH with RoHS, wires and cables are included in the scope of the proposed restriction.

A concentration limit is proposed as opposed to migration limit, as explained in Annex B, migration of phthalates varies depending on a number of factor such as type of contact, contact duration, temperature, plasticiser concentration difference, plasticiser concentration level, molecular weight and molecular structure. In addition concentration limits are easier to enforce (according to previous advice of the Forum) and for companies, especially SMEs, to comply with.

The proposed restriction anticipates that the market will be able to comply with the restriction within three years of its entry into force (i.e., 2020). It is anticipated that this will give sufficient time to impacted supply chains as substantial substitution of the four phthalates in articles has already occurred due to ongoing regulatory action (e.g., substance classification, authorisations, etc.) and as technically feasible alternatives with lower risk profile are available in the necessary quantities on the EU market and internationally at similar price levels. Furthermore, the three years is sufficient time for EU importers to communicate to their international suppliers the new requirements and for all actors on the EU market to deplete existing stock of articles containing one or more of the four phthalates. This is foreseen as feasible because:

- the sales turnover is understood as being much shorter than three years for the majority of articles, which are primarily consumer goods;
- the supply chains already have experience with ensuring compliance of phthalates in articles under the Candidate list or other regulatory action on phthalates in the EU or

[28] RoHS has in place a system of exemptions, see Annexes III and IV. Exemptions are granted only if certain conditions are met (see Article 5 for the criteria). No such exemptions currently exist for the four phthalates but companies may apply for them.

internationally.

In addition, the three year review period will also allow the authorisations (if granted) to approach its recommended review dates.[29]

2.3. Restriction scenario(s)

2.3.1. Behavioural responses of Stakeholders

The proposed restriction is anticipated to induce the following responses in the impacted supply chains:

a. EU producers of articles in the scope of the proposed restriction to transition to alternatives of DEHP. These include only those producers currently operating under a pending decision on an application for authorisation for the use of DEHP by two EU manufacturers of the substance.
b. EU compounders supplying to EU producers of articles in scope to transition to alternatives to DEHP. These include only those compounders currently operating under a pending decision on an application for authorisation for the use of DEHP by two EU manufacturers of the substance. Alternatively, the compounders to identify other markets domestically (i.e., manufacturing of articles outside the scope of the proposal) or internationally (i.e., all articles as the restriction bans the placing on the EU market and does not restrict exports). Any potential profit losses to be offset by gains EU compounders using alternative plasticisers to the four phthalates.
c. Non-EU producers to transition to alternatives for the purpose of manufacturing of articles intended for the EU market.
d. EU compounders using recycled PVC, currently operating under a pending decision on an application for authorisation for the use of DEHP by three non-integrated recyclers, as well as EU integrated recyclers manufacturing articles within scope of the proposed restriction to either:
    - focus on article production which fall outside the scope of the restriction
    - focus on exporting their products
    - transition to suppliers which guarantee DEHP-free waste.
e. EU converters using recycled PVC, currently operating under a pending decision on an application for authorisation for the use of DEHP by three non-integrated recyclers, as well as EU integrated recyclers manufacturing articles within scope of the proposed restriction (both groups representing less than 10% of recycled PVC waste (EuPC 2016)) to either:
    - focus on article production which fall outside the scope of the restriction
    - focus on exporting their products
    - transition to suppliers which guarantee DEHP-free plastisol
    - transition to virgin PVC.

[29] Art. 61 of REACH specifies that authorisation holders are required to submit a review report at least 18 months before the expiry of the time-limited review period.

f. Total volume of soft PVC waste recycled to remain unchanged as a result of the entry into force of the proposed restriction (assumed plausible given the low volume affected: less than 10%)
g. EU manufacturers of alternative plasticisers to identify new customers from the pool of companies which are transitioning away from the four phthalates. This will likely lead to profit gains for the manufacturers.
h. EU manufacturers of the four phthalates to identify new customers whose business is not impacted by the restriction. Alternatively, to identify international markets for the four phthalates they produce or scale down production leading to profit losses.
i. In the event the EU manufacturers of the four phthalates scale down production, for their employees to identify alternative employment.
j. EU importers to communicate to their international suppliers the requirements for phthalate content.
k. Prior to the entry into force of the proposed restriction, EU producers, importers, wholesalers and retailers of articles in scope to deplete existing supplies of articles in scope, produced under current EU regulatory requirements for phthalate content.
l. Consumers may face a minor increase in the price of (assumed to be only marginally better quality) articles.

These most likely responses will lead to costs to EU society, estimated in terms of:

- primarily material cost increases for actors in the supply chains listed in points a-c and price increases for end consumers (l);
- transaction costs[30] or costs increases equal to the difference between virgin and recycled PVC for actors in point e;
- profit gains or losses for actors in points g-h; and
- transaction costs for the remaining actors (d,f,i-k).

2.3.2. Transitioning to alternatives

Most actors in the supply chains affected by the proposed restriction would have to transition to alternatives of DEHP, DBP, DIBP and BBP. Suitable alternative plasticisers are available for all uses in articles in the scope of the proposed restriction. In fact, these alternatives are already widely used in the EU and internationally. Their share of total plasticiser use in article production is increasing, while that of the four phthalates has seen a steady decline over the past decades. The most common plasticisers include esters such as adipates, azelates, benzoates, citrates, cyclohexanoates, orthophthalates, sebacates, terephthalates and trimellitates (ECPI 2014).

Annex D demonstrates that there are technically feasible alternatives at similar prices, with more benign human health and environmental hazard and risk profile. Table 24 lists common alternatives from each plasticiser family and presents the main conclusions of the suitability and availability analysis.

[30] Defined as the cost of participating in a market,e.g., search and information costs, bargaining costs, etc. Assumed negligible for the purpose of this analysis.

Technical feasibility

There are a large number of technically feasible plasticisers, approximately 50 of which are today used commercially. (ECPI 2014) The choice of plasticiser depends on the processing technique, the end application of the plasticised material and economic factors. For PVC articles, the two most important factors include cost of the plasticiser and compatibility of the plasticiser with PVC (AFA 2013a). There is a high degree of familiarity of the applicability of alternative plasticisers to the specific applications of the four phthalates in plastisols and soft PVC articles produced on the EU market. The public consultations for ECHA 2013a, the call for evidence for the preparation of this dossier (ECHA 2015), as well as the applicants for authorisation did not pinpoint to a particular use of DEHP for which there is no technically feasible alternative.[31] DINP and DIDP have become dominant alternatives to DEHP due to their closeness in performance, their availability and their only moderately higher costs. Other, non-orthophthalate plasticisers have gained market share recently, e.g., DEHT, DPHP, DINCH, etc.

Many plasticisers, such as DINP and DIDP, can often replace DEHP without any major process or equipment modifications, although some are less efficient than DEHP, i.e., a higher quantity of the alternative plasticiser is needed than DEHP in order to achieve the same softness.

Technically feasible alternatives for DBP, DIBP and BBP exist for all applications of the substances and they have been fully replaced by EU based article manufacturers, as demonstrated by the absence of applications for authorisations for these three phthalates. Their use has also declined on many international markets.

Risk reduction

- None of the alternative substances have harmonised classification, or meet the criteria for PBT or vPvB, or are identified as SVHC, or are included in Annex XIV.
- In general, the alternatives have more benign human health hazard and risk profile in comparison to the four phthalates, thus, replacement with these alternatives would be beneficial with regards to risks to human health.
    - DINP is the only alternative of those included in Table 24 that exhibits anti-androgenic effects but at much higher doses than the four phthalates.
    - DNELs for repeated dose toxicity with DINP and DIDP are higher than the DNELs for reproductive toxicity for the four phthalates and ECHA (2013a) concluded that no risks are to be expected from exposure to DINP and DIDP given the existing restriction on toys and childcare articles.
- The applicants for DEHP (AFA 2013a,b,c) concluded that the alternatives have similar environmental effect profiles and comparable PECs. Thus, none of the alternatives would appear to introduce an environmental concern following substitution.

As with any assessment of alternatives, there are some uncertainties regarding the extent to which risks will be reduced following substitution. However, based on the current information, it can be concluded with sufficient confidence that the alternatives will lead to overall risk reduction for workers and the general population in comparison to continued use of the four phthalates.

[31] This is supported by other publicly available information, e.g., from a major producer of alternatives: http://www.phthalate-free-plasticizers.com/applications-plasticizers.html

Economic feasibility

The price of the plasticiser and its efficiency are the main factors that influence the change in the manufacturing costs of articles. R&D, reformulation, process and plant modification costs have been shown to be relatively minor in comparison (ECHA 2013).

Market reports have shown that the four phthalates are increasingly substituted by a large spectrum of plasticisers. DINP has been the preferred substitute to DEHP but the market share of non-phthalate plasticisers has been increasing, influenced among others by the increased regulatory attention on phthalates in recent years.

Recent information reveals that a number of alternatives exist at a similar price level as the four phthalates for all uses in the scope of this restriction proposal. The prices of alternatives which have already replaced a large market share of the four plasticisers (e.g., DINP and DIDP) are similar to DEHP. Prices of alternatives, such as DEHT, DPHP, and DINCH, which have in recent years began to take more significant market share, are approaching prices of DEHP. Specialty plasticisers tend to have higher prices than DEHP. Price differences between DEHP and its alternatives have been slightly larger on markets where the plasticiser currently dominates, e.g., China. This is on the basis of limited pricing information which is often confidential and difficult to obtain.

The transition to some of the alternatives of DEHP may lead to additional costs primarily due to efficiency differences. These are estimated to be relatively small, and are anticipated to have minor impact on the final price of the articles. For example, the efficiency factors of DINP and DIDP in comparison to DEHP are on average 1.06 and 1.1 respectively (Wilkes 2005). However, there are other plasticisers which are equally or more efficient than DEHP (see Table 23).

DBP, DIBP and BBP most likely alternatives are benzoates and terephthalates. Their prices are difficult to obtain but ECHA 2013 showed that transitioning to their alternatives would lead to 5-15% higher costs. As DBP, DIBP, and BBP have been fully phased out in the EU by 2015, their replacement is likely not very costly.

Availability of alternatives

The alternatives profiled in this report are available and already in use. The main alternatives (including those considered in the substitution scenario of the proposed restriction) are produced in the EU28 and internationally. Production capacity of non-phthalate plasticisers has also been increasing. Given the small tonnages of the phthalates to be substituted in the EU manufactured and imported articles and the availability of variety of alternatives, it is unlikely that in the event the proposed restriction comes into force, shortages and price pressures would be experienced.

In summary, on the basis of the analysis of the suitability and availability of DEHP, DBP, DIBP and BBP, the scenario in Table 23 is anticipated to unfold in the event the proposed restriction enters into force. Table 23 also includes the key information necessary for the estimation of the main compliance costs of the proposed restriction.

Table 23. Substitution of DEHP, DBP, DIBP, and BBP in articles - summary assumptions

Alternative plasticisers	**Uses of DEHP, DBP, DIBP & BBP to be replaced by alternatives**	**Comparative loading***	**Price Differential****	
			EU articles	**Imports**
DIDP	15% of all DEHP uses	1.1	1	1.05
DINP	55% of all DEHP uses	1.06	1	1.05
DEHT/DPHP/similar	30% of all DEHP uses	1.03	1	1.05
Benzoates/similar	All uses of DBP, DIBP & BBP	1.1		

Notes: * Assumed difference in the required tonnage of the alternative in comparison to DEHP (and the other three phthalates)
** Assumed difference in the price of the alternatives in comparison to the price of the four phthalates.

It is important to highlight that there are other alternatives with similar (or better) technical and economic feasibility which also have more benign risk profile than the selected alternatives. This is the scenario that appears to be most likely on the basis of publicly available information. Two additional scenarios are described in Annex E. These scenarios give an indication of the ranges of the substitution costs also on the basis of justifiable assumptions in the public domain. The confidentiality of information was one of the major deterrents to presenting more realistic substitution cost scenarios.

Table 24 Information on selected alternatives

Abbreviation	IUPAC Name	Possible alternative for	Applications
ATBC	Tributyl o-acetylcitrate	DEHP, BBP, DBP	Food packaging - cling wrap, toys, medical applications
ASE	Sulfonic acids, C10-21-alkane, Ph esters	DEHP, BBP, DBP	Toys, waterbeds, coated fabrics
DPHP	Bis(2-propylheptyl) phthalate	DEHP	Flooring, wall coverings, cladding & roofing, cables & wires, film & sheet, automotive, tubes & hoses, coated fabrics
DEHA/ DOA	Bis(2-ethylhexyl) adipate	DEHP	Flooring, wall coverings, cladding & roofing, film & sheet, automotive, tubes & hoses, coated fabrics, inks & waxes, food packaging - cling wrap, toys
DEHT/ DOTP	Bis(2-ethylhexyl) terephthalate	DEHP	Flooring, Food packaging - Cling Wrap, Toys, Medical Applications
DIDP	Di-isodecyl phthalate	DEHP, DBP	Flooring, cladding & roofing, cables & wires, film & sheet, automotive, tubes & hoses, coated fabrics, inks & waxes
DINP	Di-isononyl' phthalate	DEHP	Flooring, wall coverings, cladding & roofing, cables & wires, film & sheet, automotive, tubes & hoses, coated fabrics, inks & waxes
DINCH	1,2-Cyclohexanedicarboxylic acid, 1,2-diisononyl ester	DEHP	Flooring, wall coverings, film and sheet, automotive, adhesives & sealants, tubes & hoses, coated fabrics, food packaging - cling wrap, toys, medical applications
DEHS	Bis(2-ethylhexyl) sebacate	DEHP	
COMGHA	Glycerides, castor-oil mono-, hydro-genated, acetates	DEHP, BBP, DBP	Food packaging - Cling Wrap, Toys, Medical Applications
TOTM/ TEHTM	Tris(2-ethylhexyl) benzene- 1,2,4-tricarboxylate	DEHP	Cables and wires, Film and sheet, Medical Applications
DINA	Diiso-nonyl adipate	DEHP	Adhesives & Sealants, Food packaging - Cling Wrap, Toys & childcare articles
GTA	Triacetin	BBP, DBP	Adhesives, inks, coatings
DEGD	Diethylene glycol dibenzoate	DEHP, BBP, DBP	Flooring, important substitute for BBP and DBP in non-polymer & spread coating applications
DGD	Oxydipropyl dibenzoate	DEHP, BBP, DBP	Flooring, important substitute for BBP and DBP in non-polymer & spread coating applications
INBP	1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters	BBP	Substitute for BBP in most polymer and non-polymer applications

Notes: For details see table D5 in Annex D
Sources: AFA 2013a, ECHA 2013, ECPI 2015, Wilkes 2005

2.4. Economic, social, and distributional impacts

The proposed restriction will give rise to a number of economic, social, wider economic and distributional impacts from its entry into force. These are described in the forthcoming sections, while section 2.8 discusses how these costs are outweighed by the benefits of the proposed restriction.

2.4.1. Substitution costs

Substitution costs are the costs article manufacturers will incur due to transition to alternatives in the event of the proposed restriction on the four phthalates. According to previous studies, which draw on consultations with industry, these costs consist primarily of material costs, which are influenced by price and efficiency differences between the four phthalates and their alternatives. Other substitution costs, such as R&D, reformulation, process and plant modifications (RDRPPM) and other costs, are reported to be minor in comparison (ECHA 2012a, ECHA 2013).

On the basis of assumptions presented in Table 23, the substation costs are estimated to €15.8 million annually from 2020 (the year of the assumed entry into force of the proposed restriction) onward.[32] These costs are considered an overestimate because:

- Confidential information implies that the least cost scenario for estimating material costs is closer to the lower end of their range: €8.4 million annually (see Annex E).
- The estimates assume that the price and efficiency differences would exist throughout the selected study period of 20 years, while these would likely decline and approach zero in the long-run. This is because the effective price differences between plasticisers are expected to disappear in the long-run as the market would not support a higher price for a plasticiser which is less efficient, unless the plasticiser offers other benefits such as improved end-use product for example.[33]
- The non-quantified RDRPPM costs are shown to be negligible and likely approaching zero in the long run as no plasticiser could obtain a higher price in a competitive market if it requires higher up-front costs (unless there are other benefits for its use). Therefore, including when accounting for the uncertainty regarding the value of RDRPPM costs, the estimated total annual substitution costs of €15.8 million are considered an overestimation.
- Lastly, the analysis assumes that all substitution costs for transitioning to the alternatives of imported articles are fully passed on to EU entities (EU buyers or end-users) and are therefore, costs of the restriction to EU society. Given the high price competition on some article markets, this assumption is associated with considerable uncertainty. It is foreseeable to assume that some of the costs to substitute the four phthalates in imported articles (close to 97% of the €15.8 million annually) would be

[32] 2014 was selected as the base year for the purpose of the analysis. All values are discounted or adjusted with CPI (EuroStat consumer price index) to 2014.

[33] Such quality improvements are recognised but assumed negligible and discussed separately from substitution cost impacts for the purpose of simplifying the analysis. See section on Impacts on the quality of the good.

borne by international article manufacturers or other entities of the non-EU supply chain. This would likely lead to impacts on profits in non-EU jurisdictions.

2.4.2. Testing costs

Testing costs can be incurred by industry to ensure and self-monitor the compliance with a restriction measure. They include:

- the costs of laboratory tests in the importer, manufacturer or supplier's own laboratory or in independent, third party laboratories, as well as
- the price of the article tested as many of the tests of the phthalate content of articles are destructive tests.

The results of a survey of industry and supporting interviews concluded the following regarding testing and other compliance control costs to be incurred by industry in the event the proposed restriction enters into force:

- Information about the presence of phthalates in articles is available via means other than testing, e.g., due to obligations under REACH (e.g., the Candidate list) or other legislation.
- The majority of companies ensure compliance with EU and national legislation primarily using contractual obligations for the suppliers to abide by the law and by providing information on the restricted substances to their suppliers.
- Compliance testing by buyers is used in rare occasions, primarily for spot checks. This is practiced primarily by larger companies.
- The testing costs are dependent on the frequency of testing. Company practices are highly diverse and are often dependent on the track record of the international supplier and the variety of products supplied. Often, international suppliers are required to provide testing results, which could be used for multiple shipments and buyers.
- Many companies already have practices put in place (due to regulatory requirements or voluntary actions) regarding the presence of phthalates in their products. As these actions are part of the existing industry practices, they cannot be considered instigated by the proposed restriction and therefore, cannot be considered part of the costs of industry to ensure compliance with the proposed restriction.
- It is unlikely that these costs would occur indefinitely in the future. It is feasible to assume that the need for any testing for phthalates would decline over time with the increased familiarity with regulatory practices and the decreased incentive to use the four phthalates instead of their alternatives.

Thus, although industry would likely continue to conduct testing to ensure compliance in the event the proposed restriction enters into force, these costs, whose magnitude is highly uncertain (due to diverse industry practices), are likely largely not attributable to the proposed restriction (due to existing practices to monitor the presence of phthalates in articles under regulatory obligation or voluntary policies). Any minor uncertainties related to societal costs due to testing as a result of the restriction are already taken into account in the estimation of the substitution costs of imported articles. As stated there, a larger price differential was assumed for imported articles to account for such uncertainties.

2.4.3. Costs of the recycling sector

The majority of articles manufactured from recycled PVC are for industrial or agricultural use for which the proposed restriction foresees a derogation on the grounds that they have limited contribution to exposure to the general population and vulnerable groups. According to a survey by EuPC and Recovinyl, the proposed restriction is expected to impact less than 5 percent of the volumes of current post-consumer or between 5 and 10% of the total volume of post-consumer and post-industrial recycled soft PVC waste (EuPC 2016). The main articles impacted would be wellingtons and boots with interior lining.

Given the low volume of the soft PVC waste impacted by the proposed restriction, it is anticipated that the compounders and converters would be able to comply with it by: identifying sources of DEHP-free waste, investing in better sorting of PVC waste, transition to virgin plastisol or to DEHP-free recyclate, identifying alternative domestic (i.e., to produce articles outside the scope of the restriction) or international markets (i.e., to export DEHP containing articles or recyclate). Therefore, the costs to recyclers to comply with the restriction would range from transaction costs to the costs to transition to virgin plastisol, dry-blends or compound as the highest cost possible strategy. Assuming a mix of these strategies is pursued by industry, the costs to the recycling sector are estimated at €1.1 million annually as a whole. It is recognised that the converters that produce wellingtons and other boots would bear the majority of these costs.

Given the small volume of soft PVC waste affected, it is assumed that industry would identify a market for all DEHP-containing waste currently being recycled. Therefore, the amount of waste incinerated or sent to landfills will not increase as a result of the proposed restriction.

2.4.4. Other economic impacts

Impacts on compounders (on producers of PVC in primary forms)

Placing on the EU market of PVC in primary (semi-final) forms (pellets, plastisols, compounds) is not directly impacted by the proposed restriction because these articles are not used in indoor environment or in outdoor environment that leads to contact with skin or mucous membrane before further processing. Insofar PVC in primary forms is not further converted into products that fall within the scope of the proposed restriction, there would be no impacts on producers of PVC compounds or plastisols containing one or more of the four phthalates.

In the event of a restriction, compounders would have to consider identifying domestic markets not impacted by the restriction (e.g., manufacturing of roofing), international markets, or replacing DEHP.[34] If the former, the compounders could incur some transaction costs. If the latter, the substitution costs of compounders are assumed to be fully passed on to downstream users and these costs are taken into account in the restriction compliance cost insofar the products in primary forms are further converted into articles in the scope of the restriction. These are reported as substitution costs by end-use article group.

[34] Valid only for those compounders part of the supply chain of applicants for authorisation. Decision on these applications is pending at the time of the writing of this report.

Any possible profit losses as a result of lower demand for DEHP containing plastisol will likely be offset by profit gains of compounders of plastisol containing alternatives plasticisers.

Impacts on articles outside the scope of the restriction

It is possible that some producers with diverse product lines choose to transition to alternatives for all articles they produce. For example, producers of roofing (out-of-scope) and flooring (in the scope of the proposed restriction), could consider replacing the four phthalates in both product lines (or stop producing either flooring or roofing membranes if that is economically more sensible). This could be explained by their seeking to realise economies of scale for plasticiser purchasing or other procurement and manufacturing efficiencies, or by their pursuing marketing strategies (e.g., "green" image). It is uncertain to what extent this substitution of the four phthalates could be attributed to these (inadvertent) consequences of the proposed restriction or to other forces (e.g., other regulatory pressures which began with the introduction of the restriction on toys and childcare articles and the classification of the four phthalates). Therefore, these potential impacts are noted but not quantified for the purpose of the assessment of the proposed restriction.

Impact on exports

The proposed restriction bans the placing on the EU market of articles containing the four phthalates. Therefore, export of these articles is not directly affected by the restriction as the manufacturing process is not specifically included in the scope of the proposed restriction. EU manufacturing of DEHP containing articles[35] used indoors or outdoors with prolonged dermal or mucous membrane contact could continue for the purpose of exports, provided these EU producers are within the supply chain of authorisation holders. As it is uncertain what percentage of exports would cease as a result of the restriction (and in fact it is theoretically possible that exports increase as a result of the restriction), the costs of transitioning to alternatives for exported articles are not included in the restriction compliance costs. These costs are anticipated to be fairly minor in importance: if the costs to transition to alternatives for exports are included in the costs of the restriction, the annualised restriction costs would increase from €16.9 million to €17.2 million, while the cost-effectiveness would decline by 1.5% (see Table 34).

Impacts on the quality of the goods

Although some of the alternatives DEHP, DBP, DIBP and BBP have advantages in particular applications (e.g., extreme temperature resistance, improved permanency), to simplify the analysis, it is assumed that the quality of end products is similar or marginally improved and therefore, difficult to differentiate by consumers. Thus, these benefits to consumers are not quantified for the purpose of the estimation of the restriction compliance costs.

Impacts on substance manufacturers and their upstream supply chain

Two[36] manufacturers of DEHP currently await a decision by the EU Commission on the granting of authorisation for its use in articles which fall within the scope of the restriction. It is

[35] Only exports of DEHP containing articles are relevant as there are no applications for authorisation for DBP, DIBP and BBP for their use in articles within the scope of the proposed restriction.

[36] Following the application for authorisation, the third applicant, Arkema France, closed manufacturing facilities and withdrew their application for authorisation.

uncertain whether and to what extent these manufacturers have already refocused to export markets, to take over market share of Arkema or some of the importers, or to manufacture DEHP alternatives.[37] Although the proposed restriction will impact a small share of DEHP tonnages produced in the EU in 2013, it is possible that its entry into force would lead to a profit loss for EU manufacturers of DEHP.

At the same time, the introduction of the restriction would encourage substitution of DEHP with alternative plasticisers, many of which, including those assumed in the substitution scenario, are currently produced in the EU. Therefore, it is assumed that EU manufacturers of alternatives are anticipated to increase their profits as a result of the restriction.

For the purpose of estimating the restriction costs, it is assumed that the profit margin of all plasticiser producers is similar; therefore, any negative impacts on profits of DEHP manufacturers are anticipated to be offset (or even surpassed) by gains in profits by manufacturers of alternatives due to the restriction.

Enforcement costs

On average, all Member States spend approximately €55 600 per restriction per year (in 2014 values) to ensure compliance with Annex XVII of REACH. Therefore, it is assumed that the entry into force of the proposed restriction will be associated with these costs annually. This is likely an overestimate as enforcement costs depend on the Member State's enforcement priorities, e.g., newer, higher risk restrictions are likely associated with more frequent campaigns. Therefore, it can be anticipated that these costs will be not occur on an annual basis and they will be more likely in the early years of the entry into force of the restriction.

Impacts on SMEs

The proposed restriction is expected to have some impact on different actors in the supply chain, the majority of whom are SMEs, however, the effect should be quite limited, given the substitutes are available. There is no evidence, that certain type or size companies, e.g. SMEs, would be more affected than others. In the recycling sector, industry claims SMEs to be potentially disproportionately impacted by the proposed restriction. However, the transitional period of three years is anticipated to minimise the impact of the proposed restriction on SMEs.

2.4.5. Social, wider economic and distributional impacts

Social impacts

It is possible that as a result of the proposed restriction employment of DEHP manufacturers is impacted negatively. The size of the social impacts would depend on the degree to which the two manufactures are able to take over the share of imported DEHP to the EU or new export markets or to diversify into production of DEHP alternatives. As mentioned in the section Impacts on substance manufacturers and their upstream supply chain, the latter is already afoot as a result of the inclusion of DEHP on the Authorisation list.

Any possible employment losses to DEHP manufacturers will likely be offset by employment

[37] More suppliers emerging for DOTP http://blog.phthalate-free-plasticizers.com/2012/01/05/more-suppliers-emerging-for-dotp/

gains in manufacturing of alternative plasticisers, whose EU sales are anticipated to increase as a result of the proposed restriction.

Wider economic impacts

The proposed restriction would have minor impacts on article prices; therefore, international trade flows are likely to remain unchanged and no substantial wider economic impacts can be anticipated as a result of the restriction.

Distributional impacts

Currently, EU manufacturers could use DEHP, DBP, DIBP, and BBP in articles within the scope of the restriction proposal if they apply for an authorisation, while importers are not required to apply (as authorisation requirements do not apply to imported articles). This creates extra costs for EU manufacturers in comparison to importers to access the EU market. The entry into force of the restriction will level the playing field for EU article manufacturers and importers.

Negative impacts of the restriction on DEHP manufacturers (profits and employment) are anticipated to be offset by gains by manufacturers of alternatives. However, as DEHP manufacturers are located in Central Europe (Poland and the Czech Republic), while manufacturers of alternatives are in other European member states (or potentially outside the EU28), the proposed restriction would give rise to distributional impacts.

2.5. Total restriction costs

The net compliance costs of the proposed restriction to EU society are estimated at €16.9 million annually (Table 25). The NPV of these future costs over the next 20 years is less than €230 million in total (using 4% discount rate). These costs are less sensitive to the chosen discount rate (in comparison to benefits): applying 2% discount rate, the NPV of the total restriction costs is €310 million or €19 million annually.

Table 25. Summary of Net compliance costs of the proposed restriction, annual, 2014 - base year

Net costs from 2020 onward	**Estimates (annual)**
Substitution costs	
- Material costs	€15.8 million euro
- RDRPPM* costs	Not estimated, likely negligible
Testing costs	Uncertain, addressed in material costs
Costs of recycling sector	€1.1 million euro
Enforcement costs	€0.06 million
Costs to compounders (i.e., on producers of PVC in primary forms)	Included in material costs
Costs to substance manufacturers	Assumed €0 but potential benefits for manufacturers of alternatives are not estimated
Impacts of higher quality of the good containing the alternatives	Assumed €0 but likely on balance represent benefits (and not net costs) of the restriction
Costs to SMEs	Not estimated, likely negligible
Social impacts	On balance, likely €0
Wider economic costs	On balance, likely €0
Distributional costs	Assumed €0 but likely on balance represent benefits (and not net costs) of the restriction
Total restriction costs	**16.9 million euro**

Notes: * R&D, reformulation, process & plant modifications

The total restriction costs of €16.9 million annually are believed to adequately illustrate the anticipated costs to EU society as some costs are overstated in order to account for any uncertainties related to the non-quantified negative impacts of the restriction. In summary, the quantified impacts overstate the costs to EU society because:

- Material costs are overestimated because:
  - Confidential information supports that the costs are closer to the lower range of estimates of €8.4 million annually. (Compare to material cost estimates in the main scenario in Table 25.)
  - The main assumption of the analysis that the effective price differences between the four phthalates and their alternatives would exist throughout the sturdy period of 20 years is highly uncertain. These differences would likely approach zero in the long run. (See section D.3.1.1.4. for further details on the reasons for considering material costs overestimated)
- Enforcement costs and costs of recycling sector are assumed to remain constant throughout the study period for simplicity, while it is likely that these would be incurred in the short to medium term of entry into force of the restriction. (See sections D.3.1.3. and D.3.2. for further information.)
- The majority of costs are associated with transitioning to alternatives of imported articles: €15.3 million annually or more than 90% of total costs. The assumption that

all these costs are passed on to EU entities (EU buyers or end-users) is highly uncertain. Given the high price competition on some article markets, it is foreseeable to assume that some of these costs are borne by international article manufacturers or other entities in the non-EU supply chain. This would likely lead to impacts on profits in non-EU jurisdictions.

2.6. Human health and environmental impacts

2.6.1. Human health impacts

All four phthalates show effects on reproductive organs and fertility in experimental animals exposed prenatally and are all classified as toxic to reproduction in category 1B according to the CLP Regulation. The cause for the effects has been shown to be their anti-androgenic properties. For that reason it has been unanimously agreed in the Member State Committee that the four substances have endocrine disrupting properties.

A spectrum of adverse effects is observed in the male rat following gestational exposure to the four phthalates, known as the rat phthalate syndrome. It includes reduced semen quality, testicular injury, decreased anogenital distance (AGD), increased nipple retention, increased incidence of hypospadias, increased incidence of cryptorchidism, delayed puberty onset and changes in germ cell differentiation. It is well understood that the cause for the rat phthalate syndrome is suppression of foetal androgen action.

Biologically relevant findings seen in experimental animals should be considered relevant to humans unless convincing evidence exists to the contrary (ECHA guidance Chapter R.7a). All of the effects observed in experimental animals are considered to be biologically relevant to humans. In 14 out of 15 Member States more than 5 percent of children were at risk due to combined exposure to DEHP, DBP, DIBP and BBP.

The effects of the phthalate syndrome observed in rats have also been observed in humans and it has been suggested to have a human counterpart known as the "testicular dysgenesis syndrome" (TDS). Cryptorchidism, hypospadias and poor sperm quality are risk factors for each other in humans. These conditions are also predictive of testicular germ cell cancers. Increasing evidence also link reduced AGD in humans to this group of risk factors. The single symptoms and combinations thereof are also risk factors for reduced fecundity.

Epidemiological studies provide further evidence that effects seen in rats from exposure to the four phthalates are relevant in humans at observed exposure levels in the population.

In comparison with rodents, human males have highly variable sperm counts, generally lower than in rodents, and many men have sperm concentrations near or below WHO reference values for fertility. In a case of human subfertility even a small change in sperm count or sperm motility may lead to infertility. For this reason, a statistically significant change in sperm count in a rodent study is considered to be indicative of a potential effect on fertility in humans (OECD 2008). The interlinked testicular changes observed in experimental animals are all relevant to humans and contribute to the evidence that humans are at risk of reduced fertility caused by exposure to the four phthalates.

Hypospadias is a common birth defect of the urethra in the human male where the urinary opening is not at the usual location on the head of the penis. Cryptorchidism (undescended testes) is the absence of one or both testes from the scrotum and is the most common birth

defect in infants. Both effects are androgen dependant.

Decreased AGD in male offspring and nipple or areola retention are sensitive measures to exposure to anti-androgens and have been shown to be predictive of other effects such as hypospadias and undescended testes in the rat (OECD 2008). Nipple retention and decreased AGD are part of the rat phthalate syndrome and are considered to be an indicator of foetal androgen suppression. Foetal androgen suppression in experimental animals is biologically relevant to humans and thus the effects in the rat are considered a relevant biomarker to humans.

Overall, there is strong evidence for risks of serious and interlinked developmental effects in males, including with high probability reduction of semen quality, testicular changes, decreased anogenital distance, decreased foetal testosterone and with moderate likelihood at the estimated exposure levels, hypospadias, cryptorchidism and germ cell changes. Moreover, it has been proposed that developmentally impaired germ cells might correspond to precursors of testicular germ cell cancer in humans but overall, it is unclear whether exposure to the four phthalates has a role in testicular germ cell cancer in humans.

In addition, there is moderately strong evidence for risks of immunological effects in children from exposure to the four phthalates and a moderate evidence for reduction of semen quality from exposure in adult men. Furthermore, there is a weak probability that the four phthalates cause delayed onset of puberty in boys and girls as well as delayed mammary gland development in women from foetal exposure. Moreover, there is weak evidence for effects on female reproductive development, neurodevelopment and metabolism from exposure to the four phthalates during gestation, as well as weak evidence for liver carcinogenesis from exposure during adulthood.

Population at risk

The number of boys at risk in the population was estimated based on the number of live births in each EU28 country and the geometric mean and 95th percentile RCR values projected for 2030. The number of boys at risk due to foetal exposure is estimated to be 1.1 million boys over a time span of 20 years (2.1% of new born boys). Although the foetus is thought to be more sensitive to the effects of the four phthalates, children are among the sensitive population because of their developing reproductive system. Using the exposure values from children 3.5 million boys over a time span of 20 years (6.8% of new born boys).

In comparison, the estimated number of boys at risk in 2011 (when urinary samples were taken) is 6% of new born boys from foetal exposure and 18% of new born boys from exposure during early life. Considering the uncertainties on exposure from biomonitoring, the uncertainties related to future risk projections, and the uncertainty that the population at risk is limited to boys, a scenario can be considered where the projected risks are assumed to be twice as high. In this scenario 5.4 million boys would be at risk over the time span of 20 years from foetal exposure or 13 million from exposure during early life.

It should be noted that individuals in the population at risk have an increased probability to the disorders discussed above. It is unknown what the increased disease incidence rates of the disorders in the population at risk would be as a result of exposure to the four phthalates.

In addition, as described in Annex B, workers are exposed to DEHP during manufacturing and formulation of DEHP and the production of articles. Workers are furthermore exposed to the four substances during formulation of recycled soft PVC containing DEHP in compounds and

dry-blends. RAC concluded that the applicants did not demonstrate adequate control. The number of exposed workers was claimed confidential by the applicants, but considering the number of downstream users of the applicants, the number is of considerable size.

Overall, there is strong evidence for risks of serious and interlinked developmental effects in males, including reduction of semen quality, testicular changes, decreased anogenital distance, decreased foetal testosterone and with moderate likelihood at the estimated exposure levels, hypospadias, cryptorchidism and germ cell changes. The population of male children at risk is estimated to be in the range of 1.1 – 3.5 million over a time span of 20 years.

Additionally, there is evidence for effects that occur in boys, girls, men and women (see Table 31). These other effects may increase the population at risk.

2.6.2. Environmental impacts

The Member State Committee (MSC) unanimously agreed in December 2014 to identify DEHP as a substance of very high concern under REACH on the basis that it gives rise to an equivalent level of concern due to its endocrine disrupting properties to the human health and the environment, according to Article 57(f) of REACH. The MSC opinion states that scientific evidence shows that exposure during sensitive time windows of development may cause irreversible developmental programming effects leading to severe effects on development and reproduction, regarded as particularly serious in relation to human health and wildlife species, also because these adverse effects may first manifest themselves in later life stages as a consequence of exposure during early life stages.

Exposure to DEHP is reported to affect steroidogenesis (e.g., decreased foetal testosterone production) resulting in adverse effects in the male reproductive system (e.g., effects on sex ratio, ovo-testis) in a range of species across taxonomic groups representative of both aquatic and terrestrial environmental compartments. DEHP appears to act via relatively weak anti-androgenic or oestrogenic mechanisms. However, effects that could be mediated by the thyroid axis have also been noted by some authors for some species of fish and amphibians (ECHA 2014).

The ECHA support document (ECHA 2014) outlines that DEHP may adversely affect the reproductive ability of fish populations by changing male fish into female fish and may, according to some studies, directly reduce fish fecundity. Such reproductive effects are considered an adverse and serious effect with population level relevance associated to the long-term sustainability of fish populations, particularly because of the apparent irreversibility of effects (e.g., changes in sex ratio). The developmental and reproductive effects of DEHP observed in rats are also considered to be of particular concern in relation to mammalian wildlife including top predators (including endangered species), where the described reproductive effects are expected to cause serious effects at the population level because of a natural low reproductive output of such taxa (ECHA 2014).

These potential impacts are not monetised but presented here qualitatively.

2.6.3. Risk reduction capacity

The level of risk is based predominantly on urinary samples taken in September 2011 until February 2012. Based on the 95th percentile of combined exposure to the four phthalates a risk has been identified for children in 13 out of 15 Member States and in 6 out of 15 Member States in women (see Table 15). Overall, in 14 out of 15 Member States (93%) more than 5% of mothers or children were at risk. When extrapolating to the EU28, this would suggest that in 26 Member States more than 5% of mothers or children were at risk. As concluded in section 0, evaluation of the uncertainties to the RCRs generally point to possible underestimation of the RCRs[38]. In the EU, approximately 6% - 18% of boys are estimated to have been at risk from combined exposure to the four phthalates in 2011. It is concluded that a risk has been identified that is not adequately controlled.

The risk in the absence of the restriction in 2020 and 2039 may be projected based on the estimates of the future market of the four phthalates (the baseline). Any results of such exercise needs to be interpreted with great caution since first, the market volumes are projections themselves and associated with significant uncertainty. Second, as RAC (2012) remarked, there is no simple one-to-one relationship between volumes placed on the market and exposure levels. In other words, the percentage decline in volumes does not translate in an equal percentage decline in exposure. Possible reasons for the relationship between marketed volumes and exposure to be blurred are:

- the volume decline may not be uniform across all market segments;
- articles from certain market segments may lead to higher exposures in proportion to their volume compared with other articles[39]; and
- the length of the service-life influences the relationship between marketed volumes and exposure levels.

Bearing in mind the above caveats, a projection of future risks was attempted. Since the DEMOCOPHES biomonitoring samples used in the exposure assessment were taken in the period September 2011 until February 2012, the reference year for the risk assessment can be assumed to be 2011. It can furthermore be assumed that exposure via food is not affected by the declining baseline because the authorisation requirements do not apply to food contact materials (FCMs). It is assumed that FCMs such as food packaging and articles that are used during the processing of food (e.g., tubes, gloves, tools, recipients, etc.) are the principle source of food contamination[40]. Section 1.1.5.1.2 concluded that 75% of the exposure to DEHP is from food intake and 25% from other sources that are considered to be covered by the scope of the restriction. For DBP, DIBP and BBP the situation is inverse and only 25% of the exposure is from food intake and 75% from other sources included in the scope of the restriction. In other words, under the above assumptions, the impact of the baseline

[38] Amongst others, using volume based method of intake calculation instead of the creatinine method we used possibly doubles the RCRs; morning spot samples were taken which may lead to systematic underestimation of exposure (possibly by a factor of 1.5); children younger than 6 are likely to have higher exposure.

[39] As shown in Annex B, e.g., erasers, sext toys and sandals are examples of articles that may lead to high exposure. Also for example extensive use of mobile phones may lead to extensive dermal exposure to phthalates in cell phone covers.

[40] Non-FCM articles may come into contact with food and environmental contamination may contribute to food contamination as well, but are thought to be minor sources of food contamination.

projections will be lower for DEHP in comparison to the other three phthalates, in particular DBP and DIBP which together are responsible for the highest contribution to the combined risks.

If under the above assumptions a one-to-one relationship between the baseline volumes and the percentage of risk from articles in the scope is assumed, the projected risks for 2020 and 2039 in the main baseline scenario are as presented in Table 26 and Table 27. The projected risks in the low and high tonnage baseline scenarios are not substantially changing the picture (see section E). Similarly, the projected RCRs are not very sensitive to the assumptions taken regarding the contribution of food (results not presented[41]).

The number of boys at risk in the period 2020 - 2039 due to foetal exposure to the four phthalates is estimated to be 54 000 per year, or 2.1% of new born boys (1.1 million boys over 20 years). Using the exposure values from children, it is estimated that 175 000 boys per year are at risk, or 6.8% of new born boys (3.5 million boys over 20 years).

Table 26. RCRs for four phthalates as estimated from 95th percentile urinary biomonitoring values projected to 2020 *in the main baseline scenario (no restriction)*

		Mother						Child				
Country	**N**	**DEHP**	**DBP**	**BBP**	**DIBP**	**SUM**	**N**	**DEHP**	**DBP**	**BBP**	**DIBP**	**SUM**
SI	120	0.2	0.2	0.0	*NA*	0.4	120	0.2	0.2	0.0	*NA*	0.4
UK	21	0.1	0.1	0.0	0.1	0.3	21	0.1	0.1	0.0	0.1	0.4
CH	117	0.2	0.1	0.0	0.1	0.4	119	0.2	0.1	0.0	0.1	0.5
CY	59	0.4	0.1	0.0	0.2	0.7	60	0.2	0.1	0.0	0.2	0.6
LU	60	0.1	0.1	0.0	0.1	0.4	60	0.1	0.1	0.0	0.4	0.6
PT	117	0.3	0.1	0.0	0.2	0.6	116	0.2	0.2	0.0	0.2	0.6
IE	120	0.2	0.1	0.0	0.2	0.5	120	0.3	0.1	0.0	0.2	0.7
DE	116	0.1	0.2	0.0	0.1	0.4	120	0.2	0.3	0.0	0.2	0.7
DK	143	0.1	0.1	0.0	0.2	0.4	142	0.2	0.2	0.0	0.3	0.7
HU	115	0.2	0.2	0.0	NA	0.5	117	0.4	0.3	0.0	NA	0.7
SE	96	0.2	0.4	0.0	NA	0.5	97	0.3	0.5	0.0	NA	0.8
SK	125	0.2	0.4	0.0	NA	0.6	127	0.4	0.6	0.0	NA	1.0
CZ	117	0.2	0.4	0.0	NA	0.6	120	0.4	0.7	0.0	NA	1.1
BE	125	0.1	0.2	0.0	0.3	0.6	125	0.3	0.2	0.0	0.5	1.1
ES	118	0.2	0.2	0.0	0.2	0.6	119	0.3	0.5	0.0	0.4	1.2
RO	117	1.0	0.1	0.0	0.2	1.3	119	0.8	0.3	0.0	0.3	1.4
PL	119	0.3	0.4	0.0	0.4	1.1	115	0.5	0.6	0.0	0.6	1.7

NA = not available
Yellow marking highlights RCR levels above 1 or equal to 1 when rounded

[41] As an indication, if it would be assumed that the contribution of food to DEHP exposure is only 25% and that of DBP, DIBP and BBP 10%, the RCR for Polish children in the low tonnage baseline scenario is 1.3 in both the 2020 and 2039 projections (RCRs > 1 in 3 countries).

Table 27. RCRs for four phthalates as estimated from 95th percentile urinary biomonitoring values projected to 2039 *in the main baseline scenario (no restriction)*

		Mother						Child				
Country	**N**	**DEHP**	**DBP**	**BBP**	**DIBP**	**SUM**	**N**	**DEHP**	**DBP**	**BBP**	**DIBP**	**SUM**
SI	120	0.2	0.2	0.0	*NA*	0.4	120	0.2	0.2	0.0	*NA*	0.4
UK	21	0.1	0.1	0.0	0.1	0.3	21	0.2	0.2	0.0	0.2	0.5
CH	117	0.2	0.2	0.0	0.1	0.4	119	0.2	0.2	0.0	0.1	0.5
CY	59	0.4	0.1	0.0	0.2	0.8	60	0.2	0.1	0.0	0.2	0.6
LU	60	0.1	0.1	0.0	0.2	0.4	60	0.1	0.1	0.0	0.4	0.7
PT	117	0.3	0.1	0.0	0.2	0.6	116	0.3	0.2	0.0	0.2	0.7
IE	120	0.2	0.1	0.0	0.2	0.5	120	0.3	0.1	0.0	0.3	0.7
DE	116	0.1	0.2	0.0	0.1	0.4	120	0.2	0.3	0.0	0.2	0.7
DK	143	0.2	0.1	0.0	0.2	0.5	142	0.2	0.2	0.0	0.3	0.7
HU	115	0.2	0.3	0.0	NA	0.5	117	0.4	0.4	0.0	NA	0.8
SE	96	0.2	0.4	0.0	NA	0.6	97	0.3	0.5	0.0	NA	0.9
SK	125	0.2	0.4	0.0	NA	0.7	127	0.4	0.6	0.0	NA	1.0
CZ	117	0.2	0.4	0.0	NA	0.7	120	0.4	0.7	0.0	NA	1.2
BE	125	0.1	0.2	0.0	0.3	0.7	125	0.3	0.2	0.0	0.6	1.2
ES	118	0.2	0.2	0.0	0.2	0.6	119	0.3	0.5	0.0	0.5	1.3
RO	117	1.0	0.1	0.0	0.2	1.3	119	0.9	0.3	0.0	0.3	1.5
PL	119	0.4	0.5	0.0	0.4	1.2	115	0.5	0.6	0.0	0.7	1.8

NA = not available
Yellow marking highlights RCR levels above 1 or equal to 1 when rounded

Under the above assumptions, the proposed restriction would remove all exposure to articles in the scope of the restriction proposal from 2020 onwards. In other words, the risk from 2011 would be reduced by 25% for DEHP and 75% for DBP, DIBP and BBP. As can be seen in Table 28, the proposed restriction would be able to reduce the RCRs at the 95th percentiles of combined exposure to projected levels below 1, except in Romania and Poland where RCRs are projected to be around 1.

Table 28. RCRs for four phthalates as estimated from 95th percentile urinary biomonitoring values *in case of a restriction (2020 and onwards)*

		Mother						Child				
Country	**N**	**DEHP**	**DBP**	**BBP**	**DIBP**	**SUM**	**N**	**DEHP**	**DBP**	**BBP**	**DIBP**	**SUM**
SI	120	0.1	0.1	0.0	*NA*	0.2	120	0.2	0.1	0.0	*NA*	0.3
UK	21	0.1	0.0	0.0	0.1	0.2	21	0.1	0.1	0.0	0.1	0.3
CH	117	0.1	0.1	0.0	0.0	0.2	119	0.2	0.1	0.0	0.1	0.3
LU	60	0.1	0.1	0.0	0.1	0.2	60	0.1	0.1	0.0	0.2	0.3
CY	59	0.3	0.0	0.0	0.1	0.5	60	0.2	0.1	0.0	0.1	0.3
PT	117	0.3	0.1	0.0	0.1	0.4	116	0.2	0.1	0.0	0.1	0.4
DE	116	0.1	0.1	0.0	0.1	0.2	120	0.2	0.1	0.0	0.1	0.4
DK	143	0.1	0.0	0.0	0.1	0.3	142	0.2	0.1	0.0	0.1	0.4
IE	120	0.1	0.1	0.0	0.1	0.3	120	0.2	0.1	0.0	0.1	0.4
HU	115	0.2	0.1	0.0	NA	0.3	117	0.3	0.2	0.0	NA	0.5
SE	96	0.1	0.2	0.0	NA	0.3	97	0.2	0.2	0.0	NA	0.5
SK	125	0.2	0.2	0.0	NA	0.4	127	0.3	0.3	0.0	NA	0.6
BE	125	0.1	0.1	0.0	0.2	0.4	125	0.3	0.1	0.0	0.3	0.6
CZ	117	0.2	0.2	0.0	NA	0.4	120	0.3	0.3	0.0	NA	0.6
ES	118	0.2	0.1	0.0	0.1	0.4	119	0.3	0.2	0.0	0.2	0.7
RO	117	0.8	0.1	0.0	0.1	0.9	119	0.7	0.1	0.0	0.2	1.0
PL	119	0.3	0.2	0.0	0.2	0.7	115	0.4	0.3	0.0	0.3	1.0

NA = not available
Yellow marking highlights RCR levels above 1 or equal to 1 when rounded

It can be concluded that the proposed restriction is capable of reducing the risks to human health of combined exposure significantly (RCRs are expected to be reduced to levels equal to or below 1 at the 95th percentile) within a reasonable period of time, starting from 2020, although with some delay caused by the service-life of articles still in use. It is expected that there will be a remaining proportion of the population that is exposed at levels above the DNEL. Considering the important contribution of food consumption to exposure to the four

phthalates, in addition to the proposed restriction, the relevant authorities in the EU are encouraged take the necessary measures to reduce the risks relating to the four phthalates from food consumption. Any potential risks for the environment would in addition be reduced as a result of the proposed restriction. The proposed restriction may furthermore reduce occupational risks.

If it is concluded that no threshold exists for the endocrine properties of the four phthalates, there would be a remaining risk following the entry into force of the proposed restriction. In such event, the restriction would contribute to reducing the exposure and thus the remaining risk.

2.6.4. Quantification and monetisation of human health impacts

Male infertility

The dossier estimates the damage to society of male infertility associated with exposure to the four phthalates in articles for the purpose of demonstrating the benefits of risk reduction outweigh the costs of the proposed restriction. The social damage is estimated on the basis of the number of cases, derived from current incidence rates and monetised using direct and indirect costs per case gathered by Norden (2014) and intangible costs presented in terms of the willingness to pay (WTP) value of statistical infertility, estimated by ECHA (2014b). These costs reflect the fact that reduced semen quality can lead to infertility, which can lead to significant emotional anguish and to financial costs in the event a couple pursues assisted reproductive treatment (ART). This damage would be avoided as a result of the proposed restriction, i.e., it represents the benefits of the proposed measure.

The analysis concluded that approximately 0.08% of male infants would suffer infertility as a result of diminished androgen activity during critical foetal development or early childhood due to exposure to phthalate containing articles in the scope of the restriction. This represents more than 2 110 male children annually (see Table 29) who would experience direct, indirect or intangible costs from their desired age of fatherhood and onward, assumed age 30.

The nominal value of the social damage that would be avoided as a result of the introduction of the proposed restriction is more than €40 million annually on average from 2050 onward (Table 29). Its present value of this average annual social damage is €9.8 million after discounting with the standard social time preference rate of 4%, also used for the estimation of the costs of the proposed restriction.

Table 29. Summary of estimated social damage related to male infertility due to exposure to DEHP, DBP, DIBP and BBP in articles in scope (EU28)

Steps in analysis	**Low**	**Mid-point**	**High**
Average annual male births (EuroStat, 2020-2050)	2 600 000	2 600 000	2 600 000
Fraction of cases of infertility attributable to DEHP, DBP, DIBP, and BBP in articles	0.04%	0.08%	0.12%
Annual number of cases of infertility due to DEHP, DBP, DIBP, and BBP in articles	1 050	2 110	3 160
Direct costs*	5 780 000	11 560 000	17 340 000
Indirect costs**	2 288 000	4 046 000	5 805 000
Intangible (WTP)***	12 224 000	24 447 000	36 671 000
Total annual social costs of male infertility (from 2050 onward)	20 292 000	40 053 000	59 816 000
weighted average per case	19 230	18 980	18 900
Total annual social costs of male infertility (discounted to 2014 with 4% social time preference rate)	4 944 000	9 760 000	14 575 000
weighted average per case	4 690	4 630	4 610
Total annual social costs of male infertility (discounted to 2014 with 2% effective social time preference rate)	9 947 000	19 635 000	29 323 000
weighted average per case	9 430	9 310	9 270

Note: 2014 values, average, representative year analysis. See Table D16 in Annex D for description of scenarios.

* Direct costs in this case include costs per treatment for an average number of ICIS (intracytoplasmic sperm injection) cycles.

** Indirect costs in this case include productivity loss of patient as well as overhead public health case spending attributable to ART (assisted reproductive spending).

*** Intangible costs presented in terms of the WTP value of statistical infertility, estimated by ECHA (2014b).

Despite being comparable to other studies (see Appendix D2 in Annex D), the analysis presented in Table 29 may be underestimating the damage to society of male infertility because:

- Impacts on the male reproductive system lead to a number of health conditions which are closely associated (or lead) to male infertility. These could entail years of mental anguish and financial cost for diagnosis and treatment prior to the date of desired fatherhood. These are not captured in the presented estimates.
- Not all males who have experienced infertility are captured in the statistics used to derive the incidence rate of exposure to the four phthalates. For example, a fertile partner may compensate for the infertility of a man (EAU 2015) and couples may achieve spontaneous pregnancy in more than one year. If these couples have not sought treatment, they are not captured in the incidence rates used in the analysis. In this case, the costs associated primarily with the mental anguish of not being able to conceive for an extended period of time are not presented above. Those costs could be considerable, as ECHA 2014b shows individuals are willing to pay to reduce the time to pregnancy.
- Other reasons why the direct, indirect and intangible costs may not fully capture the total social damage associated with male infertility is because, e.g., couples may wish to have more than one child. In this case, these may be further direct and indirect costs for ART and if unsuccessful, the couple would suffer intangible costs.

In addition, ART is a long process and even if successful, the couple may suffer mental anguish for the duration. For simplicity, the analysis assumes that these would be zero (see Table 18 in Annex D).

- The standard social time preference rate of 4% does not take into account that the income elasticity of the value of health is one; therefore, an increase in wealth in the future would lead to an equivalent increase in the value of health. If the discount rate is uprated in real terms each year by real GDP per capita growth, i.e., by about 2% per year, which is also consistent with past long-term growth, the discounted value of the social benefits of avoided male infertility due to the proposed restriction is €19.6 million annually.

At the same time, a considerable uncertainty is associated with the estimated aetiological fraction of infertility cases due to exposure from the four phthalates. This is further addressed in the section Assumptions, uncertainties and sensitivities in this report.

Other human health and environmental impacts

In addition to reduced semen quality and in severe cases infertility, among the most pronounced damages are cryptorchidism and hypospadias. They are often risk factors for each other (including testicular cancer) and together they are hypothesised to comprise the testicular dysgenesis syndrome (TDS) (Norden 2014, Skakkebaek et al. 2016). These effects are established in experimental animals and are considered relevant and adverse to humans. Based on the current evidence in animals, these additional effects might be expected to occur in the population at higher exposure levels than those exposure levels estimated on the basis of biomonitoring. However, mild incidences of cryptorchidism were in fact seen at dose levels corresponding to the DNEL for DEHP (Andrade et al. 2006). This and the fact that these malformations are a part of the TDS, cast doubt on this conclusion. It may therefore be necessary to extend the conclusion that a risk has been identified to the whole spectrum of effects in the rat phthalate syndrome observed in animals. Furthermore, the many uncertainties in hazard and exposure assessment need to be kept in mind, including the uncertainty whether a threshold exists for these substances as endocrine disruptors. For these reasons, it was considered important to provide estimates of the potential social damage of cryptorchidism and hypospadias.

Employing a similar approach to male infertility, it is estimated that approximately 480 cases of cryptorchidism and 540 of hypospadias per year can be associated with exposure to the four phthalates in articles in the scope of this restriction proposal. Their direct, indirect and intangible costs are estimated to more than €13.9 million and €9.1 million annually.

The total damage to society from male infertility, cryptorchidism and hypospadias due to exposure to the four phthalates in articles in the scope of this proposal are in excess of €32.8 million annually (Table 30). The results are comparable with the results of other studies. For example, if the benefits are derived on the basis of the impacts estimated by Norden (2014), the total social damage due to exposure from the four phthalates in articles would be €23.1 million (although this estimate does not include the WTP to avoid infertility).[42] See Appendix D2 to Annex D for the results of this and other valuation studies of phthalates and endocrine disrupting chemicals (EDCs).

[42] Norden 2014 recognises that psychological (intangible) costs of infertility exist but does not estimate them.

Table 30. Damage to society from male infertility, cryptorchidism and hypospadias due to exposure to DEHP, DBP, DIBP and BBP in articles in scope: summary, EU28

2014 euro - annual, million	**Low estimate**	**Mid-point estimate**	**High estimate**
Male infertility	4.9	9.8	14.6
Cryptorchidism	1.2	13.9	39.7
Hypospadias	0.9	9.1	22.8
Total	**7.1**	**32.8**	**77.1**

Notes: All values discounted to 2014 with 4% social time preference rate. Average, representative year analysis. See Appendix D1 to Annex D for details on estimation of impacts related to cryptorchidism and hypospadias.

In addition to male infertility, cryptorchidism and hypospadias, exposure to the four phthalates in articles might be associated with a number of other human health and environmental conditions that are considerably more difficult to estimate. In the event of entry into force of the proposed restriction, it can be expected that considerable other social impacts would be avoided, e.g., sexual development such as delay in puberty, behavioural changes, metabolic disorders, and hormonally-related cancers (see Table 31). Studies that have attempted to estimate some of these suggest that the total damage to the EU society may be as high €6.7 billion annually, e.g., Trasande et al (2015), Legler et al (2015), Hauser et al (2015), Bellanger et al (2015) and Hunt et al (2016) presented in Appendix D2.

Table 31 gives an indication of the benefits to society if some of the human health and environmental impacts due to exposure from the four phthalates can be avoided as a result of the proposed restriction.

Therefore, it is plausible that the benefits of the restriction are at a minimum comprised of avoided cases of male infertility, cryptorchidism and hypospadias (in mid-point estimates), i.e., in excess of €32.8 million.

Table 31. Summary of human health effects of concert from exposure to DEHP, DBP, DIBP and BBP and an indication of their monetary value

Human health effects of concern [& overall strength of relationship between exposure & human health impacts]	**Indication of the monetary value of the associated human health concern**
Effects from exposure during development: male reproductive effects	
Reduced semen quality [Overall strength: strong]	Male infertility: estimated, see table D17 in Annex D
Increased incidence of cryptorchidism [Overall strength: moderate]	Cryptorchidism: estimated, see table D24 and Appendix D1 to Annex D
Increased incidence of hypospadias [Overall strength: moderate]	Hypospadias: estimated, see table D27 and Appendix D1 to Annex D
Testicular changes [Overall strength: strong]	Male infertility: estimated, see table D17 in Annex D
Decreased foetal testosterone [Overall strength: strong]	Decreased foetal testosterone is considered to affect several health outcomes, some of which have been monetised (male fertility, hypospadias, cryptorchidism, testicular cancer)
Decreased anogenital distance (AGD) [Overall strength: strong]	Decreased AGD is considered a sensitive marker to exposure to anti-androgens and has been shown to be predictive of other effects, some of which have been monetised (male fertility, hypospadias, cryptorchidism,

	testicular cancer)
Germ cell changes / Increased incidence of testicular germ cell cancer [Overall strength: strong for germ cell changes, weak for testicular germ cell cancer]	Testicular cancer: €81 000 of direct, indirect and intangible costs of one testicular cancer case, estimated by Norden (2014). See Appendix B for social impacts attributable to phthalates in articles. ECHA (2014e) estimates (2012 values): Value of statistical life= €3.5 million, Value of statistical case of cancer = €350 000, Value of cancer morbidity = €410 000
Effects from exposure during development: effects in males and females	
Delayed age at puberty onset for girls and boys [Overall strength: weak]	Hormone therapy may be required although more severe cases may lead to long term physical (including infertility) and behavioural or social problems.
Persistent mammary gland changes [Overall strength: weak]	Not monetised separately. Persistent mammary gland changes in male rats are considered a marker to exposure to anti-androgens. It may be considered to be predictive of other effects, some of which have been monetised (male fertility, hypospadias, cryptorchidism, testicular cancer)
Delayed mammary gland development [Overall strength: weak]	Hormone therapy may be required although more, severe case may lead to long term physical (including infertility) and behavioural or social problems.
Effects on female reproduction [Overall strength: weak]	Female infertility: WTP value for statistical infertility €29 700/case. Preterm birth: WTP of statistical case of very low birth weight (2012 values) = €126 200 (ECHA 2014b)[43] Endometriosis: Social damage per case= €10,524 (2019 value) used in ECHA 2015, €8 620 (2010 value) weighted average per case used by Hunt et al (2016) Fibroids: Hospital costs for fibroid treatment average over €3 000. Health and lost productivity cost for fibroids and endometriosis[44] per woman in the EU = €8 000. Both quoted by Hunt et al (2016). PCOS association with infertility (see above), diabetes, heart disease): Average direct costs per case of adult diabetes as estimated by (Legler 2015): €29 600 (in 2010 values) (see Appendix D2 to Annex D for the potential impact in the EU)

[43] ECHA (2015c) refers to Rautava et al. (2009) which reports the results of a national study of all VLBW infants born in Finland between 2000 and 2003. 1,169 (900 live-born) children were compared against 368 full-term controls. Compared with the controls, 1.3 QALYs had been lost by each VLBW by age 5. This implies a discounted cost per case of around €75,000 based on the NewExt median VOLY. Given that VLBW is likely to result in negative health implications throughout the individual's life, the total cost would likely be higher than this figure.

[44] Together, endometriosis and fibroids represent the most common female reproductive disorders with an estimated combined incidence of up to 70% of women overall (Hunt et al 2016).

	WTP for a 1 in 1 000 000 risk reduction of heart disease= $4.82-$9.05 (2009 US$)[45]
Neurodevelopmental effects Exposure to phthalates may contribute to increasing incidences of autism spectrum disorders, ADHD, learning disabilities, altered play behaviour (Skakkebaek et al. 2016). [Overall strength: weak]	Autism: Average costs per case = €630 000 (in 2010 euro) as estimated by Bellanger et al (2015) (see Appendix D2 to Annex D for potential impact in the EU) ADHD: Average costs per case = €90 000 (in 2010 euro) as estimated by Bellanger et al (2015) (see Appendix D2 to Annex D for potential impact in the EU) Cognitive outcomes: WTP per IQ point = $466 (2007 US$) (Von Stackelberg et al 2009)
Effects on metabolism [Overall strength: weak]	Diabetes: average direct costs per case of adult diabetes as estimated by Legler et al (2015): €29 600 (in 2010 values) (see Appendix D2 for potential impact in the EU) Obesity: average direct & indirect costs per case of adult diabetes: €290 000 (in 2010 values) estimated by Legler et al (2015) (see Appendix D2 to Annex D for potential impact in the EU)
Effect other than effects during development	
Immunological effects Exposure to phthalates may contribute to increasing incidences of allergy, asthma and eczema. [Overall strength: moderate]	Asthma: WTP to avoid asthma discomfort = €50/episode in 2012 values (ECHA 2014f) Allergy: WTP to avoid respiratory sensitisation = €17.5/episode in 2012 values (ECHA 2014f) Eczema: WTP to avoid mild dermatitis = €227/episode in 2012 values (ECHA 2014f)
Liver carcinogenesis [Overall strength: weak]	Liver cancer: ECHA (2014e) estimates (2012 value): Value of statistical life= €3.5 million, Value of statistical case of cancer = €350 000, Value of cancer morbidity = €410 000
Effects from exposure during adulthood	
Reduced semen quality from exposure during adulthood [Overall strength: moderate]	Adult male infertility in EU attributable to the four phthalates in articles = €7 630 per case (in 2010 euro) in terms of direct costs for ART, estimated on the basis of Hauser et al (2015) (see Appendix D2 to Annex D for potential impacts in the EU)
Low testosterone levels in adult men [Overall strength: weak]	Low testosterone leading to increased mortality in EU attributable to the four phthalates in articles = €320 700 per case (in 2010 values) in terms of loss of economic productivity, estimated on the basis of Hauser et al (2015) (see Appendix D2 to Annex D for potential impacts in the EU)

Source: Annex D, Table D11. It presents a summary of important elements in the evidence for human impacts resulting from exposure to DEHP, DBP, DIBP and BBP.

[45] Valuation scenario is defined as 10 year latency, sick for 5 years, then death of a person with $42 000 income at 35, 40, and 65 years of age. Cameron et al (2009).

2.7. Practicality and monitorability

Practicality

The proposed restriction is practical because it is implementable, enforceable and manageable:

Implementability

- There is a high degree of familiarity in the supply chains regarding the articles that may contain the four phthalates. Information is available to downstream users and consumers via provisions in REACH (e.g., Article 7).
- Technically feasible alternatives with lower risk are currently available at similar prices for all uses in the scope of this proposal.
- The proposed restriction gives sufficient time to the impacted supply chains to transition to alternatives.

Enforceability

- Enforcement authorities can set up efficient supervision mechanisms to monitor industry's compliance with the proposed restriction. Testing and sampling methods exist and both industry and enforcement authorities have experience applying them.
- The restriction clearly defines which articles are in its scope.
- The proposed restriction eliminates the possibility to replace the phthalates in the current restriction entry 51 with an equally hazardous substance: DIBP.

Manageability

Given the availability of information regarding which articles may contain the four phthalates and stakeholder experience with regulatory action on phthalates, the level of administrative burden for the actors concerned to implement the restriction is anticipated to be low.

Monitorability

For imported articles, the compliance control can be accomplished by border authorities and notifications of any violation of the restriction can be reported in the RAPEX system. For EU produced articles, the notification system for downstream users under Article 66 under Title VII – Authorisation of the REACH Regulation will also assist with monitoring the effectiveness and implementation of the proposed restriction. This monitoring can be done by ECHA and national enforcement authorities.

It is also possible to monitor the result of the implementation and the effectiveness of the proposed restriction via biomonitoring studies similar to the COPHES and DEMOCOPHES projects.

2.8. Affordability, cost-effectiveness and benefit-cost comparison

The last stage of the assessment against the criteria for a restriction is an analysis of whether the proposed restriction is a sound regulatory measure. According to the *ECHA Guidance on the preparation of Annex XV dossier for a restriction*, this entails among others:

- An analysis of whether the efforts from the actors to implement and enforce the proposed restriction correspond in amount or degree to the adverse effects that are to be avoided
- An analysis of whether the proposed restriction ensures a good balance between costs and benefits and is cost-effective.

The following sections demonstrate that the proposed restriction is a sound regulatory measure by examining its affordability, cost-effectiveness and the benefit-cost ratio.

2.8.1. Market evidence and affordability

One of the arguments that the restriction is justifiable arises from past trends of substitution: this clearly evident trend suggests that the restriction would likely not exert disproportionate costs to companies required to comply with it. For example:

- Assuming that all costs are passed on the EU consumers, the proposed restriction would lead to an increase in the price per tonne of imported articles of about 2%.
- Less than 10% of the total restriction costs, or about €1.5 million, would be borne directly by EU producers of plastic articles. This represents less than 0.02% of the value added at factor cost that can be attributed to producers of plastic products using DEHP.[46] Assuming there are approximately 5 600 companies who use DEHP in their production, each company would have to bear additional costs as a result of the restriction of less than €300 annually.
- The cost increases due to transition to the alternatives would likely lead to an increase in the EU PVC production costs by about 2.2%. Assuming all costs are passed on to consumers, the restriction would lead to a maximum of 2.2% increase in the prices of end-use articles.

All these statistics suggest that on average the proposed restriction would be affordable for the impacted supply chains. Although, affordability does not imply that a measure has a net benefit for society, this analysis suggests that the proposed restriction likely would not exert disproportionate costs to industry and society as a whole.

2.8.2. Cost-effectiveness analysis

The proposed restriction is anticipated to replace more than 131 560 tonnes annually of DEHP, DBP, DIBP, and BBP in articles in the scope of this restriction. This suggests that the cost to society per tonne phthalates replaced is less than €130 (Table 32).

[46] EuroStat values for manufacturing of plastic products adjusted for the share of DEHP of total plasticiser use.

Table 32. Cost effectiveness of the proposed restriction

	Proposed Restriction
Total restriction costs (annual, million euro)	€16.9
Total tonnes substituted due to proposed restriction	131 560
Cost effectiveness (euro/tonne)	€130

Note: All values discounted to 2014 with 4% social time preference rate.

The proposed restriction is much more cost-effective than other measures on phthalates: the restriction on phthalates in toys and childcare articles (i.e., restriction entry 51 and 52 in Annex XVII).[47] Depending on the scope of the then discussed RMOs for restriction on phthalates in toys and childcare articles, its ex-ante cost-effectiveness ranged between €2 270 and €2 630 in 2014 euro (or €1 780 and €2 070 in 1999 values): nearly 20 times less cost-efficient than the proposed restriction. Therefore, it can be concluded that the proposed restriction is a cost-effective measure of addressing the risks of exposure to the four phthalates in articles in the scope of this restriction.

2.8.3. Cost-benefit analysis

The total restriction costs of €16.9 million annually adequately illustrate the anticipated costs to EU society as the monetised costs are overstated in order to account for any uncertainties related to the non-quantified negative impacts of the restriction (Table 25).

Considering the many uncertainties in hazard and exposure assessment, it is plausible that the benefits of the proposed restriction are not only associated with the estimated 2 110 cases of infertility (€9.8 million annually of avoided damage to society, see (Table 29) but also with other avoided human health damages such as cryptorchidism and hypospadias (respectively 480 and 540 cases or €23.1 million annually of avoided damage, see Table 30) and even cases associated with behavioural changes, metabolic disorders, and hormonally-related cancers (see Table 31 for an indication of the value of these potential benefits). Therefore, it can be concluded that the benefits of the restriction outweigh its costs.

To justify the restriction on a cost-benefit basis, it is necessary for the restriction to prevent about 3 655 cases of male infertility annually.[48] This represents about 0.1% of the average annual male births projected in the EU28 or less than 7% of the population at risk due to foetal exposure or about 2% of the population at risk due to infant and early childhood exposure. These cases would be prevented with the entry into force of the proposed restriction from 2020 onward.[49]

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[47] However, there are differences in methodologies and target populations. Restriction entries 51 and 52 of Annex XVII of REACH is targeted at a vulnerable group: young children, while the proposed restriction targets risks to the general population and vulnerable groups: pregnant mothers and young children.

[48] Calculated assuming about €4 600 / case in 2014 values (discounted by 4% social time preference rate

[49] Appendix D1 of Annex D discusses that that for the purpose of showing that the benefits of the proposed restriction outweigh its costs, an exposure to the four phthalates in articles as a unique or contributing cause of cryptorchidism and hypospadias would have to be demonstrated in a very limited number of cases (about 380 cases of cryptorchidism and 430 cases of hypospadias) for the benefits of the restriction to outweigh the costs. The

Taking into account other health impacts that are associated with exposure to phthalates, to justify the restriction on a cost-benefit basis, it is necessary for the restriction to prevent about 2 110 cases of male infertility (mid-point estimate for male infertility) and 250 cases of cryptorchidism or 420 cases of hypospadias. This is less than 5% of the population at risk due to foetal exposure or less than 1.5% of the population at risk due to infancy and early childhood exposure.

Thus, in summary, a modest number of cases show that the benefits of the proposed restriction would exceed its costs. Therefore, it can be concluded that the proposed restriction is also justified on a cost-benefit basis. This is even more pronounced when a 2% discount rate is applied to both benefits and costs of the proposed restriction: the total benefits of male infertility alone are estimated in excess of €19.6 million annually (see Table 29), while the total restriction costs are about 19.1 million annually (see Table 25).

This conclusion that the restriction is justified and that the benefits of risk reduction outweigh its costs holds also when uncertainties are taken into account. Detailed testing of the impacts of uncertainties on the benefits of risk reduction against the costs of the restriction is presented in Annex E. Table 33 attempts to combine the effects of quantified and non-quantified impacts of the proposed restriction. It clearly shows that the benefits of risk reduction exceed the costs even when non-monetised impacts are taken into account.

Table 33. Summary of uncertainties impacting the benefit-cost (B/C) ratio of the proposed restriction

Impact	**Description**	**Direction** B/C ratio **is likely affected**
Social damage of male infertility	Likely higher than estimated leading to increased value of benefits and improved B/C ratio of the proposed restriction (see section D.3.5.4 b in Annex D)	+
Social damage of hypospadias & cryptorchidism	Likely higher than estimated leading to increased value of benefits and improved B/C ratio of the proposed restriction (see Appendix D1 section c) in Annex D)	+
Other human health impacts to be avoided (general population)– non-monetised	Not estimated. Their estimation will lead to increase in the value of benefits, resulting in an improved B/C ratio of the proposed restriction. An indication of their value is provided in Table 31.	+++
Other human health impacts to be avoided (worker exposure)– non-monetised	Not estimated. Their estimation will lead to increase in the value of benefits, resulting in an improved B/C ratio of the proposed restriction.	+
Environmental benefits – non-monetised: e.g., effects on mammals similar to those of humans	Not estimated. Their estimation will lead to increase in the value of benefits, resulting in an improved B/C ratio of the proposed restriction. An indication of their value is provided in section 2.6.2.	+
4% standard social time preference rate	The standard discount rate of 4% does not take into account that the income elasticity of the value of health is one; therefore, an increase in wealth in the future would lead to an equivalent increase in the value of health. 2% effective rate, which reflects historical long term income growth, may be more appropriate for discounting human health benefits.	++

estimated cases would represent less than 0.03% of the projected average number of male children borne in the EU28.

Substitution costs	Likely lower than estimated leading to lower overall costs of the proposed restriction, resulting in an improved B/C ratio of the proposed restriction (see section D.3.1.1.4 in Annex D)	+
Testing costs	Not estimated in main restriction scenario. Their inclusion will lead to higher total restriction costs, eroding the B/C ratio of the proposed restriction (see Annex E)	-
Costs of recycling sector	Unlikely to occur as assumed annually throughout the study period. This will decrease the total restriction costs, resulting in an improved B/C ratio of the proposed restriction (see section D.3.1.3 in Annex D)	+
Enforcement costs	Unlikely to occur as assumed annually throughout the study period. This will decrease the total restriction costs, resulting in an improved B/C ratio of the proposed restriction (see section D.3.2 in Annex D)	+
Costs to compounders (i.e., on producers of PVC in primary forms)	Cost to compounders using DEHP are assumed to be fully passed downstream, i.e., they are included in the estimated substitution costs (see section D.3.2 in Annex D). The potential benefits of the proposed restriction to compounders using alternative plasticisers are not estimated.	+
Costs to substance manufacturers	Not estimated. It is likely that the gains of manufacturers of alternatives are larger than the costs of DEHP manufacturers as some applicants for authorisation have already begun to transition their manufacturing to alternatives of DEHP (see section D.3.2 in Annex D). This would result in higher benefits and an improvement of the B/C ratio of the proposed restriction.	+
Costs to SMEs	Not estimated. It is possible that some SMEs have higher costs to transition to alternative (see section D.3.2 in Annex D).	-
Social impacts	Not estimated. It assumed that all employment losses of DEHP manufacturers are offset by employment gains of alternatives manufacturers (see section D.3.2 in Annex D).	+/-
Impacts of higher quality of the good containing the alternatives	Not estimated but likely positive, leading to lower total restriction costs and improved B/C ratio of the proposed restriction (see section D.3.3 in Annex D).	+
Wider economic impacts	Not estimated, likely negligible (see section D.3.3 in Annex D).	+/-
Distributional costs of higher quality of the good containing the alternatives	Not estimated but it is likely that on balance these represent benefits of the restriction in terms of eliminating the effects of authorisation requirements on EU industry and likely diffused impacts of the restriction along the EU and international supply chains (see section D.3.3 in Annex D).	+

Legend:

Direction in which the B/C ratio is affected: "+" denotes an improvement and "-", a deterioration of the B/C ratio of the restriction

Degree of improvement/deterioration of B/C ratio: "+/-" denotes minor, "++/--": moderate and "+++/---": significant improvement/deterioration.

3. Assumptions, uncertainties and sensitivities

Uncertainties related to cost assumptions

Annex E discusses the impact of key assumptions on the risk reduction capacity, cost-effectiveness, and benefit-cost ratio of the proposed restriction. Those include:

a) Baseline assumptions regarding the forecast of future tonnages of phthalates placed on the EU28 market in the absence of the proposed restriction: e.g., in the two extreme situations where no substitution of the four phthalates occurs past 2019 (High tonnage scenario) or when no are sought or granted post-2019.
b) Material costs, to give an indication of the costs of the combined factors (restriction and public awareness) which are relevant for industry (High cost scenario) and to give a long term estimate of the substitution costs to industry, in the EU and internationally (Low cost scenario)
c) Testing costs, whose magnitude is highly uncertain (due to diverse industry practices), and are likely largely not attributable to the proposed restriction (due to existing practices to monitor the presence of phthalates in articles under regulatory obligation or voluntary policies)
d) Transitioning to alternatives for the purpose of export, as this may be an unintentional impact of the proposed restriction on industry
e) Combined uncertainties to identify under what assumptions the restriction costs are at their highest (low cost-efficiency) and their lowest (high cost-efficiency).

Table 34 shows that the impact on the cost-effectiveness of the proposed restriction of the uncertainties related to baseline, high material costs and exports is minimal. The cost-effectiveness improves the most (by about 85%) under the assumptions of low material costs. The Low material costs scenario is considered likely as shown in Table D8 in the Annex D, the prices of the many alternatives are similar to DEHP's price even on markets such as Asia where DEHP currently is dominant. Thus, substitution costs on all markets are anticipated to be driven in the long run primarily by their comparative to DEHP efficiency. This is a fair assumption, as in fact in the long-run, it can even be expected that the prices of less efficient plasticisers would decline to remain competitive on the market (whereby the substitution costs would also begin to approach zero). Also, as DBP/DIBP and BBP have been fully substituted in the EU28 in all applications in scope of this restriction proposal, the cost differential for their alternatives is likely also approaching zero. Therefore, the Low material cost scenario also overestimates the increase of material costs due to substitution and provides some buffer for minor costs such as RDRPPM and testing costs which might occur in the short run on markets where DEHP is currently dominant. This conclusion is supported by confidential information.

The Worst case scenario, or the scenario with the lowest cost-effectiveness (about 40% lower than the restriction scenario), tests the combined effects of High material costs, High testing costs, and Low tonnage baseline scenario. These scenarios are considered unlikely for the following reasons:

- The High material costs scenario is unlikely because the prices of many alternatives are similar to DEHP's even on markets such as Asia where DEHP currently is dominant. Furthermore, DBP, DIBP and BBP are fully phased out in the EU (no applications for authorisation) which suggests that their substitution costs are rather low. The High cost scenario is presented here for the sole purpose of demonstrating that the proposed

restriction would remain cost-effective even if the four phthalates are replaced by higher cost alternatives for example due to the public preference for non-phthalate plasticisers in some niche, specialised applications. This gives an indication of the costs of the combined factors (restriction and public awareness) which are relevant for industry.

- The High testing costs scenario are unlikely because although industry would likely continue to conduct testing to ensure compliance in the event the proposed restriction enters into force, these costs, whose magnitude is highly uncertain (due to diverse industry practices), are likely largely not attributable to the proposed restriction (due to existing practices to monitor the presence of phthalates in articles under regulatory obligation or voluntary policies). Any minor uncertainties related to societal costs due to testing as a result of the restriction are already taken into account in the estimation of the substitution costs of imported articles. As stated there, a larger price differential was assumed for imported articles to account for such uncertainties. Therefore, the inclusion of testing costs in the total restriction costs estimated in the main scenario would result in further overestimation of the costs.
- The Low tonnage baseline scenario is unrealistic because it is possible that some EU manufactures obtain authorisations at least for some niche applications post 2019. (It assumes in the Low tonnage baseline scenario that the tonnages of the four phthalates in imported articles will not change in the future from 2019 levels.)

Thus, this Worst case scenario does not represent a realistic estimate of the total compliance costs of the proposed restriction.

Table 34. Impact of uncertainties on the cost-effectiveness of the proposed restriction

Costs	Proposed restriction scenario	Baseline (a)		Material costs (b)		Testing costs (Restriction scenario + testing cost) (c)			Exports (d)	Worst case Scenario (e)**
		Scenario 3: Low tonnage	Scenario 1: High tonnage	Low cost scenario *	High cost scenario	Low testing costs	Mid-point	High testing costs	Export substitution costs	
Tonnes replaced - 2020 EiF	131 562	111 717	153 690	131 562	131 562	131 562	131 562	131 562	135 895	111 717
Total restriction costs - 2020 EiF (annual, million euro)	16.9	14.7	19.4	9.6	18.2	16.9	20.4	23.9	17.2	22.8
Cost effectiveness - 2020 EiF (euro/tonne)	129	132	126	73	139	129	155	182	127	204
Tonnes replaced - 2022 EiF	133 936	111 717	159 578	133 936	133 936	133 936	133 936	133 936	137 971	111 717
Total restriction costs - 2022 EiF (annual, million euro)	15.9	13.6	18.6	9.0	17.2	15.9	19.2	22.4	16.3	21.1
Cost effectiveness - 2022 EiF (euro/tonne)	119	122	116	67	128	119	143	167	118	189
Improvement (+)/decline (-) of cost-effectiveness		-2.6%	2.1%	77.1%	-7.3%	-0.1%	-17.2%	-29.3%	1.5%	-37.1%

Notes: Numbers not rounded. "Proposed restriction scenario" denotes the scenario used to describe the impacts of the proposed restriction in the preceding sections of this main report.
* The Low material costs scenario is the best case scenario in terms of cost-effectiveness of the restriction.
** The Worst case scenario is the scenario whose cost-effectiveness is the lowest. It tests the combined effects of High material costs, High testing costs, and Scenario 3 Baseline: Low tonnage.
Source: Annex E

Uncertainties related to benefit estimation

The principal uncertainty in the valuation of the benefits of the proposed restriction relates to the aetiological fraction, i.e., the fraction of cases that can be attributable to exposure to the four phthalates in articles within scope. A number of educated assumptions were made to estimate this fraction, the biggest unknown, however, remains the fraction of cases that can be attributed to exposure to chemicals.

WHO/UNEP 2012 stated that in general for human diseases and disorders globally, as much as 24% are estimated to be due at least in part to environmental factors. For cryptorchidism, for example, studies have reported that about 4% of cases are of hereditary nature, while for hypospadias this is between 4 and 25% (see Table D26 in Appendix D1 to Annex D). In general, environmental factors could include exposure to chemicals but also, injury, lifestyle (smoking, sun exposure, alcohol consumption, etc.), side-effects of an illness or its treatment, and others. HEAL 2013, Norden 2014, AFA 2013a all assumed a share of the incidence rate attributable to chemicals ranging between 2% and 50%, with a mid-case of 20%. Therefore, after reducing the reported incidence rates for hereditary cases,[50] this analysis also applied these percentages in the valuation scenarios for cryptorchidism and hypospadias as the fraction of the incidence rate attributable to exposure to chemicals (see step c in Tables D23 and D26 in Appendix D1). This is the main difference among the three scenarios for the two malformations in Table 30 above: Low estimate (2%), Mid-point (20%) and High estimate (50%). For male infertility these percentages are slightly different: respectively 13.5%, 27%, and 40.5% (a composite percentage of steps c and d in Table D15 in section 3.5.4 in Annex D). Less variability between the scenarios was seen appropriate in this case as EAU 2015 (the main source for incidence data on male infertility) provides very detailed statistics regarding the conditions that may lead to infertility. Therefore, a lot of non-environmental, non-chemical related factors were excluded at step c of the analysis.

Even in the unlikely situation where the costs are as described under the Worst case scenario e) in Table 34 and the benefits are in the lowest valuation scenario (Low estimate in Table 30), the prevention of exposure to a small fraction of the population at risk would lead to the benefits of the proposed restriction to exceed the costs. Table 35 shows that if the combinations of cases (these two or other) are avoided due to the entry into force of the proposed restriction, its benefits would exceed the unlikely worst case restriction costs of €22.8 million (Table 34). These cases represent less than 7% of the population at risk of foetal exposure and 2% of the population at risk due to infancy and early childhood exposure. Therefore, very few cases demonstrate that the benefits of risk reduction outweigh the costs of the proposed restriction even in the worst case situation where the costs are at their highest and the benefits at their lowest.

[50] Step omitted by HEAL 2013, Norden 2014, AFA 2013a.

Table 35. Break-even analysis on the basis of estimated number of cases and social damages of male infertility, cryptorchidism, and hypospadias in EU28

Minimum number of cases for Benefits to ≥ Costs	3 160 cases of Male infertility & 185 cases of Cryptorchidism & 210 cases of Hypospadias	1 050 cases of Male infertility & 405 cases of Cryptorchidism & 455 cases of Hypospadias
Equivalent to population at risk of foetal exposure (54 000 male children/yr)	<7%	<3.5%
Equivalent to population at risk due to infancy & early childhood exposure (176 000 male children/yr)	<2%	<1.1%
Equivalent to percent of projected annual male births (2.6 million male children born per year, on average)	<0.15%	<0.1%

Notes: The number of cases is estimated on the basis of the weighted average damage to society per case in the Low estimate scenario of benefit estimation (see section 3.5.4 and Appendix D1 in Annex D).

4. Conclusion

Human health risks from exposure to the four phthalates in articles in the scope of this proposal are not adequately controlled. In several Members States the risk characterisation ratio (RCR) for combined risk assessment was clearly above 1 and evaluation of the uncertainties suggests that the RCRs may have been underestimated. It is estimated that in 2014 about 5% (i.e., 130 000) of new born boys in the EU28 were at risk through in utero exposure and about 15.5% (i.e., 400 000) boys were at risk from direct exposure. Therefore, regulatory action is required and this should be undertaken on a Union-wide level. The proposed restriction is the most appropriate Union-wide measure because it targets the risks from exposure to the four phthalates by restricting their concentration in articles which have the highest contribution to exposure. It is also capable of addressing these risks within a reasonable timeframe, i.e., from 2020 onwards.

In addition, to the proposed restriction, it is clear that FCMs contribute substantially to human health risks from the four phthalates and the risk reduction from them will be greatly enhanced if the risks associated with exposure from the four phthalates are strengthened under Regulation (EC) No 1935/2004 and Commission Regulation (EU) No 10/2011.

The proposed restriction is considered a balanced and justified measure as the benefits of risk reduction are estimated to outweigh the costs of the proposal. The reduction of risk in the EU as a result of the proposed restriction is estimated to avoid over 2 110 cases of infertility annually as well as to reduce the prevalence of cryptorchidism, hypospadias and other negative health and environmental impacts. These benefits have been estimated to be annually at least €9.8 million, if measured in terms of avoided social damage due to infertility, and additionally €23 million, if measured in terms of avoided cases of male malformations. The proposed restriction might also lead to other human health and environmental benefits. These have not been quantified but studies suggest that they could be large.

The costs of the proposed restriction are estimated at €16.9 million annually. The costs are estimated to have low impact on the affected supply chains as there are many similarly priced technically feasible alternatives with lower risk. The restriction would also have small impact on the prices of end-use articles placed on the market. The cost of the proposed restriction is estimated to be €130 per tonne of the four phthalates replaced. This is about 20 times more cost-effective than earlier similar restrictions.

The benefits and costs are sensitive to the selected discount rate. Should a 2% discount rate is used, the annual monetised benefits due to increased fertility alone are estimated at €19.6 million (instead of €9.8 million with 4% discount rate), while the costs are estimated at €19.1 million (instead of €16.9 million with 4% discount rate).

The proposed restriction is a practical and monitorable measure for industry and enforcement authorities. It builds on the existing industry compliance and Member State enforcement practices on phthalates in articles. It is implementable, enforceable and manageable.

In conclusion, the restriction dossier demonstrates that an action is required on a Union-wide level and the proposed restriction is the most appropriate measure. This conclusion is reinforced when uncertainties are taken into account.