Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

FOUR PHTHALATES (DEHP, BBP, DBP, DIBP)

ECHA/RAC/RES-O-0000001412-86-140/F

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

Agreed

16 March 2017

10 March 2017

ECHA/RAC/RES-O-0000001412-86-140/F

16 March 2017

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name:	**Bis(2-ethylhexyl) phthalate (DEHP)**
EC No.:	**204-211-0**
CAS No.:	**117-81-7**

Chemical name:	**Benzyl butyl phthalate (BBP)**
EC No.:	**201-622-7**
CAS No.:	**85-68-7**

Chemical name:	**Dibutyl phthalate (DBP)**
EC No.:	**201-557-4**
CAS No.:	**84-74-2**

Chemical name:	**Diisobutyl phthalate (DIBP)**
EC No.:	**201-553-2**
CAS No.:	**84-69-5**

This document presents the opinion agreed by SEAC. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitter's proposal, amended for further information obtained during the public consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

Denmark and ECHA have submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at http://echa.europa.eu/web/guest/restrictions-under-consideration on ***15 June 2016***. Interested parties were invited to submit comments and contributions by ***15 December 2016***.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: *Marja PRONK*

Co-rapporteur, appointed by RAC: *Betty HAKKERT*

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on ***10 March 2017***.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The opinion of RAC was adopted ***by consensus.***

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: *Jean-Marc BRIGNON*

Co-rapporteur, appointed by SEAC: *Leandros NICOLAIDES*

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on ***16 March 2017.***

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.

The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.

The draft opinion was published at http://echa.europa.eu/web/guest/restrictions-under-consideration on ***22 March 2017.*** Interested parties were invited to submit comments on the draft opinion by ***22 May 2017.***

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on ***[date of adoption of the opinion]***. **[**The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by ***[number of days]*** by the ECHA decision ***[number and date]*****]**[1].

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and][5] 71(1) of the REACH Regulation.**] [**No comments were received from interested parties during the public consultation in accordance with Article[s 69(6) and][3] 71(1)**]**[6].

The opinion of SEAC was adopted ***by*** **[*consensus*.][*a simple majority*]** of all members having the right to vote. [The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion**.]**[6].

[1] Delete the unnecessary part(s)

Contents

A. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter in the Annex XV report is:

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.

Wires & cables:

The scope of the proposed restriction included wires & cables as these articles can cause dermal exposure or release phthalates to indoor air and thus, contribute to cumulative exposure and risk of the four phthalates. However, the relevant Commission services (DG GROW and DG ENV) requested following the submission of the dossier that the ECHA's Committees (RAC and SEAC), when adopting their opinions, exclude electric and electronic equipment (EEE), as defined in Article 3(1) of RoHS, from the scope of the proposal to restrict these four phthalates under REACH. As the changes to RoHS enter into effect in mid-2019, the Dossier Submitter incorporated the consequent phasing-out of the use of the four

phthalates in wires & cables under the baseline scenarios. Therefore, the presented analysis of the effectiveness of the proposed restriction is not affected by the exclusion of wires & cables from the scope of the restriction.

A.1. THE OPINION OF RAC

See the opinion of RAC.

A.2. THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the proposed restriction on ***Bis(2-ethylhexyl) phthalate (DEHP), Benzyl butyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP)*** is the most appropriate Union wide measure to address the identified risks, as concluded by RAC, taking into account the proportionality of its socio-economic benefits to its socio-economic costs and provided that the scope or conditions are modified, as proposed by RAC or SEAC, as demonstrated in the justification supporting this opinion.

The conditions of the restriction proposed by SEAC are:

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. The following articles or any parts thereof containing DEHP, DBP, DIBP, and BBP in a concentration, individually or in any combination, greater than or equal to 0.1% by weight of each plasticised material shall not be placed on the market: a. any articles whose phthalate containing material may be mouthed or is in prolonged contact with human skin or any contact with human mucous membranes, and b. any phthalate containing articles that are used (including stored) in an interior space 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. 2. Paragraph 1 shall not apply to: a. measuring devices for laboratory use or articles that form part of measuring devices for laboratory use[2], b. toys and childcare articles subject to entry 51 of this Annex, c. articles for which it can be demonstrated that they have been placed on the market for the first time in the European Union prior to the date in paragraph 5. 3. Paragraphs 1 and 2 shall not apply to articles in the scope of: a. Food contact materials covered by Regulation (EC) No 1935/2004 and Regulation (EU) No 10/2011 on plastic materials. b. Immediate packaging of medicinal products covered by Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC

[2] See ECHA Q&A#1179 for definition of measuring devices.

	c. Medical devices covered by Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC or components for such devices. d. Articles covered under Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive). 4. The following definitions apply to this entry: a. "Prolonged contact with human skin" shall mean a daily overall contact with skin of more than 10 minutes continuously or 30 minutes discontinuously, under normal and reasonably foreseeable conditions of use. b. "Interior space" shall mean any space where people are present under normal and reasonably foreseeable conditions and potentially exposed via inhalation. Those may include buildings (residential: e.g., apartments, houses, mobile homes; or commercial areas: e.g., hospitals, restaurants, offices) or vehicles for transportation of people (e.g., railway cars, automobiles, airplanes). c. "Industrial or agricultural workplaces" shall mean any commercial activities performed by workers a workplace in in the following sectors: - agriculture, forestry and fishing [NACE A] - mining and quarrying [NACE B] - manufacturing [NACE C] - electricity, gas, steam and air conditioning supply [NACE D] - water supply; sewerage; waste management and remediation activities [NACE E] - construction [NACE F] d. "Childcare article" shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children. 5. The restriction shall apply three years from its entry into force.
Amendment of entry 51 of Annex XVII of REACH	An amendment of the restriction entry to include DIBP in its scope.

B. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

B.1. IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

B.1.1. Description of and justification for targeting of the information on hazard(s) and exposure/emissions (scope)

B.1.1.1. Summary of proposal:

The four phthalates are all classified as toxic to reproduction in category 1B. The Dossier Submitter presents the four phthalates as a group of substances on the basis of their common physicochemical properties, common anti-androgenic mode of action, and similar use.

The spectrum of effects in the male rat associated with exposure to the four phthalates is known in literature as the *phthalate syndrome*. The cause for the 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 Dossier Submitter summarises the current scientific evidence in male animals and epidemiological studies, which shows that these effects are relevant for male humans.

B.1.1.2. RAC conclusion(s):

See the opinion of RAC.

B.1.1.3. Key elements underpinning the RAC conclusion:

See the opinion of RAC.

B.1.2. Description of the risk(s) addressed by the proposed restriction

B.1.2.1. Information on hazard(s)

B.1.2.1.1. Summary of proposal:

The Dossier Submitter proposes DNELs based on NOAELs (or LOAELs) for anti-androgenic effects seen in experimental studies. The DNELs are consistent with those previously agreed by RAC with the exception of DIBP. For DIBP only a few reproductive toxicity studies are published and the substance has not been tested at doses below 100 mg/kg bw/day. To appropriately reflect the anti-androgenic potency of DIBP, the Dossier Submitter derives a new DNEL based on read-across from its isomer DBP.

Table 1. 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/epidi-dymes/ 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

Assessment factors: an allometric scaling factor of 4 for rats; a factor of 2.5 for remaining interspecies differences; a factor of 10 for intraspecies differences; a factor of 3 as extrapolation from LOAEL to NAEL if no NOAEL is available

§ Oral absorption fraction=0.7 in rats for DEHP and 1 for the other compounds

The Dossier Submitter concludes that the uncertainties in the hazard assessment point towards an underestimation of the risks. Some of the sources of uncertainties are:

- 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.
- The Member State Committee (MSC) has confirmed that these four phthalates are endocrine disruptors related to human health[3] and the Commission is considering to identify them as substances of equivalent concern (SVHC) under Article 57(f) of

[3] ECHA (2014) https://echa.europa.eu/view-article/-/journal_content/title/the-member-state-committee-unanimously-agreed-to-identify-the-phthalate-dehp-as-an-svhc-because-of-its-endocrine-disrupting-properties-in-the-environm

REACH. This raises additional uncertainties regarding the appropriateness of the derived DNELs.

B.1.2.1.2. RAC conclusion(s):

See the opinion of RAC.

B.1.2.1.3. Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

B.1.2.2. Information on emissions and exposures

B.1.2.2.1. Summary of proposal:

The Dossier Submitter estimates that in 2014 more than 170 000 tonnes of the four phthalates were contained in the articles in scope placed on the EU market and leading to exposure to the general population and vulnerable groups. These tonnages 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. As shown in Table 2, 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 2. 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**
Tonnes used in EU28 article manufacturing	62 612	13 828	9 663
% change from previous period		*-78%*	*-30%*
Tonnes contained in Exported articles	15 722	5 952	3 025
% change from previous period		*-62%*	*-49%*
Tonnes contained in Imported articles	124 245	112 965	136 474
% change from previous period		*-9%*	*21%*
Tonnes contained in articles placed on EU28 market*	171 135	120 841	143 112
% change from previous period		*-29%*	*18%*
Share of tonnes imported of total placed on EU28 market	72.6%	93.5%	95.4%

* Tonnes contained in articles placed on EU28 market = Tonnes used in EU28 article manufacturing - Tonnes contained in Exported articles + Tonnes contained in Imported articles.

The Dossier Submitter presents information on the different routes and sources of exposure of the general population to the four phthalates. 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 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 indoor environment and direct contact with articles are still relevant sources of exposure. The exposure pattern is reversed for DBP, BBP and DIBP: direct contact with articles and exposure via the indoor environment are the dominant sources of exposure.

The Dossier Submitter's exposure assessment is based on DEMOCOPHES urinary biomonitoring samples taken in 2011-12. The modelling estimates presented by the Dossier Submitter are generally consistent with the biomonitoring results for children and mothers, but appear to underestimate risks slightly in Member States with high exposure levels.

B.1.2.2.2. RAC conclusion(s):

See the opinion of RAC.

B.1.2.2.3. Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

B.1.2.3. Characterisation of risk(s)

B.1.2.3.1. Summary of proposal:

Based on the 95th percentile of combined exposure to the four phthalates in 2011, the Dossier Submitter identified a risk in 14 out of 15 Member States (93%) where the monitoring took place. The modelling estimates presented by the Dossier Submitter 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, the Dossier Submitter concludes that the identified risk to the general population is not adequately controlled and needs to be addressed. This risk is in addition to the recognised occupational risk from the use of DEHP in formulation and production of articles and any possible risk to the environment from exposure to DEHP[4].

[4] The Member State Committee (MSC) confirmed that DEHP is an endocrine disruptor in the environment and thus, there may also be risks to the environment from exposure to DEHP.

B.1.2.3.2. RAC conclusion(s):

See the opinion of RAC.

B.1.2.3.3. Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

B.1.2.4. Uncertainties in the risk characterisation

See the opinion of RAC.

B.1.3. Evidence if the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk

B.1.3.1. Summary of proposal:

Workers

Of the four phthalates, only for DEHP there are applications for authorisation for its use in articles in the scope of the restriction proposal. 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 calendaring, spread coating, extrusion, injection moulding). Workers are furthermore exposed to the substance 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[5].

General population

As mixtures containing the four phthalates are not allowed to be sold to the public, the main source of exposure of the general population to the four phthalates is from articles. As a consequence, the risk management measures and operational conditions that can be implemented and recommended by the manufacturers of DEHP are limited in scope. Manufacturers of DEHP have taken some measures to protect the general population by excluding certain article groups from the scope of the applications for authorisation (e.g., erasers and sex toys were not covered). In most countries the RCR for 95th percentile exposure to DEHP is below 1. However, in Romania the RCR for the 95th percentile exposure of children to DEHP is close to 1 and in mothers equal to 1. Moreover, combined exposure to the four phthalates raises concern with RCRs for 95th percentile of exposure above 1. This

[5] ECHA (2014, 2015) Opinions on Applications for Authorisation for Bis(2-ethylhexyl) phthalate (DEHP). https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations

implies that the existing risk management measures are insufficient and the exposure from indoor environment, food and contact with articles poses a risk.

Conclusion

The Dossier Submitter has concluded that the risk management measures and operational conditions implemented and recommended by the manufacturers and/or importers are not sufficient to control the risks from the four phthalates to workers and the general population.

B.1.3.2. RAC conclusion(s):

See the opinion of RAC.

B.1.3.3. Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

B.1.4. Evidence if the existing regulatory risk management instruments are not sufficient

B.1.4.1. Summary of proposal:

The Dossier Submitter assessed that:

- DEHP, DBP and BBP are subject to restrictions in toys and childcare articles. DIBP is only restricted in toys.

- The use of DEHP, DBP and BBP in plastic for food contact materials is regulated under Regulation (EC) No 1935/2004 and specific measures thereunder (e.g. Commission Regulation (EU) 10/2011). The use of DIBP is not allowed in plastic for food contact materials. However, significant phthalate contamination has been found in food.

- DEHP, DBP, DIBP and BBP have all been identified as Substances of Very High Concern (SVHC), and all four are already included in REACH Annex XIV and thus subject to the authorisation process (with sunset date 21 February 2015). The authorisation process, however, does not cover placing on the market of articles containing the phthalates and therefore does not cover imported articles. Numerous articles therefore still contain the four phthalates. It is also noted that the authorisation process does not take into account combined exposure from both individual articles and individual substances.

  General population

  The combined exposure to the four phthalates raises concern with RCRs for 95th percentile of exposure above 1. This implies that the existing risk management instruments are insufficient and the exposure from indoor environment, food and contact with articles poses a risk.

  Workers

  See section B.1.3.1 above. In addition to DEHP, workers are also exposed to DBP, BBP and DIBP during the service life stage of imported articles (professional handling of

PVC articles during installation of building materials and workers wearing PVC work clothes and footwear).

Conclusion

The Dossier Submitter has concluded that the existing regulatory risk management instruments are not sufficient to manage the risks from the four phthalates.

B.1.4.2. RAC conclusion(s):

See the opinion of RAC.

B.1.4.3. Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

B.2. JUSTIFICATION IF ACTION IS REQUIRED ON A UNION WIDE BASIS

B.2.1. Summary of proposal:

The Dossier Submitter concludes that risks associated with EU manufactured or imported articles containing the four phthalates need to be addressed on a Union-wide basis for the following reasons:

i. Placing on the market and use of PVC articles under scope, and exposure takes place in all Member States.

ii. Due to the free circulation of goods within the European market, either of manufactured in the EU or imported goods, there is a need for an EU-wide measure rather than an individual action by Member States.

iii. Furthermore, an EU wide measure will safeguard a level playing field in the EU market for goods and items containing the four phthalates either manufactured within the EU (currently requiring an authorisation) or imported.

B.2.2. SEAC and RAC conclusion(s):

Based on the key principles of ensuring a consistent level of protection across the Union and of maintaining the free movement of goods within the Union, SEAC and RAC support the view that any necessary action to address risks associated with the four phthalates should be implemented in all Member States.

B.2.3. Key elements underpinning the SEAC and RAC conclusion(s):

SEAC recognises that measures need to be taken in order to reduce the risks from exposure to the four phthalates in all Member States, as the circulation of articles that contain the four phthalates takes place freely in the whole internal market.

In addition, an EU-wide measure will serve the proper functioning of the European market, as articles containing the four phthalates both manufactured within the EU and imported will be restricted.

B.3. JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

B.3.1. Scope including derogations

B.3.1.1. Summary of proposal:

The Dossier Submitter proposes to restrict 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 the first time 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.

Revised restriction wording

Following the submission of the dossier, the following changes to the proposed restriction wording were made as a result of the Forum advice on the enforceability of the Annex XV proposal for restriction on four phthalates (adopted on 21.09.2016) and public consultation comments:

Electric and electronic equipment (EEE) under RoHS
The scope of the proposed restriction originally included wires & cables as these articles can cause dermal exposure or release phthalates to indoor air and thus, contribute to cumulative exposure and risk of the four phthalates. However, the relevant Commission services (DG GROW and DG ENV) requested following the submission of the dossier that the ECHA's Committees (RAC and SEAC), when adopting their opinions, exclude electric and electronic equipment (EEE), as defined in Article 3(1) of RoHS, from the scope of the proposal to restrict these four phthalates under REACH. As the changes to RoHS enter into effect in mid-2019, the Dossier Submitter incorporated the consequent phasing-out of the use of the four phthalates in wires & cables under the baseline scenarios. Therefore, the presented analysis

of the effectiveness of the proposed restriction is not affected by the exclusion of wires & cables from the scope of the restriction. The proposed restriction wording was amended to introduce a derogation on EEE falling under RoHS.

DIBP in entry 51

The scope of the originally proposed restriction already restricted DIBP in toys and childcare articles in a concentration greater than 0.1% w/w. This is because from a hazard and risk perspective there is no reason to treat DIBP differently from DEHP, DBP and BBP, which already have such a restriction (entry 51 of Annex XVII of REACH). Furthermore, although DIBP is at the moment restricted under the Toys Safety Directive, the concentration limit set for DIBP in this Directive is higher than 0.1%, and there are notable differences in the scope of entry 51 and the Toys Safety Directive (e.g., childcare articles are not covered by the Toys Safety Directive). The Forum advice indicated that the most practical way of introducing the proposed restriction on DIBP is to revise the existing entry 51 of REACH to include DIBP. The revised restriction wording follows the Forum recommendation and proposes explicitly to amend entry 51 to include DIBP in the scope of that entry.

As a result of the Forum advice, the Dossier Submitter made the following changes to the wording of the proposed restriction to improve its clarity and enforceability:

- clarifications to ensure that parts of articles are also included in the scope of the proposed restriction;
- introduction of more detailed definitions for agricultural and industrial workplaces, prolonged contact with skin, as well as for indoor/outdoor environment;
- clarifications to assist with the interpretation whether articles with dual use fall in the scope of the restriction;
- editorial changes to improve clarity, e.g., paragraphs were numbered and all definitions were gathered in one paragraph that applies to the whole restriction entry;
- rewording to define the restriction in terms of what is restricted (version B as presented in section 2.2.1 of the Background Document) rather than in terms of a total ban with derogations for the articles outside the scope (as presented in the original proposal).

Derogations

During the public consultation, requests for additional derogations were received. These requests were assessed as follows by the Dossier Submitter:

1. Components for derogated medical devices

As the intention of the proposed restriction is to still allow medical devices subject to Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC, components required for such medical devices also need to be allowed. The requested derogation is specifically directed at imported components, as these would have been affected by the originally proposed restriction. The request is considered justified by the Dossier Submitter and the derogation (for imported and EU manufactured components used in exempted medical devices) has been included in the revised restriction proposal.

2. Aerospace articles used in the interior of aircrafts

The rationale for the request is that development and implementation of alternatives in the aerospace industry is a lengthy process (2-7 years), which necessitates the demonstration of equivalent performance of aerospace articles to airworthiness authorities. The Dossier Submitter evaluated the information provided. There are no known uses for which there are no alternatives for the four phthalates and additional brief consultation with aviation industry representatives did not reveal specific cases for which recertification may be required. Therefore, the Dossier Submitter concluded there is insufficient information to justify a derogation at this stage.

3. Materials that are hidden within, or below, assemblies in vehicles (automotive) that are currently in the engineering pipeline

The rationale for the request is that more time would be required (typically 4-5 years) to allow suitable testing and validation of alternatives. Although industry has provided information that they have transitioned to alternatives and very few article types still contain the four phthalates, sufficient information (e.g., volume of phthalates used, number of vehicles impacted, definition of "hidden" articles, etc.) for an assessment of such a derogation was not provided. Therefore, the Dossier Submitter concluded that such a derogation cannot be justified at this stage.

4. Spare parts (legacy spare parts, service and remanufactured parts), for vehicles (automotive and aircraft in particular) placed on the market prior to the entry into effect of the proposed restriction

The intent of the restriction is to allow for the maintenance and repair of vehicles[6] placed on the market prior to the entry into effect of the proposed restriction. Considering risk reduction and costs, on balance, the requested derogation for the placing on the market of spare parts for vehicles is considered justified by the Dossier Submitter.

5. Wellingtons and boots made from recycled PVC

The Dossier Submitter evaluated the need for a derogation on boots and wellingtons (for which no direct skin contact is claimed due to the presence of a lining inside the boots, and only negligible emission to indoor air) at the time of the dossier preparation. The information helped establish that the DEHP containing recyclate is used mainly in industrial and agricultural applications (outside scope of the restriction proposal) and only a very small tonnage in boots and wellingtons manufacturing. While this information assisted with the justification of the derogations on industrial and agricultural applications, it was concluded that a derogation on boots and wellingtons will be problematic as it will be difficult to differentiate between those produced from virgin and those from recycled material. As very few tonnes of recyclate are used in the manufacture of boots and wellingtons, there are a number of strategies that can be taken by these manufacturers to minimise the impacts of the proposed restriction, e.g., temporarily export to markets without similar restrictions,

[6] Vehicles are wagons, bicycles, motor vehicles (motorcycles, cars, trucks, buses), railed vehicles (trains, trams), watercraft (ships, boats), aircraft and spacecraft.

source DEHP-free recyclate or virgin material, manufacture articles outside the scope of the proposed restriction, etc. The costs and benefits of a mixture of these strategies was taken into account in the estimation of the overall costs and benefits of the proposed restriction[7]. As shown in the Background Document, the proposed restriction, excluding a derogation on boots and wellingtons, is effective, practical and monitorable. The Dossier Submitter therefore concluded that the transitional period gives sufficient time to manufacturers of boots and wellingtons to comply with the proposed restriction, and considered the derogation not justified. This conclusion remains after consideration of information submitted in the Public Consultation.

B.3.1.2. RAC conclusion(s):

See the opinion of RAC.

B.3.1.3. Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

B.3.1.4. SEAC conclusion(s):

SEAC agrees with the Dossier Submitter that the proposed restriction is the most appropriate EU-wide measure.

SEAC agrees with the proposed scope for the restriction, with some minor observations regarding its clarity (as elaborated in section B.3.4.3 – Manageability), and a preference for Version B presented in the Background Document for the reasons described in the last paragraph of the following section.

B.3.1.5. Key elements underpinning the SEAC conclusion(s):

The Dossier Submitter analysed other legislative and non-legislative measures than the proposed restriction that could be implemented in order to achieve the aims of protecting human health from exposure to the four phthalates. These include authorisation requirements under REACH, Art. 68(2) of REACH, other EU directives (Water Framework Directive, Industrial Emissions Directive (IED), Waste legislation, other sector specific legislation), taxation, labelling instruments, voluntary measures. These alternative measures were rejected by the Dossier submitter on the grounds of not being as effective, practical, or monitorable as the proposed restriction. Many of these options are also not able to address all the article categories that give rise to risks to human health.

SEAC agrees with the Dossier Submitter that the authorisation under REACH would fail to address imported articles, a major source of exposure to the four phthalates. Imported articles are estimated in 2020 to constitute more than 90% of the four phthalates contained in articles in scope placed on the EU market.

[7] For example, if the boots and wellingtons are produced from a virgin material instead of recyclate, the Dossier Submitter estimated an increase in their raw material costs will be about 1-2% of their sales price.

Concerning the application of Art. 68(2) of REACH, it differs from the proposed restriction more in terms of process than outcome: impact assessment, consultation are handled in a different manner in the two processes. SEAC does not consider as being mandated to express preference or assessment on these policy-related issues.

Other EU Directives clearly do not address the significant sources of exposures and are not as effective in reducing the risks: The Water Framework, the Industrial Emissions Directive, and the Waste Directives are more intended to reduce discharges to the environment, and hence are not the most adequate tools to address exposure from article use.

As regards voluntary measures, SEAC considers there is no evidence that it would be an effective approach, especially taking into account the high number of small actors involved in complex supply chains in the present case.

SEAC notes that taxation of articles in the scope of the proposed restriction is rejected by the Dossier Submitter on the grounds that an agreement on a uniform taxation scheme within the EU is very unlikely. SEAC regards this as a political argument that is outside its remit. The Dossier Submitter did not design a potential taxation scheme and did not asses its potential effectiveness, practicality and monitorability in comparison to the proposed restriction. Therefore, SEAC cannot conduct further assessment on the appropriateness of this measure versus the proposed restriction.

In addition to the above RMOs, other restriction measures considered by the Dossier Submitter include:

- restricting the placing on the market (and also production as a further option) of all articles containing the four phthalates,
- restricting only DEHP, DBP and DIBP (not BBP),
- derogation for DIBP in toys and childcare articles,
- no derogation for food contact materials (FCMs).

SEAC agrees with the Dossier Submitter's reasoning to discard these restriction options. In particular, SEAC agrees that it would not be proportionate to restrict all articles placed on the market since many of them do not contribute to direct human exposure (still noting a positive impact of a full restriction on the emissions to the environment and indirect human exposure), and because a total ban would result in legislation overlapping and probably confusion. In addition, SEAC agrees that even if BBP has a low contribution to the benefits and costs of the proposed restriction (due to its low contribution to combined exposure and lower use in articles in scope in comparison to the other three phthalates), its inclusion in the scope together with the other three phthalates is proportionate and consistent with previous decisions for its inclusion in Entry 51 of Annex XVII of REACH. It will also ensure that it is not used as an alternative to the three other phthalates included the proposed restriction, in the future. In addition, SEAC notes that BBP is included in Annex XIV as a substance that is aimed to be replaced with suitable alternatives, which already exist.

SEAC concurs with the Dossier Submitter's position to reject a request that came in during the public consultation by manufacturers of DEHP for restricting only non-authorised uses. SEAC found that the costs of the proposed restriction to the manufacturers of the four phthalates are negligible. SEAC also concurs with the Dossier Submitter's position taken after a request during the public consultation to reject the exclusion of DEHP from the proposed

restriction, noting that the proposed restriction on articles containing all four phthalates is found to be proportionate (see section on Proportionality).

Regarding derogations, SEAC also agrees in general with the proposed derogations since they clarify the interface between the proposed restriction and other sector-specific regulations (articles under the RoHS Directive, Food Contact Materials, Medicinal products, Medical devices). In particular, SEAC agrees that the regulation of exposure to the four phthalates in Food Contact Materials, an important source of exposure, would be dealt with more efficiently by the corresponding legislation.

SEAC notes the RAC conclusion that DIBP in toys and childcare articles contributes to risk from the four phthalates and agrees that existing measures do not address this risk (e.g., the Toy Safety Directive does not include childcare articles in its scope). SEAC also takes into account that DIBP can be used as an alternative to DBP (already restricted under entry 51) and the Forum's recommendation to introduce a restriction on DIBP in toys and childcare articles via an amendment of REACH Annex XVII entry 51. SEAC agrees with Forum that including the restriction in this manner will ensure clarity for all actors in the supply chain.

SEAC notes the exclusion of articles in use in industrial and agricultural context, and for outdoor use and agrees with the clarifications on the definitions of "industrial" and "agricultural" workplaces as well as of interior spaces.

SEAC agrees to derogate articles placed on the market for the first time prior to the entry into effect of the proposed restriction, because not having this derogation would compromise the enforceability and practicality of the proposed restriction. On the other hand, it extends the lifetime of the large stock of the four phthalates in articles contributing to exposure, and slows the pace at which it will decline in the future (and this shifts the health benefits in the future, and reduces their present value).

SEAC notes the Dossier Submitter's position taken after a request during the public consultation to derogate legacy parts, spare parts and remanufactured parts for vehicles (including aircrafts) already placed on the market at the date of entry into force of the proposed restriction. Such a derogation is requested to ensure articles in use prior to the entry into force of the proposed restriction could be maintained and repaired during their useful life. However, SEAC notes that there is no sufficient information (e.g., number of articles, volumes of the four phthalates in these articles, etc.) to justify such a derogation at this time.

SEAC concurs with the Dossier Submitter's position to reject the request that came in during the public consultation for derogating wellingtons and boots for the following reasons: the amount of recyclate used in their production is small relative to the total amount of recycled PVC, the material cost of the boots will increase only about 1-2%, the proposed restriction is proportionate with their inclusion in the scope, and there are various strategies to minimise the economic impacts.

SEAC agrees with the Dossier Submitter to derogate the components of exempted medical devices, after a request that came in during the public consultation, as this will ensure that the manufacturing or maintenance of these devices are not affected by the proposed restriction but continue to be governed by the relevant EU legislation (i.e., Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC).

Regarding the Dossier Submitter's opinion after a comment during the public consultation, for materials hidden within or below assemblies in vehicles, SEAC considers these hidden parts are in the scope of the proposed restriction and that alternatives exist for all uses.

SEAC agrees with Dossier Submitter, to reject the request that came in during the public consultation for derogating aerospace articles used in the interior of aircrafts for the following reasons: alternatives exist for all uses and lack of sufficient information such as articles for which certification (and hence longer transitional period) is required, to justify such a derogation.

In conclusion, SEAC agrees with the proposed restriction and its scope as amended and considers that it provides more clarity and that it is consistent with the aims to restrict the placing on the market of only those articles that present risks to human health via the critical routes of exposure. Finally, SEAC considers that the amended restriction wording is preferable than the original proposal because it defines what is restricted rather than what is exempted from a total restriction.

B.3.2. Effectiveness in reducing the identified risks

B.3.2.1. Summary of proposal:

The Dossier Submitter proposes a restriction 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).

The Dossier Submitter concludes 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 Dossier Submitter calls on the relevant authorities in the EU to 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 Dossier Submitter concludes that suitable and technically feasible alternative plasticisers with more benign human health and environmental hazard and risk profile are available for all uses in articles in the scope of the proposed restriction. These alternatives will therefore lead to overall risk reduction for workers and the general population in comparison to continued use of the four phthalates.

B.3.2.2. RAC conclusion(s):

See the opinion of RAC.

B.3.2.3. Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

B.3.3. Socio-economic impact

B.3.3.1. Costs

B.3.3.1.1. Summary of proposal:

The Dossier Submitter estimates the total costs to EU society from the introduction of the proposed restriction at €16.9 million annually.[8] These net compliance costs are calculated over a period of 20 years from the entry into effect of the proposed restriction: assumed year 2020 for the purpose of the analysis. The NPV of these future costs is €229.1 million in total (using 4% discount rate). These costs are not highly sensitive to the chosen discount rate (in comparison to the benefit estimates): applying 2% discount rate, the total restriction costs are €19.1 million annually.

The Dossier Submitter estimates the impacts on the basis of a non-use scenario which foresees stakeholders transitioning to alternatives or identifying markets outside the scope of the proposed restriction (e.g., non-EU markets or markets of articles outside the scope of the proposed restriction). The scenario is based on previous assessments of alternatives (ECHA 2012, AFA 2013) which concluded that technically feasible alternatives with lower risk are available for all uses of the four phthalates in articles in scope and that the transition to these alternatives will result in slightly higher article manufacturing costs.

a) Substitution costs

The Dossier Submitter identified that substitution costs are the main group of costs to be incurred by stakeholders as a result of the proposed restriction. These consist primarily of material costs, which are influenced by price and efficiency differences between the four phthalates and their alternatives. To estimate these costs, the Dossier Submitter assumes a scenario that industry would transition to a mix of alternatives. The scenario takes into account the current and projected substitution trends, production volumes and production capacity of the main alternatives in the EU and internationally.

On this basis, the material substitution costs are estimated to €15.8 million annually from 2020 (the year of the assumed entry into force of the proposed restriction) onward. The Dossier Submitter concludes that this is an overestimate because:

- 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. It is possible that some of the costs to substitute the four phthalates in imported articles (close to 97% of the €15.8 million annually) would be borne by international article manufacturers or other entities of the

[8] 2014 was selected as the base year for the purpose of the analysis. All values are discounted to 2014.

non-EU supply chain. This would likely lead to impacts on profits in non-EU jurisdictions.

- The substitution costs are estimated on the basis of the assumption that industry would transition to a mix of alternatives. These are not the least-cost alternatives but those identified by users as the most likely to replace the largest share of the four phthalates proposed to be restricted. Therefore, this scenario may also reflect other company strategies[9] as technically feasible alternatives at similar price levels are available for all uses of the four phthalates in scope. Thus, the material costs of €15.8 million annually may also be capturing costs that are not fully required to comply with the proposed restriction.

- Based on confidential information on pricing and comparative loading (AFA 2013, ICIS 2015), a least cost alternative scenario (i.e., by replacing the four phthalates with their least cost technically feasible alternative for all uses) estimates substitution cost to be close to €8.4 million annually, i.e., less than the Low material costs scenario presented in the sensitivity analysis, constructed on the basis of publicly available information for the mix of alternatives.

- The analysis assumes 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 similarly to past historical trends.

Other substitution costs, such as R&D, reformulation, process and plant modifications (RDRPPM) and other costs, are reported negligible in comparison. The Dossier Submitter justifies this conclusion with the following:

- Substantial substitution of the four phthalates has already occurred in the EU and internationally, which indicates that industry has high degree of familiarity with the ability to transition to alternatives in various uses and diminishes the need for R&D expenditures. In fact, three of the phthalates are fully phased out in manufacturing of articles in scope in the EU, indicating that their total substitution costs are minor or lower than the opportunity costs of applying for authorisation.

- Drop-in alternatives to the four phthalates are available, i.e., general plasticisers such as those included in the scenario used for the estimation of the substitution.

- None of the previous dossiers discussing regulatory action on the four phthalates conclude that these costs would exist and would be substantial for industry. These analyses were developed several years ago, when industry's experience with substitution was more limited in comparison to today, e.g., restriction entry 51, applications for authorisation (AFA 2013), and the Danish restriction proposal (ECHA 2012).

[9] For example, a company may choose to transition to a more expensive alternative even if a technically feasible alternative at lower prices exist: to anticipate further regulatory actions on some of the cheaper alternatives, to impart other functionalities in the article beyond what is currently accomplished with the use of the four phthalates, to boost sales with a "greener" image. It is likely that such strategies would be undertaken because they would lead to impacts that have a positive value. This value should be deducted from their costs to substitute to comply with the restriction. The current analysis does not quantify these potential positive benefits.

b) Testing costs

The Dossier Submitter concludes that although industry would likely continue to conduct testing to ensure compliance, 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 EU regulatory obligation or voluntary policies, e.g., Eco label). 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 than anticipated on the basis of confidential information is assumed for imported articles to account for such uncertainties. This is concluded as:

- 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 primarily dependant 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.

- Dossier Submitter also noted that in a similar case, in the restriction proposal for NPE in textiles, testing costs were considered highly uncertain and were not taken into account in assessing the efficiency of the restriction

c) Costs for the recycling sector

Information received from the recycling industry by the Dossier Submitter shows that majority of articles manufactured from recycled PVC are for industrial or agricultural use for which the proposed restriction foresees a derogation. The main articles impacted would be wellingtons and boots with interior lining, i.e., between 5 and 10% of the total volume of post-consumer and post-industrial recycled soft PVC waste (EuPC 2016). Given the low volume of the soft

PVC waste impacted by the proposed restriction, the Dossier Submitter anticipates 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. The substitution costs for recyclers are therefore estimated at €1.1 million annually, assuming a mix of these strategies. The producers of wellingtons and other boot would likely 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. It is expected that the amount of waste will not increase as a result of the proposed restriction.

d) Enforcement costs

Currently, all Member States spend approximately €55 600 per restriction per year (in 2014 values) to ensure compliance with Annex XVII of REACH. Therefore, the Dossier Submitter assumes that the entry into effect 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 not occur on an annual basis and that they will be more likely in the early years of the entry into force of the restriction.

The total annual restriction costs of €16.9 million estimated by the Dossier Submitter are shown in Table 27 of the Background Document.

B.3.3.1.2. SEAC conclusion(s):

With some observations expressed hereafter, SEAC generally agrees with the argumentation, analysis, information, and assumptions of the Dossier Submitter regarding the total restriction costs. The main component of the total restriction costs is by far the material substitution costs, and therefore, SEAC assessed more thoroughly these costs and their uncertainties.

B.3.3.1.3. Key elements underpinning the SEAC conclusion(s):

a) Material substitution costs

The Dossier Submitter estimates the material substitution costs at €15.8 million per year, at 2014 price level, for the 20-year period starting from 2020 onward, and provided a rationale that these costs are overestimated. The Dossier Submitter also provided a "low cost" (€8.4 million annually) and a "high cost" scenario (€17.1 million annually) that are discussed in Annex E of the Background Document and evaluated by SEAC hereafter.

SEAC reviewed the assumptions and calculations made and has the following observations.

(i) Estimate of current volumes

Regarding the current volumes of DEHP placed on the EU market, SEAC acknowledges that the Dossier Submitter has used the best available data (from Eurostat, applications for authorisation, and market intelligence) on tonnages of DEHP contained in articles in scope. Confidence is lower for the other three phthalates, but with only a minor impact since they are fully phased out in the EU and are only present in limited volumes in imported articles. To estimate the tonnages of the four phthalates in articles, Eurostat data on import and export volumes of articles are further converted into PVC and plasticiser tonnages, using data on PVC content of articles and plasticiser content of PVC, collected in the framework of the Danish PVC tax scheme. The plasticiser tonnages in articles are then converted into tonnages for each of the four phthalates on the basis of the prevalence of the four phthalate use on the market where the articles originate (e.g., more than 50% of DEHP from Asia, as according to market intelligence this plasticiser is the most commonly used). SEAC considers that this process of calculation represents a reliable estimate of the current volumes of the four phthalates in articles in scope of the restriction proposal.

(ii) Estimate of future volumes

Regarding future annual amounts of the four phthalates in the baseline scenario (without restriction), SEAC overall agrees with the approach, procedure, and methodology followed. The Dossier Submitter's calculations are based among others on historical data, legislation in force, population growth, GDP growth, increase of outsourcing, market intelligence and information from the applications for authorisation. The rate of increase of the volumes of the imported four phthalate plasticisers during the temporal scope of the proposed restriction is a sensitive parameter because imported amounts dominate over the domestic production. It is therefore the main determinant of substitution costs. The value of this parameter depends on the reaction of non-EU manufacturers to the restriction. The annual growth rate of imported article volumes in recent years (4.2%) serves as a basis, and the Dossier Submitter concluded on a 1% annual increase rate of the four phthalates over the 20-year temporal scope of the analysis as a more realistic growth rate based on qualitative arguments regarding driving forces to substitution outside the EU. SEAC agrees that this annual rate is clearly lower than the 4.2% (since there is already a trend for substitution of the four phthalates internationally, as referred to in the next paragraph) and recognises that there is only qualitative information available, but concludes that the 1% figure is uncertain. The Dossier Submitter also used a 2% value for the "high tonnage scenario", and as it is unclear which scenario is more realistic regarding this parameter, SEAC considers that the use of 1% could have led to some underestimation of substitution costs.

(iii) Availability of alternatives

SEAC agrees with the Dossier Submitter that **there are suitable and "drop-in" alternatives** to the four phthalates, as was concluded already in the opinion on the previous restriction submitted by Denmark (ECHA 2013a). This conclusion is backed by the fact that in recent years substantial substitution of **DEHP** took place not only in the EU but also internationally (ECPI 2012). SEAC notes also that high molecular weight orthophthalates, such as DINP, DIDP, DIUP (Diisoundecyl phthalate), DTDP (Diisotridecyl phthalate), represent around 70% of the European market and that the DEHP's share in the European market is decreasing from around 25% in 2005, 21% in 2008, 16% in 2012 to around 11% in 2014

(www.plasticisers.org).

SEAC agrees that this trend is expected to continue, mainly due to rapid increase of non-phthalate plasticiser consumption and the discontinuation of large-scale production of linear phthalates (Chemical Economics Handbook). SEAC also notes that the Public Consultation for ECHA 2013a did not point to a particular use of DEHP for which there is no technically feasible alternative. The dominant competitors of DEHP are DINP and DIDP but DEHT and DINCH also have the potential to replace a large share of the DEHP market (Table D8 of BD and AfA 2013). In addition to these facts, SEAC notes the Dossier Submitter references that the industry has extensive experience in non-phthalate alternatives like ASE, ATBC, DGD, DEGD, COMGHA, GTA, TGD (Table D8 of the BD). Regarding the three other phthalates **DBP, DIBP, BBP**, which are no longer used in EU since their sunset date (21.02.2015) has passed with no application for their authorisation having been filed, SEAC notes that it has already been proven that there are technically and economically feasible alternatives for all applications as they have been replaced by EU article manufacturers.

(iv) Prices and comparative loadings

The Dossier Submitter reports and uses information on **comparative loadings and price differentials** between the four phthalates and those of the main alternatives. The price and comparative loading of the main alternatives of DEHP show a difference in the range from 1.03 to 1.15 times those of DEHP, although some more specialized plasticisers may have larger differential. The price/comparative loading of alternatives to DBP, DIBP, and BBP is assumed 1.1. SEAC, however, considers that it cannot be excluded that some supply chains may be triggered by the restriction to move to more expensive non-phthalate alternatives, as has been seen in practice in past years, even if the majority of them use the cheaper available drop-in alternatives. The Dossier Submitter considers that DEHP, for example, a general plasticiser would most likely be substituted by other general plasticisers and its substitution with specialty plasticisers would only be motivated by considerations beyond the proposed restriction (e.g., to impart additional qualities to the final product, to market non-phthalate containing products, etc.), and therefore, that this extra cost cannot be attributed to the proposed restriction. Within this context SEAC notes that there are elements from the downstream user survey in AFA 2013 indicating that some stakeholders, albeit a small percentage, already use non-phthalate alternatives as replacement for DEHP.

(v) Range of material substitution costs

Given the above context, SEAC calculated for sensitivity analysis purposes another range of the substitution material costs using the low (constant volume (111 717 tonnes) throughout the temporal scope) and high volume forecasts (increase of 2% of imports per year, from 127 909 tonnes to 182 714 tonnes) as proposed by the Dossier Submitter. This sensitivity analysis also considered two different assumptions in terms of the likely alternative mix to replace the four phthalates. The first alternative mix was constructed by including the alternatives with the lower price at relatively higher share (DINP 45%, DIDP 5%, DPHP/DEHT 40%, DEHA/DOA 10%, i.e., low tonnage-low price mix) and the second mix by including the alternatives with the higher price at relatively higher share (DINP 50%, DIDP 39%, DPHP/DEHT 10%, DEHA/DOA 1%, i.e., high tonnage-high price mix). It should be noted that the share of alternatives used by the Dossier Submitter is DINP 55%, DIDP 15%, DEHT/DPHP 30%, which SEAC considers a more balanced scenario mix. The shares of the alternatives in the above alternative mix scenarios where based on their market potential (See Annex D, Table D9 in

the Background Document). For the low tonnage-low price mix, the price of DEHP used by SEAC is that of the Asian market in November 2014.[10] For the high tonnage-high price mix, SEAC used for the price of DEHP calculated for January 2014 and extrapolated linearly from November 2013 (high) and November 2014 (low) prices on the European market.[11] The price of the three other phthalates is calculated as 1.15 times the DEHP price applied in each scenario mix, as used also by the Dossier Submitter in the high material costs scenario. The ratio of tonnages between the three phthalates to DEHP applied by SEAC is 1:9. The loading factors are as shown in Table D13 of the Background Document and used by Dossier Submitter. The full range of material costs derived from the above sensitivity analysis, is between €13.22 million and €22.72 million (at 2014 price levels), to be compared to Dossier Submitters figures of "low cost" (€8.4 million annually) and "high cost" scenarios (€17.1 million annually). This suggests a potential underestimation of material costs, especially regarding under Dossier Submitter assumptions for the low-cost alternatives mix.

However, the Dossier Submitter, using confidential information from market intelligence, estimates a feasible least-cost scenario (based on replacement of DEHP with a single alternative) with even lower cost than their "low cost" scenario. SEAC agrees that such a scenario is theoretically possible, but has no indication that it is more likely than others, given that so far the market did not switch to a single alternative for DEHP.

Conclusion on material substitution costs:

SEAC overall agrees with the method and data used by the Dossier Submitter to derive material substitution costs.

There are some assumptions and consideration that give rise to uncertainties, in regards to the range of material substitution costs computed by the Dossier Submitter (€8.4 to €17.1 million annually over 20 years).

The uncertainties identified by SEAC are the following:

Table 3 Summary of uncertainties in the estimation of material substitution costs

Description of uncertainty	Direction	Impact
All costs are assumed by the Dossier Submitter to be passed on to EU consumers but, because of the high competition among players on the market for the restricted articles, and high bargaining power of EU importers of articles, non-EU manufacturers could absorb an important part of the substitution cost	Overestimation	High/Very high
Price differences between the four phthalates and the alternatives are assumed to remain constant over the period of analysis (possibilities for increased cost/efficiency in alternatives manufacturing in the future)	Overestimation	Moderate
Dossier Submitter assumptions that primarily moderate to lower-cost phthalate alternatives will be used, whereas some stakeholders may be triggered by the restriction to use more expensive alternatives	Underestimation	Moderate
Dossier Submitter assumptions that substitution of the four phthalates internationally will lead to a lower rate of increase in the amount of the four phthalates in imported articles	Possible underestimation	Moderate

[10] As shown in Table D12 in Annex D of the Background Document.
[11] As shown in Table D12 in Annex D of the Background Document.

Overall, SEAC considers that the annual material substitution costs calculated by the Dossier submitter (range of €8.4 to €17.1 million annually and a central value of €15.8 million) is a reliable estimate, and that they could be moderately underestimated.

b) Research & development, reformulation, process and plant modification (RDRPPM) costs.

The Dossier Submitter considers RDRPPM costs to be minor and included in material costs. The Dossier Submitter's rationale is that substantial substitution is demonstrated, that drop-in alternatives exist and that previous dossiers reached similar conclusion on the basis of consultations with the public.

SEAC considers that the fact that there are still actors using DEHP is reasonable to derive that switching to alternatives implies at least some non-zero costs. SEAC notes that a manufacturer claims in its comments that increases in plasticiser costs, as well as wider production cost increases, result from, among others, production changes from moving to alternatives. SEAC also notes that a manufacturer's leaflet of an alternative plasticiser (BASF),[12] states that in order to use their plasticiser (DINCH), "only minor adjustments to formulation and process parameters" are needed. Therefore, SEAC derives that some trials and associated costs may be required. It is noted that DINCH is not one of the alternatives included in the scenarios of the present report (but it is a potential alternative as commented by industry (ECPI) during the public consultation), but nevertheless the above shows that adjustments and adaptations cannot be excluded. There is some information on reformulation costs for downstream users claimed in the applications for authorisation for DEHP submitted in 2013, but SEAC notes that this claim had not been substantiated by the applicants. Also SEAC notes that neither the plasticisers (ECPI) nor the converters (EuPC) industry have included any comment on this matter during the public consultation.

SEAC concurs with the Dossier Submitter that in the ECHA 2013 report it is stated that the RDRPPM costs are relatively small as drop-in alternatives exist. Also, previous consultations did not provide evidence of significant RDRPPM costs (ECHA 2012a, ECHA 2013), nor was this raised during the call for evidence for this restriction proposal (ECHA2015a). Furthermore, in the information gathered for this and the previous restriction proposal, there was some information from industrial stakeholders that process adaptation would not be a technical or economic concern for them. SEAC also notes that any RDRPPM costs would be one-off costs, and should be compared with recurrent material costs over a period of 20 years. SEAC finally stresses that part of RDRPPM costs would be borne and absorbed by non-EU manufacturers (as many of the articles compete on cost on the global market), and would therefore be out of the scope of the analysis.

Conclusion on RDRPPM costs:

Overall, SEAC agrees that the whole body of evidence points to a lower order of magnitude of RDRPPM costs compared to material substitution costs, although it cannot be excluded that some stakeholders might have to bear RDRPPM costs. In conclusion SEAC agrees with the

[12] www.plasticizers.basf.com/portal/load/fid255202/Hexamoll, 02.03.2017

Dossier Submitter that these costs are negligible compared to material substitution cost.

c) Testing costs

SEAC agrees with the Dossier Submitter that testing costs are highly uncertain. SEAC also agrees that these costs are largely not attributable to the proposed restriction. Indeed, they depend much more on internal industry testing policies for the various raw materials purchased, and the way these policies are implemented. These policies include contractual procedures for the manufacturer at one end of the supply chain, which are used by the majority of companies, and spot checks and audit by EU buyers at the other end.

SEAC considers that testing costs could be attributed to the proposed restriction only within the transition period during the adaptation trials, and like RDRPPM costs, would be considered as one-off costs, and should therefore be compared with recurrent material costs over a period of 20 years. It should also be stressed that such costs would partially be borne by non-EU manufacturers and not solely by EU economic actors of the supply chains. SEAC also notes that according to Article 7(2) of REACH, producers and importers of articles containing the four phthalates are obliged already to notify ECHA if these phthalates are present (since they are SVHC included in the Candidate list), if totalling over one tonne per year, in a concentration higher than 0.1% by weight. Therefore, testing of articles regarding the four phthalates content already should be taking place in the supply chain.

The Dossier Submitter included in the sensitivity analysis an illustrative calculation of the testing costs, which shows negligible effects of testing costs on article price (from 0.001% to 0.03%), and total testing costs varying between (annually) €0.02 million and €6.7 million. This range is very wide because different contrasting assumptions are accumulated in the calculations (regarding the share of articles tested, test price, and proportion of testing costs to be attributed to the proposed restriction). SEAC assessed the calculations and assumptions, and, even considering that the recycling sector might need more intensive testing, found that the "low" scenario gave a more realistic illustrative calculation, whereas parameters assumed for the "mid-point" and "high" scenarios did not (as they contained assumptions related to very low article weight and very high frequency of testing).

Conclusion on testing costs:

SEAC's conclusion on the testing costs is that they are negligible compared to material substitution costs.

d) Costs for EU manufacturers of DEHP

SEAC notes that one of the three EU manufacturers of DEHP that applied for authorisation has closed down DEHP production operations. There are currently two remaining EU manufacturers of DEHP who applied for authorisation for the use of DEHP in articles in the scope of by the proposed restriction. However, one of them started in 2010 producing DPHP and DINP using imported INA (isononyl alcohol) and 2-PH (2-propylheptanol) (IHS) and currently manufactures also DEHA, Dimethyl phthalate, Diisobutyl adipate, as advertised on their website[13]. The second manufacturer produces DEHP standard and medical grade, DIBP

[13] http://www.deza.cz.en/phthalic-anhydride-plasticizers-and-esters, 10.11.2016

and DEHT, as advertised on their website[14]. Total costs of the restriction should include potential costs specific to these manufacturers. This means that to offset the impact of the proposed restriction, they would need to find new customers for a part of their DEHP business (their total manufactured tonnage is less than the market demand of DEHP used outside the scope of the proposed restriction). For example, to market to sectors not covered by the scope of the restriction: medical and construction products, industrial and agricultural applications, some outdoor applications or to non-EU buyers. It is therefore possible that some market loss for DEHP will be incurred by these manufacturers as a consequence of the proposed restriction, as it is unsure that competition with established supply chains would allow the capture of new clients. However, these costs are likely to be distributional, as these losses would likely be compensated by gains of alternatives manufacturers (including the two companies themselves) within the EU.

Therefore, SEAC concludes that the costs on EU manufacturers of DEHP are negligible compared to material substitution costs.

e) Costs to the Recycling Sector

SEAC concurs with the Dossier Submitter that the proposed restriction is estimated to affect the recycling sector mainly due to four phthalates containing recyclates no longer being available for the manufacture of some articles, such as footwear. SEAC also agrees that the volume of non-recycled PVC waste may not increase as a result of the proposed restriction as most of the recyclate is directed to articles outside its scope. The Dossier Submitter estimated that these costs are of the order of €1.1 million per year, on the basis of 500 000 tonnes per year of total recyclates and assuming that some articles in the scope of the restriction could still be produced by transition to virgin PVC material.

SEAC notes that the European PVC Recyclers have as a target the recycling of 800 000 tonnes by 2020 and that in 2015 they recycled 514 913 tonnes of PVC (Vinyl Plus). Thus, SEAC considers that in 2020 the amount of recycled PVC will be higher than the 500 000 tonnes taken into account by the Dossier Submitter in calculating the costs to this sector. SEAC considers that an increase of around 40% up to 2020 from 2015 levels could be reasonably achieved, i.e. about 7.0% per year, amounting to 725 000 tonnes. This is backed by the fact that the volumes recycled increased from 255 000 tonnes in 2011, to 365 000 tonnes in 2012, to 445 000 tonnes in 2013, to 480 000 tonnes in 2014, to 515 000 tonnes in 2015 (Vinyl Plus) and in 2016 new recyclers/converters entered the industry with recycling capacity of about 17 000 tonnes (Vinyl Plus, 2015 minutes of the Monitoring Committee). In this case, the costs to the recycling sector for the articles to be produced and included in scope (i.e. boots and wellingtons) would rather be in the order of €1.6 million at 2014 price level.

Therefore, SEAC concludes that costs to the recycling sector are €1.6 million annually.

f) Enforcement Costs

The Dossier Submitter considers that annual enforcement costs, consisting of administrative and inspection and control costs, will be of the same level as the mean enforcement restriction costs reported by all EU Member States, i.e., of the order of €55 600 annually.

SEAC notes that those cost are extracted from an ECHA survey (unpublished) only covering

[14] http://grupaazoty.com/index.php?p=oferta&s=oxo&lang=pl, 23.11.2016

administrative costs, and excluding analytical costs. SEAC found information on unit analytical costs (€160 for DEHP plus €15 more for each of the other phthalates, if analysed in the same sample, at 2009 price level) in an assessment by the Danish EPA of the inclusion of three phthalates in the ROHS Directive[15]. However, SEAC found no information to derive a number of samples that would be analysed each year for the proposed restriction. This number could be low if Member States consider that they mainly have a fixed budget for the analytical control of all chemical legislation, but could be high compared to €55 600 in case they consider that a specific budget is worth being spent.

SEAC carried out an illustrative scenario calculation of annualised costs, based on an initial 100 samples per Member State and year[16], also assuming a linearly declining number of samples to zero 6 years after entry into force, with 4% discount rate. The total costs (administrative and analytical) were found to be in the order of magnitude of €0.17 million at 2014 price level. Based on the information included in the Swedish report on enforcement 2014-2015.[17] SEAC considers that the assumptions made for the construction of the above scenario are reasonable.

Therefore, SEAC concludes that annualised enforcement costs, including administrative/inspection as well as sample analysis costs, could be higher than assessed by the Dossier Submitter but have only a minor impact on the total restriction costs compared to other costs.

g) Total Restriction Costs

Based on the above analysis, the total annualised Restriction Costs confirmed by SEAC are €17.6 million, with an interval of sensitivity values of (€10.2 million - €18.9 million) as shown in the table below.

Table 4 Total restriction costs – summary

Cost component	Central value	Low value	High value
Material costs	€15.8 million	€8.4 million	€ 17.1 million
RDRPPM costs	Minor compared to material costs	Minor compared to material costs	Minor compared to material costs
Testing costs	Negligible compared to material costs	Negligible compared to material costs	Negligible compared to material costs
Costs to the recycling sector	€1.6 million	€1.6 million	€1.6 million
Enforcement costs	€0.17million	€0.17million	€0.17 million
Costs to substance manufacturers	Negligible compared to material costs	Negligible compared to material costs	Negligible compared to material costs
Total restriction costs	**€17.6 million**	**€10.2 million**	**€18.9 million**

[15] Maag j. et al., "Inclusion of HBCDD, DEHP, BBP, DBP and additive use of TBBPA in annex IV of the Commission's recast proposal of the RoHS Directive - Socioeconomic impacts", Report of Environmental Project No. 1317 2010 Miljøprojekt

[16] The order of magnitude comes from the following reasoning: 1310 samples were found to contain restricted phthalates in toys between 2006-2015 as indicated by RAPEX. In case of a non-compliance rate of 5%, the total number of samples taken is found to be 2620 per year, which is around a mean number of samples of 100 per MS.

[17] "The Swedish Chemicals Agency's Analyses in Conjunction with Enforcement 2014-2015", Stockholm 2016.

B.3.3.2. Benefits

B.3.3.2.1. Summary of proposal:

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 of 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.

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 the effects seen in rats from exposure to the four phthalates are relevant in humans at observed exposure levels in the population.

The Dossier Submitter rates the strength of relationship of 17 human health impacts and the exposure to the four phthalates on the basis of experimental data, epidemiological studies and the level of exposure[18]. Environmental impacts are also discussed. ECHA CSA guidance Chapter R.7a states that biologically relevant findings seen in experimental animals should be considered relevant to humans unless convincing evidence exists to the contrary. All of the effects observed in experimental animals are considered to be biologically relevant since the conditions also exist in human males.[19] In addition, there is supporting epidemiological evidence for an association between the effects occurring in humans and exposure to the four phthalates.

Reproductive risks are of obvious concern for the general population and similarly, to the individual, an impairment of the ability to reproduce and the occurrence of developmental disorders are self-evidently serious health constraints (ECHA CSA guidance Chapter R.7a). Thus, since a risk is identified for combined exposure to DEHP, DBP, BBP and DIBP in the majority of European countries (14 out of 15 Member States), there is a risk in the European population that the phthalates cause a spectrum of serious and interlinked developmental effects in males, including with high probability reduction of semen quality, testicular changes,

[18] The overall strength of the relationship between exposure estimates and human health impacts is rated as either weak, moderate or strong (≈likelihood or probability for human health impacts). The overall rating "strong" is given when both the evidence from animal studies and the evidence based on exposure considerations are strong. The overall rating "moderate" is given when (1) the evidence from animal studies is strong, but exposure considerations are moderate or weak; or (2) the evidence of both animal studies and exposure considerations are moderate. The overall rating "weak" is given in other cases where some evidence for effects from animal studies or epidemiology exists.

[19] Except increased nipple retention, but as explained earlier nipple retention is an indicator of foetal androgen suppression which is biologically relevant to humans.

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.

In addition, there is a moderate/strong probability for children suffering from immunological effects from exposure to the four phthalates and 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. 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.

These effects may increase the number of persons at risk as it includes additional populations since it not only encompasses boys but also girls, adult men and adult women.

The human health and environmental benefits associated with reduced exposure to the four phthalates in articles in scope are discussed qualitatively in the dossier. To illustrate the magnitude of these impacts and the proportionality of the proposed restriction the Dossier Submitter quantifies and monetises the impacts with the strongest strength of evidence between exposure and observed effect: male infertility (due to in utero exposure), cryptorchidism, and hypospadias.[20] The Dossier Submitter concludes (on the basis of animal studies, epidemiological data, evidence of exposure levels and uncertainties related to the hazard and risk assessment) that it is plausible that the benefits of the restriction are at a minimum comprised of avoided cases of these three human health impacts (in mid-point estimates), i.e., in excess of €32.8 million (using 4% discount rate). In addition, exposure to the four phthalates in articles might be associated with a number of other human health (about 17 listed in Table 31 in the Background document) and environmental conditions that are considerably more difficult to estimate but studies show that the avoided social damage would be large. This can be seen by the same Table 31, which gives an indication of the damage to society due to a case of each of the non-quantified and monetised adverse human health concerns.

The Dossier Submitter derives the number of cases associated with exposure to the four phthalates in articles in scope from incidence rates, adjusted accordingly to exclude cases due to exposure from other sources. The social damage is monetised using direct and indirect costs per case (Norden 2015, EuroStat 2016) and intangible costs presented in terms of the willingness to pay (WTP) values estimated by ECHA (2013a,b). Table 5 presents a summary of their results.

Table 5: Quantification and monetisation of human health benefits

	Infertility	**Cryptorchidism**	**Hypospadias**

[20] Following the official submission, the Dossier Submitter quantified and monetised asthma impacts on request of SEAC, as immunotox effects were found to have also medium to strong association between exposure and the observe effect.

Incidence rate in EU-population	15%[21]	2.4%[22]	3%[23]
Derived aetiological fraction associated with exposure to the four phthalates in articles (as % of all new born males)*	0.08%	0.018%	0.021%
Annual cases attributable to four phthalates in articles	**2 110**	**480**	**540**
% of population at risk due to foetal exposure	3.9%	0.9%	1%
% of population at risk due to infancy & early childhood exposure	1.2%	0.3%	0.3%
% of total annual cases of males seeking ART or males with malformations	0.6%	0.8%	0.7%
Annual damage to society – using 4% discount rate**	**€9.8**	**€13.9**	**€9.1**
Annual damage to society – using 2% discount rate**	**€19.6**	**€15.6**	**€10.3**

Notes:
* Derived from the incidence rate in EU population. The methodology involves a consecutive adjustment of the incidence rate to exclude cases not associated with exposure to the four phthalates in the articles in scope (i.e., cases not associated with exposure to chemicals (e.g., hereditary, trauma, other environmental factors), cases associated with exposure to substances other than the four phthalates (e.g., exposure to other EDCs which have similar anti-androgenic effects such as DINP[24]), cases associated with exposure to the four phthalates from other sources, such as food and articles outside the scope). See Tables D18, D26 and D29 in the Annex of the Background document.
** 2014 values, average, representative year analysis.

The estimates presented in Table 5 are associated with a number of uncertainties related to the estimation of the aetiological fraction, the most influential being the share of case attributable to chemicals (in this case, to substances such as the four phthalates and other with similar properties. A chemical-attributable fraction can be calculated from selected exposure-response relations in epidemiological studies. In the absence of good quality epidemiological studies, the Dossier Submitter has chosen to use the approach presented in a number of recently published studies. The specific fraction used for the main case benefit estimation scenario was established on the basis of an expert opinion by Norden (2014), specifically for the health outcomes related to TDS, presented in the dossier. Two other scenarios are presented for sensitivity purposes.

The Dossier Submitter points to a number of additional uncertainties related to the estimation of the aetiological fraction and the monetary values used to illustrate the damage to society

[21] EAU 2015.
[22] The incidence of cryptorchidism is difficult to determine as the definition of the condition varies in scientific publications. Kortenkamp et al. (2011) states that *depending on country and geographical location, it affects 2 – 4% of boys, but according to recent estimations this can be as high as 9% in some countries.* Incidence reported in the literature in data from hospital-based or central registers (with diagnosis performed from birth to 1 year of age) rates range from less than 1% to 10% (Thonneau et al 2003). Orchidopexy rates have been reported between 2.4% and 3.8% (Jones et al (1998), Campbell et al (1987), Tamhne et al (1990)). HEAL (2014) quotes an incidence rate of 6% and uses the rate of 3% for the purpose of their analysis. Therefore, for the purposes of estimating the aetiological fraction associated with exposure to the four phthalates in articles, as a starting point of the analysis is chosen the mid-point between the lower bound of the undescended testes incidence rate and the higher bound of orchidopexy rates.
[23] On the basis of Norden 2014, HEAL 2014 and taking into account significant underreporting of hypospadias cases and a trend towards increase in incidence (Toppari 2001).
[24] The rate is also reduced to account for a potential significant replacement of the four phthalates with DINP.

associated with the exposure to the four phthalates in articles in scope:

- The incidence rates chosen as a starting point of the analysis tend to be on the lower end of the spectrum of reported results in studies (e.g., cryptorchidism in Skakkebaek et al. (2016)).
- Specifically, for male infertility, 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 pregnancy without assisted reproductive treatment 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 are not presented above. Those costs could be considerable, as ECHA 2014b shows individuals are willing to pay to reduce the time to pregnancy. In addition, the desire to have more than one child is not fully taken into account in the analysis.
- The WTP values per case tend to be lower than for other studies on similar impacts.
- It is uncertain whether the intangible costs fully capture all costs associated with the pain and suffering of all impacted by the medical condition. Impacts on the male reproductive system are complex and lead to a number of health conditions, which are closely associated (or lead) to e.g., cryptorchidism. 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.
- The direct and indirect costs do not fully capture all costs of treatment that are associated with hypospadias and cryptorchidism (e.g., for those cases where testicular cancer is a secondary diagnosis).
- It is uncertain to what extent indirect costs such as overhead costs of the public health system are taken into account in the collected cost of treatment data.
- 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.

B.3.3.2.2. SEAC conclusion(s):

SEAC finds that the uncertainty of the benefits assessment is high, considerably higher than for the costs assessment. Because the uncertainty related to aetiological fractions dominates and is of unknown direction, SEAC finds it difficult to conclude on the direction of the overall uncertainty.

SEAC notes the lack of sufficient scientific information necessary for the development of dose-response functions and agrees to use the estimated monetised benefits using the aetiological (attributable) fraction approach as an indication of the magnitude of the human health benefits of the proposed restriction, noting that considerable human and environmental benefits remain not monetised. SEAC also agrees with the assumptions made by the Dossier Submitter about the data and parameters used for the monetisation of the health benefits with the aetiological fraction method, although some technical issues were identified (WTP values, cost of health interventions, discount rates, delay of benefits due to lifetime of articles). With these reservations, SEAC agrees that the monetised benefits estimates are useful to assess the proportionality of the restriction.

B.3.3.2.3. Key elements underpinning the SEAC conclusion(s):

SEAC reviewed the benefits calculations carried out by the Dossier Submitter and have the following observations:

a) Baseline incidence for monetised health impacts

In this critical step, incidence of male fertility problems, hypospadias, cryptorchidism, and asthma, is apportioned ("aetiological/attributable fraction" method) to exposure to the four phthalates, through a succession of assumptions transparently described by the Dossier Submitter, and based on (generally) recent and relevant information. These steps allow to calculate the number of cases in the baseline scenario, without the proposed restriction. Given the lack of epidemiological information, several assumptions were necessary.

For male infertility (due to in utero and early childhood exposure), the most uncertain steps are the following:

1. Infertility incidence rate in the EU is the starting point of the analysis, and is taken from EAU 2015 at 15% (where from and how this number is derived is not explained in this document, nor to what period it is referring to). WHO/Europe[25] quotes a "stable" 10-12% incidence for the WHO-Europe region (larger than the EU). Hauser 2015 reports a baseline prevalence of 8%, potentially indicating incidence lower than 8%.[26]

2. Derivation of the fraction of infertility cases associated with exposure to chemicals with anti-androgenic mode of action and other unknown causes. Among the near 20 causes of infertility, it is considered that five causes are related to chemicals and that the others are not.

3. Derivation of the fraction of the above only related to chemicals. By definition, this step is very uncertain since it needs to separate unknown causes. Overall, the approach by the Dossier Submitter and the references used appear, because of lack of information, to be qualitative and based on expert assumptions. SEAC notes that the WHO/UNEP reference used to set the assumptions considers that 24% of diseases

[25] *In* "Entre Nous", the European Magazine for Sexual and Reproductive Health, No 63, 2006, published by the Reproductive Health and Research Programme WHO Regional Office for Europe.
[26] Prevalence over a population includes both new and existing cases and should therefore be higher than incidence (only new cases). This 8% rate is however based on the number of children borne after ART and not on couples seeking ART as in EAU 2015, which could explain (part of) the difference. The 8% figure also seems to be based on Danish figures only.

are related to the environment, but that this figure covers a vast variety of diseases (from lung cancer to depression or violence) and environmental factors (from chemicals to viruses and bacteria), and is difficult to relate to the present case. Independently of their uncertainty, using the NORDEN assumptions regarding the fraction of cases attributable to chemicals is conservative because the NORDEN assumption is the fraction of all cases of infertility, whereas the Dossier Submitter has already removed cases not related to chemicals before applying the NORDEN fraction. Even if the interval proposed by Dossier Submitter (25 to 75% of unknown causes, or conversely of causes due to chemicals), is large, SEAC cannot exclude that the contribution of chemicals could lie well outside this interval.

4. Derivation of fraction of cases associated with the four phthalates, among all chemicals. Dossier submitter, based on the Kortenkamp et al. (2011) study for DG Environment, considers that the phthalates are one of nine groups of chemicals involved in male infertility[27], and therefore that this fraction is 1/9 = 11%. However, this is a strong simplification, since the number of chemicals, tonnage used, exposure pathways of each of the nine groups are not taken into account. SEAC considers that some of the groups are very different (some are legacy chemicals with possibly lower exposure such as PCBs and DDT, some encompass numerous and potentially higher exposure groups like azole pesticides[28] and the "other pesticides" group is even larger). This approach does not take into account that many chemicals have not been tested for endocrine disruption properties, and that it is possible that other chemicals or groups of chemicals not accounted for exist (possible overestimation of the aetiological fraction). SEAC therefore finds that the estimation of the fraction of cases associated with exposure to the four phthalates is very uncertain.

5. The "phthalates" group identified in Kortenkamp et al. (2011) includes other phthalates than the four phthalates. SEAC agrees with the approach taken by the Dossier Submitter to take this effect into account by withdrawing the other phthalates known to have reprotoxic effects from the percentage of attributable fraction (on the basis of respective tonnages used and relative hazard).

For additional **cryptorchidism** baseline incidence and number of attributable cases, the method followed is the same as for infertility, with therefore similar observations from SEAC regarding the main uncertainties:

1. References used to set the baseline incidence rate of cryptorchidism are quite old (publication date more than 25 years ago, data even older). It is also unclear why the more recent EAU 2015 report was not used. This report indicates an incidence rate after three months (not one year) of 1 to 2%. This value tends to support the order of magnitude of the restriction dossier, while also possibly pointing to lower incidence and overestimation of health benefits.

2. SEAC notes again that the choice of an attributable fraction is based on expert opinion and subject to high uncertainty. Independently of their uncertainty, using the NORDEN assumptions regarding the fraction of cases attributable to chemicals is conservative because the NORDEN assumption is the fraction of all cases of cryptorchidism, whereas

[27] The groups in Kortenkamp et al. (2011) are the following: PCBs, PBDEs, DDT, other organochlorine pesticides, azole pesticides, other pesticides, heavy metals, phthalates, pharmaceutical oestrogens
[28] According to the French Phytosanitary product index 2015, there are at least 25 azole pesticides (mostly fungicides) used in France in 2015.

the Dossier Submitter has already removed hereditary cases before applying the NORDEN fraction (less conservative than for male infertility however because non-chemical causes are a smaller faction in cryptorchidism).

3. The Dossier Submitter also derived a number of additional testicular cancers (compared to cryptorchidism in itself considered as a malformation), using the relative risks (RR) of testicular cancer among people with cryptorchidism as a measure of the fraction of people with cryptorchidism developing cancer (which is not the same). Dossier Submitter used the mean values of RRs quoted in Taran 2006, but the sensitivity low and high values are outside the range of studies quoted in Taran 2016, which seems to increase the uncertainty unnecessarily.

For additional **hypospadias** baseline incidence and number of attributable cases, the method followed is also the same as for infertility and cryptorchidism, with therefore similar observations from SEAC regarding the main uncertainties. Overall, in this case it seems that incidence could be underestimated:

1. References used to set the baseline incidence rate of cryptorchidism are in majority from Nordic countries and especially Denmark, but SEAC is unable to assess how this could affect the incidence rate. SEAC notes that one of the values used for incidence relates actually to prevalence (EUROCAT data). One of the studies (Sorensen, 1953) relates to very old data (1910 to 1945) and seems irrelevant. These two studies report significantly lower values (by a factor of 2 to 3) than the selected mean value, therefore excluding these two studies would lead to higher incidence rates, and higher health benefits from the restriction.

2. References used to estimate and deduct the cases related to heredity are old (published from 14 to more than 40 years ago). If there is a general upward trend of reprotoxic diseases such as hypospadias due to environmental factors, using old data for the share of cases related to heredity tends to overestimate this percentage.

3. SEAC notes again that the choice of an attributable fraction is based on expert opinion and subject to high uncertainty. Independently of their uncertainty, using the NORDEN assumptions regarding the fraction of cases attributable to chemicals is conservative because the NORDEN assumption is the fraction of all cases of hypospadias, whereas the Dossier Submitter has already removed hereditary cases when applying the NORDEN fraction (less conservative than for male infertility however because non-chemical causes are a smaller faction in hypospadias).

Overall, SEAC did not identify caveats with the approach but underlines the very high uncertainties inherent due to lack of available information. It is difficult to assess whether the uncertainty tends to over or underestimate the aetiological fractions, but there are specific reasons to think that regarding hypospadias, underestimation is possible.

SEAC welcomes the use of sensitivity values for the fraction of impacts attributable to chemicals but also finds it difficult to assess to what extent the sensitivity scenarios for benefits reflect uncertainties.

Based on RAC opinion that there is evidence of a link between immunotoxic effects and exposure to the four phthalates, and following a subsequent request by RAC and SEAC for further investigation of the immunotoxicity of the four phthalates, the Dossier Submitter estimated the social costs of asthma as a result of exposure to articles containing the four phthalates in the scope of the proposed restriction. For **asthma** cases, the Dossier Submitter adopts a similar approach as for the other monetised human health effects. SEAC in general agrees with it, with the following observations:

1. In contrast to other endpoints for which incidence was used, here the restriction is assumed to impact the number of new cases of asthma as well as the number of asthma attacks experienced by people who have been diagnosed previously. Therefore, the prevalence rate has been used. However, from the epidemiological summary provided by the Dossier Submitter, it is unclear whether this assumption is more likely than assuming only a relationship between exposure and new cases of asthma. With that said, SEAC agrees with Dossier Submitter that higher prevalence figures than the ones used for the calculations are reported elsewhere, and acknowledges that incidence figures do not seem available. It remains that incidence would be a lower percentage than the prevalence figure used (given the generally long period of the asthma pathology).

2. The Dossier Submitter used assumptions made in Rijk, 2016 regarding the proportion of asthma cases attributable to EDCs. These assumptions are based, in SEAC's understanding, on the fact that in general 10% of the burden of diseases can be attributed to the environment. Therefore, Rijk et al set the maximum proportion attributable to EDCs at 10% ("high estimate" sensitivity scenario in the BD), then assume a lower proportion at one tenth of this higher bound (that is at 1%, used in the "low estimate" sensitivity scenario), and set a base case value in-between at 2,5% (main scenario). On one hand, given that many other known environmental/lifestyle factors are involved in asthma (pollens, tobacco smoke, air pollution, mites, mold, chemicals causing sensitization and irritation[29], food consumption, etc.) the proportion attributable to EDCs could be significantly lower than 2,5% (it could be much less than one quarter of the 10%). On the other hand, given the number of potential environmental factors relevant for asthma, the environmental factors could represent more than 10% of the burden of disease for asthma, and 2,5% could be an underestimation of EDCs contribution.

3. A 4% factor is used to derive the number of cases attributable only to the four phthalates, as has been done for cryptorchidism and hypospadias. Here SEAC notes that the 4% figure based on Kortenkamp et al. (2011) used to estimate the number of asthma cases attributable to exposure to the four phthalates seems less appropriate here. Kortenkamp et al. (2011) attributed illness to phthalates among other chemical classes associated with adverse impacts on male reproductive health, which is relevant for cryptorchidism and hypospadias, but does not seem adapted for asthma, for which an anti-

29 Rava M. et al, 2017, "Genes Interacting with Occupational Exposures to Low Molecular Weight Agents and Irritants on Adult-Onset Asthma in Three European Studies", Environmental Health Perspectives, volume 125, number 2, February 2017.

androgenic mode of action is not likely to be involved.

4. SEAC also notes that for asthma only evidence for associations with exposure to DEHP, BBP and DBP is available from epidemiological studies.

Overall, the remarks above suggest that the uncertainty related to the estimated number of avoided cases is higher than for the other three health impacts.

b) Monetisation of selected health outcomes

The monetised benefits of the proposed restriction are calculated as the avoided health impacts that are related to the exposure to the four phthalates in articles in the scope of the restriction.

For each of the health outcomes, three scenarios are calculated (low, mid-point and high) that differ mainly in terms of the aetiological fraction used.

i) Infertility

The Dossier Submitter monetises each infertility case through the cost of treatment (for the proportion of males seeking treatment), the willingness to pay (WTP) for a statistical baby (for males seeking assisted reproductive treatment (ART) that are unsuccessful becoming parents), and this same WTP (and no tangible costs) for 50% of males not seeking ART.

SEAC reviewed the data and methods (other than methods used for discounting, and potential double-counting issues between outcomes, which are discussed later in the opinion) used by the Dossier Submitter to derive the avoided social costs of infertility and had the following observations:

Regarding *direct and indirect costs:*

1. The Dossier Submitter used reported ICSI (Intracytoplasmic sperm injection) costs "per child" in NORDEN 2014. However, to monetise the cost per infertility case, it seems that this per-child cost should be multiplied by the number of children that one man statistically has in the EU, or that the Dossier Submitter should have used the "per man" cost reported in the NORDEN study. In other terms, SEAC considers that direct and indirect costs are underestimated by a factor that is the ratio between "per child" and "per man" costs in the NORDEN study, that is around 1.7.

2. Costs of ART extracted by the Dossier Submitter from NORDEN 2014 are exclusively from Swedish data, and rely exclusively on the IVF (in vitro fertilisation) with ICSI technique. SEAC notes that it would have been desirable to have cost information more representative of the EU, and also account for IVF without ICSI, still much used in the EU in the context of male infertility (a ratio between the two of 70% of IVF with ICSI can be proposed[30]). Treatment costs for IVF with ICSI seem to be higher compared to IVF (French data suggests 20% cost difference per cycle[31], however with a small advantage for IVF/ICSI in efficiency in terms of deliveries/cycle[32]). This source of uncertainty is however considered to be small compared to others.

3. Before considering IVF and ICSI, some couples also use in case of unexplained infertility intrauterine inseminations as a first short term option (at lower cost but lower success rates in general). It is unknown to SEAC if omitting this option overestimates or underestimates tangible costs, but impact on the results is probably small.

4. The Dossier Submitter monetised the cost of the fertility treatment alone but generally, before couples decide whether to follow an ART treatment, they would undergo medical consultations to search for infertility causes, and get information on options for treatment. These (direct and indirect) costs are not included (underestimation factor).

Regarding *intangible* costs

5. Intangible cost per infertility case are valued using a single ECHA WTP value of a statistical case of infertility (ECHA 2015) of €29 710. Since the release of the draft paper by ECHA, the final version recommends to use the two following values for statistical case of pregnancy: a lower value of €22 000 and a higher value of €41 000, expressed in year 2012. SEAC therefore considers that those two values should have been used, and this difference causes significant underestimation of intangible benefits.

6. SEAC also considers that to value one infertility case, the desire for more than one child over the life of an individual should be taken into account. Therefore, the WTP value should be multiplied by the statistical number of pregnancies (of children if not available) per individual.

7. SEAC notes the assumption that for half of couples who do not undergo treatment, the same intangible cost is applied as for couples who undergo treatment without success. This is a crude assumption that the Dossier Submitter was unable to base on data, given the lack of information regarding couples who do not seek treatment and still actually suffer from their infertility. SEAC agrees in principle with the Dossier Submitter but considers this ratio very uncertain.

[30] Data from ESHRE suggests that IFV without ICSI has been declining before 2006 compared to IFV with ICSI in the EU, but that the relative proportion has stabilised during 2006/2012 at 30% for IFV and 70% for IVF with ICSI (Calhaz-Jorge et al., 2016).
[31] http://www.fiv.fr/cout-fiv/ gives some indications of the cost difference, based on pricing by social insurance in France (absolute prices are not relevant but differences can inform on real economic cost difference).
[32] Supplementary Tables SV and SVI from (Calhaz-Jorge et al., 2016).

8. Finally SEAC also notes that the WTP to avoid statistical infertility does not capture all social implications for a couple of being able to have a pregnancy (infertility may result in consequences far beyond those captured by the WTP value for a particular health endpoint). [33]

ii) Cryptorchidism

The Dossier Submitter also calculated the avoided social costs related to avoided cryptorchidism cases estimated to be associated with exposure to the four phthalates in articles in scope.

SEAC reviewed the data and methods (other than methods used for discounting, and potential double-counting issues between outcomes discussed below) used by the Dossier Submitter and had the following observations:

1. The Dossier Submitter quantified the number of testicular cancer cases that are associated with cryptorchidism (assumed by the Dossier Submitter at 5% of cases), but did not include tangible nor intangible costs of cancer to monetise these cases. The Dossier Submitter instead monetised the intangible costs of 5% of cryptorchidism cases using ECHA's recommended WTP for major internal birth defects, assuming that this covers psychological impacts associated with longer terms health impacts stemming from cryptorchidism. SEAC considers that it would have been more appropriate to use the more specific cancer WTP value available in the ECHA WTP study. The NORDEN 2014 study also calculated testicular cancer tangible costs and they might have been used. Overall, the approach by the Dossier Submitter is probably underestimating the social costs of cancer cases related to cryptorchidism[34].
2. Direct and indirect costs of cryptorchidism are monetised through the remediation direct and indirect costs (surgery called "orchidopexy"), retrieved from the NORDEN 2014 study. SEAC notes that the NORDEN study uses Swedish data (€4 400/patient) while it mentions a Danish unpublished study with lower tangible costs (€3 200/patient). There is also another indication of lower costs close to €3 000 in the UK[35].

[33] This comment is not specific to this restriction but has been agreed by SEAC as a general comment regarding the use of the value of WTP for statistical pregnancy from the ECHA WTP study.
[34] WTP to avoid one case of cancer is in the ECHA study very approximately one order of magnitude higher than WTP to avoid one case of major internal birth defect. However, the latency effect and corresponding discounting required to apply the cancer WTP does not hold when using the birth defect WTP, which moderates the magnitude difference. SEAC also notes that counting both costs related to cryptorchidism surgery and testicular cancer would result in some double counting, since this surgery reduces testicular cancer risks.
[35] http://www.privatehealth.co.uk/conditions-and-treatments/undescended-testicle-surgery/costs/

3. SEAC agrees with the approach to monetise intangible costs in terms of the WTP to avoid having a child with major external birth defects as a proxy. SEAC finds uncertain the proportion of 95% of cases that are "major" external birth defects (opposed to "minor" birth defect), since cryptorchidism is generally seen as easy to treat via surgery. On the other hand, SEAC has some reservations for using the WTP to avoid having a child with major internal birth defects as a proxy for the remaining cases which are assumed to lead to testicular cancer; as this might underestimate social cost for these cases. Regarding the values themselves, cases are valued using single ECHA WTP values of €26 000 (major external defect) and €29 500 (major internal birth defect) by the Dossier Submitter (in 2014 values). Since the release of the draft paper by ECHA, the final version recommends to use the following values: a lower value of €26 000 and a higher value of €330 000, expressed in 2012 values for major external birth defect, and a lower value of €128 000 and a higher value of €712 000, expressed in 2012 values for major internal birth defects. SEAC therefore considers that those values should be used to better reflect uncertainties, and would tend to increase the social costs of cryptorchidism.

iii) Hypospadias

The Dossier Submitter also calculated the avoided social costs related to avoided hypospadias cases estimated to be associated with exposure to the four phthalates in articles in scope.

SEAC reviewed the data and methods (other than methods used for discounting, and potential double-counting issues between outcomes, discussed below) used by the Dossier Submitter and had the following observation:

SEAC notes that, similar to the case of cryptorchidism, the NORDEN study mentions a Danish unpublished study with lower tangible costs (€6 800/patient) than the NORDEN figure, that is based on Swedish data (€10 300/patient). The Dossier Submitter monetised intangible costs in terms of the WTP to avoid having a child with minor birth defects as a proxy for 75% of the cases of hypospadias (those without further complications). Regarding the values themselves, cases are valued using single ECHA WTP values of €4 350 (minor birth defect) and €21 800 (major external birth defect) by the Dossier Submitter (in 2014 values). Since the release of the draft paper by ECHA, the final version recommends to use the two following values: a lower value of €4 500 and a higher value of €43 000, expressed in 2012 values for minor birth defect, and a lower of €26 000 and a higher value of €330 000, expressed in 2012 values for major external birth defect. SEAC therefore considers that those values should be used to better reflect uncertainties.

iv) Asthma

Regarding the monetisation of each avoided asthma case, SEAC agrees in general with the method used, but has the following observations:

1. The calculations by the Dossier Submitter do not integrate the intangible costs in terms of premature mortality associated with asthma (see estimates of years of life lost in The Global Asthma Report 2014[36], or note that for instance mortality rates associated with asthma are reported to be in the order of magnitude of 1/100 000 for all ages in

[36] http://www.globalasthmareport.org/resources/Global_Asthma_Report_2014.pdf

France[37]).

2. SEAC reviewed to the extent possible the tangible costs per avoided cases and overall agrees with the approach taken, and notes that a frictional method was used to value absenteeism. SEAC notes that the two studies used are relying on data only from the Netherlands. In terms of benefits per avoided case, for tangible costs, the value adopted by the Dossier Submitter (around €1 100/case/year) is lower than the value found by a recent EU-wide study[38]. This comparison confirms the order of magnitude used by the Dossier Submitter but shows the value could however be underestimated.

3. It is unsure that intangible costs as provided by the WTP ECHA 2014f study can be fully added to tangible costs without double counting, since the surveyed people were asked about the costs they would be ready to pay to avoid to take medication. It is difficult for SEAC to know from the study material available if people concentrated on pain and suffering or took to some extent the financial consequences of asthma into consideration. On the other hand, this also means that the WTP value might not take fully into account the pain and suffering and be fully representative of intangible costs.

4. Finally, the Dossier Submitter notes that the analysis assumes that asthma sufferers visit medical providers each time they experience an asthma episode, whereas, in reality, some asthma episodes are resolved with previously prescribed medication, and therefore, medical consultation may not be necessary. According to the Dossier Submitter, this points to an underestimation of the number of asthma episodes per year and thus, the intangible costs of asthma. SEAC notes that on the other hand this also points to a potential overestimation of the real number of medical consultations and therefore of associated costs, and that the overall effect might not be an underestimation.

A final comment for impacts is that the service life of articles would likely lead to further delays in the materialisation of the benefits. The process of progressive replacement of articles containing the four phthalates in use before the entry into effect of the proposed restriction by articles manufactured with alternatives will extend the temporal scope of exposure to the four phthalates. Due to insufficient information, this was not considered in the Dossier Submitters assessment. SEAC takes note of this uncertainty that is thought to moderately overestimate the benefits (because discounting of benefits is carried out).

c) Potential double-counting of benefits

SEAC examined the potential double-counting of benefits but did not identify concerns. In terms of intangible costs, WTP for statistical infertility is clearly distinct from other consequences of phthalates exposure monetised with the WTP for birth defects or WTP to avoid asthma episodes.

[37] http://invs.santepubliquefrance.fr/Dossiers-thematiques/Maladies-chroniques-et-traumatismes/Asthme/Surveillance-epidemiologique-de-l-asthme-en-France

[38] EUR 1,583 in 2010 values. However this EU study only considered adults aged between 30 and 54, and not the full population as in the present restriction dossier : Accordini et al. «The Cost of Persistent Asthma in Europe: An International Population-Based Study in Adults" Int Arch Allergy Immunol 2013;160:93–101

d) Discounting

The analysis needs to be carried out on a very long timeframe, since health impacts, especially in terms of infertility from in-utero exposure, will materialise at the time of desired fatherhood. Therefore, SEAC agrees with the temporal scope of the analysis by the Dossier Submitter: 2020 to 2039 study period, with 30 years delay for the materialisation of impacts for infertility.

Quantitative results are therefore highly sensitive to the discount rate used. SEAC reviewed the discounting approach used by the Dossier Submitter, in relation to the practice and guidance for comparable situations. The Dossier Submitter used the standard discount rate of 4%. The Dossier Submitter also provided the estimates using an alternative social discounting rate of 2% for valuing health benefits, taking into account that the income elasticity of the value of health[39] is one. This implies an assumption that the GDP growth in the EU would be 2% during the next 50 years.

SEAC also notes that the SEA guidance, and also the UK HSE guidance, recommends to use a declining rate for discounting later than 30 years in the future, and that it could have been justified to use 2% for benefits before 30 years, and a lower discount rate after 30 years (for infertility related benefits). In this case, the quantified benefit values could have been higher.

Overall, SEAC finds it is more appropriate to use 2% for benefits and 4% for costs. SEAC also considered results with 4% discount rate for benefits qualitatively when concluding on proportionality.

e) Confirmation of the risk reduction capacity of the proposed restriction

RAC confirmed the capacity of the proposed restriction to reduce the risk assessed by the Dossier Submitter, with however two comments:

- There is no one-to-one relationship between volumes put on the market because in particular of the service life of articles.
- DINP also has anti-androgenic mode of action, however at higher concentrations than the four phthalates.

For SEAC, the first comment implies that there will be an unknown delay for the materialisation of health benefits, compared to the temporal scope used in the benefits assessment by the Dossier Submitter. This means that actual discounted benefits could be lower than calculated.

The second comment implies that there is some minor uncertainty regarding the benefits, in relation to uncertainty in the risk profile of some alternatives. The Dossier Submitter has attempted to address this by reducing the baseline benefits associated with the exposure to the four phthalates, assuming that they all will be replaced by DINP.

[39] Utility of health is also considered constant in the future, and therefore GDP growth of 2% is subtracted from the 4% discount rates, and this leads to a discount rate of 2%.

f) Summary of quantified benefits

SEAC evaluated the quantified benefits calculated using both lower and higher WTP values from the reference ECHA study, 2% discount rate, and three (low/main/high) aetiological fractions (AF) used in the BD. The estimates for asthma are considered more uncertain, and are therefore, shown separately. The total quantified benefits of the proposed restriction are summarised below in Table 6:

Table 6: Summary of monetised benefits of the proposed restriction

LOW WTP **2% discount rate**			
	LOW AF	MID AF	HIGH AF
Infertility	9.9	19.6	29.3
Cryptorchidism	1.3	15.6	44.6
Hypospadias	1.0	10.3	25.7
Total (without asthma)	**12.2**	**45.5**	**91.8**
Asthma	20.2	50.6	202.5
HIGH WTP **2% discount rate**			
	LOW AF	MID AF	HIGH AF
Infertility	15.3	30.4	45.5
Cryptorchidism	14.4	144.3	360.1
Hypospadias	6.1	60.7	151.8
Total (without asthma)	**35.8**	**235.4**	**558.0**
Asthma	20.2	50.6	202.5

*AF: aetiological/attributable fraction

SEAC also notes that, except for hypospadias where a lower WTP value is used, the main proportion of benefits come from intangible costs (monetised through WTP).

g) Other, non-quantified benefits of the proposed restriction

SEAC notes that further to the quantified benefits there are several non-quantifiable health benefits that could represent a significant share of the restriction benefits, given in particular the high prevalence of several of the illnesses/effects associated with exposure to the four phthalates (delayed age of puberty, effects on metabolism, allergy and eczema). Table 33 in the Background Document details 17 groups of health effects that are to a various degrees associated with exposure to the four phthalates in articles. The example of asthma, where the Dossier Submitter has quantified and monetised the impacts, confirms that is it possible that these non-quantified avoided health impacts in combination could represent much higher benefits than the quantified ones. Allergy and eczema are two other health effects with high prevalence and for which the strength of the association with exposure to the four phthalates is thought to be moderate to strong, but lack of dose/response and attributable fraction information was missing to quantify and monetise the corresponding impacts.

Another benefit from the restriction, that has also not been quantified, is the avoided environmental exposure to aquatic organisms to DEHP. DEHP is one of the priority hazardous chemicals identified under the Water Framework Directive (2000/60/EC), from amongst those presenting a significant risk to or via the aquatic environment, and should therefore be subject to cessation or phasing out of discharges, emissions and losses. DEHP is a recognised endocrine disrupter to aquatic organisms, and has been found to be present in surface water at levels higher than Environmental Quality Standards at a significant number of locations in the EU. SEAC considers that the proposed restriction will have long term positive effects on environmental DEHP concentrations, in particular through the reduction of some direct and indirect discharges of DEHP by articles in contact with water (flooring and various articles that are washed, inflatable articles used for aquatic leisure, gardening hoses, etc.).

Summary of uncertainties in benefits assessment

Some uncertainties (for aetiological fractions) or difference in possible reference values (WTP and discount rate) are addressed in the sensitivity scenarios: WTP values (high and low), discount rate (low and high values), and aetiological fraction (three values). The following Table intends to provide a summary of uncertainties that affect the benefits assessment, and that are NOT fully addressed through the sensitivity interval of monetised values. They refer to some of the above observations by SEAC, and also take into account other qualitative uncertainties mentioned by the Dossier Submitter and additional elements noted by SEAC:

*Table 7 Summary of uncertainties in the assessment of benefits**

Description of uncertainty	Direction	Impact
Choice of the aetiological fractions is based on several steps each involving series of assumptions and/or expert opinions (see section a) above). This uncertainty is addressed in the sensitivity scenario, but the range of values chosen for the aetiological fraction might not fully reflect the magnitude of that uncertainty, that is thought to be higher than any of the other sources.	Unknown	Very High
Some methodological issues for tangible and intangible costs for infertility (in particular most significant issues under points b) ii) 1 and 6, regarding the difference between "per man" and per child" tangible costs, and the difference between WTP for avoiding infertility and WTP for a statistical pregnancy).	Underestimation	High
Several uncertainties in direct and indirect costs for cryptorchidism and hypospadias (unit costs of health interventions might be overestimated, but some tangible costs are not included or underestimated – such as testicular cancer). See section b) ii)	Unknown	Moderate
Service life of articles would likely involve further delays in benefits	Overestimation	Moderate
Other human health and environmental benefits from various effects from the four phthalates that cannot be monetised because of lack of full evidence or no	Underestimation	High to Very High

dose/response relationships: Delayed age at puberty onset for girls and boys Delayed mammary gland development Effects on female reproduction Neurodevelopmental effects Effects on metabolism Other immunological effects other than asthma (allergy, eczema) Liver carcinogenesis Environmental impacts		

SEAC took note of the large uncertainties in the benefits assessment that are mainly driven by the uncertainty regarding the aetiological fraction. SEAC concluded that is it not possible to know if these major uncertainties of the aetiological fraction would tend to over or underestimate the benefits.

Another major source of uncertainty, but clearly underestimating the benefits, is that both tangible and intangible costs have been calculated on a "per child" basis whereas they would need to be calculated on a "per couple" basis. Taking the example of infertility, the assessment uses a WTP for one pregnancy, whereas WTP for not being infertile should be used, if it were available. In other terms, one should take into consideration the fact that an infertile man would have had the desire to have a child several times in his life. The difference between the two (mean number of children conceived in the life of each man in the EU) is not known to SEAC and does not seem an available EU statistic, but SEAC believes it is significantly above one, since the mean statistical number of children per woman in the EU is around 1.7. This issue is therefore significantly underestimating the quantified benefits of the proposed restriction.

SEAC notes that the Dossier Submitter considers that only 40% of the cases attributable to phthalates would be removed by the proposed restriction, because 40% of exposure to the four phthalates come from the articles in scope. However, SEAC notes that, if phthalates are considered as threshold substances, all associated cases with phthalate exposure are removed because risk ratios are below 1 after the restriction has full effect on the general population. Because, as underlined by RAC, the Member State Committee (MSC)[40] has confirmed that these four phthalates are endocrine disruptors to human health, it could however be appropriate to consider them as non-threshold substances and in this respect to use a 40% ratio. SEAC finds consistent with the approach taken by the Dossier Submitter to use this 40% ratio, but notes here and for the further proportionality assessment that it is probably underestimating the benefits.

SEAC agrees with the approach taken, but disagrees that the overall method followed tends to underestimate rather than overestimate the monetised benefits for asthma, because the uncertainty related to the choice of the aetiological fraction dominates over the other sources of uncertainty.

[40] On 16 February 2017 the REACH Committee voted in favour of identifying the four phthalates as substances of equivalent concern under Article 57(f) of REACH:
http://ec.europa.eu/transparency/regcomitology/index.cfm?do=Search.getPDF&ds_id=49989&version=1&AttLang=en&db_number=1&docType=SUMMARY_RECORD
http://ec.europa.eu/transparency/regcomitology/index.cfm?do=Search.getPDF&ds_id=44354&version=4&AttLang=en&db_number=1&docType=DRAFT_MEASURE

In conclusion, SEAC finds that the uncertainty in the quantification of benefits is very high. Because the highest uncertainties relate to the aetiological fraction, SEAC finds it difficult to conclude on the direction of the overall uncertainty. However, SEAC agrees that there are potentially considerable human health and environmental benefits associated with avoided exposure to the four phthalates in articles that cannot be quantified**.**

B.3.3.3. Other impacts

B.3.3.3.1. Summary of proposal:

The Dossier Submitter concludes that the proposed restriction will likely lead to the following other economic, social, and distributional impacts:

- Impacts on compounders (on producers of PVC in primary forms): Plastisols and dry-blends[41] are not in the scope of the proposed restriction, as they do not lead to the exposure in question. However, some compounders whose downstream users produce articles in scope would likely transition to alternatives to respond to the demand for DEHP-free plastisols. Similarly to downstream users, compounders are expected to face primarily higher material costs, which for the purpose of avoiding double counting in the analysis are anticipated to be fully passed on to downstream users, and are therefore reported under Substitution costs above.

- 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, e.g., for both roofing (out-of-scope) and flooring (in scope). 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 other forces or to the (inadvertent) consequences of the proposed restriction. Therefore, these potential impacts of the proposed restriction are noted but not quantified for the purpose of the assessment.

- Impact on exports: While export (and manufacturing) is not restricted under the proposal, it is possible that some would also transition to alternatives also for the purpose of exports as a result of the proposed restriction. Assuming DEHP[42] is phased out for all exports, the cost-effectiveness of the proposed restriction will decline by 1.5%.

- Impacts on the quality of the goods: Many alternatives, including those used to illustrate the costs of the restriction, have been reported to be comparable or even to have technical advantages in some applications in comparison to the four phthalates. For the purpose of this analysis, these advantages are noted but not quantified.

- Impacts on substance manufacturers and their upstream supply chain: Since 2012, the majority of EU DEHP manufacturers either have discontinued operations or began transitioning to alternatives. The remaining EU manufacturers could continue to manufacture DEHP for export purposes (outside the scope of the restriction) and to

[41] Containing DEHP only as no other applications for authorisation have been submitted.
[42] Containing DEHP only as no other applications for authorisation have been submitted.

downstream users who produce articles outside the scope of the proposed restriction (as per 2011-12 estimates, the production of the remaining manufactures is estimated to be lower than the used in EU manufacturing of articles outside the scope of the proposed restriction). In addition, there have been long-term trends to substituting the four phthalates as well as long-term regulatory action. All this points to the conclusion that while the proposed restriction would have further effects on the profits of the remaining EU manufacturers, it is anticipated that the incremental impact would be minimal and any potential further closures or capacity reductions could not be solely associated with the proposed 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. The effect should be limited given: the availability of similarly priced technically feasible substitutes, long-term experience with substitution, no barriers to transitioning to alternatives such as high up-front investment or proprietary technology, long-standing knowledge of regulatory action on the four phthalates, substantial share of DEHP use remaining outside the scope, etc. In the recycling sector, industry claims SMEs to be potentially more affected by the proposed restriction. However, the transitional period of three years (as well as the proposed derogations, which also aim to accommodate the majority of the articles manufactured from recyclate) is anticipated to minimise these impacts.

- Social impacts: As stated above, the substantial share of DEHP use remaining outside the scope, the availability of similarly priced technically feasible substitutes, etc., it is anticipated that the incremental impact on employment would be minimal and any potential further closures or capacity reductions could not be solely associated with the proposed restriction.

- Wider economic impacts: The proposed restriction is estimated to have minor impacts on article prices (less than 2% increase in imported 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: The proposed restriction would likely have favourable distributional impact for the EU society, as the entry into effect of the restriction will level the playing field for EU article manufacturers and importers. 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. Some potential unfavourable distributional impacts of the restriction could arise due to the location of plasticiser manufactures. I.e., DEHP manufacturers are located in Central Europe, while manufacturers of alternatives are in other European member states (or potentially outside the EU28).

Taking into account the quantified and non-quantified economic, social and other impacts, the Dossier Submitter concludes that the total restriction costs of €16.9 million annually 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.

B.3.3.3.2. SEAC conclusion(s):

SEAC concurs with the Dossier Submitter's arguments that there are no significant other impacts of the proposed restriction.

B.3.3.3.3. Key elements underpinning the SEAC conclusion(s):

- Impacts on compounders. No significant impact on the economic activity of downstream users of the four phthalates is expected to affect compounders, as they are not within the scope of the proposed restriction. SEAC concurs that any material costs incurred by the compounders who would respond to demand for four-phthalate-free compounds as a result of the restriction are included in the substitution costs presented above, as the Dossier Submitter estimates all costs as impacts on the end user. SEAC notes that almost half of the PVC compound in Central Europe are produced by three PVC manufacturers (Plasteurope.com).

- Impacts on articles outside the scope of the restriction. SEAC agrees that there may be trends of replacing the four phthalates in articles outside the scope for various reasons, including the realisation of economies of scale, but such impacts are difficult to quantify. SEAC considers this as a non-quantified benefit if this comes as a result of the restriction, which is difficult to confirm.

- Impacts on exports. SEAC concurs with the Dossier Submitter that exports are not directly affected by the restriction and thus, may not be included in the calculation of total restriction costs. Furthermore, the change in exports quantities as a result of the proposed restriction is unforeseeable, as there may be either reduction or increase in exports. SEAC concurs with the Dossier Submitter that the impact on costs to transition to alternatives for exports are low and that they have a low impact on the cost effectiveness of the proposed restriction (less than ±4% as estimated by the Dossier Submitter).

- Impacts on quality. SEAC concurs with the Dossier Submitter that many of the similarly priced alternatives have very similar performance characteristics as those of DEHP, DBP, DIBP, BBP and that some of them have advantages in particular applications (e.g., extreme temperature resistance, improved permanency) potentially leading to increased quality of the goods but for practical reasons those have been ignored in the analysis.

- Impacts on substance manufacturers: see above the discussion in SEAC's assessment of the costs of the restriction.

- Impacts on SMEs. SEAC considers that there may be comparatively higher economic impacts on SMEs, which may be dampened by the availability of drop-in alternatives and the transition period. SEAC concurs with the Dossier Submitters conclusions that the transitional period will be sufficient for SMEs to comply with the proposed

restriction with minimal impacts.

- Social Impacts. SEAC considers that any impact on employment is likely to be small or even negligible because a substantial share of DEHP use will remain outside the scope of the proposed restriction and that any redundancies due to closure of DEHP production premises could be at least partially offset by recruitments due to increases in production of alternative plasticisers. SEAC notes however that any impact on employment may be regional and will thus affect an area of a Member State.

- Wider economic impacts. SEAC concurs with the Dossier Submitter that due to the minor impact on the price of the articles in scope, the wider economic impacts are anticipated to be minimal.

- Distributional impacts. SEAC concurs with the Dossier Submitter that the proposed restriction will level the playing field between importers (and non-EU article producers) and EU manufacturers which need to apply for an authorisation if they are to use the four phthalates in the production of articles. SEAC also considers that there may be some distributional impacts due to diversifications in the plasticiser production in Europe. These impacts may have a negligible effect due to some potential regional unemployment from decline of DEHP production, which, however, is anticipated to be offset by recruitment in production activities of manufacturers of alternatives.

B.3.3.4. Overall proportionality

B.3.3.4.1. Summary of proposal:

The Dossier Submitter concluded that:

- the benefits of the restriction exceed its costs as illustrated by the monetisation of a selected number of benefits (male infertility, cryptorchidism and hypospadias);

- 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%.

B.3.3.4.2. RAC and SEAC conclusion(s):

SEAC concludes that the proposed restriction is proportionate on the basis of an assessment of its cost-effectiveness, affordability to the affected supply chains, and its cost and benefit comparison.

B.3.3.4.3. Key elements underpinning the RAC and SEAC conclusion(s):

SEAC assessed the arguments and analysis presented by the Dossier Submitter and took note of RAC's clear conclusions on the risks associated with exposure to the four phthalates in articles in scope and the risk reduction capacity of the restriction, and concluded that the overall argumentation supports that the proposed restriction is proportionate, for the following reasons, starting with the more firmly established arguments:

(i) The proposed restriction is likely to be borne by non-EU entities, and will be affordable to the (likely minor) share of affected EU companies and consumers

SEAC agrees with arguments and illustrative figures put forward by the Dossier Submitter, and concludes that, with the possible exception of some recyclers, or manufacturers of DEHP, the proposed restriction is affordable for companies. It is also clear from the arguments and figures presented that, if all costs are assumed to be passed-on to consumers, the impact on article price would be minor. Therefore, SEAC concludes that in the event that some companies find difficult to bear substitution costs themselves, those would likely be passed on to consumers without impact on company turnover.

(ii) The proposed restriction is cost-effective, when compared to previous regulatory action taken on phthalates in articles

SEAC notes that, in terms of €/tonne of phthalates not placed on the market, the proposed restriction is 20 times more cost-effective than the previous regulatory action on toys. SEAC however notes that it is likely that one tonne of toys causes higher health impacts than other articles in the scope of the proposed restriction, for children only (not for pregnant women, which is considered the most sensitive population), given the high exposure of children via toys, and their particular sensitivity to phthalates.

It is also important to note that the additional derogations proposed by the Dossier Submitter after the Public Consultation (and agreed by SEAC) target several uses for which comparatively higher substitution costs are expected, and where exposure is often expected to be comparatively lower. This tends to further improve the calculated cost-effectiveness.

(iii) The proposed restriction is likely to bring significantly higher human health benefits than its costs. Those human health benefits could potentially be considerable:

Monetised benefits are estimated in the ranges of €12.2 million and €558 million annually, depending on WTP values, discount rates, and aetiological fractions used. If benefits for avoided asthma cases are added, total monetised benefits would be in the ranges of €32.2 million and €760.5 million annually. These total benefits have to be compared to the total costs of the restriction of €17.6 million annually central value (€10.2 million and €18.9 million for sensitivity values).

The monetised benefits are very uncertain, but SEAC concluded that a large share of the benefits associated with the restriction remain non-quantified. SEAC notes regarding these non-quantified benefits the recent vote in the REACH Committee underlining the ED properties of the four phthalates for human health and therefore, their potential widespread range of ED-related (potentially non-threshold) health effects. Therefore, despite the uncertainties and small overlap between benefit and cost estimates, the comparison of the costs and the benefits tends to confirm that the proposed restriction is proportionate.

(iv) It is plausible that more cases of infertility would be avoided than the minimum needed to make the proposed restriction socio-economically beneficial

SEAC finds in principle difficult to compare break-even percentages with percentages of population at risk. It is problematic to assess whether the reduction in RCRs due to the proposed restriction would lead to the estimated number of cases, given the unknown difference between RCR reduction and actual health impacts, stemming (among others) from the assumptions used in the risk calculation method and the impact of other factors, other than exposure to the four phthalate, leading to the quantified health effects. SEAC therefore relied primarily on the break-even analysis carried out by the Dossier Submitter which estimated the number of male infertility cases necessary for the benefits of the proposed restriction to exceed the costs. This approach was taken because SEAC can in this case compare the break-even percentage to independent epidemiological information (not used to calculate the benefits), that was found only for male infertility. For the proposed restriction to break even, it is necessary to prevent between 1 160 and 3 660 cases of male infertility annually, depending on the choice of three parameters (WTP, aetiological fraction, discount rate). This would represent between 0.01% and 0.03%[43] of all new cases of male infertility annually in the EU: even if exposure to the four phthalates under scope contributes to only this percentage, then the restriction becomes proportionate. SEAC notes that, in a recent publication (Hauser, 2015)[44] not used in the derivation of aetiological factors by the Dossier Submitter, an expert panel used biomonitoring (the DEMOCOPHES study) and epidemiological data to estimate that infertility attributable to phthalate exposure[45] was close to 9% in 2010. Direct comparison of the two figures (9% and the range of break-even figures 0.01% to 0.03%) is not possible given that the restriction only reduces a share of exposure to only four phthalates, because of the difference between incidence and prevalence, and between couple and male infertility. It should also be noted, as reported in the Background Document, that having clear epidemiological conclusion regarding phthalates is difficult in general. However SEAC considers that the comparison is sufficient to suggest that the break-even threshold is exceeded.

On request by SEAC, the Dossier Submitter also carried out a set of 12 break-even analysis scenario calculations, taking into account all monetized endpoints[46]. Overall, the highest break-even percentages across all scenarios are the following: 0.6% for male infertility,

[43] These percentages are obtained by: Number of cases for break-even/ Number of new cases of infertility annually. If the incidence rate of male infertility is assumed to be 5%, this brings to 130 000 new cases of infertility each year (130 000 = 5% * annual number of new male births of 2.6 million). Incidence of infertility in couples is reported in the Background Document as being 15%, and SEAC assumes that one third (= 5%) is related to male infertility.
[44] Hauser et al., 2015, "Male Reproductive Disorders, Diseases, and Costs of Exposure to Endocrine Disrupting Chemicals in the European Union", J Clin Endocrinol Metab, doi: 10.1210/jc.2014-4325
[45] The study was based on DBP and BBP only (DEHP and DIBP did not show associations in this study).
[46] There is an infinity of possible sets of four break-even number of cases (one for each impact), and the Dossier Submitter presents each scenario calculation for the set of break-even numbers that minimises the difference between total benefits and costs using the Solver function in MS Excel. Break-even numbers (and their ratios between different endpoints) appear to be very sensitive to the parameters, and vary widely between each scenario, while the reason for such variations is not apparent.

0.24% for cryptorchidism, 0.14% for hypospadias, and 0.001% for asthma, in terms of share of population at risk from exposure in early childhood (or share of target population for asthma). These percentages appear to be low, however, SEAC finds it difficult to compare them to the percentage of population at risk for the abovementioned reasons.

SEAC also noted that the above break-even analysis does not include the benefits from other health effects that were not monetised. Their inclusion would tend to lower the break-even percentages.

SEAC overall concludes that given the break-even analysis, the comparison of costs and benefits, and the overall evidence of the significant social damage caused by the exposure to the four phthalates in articles in scope, it is from a socio-economic viewpoint sensible for society to invest and take action for exposure reduction. Furthermore, the proposed restriction appears to be affordable and more cost-effective compared to past regulations on the four phthalates. Therefore, SEAC finds that the proposed restriction is proportionate from a socio-economic perspective.

B.3.3.5. Uncertainties in the proportionality section

The sources of uncertainties are elaborated in the concluding sections of the SEAC evaluation of costs and benefits. SEAC concluded that the main sources of uncertainties are the estimation of the aetiological fraction and the non-quantified benefits. Other sources of uncertainties in the costs and benefits estimation are considered to have low to moderate impact on SEAC's conclusion on proportionality.

B.3.4. Practicality, incl. enforceability

B.3.4.1. Summary of proposal:

The Dossier Submitter concludes on the practicality of the proposed restriction on the basis of its implementability, enforceability and manageability. The Dossier Submitter concludes the following regarding the three criteria:

B.3.4.1.1. 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.

B.3.4.1.2. 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.

B.3.4.1.3. 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.

B.3.4.2. RAC and SEAC conclusion(s):

SEAC concludes that the proposed Restriction is overall implementable, enforceable and manageable.

B.3.4.3. Key elements underpinning the RAC and SEAC conclusion(s):

(i) Implementability

SEAC considers that there is adequate information to firmly conclude that alternatives are available for all uses under the scope of the proposed restriction and that there is considerable familiarity with alternatives by all actors involved, as shown by the large scale of substitution of DEHP in the EU and internationally as well as by the phasing out of DBP, DIBP and BBP in the EU. Therefore, SEAC concludes that the proposed restriction is implementable.

(ii) Enforceability

SEAC considers that the sampling of articles by inspectors is feasible, that laboratory analytical methods are well established and capable to cover all four phthalates and that the limit value is implementable. These were also confirmed by FORUM. SEAC concurs with the Dossier Submitter and FORUM that standardisation of the methods through CEN would be preferable. Based on the above, SEAC concludes that the proposed restriction is enforceable.

(iii) Manageability

SEAC considers that the terms ''prolonged contact'', ‘‘under normal and reasonably foreseeable conditions” used in the text of the proposed restriction, may not be understandable and clear enough and may create confusion among the actors in the supply chain. SEAC notes in this respect Forum's proposal of additional text to include a label requirement.

Regarding the three years’ transitional time, SEAC agrees with the Dossier Submitter that actors involved in the supply chains will have sufficient time to adapt. Given that the four phthalates to be replaced as a result of the proposed restriction represent a small fraction of total plasticisers use, no alternative plasticisers shortage is to be expected. Eventual process adaptation and tests are not expected to be burdensome, as demonstrated by SEAC’s assessment of reformulation and testing costs.

Furthermore, SEAC did not receive comments during the public consultation from supply chain actors indicating difficulties in transitioning within three years, except from:

- ACEA requesting 4 to 5 years transitional period for hidden parts behind assemblies,
- two manufacturers, one requesting 4 years for ''difficult'' parts and both requesting ''sufficient time'' for the evaluation of alternatives and

- an aircraft manufacturer requesting a derogation until ''alternatives can be fully qualified, certified and implemented''. (See Section B.3.1.5 in Background Document.)

Taking the above into account, SEAC concludes that a three-year transitional period would ensure the manageability of the proposed restriction.

B.3.5. Monitorability

B.3.5.1. Summary of proposal:

The Dossier Submitter highlights that 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 can also assist with monitoring the effectiveness and implementation of the proposed restriction. This monitoring can be done by ECHA and national enforcement authorities.

Furthermore, 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.

B.3.5.2. RAC and SEAC conclusion(s):

SEAC agrees that the proposed restriction is monitorable.

B.3.5.3. Key elements underpinning the RAC and SEAC conclusion(s):

SEAC concurs with the Dossier Submitters that monitorability in terms of compliance control does not pose particular problems for the proposed restriction, given that the availability of analytical methods, and that the RAPEX system and REACH Article 66 provisions are adapted to the proposed restriction.

As regards the monitoring of the effects on public health, SEAC agrees that biomonitoring studies seem the only way possible, given the very high uncertainties and very low aetiological fractions of the diseases associated with the exposure to the four phthalates from articles in scope. However, the unknown time lag between withdrawal from the market of the four phthalates and exposure reduction (stock effects), the existence of multiple other exposure sources would make it very difficult to clearly quantify the impact of the restriction using biomonitoring studies. It would be difficult, when interpreting any downward trend in biomonitoring results, to attribute the decline to different causes (the proposed restriction, other past and recent or future legislation on the four phthalate, general decrease in the environmental concentrations, changes in production/consumption levels and patterns, etc.). These inherent difficulties in terms of quantifying the actual effects of the proposed restriction do not affect the possibility to monitor the effect through biomonitoring of the whole EU legislation regarding phthalates, the proposed restriction being an important component of it.

B.4. UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

RAC

B.4.1. RAC conclusion(s):

See the opinion of RAC.

B.4.2. Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

SEAC

B.4.3. SEAC conclusion(s):

Uncertainties regarding SEAC evaluation have been mentioned earlier in the opinion document. The main source of uncertainties (and unknowns) is regarding the quantification of the benefits of the proposed restriction. In comparison with health (and environmental) benefits estimation, other sources of uncertainties regarding the assessment are considered by SEAC as having low to moderate impact.

SEAC considers that, despite uncertainties regarding the benefits of the proposed restriction, the different and converging elements that are put together in perspective in the proportionality assessment provide a robust conclusion, in the sense that SEAC is confident that in the event of additional information becoming available and of reduction of uncertainties, the conclusion by SEAC regarding the proposed restriction would not change.

B.4.4. Key elements underpinning the SEAC conclusion(s):

Uncertainties regarding SEAC evaluation have been mentioned earlier in the opinion document.

B.5. ADDITIONAL REFERENCES

Accordini S, Corsico AG, Braggion M, Gerbase MW, Gislason D, Gulsvik A, Heinrich J, Janson C, Jarvis D, Jõgi R, Pin I, Schoefer Y, Bugiani M, Cazzoletti L, Cerveri I, Marcon A, de Marco R., «The Cost of Persistent Asthma in Europe: An International Population-Based Study in Adults, Int Arch Allergy Immunol 2013;160:93–10

European IVF-Monitoring Consortium (EIM) for the European Society of Human Reproduction and Embryology (ESHRE), Calhaz-Jorge C, de Geyter C, Kupka MS, de Mouzon J, Erb K, Mocanu E, Motrenko T, Scaravelli G, Wyns C, Goossens V. Assisted reproductive technology in Europe, 2012: results generated from European registers by ESHRE, Human Reproduction, Vol.31, No.8 pp. 1638–1652, 2016

"Entre Nous", the European Magazine for Sexual and Reproductive Health, No 63, 2006

MaagJ, Brandt UK, Mikkelsen SH, Lassen C, COWI A/A. Inclusion of HBCDD, DEHP, BBP, DBP and additive use of TBBPA in annex IV of the Commission's recast proposal of the RoHS Directive - Socioeconomic impacts, Report of Environmental Project No. 1317 2010 Miljøprojekt

Rava M, Ahmed I, Kogevinas M, Le Moual N, Bouzigon E, Curjuric I, Dizier MH, Dumas O, Gonzalez JR, Imboden M, Mehta AJ, Tubert-Bitter P, Zock JP, Jarvis D, Probst-Hensch NM, Demenais F, Nadif R. Genes Interacting with Occupational Exposures to Low Molecular Weight Agents and Irritants on Adult-Onset Asthma in Three European Studies, Environmental Health Perspectives, volume 125, number 2, February 2017

"The Global Asthma Report 2014", Global Asthma Network, http://www.globalasthmareport.org/resources/Global_Asthma_Report_2014.pdf