

# Cost and benefit assessments in the REACH restriction dossiers



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### Cost and benefit assessments in the REACH restriction dossiers

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# Summary

This study describes the costs and benefits of the restrictions included or proposed to be included in Annex XVII of REACH having been considered under the REACH procedure. It summarises and aggregates the information on costs and human health and environmental benefits provided in the restriction dossiers and opinions of the Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC).

The main cost category assessed in the restriction cases is substitution costs, i.e. investment and recurring costs to switch to alternative substance. The total costs assessed for all the restrictions in the EU having gone through the REACH procedure is estimated at €290 million per year, and the cost per restriction case vary between €0 and €100 million. The median cost is €5 million and the arithmetic mean is €18 million per year.

The human health and environmental impacts of restrictions are challenging to estimate. Only for few cases have the monetised benefits been estimated. The relevant restrictions introduce benefits by avoided adverse health effects and negative impacts on environment as follows:

- Health benefits equivalent to over €700 million per year
- Reduction of around 190 tonnes of releases of substances of concern per year
- Positive health impacts or removed risk for at least 81,000 consumers and workers per year.

# 1. Introduction

The process to introduce new restrictions under the REACH Regulation generates information on the impacts of the proposed restrictions in the EU. This information is reported in the background documents (BD)<sup>1</sup> and opinions of RAC and SEAC. This study describes the costs, and human health and environmental benefits of the restrictions under REACH by summarising the reported information. The analysis aggregates the information and reports the approaches and methods used in the assessments. Furthermore, it improves our understanding on how to indicate and estimate the human health and environmental benefits.

The study reported here is based on the best available information on the impacts of restrictions under REACH, and its results are relevant for any attempts to estimate the impacts of chemicals regulations. As in any analysis, the results are subject to the uncertainties in the data used in the analysed studies. In their opinions, RAC and SEAC have described the main uncertainties in the cost and benefit estimates. This report does not repeat or further evaluate these uncertainties.

Restriction reports, BDs and opinions of RAC and SEAC are available at ECHA website at <http://echa.europa.eu/web/guest/previous-consultations-on-restriction-proposals>. Annex 1 gives a synopsis of these restriction cases. In three restriction cases<sup>2</sup>, the Committees did not recommend to the Commission that a restriction should be introduced. These cases are not reported in the tables in this study. For completeness, these restriction cases and the summary of the reasoning of the Committees for not recommending the proposed restriction are also described in Annex 1.

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<sup>1</sup> The background documents provide supportive information for the opinions of RAC and SEAC. They are based on restriction reports prepared by the EU Member States or ECHA.

<sup>2</sup> Restriction proposal on 4 phthalates (2012), cadmium in artists paints (2015) and BPA (2015)

## 2. Approach

At the time of writing (April 2016), RAC and SEAC have adopted their opinions on 18 restriction proposals. Furthermore, one case where the RAC opinion and SEAC draft opinion were finalised, is covered in this study. Cost and benefit information was gathered from the opinions of the RAC and SEAC and the BDs. The three restriction cases where RAC or SEAC or both did not recommend to the Commission that the restriction should be introduced have been excluded from the quantitative analysis in this report.

To describe the costs and the benefits of the restriction cases, the following information for each case have been summarised when available:

- cost categories covered in the assessment (such as substitution and enforcement costs),
- health or environmental concern,
- indicators and proxies of the health or environmental impact,
- value of the impact, and
- monetised costs and benefits.

For all the cases monetised cost information is available.

To aggregate and summarise the human health and environmental benefits, they were grouped into three categories based on the assessments and results provided in the dossiers. The following categories were used:

- Monetised benefits
- Benefits based on reduced emissions
- Other qualitatively and quantitatively described benefits

The third category includes cases where the reason for action is not directly related to human health or environmental concern.

The costs and benefits are assessed in the restriction reports using different approaches and so the results are not directly comparable between themselves. There are also differences in what cost and benefit categories are considered quantitatively in the assessment. In addition, different temporal scopes have been applied and the results are presented based on this scope e.g. as a net present value, annualised costs or a representative year<sup>3</sup>. This makes any aggregation challenging as the chosen temporal scope affects the annualised costs e.g. when a trend is assumed in the amounts used or in the price difference between the restricted substance and the alternatives.

Despite of these challenges, annualised costs are used to aggregate the monetised costs and benefits. When not directly available, they have been derived from the information in the SEAC opinions and BDs. The cost estimates have been converted to 2015 price level by using the EU's GDP deflator. Annex 2 gives the deflators used. The timing of the impacts vary between the cases and depend e.g. on the year of entry into force of restriction.

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<sup>3</sup> Representative year is used to describe the annual costs or benefits after the restriction has become fully effective. This year could take place e.g. when all the articles currently in use have been switched to alternatives.

## 3. Analysis

### 3.1 COSTS

Information on costs were available for all cases. When not monetised, the costs have been considered negligible. The quantitative assessments consider mainly substitution costs, i.e. investment and recurring costs to switch to alternative substance<sup>4</sup>. In some cases the analysis was based on the lost consumer surplus. In addition, enforcement costs and compliance control costs to industry have been quantified in some assessments. Following the ECHA guidance document on the SEA for restrictions<sup>5</sup>, social impacts related e.g. to changes in employment, and wider economic impacts related to trade, competition and economic development have been discussed in the restriction reports.

Table 1 summarises the cost information of the restriction cases. The total cost in the EU is estimated at €290 million per year varying between €0 and €100 million per case. The median cost is €5 million and the arithmetic mean is €18 million per year. The five most expensive restrictions contributed around 88% of the total costs.

Table 1: Costs of restrictions in the EU

Case	Cost categories covered	Cost per year (€ million)	Remarks
Dimethylfumarate (DMFu) in treated articles	No costs.	0.0	Periodically renewed ban made permanent.
Lead and its compounds in jewellery	Cost difference between lead and lead-free jewellery and product testing costs.	5.0	
Mercury in measuring devices	Substitution costs of switching to mercury-free alternatives. Depending on the device, the calculations consider differences in prices, service-life and reoccurring costs (e.g. disposal costs, calibration costs and calibration frequency).	10.4	Costs are estimated individually for 10 different types of measuring devices: €10.4 million in total.
Phenylmercury compounds used e.g. in the production of polyurethane coatings	Substitution costs (R&D) and loss of export revenue.	1.3	Substitution costs €0.3 million, loss of export value €1 million per year.
Chromium VI in leather articles	Compliance cost of changing the tanning process to avoid formation of chromium VI and the cost of additional testing by authorities and industry.	100.8	
1,4-dichlorobenzene (DCB) in toilet blocks and air fresheners	Substitution costs to switch to alternative toilet blocks and air fresheners based on differences in unit price (cost of final product as purchased in the EU market) and length of service-life. Loss of consumer surplus estimated.	1.3	
Lead and its compounds in consumer articles	Substitution costs, additional testing costs and costs of product redesign, materials reformulation and alloy refinement.	26.9	

<sup>4</sup> See ECHA compliance cost guidance available at [https://echa.europa.eu/documents/10162/13576/appendix1-calculation\\_compliance\\_costs\\_case\\_restrictions\\_en.pdf](https://echa.europa.eu/documents/10162/13576/appendix1-calculation_compliance_costs_case_restrictions_en.pdf)

<sup>5</sup> See ECHA guidance document on the SEA for restrictions at [http://echa.europa.eu/documents/10162/13641/sea\\_restrictions\\_en.pdf](http://echa.europa.eu/documents/10162/13641/sea_restrictions_en.pdf)

Case	Cost categories covered	Cost per year (€ million)	Remarks
Nonylphenol (NP) and its ethoxylates (NPE) in textile	Substitution cost based on differences in unit price.	3.2	Potentially significant compliance control costs included only in the worst case scenario (€43 million per year in 2010 price level).
1-Methyl-2-pyrrolidone (NMP)	Substitution cost based on replacement of production lines.	5.1	
Cadmium and its compounds in antifouling paints	No costs.	0.0	Clarification of the restriction entry.
Use of asbestos fibres	Substitution cost based on replacement of production lines and adoption of new material.	6.0	€6.0 million in lowest and €29 million in highest cost scenario.
Ammonium salts in cellulose as insulating material	Cost of testing for ammonia emissions, costs of stabilisation, costs of substitution, and costs related to obtaining new technical approvals.	0.3	Other elements considered by the dossier submitter (training costs, depletion of stocks and changes in production process and production equipment) are not believed to induce additional costs.
Decabromodiphenyl ether (DecaBDE) as a flame retardant in plastics and textiles	Substitution costs to switch to drop-in alternative with differences in price and loading.	2.3	Companies may switch to more expensive alternatives, however, in this case un-quantified side benefits are assumed.
Perfluorooctanoic acid (PFOA) and its salts, including substances that may degrade to PFOA	Substitution costs to switch to drop-in alternative with differences in price and loading.	36.1	Companies may switch to more expensive alternatives, however, in this case un-quantified side benefits are assumed.
Methanol in windshield washing fluids	Substitution costs to switch to drop-in alternative with differences in price and loading.	40.4	Other cost elements (loss of jobs and businesses) could not be quantified and considered possibly distributional.
Siloxanes D4 and D5 in personal care products	Raw material costs, reformulation costs, product performance loss, testing costs and cost savings.	51.3	In April 2016, the costs were still under discussion in SEAC.
<b>TOTAL</b>		<b>290.4</b>	
Median		5.1	
Mean		18.1	

Source: Combined RAC and SEAC opinions and Background Documents, available at <http://echa.europa.eu/web/guest/previous-consultations-on-restriction-proposals>

### 3.2 BENEFITS

The human health and environmental impacts of restrictions are challenging to estimate mainly due to lack of information on exposure levels and exposed populations, as well as on the dose-response relationships. Because of this, different approaches and methods have been used to assess the benefits in the restriction reports. In addition to cost-benefit analysis the dossier submitters have used break-even analysis, cost-effectiveness analysis and qualitative argumentation to justify the restrictions. The monetisation of the impacts in reports has been based e.g. on values on willingness-to-pay (WTP) to avoid symptoms, cost-of-

illness (COI), avoided loss of consumer surplus and productivity loss. The assessments have quantified only risks and impacts related to the concern that triggered the restriction proposal and do not necessarily cover all impacts.

Even if all the benefits have not been quantified or monetised, the dossiers always describe relevant impacts and demonstrate a risk. The restrictions introduce health and environmental benefits for example by avoided:

- Adverse health effects such as
  - cancer,
  - dermatitis, burns, eye problems, breathing difficulties and bone fractures,
  - neurotoxic and neurodevelopmental effects (e.g. decrease in IQ), and
  - infertility.
- Negative impacts on environment such as reduced ecosystem's function and services, biodiversity and water quality.
- Concerns on PBT and vPvB substances<sup>6</sup>.

In some restriction reports other benefits, which are not directly related to human health and environment, have been reported. Examples of these are avoided legal costs of court cases, re-insulation costs and clarity of the restriction entry to stakeholders.

Table 2 summarises the information on the benefits of the restriction cases. It describes the human health and environmental concerns behind the proposal, as well as the human health or environmental impacts, or proxies of those impacts. Furthermore, it gives the values used in the assessments to better understand the societal relevance of the impacts.

Only for three cases were the benefits monetised. For one of these restriction proposals only the minimum level of the benefits based on a break-even analysis is available. Qualitative and non-monetised quantitative arguments in the restriction proposals have played an important role in the Committees' evaluations. The qualitative and quantitative arguments have been described in Table 2 to understand the breadth of known benefits.

The restriction cases are grouped into three categories, based on the level of quantification and monetisation of the benefits: i) monetised benefits, ii) benefits based on emission reduction and iii) other qualitatively and quantitatively described benefits. Per category, the restriction cases induce human health and environmental benefits by

- Health benefits equivalent to over €700 million per year
- Reduction of around 190 tonnes of releases of substances of concern per year
- Positive health impacts or removed risk for at least 81,000 consumers and workers per year.

Due to the limited information on the monetised benefits or other comparable quantified data it is difficult to further compare the cases between each other in terms of their impacts in the EU.

Table 2: Human health and environmental benefits of restrictions in the EU

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<sup>6</sup> PBT and vPvB substances are of specific concern due to their potential to remain and accumulate in the environment over long time periods. The effects of such accumulation are unpredictable in the long-term and exposure is difficult to reverse because an elimination of emissions will not necessarily result in a measurable reduction in chemical concentrations.

Case	Human health (HH) or environmental (ENV) concern	HH/ ENV	Human health or environmental impact (or proxy of the impact)	Value of the impact	Benefits per year (€ million)
Dimethylfumarate (DMF) in treated articles	DMFu causes serious acute allergic reactions such as burns, eye problems and breathing difficulties.	HH	No additional health impacts. Periodically renewed ban was made permanent under REACH.	No additional HH impacts compared to periodically renewed ban.	0
Lead and its compounds in jewellery	Lead negatively affects central nervous system and causes e.g. IQ losses in children mouthing jewellery.	HH	Reduction of 1430 IQ points lost per year for children in age of 0.5-3 exposed via mouthing. Total number of children in age 0.5-3 years: 16.7 million.	1 lost IQ point $\approx$ €10 000 (reported in 2010 price level).	15.7*
Mercury in measuring devices	Mercury and its compounds are highly toxic to humans, ecosystems and wildlife, and cause e.g. serious chronic neurotoxic and neurodevelopmental effects.	HH and ENV	Reduction of 3 t of mercury placed on the market per year.	Value of use reduction could not be estimated.	Monetised benefits could not be estimated
Phenylmercury compounds used e.g. in the production of polyurethane coatings	Mercury and its compounds are highly toxic to humans, ecosystems and wildlife, and cause e.g. serious chronic neurotoxic and neurodevelopmental effects.	HH and ENV	Reduction of 15 t of mercury released between 2018-2027 (1.5 t per year).	Value of emission reduction could not be estimated.	Monetised benefits could not be estimated
Chromium VI in leather articles	Chromium VI causes severe allergic contact dermatitis in humans and also elicits dermatitis.	HH	Approximately 1.32 million persons with chromium allergy may use leather articles without fear of symptoms and approximately 10 800 new chromium allergy cases avoided in the EU per year.	Benefits per year per case: <ul style="list-style-type: none"> <li>• WTP of avoided allergy and symptom days: €1,900</li> <li>• production losses due to sick leaves: €1,200</li> <li>• health and medication costs: €470</li> <li>• Increased consumer surplus for persons with chromium allergy as there is no need to avoid leather articles: €50.</li> </ul>	354.6
1,4-dichlorobenzene (DCB) in toilet blocks and air fresheners	1,4-DCB may cause liver cancer.	HH	80,850 male consumers and 140 toilet attendants not exposed above the DNEL based on exposure modelling.	The cancer cases were quantified only for illustrative purposes.	Monetised benefits could not be estimated

Case	Human health (HH) or environmental (ENV) concern	HH/ ENV	Human health or environmental impact (or proxy of the impact)	Value of the impact	Benefits per year (€ million)
Lead and its compounds in consumer articles	Lead negatively affects central nervous system and causes e.g. IQ losses in children mouthing jewellery.	HH	Reduction of at least 3,000 IQ points lost per year for children in age of 0.5-3 exposed via mouthing. Total number of children in age 0.5-3 years: 13.4 million.	1 lost IQ point ≈ €8,000 (reported in 2011 price level).	Over 26.9 Based on a break-even analysis assuming that costs=benefits
Nonylphenol (NP) and its ethoxylates (NPE) in textile	NPE has negative impacts in the water environment, in particular on biodiversity, impairs population stability and services provided by the water ecosystems.	ENV	Reduction of: • 24.7 tonnes (2010) • 11 tonnes (2021) • 10.7 tonnes (2031) of NP/NPE released to surface water. This corresponds to 70% reduction in the releases. For this study, an annual reduction of 15 t was assumed.	Value of emission reduction could not be estimated.	Monetised benefits could not be estimated
1-Methyl-2-pyrrolidone (NMP)	NMP causes decreased body weight gain, both in pregnant adults and their offspring which may be a disadvantage for the later development of the baby and/or adult health.	HH	Avoided risk for the pregnant adults and their offspring. The number of exposed pregnant workers was not known. Up to 9,000,000 workers were estimated to be potentially exposed.	Value of risk reduction could not be estimated.	Monetised benefits could not be estimated
Cadmium and its compounds in antifouling paints	Cadmium and its compounds are carcinogenic, mutagenic, reproductive toxic, toxic to the kidney, and in general hazardous to human health.	HH and ENV	No additional health or environmental impacts. The existing restriction wording needed to be modified as it was unclear and open for interpretations.	No additional health or environmental impacts.	0
Use of asbestos fibres	Chrysotile is carcinogen causing lung cancer and mesothelioma.	HH	Very small health impacts as the restriction was designed to put an end date to specific derogation under existing restriction.	Health impacts could not be quantified.	Monetised benefits could not be estimated
Ammonium salts in cellulose as insulating material	Ammonium causes respiratory symptoms and odour nuisance.	HH	Avoided respiratory symptoms and odour nuisance for 150 persons per year in the EU.	Costs Of Illness (COI) €49 per case. Odour nuisance not valued.	Monetised benefits could not be estimated
Decabromo-diphenyl ether (DecaBDE) as a flame retardant in plastics and textiles	DecaBDE is a PBT substance. Its transformation products are known to be toxic. DecaBDE has the capacity to cause developmental neurotoxicity.	HH and ENV	Reduction of 4.74 t of decaBDE released per year.	Value of emission reduction could not be estimated.	Monetised benefits could not be estimated

Case	Human health (HH) or environmental (ENV) concern	HH/ ENV	Human health or environmental impact (or proxy of the impact)	Value of the impact	Benefits per year (€ million)
Perfluorooctanoic acid (PFOA) and its salts, including substances that may degrade to PFOA	PFOA is a PBT substance. It may cause severe and irreversible adverse effects on the environment and human health, including cancer and infertility.	HH and ENV	Reduction of 5.7 t of PFOA and 36.4 t of PFOA-related substances released per year.	Value of emission reduction could not be estimated.	Monetised benefits could not be estimated
Methanol in windshield washing fluids	Methanol poisonings cause e.g. temporary or permanent blindness and death.	HH	82 avoided fatalities due to methanol poisonings after drinking windshield washing fluid as a substitute of consumable alcohol. Benefits due to avoided blindness were not included.	Value of statistical life €3.9 million.	323.0
Siloxanes D4 and D5 in in personal care products <sup>**</sup>	D4 is a PBT and vPvB substance and D5 a vPvB substance. They cause adverse impacts in water ecosystems.	ENV	Reduction of 121 t of D4 and D5 released per year.	WTP of €46 for D4 and €40 for D5 per year per person to reduce the risks associated with the substances reported, but not used to monetise the environmental impacts.	Monetised benefits could not be estimated

\* In the SEAC opinion, the monetisation of the benefits was based on a break-even analysis. This estimate of monetised benefits is derived from Georgiou et al. (2011): Childhood exposure to lead in jewellery articles: a 'reverse cost-benefit' approach to assessing restriction under the EU REACH Regulation.

\*\* In April 2016, the benefits were still under discussion in RAC and SEAC.

Source: Combined RAC and SEAC opinions and BDs are available at <http://echa.europa.eu/web/guest/previous-consultations-on-restriction-proposals>

### 3.3 OVERALL BENEFITS OVER COSTS

Due to the ignorance of health and environmental impact it has often not been possible to calculate the monetised (or quantified) benefits of the restriction cases. Table 3 provides a comparison of costs and benefits following the categorisation to monetised benefits, benefits based on emission reduction and other qualitatively and quantitatively described benefits summarised in Tables 1 and 2.

Table 3: Costs and health and environmental benefits of REACH restrictions in the EU

Case	Cost per year (€ million)	Benefits per year
<b>Monetised benefits</b>		
Lead and its compounds in jewellery	5.0	€15.7 million* based on reduced IQ loss
Chromium VI in leather articles	100.8	€354.6 million based on reduced chromium allergies and resulting symptoms.
Lead and its compounds in consumer articles	26.9	Over €26.9 million based on reduced IQ loss.
Methanol in windshield washing fluids	40.4	€323.0 million based on avoided fatalities.
<b>Sub-total</b>	<b>173.1</b>	<b>Health benefits equivalent to over €700 million per year</b>
<b>Benefits based on emission reduction</b>		
Mercury in measuring devices	10.4	Reduction of 3 t of mercury placed on the market.
Phenylmercury compounds used e.g. in the production of polyurethane coatings	1.3	Reduction of 1.5 t of mercury released.
Nonylphenol (NP) and its ethoxylates (NPE) in textile	3.2	Reduction of 15 t of NP/NPE released to surface water.
Decabromodiphenyl ether (DecaBDE) as a flame retardant in plastics and textiles	2.3	Reduction of 4.74 t of decaBDE released.
Perfluorooctanoic acid (PFOA) and its salts, including substances that may degrade to PFOA	36.1	Reduction of 5.7 t of PFOA and 36.4 t of PFOA-related substances released.
Siloxanes D4 and D5 in personal care products	51.3 <sup>7</sup>	Reduction of 121 t of siloxanes D4 and D5 released per year.
<b>Sub-total</b>	<b>104.6</b>	<b>Reduction of about 190 tonnes of releases of substances of concern</b>
<b>Other qualitatively or quantitatively described benefits</b>		
Dimethylfumarate (DMF) in treated articles	0.0	No additional HH impacts. Renewable ban made permanent under REACH.
1,4-dichlorobenzene (DCB) in toilet blocks and air fresheners	1.3	80,850 male consumers and 140 toilet attendants not exposed above the DNEL.
1-Methyl-2-pyrrolidone (NMP)	5.1	The number of exposed pregnant workers at risk is not known.
Cadmium and its compounds in antifouling paints	0.0	No additional health or environmental impacts. Existing restriction entry clarified.
Use of asbestos fibres	6.0	Very small health impacts. An end date added to the specific derogation under the existing restriction.
Ammonium salts in cellulose as insulating material	0.3	Avoided respiratory symptoms and odour nuisance for 150 persons.
<b>Sub-total</b>	<b>12.7</b>	<b>Positive health impacts or removed risk for at least 81,000 consumers and workers.</b>
<b>Total costs and benefits</b>	<b>290.4</b>	<ul style="list-style-type: none"> <li>✓ Health benefits of over €700 million per year;</li> <li>✓ Reduction of about 190 tonnes of releases of substances of concern; and</li> <li>✓ Positive health impacts or removed risk for at least 81,000 consumers and workers.</li> </ul>

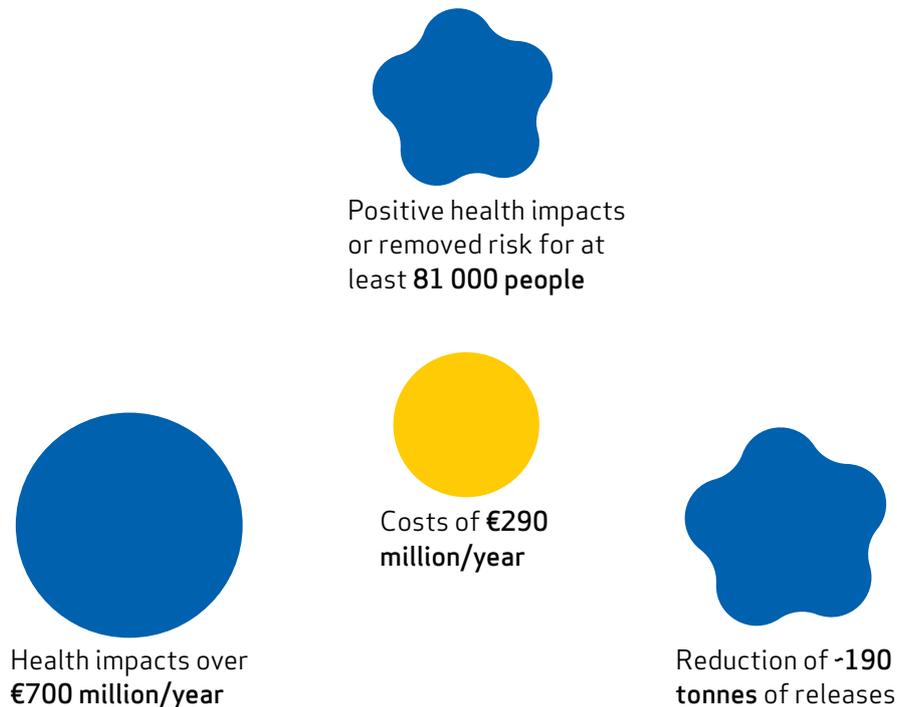
\* In the SEAC opinion, the monetisation of the benefits was based on a break-even analysis. This estimate of monetised benefits is derived from Georgiou et al. (2011): Childhood exposure to lead in jewellery articles: a 'reverse cost-benefit' approach to assessing restriction under the EU REACH Regulation.

<sup>7</sup> In April 2016, the costs were still under discussion in SEAC.

Source: Summarised information in Tables 1 and 2 from the combined RAC and SEAC opinions and BDs available at <http://echa.europa.eu/web/guest/previous-consultations-on-restriction-proposals>

It is clear from Table 3 that it is not possible to aggregate different kinds of benefits. In particular it is not possible to tell directly what is the value of the reduction of about 190 tonnes of mercury, PFOA, DecaBDE and siloxanes D4 and D5. An attempt is made in Figure 1 to illustrate the costs and the benefits of the restriction cases. At the end of the day the value (i.e. the size) of these emission reductions and the additional benefits for at least 81,000 people is in the eye of the reviewer. What is clear is that overall, the benefits of the restriction cases that have been summarised in this study outweigh the costs of €290 million per year.

Figure 1: Illustration of costs and health and environmental benefits of REACH restrictions in the EU



# Annex 1: Descriptions of the restriction cases

The following case descriptions are based on the information notes prepared by ECHA on the restriction proposals to facilitate the public consultation<sup>8</sup>. They have been updated to reflect the outcomes of the opinion forming process in RAC and SEAC.

## CASES WHERE RAC AND SEAC RECOMMENDED TO THE COMMISSION TO INTRODUCE THE RESTRICTION

### Dimethylfumarate (DMFu) in treated articles

On 15 April 2010 France proposed a restriction on DMFu in treated articles. The restriction applies from 3 June 2012.

DMFu has been used in furniture, clothing, shoes, etc. to prevent moulds that may deteriorate the product during transport and storage. Consumer articles containing DMFu can cause severe skin problems (i.e. dermatitis). At 2010, there was a temporary ban that required EU Member States to ensure that articles containing DMFu are not placed on the market. France proposed a restriction under the REACH Regulation to make this temporary ban permanent.

### Lead and its compounds in jewellery

On 15 April 2010 France proposed a restriction on lead and its compounds in jewellery. The restriction became effective on 9 October 2013.

Children may be exposed to lead when they suck or unintentionally ingest jewellery. The adverse health effects of lead are severe and children are more vulnerable than adults to the effects it can have on the central nervous system. In order to protect children from exposure to lead, France proposed that the use of lead and its compounds in the production of jewellery and the placing of such articles on the EU market should be restricted.

### Mercury in measuring devices

On 15 June 2010 ECHA proposed a restriction on mercury in measuring devices. The restriction applies from 10 April 2014.

ECHA prepared a restriction report proposing to restrict several mercury containing measuring devices (amongst others sphygmomanometers, thermometers and barometers). This restriction counted for around 1.5% of the current mercury use in the EU. Mercury and its compounds are highly toxic and there was a widely recognised need to further reduce mercury emissions at an EU and global level.

### Phenylmercury compounds used e.g. in the production of polyurethane coatings

On 15 June 2010 Norway proposed a restriction on phenylmercury compounds. The restriction will apply from 10 October 2017.

<sup>8</sup> Information notes, as well as Combined RAC and SEAC opinions and BDs, are available at <http://echa.europa.eu/web/guest/previous-consultations-on-restriction-proposals>

Norway prepared a restriction report proposing a ban on five phenylmercury substances. These substances are mainly used in the production of polyurethane coatings, adhesives, sealants and elastomers. There was a widely recognised need to further reduce mercury emissions at EU and global level. The life-cycle of the phenylmercury compounds lead to a release of mercury to the environment corresponding to around 4% of the total European mercury emissions.

### **Chromium VI in leather articles**

On 20 January 2012 Denmark proposed a restriction on the placing on Chromium VI in leather articles. The restriction applies from 1 May 2015.

Chromium VI is not intentionally used in the preparation of leather from skins and hides and in the manufacturing of articles of leather, but may be formed during the processing. The presence of chromium VI in tanned leather and articles of tanned leather can be avoided, under properly controlled conditions.

Chromium VI is known amongst other effects to cause severe allergic contact dermatitis in humans and to be able to elicit dermatitis at very low concentrations. Extractable chromium VI from shoes and other articles of leather represents a risk for the development of contact allergy to chromium for the consumers and workers.

### **1,4-DCB in toilet blocks and air fresheners**

On 19 April 2012 ECHA proposed a restriction on 1,4-dichlorobenzene in toilet blocks and air fresheners. The restriction applies from 1 June 2015.

These products are mainly used to deodorise public and domestic toilets. Consumers are exposed to the substance when they use 1,4-dichlorobenzene based products at home or when they visit public toilets deodorised with these products. In addition, professional workers employed in the public toilets are exposed.

1,4-dichlorobenzene has been classified as a category 2 carcinogen (liver tumours). It also affects the kidneys and respiratory tract. Consumers using 1,4-dichlorobenzene products at home, and professionals employed in public toilets where 1,4-dichlorobenzene products are used are exposed above safe levels, i.e. the risks from the substance in these population groups are not adequately controlled.

### **Lead and its compounds in consumer articles**

On 18 January 2013 Sweden proposed a restriction on the placing on the market or use of lead and its compounds in articles, which are supplied to the general public and can be placed in the mouth by children. The restriction will become effective on 1 June 2016.

Lead and its compounds have a wide use and have been found in a great variety of applications, some of them being articles for consumer use. Lead is usually present in metal alloys, in pigment/dyes, and to a lesser extent as pure metal and as stabiliser in plastic.

All lead compounds are classified as category 1 or 2 reprotoxic. Elemental lead is not yet classified but has been shown to cause non-threshold neurotoxic and neurodevelopmental effects, in particular for children. The restriction proposal targets the health effects of lead in small children, that may result from an exposure to lead which can migrate from materials in articles for consumer use. The main route through which small children (six to 36 months) are exposed to lead from the consumer articles is by mouthing, which results to the impairment of their developing central nervous system.

### **Nonylphenol (NP) and its ethoxylates (NPE) in textile**

On 29 July 2013 Sweden proposed a restriction on nonylphenol (NP) and its ethoxylates (NPE) in textile clothing, fabric accessories and interior textile articles that can be washed in water. The restriction will become effective on 3 February 2021.

The use of NPs and NPEs has been restricted within the EU since 2005 for the processing of leather and textiles amongst others. Exceptions are where there is no release into waste water as well as special treatment systems where the process water is pre-treated prior to waste water treatment. NPEs were however still used, primarily outside of the EU, in the manufacturing of textiles mostly as surfactants (cleaning or emulsifying agents).

When the textile articles containing NPs and NPEs are washed, the residues of NPs and NPEs are released into the environment via waste water. NP is toxic to aquatic life and enter the aquatic compartment directly or as breakdown products from NPEs. The restriction effectively reduces the emissions with benefits to society, for example from less pressure on biodiversity. The annual total release of NPs/ NPEs to EU waste water from textile washing was estimated to account for approximately half of total emissions.

### **1-Methyl-2-pyrrolidone (NMP)**

On 09 August 2013 The Netherlands proposed a restriction on manufacturing and use of NMP, unless the 8-hours average exposure of the workers (TWA) is below 5 mg/m<sup>3</sup>, the 15-minutes peak exposure remains under 10 mg/m<sup>3</sup>, and preventive measures are used for skin protection. The opinions of RAC and SEAC have been sent to the Commission on 10 December 2014.

The substance is mainly used as a solvent and cleaning agent. It is used in a variety of industries, including petrochemical, agricultural, pharmaceutical, electronics and textile industries.

NMP is classified as a category 1B reprotoxic substance. It also causes eye and skin irritation, and may cause irritation of the respiratory tract. Workers exposed to NMP in industrial and professional settings may be exposed above safe levels, i.e. the risks from exposure to the substance in these population groups are not adequately controlled. The focus of the restriction proposal was on the prenatal developmental toxicity, which is the potential effect of the substance on pregnant women and their unborn children.

### **Cadmium and its compounds in antifouling paints**

On 17 October 2013 ECHA proposed an amendment to an existing restriction (entry 23 in the Annex XVII in the REACH legislation) to extend the restriction such that cadmium and its compounds shall not be used, or placed on the markets in paints if the concentration of cadmium (expressed as Cd metal) is greater than 0.01% by weight. The opinions of RAC and SEAC have been sent to the Commission on 09 December 2014.

In the old entry, only “use” is restricted and there is no concentration limit. The reason for the amendment is that “use” could be interpreted to mean only intentional use, thus the restriction might be understood as not covering potentially present cadmium impurities. Secondly, as the current entry does not provide a limit value for cadmium in those paints, the enforcement of the restriction is challenging. Although cadmium is no longer intentionally used in antifouling paints, it has been found to exist in small amounts as impurity in copper-based anti-fouling paints used for boats and marine structures.

Cadmium and its compounds have generally been assessed to be carcinogenic, mutagenic, reproductive toxic, toxic to the kidney, and in general hazardous to human health in a number EU level assessments.

### **Use of asbestos fibres**

On 17 January 2014 ECHA proposed an amendment to an existing restriction (entry 6 in the Annex XVII in the REACH legislation), which prohibits the manufacture, placing on the market and use of asbestos fibres, and of articles and mixtures containing these fibres added intentionally. The opinions of RAC and SEAC have been sent to the Commission on 30 March 2015.

The entry gives a possibility for a Member State to exempt the placing on the market and use of diaphragms containing one of the fibres, namely chrysotile, for existing electrolysis installations. Only two electrolysis installations were currently relying on this exemption.

As the risks appeared to be minimised in the two companies, continuing or ending the possibility for exemptions would not have affected risk levels. The human health benefits from the proposed restriction are expected to be low.

### **Ammonium salts in cellulose as insulating material**

On 15 January 2014 France proposed a restriction on the placing on the market of inorganic ammonium salts in cellulose insulation materials unless emission of ammonia gas of such materials is below certain limit. The opinions of RAC and SEAC have been sent to the Commission on 25 June 2015.

About 250,000 tonnes of cellulose insulation are yearly placed on the EU market, out of which about 15,000 tonnes (around 5%, both produced and imported) contain inorganic ammonium salts as flame retarding additives. Until 2011 boron salts were widely used as additives for these applications but due to their classification as toxic to reproduction (mainly Repr. 1B) they have been replaced in the French market by inorganic ammonium salts.

Ammonium salts can lead under certain conditions (e.g. high humidity) to emissions of ammonia, a gas which is irritant to the mucous membranes and respiratory tract.

### **Decabromodiphenyl ether (decaBDE) as a flame retardant in plastics and textiles**

On 01 August 2014 ECHA proposed a restriction on the manufacturing, use and placing on the market of decaBDE, and on articles containing decaBDE in concentrations greater than 0.1% by weight. ECHA collaborated with the Norwegian Environment Agency throughout the drafting of the restriction proposal. The opinions of RAC and SEAC have been sent to the Commission on 28 September 2015.

DecaBDE is used as an additive flame retardant in plastic and textile articles. More specifically, it is used in domestic and commercial furniture and in the transport, construction and mining sector.

DecaBDE is persistent, bioaccumulative and toxic (PBT) and also very persistent and very bioaccumulative (vPvB) because it transforms to substances with these properties in the environment. It was added to the Candidate List for authorisation in December 2012. PBT and vPvB substances give rise to specific concerns based on their potential to accumulate in the environment and cause effects that are unpredictable in the long-term and are difficult to reverse, even when emissions cease. Information from environmental monitoring shows that decaBDE occurs widely in the environment and in wildlife. In addition to PBT/vPvB concerns, exposure to decaBDE and lower brominated transformation products may result in neurotoxic effects in mammals, including humans.

### **Perfluorooctanoic acid (PFOA) and its salts, including substances that may degrade to PFOA**

On 17 October 2014 Germany and Norway submitted a report proposing a restriction on the manufacturing, use and placing on the market of Perfluorooctanoic acid (PFOA) and its salts, also including substances that may degrade to PFOA (PFOA-related substances). The proposed restriction also covers articles containing these substances. The opinions of RAC and SEAC have been sent to the Commission on 12 January 2016.

PFOA and PFOA-related substances provide special properties, such as high friction resistance, dielectrical properties, resistance to heat and chemical agents, low surface energy, as well as water, grease, oil and dirt repellency. They are used in a wide range of industrial applications as well as consumer products: in fluoropolymer and fluoroelastomer production, photographic industry, surfactants in the semiconductor industry, surfactants in fire-fighting foams, wetting agents and cleaning agents, in sensor technology and medical technology, textiles and leather products, paper and cardboard products, paints and lacquers, cookware, skiwax, etc.

PFOA is a persistent, bioaccumulative, and toxic substance (PBT). Due to these properties it may cause severe and irreversible adverse effects on the environment and human health. Based on their PBT and CMR properties, PFOA and its salt (APFO) have been identified as substances of very high concern (SVHC) under REACH. PFOA-related substances are defined as fluorinated substances that are expected to degrade to PFOA under environmentally relevant conditions. PFOA and a number of PFOA-related substances are found ubiquitously in the environment and PFOA is present in human blood of the general population.

### **Methanol in windshield washing fluids**

On 16 January 2015 Poland proposed a restriction on placing on the market for the supply to the general public methanol in windshield washing fluids and denaturated alcohol. During the opinion making in the Committees, the scope was narrowed by SEAC to cover only windshield washing fluids.

Methanol is used in windshield washing fluids due to its anti-freeze properties.

The proposed restriction was intended to eliminate poisoning caused by misuse of windshield washing fluids and denaturated alcohol containing methanol in high concentrations. Individuals chronically abusing alcohol were known to consume these products as a surrogate of ethanol due to their lower prices. Ingestion of methanol may cause permanent blindness and death.

### **Siloxanes D4 and D5 in personal care products**

On 17 April 2015 The United Kingdom proposed a restriction on octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) in personal care products that are washed off in normal use. In April 2016, the opinion of RAC and the draft opinion of SEAC had been adopted.

These siloxanes perform three main functions in personal care products – as hair-conditioning agents, as skin-conditioning agents (emollient), and as solvents.

D4 and D5 have vPvB properties. D4 also has properties that are consistent with the criteria for a PBT substance. A particular concern is the release of these substances into freshwater and their subsequent persistence and build-up in aquatic sediments, followed by bioaccumulation through the food chain. Their presence in personal care products that are washed off in normal use conditions results in significant emissions of these substances into water.

**CASES WHERE RAC RECOMMENDED TO THE COMMISSION THE RESTRICTION TO BE INTRODUCED WHILE SEAC DID NOT****Bisphenol(A) in thermal paper**

On 17 January 2014 France proposed a restriction on the placing on the market of thermal paper containing Bisphenol A,4,4'-isopropylidenediphenol (BPA).

Thermal paper is a paper coated with a reactive layer that changes colour when exposed to heat. It is used in many applications such as point-of-sales tickets and receipts, self-adhesive labels, lottery tickets or fax paper. BPA is the most common dye developer in such paper.

The restriction proposal aimed to address the risks to pregnant workers and consumers from dermal exposure to BPA in thermal paper. More precisely, risks were identified for children exposed through their pregnant mothers. The risks were identified for effects on the female reproductive system, effects on brain and behaviour, mammary gland changes, as well as effects on metabolism and obesity.

RAC considered that the proposed restriction on BPA was the most appropriate EU wide measure. However, comparing the socio-economic benefits to the socio-economic costs, SEAC considered that the benefits of the proposed restriction were unlikely to be higher than the costs. However, SEAC noted that there may be favourable distributional and affordability considerations. The opinions of RAC and SEAC were sent to the Commission on 29 January 2016.

As this case is still under consideration by the Commission (in April 2016), similar summarising information to what is included in the main report for the cases where RAC and SEAC recommended to the Commission to introduce the restriction is presented in tables A1-1 to A1-3 below for the BPA.

**CASES WHERE RAC AND SEAC DID NOT RECOMMEND TO THE COMMISSION THE RESTRICTION TO BE INTRODUCED****Four phthalates (DEHP, BBP, DBP and DIBP)**

On 23 August 2011 Denmark proposed a restriction on the placing on the market and use of certain articles containing four classified phthalates (DEHP, BBP, DBP and DIBP).

These phthalates are primarily found in PVC as softeners but they can also be found in low concentrations in other plastics and in e.g. dispersions, paints and varnishes.

DEHP, BBP, DBP and DIBP are all reported to affect reproductivity. The widespread use of these phthalates is causing concern regarding human exposure from consumer articles. The dossier addresses the combined exposure of the four phthalates based on the common effects seen from exposure to these phthalates.

RAC considered that the proposed restriction was not justified because the available data did not indicate that currently (2012) there was a risk from combined exposure to the four phthalates. Taking into account RAC's conclusions, SEAC had no basis to support the proposed restriction. The Commission considered that the conditions for restriction were not fulfilled and did therefore not seek for a final decision to add the restriction to REACH regulation.

**Cadmium in artists' paints**

On 17 January 2014 Sweden proposed a restriction on Cadmium and its compounds in artist paints and in pigments, that could be used for the manufacture of artists' paints.

Cadmium pigments are stable inorganic colouring agents which can be produced in a range of brilliant shades of yellow, orange, red and maroon. They are used in plastics but they also have significant application in ceramics, glasses and specialist paints. Cadmium pigments are characterised by their particular brilliant shades, high hiding power, good intensities of colour, good temperature stability and absolute migration resistance.

During use and cleaning procedures cadmium based artists' paints are released to the waste water. When the resulting sewage sludge is applied as fertiliser in the agriculture, the cadmium compounds used in artists' paints will eventually end up in the foodstuffs. The reduction in the cadmium intake via food is explained to lead to a reduction in the number of fractures affecting women and men over 50 years of age, and in the number of women over 50 afflicted with breast cancer. Several other possible negative health effects of cadmium exposure via food are also mentioned.

RAC considered that the proposed restriction was not justified because in reducing the risks from cadmium in artists' paints alone, this restriction under REACH was not considered to be the most appropriate EU wide measure to address the negligible level of risk identified by RAC in terms of its effectiveness. Taking into account RAC's conclusions, SEAC considered that the proposed restriction was not the most appropriate EU wide measure to address the identified risks. The Commission considered that the conditions for restriction were not fulfilled and did therefore not seek for a final decision to add the restriction to REACH regulation.

Table A1-1: Costs of BPA restriction in the EU

Case	Cost categories covered	Cost per year (€ million)	Remarks
Bisphenol(A) (BPA) in thermal paper	Substitution costs to switch to drop-in alternative based on differences in price and compliance control costs.	86.0	Average yearly cost over the period 2019-2030 assuming that the market grows.

Table A1-2: Human health and environmental benefits of BPA restriction in the EU

Case	Human health (HH) or environmental (ENV) concern	HH/ ENV	Human health or environmental impact (or proxy of the impact)	Value of the impact	Benefits per year (€ million)
Bisphenol(A) (BPA) in thermal paper	BPA may cause adverse effects for the unborn children via their mother e.g. for: <ul style="list-style-type: none"> <li>the female reproductive system</li> <li>the brain and the behaviour</li> <li>vulnerability of the developing mammary gland</li> <li>increase in body weight and in cholesterol.</li> </ul>	HH	Avoided risk for 81,149 unborn children of pregnant cashiers exposed above the DNEL.	Valuation factors for group of health effects within each endpoint (central values per incidence): Mammary gland: €6,301 Immunotox: €12,810 Neurobehavior: €7,134 Reprotox: €2,194 Metabolic: €1,814	Monetised benefits could not be estimated

Table A1-3: Summary of costs and health and environmental benefits of proposed BPA restriction in the EU

Case	Cost per year (€ million)	Benefits per year
Bisphenol(A) (BPA) in thermal paper	86.0	Avoided risk for 81,149 unborn children of pregnant cashiers.

## Annex 2: Deflators to convert costs and benefits to 2015 price level

Table A2-1: GDP deflators used

2008	98.6
2009	96.5
2010	98.8
2011	101.1
2012	102.5
2013	104.0
2014	105.4
2015	108.2

The annualised costs and benefits have been converted to 2015 price level with the GDP deflators for EU-28 in Table A2-1. The deflators from quarter one of each was chosen to have 2015 deflator available. For example €100 in 2008 price level equals  $108.2 / 98.6 \times €100 \approx €106.7$  in 2015 price level.

The deflators were taken from Eurostat web pages on 5 October 2015: <http://ec.europa.eu/eurostat/en/web/products-datasets/-/TEINA110>.

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