Costs and benefits of REACH restrictions proposed between 2016-2020

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Key findings

Restrictions under REACH, protect human health and the environment from unacceptable risks posed by chemicals. They can limit the manufacturing and use of chemicals or impose a ban on their placement on the EU market. They can also be used to control imports of the chemicals from other parts of the world.

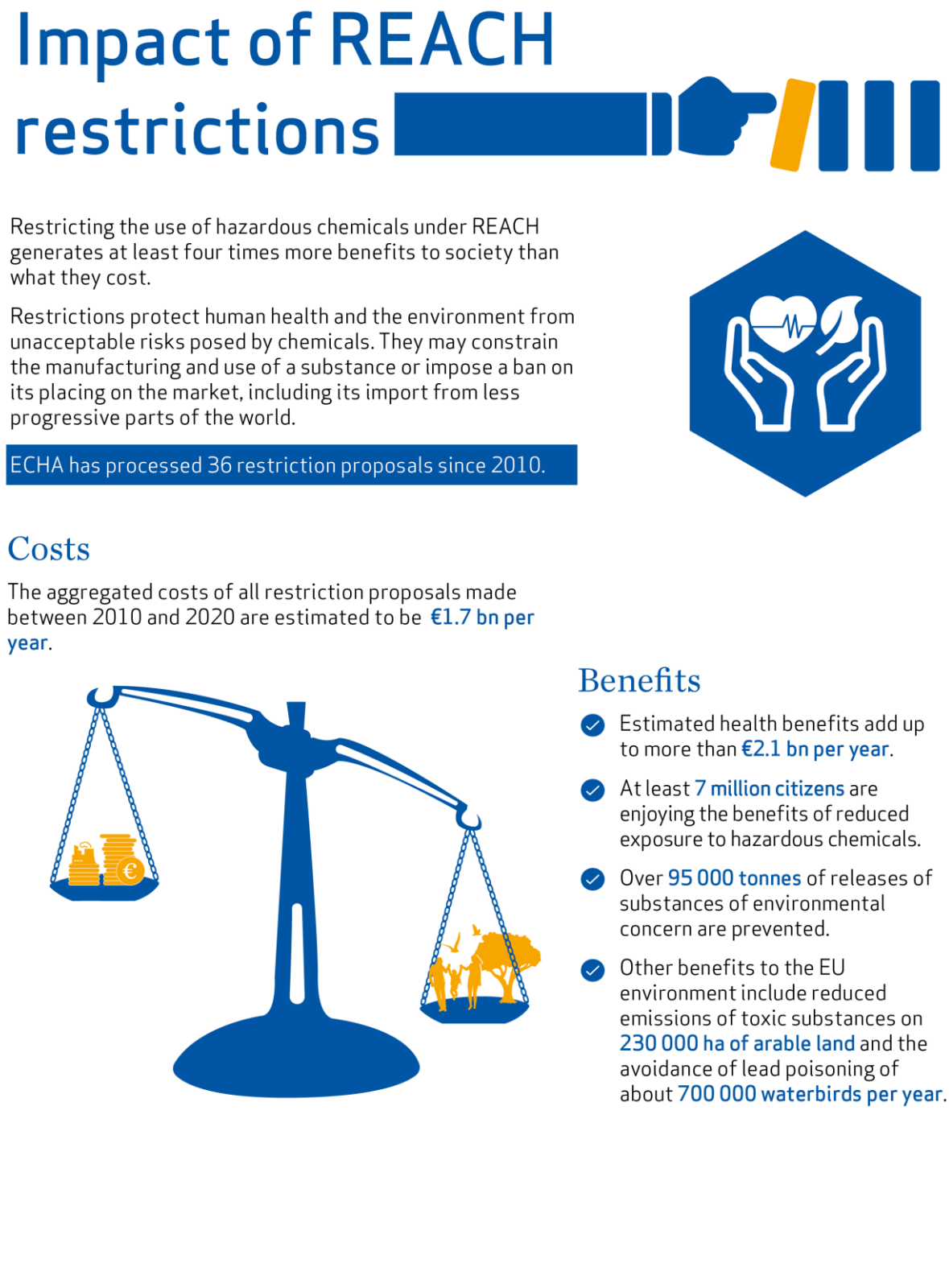
The analyses within this report indicates that restricting the use of hazardous chemicals under REACH generates at least four times more benefits to society than what they cost.

The monetised health benefits to citizens, including reduced risk of cancers, sexual development disorders, sensitisation and occupational asthma are estimated to be around €2.1 billion per year while the associated costs add up to €0.5 billion.

The aggregated costs of all restrictions proposed between 2010 and 2020 amount to €1.7 billion per year. Most of these costs relate to the investment and recurring costs needed to substitute the restricted chemicals and replace them with safer substances or alternative technologies.

In addition, restrictions are shown to reduce exposure to and mitigate the risks of harmful chemicals for at least 7 million EU consumers and workers. They also prevent the release of more than 95 000 tonnes of emissions of substances that are an environmental concern. This brings further benefits to human health in the form of a cleaner environment and further reduced exposure through the water we drink, the food we eat and the air we breathe.

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



Summary

This report summarises and aggregates the benefits to human health and the environment, as well as the costs, associated with REACH restriction dossiers and the opinions of ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC).

It updates an earlier ECHA report[1] looking at the costs and benefits of restrictions up to 2016, with information on restrictions included or proposed to be included in the Restriction List (Annex XVII) of REACH before May 2020.

Since 2010, ECHA's scientific committees have processed 36 restriction proposals – 22 prepared by Member States and 14 by ECHA alone or in collaboration with Member States.

At the time of this report, 22 of these 36 restrictions proposals have been decided by the European Commission – 20 adopted and added to Restriction List, and two rejected. A further eight cases are waiting for a Commission decision and six proposals are in the opinion development phase in ECHA's committees.

As of December 2020, after the cut-off date for the data analysed in this report, one restriction proposal has been submitted and another six intentions to prepare new restriction proposals have been declared. These will be processed in the coming years[2].

This report covers those restrictions that ECHA's scientific committees have processed so far. Cases for which the Commission concluded that a restriction was not warranted, the proposal was purely amending an existing restriction or the opinion forming had not yet been started when this report was written, have not been analysed. This leaves 33 restriction proposals in the scope of this report.

Benefits

Restrictions prevent adverse health effects and reduce negative impacts to the environment. As it is challenging to estimate the impacts of restrictions on people's health and the environment, the Restriction Task Force[3] has recommended for these impacts to, at least, be qualitatively described[4].

Health-related impacts can often also be expressed quantitatively, and their value can, in many cases, also be expressed in monetary terms.

Environmental benefits are often expressed as reduced emissions without an estimation of their environmental impact and thus the impacts are not valued either. These approaches are taken into consideration throughout this report.

The benefits of the REACH restrictions[5] are estimated to be:

- Health benefits, for example, in terms of reduced risk of cancers, disorders in sexual development, sensitisation and occupational asthma were equivalent to over **€2.1bn per year**.

[1] https://echa.europa.eu/documents/10162/13630/cost_benefit_assessment_en.pdf.
[2] https://echa.europa.eu/registry-of-restriction-intentions
[3] The Restriction Task Force brings together Member States, ECHA and the European Commission to make coherent recommendations for improving the restriction process.
[4] https://echa.europa.eu/documents/10162/13641/report_task_force_on_restriction_efficiency_en.pdf/68ba2a4f-5c93-4b55-a061-b69fd2795a21
[5] These benefits include the €700m health-related benefits plus the emission reductions of PBTs and other benefits reported in the previous report.

- Health benefits or reduced risks related to all observed adverse health effects for **more than 7 million consumers and workers per year**.
- **Reduction of 95 000 tonnes of environmental emissions** of substances of concern per year. This also leads to potential health benefits through a cleaner environment and reduced exposure to hazardous chemicals in water, food and air.

Costs

Most of the costs generated from restrictions made between 2010-2016 relate to substitution, i.e. investment and recurring costs when switching to safer alternatives. These costs total €1.7 billion per year[6]. The costs for each restriction vary from almost zero (for substances that have been phased out and are no longer produced) to €955 million per year. The median cost of a restriction was €6 million per year and the mean cost averages out at €53.3 million per year.[7]

For the restrictions processed between 2016-2020, the costs were estimated to be €1.47 billion per year. The median cost was €26 million per year and the mean cost was €86 million per year.

Implications

Since 2010, there have been 12 cases where the benefits of restriction could be monetised. For these cases, the annual benefits amount to €2.1 billion – four times higher than the associated costs of €0.5 billion.

The reduction of one kilogram of emissions of hazardous chemicals, achieved through REACH restrictions, is estimated to cost approximately €12.

The overall costs related to reducing 95 000 tonnes of emissions were estimated to be €1.2 billion per year.

In addition to the monetised benefits and reduced emissions, there are other additional benefits following the introduction of the restrictions that could not be quantified.

☞ The overall impact of restrictions has grown in the past five years compared to the beginning of the REACH Regulation.

While restrictions have become more costly since 2016, the date of the previous report, their benefits for human health and the environment have increased even more.

When interpreting the estimated impacts in this report, the uncertainties related to the accuracy of the estimated impacts and the methodologies used for estimating them should be kept in mind.

[6] The annual costs of €290m of the restrictions up to 2016 are included in these costs.
[7] In the previous report, total costs were estimated at €290m per year, and the cost per restriction case varied between close to €0 and €100m. The median cost was €5m per year and the mean cost was €18m.

Introduction

Introducing new restrictions under the REACH Regulation normally generates information on the impacts of the proposed restrictions in the EU. This information is reported in the background documents[8] and scientific opinions of ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) for each restriction.

This report provides an accessible description of the costs and benefits of the restrictions by summarising the reported information and presenting the approaches and methods used during the assessments.

The report is based on the best available information about the impacts of restrictions under REACH at the moment when the opinions of RAC and SEAC have been adopted and sent to the Commission. The results are relevant for gauging the impacts of REACH and chemicals legislation in general. As in any analysis, the results are subject to uncertainties in the data analysed in the proposals. In their opinions, RAC and SEAC have described the main uncertainties pertaining to cost and benefit estimates. This report does not repeat or further evaluate these uncertainties.

Restriction reports, background documents, and the opinions of RAC and SEAC are published on ECHA's website at https://echa.europa.eu/registry-of-restriction-intentions. Annex 1 gives a synopsis of the restriction cases processed since 2016.

Cases where ECHA's committees recommended to the European Commission that a proposed restriction should not be introduced, cases which were merely derogations for previous restrictions, and all proposals that were withdrawn or not conforming are not included in this report.

Approach

At the time of writing (December 2020), the European Commission had decided on 22 restrictions under REACH, and RAC and SEAC had adopted opinions on eight restriction proposals. Opinion development was ongoing for six proposals. Cost and benefit information was gathered from the opinions of RAC and SEAC and the background documents.

Cases where the European Commission concluded that a restriction was not warranted, cases where the restriction proposal was purely amending an existing restriction and cases where opinion forming had not yet started at the time of writing were not included. Therefore, 33 restriction proposals fall within the scope of this report.

To describe the costs and benefits of these restriction cases, the following information has been summarised for each case (where available):

- cost categories covered in the assessment (such as substitution and enforcement costs);
- health or environmental concern;
- indicators and proxies of the impacts on human health or the environment of restricting uses of a substance of concern;
- value of these impacts; and
- monetised costs and benefits.

[8] The background documents are based on restriction reports prepared by the EU Member States or ECHA and provide supplemental information to the opinions of RAC and SEAC.

For all cases, monetised cost information is available. To aggregate and summarise the human health and environmental benefits, these were grouped into three categories based on the assessments and results provided in the dossiers. The following categories were used:

- Human health-related benefits which could also be monetised.
- Environmental benefits related to prevented emissions.
- Other quantitatively or qualitatively described benefits.

The third category includes cases where it was not possible to monetise the human health benefits and cases were the reason for action is related to, for example, avoiding a regrettable substitution of the restricted substance with another hazardous substance.

The costs and benefits are assessed in the restriction reports using different approaches. Therefore, the estimates are not always directly comparable. There are also differences in the categories of costs and benefits that were quantitatively considered in the assessment. In addition, different temporal scopes have been applied and the results are often presented based on this temporal scope, e.g. as a net present value over a specific period or an annualised cost for a representative year. 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 these challenges, a simple scheme is used for annualising and making the monetised costs and benefits comparable. When not directly available, annual costs have been derived from the information in the SEAC opinions or the background documents. Importantly, the annualisation of cost estimates has not accounted for inflation and has not calculated proper annuities but instead converted net present values (NPVs) into average annual costs over the horizon in question. In certain cases, higher cost estimates or lower estimates of benefits have been used due to uncertainties in the original impacts. For example, in the four phthalates restriction the estimated benefits of respiratory sensitisation were excluded from the benefits estimates in this report due to uncertainties related to the number of potential cases.

At the time of writing (December 2020) decisions by the European Commission on restricting skin sensitisers in textiles as well as restricting the use of rubber crumb as infill material on artificial sports pitches were not yet made. To avoid overestimating the benefits, the most conservative estimates of the benefits of restricting skin sensitisers in textiles were used in this report. For the microplastics restriction, the overall costs will heavily depend on the measure that is ultimately selected to address the environmental risks posed by the granular infill material used on artificial turf pitches. To avoid inflating the benefits in this case, the highest cost estimate is used in this report.

Analysis

Costs

Information on costs were available for all cases. Whenever they were not monetised, the costs were considered negligible. The quantitative assessments mainly considered substitution costs, i.e. investment and recurring costs to switch to an alternative substance or technology.[9] In some cases, the analysis was based on reduced consumer surplus or profits of the impacted industry. In addition, enforcement costs and compliance control costs have been quantified in some assessments. Following the ECHA guidance document on the socio-economic analysis for restrictions[10], social impacts related, for example, 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 on all the restriction proposals assessed between January 2010 to May 2020 (including the previous report's figures). The overall cost of REACH restrictions in the EU is estimated at €1.7 billion per year, the cost per restriction case varies between €0 and €955 million. The median cost is €6 million, and the mean cost is €53.3 million per restriction per year.

The costs reported in the previous report were estimated at €290 million per year, and the cost per restriction case varied between €0 and €100 million. The median cost was €5 million per year and the mean cost was €18 million per year. In contrast, the costs of restrictions processed since the previous report were estimated at €1.47 billion per year, and the annual cost per restriction case varied between €0 and almost €955 million. The median cost was €25.9 million per year and the mean cost was €86.4 million per year.

Table 1: Costs

Costs of restrictions in the EU			
Case	**Cost categories covered**	**Cost per year (€m)**	**Remarks**
Dimethylfumarate (DMFu) in treated articles	No costs assessed.	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	

[9] See ECHA compliance cost guidance available at: https://echa.europa.eu/documents/10162/13576/appendix1-calculation_compliance_costs_case_restrictions_en.pdf

[10] See ECHA guidance on the SEA for restrictions at: http://echa.europa.eu/documents/10162/13641/sea_restrictions_en.pdf

Costs of restrictions in the EU			
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 recurring costs (e.g. disposal costs, calibration costs and calibration frequency).	10.4	Costs are estimated individually for 10 different types of measuring devices: €10.4m 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 €0.3m, loss of export value €1m 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	

Costs of restrictions in the EU			
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 (€43m 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 assessed.	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	€6m in lowest cost scenario; €29m 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, unquantified 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, unquantified 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.

Costs of restrictions in the EU			
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.
4,4'-isopropylidenediphenol (bisphenol A) in thermal paper	Substitution costs and compliance control costs for the thermal paper producers including thermal paper production both for EU use and for export.	97	Average yearly costs over the period 2019-2030.
Calcium cyanamide used as fertiliser	Decreased profitability in farming. Profit loss following the reduced manufacturing of calcium cyanamide for used as fertiliser.	33	Average productivity loss range in a realistic case €60m-€80m. Costs cover decreased profitability in farming, (quality, quantity losses in harvest, increased plant protection input costs and reduced manufacturing of calcium cyanamide for use as a fertiliser.
N,N-dimethylformamide	Mostly related to assumptions that industry would close down production. Closing costs taken as a one-shot cost incurred on the first year the restriction comes into effect. The cost estimate does not include profit loss, as the profit is assumed to remain in Europe despite relocation of the production activities.	79	€58m-€100m per year if simply divided by the 15-year assessment period. SEAC found the cost estimate uncertain and overestimated. It was not possible for SEAC to give an estimate on the related costs.

Costs of restrictions in the EU			
Perfluorohexane-1-sulphonic acid, its salts and related substances	Possible higher prices of imported articles and costs for not being able to use PFHxS as a substitute for PFOA.	0	There is no identified use of PFHxS, its salts and PFHxS-related substances in the EU.
Cobalt carbonate; cobalt di(acetate); cobalt dichloride; cobalt dinitrate; cobalt sulphate	Compliance, investment and operation costs to reduce workers' exposure.	3	€1m-€5m per year for RAC's recommended restriction option. In this report, the range based on the dossier submitter's estimate is used to have a benefit estimate based on the comparable assumptions available. Industry estimated the costs to be €42m-€987m per year.
Formaldehyde and formaldehyde releasers	Increase in production costs, enforcement costs.	28	For the reference year 2016, the cost increase to EU society is estimated to be in the range of €28-€79m. A value of €28m represents the dossier submitter's central estimate for the cost increase associated with the proposed restriction.
Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5); dodecamethylcyclohexasiloxane (D6)	Compliance costs for the cosmetics industry.	63	The majority of these costs i.e. around €54m per year are related to the costs of reformulations.
Skin sensitising substances in textiles, leather, synthetic leather, hide and fur	Substitution and enforcement costs.	23.8	Additionally, reformulation would amount to approximately €13.1m as a one-time cost. Enforcement costs estimated at €80k, although there is uncertainty related to the magnitude of the testing costs.

Costs of restrictions in the EU			
Polycyclic-aromatic hydrocarbons (PAHs) in rubber granules and mulches	Increased production costs (improved tyre selection) and/or revenue losses from selling incompliant infill on alternative markets, increased testing costs and enforcement costs.	5	The overall societal costs are estimated to be around €30m-€55m over a 10-year period with a mid-range scenario of €45m.
Intentionally added microplastics	Primarily compliance costs. Reformulation costs, raw material costs, enforcement costs, labelling costs and other economic costs.	955	Costs estimated at €10.8bn-€19.1bn over 20-year period depending on the selected risk management measure to address the risks. The highest cost estimate is used in this report.
Substances in tattoo inks and permanent make up	Substitution costs.	4.6	The cost of tattoo inks represents a very small share of the costs per tattoo.
Diisocyanates	Training costs at workplaces.	114	
Perfluorononan-1-oic acid (PFNA); nonadecafluorodecanoic acid (PFDA); henicosafluoroundecanoic acid (PFUnDA); tricosafluorododecanoic acid (PFDoDA); pentacosafluorotridecanoic acid (PFTrDA); heptacosafluorotetradecanoic acid (PFTDA); including their salts and precursors	No major economic costs. Industry already shifting from the use of long-chain perfluorinated substances. Some minor costs related to substitution from PFOA to shorter chain or non-fluorinated alternatives instead of to C9-C14 PFCAs may occur. For textiles, such costs would be less than €35/kg used.	0	No known EU manufacturers or intentional uses of C9-C14 PFCAs, but imported semiconductors containing the substance have been identified.

Costs of restrictions in the EU			
Lead and its compounds in shots over wetlands	Compliance costs for hunters.	44	The additional cost to an average hunter for purchasing non-lead shot ammunition in the worst case would be on average €66 per year. 141 000 guns may have to be prematurely replaced across the EU. Total replacement cost (in 2016 value) of €97m is annuitised to €7m per year and included in the overall costs.
Lead and its compounds to stabilise PVC	Substitution costs of industry switching from lead to potentially more expensive alternative stabilisers.	2.1	
Diisobutyl phthalate (DIBP); Dibutyl phthalate (DBP); Benzyl butyl phthalate (BBP); Bis(2-ethylhexyl) phthalate (DEHP)	Substitution costs when switching to more expensive alternatives. Testing costs. Costs for the recycling sector when switching to virgin plastisol or to DEHP free recyclate and identifying alternative domestic or international markets. Enforcement costs.	17.6	
TDFAs in spray products	Reformulation costs.	0.012	
TOTAL		**1 759.97**	
Median		6	
Mean		53.3	

Source: https://echa.europa.eu/registry-of-restriction-intentions/

* *Reported in the first report 2010-2016:*
https://echa.europa.eu/documents/10162/13630/cost_benefit_assessment_en.pdf

Benefits

It is challenging to estimate the impacts of restrictions on human health and the environmental as there is a lack of information on exposure levels and exposed populations, and unknown dose-response relationships. To overcome these challenges, different approaches and methods have been used to assess the benefits in the restriction reports. In addition to cost-benefit analysis, dossier submitters have used break-even analysis, cost-effectiveness analysis and qualitative argumentation to justify the proportionality of proposed restrictions.

The monetisation of prevented impacts on human health has been based, for example, on willingness-to-pay (WTP) values for avoiding symptoms or cost-of-illness (COI). In some cases, the benefits were only partially monetised. The assessments have quantified only benefits related to the substance of concern that triggered the restriction proposal and do not necessarily cover all impacts.

Even though not all benefits have been quantified or monetised, the dossiers always described relevant impacts and demonstrated a risk. For example, some restrictions introduced health or environmental benefits in terms of:

- Prevented adverse health effects such as
    - cancer;
    - dermatitis, burns, eye problems, breathing difficulties and bone fractures;
    - neurotoxic and neurodevelopmental effects (e.g. decreases in IQ);
    - infertility and other sexual development problems; or
    - immunotoxic effects.
- Prevented negative impacts on the environment such as reduced ecosystem functioning and services, loss of biodiversity, or impaired water quality.
- Concerns on PBT and vPvB substances[11].

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

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 quantified human health or environmental impacts (or proxies of those impacts). Furthermore, it gives the values used for monetarisation in the assessments to better understand the societal relevance of the impacts.

The benefits were monetised in 12 cases. For other cases, qualitative and non-monetised quantitative arguments were made by dossier submitters and consequently evaluated by ECHA's scientific committees. Both the qualitative and quantitative arguments are thus summarised in Table 2 to understand the breadth of known benefits.

Based on the level of quantification and monetisation of the benefits, the restriction cases are grouped into three categories: i) monetised benefits, ii) benefits based on prevented

[11] PBT and vPvB substances are of specific concern due to their potential to remain and accumulate in the environment over long time periods. The long-term effects of such accumulation are unpredictable, and exposure is difficult to reverse because an elimination of emissions will not resulting in fast reductions in chemical concentrations.

emissions, and iii) other quantitatively or qualitatively described benefits.

Overall, the REACH restrictions covered in this study are expected to lead to the following human health and environmental benefits:

- Health benefits equivalent to over €2.1 billion per year (compared to €700 million in the previous report);
- Annual reduction of around 95 000 tonnes of substances of concern (compared to 190 tonnes in the previous report);
- Positive health impacts or removed risk for over 7 million consumers and workers (compared to 81 000 in the previous report) per year.

In several cases, there are also unquantified benefits expected from the introduction of the proposed restrictions in addition to the monetised and otherwise quantified benefits.

Due to limited information on the monetised benefits or other comparable quantified data, it is however difficult to compare these cases in terms of their overall impacts in the EU.

Table 2: Benefits

Benefits of restrictions 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 (€m)**
Dimethylfumarate (DMF) in treated articles *	DMF 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 human health 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 1 430 IQ points lost per year for children aged 0.5-3 years exposed via mouthing. Total number of children aged 0.5-3 years: 16.7m per year.	1 lost IQ point ≈ €10 000 (reported at 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 tonnes 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 tonnes of mercury released between 2018-2027 (1.5 tonnes per year).	Value of emission reduction could not be estimated.	Monetised benefits could not be estimated.

Benefits of restrictions in the EU					
Chromium VI in leather articles *	Chromium VI causes severe allergic contact dermatitis in humans and elicits dermatitis.	HH	Approximately 1.32 million people with a 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: • WTP of avoided allergy and symptom days: €1 900 • production losses due to sick leaves: €1 200 • health and medication costs: €470 Increased consumer surplus for people with a chromium allergy as there is no need to avoid leather articles: €50.	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.
Lead and its compounds in consumer articles *	Lead negatively affects the 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 aged 0.5-3 years exposed via mouthing. Total number of children aged 0.5-3 years: 13.4m per year.	1 lost IQ point ≈ €8 000 (reported at 2011 price level).	Over 26.9 - based on a break-even analysis assuming that costs=benefits.

Benefits of restrictions in the EU					
Nonylphenol (NP) and its ethoxylates (NPE) in textile *	NPE has negative impacts in the water environment, particularly 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 a 70 % reduction in the releases. For this study, an annual reduction of 15 tonnes 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 pregnant adults and their offspring. The number of exposed pregnant workers was not known. Up to 9m 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 interpretation.	No additional health or environmental impacts.	0
Use of asbestos fibres *	Chrysotile is a carcinogen causing lung cancer and mesothelioma.	HH	Very small health impacts as the restriction was designed to put an end date to a specific derogation under an existing restriction.	Health impacts could not be quantified.	Monetised benefits could not be estimated.

Benefits of restrictions in the EU					
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.
Decabromodiphenyl 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 tonnes of DecaBDE released per year.	Value of emission reduction could not be estimated.	Monetised benefits could not be estimated.
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 tonnes of PFOA and 36.4 tonnes 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: €3.9m.	323.0
Siloxanes D4 and D5 in in personal care products *	D4 is a PBT and vPvB substance and D5 is a vPvB substance. They cause adverse impacts in water ecosystems.	ENV	Reduction of 121 tonnes 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.

Benefits of restrictions in the EU					
4,4'-isopropylidenediphenol (Bisphenol A) in thermal paper	Risks for the unborn child for the following human health endpoints: • Mammary gland • Immunotoxicity • Female reproductive system • Brain and behaviour • Metabolism and obesity	HH	Reduced risk of adverse effects of BPA for 81 149 children of exposed cashiers.	Health impacts could not be quantified.	Monetised benefits could not be estimated.
Calcium cyanamide used as fertiliser	Contamination of soil and surface water adjacent to fertilised fields.	ENV	Environmental risk from calcium cyanamide would be removed from an area of up to 230 000 ha, this means a total of 53 000 tonnes of calcium cyanamide used in fertilisers per year. The (net) environmental impact of the restriction is difficult to describe.	Value of emission reduction could not be estimated.	Monetised benefits could not be estimated.

Benefits of restrictions in the EU					
N,N-dimethylformamide	Reprotoxic category 1B via the inhalation and dermal route (the most sensitive target organ is the liver). Eye irritant.	HH	1 300-2 500 workers with reduced risks for prostate cancer, liver cancer, liver cirrhosis and skin melanoma. 520-1 000 workers would continuously have alcohol intolerance. The main concern i.e. reprotoxic effects cannot be quantified. The quantitative health benefits were calculated to liver effects by using QALY points while many other benefits are qualitative.	Monetised value of one QALY point is €75 000. Monetised value per year calculated by dividing the lowest benefit estimate by the 15-year assessment period.	2.3
Perfluorohexane-1-sulphonic acid, its salts and related substances	Very persistent and very bioaccumulative.	HH and ENV	Reduced emissions and exposure of PFHxS to humans and the environment used as a proxy of benefits. Reduction of 0.42 tonnes of releases per year.	Value of emission reduction could not be estimated.	Monetised benefits could not be estimated.
Cobalt carbonate; cobalt di(acetate); cobalt dichloride; cobalt dinitrate; cobalt sulphate	Carcinogenic (inhalation). Mutagenic, Reprotoxic. Skin and respiratory sensitisers. Genotoxic carcinogens.	HH	Reduced cancer risk for about 8 400 workers. Around 0.24 cancer cases avoided every year. Other non-quantifiable human health benefits would also be expected.	VSL of €5m per fatal cancer case.	0.9

Benefits of restrictions in the EU					
Formaldehyde and formaldehyde releasers	Toxic if swallowed, toxic in contact with skin, causes severe skin burns and eye damage, toxic if inhaled, may cause cancer, suspected of causing genetic defects and may cause an allergic skin reaction.	HH	Reduction of the exposure to formaldehyde in indoor environments to levels below the WHO guideline. Avoided adverse health effects from indoor exposure to formaldehyde related to irritation of the eyes, upper airways and nasal cancer.	300 000 homes and 690 000 individuals could potentially benefit. Cost-effectiveness: €93/home and €41/individual.	Monetised benefits could not be estimated.
Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5); dodecamethylcyclohexasiloxane (D6)	Persistent, bio-accumulative or toxic (PBT) or very persistent and very bio-accumulative (vPvB)	ENV	Reduced emissions and subsequent exposure used as a proxy.	Emission reduction of 16 500 tonnes per year i.e. 90 % of the overall emissions. Cost per kg of releases prevented are estimated to be €3 for all releases (to air and water) and €1 000 for releases to water alone. When considering releases that remain in the environment, abatement costs would be €100 per kg per year.	Monetised benefits could not be estimated.

Benefits of restrictions in the EU					
Skin sensitising substances in textiles, leather, synthetic leather, hide and fur	Skin sensitisation	HH	Avoided lifelong sensitivity to a specific allergen. For avoided new sensitisation cases, the benefits are calculated over 2023+80 years, as the average life expectancy in the EEA. For the protection of already sensitised people, the benefits are calculated over 2023+30 years.	Avoided allergic contact dermatitis in main analysis; 4-5 million current cases and 45 000 – 180 000 new cases avoided per year. A sensitivity analysis assumed a lower range of 0.4 - 0.5 million current cases and 4 500 – 18 000 new cases per year (the benefit in the final column is based on this). New sensitisation case €3 800 - €13 900. Already sensitised individuals €3 700 - €13 800 per case.	708
Polycyclic-aromatic hydrocarbons (PAHs) in rubber granules and mulches	Carcinogenic.	HH	Avoidance of excessive exposure levels of PAHs in granules and mulches. Most of the expected benefits are qualitative and not quantified. For example, the reduced risks alleviate societal concerns and social impacts of these concerns, such as worries of exercising on artificial sports pitches and playgrounds.	Avoided cancer cases over a 10-year period: < 2. Value per cancer case (updated to 2016): €5.55m. Health benefits over a 10-year period: < €11m.	1.1

Benefits of restrictions in the EU					
Intentionally added microplastics	Irreversible damage to ecosystems.	HH and ENV	Microplastics are considered as non-threshold substances with releases considered as a proxy for risk. Impact can be assessed via the reduction in predicted releases that are forecast to occur without restriction.	Reduction of 500 000 tonnes over the 20 years following implementation, which is an abatement effectiveness over the same period of 70 % compared to no restriction. After all transitional periods expire, the annual abatement effectiveness is >90 % compared to no restriction. Average cost effectiveness of avoided emissions (excluding infill) is estimated to be €19/kg, ranging from €2/kg to €133/kg.	Monetised benefits could not be estimated.

Benefits of restrictions in the EU					
Substances in tattoo inks and permanent make up	Adverse skin effects. Carcinogenicity, germ cell mutagenicity, reproductive toxicity.	HH	Avoided skin reactions and other adverse effects.	In general, the health benefits of this restriction cannot be quantified and monetised. Costs of one case of severe non-infectious inflammatory reaction is approximately €4 350. The social costs to avoid other systemic, reproductive, developmental or carcinogenic illnesses would be significantly higher, but due to uncertainties these cannot be quantified. For the costs and benefits to break even, 1 050 cases of chronic allergic reactions that require surgical removal need to be avoided annually. This is between 0.02-0.06 % of the estimated number of people getting tattoos for the first time each year. It is reasonable to expect that these cases will be avoided as a result of the restriction.	Monetised benefits could not be estimated.

Benefits of restrictions in the EU					
Diisocyanates	Respiratory sensitisation.	HH	Avoided occupational asthma cases per year.	Annual value of asthma case is calculated to be €14 589/person. 6 500 new asthma cases estimated to be caused by exposure to diisocyanates annually. Restriction is estimated to avoid over 3 000 new occupational asthma cases per year in EU. The benefits of risk reduction are estimated to outweigh the costs of this restriction proposal after 3-6 years. 1.44 million workers potentially at high risk in EU.	369.4

Benefits of restrictions in the EU					
Perfluorononan-1-oic acid (PFNA); nonadecafluorodecanoic acid (PFDA); henicosafluoroundecanoic acid (PFUnDA); tricosafluorododecanoic acid (PFDoDA); pentacosafluorotridecanoic acid (PFTrDA); heptacosafluorotetradecanoic acid (PFTDA); including their salts and precursors	PBT/vPvB. Some of the substances are toxic to reproduction in humans.	HH and ENV	Reduced emissions and subsequent exposure used as a proxy of benefits. All populations and environmental compartments are potentially at risk. Safe concentration in the environment cannot be established.	Value of emission reduction could not be estimated.	Monetised benefits could not be estimated.
Lead and its compounds in shots over wetlands	Reprotoxic. Very toxic for the aquatic life, with long lasting effects.	HH and ENV	Avoided lead emissions.	4 750 tonnes of lead emissions avoided in wetlands. Avoided opportunity cost associated with the annual mortality of approximately 700 000 waterfowl from 16 wetland bird species known to ingest lead shot.	105
Lead and its compounds to stabilise PVC	Reprotoxic. Very toxic for the aquatic life, with long lasting effects.	HH and ENV	Avoided lead emissions.	7 tonnes of prevented lead release to the environment.	Monetised benefits could not be estimated.

Benefits of restrictions in the EU					
Diisobutyl phthalate (DIBP); Dibutyl phthalate (DBP); Benzyl butyl phthalate (BBP); Bis(2-ethylhexyl) phthalate (DEHP)	Four phthalates are reproductive toxicants, and adversely affect the male reproductive organs and sexual differentiation during foetal development, due to their common anti-androgenic effects. Other possible toxicity: effects on the immune system, (allergies, eczema, asthma, other respiratory symptoms, rhinitis) on metabolism (obesity or diabetes) and on neurological development (behavioural disorders including autism spectrum disorders, ADHD, learning disabilities, and altered play behaviour).	HH and ENV	Adverse health effects potentially caused by an exposure to the four phthalates. Infants and children are the most vulnerable and most exposed to the four phthalates.	More than 130 000 tonnes of the four phthalates in articles to be replaced annually over 20 years (6 500 tonnes per year). Risks to between 1.1 – 3.5 million male children are to be reduced over a time span of 20 years in the EU. Male infertility, 1 050 – 3 160 cases/year (with total monetised benefits of €9.9m-45.5m per year). Cryptorchidism, 50 – 1 200 cases/year (with total monetised benefits of €1.3m-360m per year). Hypospadias, 50 – 1 340 cases/year (with total monetised benefits of €1m-150m per year).	235
TDFAs in spray products	Acute inhalation toxicity	HH	Avoided respiratory diseases per year.	Consumer incidents related to spray products containing TDFAs and organic solvents estimated to be 161 incidents per year.	0.09

Source: https://echa.europa.eu/registry-of-restriction-intentions/

* *Reported in the first report 2010-2016: https://echa.europa.eu/documents/10162/13630/cost_benefit_assessment_en.pdf*

Overall benefits over costs

As health and environmental impacts could not been quantified in some cases, it was not possible to monetise the benefits of all restriction proposals. Similarly, not all costs were possible to quantify. Table 3 provides a comparison of quantified costs and benefits following the categorisation to monetised benefits, benefits based on emission reduction and other quantitatively and qualitatively described benefits as summarised in Tables 1 and 2.

Table 3: Costs and benefits

Costs and health and environmental benefits of REACH restrictions		
Case	**Cost per year**	**Benefits per year**
Monetised benefits		
Lead and its compounds in jewellery	€5.0m	€15.7m based on reduced IQ loss.
Chromium VI in leather articles	€100.8m	€354.6m based on reduced chromium allergies and resulting symptoms.
Lead and its compounds in consumer articles	€26.9m	Over €26.9m based on reduced IQ loss.
Methanol in windshield washing fluids	€40.4m	€323.0m based on avoided fatalities.
N,N-dimethylformamide	€79m	€2.3m based on avoided adverse effects to liver.
Cobalt carbonate; cobalt di(acetate); cobalt dichloride; cobalt dinitrate; cobalt sulphate	€3m	€0.9m based on avoided cancer cases.
Skin sensitising substances in textiles, leather, synthetic leather, hide and fur	€23.8m	€708m based on the protection of currently sensitised people and the prevention of new cases of allergic contact dermatitis
Polycyclic-aromatic hydrocarbons (PAHs) in rubber granules and mulches	€5m	€1.1m based on avoided cancer cases.
Diisocyanates	€114m	€369.4m based on avoided occupational asthma cases.
Lead and its compounds in shots over wetlands	€44m	€105m based on avoided opportunity costs associated with annual mortality of 700 000 waterfowl. 4 750 tonnes of lead emissions also avoided in wetlands.

Costs and health and environmental benefits of REACH restrictions		
Diisobutyl phthalate (DIBP); Dibutyl phthalate (DBP); Benzyl butyl phthalate (BBP); Bis(2-ethylhexyl) phthalate (DEHP)	€17.6m	€235m based on avoided adverse effects to male sexual development. Reduction of 6 500 tonnes of emissions of the four phthalates per year over the next 20 years. Reduced risks for 1.1-3.5m boys. (Lowered estimation used due to uncertainties.)
TDFAs in spray products	€0.012m	€0.09m based on avoided respiratory diseases per year
Sub-total	**€459.5m**	**Health benefits equivalent to €2.1bn per year**
Benefits based on emission reduction		
Mercury in measuring devices	€10.4m	Reduction of 3 tonnes of mercury placed on the market.
Phenylmercury compounds used e.g. in the production of polyurethane coatings	€1.3m	Reduction of 1.5 tonnes of mercury released.
Nonylphenol (NP) and its ethoxylates (NPE) in textile	€3.2m	Reduction of 15 tonnes of NP/NPE released to surface water.
Decabromodiphenyl ether (DecaBDE) as a flame retardant in plastics and textiles	€2.3m	Reduction of 4.74 tonnes of DecaBDE released.
Perfluorooctanoic acid (PFOA) and its salts, including substances that may degrade to PFOA	€36.1m	Reduction of 5.7 tonnes of PFOA and 36.4 tonnes of PFOA-related substances released.
Siloxanes D4 and D5 in personal care products	€51.3m	Reduction of 121 tonnes of the siloxanes D4 and D5 released per year.
Calcium cyanamide used as fertilser	€33m	Removal of 53 000 tonnes of calcium cyanamide used as a fertiliser on 230 000 ha of arable land.
Perfluorohexane-1-sulphonic acid, its salts and related substances	0	Emission reduction of 0.42 tonnes PFHxS in the environment.
Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5); dodecamethylcyclohexasiloxane (D6)	€63m	Reduction of 16 500 tonnes of emissions to the environment.
Intentionally added microplastics	€955m	Reduction of 500 000 tonnes of intentionally added microplastics over 20 years i.e. on average 25 000 tonnes per year.

Costs and health and environmental benefits of REACH restrictions		
Perfluorononan-1-oic acid (PFNA); nonadecafluorodecanoic acid (PFDA); henicosafluoroundecanoic acid (PFUnDA); tricosafluorododecanoic acid (PFDoDA); pentacosafluorotridecanoic acid (PFTrDA); heptacosafluorotetradecanoic acid (PFTDA); including their salts and precursors	0	Value of emission reduction could not be estimated. The benefits derive from preventing the potential future substitution from PFOA to C9-C14 substances.
Lead and its compounds to stabilise PVC	€2.1m	Reduction of 7 tonnes of lead emissions to the environment.
Sub-total	**€1.157bn**	**Reduction of about 95 000 tonnes of releases of substances of concern**
Other qualitatively or quantitatively described benefits		
Dimethylfumarate (DMF) in treated articles	€0.0m	No additional HH impacts. Renewable ban made permanent under REACH.
1,4-dichlorobenzene (DCB) in toilet blocks and air fresheners	€1.3m	80 850 male consumers and 140 toilet attendants not exposed above the DNEL.
1-Methyl-2-pyrrolidone (NMP)	€5.1m	The number of exposed pregnant workers at risk is not known.
Cadmium and its compounds in antifouling paints	€0.0m	No additional health or environmental impacts. Existing restriction entry clarified.
Use of asbestos fibres	€6.0m	Very small health impacts. An end date added to the specific derogation under the existing restriction.
Ammonium salts in cellulose as insulating material	€0.3m	Avoided respiratory symptoms and odour nuisance for 150 persons.
4,4'-isopropylidenediphenol (Bisphenol A) in thermal paper	€97m	Reduced risk of adverse effects of BPA for 81 149 children of exposed cashiers.
Formaldehyde and formaldehyde releasers	€28m	690 000 individuals could potentially benefit from exposure reductions in indoor environments to levels below the WHO guideline.
Substances in tattoo inks and permanent make-up	€4.6m	At least 1 050 people (0.02-0.06 % of people getting tattooed for the first time) avoiding adverse effects of chemicals used in tattooing inks and permanent make-up.

Sub-total	**€142.3m**	**Positive health impacts or removed risk for over 850 000 consumers and workers (where benefits not monetised).**
Total	**€1.76bn**	✓ Health benefits of over **€2.1bn** per year; ✓ Reduction of **95 000 tonnes** of releases of substances of concern; ✓ and positive health impacts or removed risk for over **7m** consumers and workers.*

**Including estimated population for all benefit categories*
Source: Summarised information in Tables 1 and 2 from the combined RAC and SEAC opinions and background documents available at: https://echa.europa.eu/registry-of-restriction-intentions

It is clear from Table 3 that it is not possible to aggregate different categories of benefits.

However, in those 12 cases where both costs and benefits were monetised, the monetised cost estimates add up to €460 million and the benefits to €2.1 billion. Thus, the estimated monetised benefits of these REACH restrictions were more than four times higher than their costs.

The overall costs of restrictions where benefits are calculated in reduced emissions are estimated at €1.1 billion per year and the reduction is estimated to add up to about 95 000 tonnes per year. So, the costs of reduced tonnes of emissions of hazardous substances are estimated to be around €12 000 per tonne. This means that with REACH restrictions, it costs around €12 to reduce one kilogram of emissions of hazardous chemicals.

Since the first report in 2016, the proposed restrictions have become more costly but the estimated benefits in terms of monetised health impacts as well as reduced emissions have, at the same time, grown even more.

☞ ECHA has invested on average 2-3 full time equivalents (FTEs) to prepare one restriction report. This implies a cost of about €300 000 to prepare one EU wide restriction dossier. Out of the restriction dossiers processed so far, ECHA has prepared 14 proposals (~40 %) on its own (i.e. requested to do so by the European Commission) or in collaboration with Member State authorities.

Six of them have been decided, six are in the opinion development phase and ECHA's committees have adopted their opinions in three cases, but the European Commission has not yet made a final decision.

Three of the five current restriction intentions are declared by ECHA. The other restriction proposals and intentions have been prepared by the authorities of Denmark, France, Germany, Italy, the Netherlands, Norway, Poland, Sweden, and the United Kingdom.

After the sunset date has passed for substances included in the Authorisation List of REACH (Annex XIV), Article 69(2) of REACH requires ECHA to consider if uses of these substances in articles are adequately controlled. If they are not, ECHA needs to prepare a restriction dossier for such uses. Such restriction dossiers are included in the figures of this report. ECHA may also conclude that no restriction is warranted, for example, because articles do not contain a substance of very high concern. So far, ECHA has determined that no REACH restriction is warranted for five substances subject to authorisation. These reports are available on ECHA's website.[12]

[12] https://echa.europa.eu/completed-activities-on-restriction

Annexes: Descriptions of the restriction cases 2016-2020

Impact of restricting bisphenol A (BPA) in thermal paper

Restricting BPA in thermal paper protects the children of our cashiers. However, there is evidence that industry has substituted bisphenol A (BPA) with bisphenol S (BPS) which may cause similar adverse health effects. Therefore, restricting the use of BPS in thermal paper needs to be considered.

Hazards
According to harmonised classification and labelling, bisphenol A may damage fertility, causes serious eye damage, may cause an allergic skin reaction and may cause respiratory irritation.

For this restriction, BPA's effects on several human health endpoints were considered. For example, its adverse effects to the female reproductive system, the brain and behaviour, the mammary gland, metabolism and obesity.

Scope of the restriction
The original restriction proposal by France identified a risk for workers, primarily cashiers, and consumers exposed to BPA by handling thermal paper receipts. The population at risk was the unborn children of pregnant workers and consumers exposed to BPA contained in the thermal paper.

RAC concluded that the risk for consumers is adequately controlled but confirmed the risk for workers.

As the final restriction is not following the proposal, the original cost and benefit estimates cannot be used. Therefore, SEAC performed a break-even analysis and concluded that, overall, the estimated costs outweigh the potential health benefits. However, SEAC noted that the cost of the restriction amounts to a very small proportion of the total personnel costs or gross operating surplus of the affected sectors and would lead to a very small price increase if costs are transferred to consumers through increased prices. SEAC also noted that the restriction could lead to a more equitable distribution of the impacts, considering that the sub-population of cashiers potentially at risk is disproportionately affected by the adverse health effects, whereas the economic impact would be evenly shared by the wider population.

SEAC concluded that, when comparing the socio-economic benefits to the socio-economic costs, the restriction is unlikely to be proportionate. Especially if industry substitutes BPA with bisphenol S (BPS), which is the most likely substitute to BPA and has a similar toxicological profile and causes similar adverse health effects as BPA.

However, there are favourable distributional and affordability considerations for this restriction. Many benefits of the reduced exposure to BPA are related to health effects that are unquantifiable. For example, an increase in ovarian cysts, disruption of ovarian cycles, alteration of spacial memory or alteration of learning functions.

In 2016, based on ECHA's committees' opinions, the Commission decided that there is an unacceptable risk to the health of workers who handle thermal paper containing BPA. Therefore, BPA shall not be placed on the market in thermal paper in a concentration equal to or greater than 0.02 % by weight after 2 January 2020.

To avoid that the adverse effects of BPA would be superseded by the adverse effects of BPS after BPA's restriction, ECHA has monitored the use of BPS in thermal paper. According to ECHA's findings, there are clear indications of this substitution taking place. Therefore, ECHA recommends that the Commission considers whether a restriction for the use of BPS in thermal

paper would also be necessary.

Costs

Case	Cost categories covered	Cost per year (€m)	Remarks
BPA	Substitution and compliance costs	€43m-151m (average €97m)	Average yearly costs over the period 2019 - 2030

Benefits

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 (€m)
BPA	Risks for the unborn child for the following human health endpoints: - Mammary gland - Immunotoxicity - Female reproductive system - Brain and behaviour - Metabolism and obesity	HH	Reduced risks for the unborn children of cashiers exposed to BPA from thermal paper: - 39 500 daughters at risk for the mammary gland and the reproduction toxicity endpoints per year. - 81 149 children at risk for immunotoxicity, neurobehaviour effects, and effects on the metabolism per year.	Not quantifiable	Not quantifiable

Further information
Official Journal entry (R 2016/2235 (Annex XVII entry 66))
Opinions and background documents (Registry of intention)
Use of bisphenol A and its alternatives in thermal paper in the EU (2020)

Figure 2: Costs and benefits of restricting BPA

Protecting unborn babies

BPA in thermal paper

Bisphenol A (BPA) may be toxic for reproduction and has been identified as a substance affecting the hormonal systems of humans and animals. In addition, it may damage eyesight and cause allergic skin reactions and respiratory irritation.

Thermal paper is a paper coated with a reactive layer that changes colour when exposed to heat. It is used, for example, in point-of-sale tickets and receipts, self-adhesive labels, lottery tickets and fax paper.

What is the concern?

Pregnant cashiers handling receipts containing BPA could unknowingly be risking their unborn children's health.

Being exposed through the mother may affect children's sexual development, immune systems and brain development. BPA may also cause changes in female breast tissue that can lead to breast cancer later in life, and metabolic disorders that can lead to diabetes or obesity.

There is evidence that companies have substituted BPA with BPS, which is also suspected to affect human reproductive and hormonal systems.

What has the EU done?

Since January 2020, the use of BPA in thermal paper has been restricted. This restriction could avoid adverse effects to **more than 81 000 children each year** depending on the alternative substance used.

The costs to industry for replacing BPA with safer alternatives (other than BPS) are estimated to be **less than € 100 million per year**.

Even if these costs are passed on to consumers, it will only mean a small increase in the prices of everyday products, as these costs are shared among all consumers in the EU/EEA.

Impact of restricting calcium cyanamide

Around 53 000 tonnes of calcium cyanamide is used in fertilisers per year in EU. By restricting its use in fertilisers, the adverse effects on non-target organisms, soil, surface and ground water could be avoided. The environmental risk from calcium cyanamide would be removed from an area of up to 230 000 hectares.

Hazards
According to harmonised classification and labelling, when used as a fertiliser calcium cyanamide rapidly hydrolyses to cyanamide especially in water. In soil, calcium cyanamide breaks down to calcium hydroxide and cyanamide. Calcium cyanamide is also harmful if swallowed, causes serious eye damage and may cause respiratory irritation, but the restriction focuses on environmental effects.

Calcium cyanamide is classified as Acute Tox. 4 (STOT SE 3) and Eye Dam. 1, while the closely related substance, cyanamide, is classified as Aquatic Chronic 3, Carc. 2, Repro. 2, Acute Tox. 3, Acute Tox. 3, STOT RE 2, Skin Corr. 1, Skin Sens. 1, Eye Dam. 1.

Scope of the restriction
Around 130 000 tonnes of calcium cyanamide is manufactured in the EU per year of which about 53 000 tonnes are used in fertilisers. Calcium cyanamide-based fertilisers are supplied mainly to professional farmers and estimated to be used for fertilising about 230 000 hectares i.e. about 0.2 % of the arable land in the EU.

Calcium cyanamide is a slow release nitrogen fertiliser available in granulated form and used for a number of EU agricultural crops. Besides being a fertiliser, calcium cyanamide appears to have "secondary effects" helping plants to compete in stressed environments and helping farmers to prevent plant diseases and pests. However, calcium cyanamide is not approved for use in Plant Protection Products (PPPs) in the EU.

The use of calcium cyanamide as a fertiliser leads to a not adequately controlled risk for both soil and surface water adjacent to fertilised fields. According to the dossier, there does not appear to be a risk to human health from calcium cyanamide contaminated groundwater, although the quality of groundwater may be affected. However, the Biocidal Products Committee provided an opinion in December 2019 that cyanamide is an endocrine disruptor for human health and non-target organisms[13]. If this agreement is confirmed by the European Commission, it will further strengthen the case that the use of calcium cyanamide as a fertiliser leads to a risk that is not adequately controlled.

Therefore, ECHA has proposed to restrict the placing on the market of calcium cyanamide used as a fertiliser. The proposal includes a transitional period of 36 months recommended for the implementation of the restriction. Originally, a derogation was proposed if used in granulated form in a closed system, however, the derogation was challenged in the on-going committee assessments and the derogation has been dropped.

[13] On 4-5 June 2019, the Endocrine Disruptor Expert Group (ED EG) reached a broad agreement that the information available is sufficient to identify the substance as an endocrine disruptor with regard to human health. On 18-19 September, the Biocides Human Health Working Group concluded that cyanamide meets the criteria for endocrine disruption for human health and on 26-27 September 2019, the Biocides Environment Working Group agreed that the current data set is sufficient to conclude on the ED properties of cyanamide for non-target organisms.

Costs and benefits
According to the restriction proposal, the proposed restriction on calcium cyanamide would result in significant impacts for affected farmers. Reduced profits to farmers due to decreased quantity and quality of yields is expected to be substantial. Losses to manufacturers are expected to be significant, however, net societal effects are unclear as producers of alternatives would likely gain in the process.

The price of calcium cyanamide tends to be higher than the prices of alternative fertilisers and soil improvers. However, the increased value of the yield (quality and quantity) as well as potential cost savings arising from decreased plant protection activities seem to compensate the higher costs as it is continuously used by some farmers, especially in the production of high value crops.

The value of the benefits from the proposed restriction are difficult to describe in practise and cannot be quantified but have been qualitatively assessed to include better environmental quality in surface water adjacent to the fertilised fields and better soil quality.

The proposed restriction would provide net benefits for the environment where calcium cyanamide is currently used on arable land.

If cyanamide is found to be an endocrine disrupter, the case for the restriction will be more robust based on an impact on the groundwater (humans via the environment) and on other organisms.

Costs

Case	Cost categories covered	Cost per year (€m)	Remarks
Calcium cyanamide	Decreased profitability in farming (quality, quantity losses in harvest, increased plant protection input costs). Reduced manufacturing of calcium cyanamide for used as fertiliser.	€33m	Average productivity loss range in a realistic case €16m-€50m per year

Benefits

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 (€m)
Calcium cyanamide	Contamination of surface water adjacent to fertilised fields and to soil.	ENV	Environmental risk from calcium cyanamide would be removed from an area of up to 230 000 ha. Effects on non-target organisms – soil, surface water. Contamination of ground water.	Not quantifiable	Not quantifiable

Further information
Official Journal entry (Not decided)
Opinions and background documents (Registry of intention)

Impact of restricting N,N-dimethylformamide (DMF)

By bringing the exposure levels of N,N-dimethylformamide (DMF) to a safe level at workplaces, 1 300-2 500 workers, who are currently exposed to DMF at a level which might cause liver effects or developmental effects to children of female workers, would be able to continue working with reduced risks to their health. One of the main benefits of this restriction – avoiding reproductive and development effects – cannot quantified, nor monetised.

Hazards
According to harmonised classification and labelling, DMF is a reproductive toxicant (category 1B) via inhalation and dermal route but the most sensitive target organ is the liver. It is also classified as an eye irritant. A threshold for safe use can be calculated.

Scope of the restriction
DMF is an aprotic medium polar organic solvent, which is used at high volumes in the EEA for a broad range of industrial and professional uses. A large number of workers are likely to be exposed to it and therefore targeted assessment of the risk to workers is warranted.

While occupational exposure to DMF is expected, the exposure to humans through the environment can be excluded since the substance is readily biodegradable and no potential for bioaccumulation exists. Thus, this restriction proposal is targeted at occupational exposure to DMF.

Not adequately controlled risks for workers were identified, for example, for the industrial use of DMF to produce fine chemicals, pharmaceuticals, polymers and production of textiles, leather and fur.

In 2018, Italy proposed an EU-wide restriction for DMF and ECHA's scientific committees have agreed that the risks are not sufficiently controlled in workplaces and that this restriction is, therefore, warranted with the following conditions including RAC-derived DNELs:

- In their chemical safety assessment and safety data sheets, manufacturers, importers and downstream users of DMF on its own (regardless of whether it is a (main) constituent, an impurity or a stabiliser) or in mixtures in a concentration equal or greater than 0.3 % have to use a worker-based harmonised derived no-effect level (DNEL) value for long-term inhalation exposure of 6 mg/m^3 and a worker-based harmonised DNEL for long-term dermal exposure of 1.1 mg/kg bw/day by a specific date [date to be agreed when the restriction is adopted].

It is noteworthy, that the DNEL values in the original restriction dossier were lower than the RAC-derived DNELs i.e. the DNEL value for long-term inhalation exposure of 3.2 mg/m^3, and a worker-based harmonised DNEL for long-term dermal exposure of 0.79 mg/kg bw/day.

RAC and SEAC support a two-year transition period from the entry into force of the restriction as proposed by the dossier submitter.

Costs and benefits
Total overall costs for industry due to this restriction were originally estimated to be €865 million-€1.5 billion over a 15-year period. However, SEAC finds this estimate severely overestimated. The overestimation is even more significant when applying the RAC-derived DNELs, as the higher DNELs are expected to be less costly to comply with. Costs would be significantly less if sufficient time is given for industry to adjust to the restriction. SEAC does not find it likely that industry would close down due to the restriction.

The main reason for the restriction is to avoid reprotoxic effects in the form of developmental effects, unfortunately, there is no quantification of the benefit available for these effects. The

quantitative health benefits could only be calculated to liver effects (alcohol intolerance) while many other benefits are qualitative. SEAC considers that the restriction provides clear benefits despite the estimated quantitative benefits appearing significantly less than what was initially estimated. The effectiveness of the restriction is supported by qualitative analysis and although the quantitative health effects are quite uncertain, qualitative effects support them.

Costs

Case	**Cost categories covered**	**Cost per year (€m)**	**Remarks**
N,N-dimethylformamide	Mostly related to assumptions that industry would close down production.	€58m-100m (if simply divided by the 15-year assessment period)	€865m-€1.5bn over a 15-year period (original estimates in the dossier). SEAC finds the overall cost estimate severely overestimated.

Benefits

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 (€m)**
N,N-dimethyl formamide	Reprotoxic category 1B via inhalation and dermal route (the most sensitive target organ is the liver.) Eye irritant.	HH	Prostate cancer, liver cancer and skin melanoma. Liver cirrhosis.	The main, reprotoxic effects are **not** quantified. Quantified effect: €35m-68m over 15 years (4 % discount rate). Up to €77m over 15 years (with 2 % discount rate). 1 300-2 500 workers will benefit.	€2.3m (if lowest estimate simply divided by the 15-year assessment period)

Further information
Official Journal entry (not decided)
Opinions and background documents (Registry of intention)

Impact of restricting PFHxS

PFHxS is one of the most frequently detected perfluorinated substances (PFAS) in human blood samples worldwide. It is also ubiquitously detected in environmental samples. PFHxS is a very persistent and very bioaccumulative substance and it is found universally in the environment all over the world. It has been detected in wildlife even in the most remote areas like in Arctic species. This EU-wide restriction could be seen to lead the way for global risk management actions for PFHxS, such as listing it in the Stockholm Convention on persistent organic pollutants.

Hazards
PFHxS is identified as a substance of very high concern (SVHC) due to its very persistent and very bioaccumulative properties. PFHxS-related substances degrade to PFHxS.
The substance is found in high levels in the environment, and concentrations in the environment and in human blood serum are increasing.

PFHxS bioaccumulates in air-breathing mammals, including endangered species and humans. PFHxS has the longest human elimination half-life, more than 42 years, of all perfluoroalkyl and polyfluoroalkyl substances (PFAS) for which data are available.

Scope of the restriction
The proposal is to restrict the manufacture or placing on the market of PFHxS, its salts or related substances and as a constituent of another substance, in a mixture or in articles.

Although there are currently no known intentional uses of PFHxS in the EU, historically it has been used, for example, in textiles due to its water and oil repellence properties and also in fire-fighting foams. PFHxS may also be present as an impurity of perfluorooctanesulphonic acid (PFOS) in limited applications that are still permitted.

Along with PFOS and PFOA, PFHxS is the most frequently detected perfluorinated substance in human blood samples worldwide. It is also ubiquitously detected in environmental samples.

PFHxS leaches from contaminated sites, such as airports and training areas for firefighters and can be a long-term source of contamination to groundwater and drinking water. It is also still being used as a substitute for PFOS and PFOA in a number of applications outside of the EU.

This restriction is necessary to avoid regrettable substitution of PFOA with PFHxS. A restriction on PFOA has applied since 4 July 2020. Restriction would reduce the environmental emissions from articles and mixtures imported to the EU, for example, water repellent outdoor textiles.

Alternatives to PFHxS are available, many of which are fluorine-free. This EU-wide restriction may be the first step for global risk management actions for PFHxS.

Norway has already proposed to list PFHxS, its salts and PFHxS-related compounds in the annexes of the Stockholm Convention on persistent organic pollutants.

Costs and benefits
The costs to EU producers and importers of articles associated with this restriction proposal are considered negligible.

There is no safe concentration for PFHxS, thus a threshold cannot be determined. For this reason, the restriction is based upon minimising the emissions of PFHxS to humans and the environment. No monetary valuation of human health impacts is possible because a quantitative cause and effect relationship between PFHxS levels and different health endpoints has not been defined.

Summary of emissions under the baseline and under the proposed restriction:Time period	Baseline (tpa)	Restriction (tpa)
1990-2010	2.1	2.1
2011-2019	0.22	0.22
2020-	0.44	0.02

With this restriction, the PFHxS emissions could be reduced by 90 % from the 2019 level.

Costs

Case	**Cost categories covered**	**Cost per year (€m)**	**Remarks**
PFHxS	Qualitative discussion on possible higher prices of imported articles and costs for not being able to use PFHxS as a substitute for PFOA.	Limited	There is no identified use of PFHxS, its salts and PFHxS-related substances in the EU.

Benefits

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 (€m)**
PFHxS	Very persistent and very bioaccumulative	ENV	Reduced emissions and exposure of PFHxS to humans and the environment.	Reduction of 0.42 tonnes of releases per year.	Not quantifiable

Further information
Official Journal entry (not decided)
Opinions and background documents (Registry of intention)

Impact of restricting five soluble cobalt salts

With the proposed restriction on cobalt carbonate; cobalt di(acetate); cobalt dichloride; cobalt dinitrate; and cobalt sulphate, tens of thousands of workers would be less exposed to these cancer-causing chemicals every year. The volumes of these chemicals are expected to grow due to the rapidly increasing demand for rechargeable batteries.

Hazards
The cobalt salts are classified as Carcinogenic 1B (inhalation), Mutagenic 2, Reprotoxic 1B as well as skin and respiratory sensitisers.

In 2016, RAC agreed that the cobalt salts should be considered as genotoxic carcinogens with a non-threshold mode of action. All five cobalt salts are identified as substances of very high concern (SVHCs) and included in the Candidate List.

Scope of the restriction
These five cobalt salts are manufactured and used in many sectors in Europe, including the manufacture of chemicals, catalysts, battery production, surface treatments and biogas. 30 000 tonnes of the cobalt salts are used per year in the EU.

The volumes placed on the EU market have doubled in the last decade and the rise is expected to continue due to increasing demand for rechargeable batteries and biotechnology-health applications.

Around 35 000 workers at around 20 000 industrial sites are estimated to be exposed to the cobalt salts.

Therefore, the Commission has requested ECHA to assess the risks related to industrial and professional uses of these five cobalt salts and to propose a restriction to those uses where adequate control cannot be demonstrated.

ECHA's original proposal suggested that the five cobalt salts must not be manufactured, placed on the market or used as substances on their own or in mixtures in a concentration equal or above 0.01% by weight, unless a specific requirement would have been met.

The proposal is currently under the opinion forming stage in ECHA's scientific committees.

RAC modified the conditions of the original restriction proposal and additionally proposed to derive a binding occupational exposure limit value (BOELV) for cobalt and its inorganic compounds according to the EU's directive on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (2004/37/EC/CMD).

SEAC is uncertain whether the restriction as amended by RAC is the most appropriate EU-wide measure. The uncertainties are related to proportionality aspects and to the discussion on whether a binding occupational exposure limit would be a more appropriate risk management measure to address the risks.

Costs and benefits
The impacts are assessed by comparing the compliance costs with the monetised human health impacts avoided. Costs and benefits of the proposed restriction are annualised and presented at 2018 price levels. Other non-quantifiable human health benefits would also be expected to occur due to the implementation of this restriction.

SEAC considers that the costs of implementing the restriction exposure values have been underestimated in the original dossier (€1 million-€5 million). However, SEAC notes that also

the alternative assessment (€42 million-€987 million) provided during the consultation contains shortcomings and represents an overestimation of costs.

SEAC considers that the number of exposed workers might also have been underestimated which leads to an underestimation of the monetised human health benefits.

Costs

Case	**Cost categories covered**	**Cost per year (€m)**	**Remarks**
Cobalt and its salts	Compliance, investment and operation costs.	€42m-€987m for RAC's recommended restriction option.	

Benefits

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 (€m)**
Cobalt and its salts	Carcinogenicity 1B (inhalation) Mutagenic 2, Reprotoxic 1B Skin and respiratory sensitisers. Genotoxic carcinogens	HH	Number of expected cancer cases avoided 18 900 workers less exposed. Around 0.24 (as in RAC's amended calculation) cancer cases avoided every year.	€5m per fatal cancer case is used.	€0.9m for RAC's recommended restriction option.

Further information
Official Journal entry (Not decided)
Opinions and background documents (Registry of intention)

Impact of restricting formaldehyde

Around 300 000 homes or 690 000 individuals could potentially benefit from reductions in formaldehyde exposure in Europe.

Hazards
According to harmonised classification and labelling, formaldehyde is toxic if swallowed, toxic in contact with skin, causes severe skin burns and eye damage, toxic if inhaled, may cause cancer, suspected of causing genetic defects and may cause an allergic skin reaction.

Scope of the restriction
Formaldehyde is a high-production volume chemical. It is predominantly used as a chemical intermediate to manufacture formaldehyde-based resins and other chemicals.

Off-gassed formaldehyde from articles contributes to consumer exposure in indoor environments. Wood-based panels, which use formaldehyde-based resins as a bonding agent for wood particles, and articles made from such panels (e.g. furniture) are major formaldehyde emission sources.

The WHO has established an indoor air quality guideline for formaldehyde exposure of 0.1 mg/m^3, which is considered protective for the general population. Major European industry sectors have already made voluntary commitments to reduce formaldehyde emissions. Yet, under certain circumstances, there still is a potential for consumer exposure to formaldehyde levels above the WHO guideline value.

ECHA proposes a restriction under REACH to keep formaldehyde concentrations in indoor environments below the WHO guideline. ECHA's proposal would restrict the placing on the market of articles produced using formaldehyde or formaldehyde-releasing substances if the formaldehyde released from these articles exceeds the limit of 0.124 mg/m^3 (measured in the air of a test chamber).

Additionally, the concentration of formaldehyde in the interior of road vehicles and aircraft should not exceed the limit of 0.1 mg/m^3. Articles for outdoor use only, articles exclusively for industrial and professional use, second-hand articles, articles subject to other existing EU legislation (i.e. medical devices, personal protective equipment, toys, clothing and footwear), as well as the use of formaldehyde and formaldehyde releasers as a biocide are intended to be exempted from the proposed restriction. The proposal includes a 12-month transition period after the possible entry into force.

The benefits of reduced formaldehyde exposure that would result from this restriction are expected to be achievable at limited costs.

RAC proposed a tighter limit value of 0.05 mg/m^3 both for formaldehyde released from articles and for the concentration of formaldehyde in the interior of road vehicles. SEAC's draft opinion notes that while such tighter limits would potentially bring additional benefits, it would also significantly increase the costs of the restriction.

Costs and benefits
This restriction would prevent high formaldehyde emitting articles from being placed on the EU market and it would harmonise the existing rules on formaldehyde emissions for the entire Union.

Around 300 000 homes or 690 000 individuals could potentially benefit from reductions in formaldehyde exposure to levels below the WHO guideline.

Costs

Case	Cost categories covered	Cost per year (€m)	Remarks
Formaldehyde and formaldehyde releasers	Increase in production costs, enforcement costs.	€28m	For the reference year 2016, the cost increase to EU society is estimated to be in the range of €28-€79m. A value of €28m represents the dossier submitter's central estimate for the cost increase associated with the proposed restriction.

Benefits

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 (€m)
Formaldehyde and formaldehyde releasers	Toxic if swallowed, toxic in contact with skin, causes severe skin burns and eye damage, toxic if inhaled, may cause cancer, suspected of causing genetic defects and may cause an allergic skin reaction.	HH	Reduction of the exposure to formaldehyde in indoor environments to levels below the WHO guideline. Adverse health effects from indoor exposure to formaldehyde related to irritation of the eyes, upper airways and nasal cancer.	300 000 homes and 690 000 individuals could potentially benefit.	Cost-effectiveness: €93/home €41/individual. Monetised benefits could not be estimated.

Further information
Official Journal entry (Not decided)
Opinions and background documents (Registry of intention)

Impact of restricting cyclosiloxanes D4, D5 and D6

Up to 90 % of the releases of D4, D5 and D6 to the environment could be prevented by restricting their uses in cosmetic and cleaning products. There are alternatives available for the majority of identified uses of D4, D5 and D6.

Hazards
Octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6) are collectively known as cyclosiloxanes and have been identified as substances of very high concern with persistent, bioaccumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) properties.

Scope of the restriction
PBT/vPvB substances accumulate in the environment and cause long-term effects that are unpredictable. The effects are difficult to reverse even after releases stop. Therefore, the risk from PBT/vPvB substances cannot be quantified by deriving risk characterisation ratios. Emissions are therefore typically considered as a proxy for risk.

These cyclosiloxanes are manufactured in four production sites in the EU, producing up to 200 000 tonnes of D4, 50 000 tonnes of D5 and 6 000 tonnes of D6 per year. These siloxanes are used in a variety of sectors mainly as intermediates for the production of silicone polymers, but also as substances on their own or in mixtures that are used by consumers and professionals.

The total releases to the environment (air and water) from the uses of D4, D5 and D6 have been estimated to be approximately 18 000 tonnes per year. ECHA estimates that the steady-state stock of D4, D5 and D6 that remains in the environment associated with these releases is approximately 500 tonnes.

A restriction for D4 and D5 in wash-off cosmetic products has applied since 31 January 2020. Despite the existing restriction, the wide-dispersive use of D4, D5 and D6 in other types of cosmetic products remains the main source of releases.

Therefore, at the request of the Commission, ECHA has proposed to restrict the use of these siloxanes also in leave on cosmetic products and other consumer/professional products such as in dry cleaning, waxes and polishes, washing and cleaning products. According to the restriction proposal such products containing D4/D5/D6 in concentrations above 0.1% must not be placed on the market. In addition, wash off and rinse off cosmetic products containing D6 in concentrations above 0.1 % w/w must not be placed on the market. The proposal includes derogations and transitional periods of different durations for some uses to avoid disproportionate socio-economic impacts.

Higher concentration limits are also proposed for some uses of silicone polymers (where D4/D5/D6 are present as impurities above 0.1% w/w) to ensure they are not inadvertently affected by the restriction.

Although up to 90 % of the releases of D4, D5 and D6 could be reduced with this restriction proposal (from 18 000 tonnes per year to around 1 500 tonnes per year post restriction), the emissions will not totally cease as releases will continue from uses of silicone polymers where the concentration of D4, D5 and D6 is below the limits proposed in the restriction, and from derogated uses.

Costs and benefits
Only costs for the cosmetics industry were quantified. The impact of the restriction on other uses was assessed qualitatively.

Costs

Case	Cost categories covered	Cost per year (€m)	Remarks
D4, D5, D6	Compliance costs for the cosmetics industry (majority of those costs – ~€54 m per year – related to the costs of reformulations).	€63m	€703m overall (present value) in 20 years for cosmetic products, assuming a five-year transitional period.

Benefits

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 (€m)
D4, D5 and D6	Persistent, bio-accumulative or toxic (PBT) or very persistent and very bio-accumulative (vPvB).	ENV	Emissions and subsequent exposure.	Cost per kg of releases prevented are estimated to be €3 for all releases (to air and water) and €1 000 for releases to water alone. When considering releases that remain in the environment, abatement costs would be €100 per kg per year.	Cannot be quantified.

Further information
Official Journal entry (not decided)
Opinions and background documents (Registry of intention)

Figure 3: Costs and benefits of restricting D4, D5 and D6

Keeping our air and water clean

Cyclosiloxanes D4, D5 and D6

The cyclosiloxanes D4, D5 and D6 are silicone-based compounds that have been identified as being persistent, bio-accumulative or toxic (PBT) or very persistent and very bio-accumulative (vPvB).

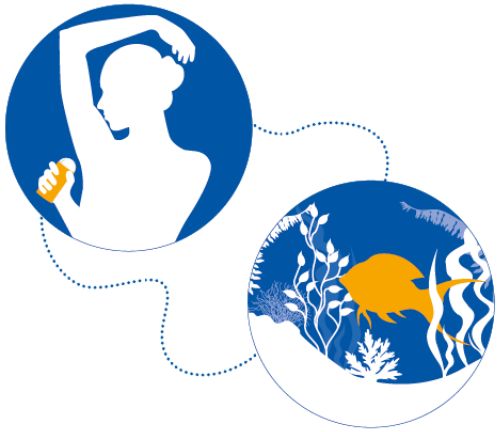
Where can you find them?

They are used in cosmetics, such as deodorants and antiperspirants, make-up, skin care and hair styling products. Car polishes and waxes might also contain these substances.

What is the concern?

The compounds build up in the environment and in aquatic food chains. D4 is suspected of damaging fertility.

The annual releases to the environment are currently estimated at 18 000 tonnes, leading to an environmental stock of approximately 500 tonnes. Cosmetics are the main source of the releases.



What is the EU doing?

ECHA is proposing to restrict the use of these chemicals in the EU. Our proposal could prevent up to 90 % of annual releases. The estimated costs to industry will be € 700 million over 20 years.

The use of D4 and D5 in wash-off cosmetics has already been restricted since February 2020.

Impact of restricting skin sensitising substances in textile, leather, synthetic leather, hide and fur articles

There is a growing concern about skin sensitisation due to exposure to chemicals in textile and leather articles. Up to 1 % of the population of the European Economic Area (EEA) is expected to be sensitised to chemical substances present in finished textile and leather articles. This means around five million citizens. Skin sensitisation is a health effect which leads to a lifelong sensitivity to a specific allergen. Restricting skin sensitisers in textiles and other articles that come into contact with skin aims to reduce the risk of sensitisation via the skin to chemical substances. The monetised benefits of this restriction could be billions of euros per year.

Hazards
Skin sensitisation of substances with a harmonised classification as skin sensitisers in category 1/1A/1B, as listed in Annex VI to the CLP Regulation. Allergic reactions caused by 24 disperse dyes that are indicated to have skin allergenic properties, but with no harmonised classification as skin sensitisers.

Scope of the restriction
This restriction proposal concerns the placing on the market of textile, leather, synthetic leather, hide and fur articles containing skin sensitising substances with direct and prolonged contact with the skin.

The dossier submitted by France and Sweden focuses on skin sensitising substances that may be present in textile and leather articles, including all substances classified as skin sensitisers under the CLP Regulation. The dynamic relationship with the CLP Regulation means that substances that are classified as skin sensitisers in the future will also be covered by the restriction.

However, SEAC concluded that for substances classified as skin sensitisers after the restriction's entry into force, there are good justifications to implement a transitional period of three years between classification and the conditions of the restriction taking effect, allowing information on alternatives or relevant specific concentration limits to be considered before the restriction took effect.

The proposal is that the substances covered by the restriction could no longer be present in articles covered by the restriction above a proposed concentration limit. A transitional period of 36 months after entry into force has been proposed.

Costs and benefits
The expected costs from the proposed restriction include:

- Raw material costs: Based on the available data on cost differences per unit used for groups of skin sensitisers and substitutes, the dossier submitter has estimated an overall total cost of between -€25 million and €3 million per year. These estimates include negative costs for substances where the substitutes are cheaper than the substances currently used. Without the negative costs, the total annual costs are estimated to be between €10 000 and €23.8 million per year. It should be noted that data on substitution costs is missing for some substances.
- Reformulation costs: A number of rubber accelerators are expected to require reformulation. The dossier submitter estimates that the total one-time cost for reformulating rubber accelerators would be €13.3 million. Reformulation may be needed for other substances as well.
- Cost of switching to best practice: For diisocyanates and possibly solvents, a change in manufacturing and processing practice can lead to a situation where the substances are not present above the proposed concentration limits in articles placed on the market for the general public. The cost related to this has not been estimated due to lack of data.

- Enforcement costs: Both industry and enforcement authorities will need to perform additional testing to ensure compliance with the restriction. Based on the available information about testing costs for phthalates esters, formaldehyde, disperse dyes, cobalt and chromium, the dossier submitter estimates that the annual testing costs during the first couple of years would be €82 800. However, information submitted in the consultations suggest that the testing costs for industry may be higher. SEAC, therefore, agreed with the dossier submitter in that there are many uncertainties related to testing costs and that the limited information at hand does not allow for a proper quantitative assessment of these costs.

The prevalence of allergic contact dermatitis caused by substances in textile and leather in the general population is estimated by the dossier submitter to be around 0.8 %-1%, which means that 4-5 million individuals would already be sensitised in the EEA. Due to uncertainties regarding the prevalence data behind these assumptions, the dossier submitter and SEAC agreed to undertake a sensitivity analysis of the expected lower boundary, assuming a 0.08 %-0.1% prevalence with a total number of 400 000-500 000 already sensitised individuals in the EEA.

The calculated incidence of allergic contact dermatitis to skin sensitising substances in textiles and leather is around 0.01%-0.04%, i.e. 45 000-180 000 new cases are expected in the EEA per year. Similarly to the prevalence calculations, the sensitivity analysis assumes a lowest boundary of 0.001%-0.004%, with 4 500-18 000 new cases per year.

The human health benefits assessment focuses on allergic contact dermatitis. The total annual costs per new case are estimated to be in the range of €3 800-€13 900 and the annual costs related to already sensitised individuals per prevalent case would be €3 700-€13 800.
For avoided new sensitisation cases, the benefits are calculated over 2023+80 years, as the average life expectancy in the EEA. For the protection of already sensitised people, the benefits are calculated over 2023+30 years. The valuation of human health benefits assumes that the restriction would protect 70%-90% of existing sensitisation cases from chemical substances in textile and leather articles.

Some not quantifiable benefits can also be expected, e.g. related to the search and purchase of allergen-free clothes and shoes by those currently sensitised.

The total annual human health benefits expected from the proposed restriction would be in the range of €7-€50 billion with a "reasonable" estimate between €10.5 billion and €33.4 billion. The widest range would be between €708 million and €78 billion when considering all the assessed uncertainties.

Costs

Case	**Cost categories covered**	**Cost per year (€m)**	**Remarks**
Skin sensitisers	Substitution and enforcement costs.	€23.8 million (highest monetised raw material cost but it should be noted that costs are missing for some substances).	Additionally, reformulation would amount to approximately €13.1 million as a one-time cost. Enforcement costs are quantified by the dossier submitter at €0.082 million. Testing costs for industry are likely to be higher but due to uncertainties, it has not been possible to undertake a proper quantitative cost assessment of these.

Benefits

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 (€m)
Skin sensitisers	Skin sensitisation	HH	Lifelong sensitivity to a specific allergen.	Avoided allergic contact dermatitis in main analysis; 4-5 million current cases and 45 000 – 180 000 new cases avoided per year. A sensitivity analysis assumed a lower range of 0.4-0.5 million current cases and 4 500-18 000 new cases per year (the benefit in the final column is based on this). New sensitisation case €3 800- €13 900. Already sensitised individuals €3 700- €13 800 per case.	€708m (The most conservative estimate).

Further information
Official Journal entry (not decided)
Opinions and background documents (Registry of intention)

Figure 4: Costs and benefits of restricting skin sensitising substances in textile

Protecting citizens from lifelong skin allergies

Up to five million people in Europe are sensitised to chemicals present in textiles, leather, synthetic leather, hide and fur. These chemicals include dyes, chromium VI, formaldehyde and nickel and cobalt compounds.

Where can you find them?

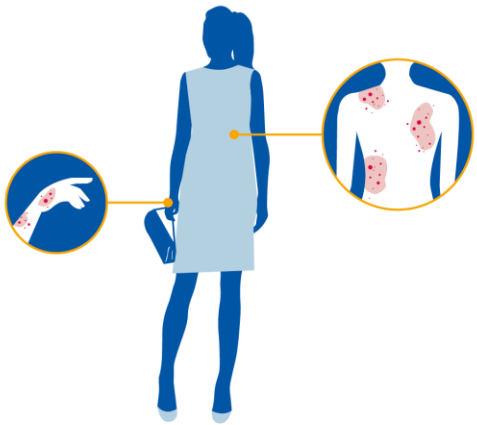
In **clothing, footwear and other articles that come into similar skin contact**. Examples include bedlinen, blankets, dresses, trousers, gloves, underwear, swimwear, wristwatch straps, sleeping bags and boots.

What is the concern?

Exposure to these chemicals can cause skin allergies – already from a very young age.

Up to 180 000 new sensitisation cases are estimated to occur every year in the EU.

Once a person is sensitised to an allergen, they must avoid exposure to it for the rest of their life to prevent allergic reactions.



What is the EU doing?

Sweden and France propose to **restrict the use of all chemicals classified as skin sensitisers and some dyes in textiles and leather articles** in the EU/EEA.

This restriction will **prevent many people from developing new skin allergies** whilst also **relieving the symptoms** of many who already are sensitised.

Preventing and avoiding these allergic reactions is expected to result in **health benefits equivalent to at least €708 million per year**.

The raw material costs for industry to replace the chemicals are estimated to be up to €23.8 million per year. There will also be costs related to reformulation, testing and enforcement.

Impact of restricting polycyclic-aromatic hydrocarbons (PAHs) in rubber granules and mulches

Tens of millions of Europeans play daily on hundreds of thousands of sports pitches and playgrounds that use rubber granules and mulches made of end of life tyres as infill material. To reduce risks posed by carcinogenic polycyclic-aromatic hydrocarbons (PAHs) included in the infill material, a restriction has been proposed limiting the maximum concentration of the sum of eight indicator-PAHs to 20 mg/kg in the infill material.

Hazards
The eight PAHs covered by this restriction proposal are all classified for carcinogenicity (category 1B). Additionally, two of the eight PAHs are classified for germ cell mutagenicity (category 1B and 2).

Scope of the restriction
The use of end of life tyres as infill in synthetic turf has increased in the last 10-15 years due to, for example, the prohibition on landfilling scrap tyres in the EU.

One of the concerns over the use of granules made out of old tyres are the PAHs that are found in the rubber material. PAHs are carcinogenic and are known constituents of both extender oils and carbon black used in the manufacture of rubber tyres.

Granules and mulches as infill material are characterised as mixtures. If the concentrations of carcinogenic PAHs are as high as the generic limit for mixtures supplied to the general public defined in REACH, there is a concern. To ensure that no granules and mulches are placed on the market with such high PAH concentrations, a lower limit needs to be set.

Therefore, in 2019, ECHA's committees adopted their opinion on the restriction proposal made by the Netherlands proposing that granules or mulches should not be placed on the market for use, or used as infill material in synthetic turf pitches or in loose form on playgrounds and in sport applications if they contain more than 20 mg/kg of the sum of eight indicator-PAHs.

Granules or mulches placed on the market for use as infill material in synthetic turf pitches or in loose form on playgrounds and in sport applications would have to be batch labelled. The restriction is proposed to apply 12 months after its entry into force. The opinion has been sent for the Commission's decision making.

Costs and benefits
This restriction proposal is based on an estimation that the population that comes into direct contact with potentially PAH-containing infill material in the EU is as high as 46 million people.

It is estimated that by 2028 there will be 34 000 full size synthetic turf pitches and 110 000 mini-pitches in EU. There are about 140 formulators of rubber granules operating in the EU and hardly any material is imported from outside the EU. Annual use tonnage of infill material derived from end of life tyres is estimated to grow from 350 000 tonnes in 2016 to 550 000 tonnes in 2028. Up to 14 000 workers are involved in installation and maintenance of synthetic turf pitches.

The use of synthetic infill material can result in environmental pollution by microplastics if the infill material is lost from the pitches. Costs and benefits of this aspect is considered in a separate restriction proposal which concerns intentionally added microplastics.

Costs and benefits are based on the original proposal (i.e. limit value of 17 mg/kg) and not on the RAC/SEAC proposal (i.e. limit value of 20 mg/kg).

Costs

Case	Cost categories covered	Cost per year (€m)	Remarks
Polycyclic-aromatic hydrocarbons (PAHs) in rubber granules and mulches	Increased production costs (improved tyre selection) and/or revenue losses from selling incompliant infill on alternative markets Increased testing costs Enforcement costs	€5m	The overall societal costs are estimated to be around €30-€55m over a 10-year period with a mid-range scenario of €45m.

Benefits

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 (€m)
Polycyclic-aromatic hydrocarbons (PAHs) in rubber granules and mulches	Carcinogenic	HH	Avoidance of excessive exposure levels of PAHs in granules and mulches. Most of the expected benefits are qualitative and not quantified in the proposal. For example, the reduced risks alleviate societal concerns and social impacts of these concerns, such as worries of exercising on artificial sports pitches and playgrounds.	Avoided cancer cases over a 10-year period: <2. Value per cancer case (updated to 2016): €5.55m. Health benefits over a 10-year period: <€11m.	<€1.1m

Further information
Official Journal entry (not decided)
Opinions and background documents (Registry of intention)

Impact of restricting intentionally added microplastics

Microplastics are small (smaller than 5mm), usually microscopic, solid particles made of a synthetic polymer. They are associated with long-term persistence in the environment, if released, as they are very resistant to (bio)degradation. The particles may also contain other substances (plastics additives) as well as residual impurities from manufacturing. The amount of intentionally added microplastics released to the EEA is estimated to be around 42 000 tonnes per year. The proposed restriction is estimated to reduce approximately 500 000 tonnes of microplastics over a 20-year period.

Hazards
The presence of small solid particles of synthetic polymer-based materials in the environment poses environmental and human health risks. Microplastics are readily available for ingestion and potentially liable to transfer within food chains. They are very resistant to environmental (bio)degradation, which leads to them being present in the environment for a very long time.

Microplastics progressively (bio)degrade in the environment into smaller and smaller particles and they are practically impossible to remove from the environment after release. A wide range of organisms, including invertebrates, fish, marine reptiles, birds and cetaceans are exposed to microplastics. Humans are exposed to microplastics through their diet.

Hazards associated with microplastic particles:
- Physical/mechanical hazards, for example, obstructing or interfering with the normal functioning of gills or of feeding apparatus or the gut.
- (Eco)toxicological hazards from the polymers themselves, or through the presence of unreacted monomers, impurities, additives or other substances within the polymer.
- Environmental pollutants, such as persistent organic pollutants (POPs) or metals that adsorb to microplastic particles in the environment and which may subsequently be released if microplastics are ingested, leading to enhanced bioaccumulation and/or adverse effects from the 'transferred' substances.

In the risk assessment under REACH, microplastics are treated as non-threshold substances, similar to PBT/vPvBs, with any release to the environment assumed to result in a risk.

Scope of the restriction
In 2017, the European Commission requested ECHA to develop a Union wide restriction proposal for the use of intentionally added microplastics. ECHA is proposing that microplastics should not be placed on the EEA market as a substance on its own or in a mixture as a microplastic in a concentration equal to or greater than 0.01% w/w. Transition periods and derogations for certain sectors have been proposed with the aim to minimise costs to society, without unnecessary delay in emissions reduction.

The scope of this restriction proposal is on microplastics in products placed on the market of the European Economic Area (EEA). The restriction is defined based on the presence of a polymer in a substance or mixture, but the intent is not to regulate the use of polymers generally but only those that meet the specific criteria to be considered as microplastics. Microplastics formed in the environment due to the wear and tear of larger pieces of plastic (secondary microplastics) are not within the scope of this restriction proposal.

Intentionally added microplastics have diverse technical functions and are used, for example, in:
- infill material on artificial turf pitches;
- agriculture and horticulture (in fertilisers and plant protection products);
- cosmetic products (both rinse-off and leave-on products);
- detergents and maintenance products (such as for fragrance encapsulation in laundry detergents and fabric softeners as well as in products for cleaning and polishing);
- paints, coatings and inks (in professional and consumer uses);
- chemicals used in the oil and gas sector;

- construction (e.g. certain types of concrete and adhesives);
- medicinal products;
- medical devices; and
- food supplements and medical food.

Approximately 42 000 tonnes of intentionally added microplastics are estimated to be released into the environment per year.

This restriction proposal has been sent to the European Commission for decision making.

Costs and benefits
The environmental and human health risks posed by microplastics are difficult to quantify.

Costs

Case	Cost categories covered	Cost per year (€m)	Remarks
Microplastics	Primarily compliance costs. (Reformulation costs, raw material costs, enforcement costs, labelling costs and other economic costs).	€10.8 billion or €19.1 billion over 20 years depending which of the two proposed restriction options for infill material will be selected, i.e. up to €955 million per year.	The cost effectiveness of avoided emissions (excluding infill) is estimated to be €19/kg, ranging from €2/kg to €133/kg.

Benefits

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 (€m)
microplastics	Irreversible damage to ecosystems (ENV)	ENV + HH	Microplastics are considered as non-threshold substances with releases considered as a proxy for risk. Impact can be assessed from the reduction in predicted releases.	500 000 tonnes of avoided releases over the 20 years following implementation (70 % reduction in releases). >90 % abatement effectiveness achieved at end of transitional periods).	Not quantifiable.

Further information
Official Journal entry (not decided)
Opinions and background documents (Registry of intention)

Figure 5: Costs and benefits of restricting intentionally added microplastics

Big actions on small particles

REDUCING MICROPLASTIC POLLUTION

Microplastics are very small solid plastic particles. They are released into the environment, for example, when car tyres wear out or when we use products that contain them.

Where can you find them?

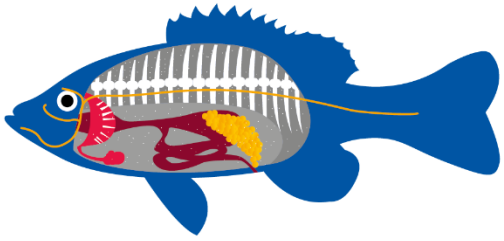
Microplastics are intentionally added to products to give them certain textures or make them function is a specific way.

Examples of these products are the soft infill used on artificial turf pitches, fertilisers, cleaning and laundry products and cosmetics.

What is the concern?

When products are used, microplastics are released to the environment where they stay for a very long time – they do not biodegrade. This leads to irreversible pollution of our ecosystems and food chains.

It is estimated that 42 000 tonnes of microplastics end up in our environment each year because of the use of products where they are intentionally added.



What is the EU doing?

The European Chemicals Agency is proposing to restrict microplastics in products in the EU/EEA.

The proposal would prevent 500 000 tonnes of microplastic releases into our environment over 20 years.

The costs for companies are estimated to be up to €19.1 billion over 20 years.

Impact of restricting substances used in tattoo inks and permanent make-up

An estimated 12 % of European citizens have a tattoo and in younger generations this number may be double. Hazardous chemicals included in tattoo inks can cause adverse effects such as adverse skin effects and other more serious health impacts and risks due to a lifelong exposure. Restricting hazardous chemicals from being used in tattoo inks and permanent make-up brings clear health benefits, while significant economic impacts are not expected. This restriction aims to make tattooing and permanent make-up safer. It does not aim to ban tattooing.

Hazards
Skin sensitisation, skin corrosion, skin irritation, carcinogenicity, germ cell mutagenicity, reproductive toxicity, serious eye damage or eye irritation.

Scope of the restriction
The number of people in the EU with tattoos and permanent make-up has been increasing in recent years. Several studies have identified human health effects due to the exposure to chemicals in tattoo inks. 68 % of tattooed people have reported skin problems in one study. In another study, after several weeks, 9 % of tattooed people reported that they still had health problems and 6 % reported persistent skin symptoms.

Coloured tattoo inks have been shown to be mainly responsible for adverse skin reactions, with one study reporting red colourants being associated with the majority of the allergic reactions. Reactions can appear months or years after the tattoo was completed. The pigments used in tattoos may also re-distribute in the body and may later be found in different organs such as the lymph nodes and the liver. This results in lifelong exposure and can potentially have a negative effect on human health.

Tattoo inks are marketed and used throughout the EU. Therefore, risk management actions should also be taken on a Union-wide basis. Therefore ECHA, together with Denmark, Italy and Norway, proposed to restrict the use of substances in tattoo inks and permanent make-up that have a harmonised classification as a carcinogen, reproductive toxicant, germ cell mutagen, skin sensitiser/irritant/corrosive, and eye irritant/damaging under the CLP Regulation, excluding any such substances if classified due to effects only following exposure by inhalation, or those restricted under the EU's Cosmetics Products Regulation. Specific thresholds are given depending on the hazard class.

The restriction will apply 12 months after the entry into force of the restriction, except for pigments Blue 15:3 and Green 7, for which the restriction will apply 24 months after the entry into force.

New entries under the Cosmetics Regulation that will fall within the scope of this restriction, will have an 18-month transition period. All mixtures that are placed on the market for use for tattooing purposes must be labelled with the text "Mixture for use in tattoos or permanent make-up", and have a unique reference number, list of ingredients and safety statements, where necessary.

More than 4 000 substances fall within the scope of this restriction proposal. Tackling this with a grouping approach has the additional benefit of helping to avoid regrettable substitution.

Costs and benefits
The overall costs of this restriction are estimated at about €4.6 million annually (at 2016 values).

In general, the health benefits of this restriction cannot be quantified and monetised. The benefits are avoided cases of adverse effects due to tattoos. Based on surveys of health effects of people with tattoos, it is estimated that 1.7 % of tattooed people develop adverse skin reactions that are severe enough to require a doctor's consultation. The costs of one case of a severe, non-infectious inflammatory reaction is approximately €4 350. The social costs to avoid other systemic, reproductive, developmental or carcinogenic illnesses would be significantly higher (for example, the willingness to pay value to avoided cancer morbidity is €410 000 at 2012 values), but due to uncertainties these cannot be quantified.

For the costs and benefits of this restriction to break even, 1 050 cases of chronic allergic reactions that require surgical removal need to be avoided annually. This is between 0.02-0.06 % of the estimated number of people getting tattoos for the first time each year. It is reasonable to expect that these cases will indeed be avoided as a result of the restriction.

Costs

Case	**Cost categories covered**	**Cost per year (€m)**	**Remarks**
Substances used in tattoo inks	Substitution costs	€4.6m	The cost of tattoo inks represents a very small share of the costs per tattoo.

Benefits

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 (€m)**
Substances used in tattoo inks	Adverse skin effects; carcinogenicity; germ cell mutagenicity; reproductive toxicity.	HH	Severe chronic dermatitis	Not quantifiable	Not quantifiable

Further information
Official Journal entry (Document 32020R2081)
Opinions and background documents (Registry of intention)

Figure 6: Costs and benefits of restricting substances used in tattoo inks and permanent make-up

Making tattooing safer

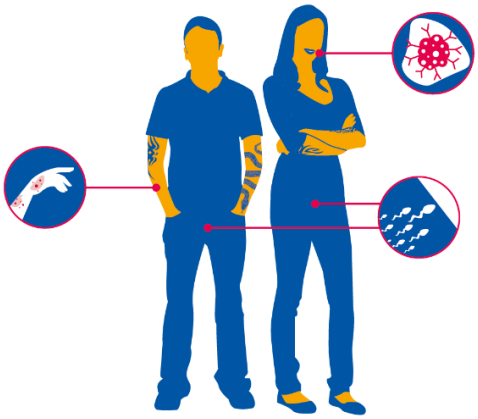
12 % of Europeans have tattoos – with 18-35 year olds twice as likely to have them. Tattoo inks, and permanent make-up such as eyeliner inks, are a mix of several chemicals. These chemicals are injected into our skin, stay in our bodies for a long time and may lead to a long-term exposure to potentially harmful ingredients.

What is the concern?

The inks used in tattooing and permanent make-up may contain hazardous chemicals that cause skin allergies and other more serious health impacts, such as genetic mutations, cancer and reproductive harm.

Adverse effects can appear months or even years after getting the tattoo.

Ink pigments can also migrate from the skin to different organs such as the lymph nodes and liver.



What is the EU doing?

The EU is not banning tattooing but is making the inks safer.

More than 4 000 hazardous chemicals in tattoo inks and permanent make-up will be restricted in the EU/EEA from early 2022.

This action may lead to over 1 000 cases of chronic allergic reactions being avoided every year. Other skin reactions and serious effects are also likely to decrease.

The cost for industry to replace the chemicals is estimated to be €4.6 million per year.

Impact of restricting Diisocyanates

Restricting diisocyanates is estimated to avoid more than 3 000 new cases of occupational asthma each year in the EU. The benefits of risk reduction are estimated to outweigh the costs of this restriction proposal after three to six years.

Hazards
Diisocyanates are respiratory and skin sensitisers.

Scope of the restriction
Diisocyanates are used in many applications (foams, sealants, coatings) throughout the EU. The total tonnage is about 2.5 million tonnes per year.

The issue of occupational asthma caused by handling diisocyanates or formulations containing such substances has been known for decades and occupational diseases caused by these products are well known.

In 2018, ECHA's scientific committees provides their opinion proposing that diisocyanates should not be used or placed on the market as substances on their own, as a constituent in other substances or in mixtures for industrial and professional uses, unless the cumulative concentration of diisocyanates in the substance or mixture is less than 0.1 % by weight.

The proposal limits the use of diisocyanates in industrial and professional applications to those cases where a combination of technical and organisational measures as well as a minimum standardised training package have been implemented. Information on how to get access to this package is communicated through the supply chains.

An exemption from the restriction is proposed for the specific use of ready-to-use products that lead to a very low risk of exposure through the dermal and inhalation route.

Costs and benefits
1.44 million workers are potentially at high risk in the EU. ECHA's committees did not give any figure of potentially reduced asthma cases, but a sensitivity analysis was presented in the opinion with 30 %, 50 % and 70 % effectiveness. The benefits were estimated to range between €3-7 billion in 20 years.

RO_n	Costs PV [€million]	Benefit PV [€million]	Net benefit [€million]
RO1: Appendix Training and Measures + Exemptions	1 550	3 010 (30% eff.) 5 020 (50% eff.) 7 010 (70% eff.)	1 460 **3 470** 5 460

Costs

Case	Cost categories covered	Cost per year (€m)	Remarks
Diisocyanates	Training costs at workplaces.	€114.05m	Annualised 4 % discount rate used.

Benefits

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 (€m)
Diisocyanates	Respiratory sensitisation	HH	Avoided occupational asthma cases.	€14 589 /avoided case	€369.38m

Further information
Official Journal entry (Document 32020R1149)
Opinions and background documents (Registry of intention)

Impact of restricting perfluorinated carboxylic acids (C9-C14 PFCAs)

The perfluorinated carboxylic acids C9-C14 belong to the group of the most persistent chemical substances known. These substances are not any longer used in the EU and intentional uses hey have only been identified in a few cases. However, more articles might be on the market, as these substances have been manufactured and used worldwide. C9-C14 PFCAs, their salts, and related substances are also present in many articles as impurities. The general population is widely exposed to these substances also in remote locations.

Hazards
C9-C14 PFCAs are PBT/vPvB substances, for which it is not possible to establish a safe level of exposure. They are ubiquitous in the environment and in humans, and they have a potential for environmental long-range transport.

They have been added to the Candidate List as substances of very high concern (SVHCs)
- C9 and C10 PFCAs as carcinogenic, mutagenic and reprotoxic (CMR) and persistent, bioaccumulative and toxic (PBT) substances; and
- C11-C14 PFCAs as very persistent and very bioaccumulative (vPvB) substances.

C9 and C10 PFCAs and their ammonium and sodium salts are also classified as Carc. 2 and Repr. 1B under the CLP Regulation.

Scope of the restriction
The main source of releases of C9-C14 PFCAs are perfluorooctanoic acid (PFOA) and PFOA-related substances. Release of approximately 12 tonnes of C9-C14 PFCA-related substances each year is estimated until the PFOA restriction becomes effective in 2020. After this, the releases are expected to decrease to 1.4 tonnes per year.

This restriction proposal aims to reduce or prevent exposure of consumers and the environment to C9-C14 PFCAs. There aren't any known EU manufacturers or intentional uses of C9-C14 PFCAs but imported semiconductors containing the substance has been identified. This proposal would also prevent a regrettable substitution of PFOA with C9-14 PFCAs, their salts and related substances.

Therefore, ECHA is proposing that C9-14 PFCAs should not be manufactured or placed on the market as substances on their own. They should not be used in the production of, or placed on the market in another substance, as a constituent, in a mixture, in an article or any parts thereof, in a concentration equal to or above 25 parts per billion (ppb) for the sum of C9-C14 PFCAs and their salts or 260 ppb for the sum of C9-C14 PFCA-related substances.

An 18-month transition period was proposed as well as some derogations and extensions to the transition period.

Costs and benefits
There are no major economic costs expected due to this restriction because industry in the EEA is already shifting away from the use of long-chain perfluorinated substances and only a few intentional uses have been identified.

There are potentially high benefits of reducing emissions of C9-C14 PFCA-related substances in the environment, but these are not quantifiable. One main benefit is to prevent the potential regrettable substitution of PFOA with C9-C14 PFCAs.

Costs

Case	Cost categories covered	Cost per year (€m)	Remarks
Perfluorinated carboxylic acids (PFCAs)	-	-	No major economic costs. Industry already shifting from the use of long-chain perfluorinated substances. Some minor costs related to substitution from PFOA to shorter chain or non-fluorinated alternatives instead of to C9-C14 PFCAs may occur. For textiles, such costs would be less than €35/kg used.

Benefits

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 (€m)
Perfluorinated carboxylic acids (PFCAs)	PBT/vPvB; Some of the substances are toxic to reproduction in humans	ENV + HH	Reduction of emissions as all populations and environmental compartments are potentially at risk. A safe concentration in the environment cannot be established.	Reduction of emissions not quantifiable	Not quantifiable.

Further information
Official Journal entry (Not decided)
Opinions and background documents (Registry of intention)

Impact of restricting lead in gunshot over wetlands

There is extensive field evidence of the adverse impacts on birds from the ingestion of lead gunshot. The proposed restriction on the use of lead shot over wetlands aims to reduce lead poisoning in waterbirds and predatory/scavenging birds. It would harmonise controls at EU level and implement the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA) in the EU.

Hazards
Human health: lead is a reprotoxic substance (may damage fertility and/or the unborn child) as well as causing specific target organ toxicity after repeated exposure (may cause damage to organs through prolonged or repeated exposure).
Environment: very toxic for the aquatic environment, with long lasting effects.
There is no safe level for lead exposure and even low levels of exposure are associated with neurodevelopmental deficits for children.

Scope of the restriction
The use of lead gunshot in wetlands leads to a risk to waterbirds that ingest spent lead shot dispersed into the environment. The use of lead gunshot in wetlands also results in a risk through secondary poisoning to species that either predate or scavenge birds that have been contaminated with lead gunshot. Ingestion of lead gunshot can result in lethal poisoning or various sub-lethal effects depending on the quantity ingested. Ingestion of a single lead gunshot may be sufficient to cause lethal poisoning in a small-sized duck.

Currently, 23 EU Member States have legislation of one kind or another to prevent or reduce the use of lead gunshot in wetlands while three Member States do not have any legislation in place. Therefore, regulating the risk at Union level was considered to ensure an appropriate level of protection throughout the EU

ECHA has proposed that lead and lead compounds should not be used in gunshot for shooting with a shot gun within a wetland or where spent gunshot would land within a wetland. To enhance the practicality of the measure, ECHA proposed that lead gunshot should not be in the possession of people in wetlands. The proposal includes sports/clay target shooting ranges or shooting grounds in wetlands.

Risk to birds is the primary concern addressed by this restriction proposal but there are also concerns related to indirect exposure to humans from consuming waterbirds that have been shot with lead gunshot and the general condition of wetland environments. These latter concerns can be considered to be co-benefits of implementing the restriction.

Costs and benefits
Based on an assessment of 22 species of waterfowl and 11 species of waders and rails, between 400 000 and 1.5 million waterbirds currently die every year from ingesting lead gunshot. Of these, 60 000-200 000 are estimated to occur in Member States where legislation prohibiting or reducing the use of lead gunshot in wetlands does not exist.

The annual consumption of gunshot cartridges in Europe is estimated to be between 600 and 700 million units. This corresponds to a total of 18 000-21 000 tonnes of lead that is annually dispersed into the environment from hunting. The proposed restriction is anticipated to reduce lead emissions to EU wetlands by 4 750 tonnes of lead per year.

Potential risks to human health from the consumption of wildfowl shot with lead shots are considered in this restriction proposal, although qualitatively.

The total cost per tonne of avoided lead emissions is estimated to be on average € 18/kg.
Costs

Case	Cost categories covered	Cost per year (€m)	Remarks
Lead in gunshot over wetlands	Compliance costs for hunters	€44.4m	The additional cost to an average hunter for purchasing non-lead shot ammunition rather than lead shot ammunition would in the worst case be €66 per year. An estimated 141 000 guns would have to be prematurely replaced across the EU. A total replacement cost (at the 2016 value) of €97m is annuitised to €7m per year including overall costs.

Benefits

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 (€m)
Lead in gunshot over wetlands	Reprotoxic; very toxic for aquatic life, with long lasting effects	ENV + HH	Reduction of lead emissions: 4 750 tonnes in wetlands 400 000-1.5 million waterbirds die every year from ingesting lead gunshot, (additional effects on other species of waterbirds and on predatory and scavenging birds that consume food containing lead gunshot) Reduced lead exposure in subsistence hunters throughout Europe. Contributes to reduced lead exposure due to groundwater contamination.	Avoided opportunity cost associated with the annual mortality of approximately 700 000 waterfowl from 16 wetland bird species known to ingest lead shot.	€105m

Further information
Official Journal entry (Document 32021R0057)
Opinions and background documents (Registry of intention)

Impact of restricting lead stabilisers in PVC

The use of lead substances to stabilise PVC will, based on 2016 tonnage estimates, cause over a long period of time around seven tonnes of lead to be released to the environment mainly through the municipal incineration of PVC articles when they are disposed as waste. The cost-effectiveness of restricting lead stabilisers in PVC is roughly €300 per kg of avoided lead emissions.

Hazards
Human health: lead is a reprotoxic substance (may damage fertility and/or the unborn child) as well as causing specific target organ toxicity after repeated exposure (may cause damage to organs through prolonged or repeated exposure).
Environment: very toxic for aquatic environment, with long lasting effects.

Scope of the restriction
ECHA has proposed to restrict the presence of lead compounds used as stabilisers in PVC articles (in concentrations equal to or greater than 0.1% w/w) with a 15-year derogation for the use of recycled PVC to produce certain building and construction articles (with a higher restriction limit of 1 % w/w) and a 10-year derogation for PVC silica separators in lead acid batteries.

PVC articles containing lead stabilisers are mainly used in building and construction-relevant applications, for example, window profiles, fittings, pipes and tubes, roller shutters and gutters, wires and cables, roofing and flooring tiles. These make up 70-80% of the PVC used in the EU.

Exposure to lead in PVC occurs mainly during the disposal phase of PVC articles. It is estimated that seven tonnes of lead would be released to the environment in the EU from the use of lead based stabilisers in the EU in 2016, mainly from the municipal incineration of PVC articles at the end of their useful life.

Lead compounds cannot stabilise PVC in a satisfactory way at concentrations below approximately 0.5% (w/w) of the plastic material. Therefore, a restriction with the proposed concentration limit of 0.1% (w/w) would effectively end the intentional addition of lead-based stabilisers in PVC. This would eliminate the presence of lead stabilisers in articles manufactured in or imported into the Union made from virgin PVC. Viable alternatives to lead in PVC already exist, in particular, calcium-based stabilisers.

Around 2 million tonnes of PVC waste, which contains 'legacy lead' around 1-2 % by weight, is generated in the EU every year. This waste can be disposed, which leads to releases to the environment, especially when incinerated, or it can be recycled which would lead to lower releases. In ECHA's view, recycling can be considered a viable risk management measure as long as the articles produced from recycled material had a low potential for service life releases.

Therefore, in ECHA's view, certain articles could continue to be made from recycled PVC (as long as lead concentration would be lower than 2 % for rigid and 1 % for flexible PVC articles).

In some cases, this derogation requires 'encapsulation' of recycled PVC with another material to avoid human exposure during service life. Without the derogation for recycling the costs of the restriction would be much higher: up to €58m per year. In addition, without recycling the actual releases of lead would increase by 20 %.

The discussion about the advantages and disadvantages of recycling lead-containing PVC currently continues on a political level. In any case, a transitional period of 24 months after entry into force is proposed to allow the use of existing stocks and to ensure that information can be efficiently communicated within the relevant supply chains.

Costs and benefits
The cost-effectiveness is estimated to be between €100-€2 500 per kg of lead emissions avoided with a central cost-effectiveness estimate of roughly €300 per kg of lead emissions avoided.

A break-even analysis suggested that the restriction breaks even if 1.24 g or more of the lead emitted per year would be ingested by young children.

Early-life exposure to lead is related to neurologic deficits, leading to reduced cognitive ability, which can be measured with standardised IQ tests. One IQ point has a social value of €10 000 measuring the productivity loss an average individual would incur should they lose one IQ point. The analysis suggests that in a given year 209 IQ points would need to be prevented from being lost due to exposure to lead for the proposal to 'break even'.

Costs

Case	Cost categories covered	Cost per year (€m)	Remarks
Lead in PVC	Compliance costs	€2.1m (2016 value)	

Benefits

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 (€m)
Lead in PVC	Reprotoxic; very toxic for the aquatic life, with long lasting effects	HH + ENV	Early-life exposure to lead is related to neurologic deficits, leading to reduced cognitive ability. Lowered IQ. Avoided lead emissions and hence reduced exposure.	7 tonnes of prevented lead release to the environment	Not quantifiable

Further information
Official Journal entry (Not decided)
Opinions and background documents (Registry of intention)

Impact of restricting four phthalates (DIBP, DBP, BBP and DEHP)

Monetised benefits of restricting bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) (the four phthalates) *are estimated to outweigh the costs by more than 10 times. The benefits are estimated at about €235 million while the costs are about €17.6 million per year in the worst-case scenario. Additionally, there are significant* non-quantified benefits.

Hazards
Bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) are toxic for reproduction, category 1B. They all also have endocrine disrupting properties for human health, while DEHP also has for the environment.

Scope of the restriction
These four phthalates are included in the Authorisation List and cannot be used after 21 February 2015 (their sunset date) without an authorisation. After this date, REACH requires ECHA to consider whether the uses of listed substances in articles pose a risk to human health or the environment that is not adequately controlled. If such risks are identified, the Agency needs to prepare a restriction proposal.

In 2017, ECHA submitted its scientific committees' opinions on the restriction proposal to the Commission. The Agency had prepared the proposal in cooperation with Denmark.

On 17 December 2018, the Commission concluded that these four phthalates pose an unacceptable risk to human health. Therefore, the four phthalates must not be placed on the EU market after 7 July 2020 in articles, individually or in any combination, in a concentration equal to or greater than 0.1 % by weight of the plasticised material in the article. There are some transition periods and derogations for specific uses/articles.

The four phthalates are commonly present in plasticised materials, such as polyvinyl chloride (PVC), polyvinylidene chloride (PVDC), polyvinyl acetate (PVA), polyurethanes, any other polymer including polymer foams and rubber material, surface coatings, non-slip coatings, finishes, decals, printed designs, adhesive, sealants, inks and paints. These are found in a wide variety of articles. The restriction bans the four phthalates, for example, in flooring, coated fabrics and paper, recreational gear and equipment, mattresses, footwear, office supplies and equipment, and other articles moulded or coated with plastic.

Exposure to the four phthalates may occur through the ingestion of food and dust, the placing of articles in the mouth, the inhalation of air and dust in indoor environments, and contact of dust and articles with human mucous membranes and skin.

Costs and benefits
ECHA's committees estimated that the costs borne by restricting the four phthalates will be €17.6 million per year (from €10 million to up to €19 million in the worst-case scenario). These costs constitute mainly those incurred by industry to substitute the use of the four phthalates.

The proposed restriction is likely to bring significantly higher human health benefits than its costs. The monetised benefits are estimated to vary between €22 million and €558 million. These estimates are associated with an uncertainty but many other benefits from this restriction are non-quantified. The non-quantified benefits include reduction of the adverse health effects that are due to the endocrine disrupting properties of the four phthalates, i.e. fewer cases of delayed age of puberty, immunological effects, effects on metabolism, allergy, eczema, as well as reduced exposure to DEHP, in particular, of aquatic organisms.

Adverse health effects potentially caused by an exposure to the four phthalates and their monetised values as used by ECHA's committees in their opinion are:

- **Male infertility,** 1 050-3 160 cases/year (with total monetised benefits of €9.9 million to €45.5 million per year)
- **Cryptorchidism,** 50-1 200 cases/year (with total monetised benefits of €1.3 million to €360 million per year)
- **Hypospadias,** 50-1 340 cases/year (with total monetised benefits of €1 million to €150 million per year)

The proposed restriction is anticipated to replace annually more than 130 000 tonnes of DEHP, DBP, DIBP, and BBP in articles in the scope of this restriction. 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 the EU.

Costs

Case	**Cost categories covered**	**Cost per year (€m)**	**Remarks**
DIBP, DBP, BBP and DEHP	Substitution costs. Testing costs. Costs for the recycling sector Enforcement costs.	SEAC used €17.6 million	Imported articles are estimated in 2020 to constitute more than 90 % of the four phthalates contained in articles in the scope placed on the EU market.

Benefits

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 (€m)
DIBP, DBP, BBP and DEHP	Toxicity for reproduction – anti-androgenic effects. Endocrine disruption HH (DEHP also for ENV) Effects on the immune system Effects on metabolism Effects on neurological development	HH	All four phthalates adversely affect the male reproductive organs and sexual differentiation during foetal development, due to their common anti-androgenic effects. All four are classified as reproductive toxicants category 1B. The anti-androgenic related effects that are suspected to be relevant in humans in relation to the four phthalates are congenital malformations of the male reproductive organs, reduced semen quality, reduced male reproductive hormone levels, and changes in pubertal timing including changes in male breast development. Other possible toxicity: effects on the immune system (allergies, eczema, asthma, other respiratory symptoms, rhinitis), on metabolism (obesity or diabetes), and on neurological development (behavioural disorders including autism spectrum disorders, ADHD, learning disabilities, and altered play behaviour). Infants and children are the most vulnerable and most exposed to the four phthalates. Exposure sources are typically the indoor environment, food and contact with articles containing these phthalates.	More than 130 000 tonnes of the four phthalates in articles in the scope of the restriction are to be replaced on average annually over 20 years since the restriction's entry into effect. Risks to between 1.1-3.5 million male children are to be reduced over a time span of 20 years in the EU.	Monetised benefits are estimated to be €235 million per year. The range of monetised benefits from €22 million to €558 million annually.

Further information
Official Journal entry (R 2018/2005 (Annex XVII entry 51))
Opinions and background documents (Registry of intention)

Figure 7: Costs and benefits of restricting the four phthalates

Protecting our future fathers

DEHP, DBP, DIBP and BBP

The phthalates DEHP, DBP, DIBP and BBP are chemicals added to plastics to increase their flexibility, transparency, durability, and longevity. They are toxic for reproduction and interfere with the human hormonal system.

Where can you find them?

Children's swimming aids, inflatable mattresses and seats, flooring, coated fabrics, recreational gear, mattresses, footwear and **office supplies**.

We are exposed to these chemicals through our food, skin and the air we breathe.

What is the concern?

Exposure to DEHP, DBP, DIBP and BBP affects **male sexual development** leading to thousands of cases of avoidable **male infertility** each year in Europe.

They may also cause **asthma**.

What has the EU done?

The use of these chemicals in articles is restricted in the EU/EEA from 7 July 2020. This restriction will save approximately **2 000 boys each year** from impaired fertility in later life.

Monetised benefits are estimated to be **€ 235 million per year** while the costs are around **€ 17 million**.

European citizens will be significantly better protected - the benefits of the restriction could be more than **10 times larger** than the costs.

Impact of restricting TDFA fluorosilanes in spray products

TDFAs: (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol, its mono-, di- or tri-O-(alkyl) derivatives have been associated with serious acute lung injuries when used with organic solvents in impregnating sprays by the general public. The purpose of this restriction is to prevent consumers' exposure to mixtures containing these substances.

Hazards
Acute inhalation toxicity causing serious acute lung injury.

Scope of the restriction
In 2015, Denmark prepared a restriction proposal covering the use of a combination of perfluorinated silanes and one or more organic solvents in sprays used by the general public for 'stain proofing', 'water proofing', 'impregnating' or for 'sealing'. The idea is to prevent consumers' exposure to mixtures containing these substances.

There had been incidents across Europe where the use of impregnating sprays had caused serious health problems for users or people staying in rooms where the sprays had been used. The cause has been unknown but research has shown that the use of perfluorinated silanes and organic solvents may cause effects like those seen. The main risk is associated with the hydrolysis and condensation products of these substances in combination with organic solvents. Inhalation of aerosol particles in the respirable range is the exposure route of concern.

In June 2019, the European Commission decided that '(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol, any of its mono-, di- or tri-O-(alkyl) derivatives (TDFAs) must not be placed on the market for supply to the general public after 2 January 2021 individually or in any combination, in a concentration equal to or greater than 2 parts per billion (ppb) by weight of the mixtures containing organic solvents, in spray products.

Spray products means aerosol dispensers, pump sprays, trigger sprays, marketed for proofing or impregnation spray applications.

The packaging of spray products containing (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and/or TDFAs combined with organic solvents and placed on the market for professional use must be marked clearly and indelibly: "for professional users only" and "Fatal if inhaled" with the toxic pictogram. Related safety data sheets must also include the same information.

Costs

Case	Cost categories covered	Cost per year (€m)	Remarks
TDFAs in spray products	Mostly reformulation costs	€ 0.012m	

Benefits

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 (€m)
TDFAs in spray products	Acute inhalation toxicity	HH	Consumer incidents related to spray products containing TDFAs and organic solvents estimated to be 8.5 – 360 incidents per year.	Costs related to avoided respiratory diseases are monetised at €160 000 - €460 000 per incident. Central value estimate for the yearly average number of incidents is 161.	€0.075 – 0.11

Further information
Official Journal entry (R 2019/957 (Annex XVII entry 73))
Opinions and background documents (Registry of intention)

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