Socio-economic impacts of REACH authorisations

A meta-analysis of the state of play of applications for authorisation

January 2021

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Key findings

Since the beginning of the authorisation process under REACH, no applications have been received for almost half of the substances of very high concern (SVHCs) on the Authorisation List. As no uses requiring an authorisation for these substances continue to exist in the EU, this is a clear indication that substitution has taken place.

For other substances on the list, more than 200 applications for authorisation have been received. In an average year, the cost to companies for preparing these applications amounted to €7-9 million per year.

Benefits of authorisation to SVHC users relate to the continued use of substances where technically feasible and economically viable alternatives are not available. For carcinogenic and reprotoxic substances, these benefits were estimated to amount to €8.7 billion per year. Continued uses of SVHCs impose related health risks that were monetised at €0.5 billion per year, implying that the societal benefit from these SVHC uses is almost 20 times larger than the monetised health risks.

Continued emission of environmentally harmful substances is another negative consequence of authorisation. Thanks to the conditions set in the opinions of the Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC), the emission of endocrine-disrupting substances subject to authorisation are projected to decrease by over 90 % from some 10 tonnes per year in 2020 to 0.7 tonnes per year in 2032. At the same time, the continued use of these substances is expected to preserve societal benefits of at least €6.1 billion per year.

The dynamic effects of promoting substitution have been assessed for the first time in this report. The findings suggest that the use volumes of the first 24 SVHCs for which authorisations have expired dropped by 97 % at the review stage – strongly indicating that substitution has taken place.

Additional conditions recommended in more than half of the opinions of ECHA's scientific committees aim to further reduce the risks associated with continued use. The committees' recommendations to have shorter review periods than those requested by applicants have the same effect.

Overall, these developments support ECHA's conclusion that the authorisation requirements have promoted substitution and helped to significantly reduce the risks associated with the continued use of SVHCs, while ensuring that companies in the EU can remain competitive.

Summary

REACH authorisation aims to ensure the good functioning of the internal market while assuring that risks from substances of very high concern (SVHCs) are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies, where these are economically and technically viable.

To this end, all manufacturers, importers and downstream users applying for authorisations need to analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.

Authorisations are granted if either the related risks to human health or the environment from the use are adequately controlled or if the socio-economic benefits outweigh the risks and if there are no suitable alternatives.

In their applications for authorisation, companies need to describe how the socio-economic benefits of their use are weighed against the risks and analyse whether there are suitable alternatives and, if such alternatives exist in general, provide a substitution plan.

ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) evaluate the applications and form an opinion, which the European Commission considers when it takes, together with the Member States, decisions on granting or refusing an authorisation.

The authorisation system has been in place for a decade and now is a good time to take stock of how the system has been delivering against its objectives.

Study premises and highlights

This study presents ECHA's analysis on socio-economic impacts based on the data and knowledge gathered while implementing the authorisation process. It reflects on the period from 2010[1]-2020 in which:

- 54 substances or groups of structurally similar SVHCs were subject to authorisation under REACH[2].
- Of the 43 substances which have had the latest application date before 2021, ECHA had received applications for 28 SVHCs. For 15 substances (35 %), ECHA had not received any applications indicating substitution or cessation of these uses.
- 346 applicants have submitted 213 applications for authorisation covering 340 distinct uses. Each application can include many applicants and uses.

[1] On 28 October 2008, ECHA published the first Candidate List and on 1 June 2009 it sent its first recommendation for inclusion of priority substances in the Authorisation List (Annex XIV) to the Commission. The Commission added the first substances to the Authorisation List on 25 March 2010. The latest application date for the first substance was 21 February 2013.

[2] 209 additional substances were on the Candidate List for eventual inclusion in the authorisation procedure.

- For 11 substances, the latest application date is in 2021-2022. For these, ECHA predicts that for nine substances (82 %) applications will not be received.

SVHCs are progressively replaced by suitable alternatives or technologies

The analysis in this report suggests that the REACH authorisation system is achieving its objective of progressively replacing SVHCs with suitable alternatives, where these are technically feasible and economically viable.

For 15 of the 54 SVHCs in the Authorisation List (Annex XIV of REACH), ECHA has not received applications. Moreover, the Agency projects that for nine substances, no applications will be received. This suggests that for 24 SVHCs (44 %) uses requiring authorisation no longer exist in the EU.

The authorisation system has inbuilt dynamics as the authorisation decisions are subject to regular review. So far, 24 authorisation decisions have become subject to review. The aggregated volume of applied uses in the original 24 applications was 19 kilotonnes. In the review phase, the volume reduced to 0.9 kilotonnes. This means a 97 % reduction in the volume of applied uses, indicating that the review system inherent to the Authorisation title plays an important role in promoting substitution.

Additionally, ECHA's recent report on the impacts of REACH restrictions and authorisation on substitution in the EU suggests that REACH authorisation provides an incentive for companies to move away from SVHCs.

Assuring that the risks from SVHCs are properly controlled

Where substitution is not (yet) possible, risk management becomes one of key aspects of the authorisation process. Applicants need to examine their manufacturing process and improve it by minimising risks and reducing their SVHC emissions as far as technically and practically possible. In many cases, granted authorisations are conditional on additional risk management measures being put in place. Indeed, ECHA's scientific committees recommended in 52 % of their opinions that additional risk management measures, operational conditions and monitoring arrangements be included in the authorisation decisions to ensure that the risks from the uses of SVHCs are properly controlled. Furthermore, the committees added conditions to which the applicants must adhere to should they submit a review report in 68 % of their opinions.

The evaluation of the applications did not only result in recommendations for additional conditions to reduce risks if an authorisation is granted, but ECHA's scientific committees also scrutinised the proposals of the applicants on the length of the review period. On average, this scrutiny has resulted in review periods that were 2.7 years shorter than those proposed by applicants.

As authorisation holders who have not found technically feasible or economically viable alternatives need to start preparing a review report approximately three years before their authorisation expires, periodic scrutiny is in place to ensure that the risks of continued SVHC use are properly controlled. The remaining risks to people's health were estimated to be €0.5 billion per year. Remaining emissions of environmentally damaging SVHCs were expected to reduce from about 10 tonnes in 2020 to 0.7 tonnes between 2020 and 2032.

Ensuring good functioning of the EU market

A third goal of the REACH authorisation title is to ensure that the internal EU market

functions well. The analysis of RAC and SEAC's opinions on 346 applications for authorisation shows that the benefits of continued use of SVHCs were estimated to be, on average, about 20 times greater than the remaining risks to human health. The total annual benefit for society of continuing controlled SVHC uses in the EU was estimated to be around €14.9 billion.

Introduction

The authorisation title of the REACH Regulation is a flexible policy tool to manage the use of hazardous chemicals in the EU (including the European Economic Area). Where this is viable, it seeks to incentivise the substitution of substances of very high concern (SVHCs). It does so by requiring that, after a specific sunset date, firms operating in the EU (or their direct suppliers) obtain an authorisation for continuing to use or place those substances listed in the Authorisation List of REACH Annex XIV on the market.

For substances for which a safe threshold has been established, authorisations must be granted whenever the risk to human health or the environment from the use applied for is adequately controlled. Authorisations for the use of SVHCs for which it is not possible to determine or meet such a threshold may still be granted under certain conditions. In particular, applicants for authorisation have to credibly demonstrate that suitable alternative substances or technologies to their specific substance use are not yet available and the socio-economic benefits of continuing this use outweigh the associated risk to human health and the environment.

Together with EU Member States, the European Commission decides which substances are added to the Authorisation List.[3] The substances added to this list are:

(i) carcinogenic, mutagenic or toxic to reproduction (CMR);

(ii) persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB); or

(iii) of an equivalent level of concern (e.g. endocrine disrupters).

Firms, in turn, decide whether they wish to continue using a substance beyond its sunset date – and thus apply for authorisation on their own or under the umbrella of an upstream application – or discontinue the use of the substance in the EEA. If a firm decides to apply, they submit an application specifying for which substance and use they are seeking an authorisation. An application has to contain a chemical safety report (CSR) and an analysis of alternatives (AoA). In many cases, applicants have also provided a socio-economic analysis (SEA) and, where applicable, a substitution plan (SP).[4]

ECHA's committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) examine these applications and forward an opinion on each of them to the European Commission, which decides – together with the EU Member States – whether and for how long an authorisation should be granted.

[3] ECHA publishes the latest Authorisation List with the substance-specific sunset dates on its website. As of December 2020, the list contained 54 entries.

[4] Inclusion of an SEA is optional, but most applicants have provided at least some socio-economic information.

By December 2020, ECHA had received 213 applications for authorisation by 346 applicants covering 340 distinct uses of SVHCs plus four review reports for six of these uses (see Table 1)[5]. ECHA's scientific committees had issued 420 independent opinions on the applications based on which the European Commission had made 288 authorisation decisions.

Table 1: Summary table of applications and review reports received, assessed and decided upon.

Year	Applications received [a] (#)	Distinct uses (#)	RAC-SEAC opinions [b] (# per use)	RAC-SEAC opinions [c] (# per use and applicant)	Commission decisions [d] (#per use and applicant)
2012	0 (0)	0	0	0	0
2013	8 (10)	17	1	1	0
2014	19 (33)	38	30	34	2
2015	7 (20)	13	25	51	10
2016	77 (132)	112	63	180	52
2017	12 (15)	20	58	74	46
2018	6 (8)	6	26	30	72
2019	62 (87)	95	14	18	45
2020*	26 (45)	45	32	42	61
Total	**217 (350)**	**346**	**249**	**425**	**288**

Table notes: * As of 8 December 2020, incl. review reports; [a] An application is received when ECHA has received the application fee under the terms of Article 64(1) of REACH; [b] One opinion refers to a compiled version of the final opinions of RAC and SEAC for each use contained in each application; [c] This refers to compiled final opinions of RAC and SEAC for each use and applicant. For instance, if one application has been submitted by three applicants for one substance and two uses there will be (3 x 1 x 2 = 6) six RAC-SEAC opinions and subsequent Commission decisions; [d] Final decisions are made for each use and applicant.

As can be seen from Table 1, the number of applications received has fluctuated over the years, ranging from as many as 77 in 2016 to as few as six in 2018. This is because the SVHCs on the Authorisation List have different sunset dates, resulting in application peaks whenever the sunset date for a widely used substance approaches. In contrast, the number of uses per authorisation (i.e. the ratio between distinct uses and applications received) has been fairly constant. On average, an application contained 1.6 uses. Note that in joint applications not all applicants applied for all uses so the number of opinions per use and applicant is not a common multiple of uses and applicants.

Table 2: Applications of SVHCs in the Authorisation List in 2013-2022.

Latest application date	2013-20	2021-22*	Total	Share
Applications received	28	2	30	56%
No applications	15	9	24	44%
Total	**43**	**11**	**54**	**100%**

*Estimated based on ECHA (2020a)

Table 2 summarises for how many SVHCs ECHA has received applications or is projected to receive them in 2021-2022. Up to now, ECHA has not received applications for 15 of

[5] ECHA maintains an up-to-date summary of applications received and substances applied for. As of December 2020, applications had been received for 28 of the 54 listed (groups of) substances.

the 43 SVHCs where the latest application date has passed.[6] In ECHA (2020a), 11 substances that the European Commission recently added to the Authorisation List were analysed and it was projected that ECHA would receive applications for only two of these substances.

Purpose of the report

As the authorisation process has now been in operation for 10 years, it is an opportune moment to take stock and analyse the applications for authorisations received so far and the corresponding opinions issued by ECHA's scientific committees.

Accordingly, the purpose of this report is:

1) to describe and analyse the applications for authorisation received so far in terms of substance uses, use volumes, corresponding exposures, and associated risks to human health and the environment as well as the socio-economic benefits of continuing the use of SVHCs beyond the legal sunset dates;

2) to review the opinions of ECHA's scientific committees on these applications. Special attention is given to the extent to which applicants have assessed the impacts of continued SVHC use from a broader societal perspective. This is relevant because firms are often aware of their own costs of ceasing the use of an SVHC and, possibly, of the health impacts to their workers. However, they have demonstrated difficulties in considering the wider socio-economic implications of authorisations;

3) to gather the available information on the impacts of authorisation on firms using or intending to use SVHCs and to report on the approaches and methods used to quantify those impacts.

[6] It is possible for companies to apply after the "latest application date", which implies that they cannot use the SVHC until a decision is made on their application. If companies apply before the "latest application date", it is possible for them to continue to use the SVHC while their application for authorisation is processed.

Methods

Data

This report looks at all applications for authorisation on which ECHA's scientific committees had issued an opinion by December 2020.[7] The various pieces of information are briefly explained here and summarised in Tables 2 and 3.

APPLICANT-SPECIFIC INFORMATION. Applicants provide information about the size and location of their operation as well as their role within the supply chain. This information allows narrowly defined downstream user applications and broadly defined upstream applications to be distinguished. Because upstream authorisation holders can potentially cover all downstream users of a substance within their supply chain, the information presented is often incomplete regarding the total number of firms that are beneficiaries of an authorisation. In addition to the information in the applications, ECHA has systemically asked applicants how much effort (in terms of staff time and costs) they had made to file their application. About 40 % of the applicants have replied to this inquiry, allowing cautious conclusions on the cost of filing an application to be drawn.

USE-SPECIFIC INFORMATION. Applicants may apply for the use of one or several SVHCs but have to specify their uses. As part of this specification, information has to be provided on the annual use volume of a substance.[8] Moreover, different SVHCs are associated with different carcinogenic, mutagenic or reprotoxic health endpoints, or they are PBT or vPvB (or give rise to an equivalent level of concern). Dose-response functions and derived no-effect levels (DNELs) are typically used to map exposure levels to one or more adverse health endpoint. Based on these mappings, applicants establish and ECHA's scientific committees assess the excess risk levels associated with each SVHC use applied for.

APPLICATION-SPECIFIC INFORMATION. Based on the number of workers and members of the general population exposed, the individual excess risk estimate can be converted into the expected number of excess cases of the respective health endpoint. This conversion is an intermediate step in the impact assessment, which is followed by multiplying the estimated excess cases by the respective willingness-to-pay (WTP) value per statistical case.[9] In economic terms, monetised risk estimates internalise the negative impacts on human health so that these can be compared to the socio-economic benefit of continuing to use the SVHC.[10] In applications for authorisation, the benefit of continued use equates to the opportunity cost that arises if the applicant is no longer able to use the substance. This opportunity cost is composed of both producer and consumer surplus loss in the

[7] Public versions of the application documents and the corresponding opinions are published on ECHA's website. For nonyl- and octylphenols, ethoxylated, the draft opinions up to October 2020 were used so that the projected emissions up to 2032 could be reported.

[8] If the annual use volume is claimed to be confidential information, applicants must indicate a tonnage range (e.g. 1-10 tonnes per year). In this case, Table 2 displays the maximum annual use volume.

[9] ECHA has provided both dose-response functions for the use of specific SVHCs and reference WTP values for specific health endpoints on its website. See for instance ECHA (2013a) on hexavalent chromium.

[10] Monetary impacts in Tables 2 and 3 were annuitised to allow comparisons to be made across the different applications received. Consistent with the ECHA Guidance on SEA, a discount rate of 4 % was used for the annuitisation. Moreover, the highest risk estimates and smallest plausible benefits of continued use were considered throughout to be consistent with the reasonable worst-case approach of ECHA's scientific committees.

market that the applicant (or its downstream users) operates in.

For some substances, it is not possible to reliably predict the negative impacts that exposure to or emissions of them would have on human health or the environment. In such cases, the risks associated with continued SVHC use cannot be quantified. Instead, ECHA's scientific committees have agreed to use emissions as a proxy for risk and to compare these measurable units to the benefits of continued use. For such applications, the ratio between expected benefits of continued use and emissions/exposures are reported.

OPINION-SPECIFIC INFORMATION. During the opinion-making process, ECHA's scientific committees can ask questions for clarification and – based on the answers by the applicant – they may re-assess the level of prevailing excess risk, the monetised health impacts or the socio-economic benefits of continued use. In turn, this may lead the committees to recommend a shorter review period than proposed by the applicant and/or additional conditions in terms of risk management measures (RMMs), operating conditions (OCs) and monitoring arrangement (MAs).

Shorter review periods may be recommended for several reasons including (but not limited to) the overall quality of the application, the evidence provided on possible alternatives to the use applied for, the workplace conditions, and additional information on the use obtained during the public consultation and trialogue.[11] Table 3 documents these opinion-specific assessments of the committees and their recommendations to the European Commission. While the committees strive for consistency across authorisation dossiers, each case is assessed on its own merits.

INCOMPLETE OR MISSING INFORMATION. The extent and quality of the assessment of benefits and risks of the continued use of SVHCs varies widely. All values displayed in Tables 3 and 4 are subject to uncertainty and should not be understood as a full-fledged assessment of all socio-economic impacts associated with the authorisation cases assessed. In sector-wide upstream applications it has proven to be particularly difficult for applicants to come up with a sound quantification of the social benefits of continued use. With this limitation in mind, the values presented are the most accurate assessment of the possible socio-economic impacts of REACH authorisations to date.

Analytical approach

Qualitative methods were used to analyse the information obtained on the applications for authorisations received and evaluated by December 2020. Emphasis was given to the aggregate benefits, the remaining risks as well as the substances and uses applied for. Moreover, the analysis looked closely into structural changes that have occurred since the inception of the application for authorisation system in 2013.

The results of this meta-analysis should, however, be interpreted with care. Given the limited number of cases for certain SVHCs and important variations between large-scale upstream and small-scale downstream applications, all results are necessarily indicative; nonetheless, they offer useful insights to the extent that they support or negate some common perceptions of the authorisation process.

[11] Trialogue meetings are frequently held between the rapporteurs of ECHA's committees, the applicants, and third parties wishing to challenge or support the claims made in a specific application for authorisation or meet and discuss specific elements of an application. The results of these trialogue meetings are documented in the opinions of ECHA's scientific committees.

Table 3: Summary of uses applied for before January 2020.

SVHC (threshold substances in italics) [a]	Total uses (#)	Downstream uses (#)	Upstream uses (#)	Use description [b] (#)	Use volume [c] (t/y)
Bis(2-ethylhexyl) phthalate (DEHP)	15	4	11	Formulation: 3 Softener: 9 Industrial use: 1 Retracted: 2	320 205 [∅21 347]
Dibutyl phthalate (DBP)	7	2	5	Softener: 6 Industrial use: 1	2 433 [∅348]
Diglyme	10	10	0	Solvent: 10	374 [∅37]
Hexabromocyclododecane (HBCDD)	2	0	2	Formulation: 1 Flame Retardant: 1	8 000 [∅4 000]
Lead chromates	13	1	12	Formulation: 2 Flame Retardant: 1 Paints: 10	3 000 [∅231]
Diarsenic trioxide	6	3	3	Formulation: 2 Cleaner: 1 Process aid: 2 Separation: 2	848 [∅141]
Hexavalent chromium compounds	122	76	39	Formulation: 16 Corrosion inhibitor: 17 Process aid: 8 Separation: 1 Spraying: 3 Surface treatment: 68 Packaging: 1	30 920 [∅253]
Trichloroethylene (TCE)	19	12	7	Formulation: 2 Packaging: 1 Solvent: 16	41 813 [∅2 201]
1,2-Dichloroethane (EDC)	20	0	3	Solvent: 17 Process aid: 1 Swelling agent: 2	1 642 [∅82]
Technical MDA	2	2	2	Formulation: 1 Industrial use: 1	58 [∅29]
2,2'-dichloro-4,4'-methylenedianiline (MOCA)	1	0	1	Industrial use: 1	516 [∅516]
Pitch, coal tar, high-temperature (CTPHT)	8	6	2	Mixtures: 4 Binder: 2 Process aid: 1 Industrial use: 1	433 933 [∅54 242]
4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated (OPE)	97	71	26	IVD tests/kits: 59 Siliconized containers: 6 Hardener: 2 Membranes: 2 Mixtures: 1 Separation: 2 Surfactant: 1	385 [∅4]
4-Nonylphenol, branched and linear, ethoxylated (NPE)	19	11	8	IVD test/kits: 14 Separation: 1 Process aid: 2 Hardener: 2	6 [∅0.3]
Anthracene oil (AO)	4	4	0	Mixtures: 4	136 000 [∅34 000]
Total	**341**	**223**	**118**		**980 133** **[∅2 832]**

Table notes: [a] Substances for which a DNEL for humans can be determined; [b] Categorisation based on brief use description submitted by applicants; [c] Where applicants indicated ranges (e.g. 1-10 tonnes per year), maximum use volumes are reported.

Table 4: Summary of authorisation opinions adopted by December 2020.

SVHC (threshold substances in italics) [a]	Average review period proposed [b] (y)	Average review period recommended [c] (y)	Conditions for authorisation [d] (% of uses)	Recommendations for review report [d] (% of uses)
Bis(2-ethylhexyl) phthalate (DEHP)	8.8	5.2	13%	13%
Dibutyl phthalate (DBP)	10.7	7.9	14%	14%
Diglyme	11.0	8.9	60%	70%
Hexabromocyclododecane (HBCDD)	2.0	2.0	100%	100%
Lead chromates	12.0	9.2	100%	100%
Diarsenic trioxide	11.3	7.8	33%	67%
Hexavalent chromium compounds	11.4	8.8	67%	75%
Trichloroethylene (TCE)	12.2	8.8	42%	89%
1,2-Dichloroethane (EDC)	13.0	10.3	40%	60%
Technical MDA	12.0	12.0	0%	50%
2,2'-dichloro-4,4'-methylenedianiline (MOCA)	12.0	4.0	100%	100%
Pitch, coal tar, high-temperature (CTPHT)	12.0	12.0	0%	13%
4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated (OPE)	11.1	9.7	49%	72%
4-Nonylphenol, branched and linear, ethoxylated (NPE)	8.4	8.4	52%	63%
Anthracene oil (AO)	12.0	12.0	0%	0%
Total	**11.5**	**8.8**	**52%**	**68%**

Notes: [a] Substances for which a DNEL for humans can be determined; [b] As proposed by the applicants; [c] As recommended by ECHA's scientific committees; [d] These may concern monitoring arrangements as well as additional risk management measures such as the introduction of lids, gloveboxes, ventilations etc.

Results

Overview of applications received

As of December 2020, applications for 28 different SVHCs (or broader groups of SVHCs) were received. For analytical purposes, these are grouped into eight substance groups, which are used in specific annual volumes and for specific use categories (or industrial applications).

Figure 1 summarises the information available on the actual uses applied for, illustrating that different substance groups and use volumes are used in distinct use categories. This reflects differences in both the technical functionalities of the substances requiring an authorisation and the organisation of the supply chain in which the substances are used.

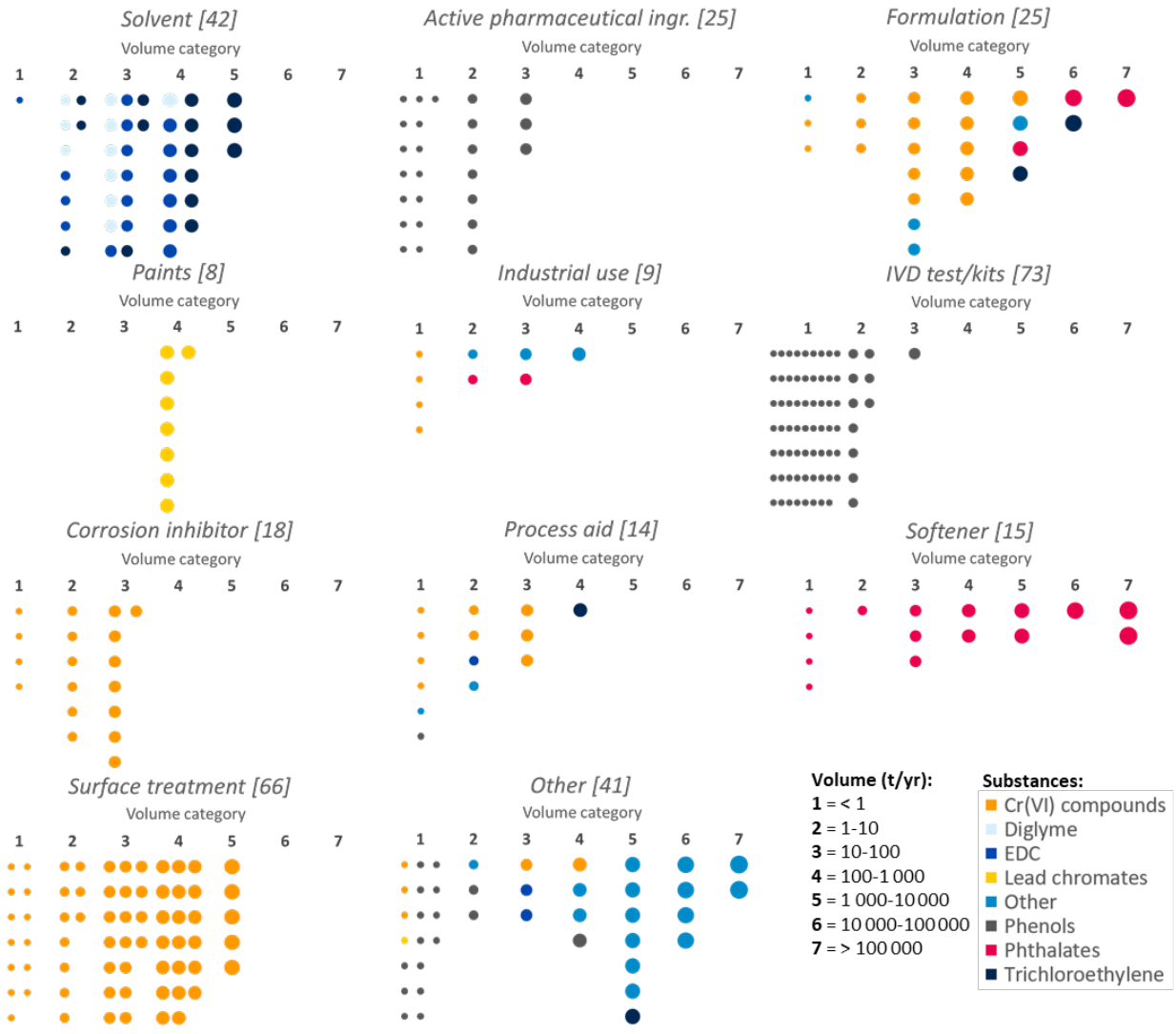

Figure 1: Substance groups, use categories and annual use volumes for which ECHA received applications for authorisations before January 2020.

As Figure 2 shows, applications for small annual use volumes (≤10 tonnes per year) have become more frequent over time and now account for the majority of uses applied for (~60 % of all uses applied for), whereas in the beginning applications for small and large use volumes (>10 tonnes per year) were balanced.

There are at least two conceivable reasons for this development. First, large upstream applications have become less popular over time. Second, the authorisation applications for octyl- and nonylphenols ethoxylated (OPE and NPE) were submitted almost exclusively by single firms reflecting business practices in the pharmaceutical sector. As these uses do not consume large quantities of OPE and NPE, they have a strong impact on the overall trend.

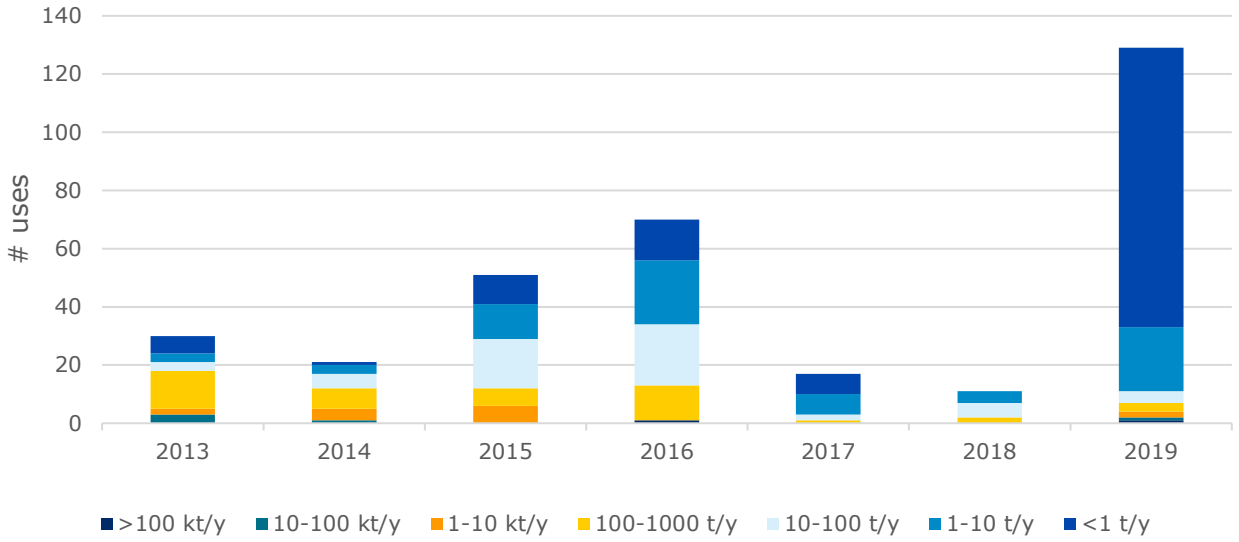

Figure 2: Annual use volumes applied for (in tonnage bands) over the period 2013-2019.

These developments are further supported by Figure 3, which provides a breakdown into downstream applications (made by users, formulators) and upstream applications (made by importers, manufacturers, only representatives), and a further differentiation among the former into applications submitted by SME companies and non-SME companies. As can be seen, the vast majority of downstream user applications were made by non-SME companies. This may indicate that SMEs mostly rely on upstream applications to cover their SVHC uses.

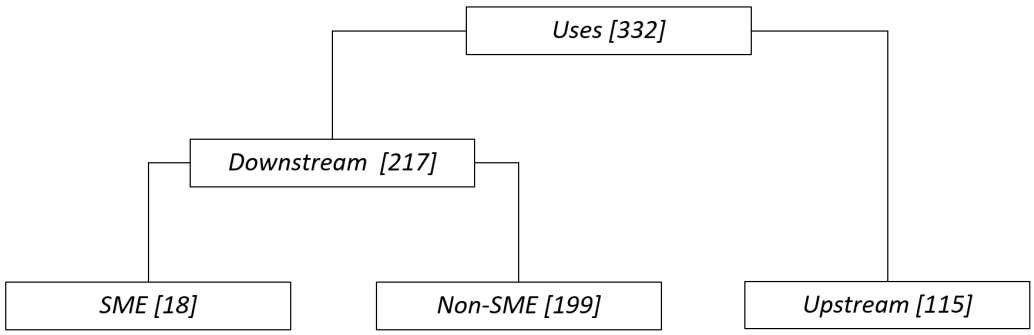

Figure 3: Breakdown of applications for authorisation received before January 2020.

Figure 4 shows that applications were received from most EU Member States, Norway and the UK.[12] Unsurprisingly, the number of applications received per Member State correlates strongly with the sales volume of the chemicals sector in that Member State. Indeed, a recent report of the European Chemical Industry Council (Cefic) suggests that Germany, France, Italy, the UK, and the Netherlands accounted for almost 70 % of EU chemicals sales in 2018 (Cefic 2020).

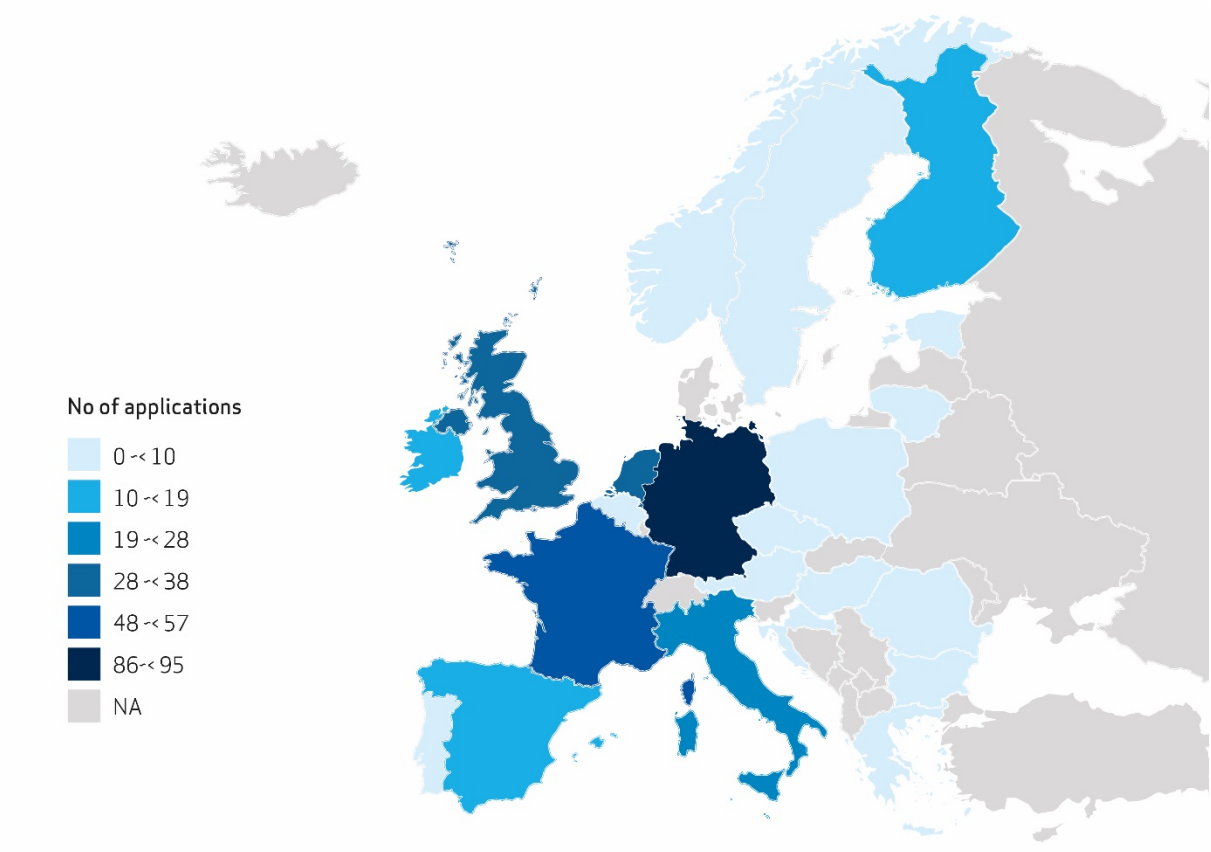

Figure 4: Geographical spread of applicants for authorisation.

Cost of applying

One tenet of the authorisation system is that applicants decide whether they can replace an SVHC use or seek an authorisation. If they decide to apply for authorisation, they will typically incur costs in terms of application fees (depending on company size the application fees range from about €1 000 per use for micro enterprises to €54 000 per use for large companies), consultancy fees, and staff time.[13] Based on 84 responses (response rate: 40 %) to a survey of the applicants, ECHA estimates that the average cost has been close to €200 000 per use (Figure 5).[14]

[12] It is important to remember that one application can be made by several applicants operating in one or more Member States and upstream applications may cover downstream users in all Member States. For this map, the addresses of legal entities applying for authorisation were used.

[13] In 2018, fees to be paid for applications for authorisation of SVHCs under REACH were revised by the European Commission. More information on the changes can be found on ECHA's website.

[14] For the analysis, it was assumed that staff time used by applicants was worth €96 000 per full time equivalent.

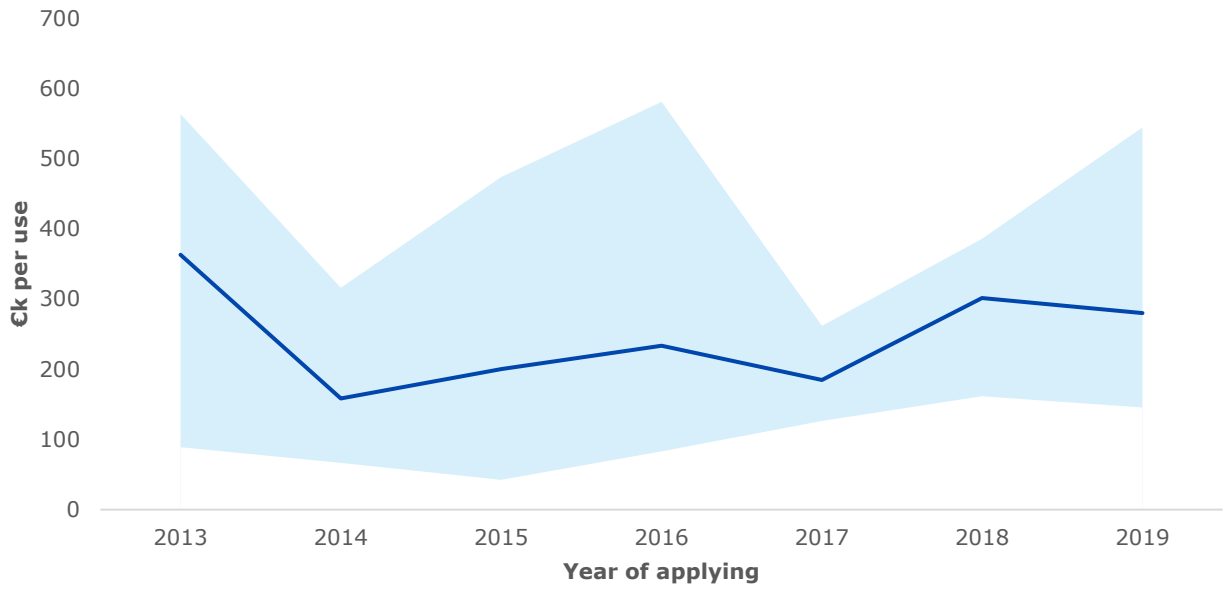

Figure 5: Average application cost per use in 2013-2019.

According to the responses of the applicants, the authorisation fees made up about a quarter of the total application costs, the applicant's own staff resources represented another third, and the rest was spent on consulting and other services. Application costs per year have strongly fluctuated as these depend on the legal sunset dates coming up (cf. Figure 2). Based on the information provided by applicants, ECHA estimates that over the period 2013-2019, application costs amounted to €7-9 million per year.

With the caveat that the response rate of the survey was 40 %, it seems that the application cost per use has decreased initially, then plateaued around €200 000 in the following years and rose again in 2018 and 2019 when big pharmaceutical companies applied for authorisation. Direct costs incurred by the applicant appear to have remained approximately the same as the application fees have not changed. The average staff time needed to prepare the application appears to have increased over time. This increase probably reflects the understanding of the applicants of the need to prepare well documented applications to the scrutiny of ECHA's scientific committees and the European Commission during the decision making.

Interestingly, application costs appear to be higher for applications that resulted in longer review periods being recommended. For example, the application costs for hexavalent chromium compounds suggest that applicants' costs for applying for a use with a recommended review period of 12 years were on average twice as high as those for similar applications that were recommended up to seven years. Similar differences can be observed with respect to application costs for other SVHCs. These differences may be the result of reduced application effort or they may indicate that applicants applying for shorter review periods would focus their efforts on fast substitution.

Socio-economic benefits of continued use

The benefits of continued use of SVHCs relate on one hand to the continuous availability of specific products and services to consumers. On the other hand, they relate to business maintenance and job security in the EU and other detrimental consequences that ceasing an SVHC use may have. In this section, the benefits are described for most of the substances under authorisation. In the Annex, the status of the four other SVHCs subject to authorisation is reported separately as they have not been included in the analysis.

The appropriate way of measuring these benefits hence requires an assessment of the opportunity cost arising to society if the applicant does not receive an authorisation and would have to stop using the substance applied for.[15] Applicants have typically highlighted aspects of their SVHC uses that are in favour of granting an authorisation but have ignored or misrepresented aspects that would reduce or balance the benefit of granting an authorisation (Georgiou et al. 2018). Applicants have often had difficulties in quantifying the value their activities added to society, for example, by taking forward use-related turnovers rather than surplus losses expected from ceasing the use applied for.

Moreover, many applicants ignored spill-over effects of an authorisation on:

- competitors who might incur gains in producer surplus;
- users of their products and services who might incur consumer surplus losses if alternative products are of inferior quality, have a higher price, or both; and
- workers who might temporarily lose their jobs.

When scrutinising the information by applicants, SEAC evaluated the reported benefits of continued SVHC use on a case-by-case basis. For carcinogens, this has resulted in benefit estimates (€8.7 billion on the aggregate) that are a fifth of those reported by applicants (€41.4 billion on the aggregate). It is, however, important to note that SEAC did not reassess welfare impacts that applicants had incorrectly quantified or ignored altogether; instead, they noted where such effects are likely to exist. It would thus be misleading to conclude that the benefits of continued use of SVHCs had been conclusively established in ECHA's opinions.

Risks to human health and the environment

The social benefits of granting authorisations ought to be seen against the risks of continued SVHC uses to human health and the environment. A worst-case estimate of the number of fatal excess cancer cases per year expected in workers and the general population from the continued use of the substances applied for was established at 112 statistical cases in the application dossiers scrutinised, and at 124 statistical cases in the respective opinions.[16]

It should be kept in mind, however, that the aggregate of the excess statistical cases is strongly affected by the assumptions on representative exposures in some of the upstream applications as these cover thousands of workplaces across the EU. For instance, several of the applications for hexavalent chromium compounds are based on a reasonable worst-case exposure of 2 $\mu g/m^3$ as proposed by the corresponding applicants. When assessing these applications, ECHA's scientific committees considered that measurement campaigns in various Member States suggest the actual exposure to hexavalent chromium is closer to 1 $\mu g/m^3$ in many European plating shops.

Comparing applicants' risk assessments against the evaluations made by RAC results in somewhat higher fatal excess cancer risk on average, with 10 % (11 out of 109) of uses scrutinised accounting for more than 90 % of the additional excess cancer cases assessed by RAC. While this result is based on the maximum plausible risk estimate, it indicates that applicants in some cases might have downplayed the actual exposure to SVHCs prevailing in the firms to be covered by the authorisation applied for.

[15] The notion of "continued use" relates to the continuation of the SVHC use beyond the legal sunset date and does not preclude the authorisation of uses that did not exist at the time the application was made.

[16] For normalisation purposes, these estimates were derived by dividing the monetised risk by a Value of Statistical Life (VSL) of €3.8 million which corresponds to the median VSL used in the opinions.

Overall, however, there is growing evidence that the REACH authorisation system has helped to reduce workers' exposure to SVHCs, thereby reinforcing occupational safety and health (OSH) legislation. Perhaps the most pertinent example relates to the use of hexavalent chromium for surface treatment which is undertaken in hundreds of workplaces across the EU. There is some evidence that the inclusion of hexavalent chromium compounds on the Candidate List in late 2010 and the subsequent promotion to Annex XIV in mid-2013 together with stricter national occupational exposure limit (OEL) values for hexavalent chromium in various EU Member States has led companies to invest in additional risk management measures, leading to a steady decline in exposure levels at workplaces (Vincent et al. 2015).

Moreover, in 2016 the Commission proposed a Union-wide binding OEL (BOEL) for hexavalent chromium of 25 µg/m^3 per 8 hours. During the legislative process, it became clear however that almost all companies that had applied for an authorisation of hexavalent chromium uses under REACH had exposure levels well below 5 µg/m^3. As a result, the European Parliament requested to lower the BOEL. The final BOEL for hexavalent chromium set in Directive (EU) 2017/2398 was subsequently reduced to 10 µg/m^3 until 17 January 2025, and 5 µg/m^3 thereafter.[17] Figure 6 illustrates this development against the backdrop of the empirical cumulative distribution function of exposure data reported in various applications for the authorisation of hexavalent chromium uses (see Rheinberger 2021 for a methodological discussion).

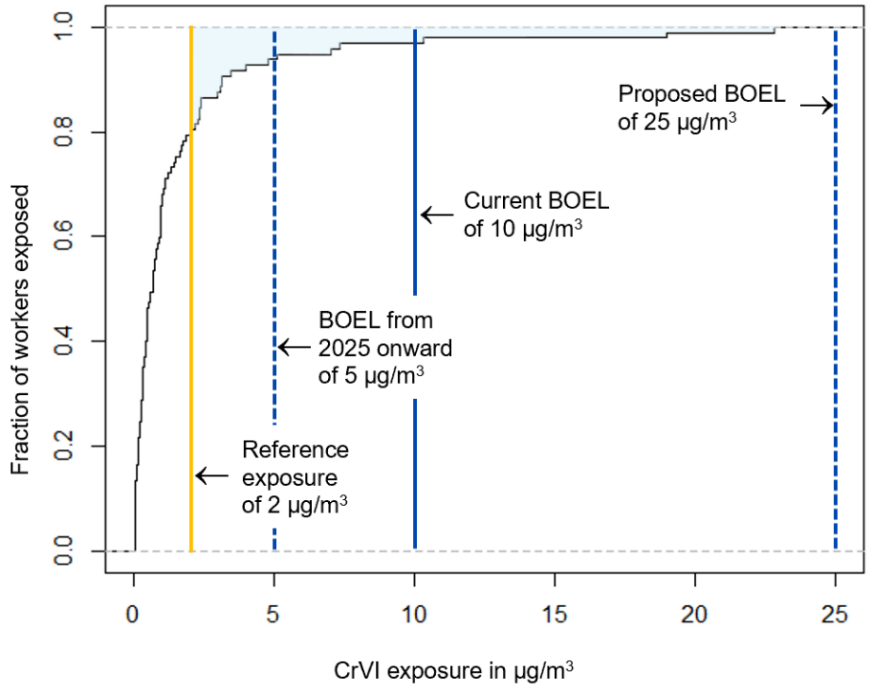

Figure 6: Cumulative exposure distribution in applications for authorisation of hexavalent chromium (CrVI) uses (ECHA 2017a).

[17] This is summarised in the corresponding opinion of the European Commission (2017):

- EU Member States: "REACH authorisation applicants for some chromium VI compounds in specified manufacturing processes have accepted 2 µg/m^3 as a basis on which to estimate the additional statistical cancer cases in their socioeconomic assessments." This calls for a value in the range of 1-5 µg/m^3."
- Workers' interest group: "Exposure data from REACH authorisations clearly show that this [1 µg/m^3] level of residual cancer risk is technically feasible for companies who applied for uses in the scope of authorisation (e.g. chrome plating)."

Benefits vs monetised risks

For substances for which a threshold could not be determined, applicants had to demonstrate that the social benefit of continuing to use the SVHC outweighs the associated risks to human health and the environment.[18] Money typically serves as the unit of comparison in socio-economic analysis. This requires the risks associated with the continued use of SVHCs to be converted into a social cost, which amounts to pricing in the detrimental impacts imposed on workers and the general population (via the environment).

Most applicants have used benefit transfer methods to monetise the risks associated with their SVHC uses by first establishing the number of fatal and non-fatal excess cancer cases expected from continued use, and then multiplying these case numbers by WTP values for the relevant health endpoints.[19]

To facilitate a meaningful comparison with the benefit of continued use (i.e. the opportunity cost of ceasing the use of SVHCs), the monetised risks need to be properly annuitised. For this report, this was done assuming a social discount rate of 4 %. The monetised annual risks reported by applicants suggests that, on aggregate, the continued use of SVHCs would results in negative health externalities of €423 million. In their scrutiny, SEAC took note of RAC's assessment of risks and raised the applicants' aggregate estimate by 11 % to €470 million. In general, however, SEAC only made adjustments relating to minor methodological mistakes.

Since the establishment of both the benefits and monetised risks is subject to uncertainties, the lower bound estimates of benefits and the upper bound estimates of costs (i.e. monetised risks) as evaluated by the committees are reported in Table 5 for those 109 uses for which sufficient information was available to establish monetised risks. After correcting for rounding errors, it was found that for every euro of health externality incurred, around €19 of economic value are preserved. Whilst this ratio holds for the aggregate impacts of authorisations as evaluated by ECHA's scientific committees, there is substantial heterogeneity on a use-specific level reflecting the different scopes of individual applications for authorisation.

Table 5: Summary of benefits and monetised risks for opinions adopted by December 2020 (N=109).

SVHC	Benefits of continued use (€m/y)	Monetised risks of continued use (€m/y)	Total net benefits (€m/y)	Benefit-risk ratio
Lead chromates	126.2	0.2	126	633:1
Diarsenic trioxide	85.0	4.8	80	18:1
Hexavalent chromium compounds	8 320	462	7 857	18:1
Trichloroethylene (TCE)	68.3	2.4	66	29:1
1,2-Dichloroethane (EDC)	89	0.03	89	3 487:1
Technical MDA	6.4	0.0004	6.4	17 326:1
2,2'-dichloro-4,4'-methylenedianiline (MOCA)	0.4	0.1	0.3	4:1
Total	**8 695**	**470.2**	**8 225**	**19:1**

[18] According to Article 60(2) of REACH, this is not required if the applicant demonstrates "the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled".

[19] Benefit transfer is the "practice of […] adapting value estimates from past research […] to assess the value of a similar, but separate, change in a different resource" (Smith et al. 2002: p.134). To ensure consistency in the monetisation of health risks, ECHA commissioned a large valuation study providing unit values for the most common health endpoints related to chemicals exposure (ECHA 2016).

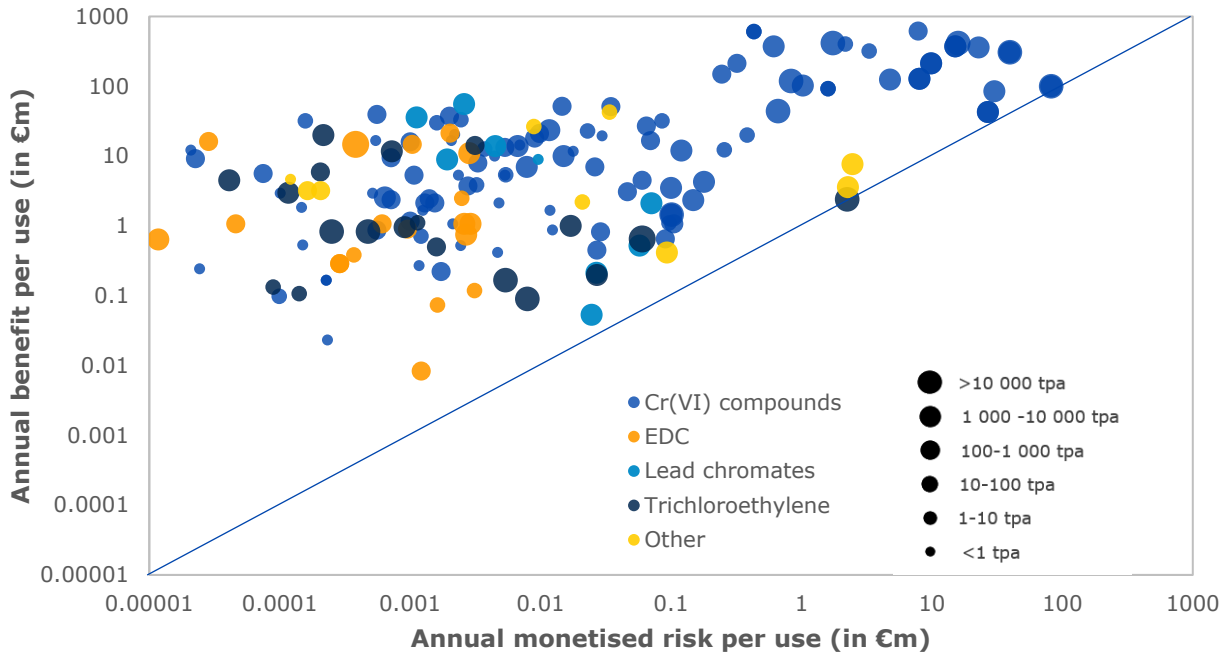

Figure 7: Benefits and risks of authorisations according to the opinions.

Figure 7 compares the annual benefits and monetised risks on a use-by-use basis (on logarithmic scales). Ratios of benefits vs monetised risks for uses involving smaller annual volumes tend to be larger than those for uses involving larger annual volumes. This is related to the type of application: smaller use volumes are typically associated with more narrowly defined downstream-user applications for which both benefits and risks can be determined with some certainty. On the other hand, large annual use volumes are mostly part of upstream applications sometimes covering whole industry sectors. In these cases, it is difficult to assess the full economic impacts of continued use as knock-on impacts on the relevant supply chains are hard to establish. While all of the substances on the Authorisation List are of very high concern, Figure 7 illustrates that they differ in terms of their risk potential. Uses involving hexavalent chromium (CrVI) compounds imply health risks that are orders of magnitude larger than uses of other bulk chemicals such as trichloroethylene (TCE) and dichloroethane (EDC). These differences result from both the potency of different SVHCs and use-specific exposures.

Benefits vs emissions

For some substances on the Authorisation List it is neither possible to establish a safe level of exposure nor are there reliable methods to quantify the risks.

OCTYL- AND NONYLPHENOLS, ETHOXYLATED. In non-ethoxylated form, octyl- and nonylphenols have endocrine disrupting properties in the environment, for example, in various fish species. However, after a careful review of the available scientific literature, RAC came to the conclusion that a predicted no effect concentration (PNEC) for octyl- and nonylphenols, ethoxylated (OPE and NPE) in the aquatic environment could not be reliably established.[20] Instead, RAC and SEAC decided to use end-of-pipe emissions of OPE/NPE in ethoxylated form as a proxy for risk.[21] To compare emissions to the benefits of continued substance use, applicants were invited to provide estimates of benefit-emission ratios, which ECHA's scientific

[20] A RAC note explains the reasoning behind this conclusion.

[21] A SEAC note explains the reasoning for using emissions as a proxy for risk.

committees evaluated.

Table 6 provides a summary of benefit-emission ratios for those OPE/NPE uses on which the committees had adopted an opinion or agreed on a draft opinion by December 2020. Releases are expressed in kilogrammes of OPE or NPE, i.e. in ethoxylated form of octylphenols (OP) and nonylphenols (NP). As a worst-case scenario, one might assume that the totality of OPE and NPE will eventually degrade into OP and NP once emitted to the environment. As the ratio of non-ethoxylated vs ethoxylated is approximately equal to 0.32, applicants assumed that the releases of OP and NP to the environment are one third of their releases in ethoxylated forms.

Table 6: Summary of benefits and emissions for authorisation opinions adopted by December 2020.

SVHC	Benefits of continued use [a] (€m/y)	Annual emission volumes [b] (kg/y)	Benefit-emission ratio (€m/kg)
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (OPE)	3 718	8 645	0.43
4-Nonylphenol, branched and linear, ethoxylated (NPE)	2 339	1 873	1.2
Total	**6 056**	**10 518**	**0.6**

Notes: [a] excluded health-related benefits of *in vitro* diagnostic kits and medicines as these are not quantified; [b] reported in ethoxylated form.

Importantly, the emissions reported in Table 6 reflect the situation at the time of application. However, many applicants had at the time of applying already identified substitutes and were requesting an authorisation only for a limited time period so that they could finalise the research and development work and obtain the necessary approvals for their altered products. As seen in Figure 8, the applicants projected that emissions of OPE/NPE would drop by 93 % from roughly 10 tonnes per year in 2020 to 0.7 tonnes per year by 2033.

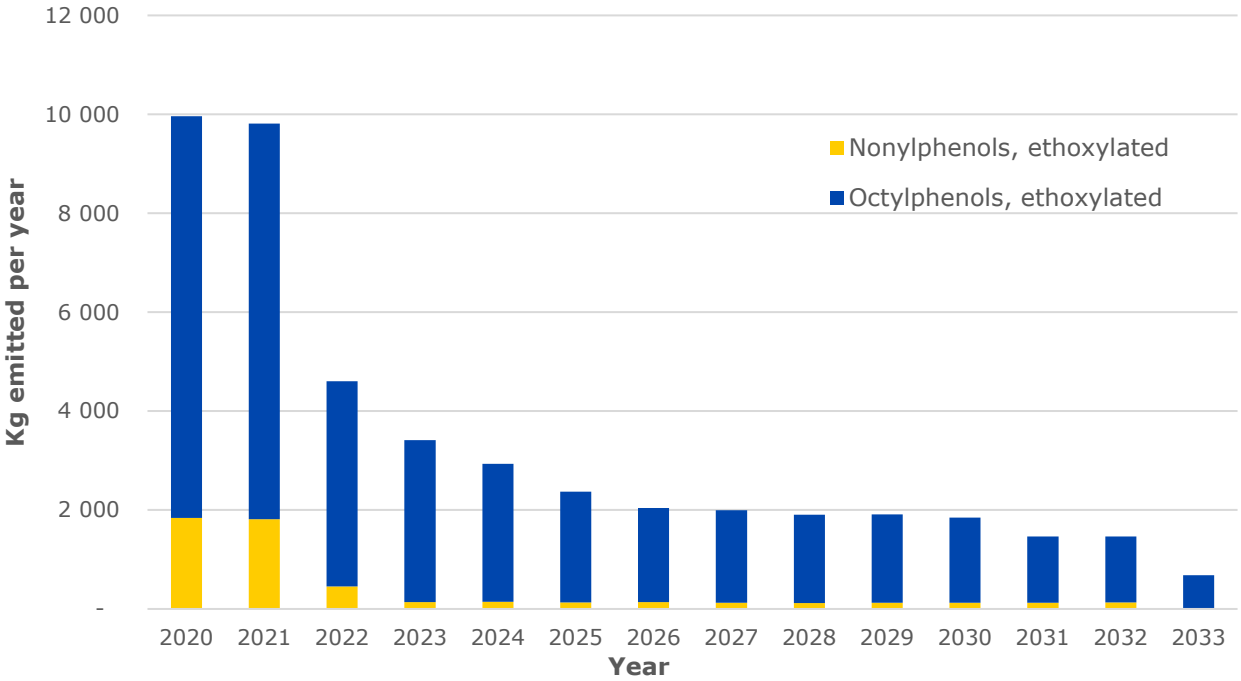

Figure 8: Forecasted annual emissions of nonyl- and octylphenols, ethoxylated, for applications evaluated by December 2020.

ECHA has made an effort to triangulate the emissions arising from the applications with those reported to the European Pollutant Release and Transfer Register (E-PRTR). The latest available data in the E-PRTR is for 2017 and includes releases reported by industrial facilities but also pollutant levels measured in wastewater treatment plant effluent. The purpose was to understand to what extent the authorised uses were contributing to the total amounts of OPE and NPE in the EU. The comparison showed significant differences.

OP/OPE emissions reported to the E-PRTR were significantly lower than the release estimates in the applications. The emissions in the applications were estimated to amount to 8.6 tonnes (Table 6), i.e. much higher than the emissions in the E-PRTR of 0.3 tonnes in non-ethoxylated form, equivalent to 1 tonne in ethoxylated form in 2017 in the EU-27[22]. It is important to find out why there is such a discrepancy[23].

NP/NPE emissions reported to the E-PRTR were significantly higher than the release estimates in applications. The emissions in the applications were estimated to amount to 1.9 tonnes (Table 6), i.e. much lower than the emissions in the E-PRTR of 13.5 tonnes in non-ethoxylated form, equivalent to 42.2 tonnes in ethoxylated form in 2017 in the EU-27[24]. Most of the releases reported to the E-PRTR come from wastewater treatment plants. It is likely, that NP/NPE contained in imported textiles are washed away to wastewater and are thus an important source of emissions and are reported in E-PRTR. NPE contained in imported textiles is not subject to authorisation[25]. Thanks to the REACH restriction proposal of Sweden on NP, the Commission decided in 2016[26] to restrict this source of emissions. As the restriction comes into effect in 2021 the municipal emissions of NP are expected to be reduced significantly.

Overall, while the comparison between emissions subject to authorisation and E-PRTR showed large differences it pointed out a better way to capture how significant the authorised uses compared to the overall environmental emissions in the EU.

COAL TAR PITCH, HIGH TEMPERATURE AND ANTHRACENE OIL. Other SVHCs leading to environmental emissions are coal tar pitch, high temperature (CTPHT) and anthracene oil. ECHA has received eight applications for uses of CTPHT and four for uses of anthracene oil. Because of the presence of polycyclic aromatic hydrocarbons (PAHs) in their composition, both CTPHT and anthracene oil are PBT and vPvB substances; moreover, CTPHT is a carcinogen.[27] Annual emissions of PAHs from CTPHT to the environment were estimated to be 140-1 400 tonnes per year in the opinions of ECHA's scientific committees. In comparison, the emissions arising from uses of anthracene oil were estimated to be small. Table 7 presents the estimated emissions and benefits of continued use as reported in the opinions of ECHA's scientific committees.

[22] In addition, in the E-PRTR in the UK the emissions were 50 kg in non-ethoxylated form, equivalent to 160 kg in ethoxylated form of OP.
[23] For instance, it is possible that the OPE contained in *in vitro* diagnostic test kits and released by hospitals is not picked up by the E-PRTR because i) some of these test kits are likely incinerated after use and thus not discharged to wastewater and ii) OPE emissions that are released by hospitals into the municipal sewer are diluted to a large degree and might thus be under reported.
[24] In addition, in the E-PRTR in the UK the emissions were 15 tonnes in non-ethoxylated form, equivalent to 46.9 tonnes in ethoxylated form of NP. It is not clear why reported releases in the UK outweigh reported releases in the EU-27.
[25] Thus, these emissions are naturally not included in the estimates summarised in Table 6.
[26] See Commission Regulation (EU) 2016/26.
[27] The anthracene oil used by the applicant contains benzo[a]pyrene in concentrations below 0.005% (w/w), and consistent with entry 40 to Annex XIV of REACH the substance does not meet the criteria for identification as a carcinogen.

Table 7: Summary of benefits and emissions for CTPHT authorisation opinions adopted by December 2020

SVHC	Benefits of continued use [a] (€m/y)	Annual emission volumes [b] (kg/y)	Benefit-emission ratio [b] (€/kg)
Coal tar pitch, high temperature (CTPHT)	11	770 000	€14/kg
Anthracene oil (AO)	3	1.2	€2 500 000/kg
Total	**14**	**770 000**	**€18/kg**

Notes: [a] Estimated based on the applications for authorisation; [b] Estimated based on mid value of emission range.

In December 2020, ECHA's scientific committees issued opinions on various uses of CTPHT and anthracene oil. While the committees made no particular observations on formulation uses, they had substantial reservations about the use of CTPHT as a binder in clay targets for sports shooting and considered that suitable alternatives are readily available in the EU. Accordingly, SEAC did not recommend a review period for this use of CTPHT.

The emissions estimated in the opinions on CTPHT use in clay targets were based on the information provided to the ECHA's scientific committees in the applications. As the sunset date for CTPHT has passed, ECHA is currently investigating – on the basis of Article 69(2) of REACH – the need to prepare a restriction dossier to address the risks of CTPHT in articles, in particular clay targets, that are potentially imported and placed on the EU market. As part of this work, the International Sports Shooting Federation (ISSF) informed that the emissions of CTPHT produced in the EU are some 157 tonnes per year and that an additional 145 tonnes would be emitted annually from imported clay targets (including imports from the UK to EU-27).

Recommendations made in ECHA's opinions on applications for authorisation

For each SVHC use applied for, ECHA's scientific committees sent an opinion to the European Commission comprising:

i) elements that help the Commission to grant or refuse authorisation;

ii) a recommended review period (i.e. a proposal for the duration over which authorisation is granted before a review report is required); and

iii) further recommendations with respect to workers' and/or public safety.

Next, the opinions sent to the European Commission so far are analysed with regard to these recommendations and their interplay.

REVIEW PERIODS. While ECHA's scientific committees have recommended the authorisation of all applications received so far, the recommendations on the review period have varied from 22 months to 12 years. This contrasts with the applicants' suggestions for review periods of up to 27 years.[28] Figure 9 summarises the review periods proposed by applicants and those recommended by the committees. On average, the latter were about three years shorter than the former (8.8 vs 11.5 years). In ECHA (2017a), the periods proposed by the applicants and

[28] Most applicants based their proposals for review periods on ECHA (2013b). It explains based on which criteria ECHA's scientific committees recommend a review period to the European Commission. This note assumed a default period of seven years, which can be shortened to e.g. four years or extended to 12 years based on (the lack of) fulfilling the criteria. As the services of the European Commission had endorsed the criteria, applicants mostly made proposals within the scope of the note. However, the note mentioned the possibility to propose review periods longer than 12 years in "particular and exceptional cases". For 46 uses, applicants did so.

recommended in the opinions were somewhat shorter (8.4 vs 11.1 years) suggesting that pharmaceutical uses of OPE and NPE obtained, on average, slightly longer periods.

For a quarter of the uses, the applicants had already identified technically feasible and economically viable alternatives but needed some time for implementation.[29] For most of these bridging applications, ECHA's scientific committees considered the proposed length of the review period to be justified. Similarly, when applicants had not found suitable alternatives despite demonstrated efforts, the committees generally accepted this as part of a justification for the proposed review period. For 114 uses (42 %), the committees recommended shorter review periods than proposed by applicants – either because the analysis of alternatives failed to convincingly demonstrate that suitable alternatives would not become available over the next years, or because the assessment of risks or socio-economic impacts contained substantial uncertainties and/or methodological shortcomings.

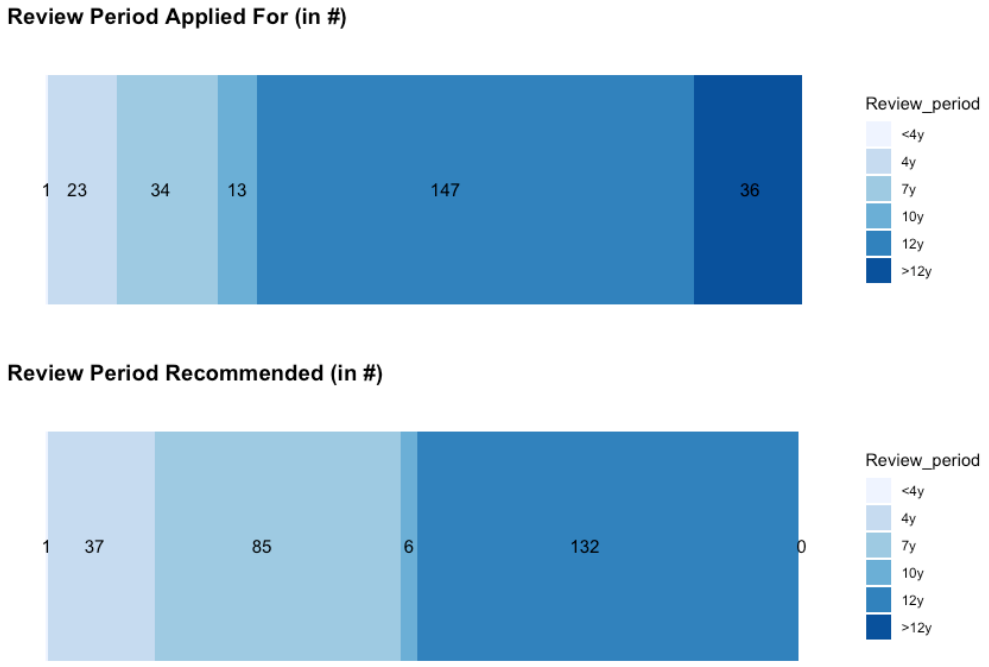

Figure 9: Summary of review periods proposed by applicants (upper panel) and recommended by ECHA's scientific committees (lower panel).

CONDITIONS AND MONITORING ARRANGEMENTS. ECHA's scientific committees may propose additional conditions (e.g. improved risk management measures or operating conditions) to further reduce the risks to workers and/or the general population (via emissions to the environment) and/or specific monitoring arrangements that enable the applicant to reduce existing limitations and uncertainties in their risk assessment. ECHA's scientific committees may also make recommendations for the review report (e.g. to allow RAC and SEAC to evaluate the review report efficiently).

In their decision, the European Commission may require the implementation of proposed conditions and monitoring arrangements and recommendations for the review report either as part of the authorisation or for the review report. ECHA's scientific committees recommended that additional conditions and monitoring arrangements should be included in the Commission decision in half of their opinions during 2013-20. Furthermore, for two thirds of the uses, the

[29] Examples include the use of the plasticiser DEHP in fan blades of aircraft engines and the use of HBCDD as a flame retardant additive, or OPE and NPE to produce IVD kits.

committees made recommendations that the authorisation holders need to account for in a possible review report. The number of times in which conditions were recommended by ECHA's scientific committees increased in 2017-2020 compared to the earlier period (Table 8).

Table 8: Conditions recommended per use in the opinions issued in 2013-2020.

	2013-2016		2017-2020		2013-2020	
Conditions	**Number of uses (adopted opinions)**	**Share of opinions including a condition**	**Number of uses (adopted opinions)**	**Share of opinions including a condition**	**Number of uses (adopted opinions)**	**Share of opinions including a condition**
for decision	53	41 %	110	56 %	163	50 %
for review report	76	59 %	146	72 %	218	67 %
Total	**129**		**197**		**326**	

Upstream applications

The REACH authorisation title allows upstream actors in the supply chain such as manufacturers and importer of the substance to apply for downstream users that they supply. There are various challenges relating to upstream applications because they may cover hundreds of companies and dozens of different substance uses. In theory, applicants should be able to provide use-specific information on all uses. In practice, however, such information is often not or only partially available.

In 2018, the Commission recognised in its REACH Review (Action 6) that the authorisation process should be simplified to improve the workability of the authorisation process. The simplification of applications for so-called 'legacy spare parts' is likely to take place in 2021. However, addressing the difficulties related to applications covering multiple operators has proven to be challenging.[30] With the caveat that it is not always obvious to determine when an application is 'upstream' or 'downstream', Figure 10 shows the share of upstream applications which has reduced considerably since the beginning of the application process.

Several reasons may have contributed to the reduced popularity of upstream applications. Considering the larger uncertainties involved, review periods recommended in ECHA's opinions on similar uses have generally been shorter for upstream applications than for downstream applications. Moreover, it has taken a long time for some important 'upstream' applications to obtain a decision which – according to information received from downstream applicants –has created business uncertainty, in particular for uses of hexavalent chromium.

[30] These are also known as "upstream" applications, where applications made be the manufacturers or importers of SVHC for the whole supply chain.

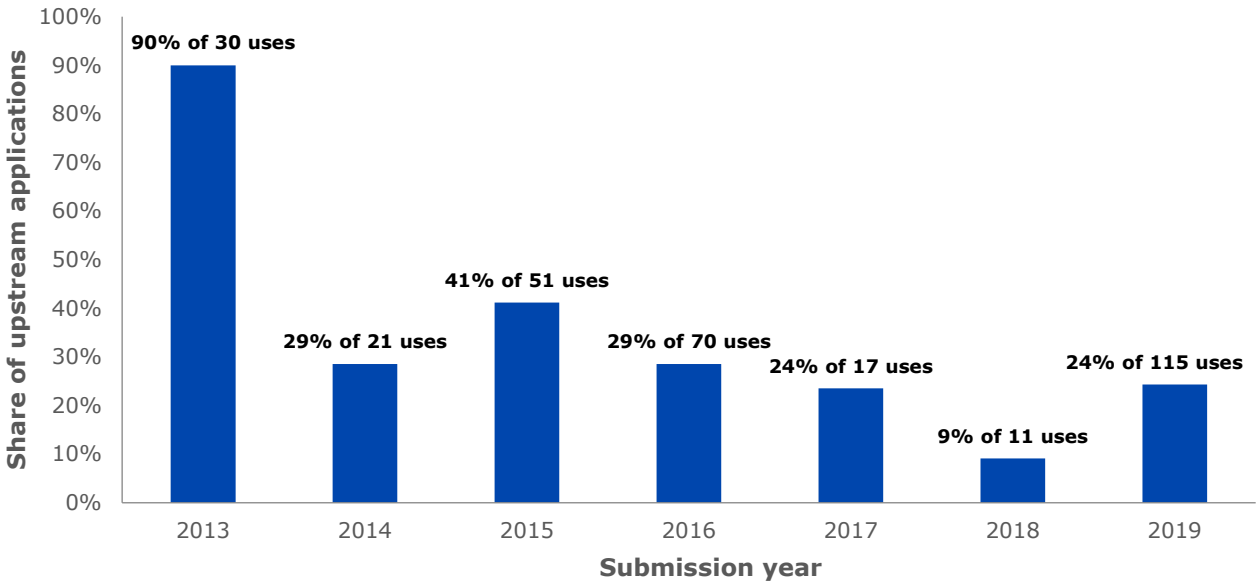

Figure 10: Development of upstream applications over the period 2013-2019.

In the future, it will be important to ensure the workability of the 'upstream' application system. ECHA's guideline on how to apply for authorisation (ECHA 2017b, p. 19) recommends a "two-level application strategy". This strategy was used partially in the applications for OPE and NPE whereby formulators applied for their own use (e.g. the manufacture of IVD tests/kits) as well as for the use of the IVD tests/kits by thousands of hospitals and laboratories.

From this experience, it can be concluded that the functioning of an upstream application system crucially depends on good communication in the supply chain from the users to the manufacturers and importers of a substance. This communication should ensure that precise descriptions of the risk management measures and operational conditions needed to lower exposures and emissions of the SVHCs reach the downstream users.

Furthermore, the communication should result in an improved analysis of the technical feasibility and economic viability of alternatives and a better inclusion of the expertise of alternative providers in the preparation of the applications. Such measures would improve the information basis both for preparing and evaluating applications for authorisation, and thus, reduce the overall burden of the authorisation system.

Substituting substances of concern with safer alternatives

One central objective of the REACH authorisation title is to incentivise companies to substitute away from substances of concern. According to ECHA's recent study (ECHA 2020b) on the impacts of REACH restriction and authorisation on substitution in the EU, 25 % of the surveyed companies indicated that they had started substitution activities at the time when the substance was officially added to the Candidate List.

Approximately the same number of respondents (27 %) traced the origin of substitution activities to the inclusion of the substances in the Authorisation List, while 17 % of the companies allegedly began their substitution activities sometime during the application for authorisation process. On the whole, in about 65 % of the cases substitution activities were reported to be undertaken after the inclusion of the substance in the Authorisation List, see Figure 11.

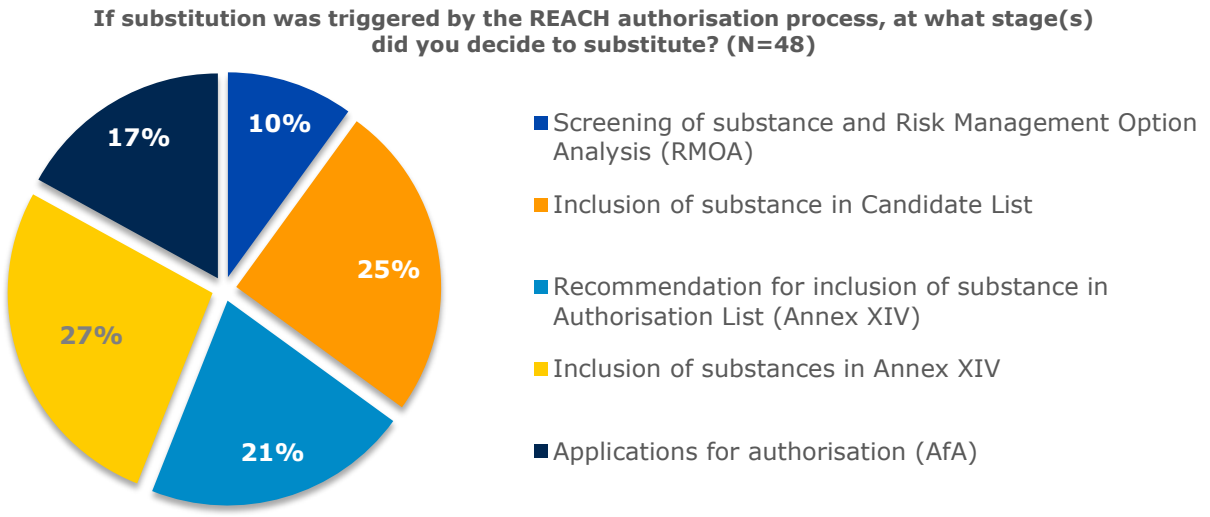

Figure 11: Stages at which substitution starts (source: ECHA 2020b).

SUBSTANCES FOR WHICH NO APPLICATIONS FOR AUTHORISATION WERE RECEIVED. As of December 2020, the Authorisation List comprised 54 substances or groups of substances of very high concern. For 43 substances, ECHA should have received applications for authorisation as the latest application date had passed. For 15 out of 43 substances (35 %) ECHA had not received any applications by the latest application date (Table 9).

In February 2020, the European Commission added 11 substances to the Authorisation List. According to its forecast (ECHA, 2020a), ECHA does not expect to receive applications for nine of these substances. For two newly added substances – trixylyl phosphate (EC number 246-677-8) and UV-328 (EC number 247-384-8) – ECHA received indications that some applications for authorisation may be submitted. Pulling these results together, it can be expected that for 24 of 54 substances (44 %) no applications will be submitted, suggesting that these uses were either substituted as the result of the entry to the Authorisation List (or earlier) or simply ceased.

For the remaining 28 substances, ECHA had received 217 applications for 346 uses by December 2020. Notably, some authorisation holders did not re-apply after expiry of their authorisation. In other cases, applicants have stated that authorisations have been applied for to continue the use of an SVHC temporarily until suitable alternatives becomes available. When suitable alternatives are developed, companies typically phase out the use of an SVHC. Of the 270 uses for which a draft opinion was adopted by December 2020, 64 uses (24 %) were considered such “bridging” applications.

Table 9: List of SVHCs for which no applications were received by December 2020.

SVHC	Entry number	EC number
5-tert-butyl-2,4,6-trinitro-m-xylene	01	201-329-4
4,4'-Diaminodiphenylmethane (MDA)	02	202-974-4
Benzyl butyl phthalate (BBP)	05	201-622-7
Diisobutyl phthalate (DIBP)	07	201-553-2
Diarsenic pentaoxide	09	215-116-9
Tris(2-chloroethyl) phosphate	13	204-118-5
2,4-dinitrotoluene (2,4-DNT)	14	204-450-0
1-bromopropane (n-propyl bromide)	32	203-445-0
Diisopentyl phthalate	33	210-088-4
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	34	276-158-1
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	35	271-084-6
1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear	36	284-032-2
Bis(2-methoxyethyl) phthalate	37	204-212-6
Dipentyl phthalate	38	205-017-9
n-pentyl-isopentylphthalate	39	933-378-9

Even when making a bridging application, it is possible that authorisation holders fail to substitute; for instance, because the research and development work undertaken with the identified alternative did not result in the desired performance. One way of finding out if applicants succeeded to substitute (or otherwise ceased the use of the substance) is to see whether they submitted a review report. As Table 10 reports, ECHA received review reports for only 8 of 24 granted authorisations that had or were about to expire by December 2020. This means that 97 % of the authorised volumes of SVHCs are no longer used in the EU.

Table 10: Annual use volumes of SVHCs in the first 24 applications and the respective review reports.

Status	Uses (#)	Use volume applied for (t)	Use volume in the review report (t)	Absolute reduction in use volume (t)	Relative reduction in use volume (%)
No review report received	16	6 978	0	6 978	100%
Review report received	8	12 190	587	11 603	95%
Total	**24**	**19 168**	**587**	**18 581**	**97%**

Table note: Concerns the following substances: two phthalates (DEHP and DBP), HBCDD, lead chromate pigments, hexavalent chromium, diarsenic trioxide, trichloroethylene and EDC.

EXAMPLES OF SUCCESSFUL SUBSTITUTION. While this report focuses on the experience related to the applications for authorisation received and evaluated by ECHA's scientific committees, it is insightful to see how the authorisation requirement has promoted substitution, and why no applications were received for specific substance uses. The first example (Box 1) is recent and concerns the successful replacement of sodium perborate by sodium percarbonate. The second example (Box 2) is very specific. It shows how government may be able to help in finding substitutes thereby reducing health risks. These examples illustrate the dynamic nature of authorisation and how it encourages substitution, when and where suitable alternatives are available. It is not possible for ECHA to report on such substitution activities in a systematic manner because it seldom learns about successful substitutions. This does, however, not mean that such substitutions do not take place.

Box 1: Replacement of sodium perborate by sodium percarbonate.

Sodium perborate (EC number 239-172-9) was one of the 11 substances added to the Authorisation List in February 2020 because of its toxicity to reproduction. It is primarily used as a source of oxygen in laundry detergents and peroxide-based bleaches. According to ECHA (2020a) no applications were expected for the substance due to the availability of technically feasible and economically viable alternatives. Several sources confirmed to ECHA that sodium percarbonate is the main alternative substance to replace sodium perborate and that it fully meets functionality and performance requirements without the hazards associated with sodium perborate. The substitution of sodium perborate had started before the inclusion of the substance in the Authorisation List. The latter ensured that the substitution would definitively take place.

Box 2: Replacement of arsenic trioxide by safer alternatives – Murano Glass.

Arsenic trioxide (EC number. 215-481-4), a carcinogenic substance, was added to the Authorisation List in February 2012 with a sunset date on 21 May 2015. The substance was widely used on Murano Island (Italy) to manufacture the world-famous Venetian art glass. The Murano glassmakers were now confronted with the dilemma – to apply for authorisation or to search for alternatives. They opted for the latter. The Italian government set up an R&D programme to help the glass makers to find substitutes. A mix of antimony trioxides and nitrate or carbonates of alkaline metals was identified as a suitable alternative. Some companies substituted to alternative substances or techniques and thus stopped using arsenic trioxide. Some glassmakers stopped producing the specific type of glass for which the use of arsenic trioxide was essential. As a result of these changes, the concentration of arsenic in the ambient air in the whole island of Murano dropped by 98 % (from an average of 200 ng/m^3 to 4 ng/m^3) bringing the levels below the EU target annual limit of 6 ng/m^3.[31] The Murano Glass case is a fine example of substitution taking place, and the positive health effects, due to the inclusion of a substance into the Authorisation List.

EXAMPLE OF RELOCATION. The authorisation requirement may also cause relocation, where the use of the substance would continue outside the EU. It is naturally difficult to tell with certainty if the authorisation requirement was the cause of the relocation. Box 3 describes such an exemplary cessation of use in the EU.

Box 3: Example of relocation because of the authorisation requirement.

One example of an impact of authorisation requirement concerns the specific use of 1,2-dichloroethane (EC no. 203-458-1). Even if the substance itself is a carcinogen, one company in the EU had used it as a processing aid in the development of an innovative cancer treatment. This company was a subsidiary of a non-EU company and used less than 10 kg of 1,2-dichloroethane per year for a specific high-tech treatment technology applied in hygienic conditions. The exposure to workers was therefore low. The non-EU owner of the company decided to relocate the production to its main production site outside the EU since it did not want to apply due to the perceived "business uncertainty". This also meant that the value added as well as the know-how of the production technology was no longer accrued in the EU.

[31] See also the results of a recent study by Formenton et al. (2020).

Conclusions

Taking stock of the applications for authorisation received and evaluated so far, the authorisation system has had socio-economic impacts at various levels. The requirements for authorisation do reduce the risks posed by SVHCs to workers and the general population, while permitting European industry to continue the use of SVHCs where and when substitution is currently not possible.

The conditions set in authorisation decisions also reduce the emissions related to the authorised uses of SVHCs and these are reinforced through the dynamic effects brought by the review requirement of the authorisation system.

The authorisation system has entailed costs on applicants as well as on regulatory authorities. On the other hand, as was also indicated in ECHA's recent report on the impact of REACH authorisations and restrictions on substitutions, the authorisation requirement has been a driver for industry to substitute SVHCs with alternative substances and technologies. Thereby, the system has also promoted innovation and growth of alternative producers.

When looking at the social benefits of authorising the continued use of SVHCs and the remaining risks that arise from these uses, the following conclusions can be made:

1) The risk reductions brought about by better risk management measures and operating conditions, as recommended by ECHA's scientific committees, have substantially reduced the exposure of workers and the general population to harmful chemicals. The risk reduction related to hexavalent chromium and the plasticiser DEHP is particularly noteworthy.

2) The authorisation system has helped to lower the burden of occupational diseases in the EU thereby reinforcing occupational safety and health legislation.

3) In the applications for authorisation received and analysed, the benefits outweighed the remaining risks to human health. ECHA's scientific committees estimated that the annual benefits (€8.7 billion) of authorisation – to allow the continued use of SVHCs when technically and economically feasible alternatives are not available – would be about 20 times higher than the remaining health risks.

4) In the applications for authorisation of environmental endocrine disruptors – octyl- and nonylphenols, ethoxylated – the annual benefits (€6.1 billion) were estimated. The remaining emissions to the environment were projected to reduce by over 90 % over the next decade from about 10 to 0.7 tonnes per year.

5) In addition to octyl- and nonylphenols, ethoxylated, the authorisation system has demonstrated its ability to address environmental emissions. This is particularly important concerning the use of coal tar pitch high temperature in clay targets where current emissions are still hundreds of tonnes of PAHs per year.

6) The dynamic effects of the authorisation system were analysed for the first time. For instance, due to substitution and the reduced need to use the substance, the first 24 authorisation holders reported that, overall, the use volume of the substances subject to authorisation had dropped by 97 % at the review stage.

7) On average, ECHA's scientific committees have recommend to the European Commission review periods that are 2.7 years shorter than those proposed by applicants. In half of the evaluated uses, additional conditions and/or monitoring arrangements were recommended.

This report highlights that – despite the remaining challenges – the REACH authorisation

system has not hampered the functioning of the EU internal market by authorising continued uses of SVHCs where and when suitable alternatives to these uses have not been available. The requirement to obtain an authorisation has, in many cases, led to substitution and also lowered the health risks of the continued use of certain SVHCs and reduced the emissions of others.

Annex: Status of other substances subject to authorisation

In addition to substances analysed in this report, four additional substances have been subject to authorisation. These are listed in Table 11.

Table 11: Other SVHCs subject to authorisation.

SVHC	Benefits of continued use [a] (€m/y)	Annual use volume [b] (t/y)	Estimated annual use volume in 2020 (t/y)
Hexabromocyclododecane (HBCDD)	0.02	8 000	0
Diglyme	40	374	374
Bis(2-ethylhexyl) phthalate (DEHP)	31	320 205	< 10 000
Dibutyl phthalate (DBP)	39	2 433	2 433

Notes: [a] Estimated based on the applications for authorisation; [b] Estimated based at the time of application.

HBCDD. The use of this flame retardant was authorised for only two years between 2015 and 2017. While the annual use was 8 kilotonnes the annual emissions were estimated to be 0.5 tonnes. Furthermore, some 3.2 tonnes were estimated to be released from demolition and disposal at later stages from four years of use of HBCDD. ECHA did not receive a review report after 2017 as the authorisation holders were able to substitute HBCDD with a brominated co-polymer of styrene and thus the emissions stopped.

DIGLYME. This solvent is toxic for reproduction and has a derived no-effect level. All nine applicants[32] demonstrated that they were below this threshold and thus, no remaining risks related to the reprotoxicity of the use were identified.

DEHP AND DBP. These plasticisers are toxic for reproduction and have a derived no-effect level. Because of their threshold nature there was no estimate of the remaining risks related to their use. Three manufacturers and three recyclers of plastics applied for an authorisation for DEHP and DBP in 2013. In 2016, ECHA proposed a restriction on the use of these substances (as well as DIBP and BBP) in articles based on Article 69(2), as the risk of their use was considered unacceptable. Following the Commission decision, the restriction entered into effect in July 2020. In the meantime, two of the applicants informed ECHA that they had ceased the manufacture of DEHP and DBP and thus withdrew their application. Furthermore, one recycler did not submit a review report and one withdrew the review report as it ceased its recycling activities. In 2020, the Commission requested the third applicant to provide a substitution plan to ECHA. Originally the applicants applied to use 320 kilotonnes of DEHP per year. The current use is a fraction of this, less than 10 % of the user in 2013 of the remaining applicant (Deza, 2020). Following the evaluation of the substitution plan, the Commission will decide whether to grant or reject the authorisation.

Overall, it is clear that the authorisation system – including the use of Article 69(2) to restrict the use of the use of DEHP and DBP in articles – has significantly (by over 95 %) reduced the use of these substances in the EU and thus had a major contribution to substitution.

[32] One applicant made two applications. In the first one the risks were not demonstrated to be adequately controlled.

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