

Socio-economic impacts of REACH authorisations

—A meta-analysis of the first 100 applications for authorisation

September 2017

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Socio-economic impacts of REACH authorisations – A meta-analysis of the first 100 applications for authorisation

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European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland

Visiting address: Annankatu 18, Helsinki, Finland

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Summary

One new element of the REACH Regulation is the authorisation title. It aims to ensure a sufficiently high level of protection for human health and the environment whilst allowing firms to continue the use of specific substances of very high concern (SVHCs), if the risks are adequately controlled. Otherwise, uses may still be authorised if the socio-economic benefits from the use of the substance are shown to outweigh the risks connected with its use and there are no suitable alternative substances or technologies that are economically and technically viable. Taking into account the good functioning of the internal market, the European Commission would grant an authorisation for the continued use.

This study looks at the first batches of applications for authorisation of some 20 SVHCs made to the European Chemicals Agency (ECHA) from 2013 to 2016. It summarises the available information on risks to human health and the environment associated with the continued use of these substances. Where possible, human health impacts have been monetised to help compare the costs and benefits of authorisations where the latter correspond to the opportunity cost of non-authorisation, i.e. the cost society would have to bear if an authorisation is not granted.

The study also compares the expected impacts of an authorisation (in terms of its benefits and risks) as described by the applicants to the evaluation of ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC).

Aggregated over the 118 uses of SVHCs that had gone through the REACH opinion making process by the end of 2016, the monetised risks to human health in the EU associated with the continued use of substances that require authorisation is estimated at €254m per year by applicants, and at €281m per year by ECHA's scientific committees. Similarly, applicants estimated that ceasing the uses they applied for would entail opportunity costs of €25.3bn per year. ECHA's scientific committees re-assessed these opportunity costs to be at least €4.2bn per year. The aggregate benefit-cost ratio per continued use in the applications was 100:1, whilst the aggregate benefit-cost ratio per continued use based on the assessment of RAC and SEAC was 15:1.

In their evaluation of the applications received, ECHA's scientific committees recommended to the Commission that, on average, the review period should be 8.4 years instead of 11.1 years as proposed by applicants.¹ Moreover, RAC recommended in the evaluation of this sample of 85 out of the 118 uses (72 %) to the European Commission that additional risk management measures, operating conditions or monitoring requirements be imposed as part of an authorisation. Whilst the impacts of these conditions are unknown yet, an illustrative estimation made for hard chrome plating with hexavalent chromium suggests that the risk reductions achieved are significant.

Generally, it is difficult to quantify the impact that the REACH authorisation title has had on reducing chemical risks to human health and the environment—either through successful substitution or better risk management practices in firms handling SVHCs. The conceptual difficulty is that it is impossible to know what the corresponding risks across

¹ It should be kept in mind that, in agreement with the European Commission, ECHA's scientific committees normally recommend review periods of 4, 7, or 12 years and deviate from these standard periods only if it is justified, e.g. in a bridging application to allow substitution taking place over a specific timeframe.

the EU would be if REACH was not in place. Moreover, attributing observed benefits to the implementation of REACH requires various assumptions to be made about the baseline scenario. Furthermore, it is difficult to know to how much substitution has taken place because of the authorisation requirement, because ECHA does not receive information of from companies that do not need an authorisation. Recognising these limitations, the current study assumed that the baseline to compare to would be the situation before the REACH authorisation title came into force.

Based on industry-wide exposure measurements, it is then possible to come up with approximate estimates of statistical cancer cases prevented partly due to the authorisation requirements. The illustrative example for hard chrome plating, for instance, suggests that better risk management measures may prevent 2.7 to 11 statistical cancer deaths per year depending on the assumed number of workers exposed throughout the EU and the preventive effect of additional risk management measures to be implemented as part of the authorisation. Monetising these cancer cases implies social benefits of approximately €10-55m per year, which may be attributable to REACH. While these impacts are uncertain, they are clearly important: chemicals risks to European workers and the public at large have been and will be reduced in a notable manner.

Introduction

The authorisation title of the REACH Regulation is a new way of approaching the management of hazardous chemicals, which incentivises firms in the European Union (EU) to substitute away from SVHCs where this is feasible.² In particular, SVHCs listed under Annex XIV to REACH must not be used after a specified sunset date unless a user or their supplier (e.g. the manufacturer or importer of the substance) hold an authorisation.

For substances for which a threshold in accordance with Annex I to REACH was established authorisations must be granted if the risk to human health or the environment from the use applied for is adequately controlled. Authorisations for substances for which it is not possible to determine a threshold may be granted if suitable alternatives to the specific use of the substance are not available and the applicant can credibly show that the socio-economic benefits of continuing its SVHC use beyond the sunset date outweigh the associated risk to human health and the environment.

The REACH authorisation title provides a flexible policy tool to manage the risks associated with the use of SVHCs. Together with EU Member States, the European Commission adds substances to Annex XIV to REACH. This 'authorisation list' includes substances which:

- (i) are carcinogenic, mutagenic or toxic to reproduction (CMR);
- (ii) are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB); or
- (iii) give rise to an equivalent level of concern (e.g. endocrine disrupters).

Firms, in turn, decide whether they wish to use a specific substance after the 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.

ECHA and its scientific committees then examine the claims made by the applicants in their applications and forward an opinion on each application to the European Commission, which then decides together with the Member States whether and for how long an authorisation will be granted.

As of May 2017, ECHA had received 115 applications for authorisation for 199 of some 20 different SVHCs (see Table 1).³ Each of these applications includes a specification of the substance and the use for which authorisation was applied for, supported by a chemical safety report (CSR), an analysis of alternatives (AoA) and a socio-economic analysis (SEA).⁴

² Consistent with the ECHA guidance on SEA, this comprises all countries in the European Economic Area.

³ For an up-to-date summary of applications received and substances applied for, see: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/received-applications>.

⁴ The provision of the SEA is optional, but most applicants have provided at least some socio-economic information.

ECHA's Committee for Risk Assessment (RAC) assesses the risks to human health and the environment arising from the specific use of the substance as well as the appropriateness and effectiveness of the risk management measures as described in the CSR. ECHA's Committee for Socio-economic Analysis (SEAC) examines the applicant's report on the availability and suitability of alternatives for the use applied for and assesses the socio-economic consequences of the authorisation decision. RAC and SEAC then provide a joint opinion to the European Commission for supporting regulatory decisions.

Table 1: Summary table of applications received, assessed and decided upon (as of May 2017).

| Year | Received notifications to submit | Pre-submission information sessions held | Applications received ^a (applicants) | No. of uses | RAC-SEAC opinions per use ^b | RAC-SEAC opinions per use and applicant ^c | Commission decisions per use and applicant ^d |
|--------------|----------------------------------|--|---|-------------|--|--|---|
| 2012 | 5 | 1 | 0 (0) | 0 | 0 | 0 | 0 |
| 2013 | 11 | 9 | 8 (10) | 17 | 1 | 1 | 0 |
| 2014 | 170 | 14 | 19 (33) | 38 | 30 | 34 | 2 |
| 2015 | 72 | 29 | 7 (20) | 13 | 25 | 51 | 10 |
| 2016 | 17 | 10 | 77 (132) | 112 | 63 | 180 | 52 |
| 2017* | 4 | 4 | 4(4) | 8 | 25 | 38 | 15 |
| Total | 279 | 67 | 115 (199) | 188 | 144 | 304 | 79 |

Table notes: * As of 15 May 2017; ^a An application is received in terms of Article 64(1) of REACH when ECHA has received the application fee; ^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 =) six RAC-SEAC opinions and subsequent Commission decisions; ^d Final decisions are made for each use and applicant.

Purpose

As the authorisation process is fully implemented, it is an opportune moment to take stock and analyse the applications for authorisations received so far. The purpose of this report is:

- 1) to describe and analyse the applications for authorisation received so far in terms of the substance uses applied for, their use volumes, the corresponding exposures, and the associated risks to human health and the environment as well as the socio-economic benefits of the continued use of SVHCs (i.e. the use beyond the legal sunset date);
- 2) to describe and analyse the opinions of ECHA's scientific committees on these applications. Special attention is given to the extent to which applicants have analysed the impacts of the benefits and remaining risks from a social point of view. This is relevant because firms are often aware of their own cost of substituting away from a SVHCs and, possibly, of the health impacts to their workers. However, they have demonstrated difficulties in seeing 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 listed in REACH Annex XIV and to report on the approaches and methods used to quantify those impacts.

Given the above objectives, the report proceeds as follows: the next section presents a summary of the available data and the methodological approach of the study. The results are presented and discussed with a particular focus on aggregate impacts in terms of the benefits and risks of the continued use of SVHCs. The report concludes with key learnings that can be drawn from the results, including any improvements to the continued implementation of the REACH authorisation title.

Methods

Data

The starting point for the study are all applications for authorisation and the corresponding opinions provided by ECHA's scientific committees as of December 2016.⁵ The various pieces of information are briefly explained hereafter 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. It is important to bear in mind that an upstream authorisation holder can potentially cover all downstream users of a substance within their supply chain. Therefore, the information presented is often incomplete with regard to the total number of firms that are beneficiaries of an authorisation.

USE-SPECIFIC INFORMATION. Applicants may apply for the use of one or several SVHCs but have to specify their use(s). As part of this specification, information has to be provided on the annual use volume of a substance.⁶ SVHC exposure is associated with carcinogenic, mutagenic or reprotoxic health endpoints, or otherwise gives rise to an equivalent level of concern. Dose-response functions and DNELs (derived no-effect levels) are typically used to map exposure levels to one or more adverse health endpoints. 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(s). This conversion is an intermediate step in the impact assessment of the continued use of SVHCs, which is followed by multiplying the estimated excess cases by the respective willingness-to-pay (WTP) value per statistical case.⁷

In economic terms, the monetised risk estimate internalises the negative impacts on human health so that they can be compared to the socio-economic benefit of continuing

⁵ Public versions of the application documents and the corresponding opinions are published on ECHA's website, see: <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations>.

⁶ If the annual use volume is claimed confidential information, applicants have to indicate a tonnage range (e.g. 1-10 tonnes per year). In this case, Table 2 displays the maximum annual use volume.

⁷ ECHA has provided both dose-response functions for the use of specific SVHC and reference WTP values for specific health endpoints, see: <https://echa.europa.eu/applying-for-authorisation/evaluating-applications>.

to use the SVHCs.⁸

In the assessment of applications for authorisation, this benefit is equal to the opportunity cost that arises if the applicant is no longer able to use the substance as discontinuing the use applied for is likely to involve producer and consumer surplus changes in the market the applicant is operating in.

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 requirements (MRs).

Shorter review periods may be recommended due to 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.⁹ 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 vary widely. All values displayed in Tables 2 and 3 are therefore subject to uncertainty and should not be interpreted as representing all socio-economic impacts that might be associated with the authorisation cases assessed. In particular, in sector-wide upstream applications it has proven to be 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 the REACH authorisation title to date.

Analytical approach

Qualitative methods were used to analyse the information obtained on the applications for authorisations received *and* assessed until the end of 2016. Particular focus was given to the aggregated benefits, the remaining risks as well as the substances and use volumes applied for. The results of the meta-analysis should be interpreted with care, however. Given the limited number of cases and important variations between large-scale upstream and small-scale downstream applications, they are necessarily indicative; nevertheless they may offer useful insights to the extent that they support or negate some common perceptions of the authorisation process.

⁸ Monetary impacts in Tables 2 and 3 were annuitised to allow for comparison 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.

⁹ Trialogue meetings between the rapporteurs of ECHA's committees, the applicant(s) and third parties wishing to challenge or support the claims made in a specific application for authorisation are frequently held.

Table 2: Summary table of uses applied for between 2013 and 2016.

| SVHCs (threshold substances ^a in italics) | No. of uses (applicants) | Use description ^b | Annual use volume ^c (t) | Applicant ^d | Workers exposed (per use) | Local population exposed (per use) | Maximum excess cancer cases (p.a.) ^e | Maximum monetised risk (€m/y) ^f | Minimum benefits of continued use (€m/y) ^g |
|---|---------------------------------|--|---|-------------------------------|--|--|--|--|--|
| <i>Bis(2-ethylhexyl) phthalate (DEHP)</i> | 13 (17) | Formulation: 2 Softener: 11 | Min: 1.0E0 Max: 1.0E5 Mean: 2.5E4 Med.: 4.0E1 | DU: 4 UP: 9 | -- | -- | -- | -- | Min: 1.0E1 Max: 9.7E1 Mean: 3.5E1 Med.: 1.2E1 |
| <i>Dibutyl phthalate (DBP)</i> | 4 (4) | Softener: 4 | Min: 2.0E1 Max: 1.0E3 Mean: 5.3E2 Med.: 5.5E2 | DU: 1 UP: 3 | -- | -- | -- | -- | Min: 3.6E1 Max: 1.8E2 Mean: 1.1E2 Med.: 1.0E2 |
| <i>Diglyme</i> | 1 (1) | Solvent: 1 | Min: 1.0E1 Max: 1.0E1 Mean: 1.0E1 Med.: 1.0E1 | DU: 1 UP: 0 | -- | -- | -- | -- | Min: 9.7E0 Max: 9.7E0 Mean: 9.7E0 Med.: 9.7E0 |
| <i>Hexabromocyclododecane (HBCDD)</i> | 2 (13) | Formulation: 1 Flame Retardant: 1 | Min: 4.0E3 Max: 4.0E3 Mean: 4.0E3 Med.: 4.0E3 | DU: 0 UP: 1 | -- | -- | -- | -- | Min: 2.1E2 Max: 3.2E2 Mean: 2.7E2 Med.: 2.7E2 |
| Lead chromates | 13 (2) | Formulation: 2 Flame Retardant: 1 Paints: 10 | Min: 1.2E-2 Max: 6.3E2 Mean: 3.3E2 Med.: 2.7E2 | DU: 1 UP: 8 | -- | -- | Min: 1.03E-6 Max: 1.28E-2 Mean: 4.00E-3 Med.: 1.54E-3 | Min: 7.3E-5 Max: 8.1E-3 Mean: 2.5E-3 Med.: 4.8E-4 | Min: 5.0E-2 Max: 7.3E1 Mean: 2.1E1 Med.: 8.9E0 |
| Diarsenic trioxide | 5 (4) | Formulation: 1 Cleaner: 1 Process aid: 1 Separation: 2 | Min: 5.0E-3 Max: 7.0E2 Mean: 2.1E2 Med.: 7.3E1 | DU: 5 UP: 0 | Min: 4.0E1 Max: 1.3E2 Mean: 7.4E1 Med.: 5.0E1 | Min: 2.67E4 Max: 1.94E5 Mean: 9.03E4 Med.: 5.00E4 | Min: 1.8E-6 Max: 3.64E-1 Mean: 1.39E-1 Med.: 4.67E-3 | Min: 1.2E-4 Max: 2.5E0 Mean: 1.2E0 Med.: 1.1E0 | Min: 4.7E0 Max: 1.1E2 Mean: 3.2E1 Med.: 7.5E0 |
| Hexavalent chromium compounds | 57 (171) | Formulation: 6 Corrosion inhibitor: 12 Process aid: 2 Separation: 1 Spraying: 3 Surface treatment: 33 | Min: 4.0E-2 Max: 9.0E3 Mean: 4.5E2 Med.: 1.0E1 | DU: 40 UP: 17 | Min: 6.0E0 Max: 6.2E4 Mean: 3.3E3 Med.: 4.3E1 | Min: 2.00E2 Max: 1.59E7 Mean: 1.07E6 Med.: 1.00E4 | Min: 2.00E-6 Max: 2.11E1 Mean: 1.10E0 Med.: 1.11E-3 | Min: 0.0E0 Max: 7.8E2 Mean: 4.3E0 Med.: 1.7E-2 | Min: 2.7E-1 Max: 5.7E3 Mean: 4.0E2 Med.: 1.7E1 |
| Trichloroethylene (TCE) | 18 (19) | Formulation: 2 Packaging: 1 Solvent: 15 | Min: 1.4E0 Max: 3.0E4 Mean: 2.3E3 Med.: 2.0E2 | DU: 12 UP: 6 | Min: 5.0E0 Max: 1.0E5 Mean: 6.0E3 Med.: 5.6E1 | Min: 4.39E2 Max: 1.57E9 Mean: 1.20E7 Med.: 2.07E4 | Min: 4.0E0-6 Max: 1.19E0 Mean: 6.69E-2 Med.: 2.15E-5 | Min: 3.9E-5 Max: 2.2E0 Mean: 1.3E-1 Med.: 4.9E-4 | Min: 1.3E-1 Max: 3.1E2 Mean: 4.1E1 Med.: 6.7E0 |
| 1,2-Dichloroethane (EDC) | 5 (5) | Solvent: 5 | Min: 1.0E1 Max: 2.5E2 Mean: 9.2E1 Med.: 6.0E1 | DU: 5 UP: 0 | Min: 1.0E1 Max: 1.6E3 Mean: 3.3E2 Med.: 3.5E1 | Min: 5.45E3 Max: 1.00E4 Mean: 9.10E3 Med.: 1.00E4 | Min: 7.53E-8 Max: 5.30E-4 Mean: 1.14E-4 Med.: 8.00E-6 | Min: 7.6E-7 Max: 1.3E-3 Mean: 3.2E-4 Med.: 7.9E-5 | Min: 1.1E0 Max: 3.8E1 Mean: 1.4E1 Med.: 1.1E1 |

Table notes: -- indicates that data was not relevant or incomplete; ^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 p.a.), maximum use volumes are reported; ^d Specifies role of applicant(s) in the supply chain: downstream user (DU), upstream manufacturer, only representative, importer or formulator (UP).

Table 3: Summary table of uses assessed by ECHA's scientific committees (as of end 2016).

| SVHCs (threshold substances^a in italics) | No. of uses (applicants) | Review period proposed by applicants (yrs) | Review period recommended by committees (yrs) | Conditions for authorisation^b | Conditions for review report^c | Maximum re-assessed excess cancer cases (p.a.) | Maximum re-assessed monetised risk (€m/y) | Minimum re-assessed benefits (€m/y) |
|--|---------------------------------|---|--|---|---|--|--|--|
| <i>Bis(2-ethylhexyl) phthalate (DEHP)</i> | 13 (17) | Min: 4 Max: 12 Mean: 7.5 Med.: 10 | Min: 4 Max: 7 Mean: 4.7 Med.: 4 | YES: 0 NO: 13 | YES: 0 NO: 13 | -- | -- | Min: 9.3E1 Max: 9.3E1 Mean: -- Med.: -- |
| <i>Dibutyl phthalate (DBP)</i> | 4 (4) | Min: 2 Max: 2 Mean: 2 Med.: 2 | Min: 2 Max: 2 Mean: 2 Med.: 2 | YES: 0 NO: 4 | YES: 0 NO: 4 | -- | -- | -- |
| <i>Diglyme</i> | 1 (1) | Min: 7 Max: 7 Mean: 7 Med.: 7 | Min: 7 Max: 7 Mean: 7 Med.: 7 | YES: 0 NO: 1 | YES: 0 NO: 1 | -- | -- | Min: 7.5E0 Max: 7.5E0 Mean: -- Med.: -- |
| <i>Hexabromocyclododecane (HBCDD)</i> | 2 (13) | Min: 2 Max: 2 Mean: 2 Med.: 2 | Min: 2 Max: 2 Mean: 2 Med.: 2 | YES: 2 NO: 0 | YES: 2 NO: 0 | -- | -- | Min: 9.0E-3 Max: 1.0E1 Mean: -- Med.: -- |
| Lead chromates | 13 (2) | Min: 12 Max: 12 Mean: 12 Med.: 12 | Min: 7 Max: 12 Mean: 9.2 Med.: 7 | YES: 9 NO: 0 | YES: 9 NO: 0 | Min: 3.18E-4 Max: 2.00E-2 Mean: 6.30E-3 Med.: 3.06E-3 | Min: 1.1E-3 Max: 7.1E-2 Mean: 2.2E-2 Med.: 9.6E-3 | Min: 5.3E-2 Max: 5.6E1 Mean: 1.4E1 Med.: 9.0E0 |
| Diarsenic trioxide | 5 (4) | Min: 1.8 Max: 20 Mean: 11.2 Med.: 7 | Min: 1.8 Max: 12 Mean: 8.0 Med.: 7.0 | YES: 1 NO: 4 | YES: 3 NO: 2 | Min: 1.80E-6 Max: 3.65E-1 Mean: 1.39E-1 Med.: 4.67E-3 | Min: 1.2E-4 Max: 2.5E0 Mean: 1.2E0 Med.: 1.1E0 | Min: 3.6E0 Max: 2.6E1 Mean: 1.1E1 Med.: 6.2E0 |
| Hexavalent chromium compounds | 57 (171) | Min: 4 Max: 27 Mean: 11.5 Med.: 12 | Min: 4 Max: 12 Mean: 9.0 Med.: 7 | YES: 33 NO: 24 | YES: 44 NO: 13 | Min: 2.5E-5 Max: 2.22E1 Mean: 1.27E0 Med.: 4.05E-3 | Min: 1.5E-4 Max: 8.2E2 Mean: 4.8E0 Med.: 2.3E-2 | Min: 2.7E-1 Max: 4.2E2 Mean: 6.8E1 Med.: 1.0E1 |
| Trichloroethylene (TCE) | 18 (19) | Min: 4 Max: 25 Mean: 12.2 Med.: 12 | Min: 2.2 Max: 12 Mean: 8.6 Med.: 7 | YES: 7 NO: 11 | YES: 16 NO: 2 | Min: 7.60E-6 Max: 1.19E0 Mean: 6.75E-2 Med.: 1.99E4 | Min: 4.1E-5 Max: 2.2E0 Mean: 1.3E-1 Med.: 1.0E-3 | Min: 9.0E-2 Max: 2.0E1 Mean: 3.6E0 Med.: 8.9E-1 |
| 1,2-Dichloroethane (EDC) | 5 (5) | Min: 12 Max: 12 Mean: 12 Med.: 12 | Min: 7 Max: 12 Mean: 11 Med.: 12 | YES: 1 NO: 4 | YES: 2 NO: 3 | Min: 9.00E-6 Max: 8.35E-4 Mean: 3.31E-4 Med.: 1.30E-4 | Min: 4.6E-5 Max: 2.9E-3 Mean: 1.6E-3 Med.: 2.0E-3 | Min: 1.1E0 Max: 2.1E1 Mean: 5.1E0 Med.: 1.1E0 |

Table notes: -- indicates that data was not relevant or incomplete; ^a Substances for which a DNEL for humans can be determined; ^b Monitoring is typically required when measurement data are insufficient to assess exposure levels reliably; ^c Examples include the introduction of lids, gloveboxes and other technical risk management measures; ^d Specifies role of applicant(s) in the supply chain: downstream user (DU), upstream manufacturer, importer or formulator (UP).

Results

Overview of applications received

As of December 2016, applications for 21 different substances (grouped into broader substance groups were applicable) were received. For analytical purposes, these are grouped into nine substance groups, which are used in specific annual volumes and for specific use categories (or industrial applications).

Figure 1 summarises the information available on uses, illustrating that the different substance groups are used in distinct use categories.

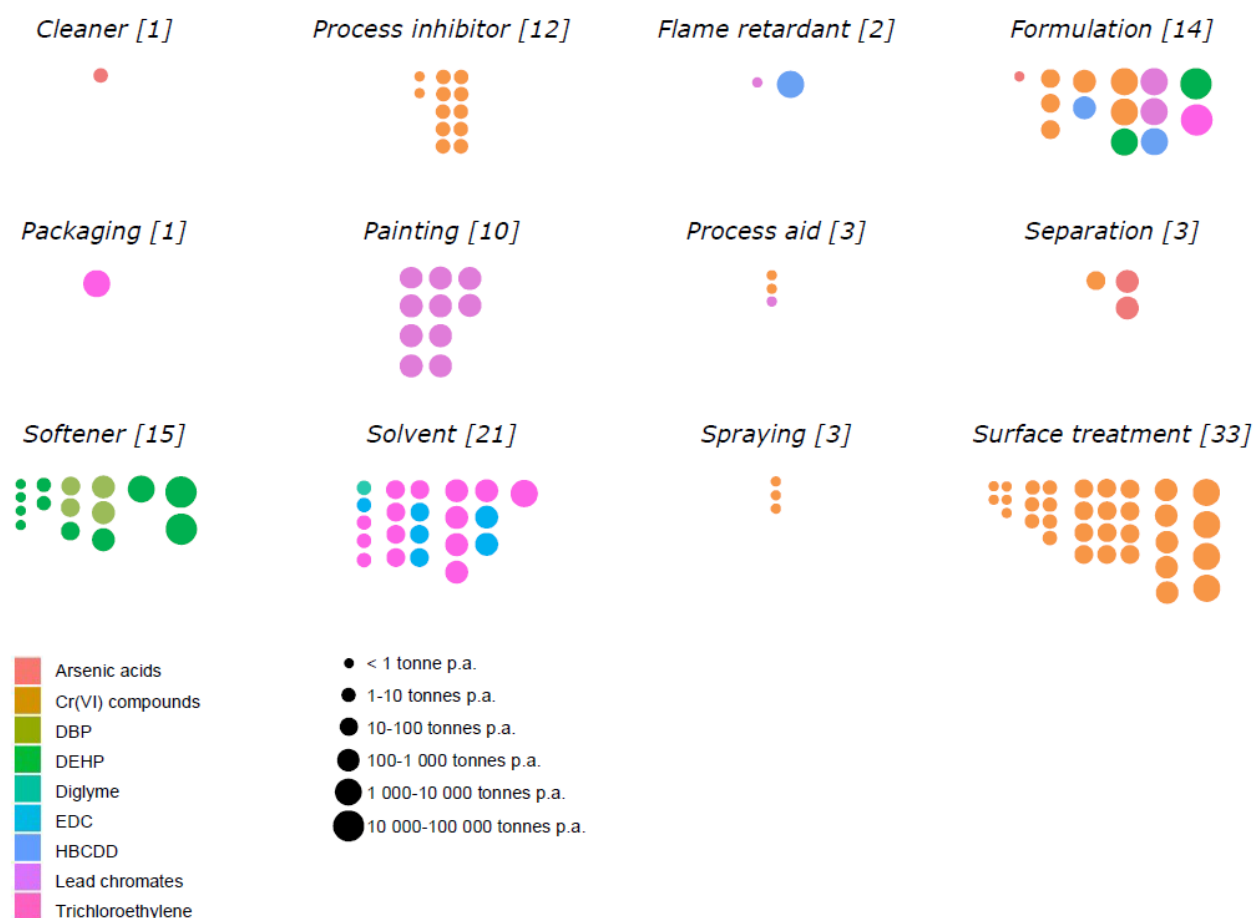


Figure 1: Substance groups, use categories and annual use volumes for which ECHA received applications for authorisations between 2013 and 2016.

Figure 1 demonstrates that small scale (≤ 10 t/y) and large scale (> 10 t/y) uses of SVHCs have so far been in balance, suggesting that there are reasons for and against applying as part of an upstream application.

This interpretation is supported by Figure 2, which provides a breakdown into upstream and downstream applications, and among the latter into SME and non-SME applications. The majority of individual downstream user applications were made by non-SMEs. This may indicate that SMEs mostly rely on upstream applications to cover their SVHC uses.

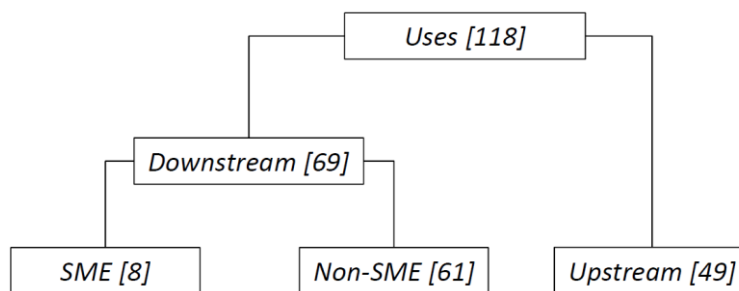


Figure 2: Breakdown of applications for authorisation received by ECHA between 2013-2016.

Figure 3 shows that applications were received from the majority of Member States.¹⁰ Unsurprisingly, the number of applications received per Member State strongly correlates with the sales volume of the chemicals sector in the respective Member State. Indeed, a recent report of the European Chemical Industry Council suggests that Germany, France, Italy, the UK, and the Netherlands accounted for almost 70 % of EU chemicals sales in 2015 (Cefic 2017). As Figure 3 shows, these five countries are also home to 74 % of the firms that had applied for authorisation by the end of 2016.

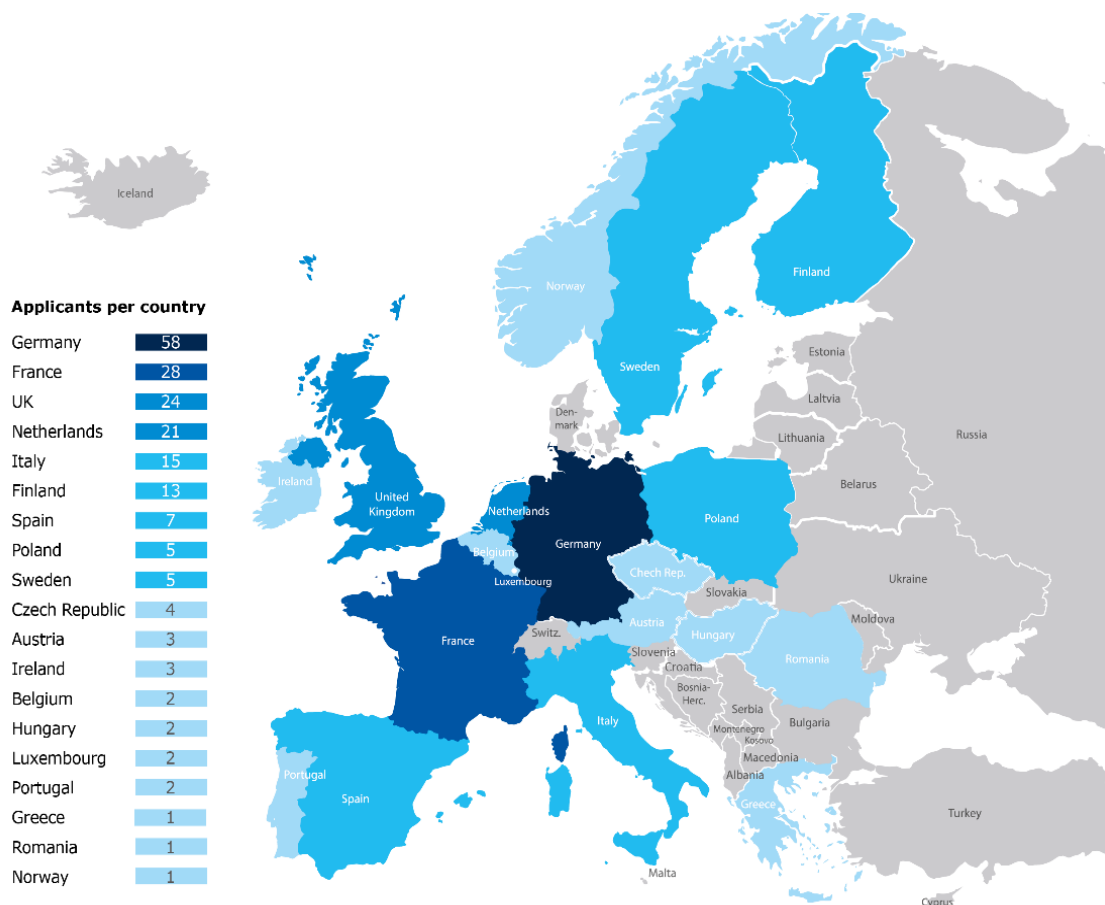


Figure 3: Map of applicants per Member State (2013-2016).

¹⁰ It is important to remember that one application can be made by several applicants operating in one or more Member States. Similarly, upstream applications may cover downstream users in all Member States.

Socio-economic benefits of continued use

The appropriate way of measuring the benefits of continued use of SVHCs 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.¹¹

Applicants have typically highlighted aspects of their SVHC use that are in favour of granting an authorisation, but have ignored or misrepresented aspects that would reduce or limit the benefit of granting an authorisation. In particular, applicants have 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 have ignored spill-over effects of an authorisation on:

- (i) competitors who might incur gains in producer surplus;
- (ii) 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
- (iii) workers who might lose their jobs, but eventually find employment elsewhere in the economy.

When scrutinising the evidence provided by applicants, SEAC evaluated the social benefits of continued SVHC use on a case-by-case basis. Figure 4 displays the cumulative annual benefits (in €m) across the 94 uses for which benefit assessments were available (considering the minimum estimates suggested by applicants and evaluated by ECHA's scientific committees).

Obviously, there is a large difference between the two cumulative distributions with the aggregated benefits established by applicants being roughly six times larger than the aggregated benefits evaluated by SEAC (€25.3bn vs €4.2bn).

A closer look at the cumulative distribution depicted in Figure 4 indicates that 16 of the 94 uses (those in the red box) accounted for more than 90 % of the difference between the benefits of continued use established by applicants and those evaluated by SEAC. Moreover, a case-by-case comparison of applicant-established benefits vs benefits evaluated by SEAC suggests that applicants had overstated the benefits of continued use in 70 out of the 94 uses identified.¹²

¹¹ 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.

¹² Further research is needed to determine whether these overstatements were made for strategic reasons or out of ignorance. One reason could be that, in their evaluations, SEAC have not always re-assessed benefits that applicants had erroneously quantified (instead, opinions have often discussed these in qualitative terms).

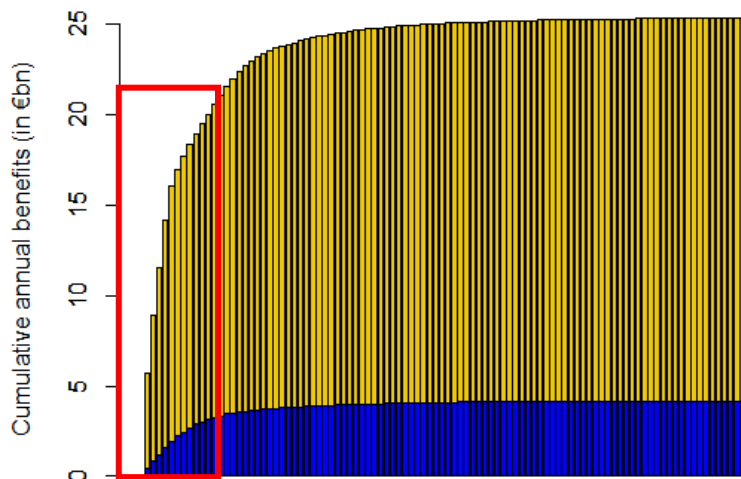


Figure 4: Cumulative annual benefits (in €m) of uses applied for; yellow: benefits established by applicants; blue: benefits evaluated by SEAC; red: uses accounting for >90 % of the difference.

Remaining 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 cancers per year expected in workers and the general population from the continued use of the substances applied for was pegged at 64.2 statistical cases in the application dossiers scrutinised, and at 74.5 statistical cases in the respective opinions.

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

Comparing applicants' risk assessments against those done by RAC results in a 15 % underestimation of fatal excess cancer risk on average, with 7 out of the 94 applications scrutinised accounting for more than 90 % of the additional excess cancer cases assessed by RAC (see the red box in Figure 5). 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.

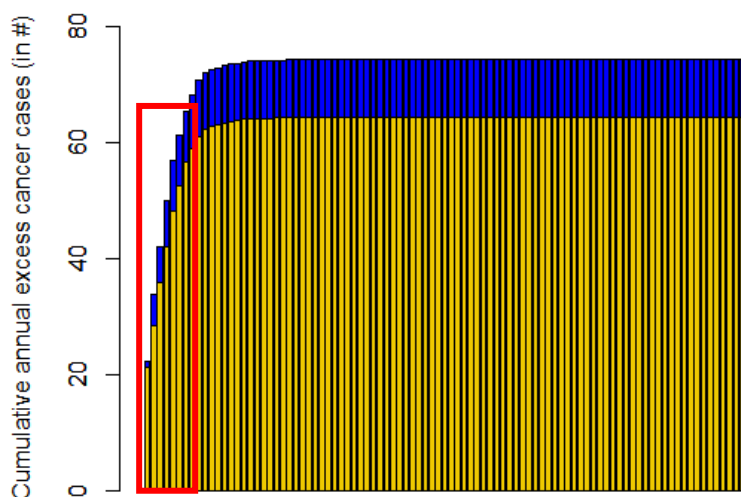


Figure 5: Cumulative annual excess cancer cases (in #) associated with uses that have lung or intestinal cancer as relevant health endpoint; yellow: cancer cases established by the applicants; blue: cancer cases evaluated by RAC; red: uses that account for >90 % of the difference.

How are the negative impacts of the continued use of SVHCs spread across the EU? Figure 6 illustrates the number of workers (left panel) and members of the general population (right panel) exposed to the substance groups for which applications have been made. Over all uses, ECHA's scientific committees found a total of 0.3 m workers exposed to SVHCs for which an authorisation is required.

The aggregate number of members of the public exposed indirectly via the environment (through diet, drinking water, air and soil) amounts to 251.4 m highlighting that the REACH authorisation title potentially affects a considerable fraction of EU citizens.¹³ Workers bear individual annual excess cancer risks, which are on average sixty times higher to those risks borne by local populations (living within 10 km of a given plant). Indeed, the average excess lifetime risk for workers was 4.6 in 100 000 whilst for local populations this was estimated at 0.8 in 1m individuals.¹⁴

Averaged over all individuals potentially exposed to SVHC uses for which authorisation has been sought, the excess lifetime risk of developing cancer amounts to roughly one in a million.

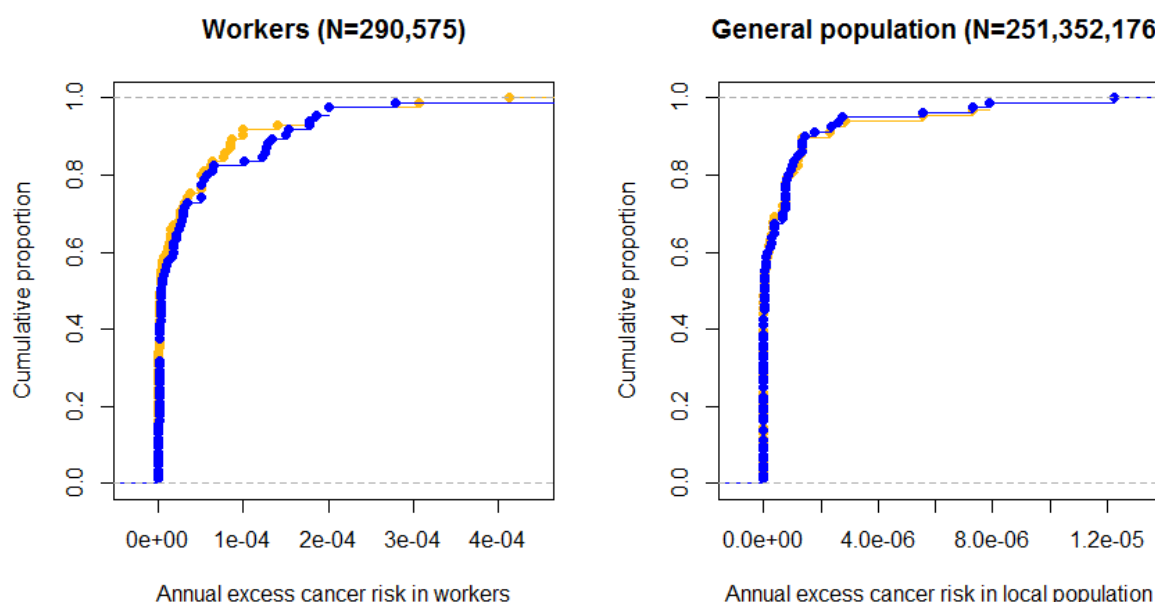


Figure 6: Individual excess lifetime cancer risk in workers (left panel) and local populations (right panel) exposed to SVHCs for which authorisations were sought; yellow: risk assessed by the applicant; blue: risk evaluated by RAC.

¹³ Risks associated with different SVHC uses might affect one and the same individual. Hence, it might be fallacious to conclude that almost half of the EU population is exposed to continued use of SVHCs.

¹⁴ These excess cancer risks can be interpreted as follows. If 100 000 workers were exposed to the working conditions of the average worker described in the applications for authorisation over their whole work life of 40 years, then one would expect every year 4.6 fatal lung cancer cases among them that could be directly associated with their exposure to SVHCs.

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 SVHCs outweighs the associated risks to human health and the environment.¹⁵

Money typically serves as the unit of comparison in the socio-economic impact assessment. 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 by first establishing the number of fatal and non-fatal excess cancer cases expected from the continued use of the substance applied for and then multiplying these numbers by WTP values for the relevant health endpoint.¹⁶

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. Annuitisation of the monetised risks assessed by applicants suggests that, on an annual basis, the continued use of SVHCs applied for results in negative externalities of €245m.

In their scrutiny of these estimates, SEAC took note of RAC's assessment of risks and raised the applicants' aggregate estimate by 15 % to €281m. In general, however, SEAC made only minor adjustments relating to small 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 displayed.

After correcting for rounding errors, the ratio of benefits to costs as established by the committees is 15:1, meaning that for every Euro of health externalities incurred, €15 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 4 reports the benefit-monetised risk ratios as well as the annual net benefits pertaining to those 94 for which sufficient information was available in both the applications and opinions.

¹⁵ 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".

¹⁶ Benefit transfer has been defined as 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 some of the most common health endpoints related to chemicals exposure (see ECHA 2016). These unit values were not yet available when the first applications for authorisation were submitted, but some older reference values were recommended in the ECHA guidance on Socio-economic Analysis. As a result, there is some variation in the value per statistical life (VSL) across the applications for authorisation studied here (median VSL: €4.1m, interquartile range: €3.3m to €8.9m).

Table 4: Summary of use-specific benefit-monetised risk ratios and annual net benefits (in €m).

| Uses by | Min. | 1 st Qu. | Median | Mean | 3 rd Qu. | Max. | NA's |
|--|--------|---------------------|--------|--------------|---------------------|-------|------|
| Benefit-monetised risk ratio (application) | 3.0E0 | 8.8E1 | 3.2E3 | 3.9E5 | 7.7E4 | 7.7E6 | 21 |
| Benefit-monetised risk ratio (opinion) | 1.1E0 | 2.2E1 | 5.9E2 | 6.8E3 | 3.3E3 | 1.1E5 | 21 |
| Annual net benefit in €m (application) | 5.0E-2 | 1.9E0 | 1.2E1 | 2.6E2 | 7.3E2 | 5.7E3 | 21 |
| Annual net benefit in €m (opinion) | 2.9E-2 | 9.7E-1 | 4.5E0 | 4.1E1 | 2.0E1 | 4.1E2 | 21 |

For non-threshold substances (mostly carcinogens), a more in-depth analysis can be undertaken. Figure 7 compares the benefits and monetised risks on a use-by-use basis (on logarithmic scales). It appears that the benefit-cost ratios of uses involving smaller annual use volumes are larger (and involving larger annual use volumes are smaller).

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.

Whilst all of the substances on the authorisation list are of very high concern, Figure 7 also illustrates that they differ in terms of their risk potential. Uses involving hexavalent chromium (Cr6) compounds imply health risks that are orders of magnitude larger than comparable uses of other bulk chemicals such as trichloroethylene (TCE) and dichloroethane (EDC). The differences result from both the potency of different SVHCs as well as from use-specific exposures.

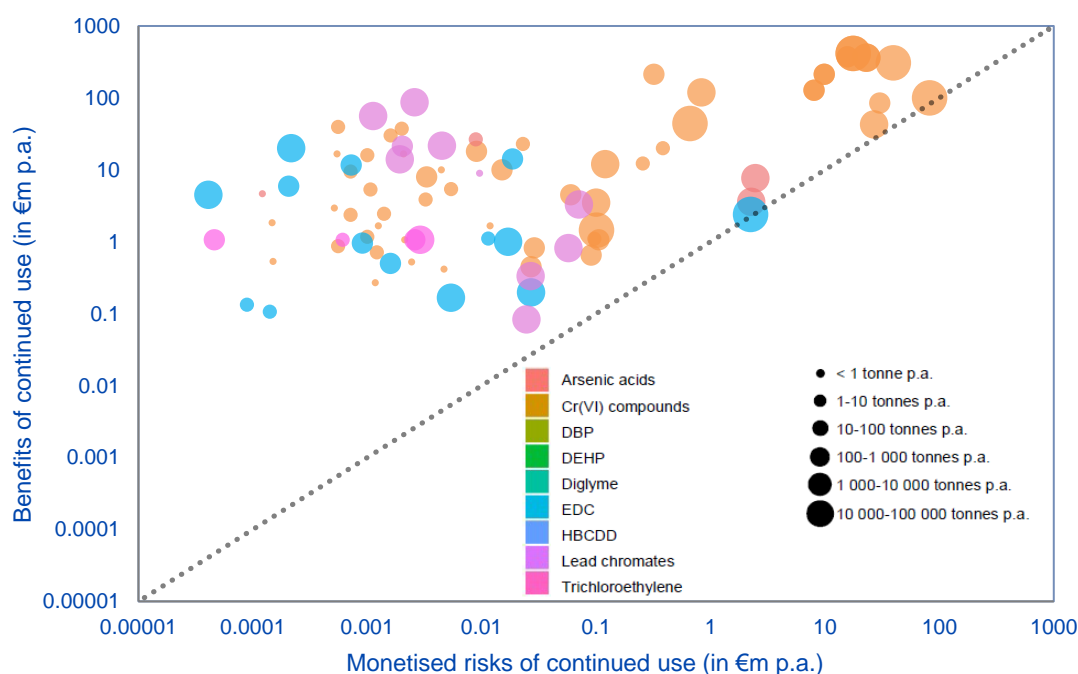


Figure 7: Comparison of use-specific benefits vs monetised risks (on an annual basis) for different substance groups and use volumes.

Recommendations made on applications for authorisation

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

- i) a recommendation 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. Whilst ECHA's scientific committees have recommended the authorisation of all applications received so far, the recommendations on the review period have varied from 26 months to 12 years. This contrasts with the applicants' suggestions for review periods of up to 27 years.¹⁷

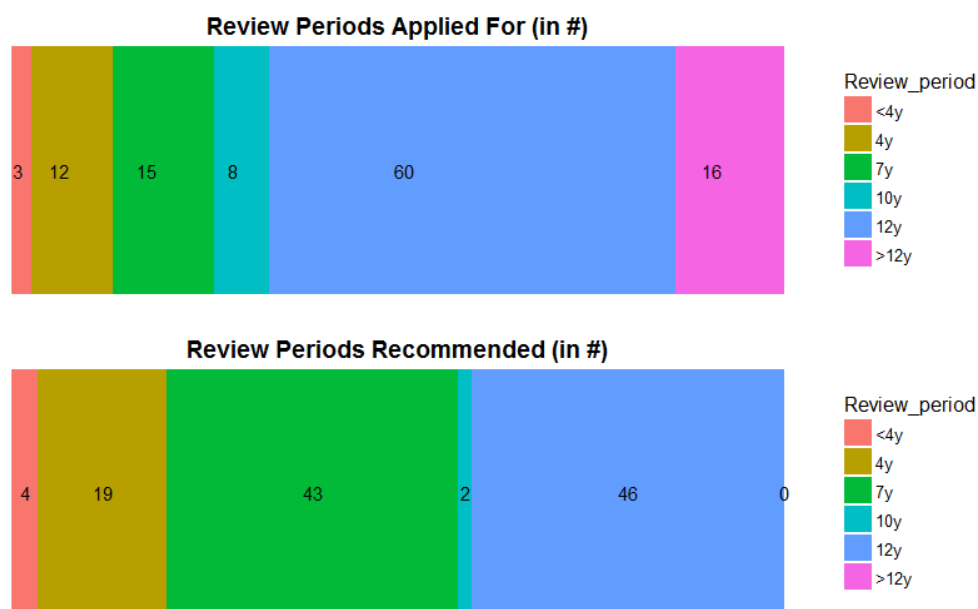


Figure 8: Summary of review periods proposed by applicants (upper panel) and recommended by ECHA's scientific committees (lower panel).

¹⁷ Most applicants based their proposals for review periods on a note that SEAC had issued to explain based on which criteria they would recommend a review period to the European Commission (ECHA 2013a). The 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 European Commission service had endorsed the criteria as well, applicants mostly made proposals within the scope of the note. However, the note mentions the possibility to propose review periods longer than 12 years in "particular and exceptional cases". Applicants did so in 16 cases.

Figure 8 summarises the review periods proposed by applicants and those recommended by the committees. On average, the latter were about three years shorter than those applicants had proposed (8.4 vs 11.1 years). In some cases, the applicants had already identified technically and economically viable alternatives, but needed some transitional time for implementation.¹⁸

For most of these bridging applications, the 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.

In 55 cases (47 %), however, the committees recommended shorter review periods than proposed by applicants — either because the AoA 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.

CONDITIONS AND MONITORING REQUIREMENTS. ECHA’s scientific committees may recommend additional conditions (e.g. improved risk management measures) 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.

In their decision, the European Commission may then require the implementation of the recommended conditions and monitoring requirements either as part of the authorisation or for the review reporting. In 53 cases, the committees have recommended conditions to be implemented with immediate effect; in 76 cases, they recommended additional monitoring for a possible review report (i.e. for an application to extend an existing authorisation). Figure 9 provides an overview by substance group.

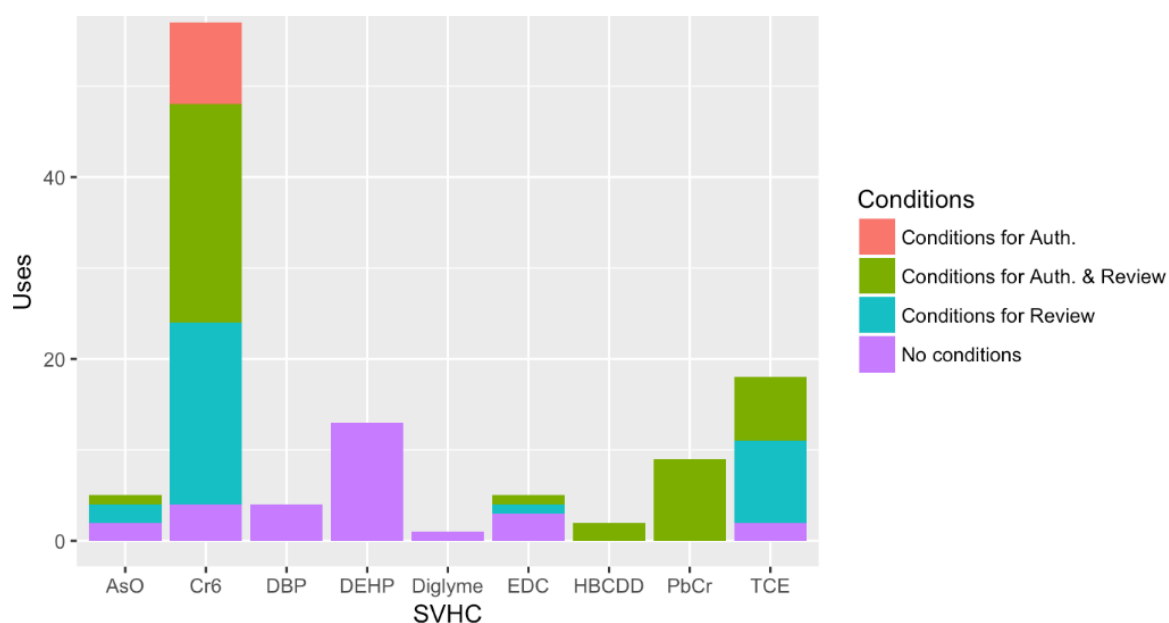


Figure 9: Overview of conditions/monitoring requirements recommended by RAC.

¹⁸ Examples include the use of the plasticiser DEHP in fan blades of aircraft engines and the use of HBCDD as a flame retardant additive.

Illustrative example of preventive benefits of authorisation

One way for gauging the preventive impact of the REACH authorisation title is to look at reductions in exposure to SVHCs on the authorisation list over time. For example, Vincent et al. (2015) conducted a well-designed and standardised measurement campaign for hexavalent chromium (Cr6) compounds in 97 French hardchrome plating shops during 2010-2013.

Based on this measurement campaign, the empirical cumulative distribution function $F(x)$ of exposure to Cr6 (measured in $\mu\text{g}/\text{m}^3$) prevailing in the French chrome plating industry *before* Cr6 compounds were added to the authorisation list can be estimated as shown in Figure 10.

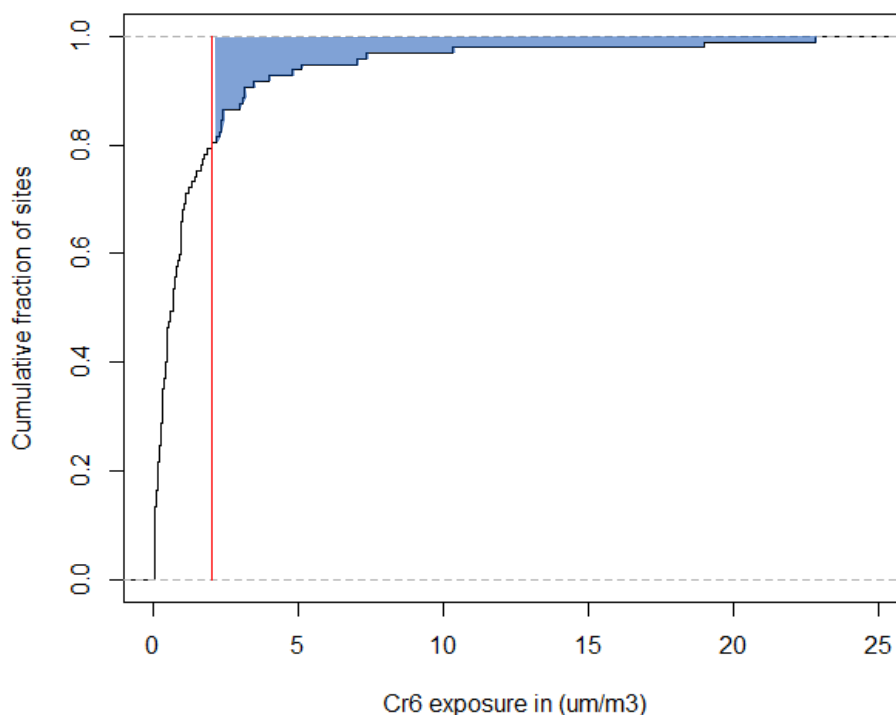


Figure 10: Empirical cumulative distribution of Cr6 exposure in French chrome coating shops over the period 2010-2013 (Vincent et al. 2015); red line: exposure constraint at $2 \mu\text{g}/\text{m}^3$; blue area: cumulative exposure reduction brought about by the constraint.

Formally, the expected exposure to the statistical worker can be written as:

$$\mathbb{E}[X] = \int_0^{\infty} xf(x)dx,$$

where $f(x)$ is the probability density function of exposure in the relevant industry sector. It is assumed that the French measurement campaign is representative of the Cr6 exposure encountered in the chrome plating industry in France (and likely in other EU Member States as well). Therefore, it seems plausible to model the exposure X in any given coating shop as a random draw from $f(x)$.

In upstream applications for authorisation of Cr6 compounds processed so far, applicants have based their SEA on the assumption of a maximum exposure of $2 \mu\text{g}/\text{m}^3$ per working day. (This applicant-imposed constraint on exposure is denoted by δ and depicted by the red line in Figure 10.)

The corresponding limited expected exposure under this constraint equals (Dutang et al. 2017):

$$\mathbb{E}[X \wedge \delta] = \int_0^{\delta} 1 - F(x) dx.$$

Now, let $\Delta X_{\delta} = \mathbb{E}[X] - \mathbb{E}[X \wedge \delta]$ denote the expected exposure reduction brought about by taking δ forward as a condition for authorisation. Applied to the French dataset, this results in an expected exposure reduction of $0.74 \mu\text{g}/\text{m}^3$ per working day. Similarly, one can evaluate the impact of a reduction in daily exposure to $1 \mu\text{g}/\text{m}^3$ as stipulated by occupational exposure limits in some Member States. Conducting the same analysis for $\delta = 1 \mu\text{g}/\text{m}^3$ results in an expected exposure reduction of $0.99 \mu\text{g}/\text{m}^3$ per working day.

One may convert these expected exposure reduction into an estimate of prevented cancer cases per year by applying the reference dose-response relationship for Cr6 compounds established by RAC (ECHA 2013b), which establishes the following relationship between a worker's Cr6-inhalation daily exposure and their excess lifetime risk (ELR) of fatal lung cancer, using the following equation:

$$ELR = 4\text{E-}3 \times \Delta X_{\delta}.$$

Maintaining the assumptions underlying the reference dose-response function, this suggests that the annual risk of developing a fatal lung cancer due to exposure to Cr6 compounds is reduced by $7.4\text{E-}5$ ($=2.96\text{E-}3/40$ yrs) and $9.9\text{E-}5$ ($=3.96\text{E-}3/40$ yrs) when $\delta = 2 \mu\text{g}/\text{m}^3$ and $\delta = 1 \mu\text{g}/\text{m}^3$ are imposed as exposure constraint, respectively.

An illustrative calculation can be made assuming that the French data are representative of working conditions in coating shops across the EU. A Dutch industry report (Panteia 2016) suggested that there might be up to 736 000 workers employed in EU industry sectors using Cr6. Suppose that 5-15 % of these workers are exposed to Cr6 compounds on a daily base.¹⁹ Table 5 displays the statistical lung cancer deaths annually prevented under varying assumptions about the workers exposed. As can be seen, 2.7-11.0 statistical lung cancer deaths might be prevented annually by the additional risk management measures recommended for the authorisation of the upstream Cr6 applications.²⁰

These results should be interpreted with care since several assumptions entered into the computation. Nevertheless, this illustrative example gives an indication of the possible preventive effects of the REACH authorisation title.

Table 5: Illustrative example: Possible preventive impacts in terms of statistical cancer cases based on varying assumptions about the expected exposure reduction in the average firm and the number of exposed workers in hard chrome plating shops throughout the EU.

| Exposure constraint δ set to: | Lung cancer deaths prevented presuming 5 % of EU Cr6 workers exposed | Lung cancer deaths prevented presuming 10 % of EU Cr6 workers exposed | Lung cancer deaths prevented presuming 15 % of EU Cr6 workers exposed |
|--------------------------------------|--|---|---|
| 2.0 $\mu\text{g}/\text{m}^3$ | 2.7 statistical cases p.a. | 5.5 statistical cases p.a. | 8.2 statistical cases p.a. |
| 1.5 $\mu\text{g}/\text{m}^3$ | 3.1 statistical cases p.a. | 6.3 statistical cases p.a. | 9.4 statistical cases p.a. |
| 1.0 $\mu\text{g}/\text{m}^3$ | 3.7 statistical cases p.a. | 7.3 statistical cases p.a. | 11.0 statistical cases p.a. |

¹⁹ The exact number of exposed workers is currently unknown but might be estimated with more precision once the downstream user notifications for the Cr6 applications become available.

²⁰ As numerical example, consider $50\,000$ [workers] \times $4\text{E-}3$ [per $\mu\text{g}/\text{m}^3$ exposure over 40y] \times 0.74 [$\mu\text{g}/\text{m}^3$ exposure reduction over 40y] / 40 [y] = 3.7 [statistical lung cancer deaths prevented p.a.] at $\delta = 2 \mu\text{g}/\text{m}^3$.

Conclusions

Looking back at the first 100 applications for authorisation under the REACH Regulation it is concluded that the authorisation title has had socio-economic impacts at various levels. The requirements for authorisation have reduced chemicals risks to workers and the general population whilst permitting European industry sectors to continue the use of SVHCs where substitution is currently not possible.

The system that was set up for handling applications for authorisation has entailed costs on both applicants and regulatory authorities. On the other hand, the authorisation requirements and perhaps the reputational issues of continuing to use SVHCs have driven substitution towards safer alternatives, thereby promoting innovation and growth of alternative producers.

This report focuses on the social benefits of authorising the continued use of SVHCs and the remaining risks that arise from these uses.²¹ Three findings of this meta-analysis of applications and the corresponding opinions stand out:

- 1) Whilst the remaining risks associated with the continued use of SVHCs are important, 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 to harmful chemicals to workers and general population. Thereby, the authorisation system has helped to lower the burden of occupational and other diseases in the EU.
- 2) In all the applications for authorisation received and analysed herein the benefits outweighed the remaining risks to human health and the environment. Where applicable, the net benefits established by applicants (i.e. the difference between the benefit of continued use and the monetised risk associated with it) ranged from €0.05m to €5.7bn per year, whereas the net benefits as evaluated by ECHA's scientific committees ranged from €0.03m to €0.41bn per year.²² The substantial downward adjustment suggests that in several cases applicants had overestimated the benefits to society from their SVHC uses while at the same time underestimating the negative impacts on workers and the general public. At this stage, it is difficult to conclude whether these were strategically made or due to a lack of skills in assessing risks and benefits.
- 3) ECHA's scientific committees recommended to the European Commission that, on average, the review period should be 2.5 years shorter than proposed by the applicants and that, in 72 % of the evaluated uses, additional conditions and/or monitoring requirements would be indicated. As demonstrated by the recommendations on review periods and additional conditions, the scientific scrutiny of the applications manifests itself in the opinion making process of ECHA's scientific committees.

Several topics deserve further research. In particular, these relate to what elements in the applications drive the recommended lengths of review periods and the necessity and type of additional conditions as well as to applicants' efforts in finding suitable alternatives.

²¹ The European Commission is currently conducting a study on the impacts of REACH authorisations, which will provide a detailed assessment of the administrative cost associated with the handling of dossiers and other costs related to the authorisation system. It will also look into the substitution of substances on the authorisation list. Albeit most evidence on substitution is anecdotal, the fact that ECHA has not received applications for authorisation of 7 out of 31 relevant substances on the authorisation list points towards ongoing substitution efforts among users of SVHCs.

²² These net benefits constitute a lower bound estimate in as far as they are based on the smallest benefit and largest risk estimate per use. It should be re-emphasised that some of the economic impacts on the applicants, their supply chains, their competitors and society as a whole as well as some of the remaining risks have been assessed in a qualitative manner only.

In conclusion, the present study highlights the importance of reporting key information in a standardised manner. Tracing the benefits and remaining risks as well as other relevant information from the applications for authorisation is essential for ECHA's scientific committees to develop their opinions effectively. Likewise, documenting such information clearly in the opinions helps the European Commission in making the decision on granting or refusing an authorisation together with Member States. For these reasons, ECHA intends to ensure that both applications and opinions report key information in a standardised, easily comparable manner. This would enable an increased understanding of the impacts of the applications for authorisation system in the years to come.

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EUROPEAN CHEMICALS AGENCY
ANNANKATU 18, P.O. BOX 400,
FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU