Unlock the market - Economic incentives for alternatives to hazardous chemicals

Final report

ChemSec

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Disclaimer

Foreword by ChemSec

This eftec report was commissioned by ChemSec in 2021, with the aim of analysing economic incentives for producing and using alternatives to hazardous chemicals. The report estimates potential lost revenue for producers and users of alternatives, if regulations disfavour the market for alternatives.

The idea for this report was born after years of engaging in regulatory processes to phase out the use of hazardous substances, while also collaborating with companies producing alternatives. It has become clear that there is an imbalance in how the legal framework is implemented, which somehow tends to disfavour alternative producers. This is what the report illustrates.

The data in this report derives from publicly available data, complemented by stakeholder information obtained via an interview. eftec, a consultancy firm specialized in calculating socioeconomic effects of policy implementation, has performed the analysis and produced all the content of the report.

Executive summary

In October 2020, the European Commission launched its EU Chemicals Strategy for Sustainability[1]. Its overarching aims are to (i) better protect citizens and the environment, and (ii) boost innovation for safe and sustainable chemicals. Within the strategy, the European Commission acknowledges that regulatory intervention will be needed to phase out the production and use of hazardous chemicals, as the transition to safer alternatives has not happened at the pace expected[2].

In line with the EU Chemicals Strategy, this report focusses on transition to alternatives as the desired solution to the adverse impacts caused by production and use of hazardous chemicals. Since private companies are often driven by financial targets, maintaining economic incentives to substitute away from hazardous chemicals within regulations and other policy measures is a powerful tool. This report explores the nature of economic incentives present within different types of chemicals regulations and policy measures.

A key measure for regulating the use of hazardous chemicals within the EU is currently the REACH authorisation system, as it is built on fundamental principles aligned with the EU's Chemicals Strategy and the overall approach to chemicals regulation. These include the: (i) 'Polluter pays principle', 'Precautionary principle', 'Substitution principle', and 'Right to know principle'. This measure was therefore chosen for a more in-depth analysis in this report.

A broad set of economic incentives for switching to safer alternatives is intrinsic within REACH authorisation system, which are linked to (i) Avoided costs of applying for an authorisation, (ii) Avoided risks to business continuity, and (iii) Business opportunities from early transition to alternatives.

The strength of these economic incentives is, however, contingent on the implementation of system, i.e. whether decisions to allow continued use favours alternative suppliers or not. On what grounds an authorisation should be granted has been heavily debated since early days of REACH, where the recent court case on the DCC Maastricht authorisation (re)established some important principles to be upheld, including: (i) The burden of proof lies solely with the applicant, and uncertainty regarding the availability of alternatives should result in a refusal of the

[1] EC (2021). *Chemicals Strategy for Sustainability - Towards a Toxic-Free Environment*. Available at: https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

[2] REACH Review (2017). *The REACH REFIT evaluation (REACH Review).* Available at: https://ec.europa.eu/growth/sectors/chemicals/reach/reach-refit-evaluation-reach-review_en#:~:text=The%20REACH%20REFIT%20evaluation%20%28REACH%20Review%202017%29%20will,effectiveness%2C%20efficiency%2C%20relevance%2C%20coherence%20and%20EU%20added%20value; ECHA (undated(a)). *Candidate List of substances of very high concern for Authorisation.* Available at: https://echa.europa.eu/candidate-list-table & EC (2018a). *A sustainable bioeconomy for Europe: strengthening the connection between economy, society and the environment*. Available at: https://op.europa.eu/en/publication-detail/-/publication/edace3e3-e189-11e8-b690-01aa75ed71a1/language-en/format-PDF/source-149755478

application not a shortened review period ('Polluter pays principle'), and (ii) Proportionality is irrelevant where the conditions for the granting of an authorisation are not met ('Substitution principle');

The European Court of Justice concluded that the DCC Maastricht authorisation for the continued use of lead chromate pigments was wrongfully granted, because alternatives were available on the market. This implies that companies supplying alternatives to these lead chromate pigments incurred financial losses during the period for which the authorisation was granted. A simplified calculation based on the information provided by DCC Maastricht in its application showed that the **loss to these alternative providers may be in the order of magnitude of €200 million – €4.4 billion over the review period granted[3].**

It is likely that other applications have also been granted an authorisation in the past, where uncertainty with regards to the availability of alternatives existed, that would not have been granted today in light of the court ruling. The DCC Maastricht authorisation only comprise 0.3% of the total volume of substances of very high concern (SVHCs) used in the 213 applications for authorisation submitted to ECHA since 2013[4], so if only a small share of the applications has been wrongfully granted, alternative providers across the EU may have incurred significant loss in sales revenue. In a hypothetical scenario where 5% of the total volume applied for has wrongfully received an authorisation, **a loss in the order magnitude of €1 billion – €10 billion per year could have occurred**[5].

Neglecting economic incentives within policy measures limits the opportunities for return on investment in alternatives (i.e. companies would incur cost of substitution without increasing market shares or their income otherwise), which will ultimately result in companies trying to avoid substitution for as long as possible. On the other hand, by acknowledging that companies are driven by financial targets and ensuring that policy measures have economic incentives, a more progressive transition to safer and more sustainable substances may be achieved.

[3] Estimated as present value, with a 4% discount rate and given in 2020 prices.

[4] ECHA (2021c). *Socio-economic impacts of REACH authorisations.* Available at: https://echa.europa.eu/documents/10162/17229/socioeconomic_impact_reach_authorisations_en.pdf/12a126f2-9267-1dcd-75e3-ce0f072918e4?t=1619782167012

[5] This assumes that the loss per tonne substance is comparable to that of the alternative providers associated with the DCC Maastricht application.

Contents

1. Introduction

1.1 Project objective and scope

This report explores the role of 'economic incentives' in driving substitution from hazardous substances to safer chemicals and highlights benefits of maintaining such incentives within policy measures. The assessment investigates the type and the strength of economic incentives found within different types of regulations and other policy measures, and what can affect the effectiveness of the incentives. A high-level assessment is carried out for a broader set of measures, whilst REACH authorisation is assessed in more detail. The intention of this report is not to compare and recommend specific government interventions (i.e. this is not a risk management option analysis), but rather investigate how different types of measures may contain or trigger economic incentives for substitution. The measures are therefore only assessed in terms of potential impact on substitution levels, and other aspects such as proportionality and practicality are not considered in this report.

A case study is included to highlight the scale of economic disincentives that may occur if a policy measures disfavours alternative providers. The chosen case study is linked to the recent court case on the DCC Maastricht application for authorisation. The analysis is not a socio-economic analysis, meaning the net costs and benefits of substitution in itself is not assessed.

1.2 Background

In October 2020, the European Commission launched its Chemicals Strategy for Sustainability. Its overarching aims are to (i) better protect citizens and the environment, and (ii) boost innovation for safe and sustainable chemicals. The strategy is part of the EU's zero pollution ambition, which is a key commitment of the European Green Deal.

1.2.1 The need to substitute away from hazardous chemicals

The transition to a non-toxic environment will require progressive substitution away from the use of Substances of Very High Concern (SVHCs)[6] to safer and sustainable substances. Hazardous substances are still being used in society because of specific desirable properties of these substances such as fulfilling certain technical functions/requirements. The production process of companies using these hazardous chemicals have also been optimised over time to produce their product(s) as cost-efficiently as possible.

This means that phasing out hazardous substances will be difficult to achieve without regulatory intervention (i.e. society cannot rely on just market forces to ensure this transition), as there will be technical challenges to overcome and costs that falls on industry.

This is acknowledged in the EU chemicals strategy which states "*regulatory tools need to be exploited to drive and reward the production and use of safe and sustainable chemicals. It is particularly important to incentivise industry to prioritise innovation for substituting, as far as possible, substances of concern. Moving to safe and*

[6] A substance of very high concern (SVHC) is a chemical substance (or part of a group of chemical substances) concerning which it has been proposed that use within the European Union be subject to authorisation under the REACH Regulation.

sustainable-by-design chemicals, including to sustainable bio-based chemicals, and investing in finding alternatives to substances of concern is crucial for human health and the environment, as well as an important precondition for reaching a clean circular economy"[1,2].

Regulatory intervention may involve 'forcing' the phase-out of the use of certain substances through prohibiting their manufacture and use, but the transition to safer chemicals can also be assisted through other measures such as taxes, subsidies, operational conditions, and information requirements. In the latter category, where substances are not banned, the effectiveness of the measures often rely on its intrinsic economic incentives.

1.2.2 REACH

The European Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) came into force in 2007, replacing the former legislative framework for chemicals in the EU. REACH "*shifts the responsibility from public authorities to industry with regards to assessing and managing the risks posed by chemicals and providing appropriate safety information for their users. It impacts on a wide range of companies across many sectors beyond the chemical industry. It requires new forms of cooperation among companies, enhancing communication along the supply chain, as well as developing tools to guide and assist companies and public authorities in its implementation*"[7].

Its core principle is that it is the responsibility of "*manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment*.", and its "*provision are underpinned by the precautionary principle*"[8]. The EU chemicals strategy promotes that "REACH and CLP[9] Regulations should be reinforced as EU's cornerstones for regulating chemicals"[1]. Therefore, this study focuses on the principles underlying REACH, using REACH Authorisation as an example for more detailed discussions.

Key risk management measures

The REACH regulation is divided into 15 parts (labelled TITLE I-XV), which set out the different obligations and routes of regulating substances (e.g. registrations and authorisation). Its main risk management options are:

- **Registration (TITLE II)** - Companies are responsible for collecting information on the properties and uses of the substances they manufacture or import above one tonne a year and assessing the hazards and potential risks presented by the substances. This information is communicated to ECHA through a registration dossier containing the hazard information and, where relevant, an assessment of the risks that the use of the substance may pose and how these risks should be controlled[10].
- **Authorisation (TITLE (VII) -** The authorisation process aims to ensure that SVHCs are progressively replaced by less dangerous substances or technologies where technically and economically feasible

[7] EC (undated). *REACH*. Available at: https://ec.europa.eu/growth/sectors/chemicals/reach_en

[8] REACH (2006). *REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006.* Available at: https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20210215#tocId4

[9] Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging of Substances

[10] ECHA (undated(b)). *Registration*. Available at: https://echa.europa.eu/regulations/reach/registration

alternatives are available[11].

- **Restriction (TITLE VIII)** - Restriction is an instrument to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions are normally used to limit or ban the manufacture, placing on the market (including imports) or use of a substance, but can impose any relevant condition, such as requiring technical measures or specific labels[12].

1.2.3 Principles within REACH Authorisation

The Commission is currently examining how REACH Authorisation may change in the future. ChemSecadvocate that important core principles already in the current REACH system should remain[13]. These are:

- **The Polluter pays principle** – This is one of the key principles underlying the European Union's (EU) environmental policy. Application of the principle means that polluters bear the costs of their pollution including the cost of measures taken to prevent, control and remedy pollution and the costs it imposes on society. By applying the principle, polluters are incentivised to avoid environmental damage and are held responsible for the pollution that they cause[14].
- **The Precautionary principle** - The Precautionary principle enables decision-makers to adopt precautionary measures when scientific evidence about an environmental or human health hazard is uncertain and the stakes are high[15].
- **The Substitution principle** - The general intention of the Substitution principle is that a chemical substance must be substituted when a safer alternative is available. But substitution can be costly and complex; without incentives for companies to shift to safer alternatives, it rarely happens. Strict regulation has proven to be a very effective incentive[16].
- **The Right to know -** Chemical manufacturers and downstream users of these chemicals have better information about their product than the general public and regulators (e.g. how much of a substance is used, how it is used, if there are any risks to human health and the environment, and if so, to what extent are any of these risks to human health and the environment are controlled/minimised). The Right to know principle seeks to address this information imbalance, so that information is available to everyone so that people can make more informed decisions.

[11] ECHA (2021a). *Authorisation*. Available at: https://echa.europa.eu/substances-of-very-high-concern-identification-explained

[12] ECHA (undated(c)). *Restriction*. Available at: https://echa.europa.eu/regulations/reach/restriction

[13] Report available at: https://chemsec.org/publication/authorisation-process,chemical-strategy,reach/removing-authorisation-from-reach-may-jeopardise-key-principles-for-effective-chemicals-regulation/

[14] European Court of Auditors (2021). *The Polluter Pays Principle: Inconsistent application across EU environmental policies and actions*. Available at: https://www.eca.europa.eu/Lists/ECADocuments/SR21_12/SR_polluter_pays_principle_EN.pdf

[15] European Parliament (2015). *The precautionary principle: Definitions, applications and governance*. Available at: https://www.europarl.europa.eu/thinktank/en/document.html?reference=EPRS_IDA(2015)573876

[16] ChemSec (2021). *The principles of the authorisation process are key to efficient chemicals regulation*. Available at: https://chemsec.org/publication/authorisation-process,chemical-strategy,reach/removing-authorisation-from-reach-may-jeopardise-key-principles-for-effective-chemicals-regulation/

1.3 Method

This project was primarily a desk-based exercise based on publicly available information. Views from industry stakeholders were sought in relation to one specific REACH application for authorisation application (used as a case study) to better understand the economic impacts on their business of this particular authorisation decision.

1.4 Structure of this report

This report has three other chapters:

- Chapter 2: Economic principles
- Chapter 3: Policy measures and their economic incentives for substitution
- Chapter 4: Case study – When the system fails the frontrunners

2. Economic principles

2.1 Introduction

The Polluter pays principle and the Right to know principle relate to what economists refer to as types of 'market failure'. It is essentially a recognition that if unregulated, the market (for goods and services) will not always result in the best outcome for society, and that government interventions may be needed to ensure that companies fully account for the impacts their activities have on wider society.

There are many types of market failures, but the primary focus of this chapter relates to addressing what economists refer to externalities, in particular negative externalities associated with the production and use of chemicals. Externalities can be viewed as unintended (and sometimes unknown) 'side effects' associated with economic activities such as the manufacture of products using chemicals.

2.2 Side effects of economic activities

Most private companies are set up with a key objective to maximise their profits[17]. Profits may not be the only motive, but economic theory suggests that companies will seek to maximise income and minimise costs to ensure the long-term viability of their business. For example, if a company does not minimise production costs, it might have to charge a higher price for its products than its competitors. This will likely lead to lost market shares and potentially the company could be forced out of business[18]. Profit-maximising behaviour means that companies do not fully account for the impacts of their operations on society that does not directly affect their costs or income, i.e. the externalities (side effects) of their operations are not reflected in the price of the products. The market and its actors' lack of considerations of externalities are what economics calls "market failure".

Economic literature distinguishes between positive and negative externalities[19]. A common example of a positive production externality is associated with research and development (R&D)[20]. This type of activity frequently improves the existing knowledge base beyond the initial investment of the company investing in R&D and consequently benefits wider society. For example, if a company substitutes away from using certain hazardous chemical(s), this information may be later used by other third-party companies improving their processes. Even if the initial company ('frontrunner'[21]) makes a return from selling its products, this does not include the returns of third-party beneficiaries who also subsequently substituted, i.e. the value of the investment to society is higher than the value to the frontrunner making the investment. If the frontrunner investing in R&D does not take into account these additional benefits to society, it will allocate less resources to R&D than what would be optimal from a societal perspective.

Costs inflicted on society from economic activities, is what economists would refer to as a 'negative

[17] It is recognised that some private companies are setup as "not for profit" for example.

[18] Note that this relates to substitutable products with close to identical properties. If differences in e.g. quality would differ, the market would not be fully overlapping.

[19] Production externalities primarily refer to the impacts (costs or benefits) to society as a whole (IMF, 2020) resulting from the economic activity of producers of goods or services that are not reflected in the prices of the goods or services sold.

[20] IMF (2020). *Externalities: Prices Do Not Capture All Costs*. Available at: https://www.imf.org/external/pubs/ft/fandd/basics/external.htm

[21] Companies that lead the transition towards the use of safe chemicals and have a sustainable-by-design approach to chemicals – often achieved through technical and scientific innovation/expertise.

externality'. For example, companies manufacturing or using hazardous substances may induce adverse health effects such as cancers, autoimmune disorders, and infertility[22] as well as impacts on the environment (e.g. destroying habitats and decreasing the survival rate of ecosystems)[23].

In socio-economic terms, these externalities lead to indirect costs such as decreased quality of life, higher healthcare costs, forgone production opportunities, loss of biodiversity or environmental degradation, to name a few[24]. Since the companies causing these adverse effects are not incurring the associated costs (i.e. their bottom line is not affected), the companies are likely to continue their economic activities causing the negative effects at a level that is not beneficial for the society as a whole. It may also divert resources from more beneficial applications e.g. the same resources could be used to manufacture a similar good using alternative substances or techniques that would not (or to a lesser extent) inflict negative impacts on society.

2.3 How to correct for economic side effects

There are many ways policymakers can make firms better account for their negative externalities. Irrespective of the policy instrument they deploy, their aim is to force or incentivise companies to respond to the damage caused to other parts of society[24]. The Polluter pays principle suggest if companies producing or using hazardous substances were forced to fully account for (internalise) any negative environmental and health impacts of their operations and products, they might choose to minimise their use of hazardous substances or mitigate any risks during their serve life and end of life, or even substitute away from using hazardous substances.

Policy interventions vary depending on what they are meant to achieve and how they achieve it. There are many ways to classify policy interventions, with **Table 1** setting out four categories that are commonly distinguished[25].

[22] ChemSec & ClientEarth (2018). *How to find and analyse alternatives in the Authorisation Process*. Available at: https://chemsec.org/publication/authorisation-process,reach/how-to-find-and-analyse-alternatives-in-the-authorisation-process/#:~:text=%20How%20to%20find%20and%20analyse%20alternatives%20in,60%20%284%29%2C%20which%20requires%20that%20no...%20More%20

[23] EPA (2021). *Health and Ecological Hazards Caused by Hazardous Substances*. Available at: https://www.epa.gov/emergency-response/health-and-ecological-hazards-caused-hazardous-substances

[24] Britannica (2020). *The Coase theorem*. Available at: https://www.britannica.com/topic/environmental-economics/The-Coase-theorem

[25] Bouwma, I.M., A.L. Gerritsen, D.A. Kamphorst & F.H. Kistenkas (2015). *Policy instruments and modes of governance in environmental policies of the European Union*. Available at: https://edepot.wur.nl/373629

Table 1: Types of policy instruments

Type of policy instrument	Brief description
Regulatory measures	These types of interventions denote a wide variety of laws and regulations. The common feature found across these types of measures is the definition of 'binding requirements' which must be complied with under the threat of sanctions. Such measures are commonly called '*command-and-control*' and can be prohibitive (e.g. ban certain activities) or prescriptive (e.g. require certain activities)[25]. Regulatory measures are highly effective, as they directly dictate the actors' behaviours. However, their effectiveness is dependent on the design and implementation, e.g. avoiding 'loopholes' and ensuring enforcement.
Economic and fiscal measures	Economic and fiscal measures rely on market mechanisms, whether they target the price of a harmful product (or service), or the quantity sold. Policy approaches affecting the price such as taxes, loans or subsidies aim to adjust the market prices to reflect the additional costs or benefits to society (externality) caused by the economic activity. For example, increasing the price of a product through a tax should lead to less demand for that product, and thereby reduce the associated negative externalities. Similarly, subsidies and other support measures can be used to increase the production and sales of products that are not associated with negative externalities. These types of measures create economic incentives so that the best (most rational) actions for the market actors are aligned with what is best for society.
Agreement based measures	Policymakers and/or private actors may jointly agree to behave in a certain way on a voluntary basis, which is commonly called an agreement-based (or cooperative) measure. An example is the EU agreement that plastic bottles will at least contain 30% recycled plastics by 2030, whilst individual companies have pledged to use much higher proportion of recycled plastic earlier than 2030[26]. These types of measure are suitable for situations where the agenda and desired change are mutually shared across multiple actors. Measures requiring agreement may be difficult to deploy if any conflict between the parties involved arises or the responsibilities are not clearly defined[26].

[26] Beverage daily (2019). *EU sets out 30% recycled content target for plastic bottles*. Available at: https://www.beveragedaily.com/Article/2019/05/21/European-Council-sets-out-30-recycled-content-target-for-plastic-bottles

Type of policy instrument	Brief description
Information and communication measures	Information and communication measures aim to influence behaviour through dissemination of information. Depending on the end goal, these measures can be wide-reaching (e.g. information campaigns) or focused (e.g. workshops or coaching). Information measures are most effective in the presence of asymmetric information, for example if a manufacturer knows that its products contain hazardous substances, but customers are unaware of this fact. Information and communication measures can be voluntary, where companies choose to be transparent about their products and processes, or they are imposed by the government. A common example would be the required labelling on products to inform consumers about specific product features e.g. sugar content in food products or whether a product contains toxic substances. This may in turn lead to consumers choosing to purchase alternative products, that do not contain the hazardous ingredients. Information measures can impactful, resulting in alternative products significantly increasing their market shares[27]. Another example is the listing of a substance as an SVHC under REACH, which informs companies that regulators will want to see these progressively phased out. This sends an early signal for companies to start to evaluate internally the necessity to use these substances and R&D required to phase out their use in their operations. It may be difficult to predict the size and the timing of the effect induced by these types of measures, since the change in behaviour (e.g. consumers purchasing alternative products, or companies phasing out hazardous substances before they are regulated) is voluntary[28].

[27] Costmeticsdesign (2020). *Fragrance Ingredient Trends for the Future*. Available at: https://www.cosmeticsdesign.com/Article/2020/07/15/Fragrance-Ingredient-Trends-for-the-Future

[28] Tickner and Jacobs (2016). *Improving the Identification, Evaluation, Adoption and Development of Safer Alternatives: Needs and Opportunities to Enhance Substitution Efforts within the Context of REACH*. Available at: https://echa.europa.eu/documents/10162/13630/substitution_capacity_lcsp_en.pdf/2b7489e1-6d96-4f65-8467-72974b032d7b

3. Policy measures and their economic incentives for substitution

3.1 Substitution as a policy objective

The most direct approach to mitigate negative impacts from the manufacture and use of hazardous substances is simply to stop using them, whereby substitution is usually preferable over ceasing production. Substitution refers to *the replacement or reduction of hazardous substances in products or processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organisational measures*[8]. This is important as substitution does not need to be narrowly confined to switching to alternative substances but can be achieved by technological or organisational measures.

In the Chemicals Strategy for Sustainability, the European Commission highlights that substitution of the most harmful substances has not occurred at the expected pace and that frontrunners still encounter major economic and technical barriers. As set out in **Box 1**, the European Commission argues that regulatory tools need to be exploited to drive and reward the production and use of safe and sustainable chemicals. It is particularly important to incentivise industry to prioritise innovation into substituting away from substances of concern.

Box 1: Regulatory intervention required to drive substitution of harmful substances

"Regulatory and market initiatives have to a large extent been established, but substitution of most harmful substances has not occurred at the expected pace and frontrunners still encounter major economic and technical barriers. This transition needs stronger policy and financial support, as well as advice and assistance in particular for SMEs, and requires a concerted effort from all: authorities, businesses, investors and researchers.

Moving to safe and sustainable-by-design chemicals, including to sustainable bio-based chemicals, and investing in finding alternatives to substances of concern is crucial for human health and the environment, as well as an important precondition for reaching a clean circular economy"[1].

The strategy has substitution of the most harmful substances as an objective within itself. This is regardless of the risks-benefit ratio associated with the continued use of these substances. Therefore, whilst there are other approaches beyond substitution that can internalise the negative side effects from the production and use of hazardous substance, the focus of this report is on incentives for substitution.

3.2 Policy measures

3.2.1 Introduction

This section provides a brief overview of a selection of broad categories of policy measures that can be used to facilitate, encourage and sometimes 'force' substitution, either on it its own or combined with other measures. For each type of measure, the key economic incentives for substitution as well as what can affect the strength of these incentives are described. The list is not a complete set of all possible measures, but it

broadly covers the types of measures that can be employed.

3.2.2 Restrictions and other bans

Restrictions impose limits or other conditions for the production, import and use of a substance. Authorisations (or a lack of thereof) can limit the use of a substance and is found within EU regulations such as REACH Restrictions, REACH authorisation, the Stockholm Convention, Biocidal Products Directive (BPD), and the Restriction of Hazardous Substances (RoHS) Directive. Some EU Member States have also implemented national restrictions, e.g. under the Biocides Regulation.

A complete ban on production and/or use of a hazardous substance does not require economic incentives to ensure phase-out of the substance. However, most restrictions (e.g. under REACH Restrictions and the Stockholm Convention) typically consider socio-economic impacts on the proposed restriction. If justified, derogation and transition period(s) are included to mitigate some of the socio-economic impacts, whilst still seeking to phase-out the majority of the risks (releases of emissions and/or reducing exposure). The type of derogation and transition period(s) included may create (economic) incentives to increase or reduce the efforts spent on substitution. For example, a time-limited derogation will create more incentives to substitute than a derogation without any time constraints[29]. For some regulation such as the RoHS Directive and the Biocides Regulation, exemptions are by default time-limited (maximum 5 years), after which a re-application / further exemption request is required. However, in some REACH restrictions cases, derogations have been granted with no time limits.

There is also the option to impose conditions e.g. reporting their efforts/developments made on R&D on alternatives, implement monitoring programs or operational conditions, which is frequently used in REACH authorisations. Such conditions may be costly for companies to comply with and thereby create economic incentives to switch to alternatives.

REACH restrictions generally do not follow the polluter pay principle as it is the responsibility of the dossier submitter to prove that there is an unacceptable risk and that the regulatory action proposed is proportionate. However, there is a precedent for requiring that industry should provide evidence justifying why a derogation or specific transition period would be needed. This may create economic to substitute, or at least, to carry out R&D to identify if there are any alternatives they can use instead.

On the other hand, REACH authorisation and some other authorisation-based regulations have provisions within the legal text which requires the applicant to prove that suitable alternatives do not exist. If compelling evidence is not provided the authorisation should be refused, which can lead to significant costs to the company in question and is thus a strong financial motivator.

Generally, for these types of measures substitution can be further encouraged by setting out strict(er) requirements for derogations, transition periods and granting authorisations.

[29] It is recognised that regulators can update a restriction in the future in light of new evidence.

3.2.3 Exposure limit values and mandatory technology

The use of exposure limit values and the use of mandatory technology (e.g. a closed production process) are implemented to reduce exposure of hazardous substances to people and the environment. Binding limit values are used, for a limited number of substances, in EU legislation such as Occupational Exposure limits (OELs) under the Carcinogens or mutagens at work directive (CMD), as well as under the Environmental Quality Standards (EQS). Limit values does not within itself require substitution, as companies may choose to implement exposure reduction measures to comply with the limit.

CMD has additional requirements through a hierarchy of control measures, where substances should be replaced as far as technically possible, regardless of economic considerations [30,31]. Based on the legal text, CMD is thus less reliant on economic incentives. There are, however, no formal requirements for how companies should 'prove' that there are no technically feasible alternatives (as under REACH and BPD), but companies "*shall, upon request, submit the findings of his investigations to the relevant authorities*"[8] The lack of information requirements can, in some cases, weaken the drive towards substitution, as economic incentives to carry out less R&D ('investigation') may occur if companies believe (prior to extensive R&D) that transitioning to alternatives will be more costly than other exposure reduction measures.

The use of mandatory technology is inherent in EU legislation like the use of Best Available Technology (BAT) under the Industrial Emissions Directive (IED), which can reduce emissions of hazardous substances that are emitted into the environment (e.g. air and water). Under REACH Registration, registrants can require downstream users to use certain technologies (e.g. use of closed systems or certain personal protection equipment) as set out in the Chemical Safety Report (CSR) to ensure safe use of the substance. Since it is not required to substitute if suitable alternatives exist, this type of measure does not align with the substitution principle. However, since compliance costs are borne by the companies using hazardous substances, the polluter pays principle is upheld.

The economic incentives triggering substitution for measures within this category are the potential costs of available exposure reduction measures or the mandatory technology. Broadly speaking, companies will switch to alternatives if this is the least costly option. When using limit values as a policy measure, stronger incentives for substitution can be achieved by lowering limit values or by adding additional requirements, as is done under CMD. Specific technology requirements are less flexible, but an increased drive towards alternatives can be obtained by requiring expensive technologies.

3.2.4 Taxes, subsidies, and fees

Economic measures fully rely on economic incentives to trigger a change in companies' behaviour and are therefore not aligned with the substitution principle. These measures may still be equally effective in

[30] OSH (undated). *Hierarchy of controls applied to dangerous substances*. Available at: https://oshwiki.eu/wiki/Hierarchy_of_controls_applied_to_dangerous_substances

[31] EC (2004). *Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.* Article 4.1. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02004L0037-20190726&from=EN

driving substitution if the target and size of the economic incentives are carefully calibrated.

Taxes and fees create direct economic incentives by increasing the cost of using hazardous substances. The incentives for substitution can be enhanced by increasing taxes and fees, where alternatives become increasingly more attractive the higher the taxes and fees are.

An example of fees is the application fee associated with REACH authorisation. Currently, this is low compared to other costs of applying for an authorisation (further discussed in Section 3.3) and is therefore not expected to be the main driver for substitution associated with REACH authorisation. Since the fee is a direct cost for the company, increasing the fee would increase the incentives for switching to alternatives.

There are not many examples of where taxes have been used as a measure to reduce the risks and/or use of hazardous chemicals. A possible tax design could be to tax the use of a hazardous substance – €/kg substance used. Anyone using an alternative to the hazardous substance would avoid this cost, and this may (partially) offset the costs of switching to an alternative and therefore creates incentives for substitution. The tax could provide significant economic incentives to substitute for companies using larger volumes but less so for companies using low volumes, as the tax bill would increase with the volume used. A tax is a highly flexible mechanism, where strength of the economic incentives and drive towards alternatives can be 'fine-tuned' by adjusting the size of the tax.

Subsidies[32] and grants can cover (parts of) the increased investment and operational costs associated with the switch to alternatives. Grants are typically used to (partially) offset investment costs whilst subsidies for using safer alternatives is linked to the operational costs. Reducing the costs of implementing and using alternative increase will increase the competitiveness of companies supplying or using alternatives. This may result in these companies gaining a higher market share (implying that users of the hazardous substances will lose market shares) and thereby increasing their income. The economic incentives for these measures are therefore twofold: (i) reduced cost of switching to alternatives, and (ii) avoided loss of market shares to other companies that use alternatives. Similarly as for taxes, these are highly flexible measures, where the higher and more available the grants and subsidies the stronger the economic incentives for substitution.

3.2.5 Information related measures

Information measures (e.g. SVHC listing) targeting users and consumers of hazardous substances raise awareness of their use. An example of this is Article 33 of REACH, which is where supply chain communication requirements are triggered when companies who supply products that include any article containing more than 0.1% w/w of any SVHC[33]. This dissemination of information may change customers' purchasing patterns and reduce the market demand for the products containing SVHCs. It may also reduce the willingness to invest in the associated companies or sectors, as investors know that SVHCs should be

[32] Subsidies also includes tax reliefs.

[33] ECHA (undated (d)). *Communication in the supply chain*. Available at: https://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles/communication-in-the-supply-chain

phased out and regulatory measures are likely to be imposed.

Information can also be used to raise awareness about hazardous substances prior to regulation. For example, the Candidate list and ChemSec's SIN list, which are continuously updated, contain substances of concern which could be regulated in the future. ChemSec indicate that "*Many investors and financial analysts are using the SIN List to avoid investing in companies producing hazardous substances and the financial risk that this implies*".

Another example is the recently launched SCIP database, where companies supplying articles containing SVHCs above 0.1% w/w must submit information on these articles to ECHA. The publicly available database collates information on articles containing SVHCs throughout the whole lifecycle of products and materials, including at the waste stage. The gathering and submission of information imposes costs to the users of SVHCs (i.e. the polluter pays principle) and creates more knowledge for consumers and waste operators (i.e. the right-to-know principle) and therefore creates economic incentives to substitute away from hazardous substances.

The primary mechanism within information measures is to allow consumers and companies to make informed choices by enforcing transparency in the use of hazardous substances. This may lead to immediate reduction in sales of products containing such substances, e.g. through stigma effects. Furthermore, disseminating information may start consumer trends which may lead to a significant, long-term market push towards the use of safer and more sustainable substances. There are clear economic incentives for substitution, however, it can be difficult to predict the size of the effects since it comes down to 'personal' choices of consumers.

3.2.6 Combinations of policy measures

Policy measures are never implemented in a vacuum, so it is important to consider potential interactions - both synergy effects and unintentional counter effects.

Combining information measures and regulatory measures can be an effective approach to create synergy effects for encouraging the transition to alternatives. For example, in a REACH restriction proposal the dossier submitter recommended to restrict the use of intentionally added microplastics[34] but also suggested conditions for labelling and reporting for specific uses where a time-limited transition period was granted. These requirements (effectively an information measure) add additional pressure to phase out the use of microplastics, as companies may lose customers if they need to label their products as containing microplastics. The economic incentives created by the fear of losing customers strengthen the drive towards substitution, even during the time-limited transition period in which continued use of microplastics is allowed.

Another approach is to combine different types of economic measures to strengthen the economic incentives for substitution, e.g. a 'carrot and stick' approach. Fees or taxes collected from users of hazardous substances can be earmarked to support substitution efforts, for example through government grants. If a company transitions to alternatives it will avoid the taxes and fees. At the same

[34] For more examples see: https://echa.europa.eu/hot-topics/microplastics

time they may be granted financial support to (partially) cover the costs associated with substitution and are thereby 'double' incentivised to switch to alternatives. Economic measures can also be combined with regulatory measures to create similar synergy effects. Regulations triggers compliance costs, which can be avoided through substitution, and additional financial support can be provided through subsidies or grants.

Equally important as strengthening economic incentives is to ensure that unintended 'perverse' incentives are avoided, i.e. where companies might be better off by not searching for alternatives. For example, a regulation might allow continued use of a restricted substance until a suitable alternative has been found. If it is not required that the actors benefitting from the exemption must search for alternatives, companies may choose to not initiate R&D to avoid the associated R&D costs and costs of having to transition to the alternative.

In the following sections, a more in-depth assessment is carried out for REACH Authorisation, to showcase the role of economic incentives.

3.3 Example - The REACH authorisation system

3.3.1 Introduction

This section uses the REACH authorisation scheme as an example to study economic incentives more closely. The assessment focusses on key objectives and mechanisms that can trigger economic incentives within the system as designed.

3.3.2 Aims and principles behind the REACH authorisations system

The objective of the authorisation route is to "*ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable*[8]."

What is uniquely expressed here, which is not as explicit in other regulatory measures, is that substitution is an objective in itself, i.e. the Substitution principle. That means that if suitable alternatives exist, the substances on the authorisation list must be substituted, and other socio-economic considerations only come into play if no suitable alternatives exist. Another characteristic with this system is that it puts the burden of proof on the users of SVHCs, following the Polluter pays principle (e.g. it is up to the applicant to prove safe use/and/or minimisation of exposure/emissions, that there are no suitable alternatives, and that benefits of continued use outweigh the risks).

3.3.3 Economic incentives within the REACH authorisation system

As explained in Section 2, the primary aim for most private companies is profit maximisation. Companies that are using SVHCs, are doing so for various reasons, e.g. due to their technical or economic superiority to the alternatives, change of substance or technology may be perceived as difficult or the avoidance of R&D costs associated with identifying and implementing alternatives. There are therefore clear economic

incentives for the continued use of SVHCs, and this would be the preferred option for these companies in the absence of regulations or other government interventions (all other factors, such as supply and price of the substances remaining the same). Companies that implement alternatives to the SVHCs before regulatory intervention (so-called 'frontrunners') thus take a large risk when deciding to invest in the development and implementation of alternatives, both in terms of cost of substitution as well as potential lost sales. Lost sales may occur because the SVHCs usually have a competitive advantage as the established technologies and, in many cases, they are also cheaper than the alternative(s).

Substitution is therefore unlikely to occur unless regulations are in place. The authorisation system is intended to ensure that companies progressively transition to alternatives through its key principles and the economic incentives these create. The following sections explore further the economic incentives and how their effectiveness can be affected based on discretionary regulatory decisions within the system itself.

Direct economic incentives for substitution

An economic incentive for substitution is considered to be a 'direct economic incentive' if a company knows with complete certainty that their income will increase, or costs will reduce by transitioning to alternatives[35]. The following direct economic incentives for substitution are associated within the authorisation scheme:

- The avoided application fees;
- The avoided cost of preparing an application for authorisation (AfA);
- The avoided cost of responding to regulators during the evaluation of the AfA; and
- The avoided costs of compliance with any conditions imposed.

The effectiveness of these incentives is related to the size of the costs and fees in comparison with the costs/losses associated with transitioning to alternatives or otherwise ceasing the use of the SVHC. The ECHA fees are today adjusted based on the size of the company applying, number of uses and substances applied for [36,37]. However, considering that the application fee comprises between 15% and 25%[38] of the total costs of applying for an authorisation, the cost of preparing an authorisation will be the main driver for substitution. It is therefore inferred that companies with lower profits (often smaller companies) have stronger direct economic incentives for substitution (or cease of production). Meanwhile companies with higher turnover and profits are less likely to feel the costs of obtaining an authorisation, which means that the incentives to substitute are weaker for these companies.

Albeit the cost of developing an AfA is mostly outside the regulators control, the effectiveness of the direct economic incentives for substitution can be enhanced by increasing the size of the fees, requiring narrower use definitions in the applications (as the fees increase with the number uses), the required level of details

[35] Cost savings or income increases do not necessarily mean that the profits (i.e. total income minus total costs) will increase, as other costs of transitioning to alternatives (e.g. cost of R&D) may dominate.

[36] EC (2008b). *COMMISSION REGULATION (EC) No 340/2008 of 16 April 2008*. Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:107:0006:0025:EN:PDF

[37] EC (2018c). *COMMISSION IMPLEMENTING REGULATION (EU) 2018/895 of 22 June 2018*. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0895&from=EN

[38] Rheinberger and Vainio (2018). *Benefit-Cost Analysis in EU Chemicals Legislation: Experiences from over 100 REACH Applications for Authorisation*. Available at: https://www.researchgate.net/publication/324545246_Benefit-Cost_Analysis_in_EU_Chemicals_Legislation_Experiences_from_over_100_REACH_Applications_for_Authorisation

of information provided in the AfA, or the stringency of the conditions for the authorisation, e.g. requiring implementation of further risk management measures or additional monitoring requirements.

Indirect economic incentives

The most effective economic incentives for substitution induced by the authorisation scheme are however indirect in nature, which means that they work through changes in market actors' behaviours and resulting changes to the market affected. The strength of the indirect economic incentives is linked to regulatory decisions taken within the system as well as the consistency of these, which is discussed further below.

The mechanisms incentivising substitution are interlinked, but can broadly be summarised as follows:

A. Risk to business continuity if authorisation is not granted or from receiving a short review period[39], which may induce:

- Temporary cease of production;
- Urgent transition to alternatives, which may be more costly than a phased transition;
- Loss of customer confidence, leading to lost market shares;
- Loss of investor confidence, leading to less growth opportunities;
- Permanent cease of production in the EU; and/or
- Increased costs associated with imposed additional monitoring and risk management measures.

B. Other risks to business continuity

- Downstream user pressure to substitute away from substances requiring authorisation;
- Key workers migrating to companies supplying or using alternatives, e.g. due to job safety and a desire to work at a 'greener' company; and/or
- Negative reputational effects from using SVHCs, which may persist even after transition to alternatives.

C. Business opportunities from early transition to alternatives

- Gaining technological lead and potential patents;
- Attracting new customers that prefer 'greener' products;
- Attracting new customers that wants to lower their business risks associated with companies using SVHCs;
- Attracting new investors focussing on more sustainable companies; and/or
- Attracting workers that desire to work at a 'greener' company for moral reasons or job security.

The above list shows that the indirect economic incentives are a mix of avoiding business risks (potential loss) – set out in point A. and B. - and creating business opportunities (potential gain) - exemplified in point

[39] The review period is the timeframe for which the authorisation is granted

C. There might be additional financial benefits associated with substitution, such as reduced spend on hazardous waste treatment, reduced sick leave, and avoided costs of personal protective equipment (PPE). However, these are not economic incentives triggered by the regulation itself, as they will occur in the absence of a regulation and is thus not further discussed.

Effectiveness of the indirect economic incentives

When it is proven that there are no technically and economically feasible alternatives available anywhere on the market for a specific use of an SVHC, and the use is proven to provide overall benefits to society, the authorisation system allows for continued use of the SVHC for a limited period of time. The economic incentives for substitution are here triggered by the length of the review period granted, where a shorter review period can give strong incentives for further R&D on the suitability of possible alternatives.

In other cases, alternatives may be available on the market, but they are not available or known to all companies. There might be several reasons for this, e.g. varying levels of investment in R&D, some companies may have started looking for alternatives at an earlier stage and substitution efforts may not always be successful. The applicant will have comprehensive knowledge of its own technology, but less knowledge about competitors', which means that there may be alternatives available on the market provided by other companies, but the applicant is not aware of, or has access to these. There might also be alternatives to products further down the supply chain, which the applicant has not considered.

Regulators can therefore not only rely on the information set out in the application for authorisation, but also need to carefully consider information provided by external stakeholders. Issues may still arise if the applicant claims that no alternatives exist, whilst third-party stakeholders claim that alternatives are available on the market. The question then comes down to what type of evidence, and the level of details, is needed for a provider or user of an alternative to 'prove' that their alternative(s) is suitable and readily available in sufficient supply on the market.

As mentioned in Section 3.3.2, one of the key principles in the authorisations system driving substitution is the Polluter pays principle. In following this principle, the burden of proof to show that no alternatives exist should be on the applicant, rather than the alternative provider having to prove that alternatives do indeed exist. However, what is considered 'enough' information to show that alternatives do or do not exist is not set out in the regulation itself and will thus be determined at the regulator's discretion.

Different regulatory decisions can either strengthen or reduce the incentives for substitution that are associated with potential future substances being placed on the authorisation list. The following list provides three simple examples of how economic incentives for substitution may be increased or decreased following regulatory decisions. These are all under the context of there being conflicting evidence on the availability of alternatives:

(i) Refuse all authorisations for this specific use on the grounds that suitable alternatives exist on the market

This approach will create losses for the companies that are relying on SVHCs for (parts of) their operations, as set out under *"A) Risk to business continuity if authorisation is not granted..."* in the list above. On the other hand, the companies that have transitioned to alternatives will benefit from

this decision, exemplified under "*C) Business opportunities from early transition to alternatives*". In practise, what will happen is that customers and workers will migrate from the companies whose technology relies on SVHCs to the companies that are providing and using alternatives.

This approach will strengthen the incentives for substitution of subsequent substances from ending up on the authorisation list. This is due to the high risk to business continuity associated with relying on an authorisation as well as the good prospects for businesses associated with the transition to alternatives. Due to this, the approach will be highly effective in achieving the objectives of phasing out SVHCs.

(ii) Grant (some) authorisation for this specific use on the grounds that the applicant claims that no suitable alternatives exist for them

On the other end of the scale, the regulators may choose to grant authorisations for companies that cannot substitute to a suitable alternative for them, despite alternatives being placed on the market by competing companies. This will benefit the applicants continuing to use SVHCs, whilst the companies that have transitioned to alternatives will lose the abovementioned business opportunities.

Granting authorisations when there is conflicting evidence with regards to the availability of alternatives significantly weakens incentives for substitution. If the prospects of economic gains from transitioning to alternatives are removed, there are hardly any economic incentives for companies to invest in R&D in order to transition to alternatives before the subset date. Instead, the preferred approach for most companies will be to apply for an authorisation, thus the effectiveness of the authorisation system in driving substitution becomes limited.

(iii) Grant (some) authorisations for this specific use, but for a shorter time than requested and/or impose conditions for the authorisation

This is a hybrid version of the two actions set out above, however, the effects are closer to **(ii)** than **(i).** The reason for this is that the authorisation system allows for a review application at the end of the expiry of the authorisation, i.e. the end of the review period. A company that has not transitioned to alternatives by the end of the review period, may therefore be granted a new authorisation for the continued use of the SVHC. As with (ii), this will benefit the companies continuing to use SVHCs, whilst the companies that have transitioned to alternatives will lose their return on investment, i.e. the expected business opportunities from investing in alternatives will be lost.

The strength of the economic incentives can, to some extent, be maintained if stricter requirements for the review application are applied, e.g. if evidence of significant investments in R&D to identify or implement alternatives is required.

These three simplified examples of regulatory decisions are intended to illustrate how economic incentives may change based on regulatory decision-making within the authorisation framework. In reality, the decision-making process is considerably more complex, however, the core principle remains the same: granting authorisations when there are substantial claims of alternatives being available on the market weakens the Polluter pays principle and reduces the economic incentives for substitution.

4. Case study – When the system fails the frontrunners

4.1 Introduction

The purpose of this case study is to illustrate the order of magnitude of the loss in sales that users and suppliers of alternatives may incur if continued use is granted despite alternatives existing on the market. The estimated loss to alternative providers is not a net cost to society but is part of the distributional effects providing economic incentives for substitution. Since the REACH authorisation system is the primary substitution mechanism under REACH, this was chosen as the basis for the case study.

The quantitative analysis is based on DCC Maastricht's application for authorisation for the use of lead chromates. This case was chosen because the recent court rulings has established that this application for authorisation should not have been granted. The analysis does not assess costs and benefits to society associated with granting the DCC AfA. For example, there will be costs to human health and the environment, cost savings for DCC Maastricht and/or downstream users from not having to invest in the implementation of alternatives or use of the alternative (e.g. if there are differences in the technical performance when using an alternative).

Section 4.4 takes a broader societal perspective. It considers whether there is a wider problem in granting authorisations when there are alternatives available i.e. DCC Maastricht is perhaps not the only case of this. The section also presents hypothetical estimates as to the potential total loss to alternative providers under certain scenarios, whilst discussing what is lost by not rewarding frontrunners, and what could potentially be gained by doing so.

4.2 Overview of the DCC Maastricht application for authorisation process

DCC Maastricht BV applied for authorisation (under the REACH authorisation system) on the 19th of November 2013 for six uses of lead sulfochromate yellow (PY.34) and lead chromate molybdate sulphate red (PR.104) for the EU market[40], covering distribution, mixing and various industrial and professional applications of paints.

In its analysis of alternatives (AoA) DCC Maastricht claimed that no pigments existed on the market that possess all the characteristics associated with PY.34 and PR.104. They voiced concerns about the ability to produce the "*deepest colours of yellow, orange and red without the use of PY.34 and PR.104*", resulting in lack of contrast and visibility which was needed in its applications. Despite this concern, a substantial list of potential alternatives is cited in the AoA, including inorganic pigments, organic pigments and Diketopyrrolopyrrol (DPP) pigments.

[40] EC (2016). *Granting an authorisation for some uses of lead sulfochromate yellow and of lead chromate molybdate sulfate red under Regulation (EC) No 1907/2006 of the European Parliament and of the Council*. Available at: https://ec.europa.eu/docsroom/documents/18670

The socio-economic assessment attached to the DCC Maastricht AfA cited three areas in which it believed the alternatives were economically inferior. Firstly, the alternative pigments are more expensive (i.e. higher price per kg), secondly, a greater quantity of alternative pigment is required in comparison to PY.34 and PR.104 and thirdly, there is a need to apply additional layers (2-3 layers) of paint when using the alternative. The expected economic burden is largely a result of "*poor technical performance of alternative pigments when compared to PY.34 and PR.104*"[41].

The AoA concluded that none of the alternatives were technically nor economically feasible. Furthermore, none of the alternatives were deemed to be available in sufficient volumes.

Information from third parties

A public consultation was carried out in 2014 for the DCC AfA, whereby stakeholders were invited to provide information. Around 15 stakeholders engaged in the process, some of whom claimed that suitable alternatives for the uses applied for were already available on the market[42].

Assessment and outcome of the application

The Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) adopted their opinions[43] on the DCC AfA in December 2014, followed by the European Commission implementing decision in September 2016[43].

SEAC deemed that the total benefits of continued use of the lead chromate pigments outweighed the human health and/or environmental risks associated with the uses applied for. SEAC confirmed the applicant's conclusion that there were no suitable alternative substances or technologies that were technically or economically feasible for the applicants' downstream users, however it was noted that there were difficulties in fully ascertaining the lack of feasible alternatives. With regards to availability, SEAC stated that there were challenges in obtaining this information and recommended that the applicant should be required to provide regular updates on the availability of potential alternate substances as a condition of their authorisation. SEAC recommended that for use 1, 2, 4 and 5 the review period be set at 12-years, while use 3 and 6 should be set at 7 years. A shorter review period for use 3 and 6 was recommended by SEAC due to evidence of substitution or prohibition of Lead chromate in road markings within some member states.

The European Commission reiterated the "*difficulties in fully ascertaining the lack of technically feasible alternatives for the entire scope of the uses covered by the application*". An additional condition requiring DCC Maastricht to submit "*a report on the status of the suitability and availability of alternatives for his downstream users and on that basis refines the description of the authorised uses.*", was therefore imposed. The European Commission also reduced the review period (compared to SEAC's recommendations) to 7 (instead of 12) years and 4 (instead of 7) years for the respective uses. It was also specified that the volume of the lead

[41] DCC Maastricht BV SEA (2013). *Lead chromate molybdate sulphate red (C.I. Pigment Red 104*'. Available at: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/5743/term

[42] ECHA (2014a). *COMMENTS AND RESPONSE TO COMMENTS ON AUTHORISATION - Lead chromate molybdate sulphate*. Available at: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/5739/term

[43] ECHA (2014b). *Committee for Risk Assessment (RAC) Committee for Socio-economic Analysis (SEAC) Opinion on an Application for Authorisation for Lead chromate molybdate sulphate*. Available at: https://echa.europa.eu/documents/10162/87f426a0-374f-4d1d-999f-8dcea782492c

chromate used could not exceed the volumes in the AfA, namely 2,100 tonnes/year for PY. 34 and 900 tonnes/year for PR. 104.

4.2.1 Court case

In November 2016 Sweden[44] decided to take the case to court, seeking annulment of the European Commission decision to grant an authorisation for the DCC AfA. Sweden's primary argument was that Lead Chromate had not been used in paints within their country for 30 years and there were safer alternatives demonstrably available and that were commercially viable. They argued that the European Commission had not adequately considered the alternatives available on the market. A judgement was made in March 2019 whereby the General Court stated that the European Commission had made an error in law and failed in its obligations to verify the unavailability of a safer replacement and annulled the granting of authorisation for the DCC AfA. The General Court's ruling was appealed but the European Court of Justice also concluded that the European Commission had failed to fulfil its obligation to verify the lack of available alternatives for the various uses of Lead chromates considered[45]. The European Court of Justice also decided that DCC Maastricht's authorisation should be maintained until the European Commission had made a new decision on the application[45].

4.2.2 Observations and implications

From the beginning of the authorisation process through to the court rulings, DCC Maastricht's claim that suitable alternatives were not available was questioned. The General Court emphasised that it is for the applicant to establish the absence of a technically and economically viable alternative, which had not been adequately done within this application. This emphasis reiterated the authorisation system's key principle of the burden of proof lying with the applicant, in line with the Polluter pays principle.

The process also raised questions as to what could be considered a technically feasible alternative. It was underlined by the court that a zero loss in performance was not an appropriate benchmark for technical suitability. This was highlighted by the European Court of Justice statement *"[…] to decide, as a matter of principle, that replacement must not entail any reduction in performance not only amounts to adding a condition not provided for in that regulation [REACH], but is likely to prevent that replacement and, consequently, to deprive that regulation of much of its effectiveness"*[45].

Another key takeaway from these rulings is that the court considers the European Commission's plea of proportionality irrelevant where the conditions for the granting of an authorisation are not met[46]. This reemphasises that the Substitution principle maintains a key principle within the authorisation system, i.e. hazardous chemicals should be substituted when suitable alternatives are available, without regards to other socio-economic considerations.

[44] The EC decisions received the support of 23 member states, however Sweden voted against the EC's draft decision alongside two other members states on the basis that there were alternatives available.

[45] ECJ (2021). *APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 20 May 2019*. Available at:https://curia.europa.eu/juris/document/document.jsf?text=&docid=238162&pageIndex=0&doclang=FR&mode=lst&dir=&occ=first&part=1&cid=1452930

[46] Ashurst (2019). *EU Court sides with Sweden and annuls REACH authorisation for lead chromates*. Available at: https://www.ashurst.com/en/news-and-insights/legal-updates/eu-life-sciences-3---eu-court-sides-with-sweden-and-annuls-reach-authorisation-for-lead-chromates/

One of the outcomes of this court case, is that ECHA has updated its guidance on how alternatives are to be assessed under REACH authorisation, where the perspective of the analysis has been changed from the applicant's only to a broader market perspective. The applicants must now also show that any alternatives that are 'available in general' are not suitable for them. This was previously not considered a requirement in REACH applications for authorisation[47]. If the alternatives 'available in general' are not currently suitable for the applicant, a substitution plan is required within the AfA where the applicant must show the steps it will take to make these alternatives suitable for them. The substitution plan is, as defined in REACH, "*a commitment to take the actions needed to substitute the Annex XIV substance with a suitable alternative substance or technology within a specified timetable*"[48].

The burden of proof on the applicant has also increased as a result of the court case, which aligns with the Polluter plays principle. Previously, uncertainty in the AoA most often resulted in a shorter review period, rather than a refused application. However, now the Court has established that "*where (…) there remain uncertainties as regards the condition relating to the lack of availability of alternatives, it must be concluded that the applicant for authorisation has not discharged the burden of proof and, therefore, that he cannot be granted authorisation' (par. 79)*"[45].

It is believed that the court case (and the appeals) will "*bolster assessment of safer alternatives before SVHCs can be permitted for certain uses*"[49] and sets a new precedent when assessing exemptions and authorisations for the use of hazardous substances in the EU.

4.3 Loss to alternative providers associated with the DCC AfA

A consequence of granting the DCC AfA when alternatives were available was that the expected increase in sales of alternatives to PY. 34 and PR. 104 never materialised, causing significant loss in sales for the suppliers of these alternatives. DCC Maastricht upheld in its AfA that alternatives were not available in sufficient amounts to replace PY. 34 and PY. 104, and that some companies may import articles coated with PY. 34 and PR. 104 outside the EU instead of switching to paints containing alternatives. However, SEAC was not able to verify this, so no judgement is made in this analysis with regards to the validity of this claim.

In the absence of information on the exact composition of the alternatives and their corresponding availability, prices etc., the following analysis is based on the data DCC Maastricht used in the cost analysis within their AfA (publicly accessible version only). **Table 2** summarises key information on the lead chromates used and the most likely alternatives presented in the DCC AfA, which has been used to quantify the potential lost sales for alternative providers. The sales volumes for the alternatives shown in the table were estimated based on the use volumes for the lead chromate pigments, adjusted for the difference in

[47] EC (2020). *ASSESSMENT OF ALTERNATIVES: SUITABLE ALTERNATIVE AVAILABLE IN GENERAL & REQUIREMENT FOR A SUBSTITUTION PLAN*. Available at: https://echa.europa.eu/documents/10162/13637/ec_note_suitable_alternative_in_general.pdf/5d0f551b-92b5-3157-8fdf-f2507cf071c1

[48] ECHA (2021b). *Guidance on the preparation of an application for authorisation*. Available at: https://www.echa.europa.eu/documents/10162/17235/authorisation_application_en.pdf/8f8fdb30-707b-4b2f-946f-f4405c64cdc7?t=1610458546310

[49] Chemical Watch (2021). *European Commission loses landmark appeal case on lead chromate authorisation.* Available at: https://chemicalwatch.com/222426/european-commission-loses-landmark-appeal-case-on-lead-chromate-authorisation

loading and number of coatings needed (i.e. no new assumptions were made).

Table 2: Information on lead chromates and the most suitable alternatives cited in the AfA

	PY. 34 - Yellow	Alternatives to PY. 34		PR. 104 - Red	Alternatives to PR. 104	
		Low	High		Low	High
Loading	7.5%	10%	15%	7.5%	10%	15%
Number of coatings	1	2	3	1	2	3
Volume used (t/y)	2,100	5,600	12,600	900	2,400	5,400
Price of pigment (€/kg)	4.7	22	35	7	45	55

Notes:

1. Prices are directly taken from the DCC AfA and therefore given in 2013 prices
2. The price of alternatives to PR. 104 was cited in the AfA as an average of two pigments with price ranges: €30/kg - €40/kg & €60/kg – €70/kg

As part of eftec's research, invitations to discuss the availability of alternatives to these lead chromates were sent to 13 stakeholders, all of whom either participated in the Commission stakeholder consultation on the DCC AfA or were directly mentioned by another stakeholder as a provider or user of alternative substances. Only one company, Clariant AG, agreed to partake in an interview, which was held in August 2021.

Clariant manufacture different organic pigments and they informed eftec that their portfolio of pigments can be used as technically equivalent alternatives to PY. 34 and PR. 104 covering all the uses applied for by DCC Maastricht, i.e. not only for road markings. According to Clariant, these organic pigments are usually more expensive (per kg) but require lower loading than the lead chromate pigments, hence the difference in cost of use may not be as distinct as claimed by DCC Maastricht. To account for the possibility that there are alternatives that are less costly than indicated in the DCC AfA, another more conservative scenario was constructed, shown in **Table 3**.

Table 3: Conservative scenario based on information from Clariant AG

	Conservative scenario – partly based on information from Clariant	
	Alternatives to PY. 34	Alternatives to PR. 104
Loading	5%	5%
Number of coatings	1	1
Volume used (t/y)	1,400	600
Price of pigment (€/kg)	22	45

Notes: Prices are directly taken from the DCC AfA and therefore given in 2013 prices

The order of magnitude of the loss in sales of alternatives to PY. 34 and PR. 104 resulting from granting the DCC AfA, which was estimated based on the information set out in **Table 2** and **Table 3**, and is presented

in **Table 4**. Calculating the present value (PV) of the total loss over the review periods granted[50] (a weighted average based on tonnes = 6.4 years), the estimated total loss ranges from a conservative estimate of **€200 million (PV) to a high estimate of €4.4 billion (PV)**. The large range is a result of combining lower (higher) loading, prices, and number of coatings.

It should be noted that that there are inherent uncertainties associated with these estimates, as it is not known to what extent the alternatives would have been available in sufficient supply. If the production capacity for the alternatives could not meet the market demand in full, the losses would be lower and/or moved forward in time (creating a backlog due to excess demand).

Table 4: Lost sales for suppliers of alternatives

	Conservative	Low	High
Source of information	*DCC AfA & Clariant*	*DCC AfA*	
Annual (€ million/year)	40	260	820
Total over the review periods (€ million) - PV	200	1,400	4,400

Notes:

1. Values have been uplifted to 2020 prices and rounded to nearest 10 million
2. A 4% discount rate has been applied
3. Assumed no market growth
4. The review period applied is a weighted average based on tonnage per use, which equals 6.4 years

The estimated loss is not a net cost to society, but rather a distribution of income and cost savings from the provider and users of the SVHCs. In other word, DCC Maastricht maintained their revenue from sales of the lead chromates and its downstream users avoided costs associated with the higher prices of the alternatives.

Albeit only indicative of the order of magnitude, the estimates clearly show that the providers of alternative pigments likely incurred sizable losses as a result of the granted authorisation for these lead chromates. This, in turn, will create disincentives for companies to phase out SVHCs before the sunset date (instead of applying for an authorisation) in the future, as they run the risk of losing customers and sales if the alternatives are more expensive (to use) than the SVHCs.

4.4 Societal perspective

4.4.1 A wider problem?

To date there has only been one authorisation that has been annulled as a result of breaching the REACH requirement that the applicant must prove that no suitable alternatives are available on the market. This does not necessarily mean that there are no other AfAs that should have been refused on the grounds of alternatives being available. In the article "How to find and analyse alternatives in the Authorisation Process"[22] ChemSec highlights several AfAs where there was conflicting evidence on alternatives, for

[50] Note that due to the court case DCC Maastricht was allowed to continue to use lead chromates beyond the review period for some of the uses. This has not been accounted for here but would overall increase the size of the loss to alternative providers.

example:

"[…] in the Lanxess case, the applicant fully rejected the arguments presented by the alternative providers, affirming that its alternative was feasible for applications in the automotive industry. Volkswagen however released a new model with the technology a few months later, using a solution from an alternative provider, Oerlikon Balzers."

In the case of the DCC AfA, shorter review periods were used to address the uncertainties induced by the conflicting evidence on the availability of suitable alternatives (i.e. approach (iii) from Section 3.3.3). ECHA state that SEAC's recommended review periods "[…] were 2.7 years shorter than those proposed by applicants[11]". For 42% of the uses where a shorter (than applied for) review period was recommended by SEAC, the reason was because the applicant "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"[11]. It is therefore considered highly likely that alternatives exist(ed) at least for some of the (applications within) uses that have received an authorisation.

213 AfAs have been submitted to ECHA since 2013 with a combined annual volume of 980,133 tonnes of SVHCs applied for[11,51], of which the volumes of SVHCs used in the DCC AfA only comprise 0.3%[52]. For illustrative purposes it is assumed that the market value lost for alternative providers within the DCC AfA is representative for the orders of magnitude of loss that would occur in other markets. It is then possible to construct hypothetical scenarios to illustrate potential losses associated with granting authorisations for uses where alternatives exist – on a broader scale. As an example, if only 5% of the volume applied for received an authorisation when alternatives exist, this could have resulted in total loss to alternative providers of between €650 million and €13.4 billion per year.

Due to a lack of information on the representativeness of the lost sales associated with the DCC AfA and the share of uses/applications receiving an authorisation when alternatives exist, it is not possible to provide robust estimates on the potential order of magnitude the total loss to alternative providers and users. Nonetheless, the sizable loss associated with the DCC Maastricht application alone combined with the fact that conflicting evidence regarding alternatives have been observed for a number of applications, it is likely that alternative providers have incurred significant losses of revenue (in the order of magnitude of €1 – €10 billions) since 2013. As previously mentioned, the size of the loss may be lower or the timing might be delayed, if the supply of the alternatives was not sufficient to meet market demand during the review period for the authorisations.

What could have been different?

As described in the previous section, the Court has now established that it is not a legal approach to use reductions in the review period to account for analytical uncertainties, and when significant uncertainties exist regarding the availability of suitable alternatives, the authorisation should be refused.

[51] As per December 2020

[52] ECHA (2021c). *Socio-economic impacts of REACH authorisations.* Available at: https://echa.europa.eu/documents/10162/17229/socioeconomic_impact_reach_authorisations_en.pdf/12a126f2-9267-1dcd-75e3-ce0f072918e4?t=1619782167012

If this 'hard-line' approach had been the practise since the start of the authorisation system in 2013, a **large share of the lost revenue for alternative providers described and estimated above could likely have been avoided**. Additionally, it could have led to knock-on effects on the AfAs submitted:

- **More downstream applications**, instead of upstream applications, due to the difficulties with gathering data and robust analysis when a large number of companies are covered within the AfA.
- **Narrower use definitions**, but possibly a higher number of uses. This is because a broad use definition makes it more difficult to prove that there are no alternatives suitable for any applications of the SVHCs within the scope of the use, whilst this is more straightforward for a use that consists of a small (and/or homogenous) set of applications.
- **A higher number of refused authorisations** due to uncertainties in evidence presented in the AfAs.
- **Fewer applicants**. The number of applications would not necessarily decrease (due to the first two points), however, it is likely that more companies would start the substitution process earlier resulting in fewer companies applying for authorisations.

4.4.2 The dangers of making frontrunners the financial losers

The loss in sales for alternative providers quantified in the previous sections does not represent a cost to society, as it is a loss for the alternative providers but a gain for the DCC Maastricht and its downstream users (i.e. the supplier and users of the SVHCs). However, it is integral to consider these types of 'perverse' distributional effects as they strongly disincentivise substitution, breaching both the Polluter pays principle as well as the Substitution principle.

A common argument for allowing continued use of SVHCs is that the benefits outweigh the costs for a specific use. However, when carrying out traditional cost-benefit analysis for regulatory purposes, it is common to assess the impacts of one action (e.g. a regulatory decision) in isolation, and implications of systemic changes are usually not considered[53]. For example, the short-term benefit-cost ratio for a company's specific use of an SVHCs may favour continued use because of the high costs of substitution, and other companies operating in the same market may be in the same situation. If one (or a few) companies invest in R&D and successfully implement alternatives, this could, however, change the situation for the whole market. The initial (high) costs may only be incurred by a few actors (as opposed to all companies on the market), and these companies might be able to expand their capacity to meet the market demand (i.e. the use of the SVHC is no longer needed). Another possibility is that other companies will learn from the new technology on the market and thereby reducing their own substitution costs.

This type of positive externality (as was discussed in Section 2.2) created by the substitution efforts of the frontrunners is usually not accounted for in the narrower cost-benefit analyses carried out in relation to authorisations or restriction derogations. It also illustrates that it is often the frontrunners that will incur the majority of the costs, which underlines the importance of financial rewards or support for these companies. If companies see limited opportunities for return on their investments (i.e. they would incur

[53] Not considering systemic changes is not necessarily an error in the analysis, but rather an issue resulting from a narrow scope of the analysis. There could also be methodological errors, such as not accounting for the increased revenue for alternative providers if an authorisation is refused, but these are not further discussed here.

cost of substitution without increasing market shares or their income otherwise), they will likely not invest. Technical and economic barriers for substitution as well as limitations in availability of alternative will then remain, and substitution may never become the best course of action for many users of SVHCs.

4.4.3 What can be gained by rewarding frontrunners

EU regulations is indeed driving substitution, where 36% - 46% of companies surveyed stated that EU regulation was their primary driver for substitution[54]. The same study highlights that, financial benefits were rarely a motivation for substituting away from SVHCs, which reinforces the conclusion that further financial incentives may be required in encouraging substitution efforts above what has been seen to date.

Figure 1 shows only 35% of companies start the substitution process at the candidate list stage or before. If the benefits of substituting early (potential financial gain) was considered more certain, it is likely that more companies would start their substitution process earlier in time, and successful substitution will likely occur earlier[55].

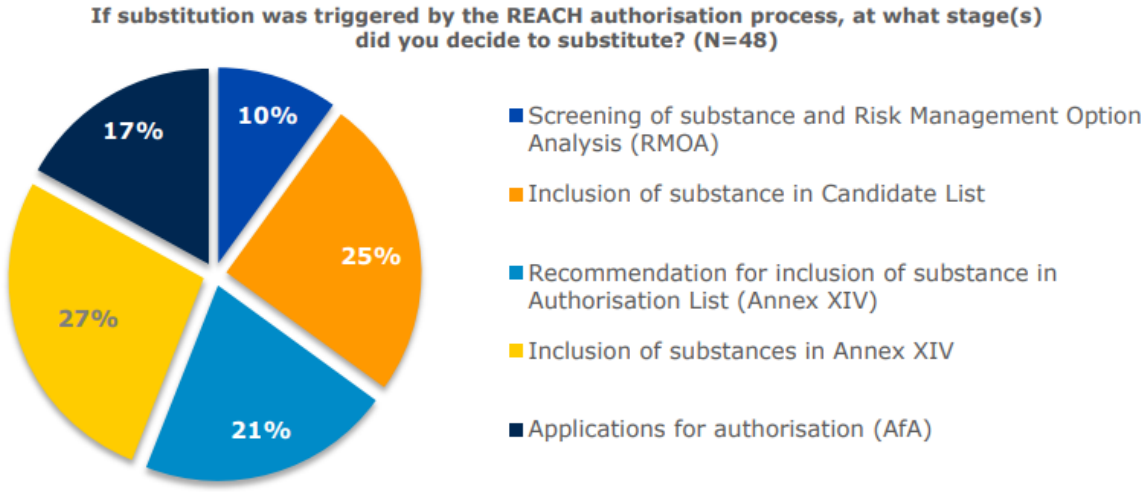

Figure 1 Stage when companies start their substitution process[54]

Even though regulations have been the main driver for substitution to date, it does not exclude the option of creating new systems (complementing or replacing existing ones) incentivising substitution. As shown in Section 3.2, there are a multitude of policy measures that can be utilised. A key point is that distributional effects and economic incentives must be carefully considered as to how they enhance the desired policy objective for substitution. For example, by combining measures that induces costs for the suppliers and users of SVHCs with measures that reward the frontrunners.

[54] ECHA (2021c). *Socio-economic impacts of REACH authorisations.* Available at: https://echa.europa.eu/documents/10162/17229/socioeconomic_impact_reach_authorisations_en.pdf/12a126f2-9267-1dcd-75e3-ce0f072918e4?t=1619782167012

[55] Note that increasing the economic incentives for substitution does not mean that the market actors will be successful in their substitution efforts. However, it is likely that the efforts (i.e. time and money invested) will increase, and thereby increase the likelihood of substitution earlier in time.

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