TEXTE
06/2021

Final report

Development of REACH – Review of evidence on the benefits & costs of REACH

by:

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publisher:
German Environment Agency

German Environment Agency

Umwelt Bundesamt

TEXTE 06/2021

Ressortforschungsplan of the Federal Ministry for the
Enviroment, Nature Conservation and Nuclear Safety

Project No. (FKZ) 3717 67410 0

Report No. FB000108/ENG,ZW,2

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On behalf of the German Environment Agency

Imprint

Publisher
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Report completed in:
October 2020

Edited by:
Section IV 2.3 Chemicals
Doreen Einhenkel-Arle

Publication as pdf:
http://www.umweltbundesamt.de/publikationen

ISSN 1862-4804

Dessau-Roßlau, January 2021

Abstract: Development of REACH – Review of evidence on the benefits & costs of REACH

This report is provided in the scope of the project "Advancing REACH", funded by the research plan of the German Ministry of the Environment. The project aims to develop options to improve the (implementation of) the REACH regulation by analysing various REACH processes and related issues, including substitution, sustainable chemistry, precautionary principle, articles, cost-benefit analyses, socio-economic analyses and financing ECHA.

The objective of this work package was to review the existing literature to determine the current level of knowledge of the benefits and costs associated with REACH. The primary focus was on the identification of the gaps in the assessment of benefits, as multiple studies have already concentrated on the costs caused by the implementation of the REACH Regulation.

Sections 2 and 3 summarise the assessment framework and the reports reviewed in this study.

In Sections 4 and 5, the current state of knowledge and any gaps in the benefit and cost data/information are broken down by each single component of REACH regulation, namely Registration, Information in the Supply Chain, Evaluation, Authorisation, Restriction, Guidance, Inspection and Enforcement.

Section 6 presents the conclusions of this report.

Kurzbeschreibung: REACH-Weiterentwicklung - Überprüfung der Evidenz zu Nutzen und Kosten von REACH

Dieser Bericht ist Teil des Ressortforschungsplan Vorhabens „REACH-Weiterentwicklung", das basierend auf Analysen verschiedener REACH-Prozesse sowie angrenzender Fragestellungen (Substitution, Nachhaltige Chemie, Vorsorgeprinzip, Erzeugnisse, Kosten-Nutzen Analysen, Sozio-Ökomische Analysen, Finanzierung der ECHA) Optionen für eine Verbesserung der (Umsetzung der) REACH-Verordnung entwickelte.

Ziel dieses Berichts ist es, die vorhandene Literatur hinsichtlich des aktuellen Kenntnisstands über die mit REACH verbundenen Vorteile und Kosten zu bewerten. Da sich mehrere Studien bereits auf die Kosten durch die Implementierung der REACH-Verordnung konzentriert haben, liegt der Schwerpunkt dieser Arbeit auf der Identifizierung von Lücken bei der Einschätzung des Nutzens.

Die Abschnitte 2 und 3 fassen den Bewertungsrahmen und die in dieser Studie überprüften Berichte zusammen.

In den Abschnitten 4 und 5 werden der aktuelle Wissensstand und etwaige Lücken bei Daten bzw. Informationen zu Nutzen und Kosten gegliedert nach den einzelnen Teilbereichen der REACH-Verordnung aufgeschlüsselt. Dies umfasst die Registrierung, Informationen in der Lieferkette, die Bewertung, die Zulassung, die Beschränkung, die Unterstützung von Firmen, die Überwachung und den Vollzug.

In Abschnitt 6 werden die Schlussfolgerungen dieses Berichts präsentiert.

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List of abbreviations

AfA	Application for Authorisation
AoA	Analysis of Alternatives
C&L	Classification and labelling
CLP	Classification, labelling and packaging
COM	The European Commission
ECHA	European Chemicals Agency
EU	European Union
DNEL	Derived No Effect Level
IUCLID	International Uniform Chemical Information Database
PIC	Prior Informed Consent (Regulation)
OSH	Occupational Health & Safety
(Q)SAR	(Quantitative) Structure Activity Relationship
REACH	Registration, evaluation, authorisation and restriction of chemicals
REACH IT	The central IT system used to securely submit, process and manage data and dossiers
PNEC	Predicted No-Effect Concentration
RMM	Risk Management Measure
SCIP database	Substances of concern in products database
SDS	Safety Data Sheet
SEA	Socio-Economic Analysis
SIEFs	Substance Information Exchange
SME	Small, medium and large enterprises
SVHC	Substance of very high concern

Summary

The current report is one of the results of the project "Advancing REACH", which is funded by the research plan of the German Ministry of the Environment. Within the project framework, various aspects of the REACH regulation and its implementation are analysed and improvement options developed, including potential changes in the regulatory text and its annexes.

The project "Advancing REACH" consists of 18 sub-projects, which discuss different aspects of (the implementation of) the regulation and related improvement options. Topics of the sub-projects are the REACH processes dossier evaluation, substance evaluation, restriction, authorisation and consultation, as well as the role of the board of appeal and the interplay of the processes. In addition, the relation between REACH and sustainable chemistry, the implementation of the precautionary principle, the enhancement of substitution and the assessment of benefits of REACH are evaluated, as well as the procedures of the socio-economic analysis, options to regulate substances in articles and the financing of the European chemicals agency's (ECHA) tasks.

The objective of this report is to review the existing literature to determine the current level of knowledge of the benefits and costs associated with REACH. The primary focus is on the identification of the gaps in the assessment of benefits, as multiple studies have already concentrated on the costs caused by the implementation of the REACH Regulation. The study does not cover the impact assessment work that has been carried out on the potential increase in information requirements for substances registered at 1-10 tonnes. It also does not touch upon the potential inclusion of polymers into REACH.

Sections 2 and 3 summarise the assessment framework and the reports reviewed in this study.

In Sections 4 and 5, the current state of knowledge and any gaps in the benefit and cost data/information are broken down by each single component of REACH regulation, namely Registration, Information in the Supply Chain, Evaluation, Authorisation, Restriction, Guidance, Inspection and Enforcement. The results of the literature review have been used to as a basis for proposing potential solutions for addressing the key data gaps.

The overall results of the study in Section 6 suggest that the key benefits of REACH considered in the available literature relate to the reduction of risks caused by hazardous substances on all impact groups (environment, consumers, workers, man via the environment), the withdrawal/restriction of hazardous substances and reduction of environmental releases. Another important benefit of REACH is the production of more and better information on substances at the disposal of all the relevant stakeholders. Equally important is information sharing along the supply chains that many drivers within REACH have actively encouraged. The information exchange in the supply chain has been essential for raising the level of awareness and inducing firms to adopt new or improved Risk Management Measures (RMMs).

The literature review shows that very limited quantification and monetisation estimates of the benefits associated with REACH are available, mainly due to a lack of monitoring data and limitation in official databases.

REACH has had a relevant role in creating a single market for chemicals, with this delivering several benefits for the EU economy such as for instance greater competition, increased trade between Member States, lower prices and availability of products to end-users and so on. Evidence of the impact of REACH on the competitiveness of EU producers is mixed. Some suggest that REACH has created an excessive burden thus putting EU-based producers at a disadvantage in relation to third-country operators. However, some other evidence denies that REACH has had any impact at all.

Similarly, there is partial evidence on the impacts of REACH on innovation. REACH Authorisation has been an effective driver of innovation, and the SVHC Candidate Listing process is also recognised as having driven some level of substitution and hence innovation. However, the extent of substitution and the role of REACH on its own is not clear. Although REACH encourages substitution with safer substances it is difficult to attribute substitution effects only to REACH as substitution may also be driven by other legislation (e.g. OSH) and supported by drivers independent from REACH (e.g. circular economy, consumer preferences). Clearly, innovation is taking place and it is being facilitated by REACH. Nevertheless, to what extent REACH is directly and indirectly encouraging companies to allocate their resources to their research programmes is unclear in the literature. In addition, there is evidence that Authorisation has in some cases resulted in regrettable substitutions rather than true innovation.

The available information suggests that REACH has helped enhance the development, use and acceptability of alternative methods to replace, reduce, refine animal testing, but there are still areas of improvements regarding the use of adequate alternative methods. As for innovation away from SVHCs, innovation in test methods is being driven by a broader set of legislative drivers (including OSH, cosmetics, plant protection and biocidal products), as well as by animal rights groups and authorities' wish to replace animal testing with other methods.

Direct and indirect costs arise from implementation of most of the main drivers within REACH. These include costs to those directly affected by REACH and its legal obligations, i.e. manufacturers, importers and downstream users of chemicals, but also MS Authorities, the European Chemicals Agency (ECHA) and the European Commission. Quantitative / monetary estimates of the most significant direct cost elements were developed as part of the original impact assessments, and have been subject to ex post assessments as part of the various evaluations.

Costs arising at the national level as part of MS implementation (e.g. inspection related costs) and from on-going implementation decisions which are not subject to IA requirements (e.g. changes agreed within Caracal to the requirements set out in ECHA's guidance or in the implementation and enforcement of REACH) have been less covered, partially because they are harder to model or predict. Examples include changes in requirements as part of ECHA's up-dating of guidance documents that impact directly on REACH registrants, as well as decisions with respect to definitions that are not given in the regulation, etc. which are agreed between the Commission Services, MS authorities and ECHA.

To address the key data gaps with regards to the benefits of REACH, it is recommended that priority should be given to make a more efficient use of available data. However, efforts could also aim at creating a more comprehensive dataset at the EU level, as this is a pre-requisite for quantifying and monetising whenever possible the benefits. To this end, a series of recommendations are advanced in Section 6.3. On the cost side, we would see as the priority for any future research conditions placed on granted authorisations and actions taken by ECHA which are not subject to assessment requirements.

Zusammenfassung

Der vorliegende Bericht ist ein Teilergebnis des Ressortforschungsplan-Vorhabens „REACH-Weiterentwicklung“. Im Rahmen dieses Vorhabens wurden verschiedene Aspekte der REACH – Verordnung und ihrer Umsetzung analysiert und Verbesserungsoptionen, einschließlich einer möglichen Veränderung des Verordnungstextes und seiner Anhänge, aufgezeigt.

Das Vorhaben REACH-Weiterentwicklung besteht aus insgesamt 18 Teilprojekten, die sich mit unterschiedlichen Aspekten der (Umsetzung der) REACH-Verordnung und Optionen für deren Weiterentwicklung auseinandersetzen. So werden in den jeweiligen Teilprojekten die REACH Prozesse Dossierbewertung, Stoffbewertung, Beschränkung, Zulassung und Konsultationen sowie die Rolle der Widerspruchskammer und das Zusammenspiel der Prozesse analysiert. Auch die Verbindung von REACH zur Nachhaltigen Chemie, die Umsetzung des Vorsorgeprinzips, die Förderung der Substitution und die Abschätzung des Nutzens der REACH-Verordnung werden untersucht sowie das Verfahren der sozio-ökonomischen Analyse, Optionen zur Regulierung von Stoffen in Erzeugnissen und die Finanzierung der Aufgaben der Chemikalienagentur ECHA.

Ziel dieses Berichts ist es, die vorhandene Literatur hinsichtlich des aktuellen Kenntnisstands über die mit REACH verbundenen Vorteile und Kosten zu bewerten. Da sich mehrere Studien bereits auf die Kosten durch die Implementierung der REACH-Verordnung konzentriert haben, liegt der Schwerpunkt dieser Arbeit auf der Identifizierung von Lücken bei der Einschätzung des Nutzens. Die bereits durchgeführten Arbeiten zur Folgenabschätzung einer potenziellen Erhöhung der Informationsanforderungen für Stoffe, die im Tonnagebereich von 1 bis 10 Tonnen registriert sind, werden von der Studie nicht abgedeckt. Es wird außerdem nicht auf die mögliche Einbeziehung von Polymeren in REACH-Registrierungspflicht eingegangen.

Die Abschnitte 2 und 3 fassen den Bewertungsrahmen und die in dieser Studie überprüften Berichte zusammen.

In den Abschnitten 4 und 5 werden der aktuelle Wissensstand und etwaige Lücken bei Daten bzw. Informationen zu Nutzen und Kosten gegliedert nach den einzelnen Teilbereichen der REACH-Verordnung aufgeschlüsselt. Dies umfasst die Registrierung, Informationen in der Lieferkette, die Bewertung, die Zulassung, die Beschränkung, die Unterstützung von Firmen, die Überwachung und den Vollzug. Die Ergebnisse der Literaturrecherche wurden als Basis für Vorschläge möglicher Verbesserungen zur Schließung der Lücken bei Schlüsseldaten verwendet.

Die Gesamtergebnisse der Studie in Abschnitt 6 legen nahe, dass die in der verfügbaren Literatur berücksichtigten Hauptvorteile von REACH in der Verringerung des Risikos durch gefährlicher Stoffe bei allen zu schützenden Gruppen/Gütern (Umwelt, Verbraucher, Arbeitnehmer, Mensch über die Umwelt), im vom Marktnehmen bzw. der Beschränkung gefährlicher Stoffe und der Verringerung von Umweltfreisetzungen liegen.

Ein weiterer wichtiger Vorteil von REACH ist die Bereitstellung von zusätzlichen und besseren Informationen zu Stoffen, die allen relevanten Interessengruppen zur Verfügung stehen. Ebenso wichtig ist der Informationsaustausch entlang der Lieferketten, den viele Faktoren innerhalb von REACH aktiv gefördert haben. Der Informationsaustausch in der Lieferkette war von wesentlicher Bedeutung für die Steigerung des Problembewusstseins und, um Unternehmen zu ermutigen, neue oder verbesserte Risikomanagementmaßnahmen (RMM) zu ergreifen.

Die Literaturübersicht zeigt, dass nur sehr begrenzte Schätzungen zur Quantifizierung und Monetarisierung der mit REACH verbundenen Vorteile verfügbar sind. Fehlende Überwachungsdaten und begrenzte Datenverfügbarkeit in offiziellen Datenbanken sind die Hauptgründe hierfür.

REACH hat eine wichtige Rolle bei der Schaffung eines Binnenmarktes für Chemikalien gespielt. Dies hat der EU-Wirtschaft mehrere Vorteile erbracht, wie zum Beispiel einen stärkeren Wettbewerb, einen verstärkten Handel zwischen Mitgliedstaaten, niedrigere Preise und die Verfügbarkeit von Produkten für Endverbraucher, etc. Die Hinweise auf die Auswirkungen von REACH auf die Wettbewerbsfähigkeit der EU-Hersteller sind uneinheitlich. Einige Hinweise deuten darauf hin, dass REACH eine übermäßige Belastung geschaffen hat, wodurch die in der EU ansässigen Hersteller gegenüber Produzenten aus Drittländern benachteiligt werden. Andere Hinweise lassen jedoch daran zweifeln, dass REACH überhaupt Auswirkungen hatte.

Ebenso gibt es zum Teil Hinweise auf Auswirkungen von REACH auf das Innovationspotential. Die REACH-Zulassung war ein wirksamer Innovationstreiber. Ebenfalls hat der SVHC-Kandidatenlistenprozess ein gewisses Maß an Substitution und damit Innovation vorangetrieben. Das Ausmaß der erfolgten Substitutionen und die Rolle von REACH dabei sind jedoch nicht klar. Obwohl REACH die Substitution durch sicherere Substanzen fördert, bleibt es schwierig, Substitutionseffekte nur REACH zuzuschreiben, weil die Substitution auch durch andere Rechtsvorschriften (z. B. im Arbeitsschutz) getrieben und durch von REACH unabhängigen Faktoren (z. B. Kreislaufwirtschaft, Verbraucherpräferenzen) unterstützt werden kann. Es ist aber erkennbar, dass Innovationen erfolgen und diese von REACH befördert werden. Inwieweit REACH Unternehmen direkt oder indirekt dazu ermutigt, ihre Ressourcen für Forschungsprogramme bereitzustellen, wird aus der Literatur nicht deutlich. Darüber hinaus gibt es Hinweise darauf, dass das Zulassungssystem in einigen Fällen eher zu unerwünschten Substitutionen als zu echten Innovationen geführt hat.

Die verfügbaren Informationen deuten darauf hin, dass REACH zur Entwicklung, Verwendung und Akzeptanz alternativer Methoden beigetragen hat, die Tierversuche ersetzen, reduzieren oder erträglicher gestalten. Es gibt jedoch noch Verbesserungsmöglichkeiten hinsichtlich der Verwendung angemessener alternativer Methoden. Wie auch bei Innovationen in Bezug auf die Substitution von SVHCs wird die Innovation bei Testmethoden von einer breiteren Palette gesetzlicher Faktoren (einschließlich der Gesetzgebung zum Arbeitsschutz, zu Kosmetika, zu Pflanzenschutzmitteln und zu Biozidprodukte), von Tierrechtsgruppen und dem Wunsch der Behörden, Tierversuche durch andere Methoden zu ersetzen, vorangetrieben.

Direkte und indirekte Kosten entstehen durch die Implementierung der meisten Haupttreiber innerhalb von REACH. Dazu gehören Kosten für diejenigen, die direkt von REACH und den gesetzlichen Verpflichtungen betroffen sind, also Hersteller, Importeure und nachgeschaltete Anwender von Chemikalien, aber auch für die Behörden der Mitgliedsstaaten, die Europäische Chemikalienagentur (ECHA) und die Europäische Kommission. Quantitative/monetäre Schätzungen der wichtigsten direkten Kostenelemente wurden im Rahmen der ursprünglichen Folgenabschätzungen entwickelt und als Teil der verschiedenen ex-post Bewertungen erneut betrachtet.

Umsetzungskosten, die auf nationaler Ebene entstehen (z.B. überwachungsbezogene Kosten) und Kosten aus aktuellen Entscheidungen der Umsetzung, die nicht der Notwendigkeit einer separaten Folgenabschätzung unterliegen (z.B. Änderungen der ECHA-Leitfäden, die innerhalb von Caracal vereinbart wurden oder Änderungen in der Umsetzung und dem Vollzug von REACH) wurde von den Folgenabschätzungen weniger abgedeckt, teilweise wohl auch, weil sie schwerer zu modellieren und vorherzusagen sind. Beispiele hierfür sind Änderungen bei den Anforderungen durch Aktualisierung der Leitfäden durch die ECHA, die Auswirkungen auf REACH-Registranten haben, sowie Entscheidungen in Bezug auf Definitionen, die nicht in der Verordnung enthalten sind, die zwischen der Kommission, den Behörden der Mitgliedsstaaten und ECHA vereinbart wurden, etc.

Um die Lücken der Schlüsseldaten in Bezug auf die Vorteile von REACH zu schließen, wird empfohlen, prioritär verfügbaren Daten effizienter zu nutzen. Jedoch könnte auch versucht werden einen umfassenderen Datensatz auf EU-Ebene zu erstellen, weil dies eine Voraussetzung für die Quantifizierung und Monetarisierung der Vorteile ist. Diesbezüglich wird in Abschnitt 6.3 eine Reihe von Empfehlungen detaillierter vorgestellt. Auf der Kostenseite sollten zukünftige Forschungen prioritär auf erteilte Zulassungen und Maßnahmen der ECHA gelegt werden, für die nicht die Notwendigkeit von Folgenabschätzungen fokussieren.

1 Introduction

1.1 Objectives of Work Package 2

The aim of this report is to provide an overview of the types of benefits and costs that have been identified and analysed in previous work on the evaluation of REACH. The main focus is on the benefits of REACH to society, environment and industry. It is assumed that the costs of REACH have already been sufficiently evaluated and the cost element of this work package is thus less extensive. Building upon the literature review, proposals for addressing the key data gaps have been developed.

This study focuses on the following research questions:

- What key benefits and costs of REACH have already been identified and how significant are they (data collection/quantification)?
- How could the benefits and costs that have not been sufficiently considered be quantified and integrated into evaluations in a meaningful and practical manner?

1.2 Structure of this report

The remainder of this report is organised as follows:

- Section 2: Overview of the assessment framework
- Section 3: List of studies selected for review
- Section 4: Overview of the key benefit categories considered in the relevant studies
- Section 5: Overview of the key cost categories considered in the relevant studies
- Section 6: Summary of the key benefits and costs and proposals for addressing the key data gaps
- Section 7: References

This report is complemented with three annexes:

- Annex A: Review of the three pilot case studies
- Annex B: Review of the remaining studies
- Annex C: General aspects – other reviewed studies

2 Overview of the assessment framework

2.1 Overview

Before starting the literature review, analysis and synthesis work required under WP2, a systematic framework for identifying the positive and negative impacts of REACH was developed. As discussed during the kick-off call, the aim is to identify the range of potential impacts, where this includes both "costs" and "benefits" but to then focus the more detailed assessment work on the benefits; it is important to note that within the context of this study, benefits may include cost-savings, benefits associated with reduced impacts on the environment and benefits associated with reduced impacts on human health.

Several previous studies have tried to analyse - ex-ante and ex-post - the costs and benefits of REACH. These have all been partial analyses. To a great extent, this has been due to the fact that REACH was brought into force with the aim of addressing a range of regulatory and information gaps that were leading to market failures. Due to a lack of information across a range of key factors, such as the hazards and exposures arising from current uses of industrial chemicals placed on the EU market, there are key gaps in the analysis of the benefits, in particular, that could be directly linked to REACH in qualitative or quantitative terms.

The framework set out below has been developed with the aim of providing the following:

- A description of the key provisions in REACH that have been identified in the past as potentially leading to costs and benefits (i.e. the cost and benefit drivers), with the linkages for costs being at a higher level than for benefits;
- Identification of the types of mechanisms/pathways that may lead to such benefits and then the potential nature of those benefits (including who benefits); and
- For the different types of benefits, a framework for indicating whether and how the benefits have been assessed, e.g. in qualitative terms, using proxy or physical indicators, or more directly in quantitative terms via monetary valuation.

Through this stepped approach, it should be possible to identify those impacts that have not been assessed in detail in the past and, of these, those which should be prioritised for further research.

Note that given the resources available for this study, we are drawing on past studies, such as the 2012 study on the benefits of REACH[1]. This study in particular has acted as a starting point for this initial framework, as it provides a structure for developing a systematic approach.

2.2 Core REACH obligations

The 2012 study referred to above, reviewed the different provisions within REACH and the corresponding obligations that they placed on the various duty-holders. The results of this exercise are set out in Figure 1, which shows the main obligations (registration, authorisation, restriction, information in the supply chain), the enhancement tools to check and ensure the compliance with these obligations (evaluation, inspection and enforcement, guidance and support), the main groups of actors playing a role during the life-cycle of a substance (manufacturers and/or importers, downstream users [formulators, industrial end-users, professional end-users], distributors and consumers) and the legislation with which REACH has synergies that will help in the

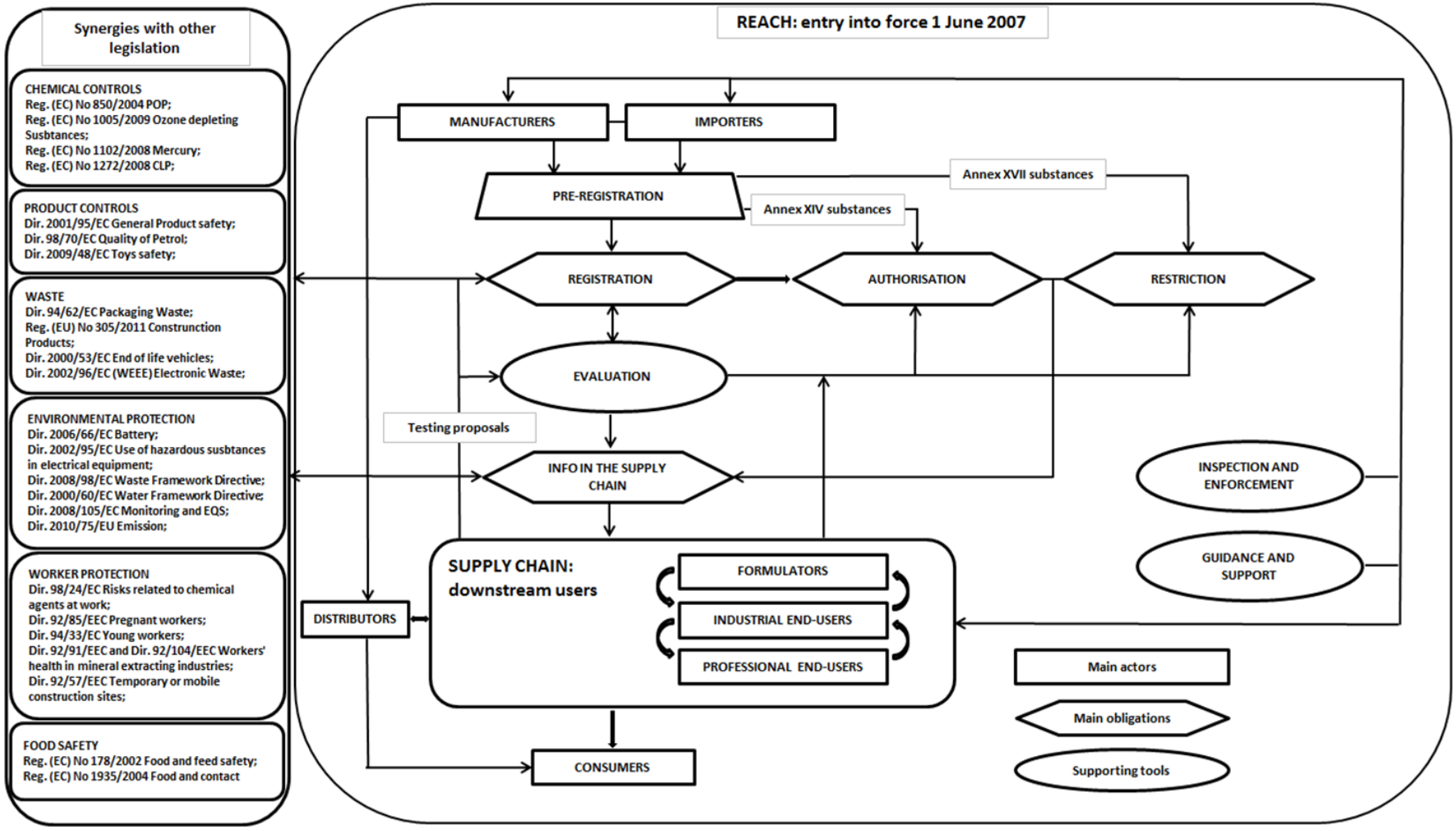
[1] RPA, Oekopol and DHI (2012): Assessment of the Health and Environmental Benefits of REACH, Final Part A and Part B Reports to DG Environment, European Commission, ref. ENV.D.3/SER/2011/0027r

achievement of benefits (e.g. the CLP, worker safety legislation, the WFD, IPPC, waste legislation, etc.).

As defined for this study, the key components to the assessment framework are as follows:

- An obligation is one of the main obligations in REACH: Registration; Information through the supply chain; Authorisation; Restriction; and Evaluation, Inspection and Enforcement activities;
- A driver is a set of legal provisions with a direct or indirect effect and which triggers a cost or a benefit;
- A pathway is the qualitative description of the cause-effect link between the drivers and the benefits;
- A description of the nature of the positive effect includes the type of benefit (human health, environment, etc.) together with the stakeholder that is likely to accrue this benefit and/or the relevant lifecycle stage;
- A description of the methods used to assess the benefits including whether they were assessed in quantitative, qualitative, or monetary terms, and whether they were considered directly or through a proxy (e.g. aA proxy indicator for the quantitative description of the cause-effect link); and
- Enhancers are all those provisions that help to realise the benefits through control and enforcement and thus assist or ensure compliance with the main obligations.

Figure 1: Main Actors, Main Obligations, Enhancement Tools and Synergies with Other Legislation



Source: M. Postle et al. (2012)

2.3 Drivers, pathways and nature of REACH benefits

2.3.1 Overview

By examining each of the drivers in detail, the pathways through which benefits should be delivered by REACH can be described, together with the nature of these benefits. For each of these, it should then be possible to establish what impacts have been assessed in the past, how they have been assessed and to identify any gaps.

For WP2, the starting point will be the drivers and pathways identified from the 2012 work. A summary of these is presented in this note; this summary will be further developed based on the review of the additional studies, which will require consideration of potentially other drivers and other pathways).

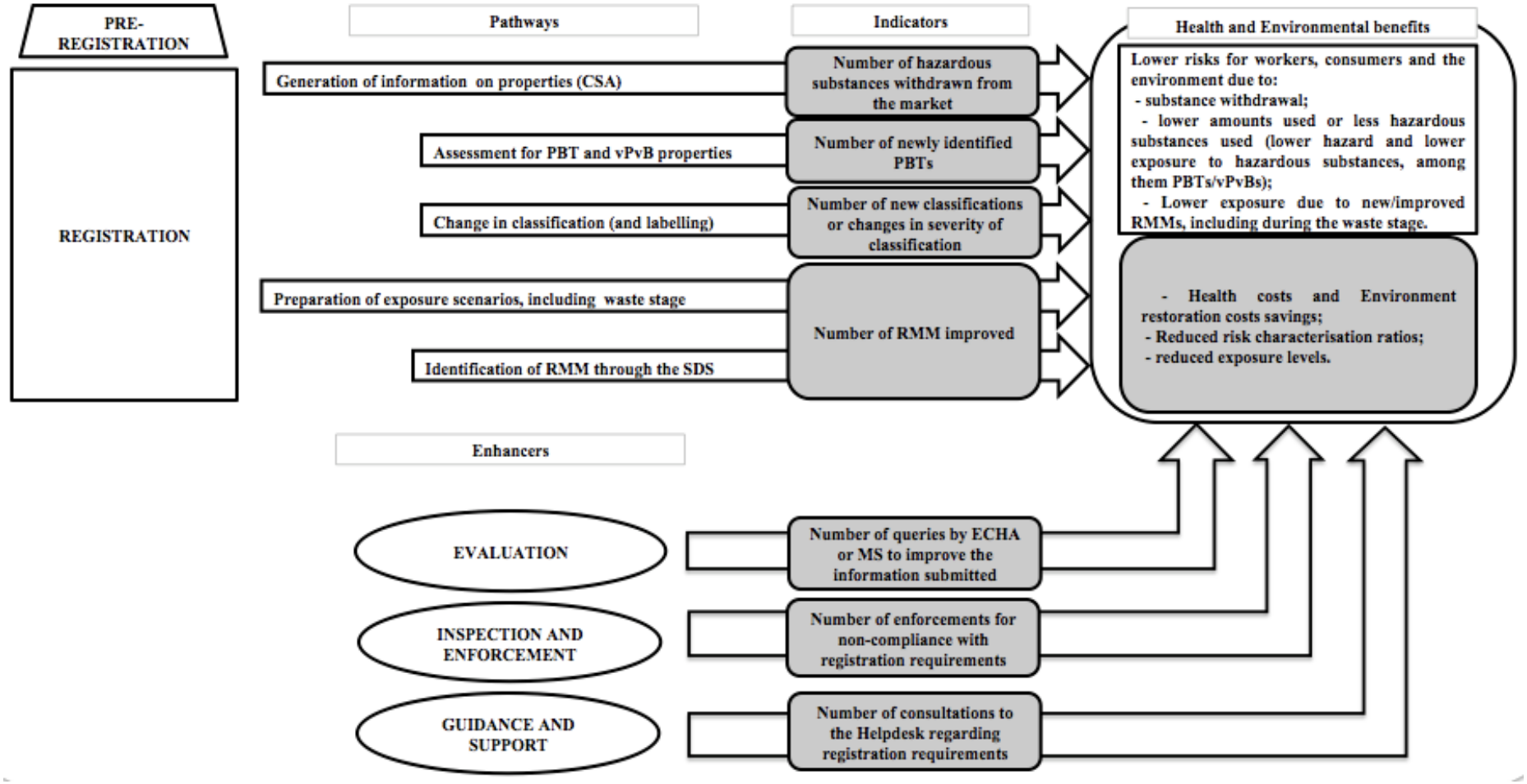
The key drivers relate to the main obligations of REACH, with those of particular relevance to the generation of human health and environmental benefits being:

- Registration;
- Information through the supply chain;
- Authorisation;
- Restriction; and
- Evaluation, Inspections and Enforcement activities.

The first four of these are considered to act as direct generators of benefits, while evaluation, inspections and enforcement activities have been defined for the purposes of this study as "enhancers" of the benefits delivered by the four main sets of provisions. In addition, the provision of guidance by ECHA and dissemination of reports on the operation of REACH as well as other forms of feedback to industry and Member States on how best to fulfil their duties and obligations can be considered to act as an enhancer.

The subsequent sections provide a summary of the drivers, pathways, and benefits identified in the 2012 study for REACH registration, information through the supply chain, evaluation, authorisation, restriction and inspections and enforcement activities.

Figure 2: The Drivers, Pathways, and Indicators of Benefits under Registration



Source: M. Postle (2012)

Table 1: List of the Key Provisions by Duty-holders, Pathways and Benefits for Registration (reproduced from M. Postle et al. 2012)

Article	Provisions	Duty-holders	Pathways	Human health and environmental Benefits
5	Prohibition on manufacture or import of substances on their own, in mixtures or in articles unless they have been registered	M, I	Withdrawal from the market of hazardous substances (partial or complete) and substitution with less hazardous ones. Number of newly introduced non-hazardous substances compared to pre-REACH notifications	Lower number of exposed people/ environments due to the withdrawal and substitution of specific hazardous substances from certain uses in the market, where exposure acts as a proxy for the likelihood of an adverse health or environmental effect
6(1)	Requirement on a manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of one tonne or more per year to submit a registration to the Agency	M, I	As above	As above
6(2)	Obligation to register for monomers that are used as on-site intermediates or transported isolated intermediates	M	As above	As above
6(3)	Requirement on a manufacturer or importer of a polymer to submit a registration to the Agency for the monomer substance(s) or any other substance(s) that have not already been registered by an actor up the supply chain (under conditions)	M, I	As above	As above
7(1)	Requirement on a producer or importer of articles to submit a registration to the Agency for any substance contained in those articles and which are present in quantities over one tonne and where the substance is intended for release under normal or reasonably foreseeable conditions of use	Article producer or Importer	As above	As above
7(2) and (4)	Requirement on a producer or importer of an article to notify the Agency of information provided in Article 7(4)	Article producer or Importer	Generation of information	Cost savings through more controlled use of the substance and the adoption of more appropriate risk management measures (thereby preventing potential future damages)

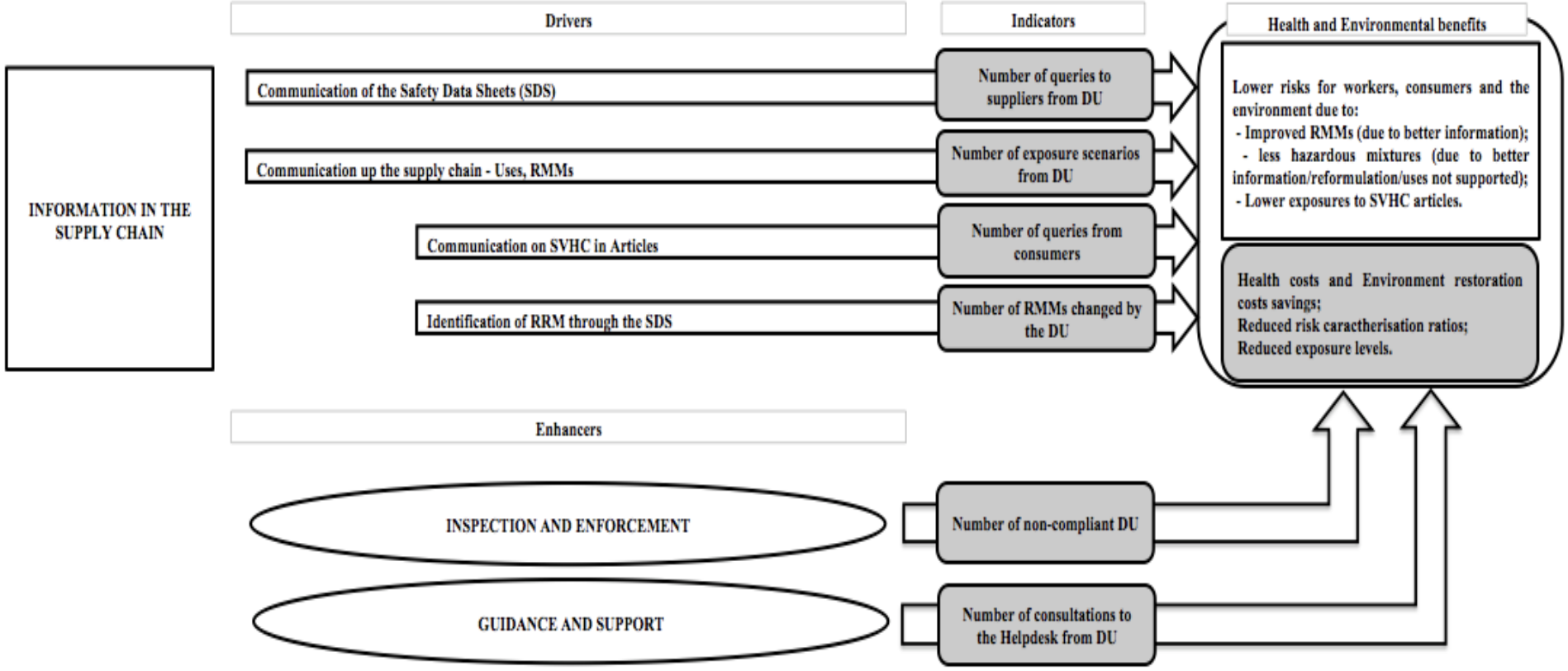
Article	Provisions	Duty-holders	Pathways	Human health and environmental Benefits
7(3)	Requirement on a producer or importer to supply appropriate instructions to the recipient of the article	Article producer or Importer	General information	As above
7(5)	A registration shall be submitted if the Agency takes this decision based on the criteria set in Article 7(5)	Article producer or Importer	Withdrawal from the market of hazardous substances	Lower exposure due to the withdrawal from the market of hazardous substances and the replacement by less hazardous alternatives, where exposure acts as a proxy for reduced adverse effects
10	The information to be submitted for registration shall contain the technical dossier and the CSR	M, I	Generation of information	Improved information on substance properties, CSA and resulting RMMs should provide the information needed to ensure the improved management of risks to human health and the environment
12(1)	Requirement to include in the technical dossier all physico-chemical, toxicological and ecotoxicological information that is relevant and available to the registrant	M, I	Generation of information	As above
12(2)	Requirement on a manufacturer and importer to notify ECHA with additional information where it reaches the next tonnage threshold	M, I	Generation of information	As above
14(1)	A CSA shall be performed and a CSR completed for all substances subject to registration in accordance with this Chapter in quantities of 10 tonnes or more per year per registrant.	M, I	Generation of information	As above
14(3) and (4)	The CSA shall follow the steps described in Article 14(3) and the additional steps of Article 14(4) if the substance is classified under the CLP Regulation or is a PBT or vPvB	M, I	Generation of information on risks, including for PBT and vPvB properties	Reduction of environmental effects if this results in lower exposures to PBT and vPvB

Article	Provisions	Duty-holders	Pathways	Human health and environmental Benefits
ANNEX I	Under the Exposure Assessment the CSR should identify the waste management measures to reduce or avoid exposure of humans and the environment to the substance during waste disposal and/or recycling	M, I	Creation of Waste Management Measures	Reduction of risk expressed as lower exposures to substances during waste disposal and/or recycling
14(6)	Requirement on a registrant to identify and apply the appropriate measures to adequately control the risks identified in the CSA and where suitable recommend them in SDS.	M, I	Generation of Risk Reduction Measures through the SDS	Exposure reduced as Risk Reduction Measures will be improved
14(7)	The CSR shall be kept available and up to date.	M, I	Generation of information	Improved information on substance properties, CSA and resulting RMMs should provide the information needed to ensure the improved management of risks to human health and the environment
17(1) and (2)	Requirement on a manufacturer to register on-site isolated intermediate manufactured in quantities of one tonne or more per year. Registration shall include information as listed in Article 17(2)	M	Generation of information	As above
18(1), (2) and (3)	Requirement on a manufacturer to register transported isolated intermediate manufactured or imported in quantities of one tonne or more per year. Registration shall include information as listed in Article 18(2). Requirements on manufacturers registering transported isolated intermediate manufactured or imported in quantities of more than 1000 tonnes per year to include information specified in Annex VII	M	Generation of information	As above

Article	Provisions	Duty-holders	Pathways	Human health and environmental Benefits
20(2)	Requirement to complete the registration and to submit it to ECHA within the deadline set in case of incomplete registration	M, I	Generation of information	As above
21(1)	Requirement for registration of substance prior to starting or continuing the manufacture or import of a substance or production or import of an article if there is no indication to the contrary from ECHA	M, I	Generation of information	As above
22(1)	Requirement on a registrant to update its registration whenever needed	M, I	Generation of information	As above
22(2)	Requirement on a registrant to submit ECHA an updated registration providing information as required by a decision.	M, I	Generation of information	As above
24(2)	Requirement on a registrant to notify, in accordance with articles 10 and 12, where the quantity of a notified substance reaches the next tonnage threshold.	M, I	Generation of information	As above

2.3.2 Information through the supply chain and downstream user requirements

Figure 3: Flow Chart of the Drivers under Title IV "Information in the Supply Chain" and Title V "Downstream users"



Source: M. Postle et al. (2012)

Table 2: List of the Key Provisions by Duty-holders, Drivers and Benefits for Information in the Supply Chain (reproduced from M. Postle et al. 2012)

Article	Key Provisions	Duty-holders	Pathways	Human health and Environmental Benefits
31(1)	Requirement on a supplier of a substance or a mixture to provide recipient with a SDS compiled in accordance with Annex II.	M, I, D	Communication of the Safety Data Sheets (SDS)	Enhanced guidance to Downstream Users on the control of risks to human health and the environment
31(2)	Requirement on any actor in the supply chain who has been requested to perform a CSA to ensure that information in the SDS is consistent with the information in the assessment.	M, I, D	Communication of the Safety Data Sheets (SDS	As above
31(3)	Requirement on a supplier to provide a SDS when requested for a mixture which falls within paragraph 3.	M, I, D	Communication of the Safety Data Sheets (SDS	As above
31(4)	Requirement on a supplier to provide downstream user or distributor with a SDS when requested for a mixture or dangerous substance which is offered or sold to the general public.	M, I, D	Communication of the Safety Data Sheets (SDS	As above
31(5)	The SDS shall be provided in the language of the Member State concerned.	M, I, D	Communication of the Safety Data Sheets (SDS	As above
31(6)	The SDS shall contain the information listed in article 31(6).	M, I, D	Communication of the Safety Data Sheets (SDS	As above
31(7)	Requirement on actors in the supply chain to place the relevant exposure scenarios in an annex to the SDS.	M, I, D	Communication up the supply chain - uses, RMMs	Lower exposure due to the improvement of Risk Reduction Measures
31(7)	Requirement on a downstream user to include the exposure scenarios in their own SDS for identified uses.	DU	Communication up the supply chain - uses, RMMs	As above
31(7)	Requirement on a distributor to pass on relevant exposure scenarios and use other relevant information from the SDS when compiling his own data sheet.	D	Communication up the supply chain - uses, RMMs	Lower exposure due to the improvement of Risk Reduction Measures
31(8-9)	The SDS shall be provided free of charge either electronically or on paper.	M, I, D	Communication of the Safety Data Sheets (SDS)	Enhanced guidance to downstream users on the control of risks to human health and the environment

Article	Key Provisions	Duty-holders	Pathways	Human health and Environmental Benefits
31(8-9)	Requirement on a supplier to update the SDS and provide it free of charge to all former recipients.	M, I, D	Communication of the Safety Data Sheets (SDS)	As above
32 (1)	Requirement on a supplier of a substance who does not have to supply a SDS to provide the recipient with the information in paragraph (1).	M, I, D	Communication of the Safety Data Sheets (SDS)	As above
33(1)	Requirement on a supplier of an article to provide the recipient with sufficient information to allow safe use, including as a minimum the name of that substance.	M, I	Communication on SVHC in Articles	Lower exposure to SVHC
33(2)	Requirement on a supplier of an article to provide a consumer on request with sufficient information to allow safe use, including as a minimum the name of that substance, free of charge and within 45 days of the request	DU, R	Communication on SVHC in Articles	Lower exposure to SVHC
34	Requirement on every actor (including distributor) in the supply chain to communicate the information on new information or any other information that might call into question the appropriateness of the risk management measures to the next actor or distributor up the supply chain.	M, I, D, DU, R	Communication up the supply chain - uses, RMMs	Lower exposure due to the improvement of Risk Reduction Measures
35	Requirement on an employer to provide workers and their representatives with access to information received in accordance with articles 31 and 32 in relation to substances or mixtures which they may use or be exposed to in the course of their work.	M, I, DU, D, R	Communication of the Safety Data Sheets (SDS)	Enhanced guidance to downstream users on the control of risks to human health and the environment

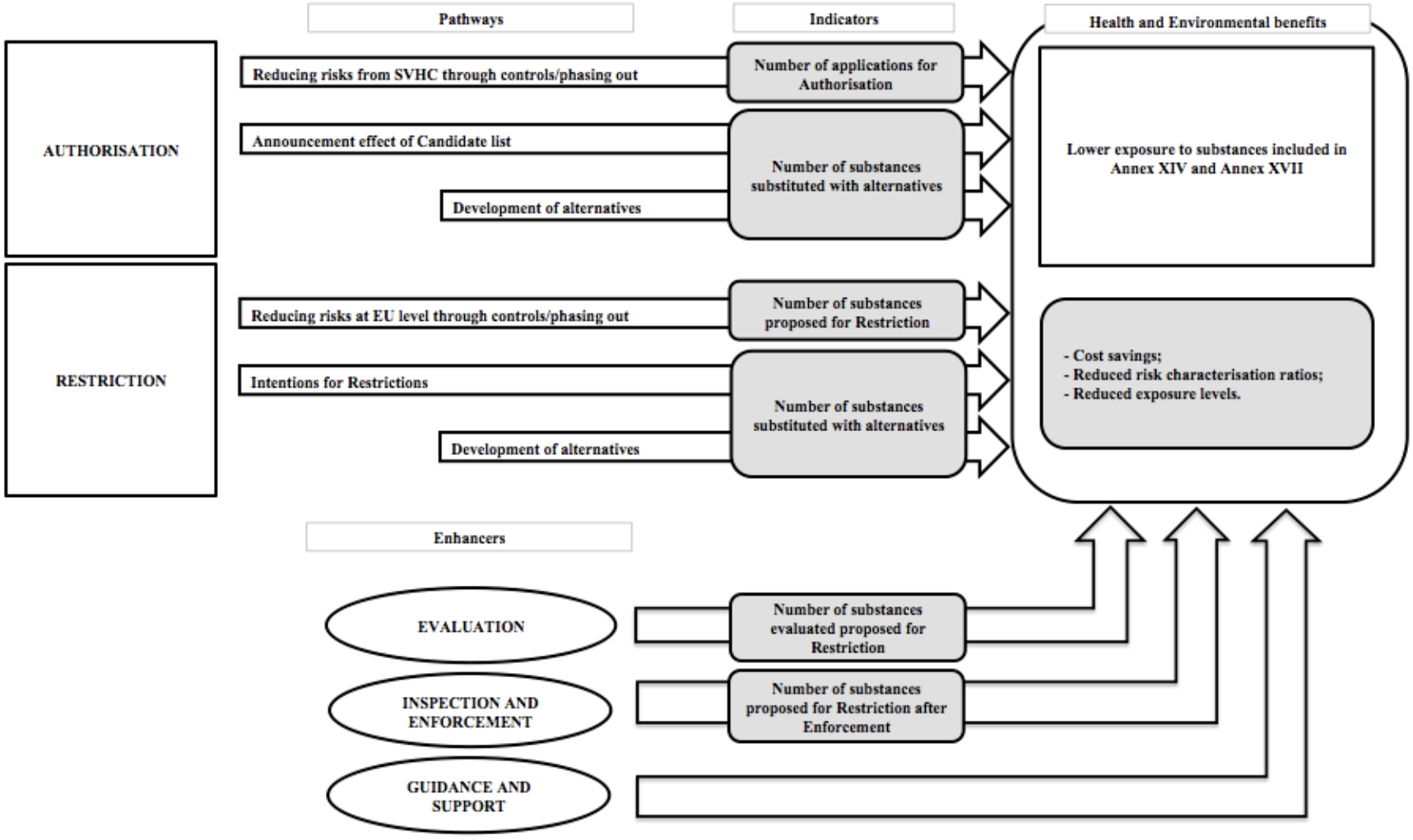
Table 3: List of the Key Provisions for Downstream Users, Drivers and Benefits for Information in the Supply Chain (reproduced from M. Postle et al. 2012)

Article	Key Provisions	Duty-holders	Pathways	Human health and Environmental Benefits
39	Article 39 states that downstream users shall comply with the Article 37 obligations at the latest 12 months after receiving a registration number.	DU	Identification and application of RRMs	Lower exposure due to the improvement of Risk Reduction Measures
37(5)	Requirement on downstream user to identify and apply appropriate measures to adequately control risks identified in (a) an SDS supplied to it: (b) its own chemical safety assessment or (c) any information received in accordance with article 32. Requirement on downstream user to recommend, where suitable, measures to adequately control the risks identified in (a) an SDS supplied to it; (b) its own chemical safety assessment or (c) any information received in accordance with article 32.	DU, M, I, D	Identification and application of RRMs	As above
37(2)	Requirement on a downstream user to have the right to make a use known in writing. Requirements on distributors to pass on such information to the next actor up the supply chain.	DU, D, M, I	Communication up the supply chain - uses, RMMs	As above
37(4)	Requirement on a downstream user to prepare a CSR in accordance with Annex XII for any use outside either the conditions described in an exposure scenario or a use and exposure category in a SDS or for any use his supplier advises against.	DU	Identification and application of RMMs	As above
37(6)	Requirement on a downstream user to identify and apply appropriate risk management measures needed to ensure that the risks to human health and the environment are adequately controlled.	DU	Identification and application of RMMs	As above
37(7)	Requirement on downstream users to keep their chemical safety report up to date and available.	DU	Communication up the supply chain - uses, RMMs	As above

Article	Key Provisions	Duty-holders	Pathways	Human health and Environmental Benefits
39	Article 39 states that downstream users shall comply with the Article 38 obligations at the latest 6 months after receiving a registration number.	DU	Communication up the supply chain - uses, RMMs	As above
38(1)	Requirement that downstream user reports information in article 38(2) to ECHA before commencing or continuing with a particular use of a substance that has been registered by an actor up the supply chain.	DU	Communication up the supply chain - uses, RMMs	As above
38(2)	Requirement that a downstream user includes the information listed in article 38(2).	DU	Communication up the supply chain - uses, RMMs	As above
38(3)	Requirement that downstream users update the information provided in article 38(2) without delay in the event of a change in information.	DU	Communication up the supply chain - uses, RMMs	As above
38(4)	Requirement that a downstream user reports to ECHA if its classification of a substance is different to that of its supplier.	DU	Communication up the supply chain - uses, RMMs	As above

2.3.3 Authorisation and Restriction of chemicals under reduced risks

Figure 4: Flow Chart of the Drivers under Title VII "Authorisation" and Title VIII "Restriction"



Source: M. Postle et al. (2012)

Table 4: List of the Key Provisions by Duty-holders, Drivers and Benefits for Authorisation (M. Postle et al. 2012)

Article	Key Provisions	Duty-holders	Pathways	Human health and Environmental Benefits
55	Requirement on all manufacturers, importers and downstream users applying for authorisations to analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.	M, I, DU	Reducing risks from SVHCs through controls/phasing out	Lower exposure to substances included in Annex XIV
56(1)	Requirements on manufacturers, importers or downstream users not to place a substance on the market for a use or use it itself if that substance is included in Annex XIV unless sub-paragraph (a), (b), (c), (d) or (e) are satisfied.	M, I, DU	As above	As above
56(2)	Requirements on downstream users not to use a substance otherwise than in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use.	DU	As above	As above
60(8)	Requirement to ensure the respect of the conditions linked to the authorisation.	M, I, DU	As above	As above
65	60(10)	Requirement on a holder of an authorisation to ensure that the exposure is reduced to as low a level as is technically and practically possible.	As above	As above
66(1)	Requirement on a DU using a substance in accordance with article 56(2) to notify ECHA within three months of the first supply.	DU	As above	As above

Table 5: List of the Key Provisions by Duty-holders, Drivers and Benefits for Restriction (M. Postle et al. 2012)

Article	Key Provisions	Duty-holders	Pathways	Human health and Environmental Benefits
67(1)	Prohibition on the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article for which Annex XVII contains a restriction unless the manufacture, placing on the market or use of a substance on its own complies with the conditions of that restriction.	M, I, DU	Reducing risks from through controls/phasing out	Lower exposure to substances included in Annex XVII

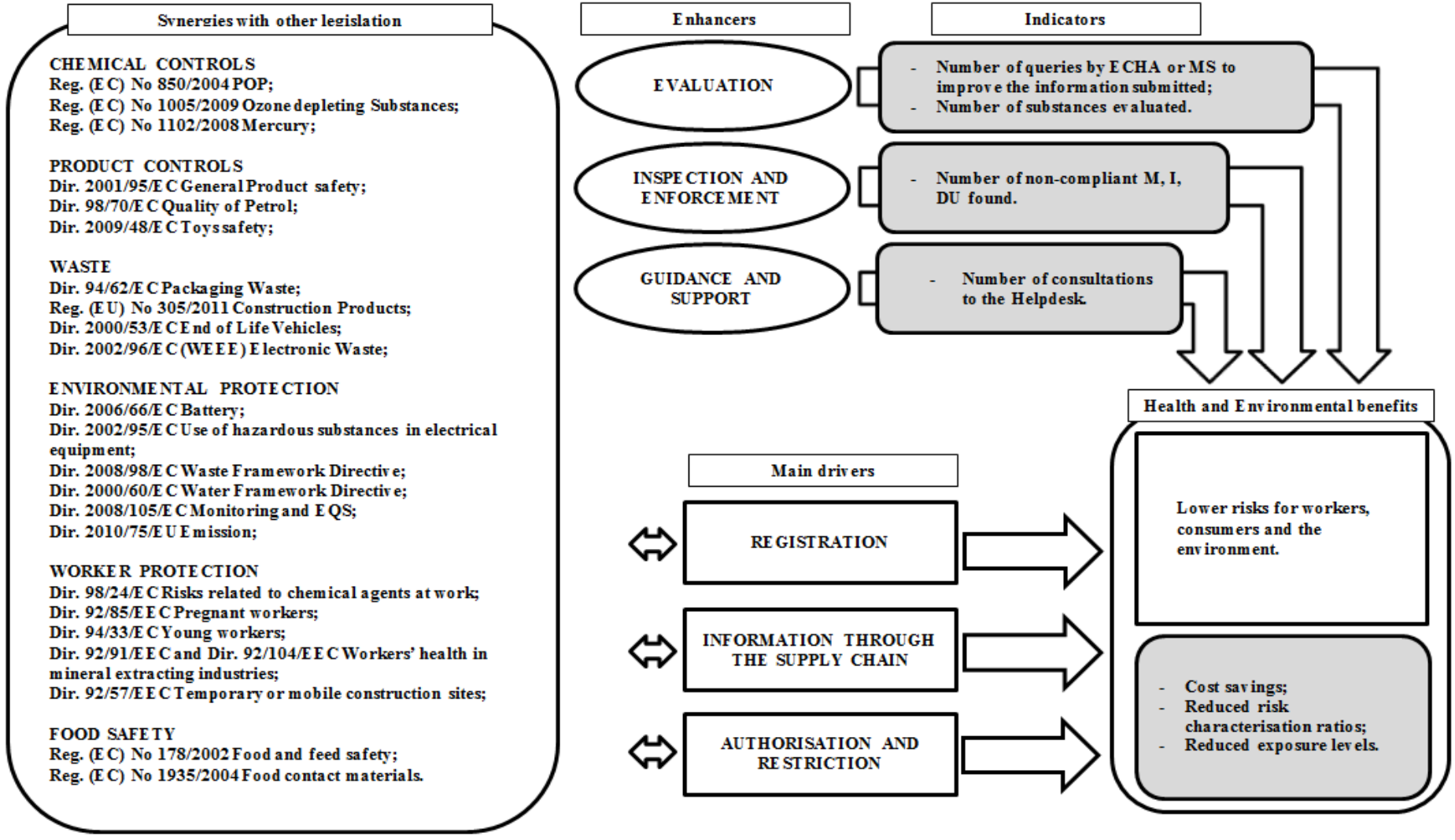
2.3.4 Enhancers

The key enhancers relate to:

- Evaluation;
- Inspection and enforcement;
- Synergies with other legislation; and
- Guidance and other support, including the dissemination of information to external stakeholders.

The linkages between these and each of the main drivers are illustrated in Figure 5.

Figure 5: Action of the enhancers and synergies with other legislation



Source: M. Postle (2012)

2.4 Summary of the assessment framework

As noted above, the proposed assessment framework is built around the following aspects:

- The obligations;
- The benefit drivers and enablers;
- The key pathways for the delivery of the benefits;
- The nature of the benefits;
- The methods used for their assessment; and
- The key gaps.

Table 6: Explanations of the key terms as adopted for this study

Term	Definition
Obligation	An obligation is one of the main obligations in REACH: Registration; Information through the supply chain; Authorisation; Restriction; and Evaluation, Inspection and Enforcement activities.
Driver	A driver is a set of legal provisions with a direct or indirect effect and which triggers a cost or a benefit.
Enhancer	Enhancers are all those provisions that help to realise the benefits through control and enforcement and thus assist or ensure compliance with the main obligations.
Pathway	A pathway is the qualitative description of the cause-effect link between the drivers and the benefits.
Nature of benefit	A description of the nature of the positive effect includes the type of benefit (human health, environment, etc.) together with the stakeholder that is likely to accrue this benefit (society, workers, consumers, industry, the environment) and/or the relevant lifecycle stage (manufacturers and/or importers, downstream users [formulators, industrial end-users, professional end-users], distributors, consumers.
Assessment methods	A description of the methods used to assess the benefits including whether they were assessed in quantitative, qualitative, or monetary terms, and whether they were considered directly or through a proxy (e.g. a proxy indicator for the quantitative description of the cause-effect link).
Gap	Benefit not considered in any of the reviewed studies or key benefit that has not been assessed in quantitative terms or, where desirable, without the use of an imperfect proxy.

The table below provides a simple example of how the assessment framework could be applied, drawing on a hypothetical set of studies 1-30 (please note that this is a hypothetical example and these studies do not correspond to the studies in Table 8). Please note that this table has been developed as the review progressed. The full table draws on all of the benefit drivers, pathways and benefit categories presented in Section 1.3, as well as any further benefits identified in any of the reviewed studies.

Table 7: List of the Key Provisions by Duty-holders, Pathways and Benefits for Registration

Aspect	Factor type	Factor	Considered in the following studies
Obligation	Registration		Considered in all reviewed studies except Studies 9, 11, 14
Driver or enhancer	Registration requirement		Considered in all reviewed studies except Studies 9, 11, 14
Pathway	Chemical Assessment as part of the Chemical Safety Report		Considered in Studies 1, 2, 7, 20, 21, 22, 25
Nature of the benefit	Type of benefit:	Reduction in adverse health effects	Considered in Studies 1, 2, 7, 20, 21, 22, 25
Nature of the benefit	Stakeholder benefitting	Workers, consumers, general public	All considered in Studies 1, 2, 7, 20, 21, 22, 25
Nature of the benefit	Lifecycle stage	All lifecycle stages	Considered in Studies 1, 2, 7, 20, 21, 22, 25
Assessment methods	Qualitative assessment (direct vs proxy)	Direct qualitative assessment listing key effects and exposure routes	Considered in Studies 1, 2, 7, 20, 21, 22, 25
Assessment methods	Quantitative assessment (direct vs proxy)	Direct: changes in numbers of cases of ill health (by effect) Proxies: changes in DNELs, number of new RMMs of increased stringency, no. of "uses advised against", etc.	Study 1: Rough estimate of the changes in ill health for occupational cancer but no other effects Studies 2, 7, 20, 25: Changes to DNELs Studies 21 and 22: No of uses advised against
Assessment methods		Monetised: Yes/No?	Study 1: Rough estimate of prevented cancer cases monetised using generic cancer costs per case
Assessment methods	Monetary assessment	Monetised: Yes/No?	Study 1: Rough estimate of prevented cancer cases monetised using generic cancer costs per case
Key gaps	Benefits not considered quantitatively		Reductions in disease cases and health damages: cancer, reprotox, skin, etc. Reductions in emissions to the environment and environmental damage: water, land, air, soil
Key gaps	Benefits not monetised		All except for cancer

2.5 Pilot – review of three selected studies

Before starting the literature review, analysis and synthesis work required under WP2, a systematic framework for identifying the positive and negative impacts of REACH was developed. This was the pilot test which allowed both the study team and UBA to check whether or not the framework would collect the information required to answer the study questions.

The three studies listed below were reviewed as part of the pilot.

Table 8: Pilot studies

Title of the Study	Year of Publication	Short description	Link
Study on the costs and benefits of authorisation	2017	Assess the performance of the authorisation procedure of REACH, providing evidence to assess if it is working as intended and achieving its objectives in terms of progressive substitution of Substances of Very High Concern (SVHCs) by less hazardous alternatives and control of the risks.	https://ec.europa.eu/docsroom/documents/26847/attachments/1/translations/en/renditions/native
Eurobarometer survey on the perception of chemical safety	2016	Provide information on the general public's perception and understanding of chemical substances, as well as attitudes towards their safety and awareness of involving chemicals in daily products.	http://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2111
ECHA: Assessment of the current substance evaluation process under REACH (Amec Foster Wheeler)	2015	The purpose is to undertake an objective assessment of the functioning of the current substance evaluation process (i.e. effectiveness, efficiency, transparency, workability of the process).	https://echa.europa.eu/documents/10162/13628/sev_survey_2015_en.pdf

In selecting these three studies, the intention was to test how well the analytical framework performed across different types of benefits; in the three studies, the benefits of REACH range from those that are relatively easy to discern as a result of authorisation, to those that occur as a result of conclusions on risk or wider perceptions of chemical safety. It was also expected that the information presented in these studies was likely to range from attempts at quantification to qualitative statements to reporting of public perceptions.

The key conclusions on the basis of the pilot were:

- The proposed table on benefit indicators in the Assessment Framework document (as dated 11 November 2019) was well suited for summarising the types of benefits that are considered in the individual studies.
- Although it was not possible to complete the same table for the Eurobarometer study, this does not necessitate a change to the approach since the Eurobarometer study is expected to be different to the other studies to be reviewed.
- It is, however, difficult to discern how the different types of benefits were considered in the individual studies by merely listing them. It may, therefore, be advisable to introduce a coding system to show how the relevant benefit categories were considered:

- Mentioned
- Qualitative
- Semi-quantitative
- Quantitative
- Monetised

► Although it is useful to provide an overview of the gaps for each study, given the number of studies to review (around 30), it was proposed that this is not done in a comprehensive and detailed manner but only in a way that helps with the identification of the overall key gaps across all studies.

3 List of studies selected for review

The studies selected for review are listed in Table 7. The list includes the studies and meta-studies published in relation to REACH up to the end of 2019. The focus is on the benefits of REACH, with a particular focus on its benefits. There are also studies that take a global perspective on the benefits of chemicals policy and which may therefore have implications for the assessment of the benefits of the REACH Regulation as well. Relevant reports from NGOs and academic papers have also been selected for the literature review in order to ensure its representativity. The scope of work was to undertake a review of around 30 papers, with 38 considered by the study team.

Table 9: List of studies

No.	Title of the Study	Year of Publication	Link
1	Monitoring the impact of REACH on innovation, competitiveness, and SMEs	2015	http://ec.europa.eu/DocsRoom/documents/14581/attachments/1/translations
2	Study on the Calculation of the benefits of chemical legislation on human health and the environment	2016	http://ec.europa.eu/environment/chemicals/reach/pdf/study_final_report.pdf
3	ECHA Report on the operation of REACH 2016	2016	https://echa.europa.eu/documents/10162/13634/operation_reach_clp_2016_en.pdf
4	ECHA: Evaluation Progress Report 2017	2017	https://publications.europa.eu/en/publication-detail/-/publication/06ab3ae9-4f46-11e8-be1d-01aa75ed71a1
5	Scientific and technical support for collecting information on and reviewing available tools to track hazardous substances in articles with a view to improve the implementation and enforcement of Article 33 of REACH	2012	https://op.europa.eu/en/publication-detail/-/publication/58f951af-809b-11e7-b5c6-01aa75ed71a1
6	REACH baseline study	2009	http://ec.europa.eu/eurostat/documents/3888793/5844937/KS-RA-09-003-EN.PDF/351b1a93-fe8a-4085-8c67-4566fc8c6b48?version=1.0
7	REACH baseline study – 10 years update	2017	http://ec.europa.eu/DocsRoom/documents/22664
8	Restricted Success EEB's appraisal of restriction under REACH	2017	https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwj79_DV49brAhVMzaQKHQf_BmUQFjAAegQIARAB&url=https%3A%2F%2Feeb.org%2Fpublications%2F31%2Fchemicals%2F33788%2Frestricted-success-

No.	Title of the Study	Year of Publication	Link
			eebs-appraisal-of-restriction-under-reach.pdf&usg=AOvVaw37icBQdd2AMB7uk8nm__Dx
9	Case study on "Announcement effect" in the market related to the candidate list of substances subject to authorisation	2007	https://ec.europa.eu/environment/chemicals/reach/pdf/background/report_announcement_effect.pdf
10	Health Impact Assessments of policy measures for chemicals	2008	https://www.rivm.nl/bibliotheek/rapporten/320015001.pdf
11	Environmental Effects on Public Health: An Economic Perspective	2009	https://www.researchgate.net/publication/26800478_Environmental_Effects_on_Public_Health_An_Economic_Perspective
12	The costs of not implementing the environmental acquis	2011	https://ec.europa.eu/environment/enveco/economics_policy/pdf/report_sept2011.pdf
13	Assessment of the Health and Environmental Benefits of REACH	2012	https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKEwibpbKk5sHlAhVynVwKHZLBAGMQFjAAegQIABAC&url=http%3A%2F%2Fec.europa.eu%2FDocsRoom%2Fdocuments%2F11899%2Fattachments%2F1%2Ftranslations%2Fen%2Frenditions%2Fnative&usg=AOvVaw2ZWkzmkU8UE7idBj_GFEZg
14	Late lessons from early warnings: science, precaution, innovation	2013	https://www.eea.europa.eu/publications/late-lessons-2
15	Study on workability issues concerning the implementation of Annex VIII of Regulation (EC) No 1272/2008 on harmonised information relating to emergency health response and preventative measures	2019	http://files.chemicalwatch.com/02%20-%20Annex_VIII_workability_study_2nd_interim_report.pdf
16	Study to develop EU enforcement indicators for REACH and CLP	2015	http://ec.europa.eu/DocsRoom/documents/10364/attachments/1/translations
17	Service contract for technical assistance to review the existing Member State reporting questionnaire under Article 117 REACH, including the evaluation and configuration of an appropriate IT tool for the reporting	2016	http://ec.europa.eu/environment/chemicals/reach/pdf/final_report_2016.pdf
18	Study on the cumulative health and environmental benefits of chemical legislation	2017	https://op.europa.eu/en/publication-detail/-/publication/b43d720c-

No.	Title of the Study	Year of Publication	Link
			9db0-11e7-b92d-01aa75ed71a1/language-en
19	Commission General Report on the operation of REACH and review of certain elements	2018	https://ec.europa.eu/docsroom/documents/28201
20	REACH baseline study - 5 Year update	2012	http://ec.europa.eu/eurostat/documents/3888793/5851097/KS-RA-12-019-EN.PDF
21	Evaluation of ECHA	2017	http://ec.europa.eu/docsroom/documents/24301
22	ECHA: Evaluation Progress Report 2016	2016	https://echa.europa.eu/documents/10162/13628/evaluation_report_2016_en.pdf/f43e244f-7c90-75bd-e1b2-3771bcb1f8e8
23	ECHA: General report 2017	2018	https://echa.europa.eu/documents/10162/3048539/FINAL_MB_03_2018_%282%29_General_Report_2017_MB49.pdf/d6c665cc-8c84-d33f-2f82-fa148e366f5d
24	REFIT Platform Recommendations - Chemicals - Chemicals/OSH	2016	https://ec.europa.eu/info/sites/info/files/opinion_chemicals.pdf
25	Heyvaert, V. H. 2008: The EU Chemicals Policy: Towards Inclusive Governance? LSE Law, Society, and Economy Working Papers 7/2008, London.	2008	http://www.lse.ac.uk/law/working-paper-series/2007-08/WPS2008-07-Heyvaert.pdf
26	Schenten, J., Führ, M. 2016: SVHC in imported articles: REACH authorisation requirement justified under WTO rules, Environ Sci Eur (2016) 28:21, DOI 10.1186/s12302-016-0090-9;	2016	https://link.springer.com/content/pdf/10.1186%2Fs12302-016-0090-9.pdf
27	Positionspapier des ERF “The Innovation Principle Overview“	2014	http://www.riskforum.eu/innovation-principle.html
28	Strategy to promote substitution to safer chemicals through innovation	2017	https://echa.europa.eu/documents/10162/2792271/mb_58_2017_2_annex_strategy_substitution_safer_alternatives_en.pdf/d1c31c63-4047-e7be-75d1-12320a4a8489
29	A study to gather insights on the drivers, barriers, costs and benefits for updating REACH registration and CLP notification dossiers	2017	https://echa.europa.eu/documents/10162/2293101

No.	Title of the Study	Year of Publication	Link
			1/study_drivers_and_obstacles_reach_clp_updates_en.pdf/
30	Baseline Estimates Report for Selected Draft Indicators Proposed for Voluntary Reporting to the ICCM on SAICM	2008	http://www.saicm.org/Portals/12/Documents/reporting/ICCM3_INF_5_%20baseline%20report.pdf
31	Scoping Study for the Evaluation of the EU REACH Regulation and CLP Regulations	2009	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/399115/eu-reach-clp-regs-report.pdf
32	Socio-economic impacts of REACH authorisations — A meta-analysis of the first 100 applications for authorisation September 2017	2017	https://echa.europa.eu/documents/10162/13637/tecch_report_socioeconomic_impact_reach_authorisations_en.pdf
33	Assessing the Health and Environmental Impacts in the Context of Socio-economic Analysis under REACH	2011	https://echa.europa.eu/documents/10162/13580/reach_sea_part1_en.pdf
34	Cost of inaction	2012	http://wedocs.unep.org/bitstream/handle/20.500.11822/8412/-Costs%20of%20inaction%20on%20the%20sound%20management%20of%20chemicals-2013Report_Cost_of_Inaction_Feb2013.pdf?sequence=3&isAllowed=y
35	The impact of REACH on classification for human health hazards	2014	https://www.ncbi.nlm.nih.gov/pubmed/25128672
36	Impacts of REACH – Authorisation (Final Report)	2017	https://ec.europa.eu/docsroom/documents/26847/attachments/1/translations/en/renditions/native
37	ECHA: Assessment of the current substance evaluation process under REACH	2011	https://echa.europa.eu/documents/10162/13628/sev_survey_2015_en.pdf/b1532056-a551-4d25-aa6e-d29998713685
38	Eurobarometer survey on the perception of chemical safety	2016	https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwjiupuamIrtAhWDYsAKHXuMARkQFjADegQIBxAC&url=https%3A%2F%2Fchemicalwatch.com%2F98037%2Fimpact-of-chemicals-still-a-worry-for-

No.	Title of the Study	Year of Publi-cation	Link
			majority-of-eu-citi-zens&usg=AOvVaw3_KZiqkC4AU-heg_cp3JlBk

4 Overview of the benefits considered in the relevant studies

4.1 Introduction

As a starting point for identifying the types of indicators of benefits that have been used in the past as proxies for impact assessments, Table 8 was created during the pilot trial phase. This table was taken as the starting point for the literature, which then expanded the actual indicators that have been identified and assessed. This then fed into the gap analysis.

Note that at the pilot trial phase, this table included a column setting out illustrative gaps in the impacts considered to highlight those impacts that would ideally (and theoretically) be assessed should there be sufficient data in order to quantify benefits either in terms of a physical unit (i.e. cases of disease avoided) or in monetary terms (environmental clean-up costs avoided in the future). This column has been removed from Table 8 for this final report, as it is superseded by the actual findings of the gap analysis as presented in the sections which follow.

Table 10: Pilot trial list of potential benefit indicators

Drivers and enhancers	Pathways	Examples of benefit indicators
Registration	Chemical Assessment as part of the Chemical Safety Report	Changes in DNELs, PNECs; Number of new RMMs of increased stringency; No. of "uses advised against"
Registration	New classification and data quality	No. of new classifications; Changes in severity of classifications due to the availability of new data; Changes in self-classification of substances by manufacturer as given in IUCLID 4 or elsewhere; Increase in the level of harmonisation (proxy: No. of SIEFs);
Registration	Assessment of PBTs and vPvBs	No. of newly identified PBTs or vPvBs
Registration	Substance withdrawal for hazard properties reasons	No. of substances withdrawn from the market due to hazard properties or less hazardous substances added to the market
Information in the supply Chain	Safety Data Sheets and Communication through the Supply Chain	No. of exposure scenarios generated by DUs No. of RMMs applied to processes changed by the DUs because of REACH information No. of ES for registered substances Quality of ESs at formulators level and usefulness for downstream communication
Information in the supply Chain	Communication on SVHC in articles	No. of hazardous substances removed from articles due to "announcement effect" Number of queries from consumers on candidate SVHC in articles

Drivers and enhancers	Pathways	Examples of benefit indicators
Authorisation	Listing of SVHC on candidate list	No. of applications: adequate control route applications versus SEA route applications; number of approvals; number of exemptions in Annex XIV Decisions to phase out substances or to not-support uses because of listing on candidate list (predictive character of the candidate list) No. of substances replaced with alternatives
Restriction	Restriction as a process for earlier realisation of benefits	No. of substances proposed for Restriction Percentage of applications covered and risk reduction assumed to be achieved by restriction No. of substances replaced with alternatives
Evaluation		No. of queries by ECHA or MS to improve the information submitted No. of substances evaluated
Inspection and Enforcement		No. of enforcements for non-compliance with registration requirements No. of non-compliant manufacturers, importers, downstream users in the implementation of ESs
Guidance and Support		No. of consultations to the Helpdesk

The following tables summarise the REACH benefit categories considered in the literature reviewed for this study. This starts with consideration of the overall benefits arising from REACH, and then works through the different drivers of benefits as identified in section 2 of this report. It is of note that with respect to the "overall benefits of REACH" some of the indicators included here as potential indicators of benefits may equally be potential indicators of costs.

The individual studies are numbered 1-38 in the order in which they are listed in Section 3.

In the following tables indicator words are used to show how and to what extent the different benefits have been assessed:

- Mentioned
- Qualitative
- Semi-quantitative
- Quantitative
- Monetised

4.2 Overall benefits of REACH

Table 11: Overall benefits of REACH

Pathways	Indicators	Gaps in impacts considered
Requirements to be met for chemicals placed on the EU market	**Mentioned** Increased expertise and information on chemicals for public authorities and industry to carry out risk assessment and risk management activities. Increase in level of trust in the safety of chemicals placed on the EU market. Reputational benefits for EU manufacturers of chemicals **Qualitative** Increase in the demand for REACH-related consultancy; Increase in demand for lab testing Investments from non-EU countries into EU-based chemical companies; "Brussels effect": other countries following in the steps of REACH Regulation by adopting similar measures (South Korea, China, Canada) **Semi-quantitative** Substance withdrawal: i.e. respondents providing examples of where substitution has not yet happened, but where substitutes are being sought and there is investment in substitution related activities (36); Replacement of animal testing with alternatives (evidence for alternative test methods for skin and eye irritation) Implementation of RMMs; Labour market – employment effects in chemical and non-chemical industry **Quantitative**	**Macro-level effects: prices, competition, international trade** • Impacts on international trade and EU competitiveness: Lack of proper quantitative indicator that can enable assessment of effects of chemical regulations on international trade • More thorough sectorial analysis is needed to assess the performance of the EU chemicals market at the global level • Limited quantification and no monetisation of employment effects • Limited information on the value of R&D in terms of new innovations / products **Health and environmental effects** • Limited quantification and monetisation of environmental impacts due to a lack of environmental quality/monitoring data and a lack of available valuations. Could be linked to other areas of environmental legislation (e.g. Water Framework Directive) • Further work is required on the valuation of benefits from reduced levels of PBT and vPvB substances, as this remains an area of significant methodological uncertainty. • More understanding is needed on the issue of boundary conditions and effects of major/catastrophic impacts • Primary valuation studies with respect to chemicals in the environment • A need for further work on assigning monetary values to ecosystem services is recognised as well as further research on how risk travels across systems (systemic risks) • Limited quantification and monetisation of health benefits, with only a subset having been quantified and monetised due in part to a lack of good cause and effect and exposure data • Limited attention to latency effects, links between specific occupations and exposure to specific chemicals (i.e. doctors don't always ask patients about their past occupations)

Pathways	Indicators	Gaps in impacts considered
	Number of new substances registered and the number of Product and Process Oriented Research and Development (PPORD) notifications **Monetised** Trade surplus; share of EU sales in the global chemicals market; intra-EU compared to extra-EU trade (several studies, industry reports, CEFIC) Capital spending (CSES et al., 2015), R&D spending (CEFIC, 2016a) Increase in R&D activity for some 26% of companies surveyed (CATI), although in the OBS, only 10% indicated that their R&D budgets had increased. (1); Health benefits (6, 18, 19,2,36); Environmental benefits (6, 36, 19)	• Further work needed to establish correlations, e.g. instance cancer data matched with social security data, this would allow to attribute impacts to specific occupations and level of exposure • Need to differentiate impacts from genotoxic substances compared to those causing tumours through repeated-dose effects. • For neurotoxic substances, there is lack of a relevant hazard classification. Similarly, further work to understand the issues of (clinical) thresholds and how these are used to evaluate the presence of adverse effects would be beneficial. • There is a need for improved biomonitoring in Europe in order to understand the impacts of chemicals. • Further work is needed to determine whether it is feasible to extrapolate the findings for individual chemicals to other similar chemicals, in terms of risks and hence impacts; this would help to provide an improved picture on the total number of substances of concern and the associated burden of impacts. • Limited evidence on the impacts of combined exposure to multiple chemicals • More could be done in future studies to assess the benefits achieved thanks to the fact that legislation now addresses pre-emptive actions. • Any estimates are the result of a “bottom up” approach, whereby site-specific or Member State level data are extrapolated to have aggregate estimates at the EU level. No evidence of any study taking on a pan-European perspective. **Animal testing** • No extensive study on the effects of REACH on animal testing: only partial and semi-quantitative evidence • Limited evidence on the impacts of EC investments to promote alternative animal testing

4.3 Registration

Table 12: Registration

Pathways	Indicators	Gaps in impacts considered
Chemical Assessment as part of the Chemical Safety Report	No specific indicators identified	Potential indicators could include: • Changes in DNELs, PNECs; • Number of new RMMs of increased stringency; • No. of "uses advised against"
New classification and data quality	**Mentioned** Number of CLH (2); Increase in no of self-classifications (2); Quality of registration dossiers (19) **Quantitative** Screening results 2010-2015 (percentage of dossiers that pass the automated screening) (3); No. of data sharing disputes and their outcome (3); No. of registration dossiers by type and year (NONS included) (3); Total no. of substances registered (3); New substances registered per annum (3); Number of updates (3); No. of substance evaluations started and concluded (3); concerns/hazards under investigation (3); No of substances produced at very high tonnages with a classification in a registration dossier that does not have a harmonised classification (36)	• Reduction in disease cases and health damages associated with increases in more stringent classifications due to new data • Reductions in use of more hazardous substances for the environment by volume, and indirectly reductions in environmental damage costs • Number of updates and the extent to which the current system incentivises spontaneous updates by registrants • On-going quantification of the level of improvement in data quality with respect to the ability to identify priority substances for SVHC identification or other regulatory actions
Assessment of PBTs and vPvBs	**Quantitative** No of substances discussed in the PBT expert group 2012-2015 and the outcomes (3)	• Reductions in future environmental damage costs due to the identification and intervention on PBTs and vPvBs
Substance withdrawal for hazard properties reasons	**Quantitative** % of companies having experience with substance withdrawal (1); % of companies experiencing an increase in R&D activity (1)	• Reductions in future environmental damage costs due to the identification and intervention on PBTs and vPvBs

Pathways	Indicators	Gaps in impacts considered
Development of substance dossiers	**Qualitative** Accessibility of health and safety information (29); Effective use of the available information (29); Updated dossiers (29)	• Limited quantitative data available and no monetisation. Constitutes a gap in understanding the extent to which the availability of new information has led to e.g. practical changes in workplace activities and hence in occupational illnesses/disease

4.4 Information in the supply chain

Table 13: Information in the supply chain

Pathways	Indicators	Gaps in impacts considered
Safety Data Sheets and Communication through the Supply Chain	**Qualitative** Type of information communicated (5); Usefulness of existing tools to supporting a non-toxic environment (5)	• Quantitative data on reduction in worker safety illnesses and consequent reduction in health costs and costs to employers and national governments due to better information on appropriate RMMs • Cost-benefit analysis of harmonising methodology to derive DNELs and IOELVs/BOELVs
Communication on SVHC in articles	**Qualitative** Type of information communicated (5); Usefulness of existing tools for supporting a non-toxic environment (5);	• Reduction in associated cases of diseases/illness in consumers due to reduced exposures; reduction in environmental damages due to reduced emissions to the environment
Sharing information along supply chain	**Qualitative** Level of information available to chemical suppliers on the properties and uses of the chemicals (19); Information on long term endpoints (19);	• Flow of information happens but slower than expected: how many more benefits could be generated if this slowness is improved? • Lack of specific information about nanoforms
Knowledge on the options for substitution **Substance technical knowledge**	**Qualitative** Transparency about what knowledge is still missing and better awareness of the needs of upstream and downstream value chains (28); Information in a practical and easily applicable form to enable adoption of new RMMs (28);	• Knowledge on options for substitution is not equally shared throughout supply chain, with downstream users and product manufacturers benefitting less. This may be creating unnecessary burdens for some categories of stakeholders. Research questions to address are if and how cost-effectiveness can be improved, what other channels can be used to convey information to all categories of stakeholders

Pathways	Indicators	Gaps in impacts considered
	Increased recycling and uptake of secondary raw materials (28)	• No quantification and monetisation about level of recycling and uptake of secondary raw materials per effect of information sharing. Unclear how waste management sectors could be more involved in REACH information sharing mechanism[2]

4.5 Evaluation

Table 14: Evaluation

Pathways	Indicators	Gaps in impacts considered
Evaluation leads to risk management	**Mentioned** RMOAs launched as a result of evaluation (19); Proposals for regulatory risk management (19); Clarifications of concern without needing a formal decision (19); Cases where SEv triggered changes in company level risk management without need for EU wide regulatory risk management (19) Proposals for REACH regulatory risk management (19); Proposals for other EU legislative risk management (19) **Semi-quantitative** N. of substances evaluated: 82 decisions on substance have taken place, contrary to 448 expected (28) **Quantitative** No. of dossiers checked (4); No. of adopted decisions (4); No. of information requests (broken down by type) (4) No. of follow-up evaluations and reasons for their initiation (4); No. of candidates for CLH as a result of substance evaluation (4);	• Types of effects typically identified • Number of RMOAs launched as a result • Number of proposals for regulatory risk management • Number of clarifications of concern without needing a formal decision • Number of cases where SEv triggered changes in company level risk management without need for EU wide regulatory risk management

[2] The potential benefits to be expected by the launch of the SCIP-DB are discussed in section 6.3

Pathways	Indicators	Gaps in impacts considered
	No. of cases flagged by ECHA for substance evaluation (4); No. of substances evaluated by Member States and no. of requests for further information (4); % of cases in which evaluating Member State concluded further regulatory risk management might be needed (4); No. of substances subject to a restriction(2); No of recommendations for inclusion in Annex XIV and included in Annex XIV (3); Review periods recommended by RAC and SEAC with/without additional conditions/monitoring arrangements (3); % of registration dossiers selected for a compliance check (3); Testing proposals (4)	

4.6 Authorisation

Table 15: Authorisation

Pathways	Indicators	Gaps in impacts considered
Listing of SVHC on candidate list ("announcement effects") **Authorisation process:** **Adequate control route (threshold substances)** **SEA route**	**Mentioned** Conditions being imposed on safe handling and use of an SVHC (36); No. of cases in which imported goods were inspected and found non-compliant with REACH and CLP (36, 26)[3]; **Mentioned** - Formal and effective involvement of all stakeholders in the chemicals management; Improved balance between private and public interests, stakeholders' attitudes, feelings and opinions (25); Better information available for authorities: they know more about remaining uses of SVHCs and their	• Tonnage information is extracted from ECHA – results in gaps in information on changes in demand for SVHC and quantities continuing in use • Limited number of reviewed studies relevant to the type of health endpoints associated with the chemicals of concern under REACH, which restricts the degree to which benefit transfer methods can be used as a valuation method for morbidity effects • No historical data on the number of workers exposed and changes in exposure level over time (some of these data do exist at Member State (MS) level as some Member States have confidential databases (for their MS) containing historical values for worker exposure (which the study team were unable to obtain) • Substitution • Limited information on the number of companies who have decided to phase out listed substances rather than apply for authorisation

[3] According to a pilot project by ECHA's Enforcement Forum, 23 % of inspected products were non-compliant with REACH and CLP. Some imports contained illegal amounts of hazardous substances that are restricted in the EU, while others had incorrect hazard labelling. See for more details on the project: https://echa.europa.eu/-/1-in-4-imported-products-found-to-be-non-compliant-with-reach-and-clp

Pathways	Indicators	Gaps in impacts considered
	production sites, and have more data to support control of exposure and emissions (36) **Qualitative** - Reduction in the number of suppliers of SVHCs (36); Reduced availability of the SVHC for downstream use (36); Quantity of goods imported from non-EEA countries containing SVHC substances (36, 26) **Semi-quantitative** - Number of companies who adopted new RMMs or improved upon them (28) Comparison of substances listed for authorisation and applications actually submitted (19) SVHC being removed from the market (36) **Quantitative** - No. of applications: no. of uses, no. of applicants by March 2016 (3); Market data on sales and revenues of SVHCs and alternatives (trend in SVHC substances as compared to others, suppliers of alternatives) (37; Substitution of SVHCs – in particular, among SMEs (36) **Monetised** - Monetary benefit of granted authorisation per applicant per use (potential cost of refused authorisation) (3, 33) Spending on R&D due to Authorisation (19, 36)	• Uncertainty over the extent of regrettable decisions – how is this impact on the benefits delivered by REACH? • EU level • Limitations in the data (PRODCOM, Eurostat) do not enable an assessment of the degree to which REACH has led to a reduction in EU sales of SVHCs with suitable alternative substances or technologies • International level • Effects of REACH Authorisation on non-EEA based companies – if and what is the extent of any "Brussels effect", convergence to EU standards • Only partial evidence that relocation outside EEA is likely to be rare, possibly also due to the fact that all applications to date have been successful • Not enough information on whether reduction in EU manufacture and use is accompanied by reduction of imports SVHCs in articles

4.7 Restriction

Table 16: Restriction

Pathways	Indicators	Gaps in impacts considered
Reducing risks through controls/phasing out	**Mentioned** - Application of precautionary principle (4 substances) (19) **Semi-quantitative** - No of restriction proposals, No of restrictions entered into Annex XVII, Average no. of restrictions per year (3) No. of consumers and workers benefiting (3); Reduction of emissions of PBT and vPvB substances (3); Cost-benefit comparison of the restriction process (3); Summary of HH and EV benefits of specific restrictions (monetary value or no. of people benefiting) (3) Reduction of releases to the environment (19) Health benefits (expressed in DALYs) (33) Healthcare costs, productivity losses and suffering avoided (28) **Quantitative** - No. of substances subject to a restriction (2) Reduction of specific disease cases per year (33); Reduction of specific disease cases per year (33) **Monetised** - Monetary value of health and environmental benefits linked to restrictions adopted since 2009 (3); Benefit-cost comparison of the restriction process (3); Health benefits for consumers and workers (19); N. of consumers and workers positively impacted: in UK, Estimated to be ca. 81,000; Health and environmental benefits of the restrictions adopted during the reporting period for this review have outweighed the costs of their implementation, with human health and environmental benefits of more than EUR 380 million per year, and a reduction of about 70 tonnes of releases of substances of concern, positive health impacts or removed risk (28); Exposure of consumers to chemicals in non-food and food products (33); Potential benefits for the environment (i.e. bee pollination, costs avoided for the sewage treatment plants, sludge disposal and/or fish cleaning) (33); Average Economic Value per Household of Threatened Endangered and Rare Species (33)	• Cost-effectiveness of drawing on precautionary principle • Benefits from innovation following restrictions on the use of substances • Only a few studies have been identified that have tried to quantify consumer exposures within a health impact assessment type of framework • In relation to the attempts at monetising environmental benefits, emphasis on human perception may underestimate risk • DALYs have not been monetized because there are many conflicting views, based on methodological and technical as well as on practical and ethical grounds. • Detailed data are available only on limited number of restricted substances (i.e. restriction of chromium (VI) in leather articles)

4.8 Guidance

Table 17: Guidance and support

Pathways	Indicators	Gaps in impacts considered
Guidance and support	**Quantitative** Data made available through the websites and via dissemination pages (3)	• Level of use and the degree to which centralised guidance has reduced burden on MS to provide similar guidance and support

4.9 Inspection and Enforcement

Table 18: Inspection and Enforcement

Pathways	(Previous) Indicators	Gaps in impacts considered
Inspection and Enforcement	Data should now be available from activities by the Forum, but was not available from any of the documents reviewed	• No. of enforcements for non-compliance with registration requirements • No. of non-compliant manufacturers, importers, downstream users in the implementation of ESs

5 Overview of the costs in published literature

5.1 Introduction

At the start of the study, the team also identified the types of costs that had been assessed in the past as part of impact assessment work or to act as indicators of the impacts of chemicals legislation. This starting list was created during the pilot trial work and is set out in Table 17 below.

It is important to note that identification of the types of costs that have been assessed and gaps in the cost assessments was not to be a focus of the literature review work. The team were asked, however, to provide an assessment based on what was identified from the study covered by the literature review and their own experience in undertaking REACH impact assessments and evaluations. As a result, the same level of detail is not available in the fuller assessment presented in the sections which follow.

Note that this assessment relates to REACH and its requirements as of the end of March 2020. It does not also cover the impact assessment work that has been carried out on the potential increase in information requirements for substances registered at 1-10 tonnes per year. Nor does it detail the costs that have been assessed from the potential inclusion of polymers into REACH. Both of these topics have been subject to multiple studies and detailed cost assessments of varying scope, depending on the options under consideration.

Table 19: Pilot Trial list of costs arising from REACH

Drivers and enhancers	Pathway	Example types of cost	Potential indicators
Registration	Substance registration	Manufacturer or importer registering a substance	€ per registration (average, range, etc.) € for all registrations
Registration		ECHA checking registrations and publishing information	€ to ECHA per registration
Registration	New classification or change to severity of classification	Costs due to a new classification or changed classification category	Number of substances with a new classification Regulatory action for these substances (authorisation, restriction, OSH legislation)
Registration	Substance withdrawal for hazard properties reasons	Companies substituting non-hazardous substances for hazardous substances	No. of substances withdrawn from the market due to hazard properties or less hazardous substances added to the market € per substance
Information in the Supply Chain	Safety Data Sheets and Communication through the Supply Chain	Companies in the supply chain implementing RMMs	No. of RMMs applied to processes changed by the DUs because of REACH information Cost of these RMMs
Information in the Supply Chain	Communication on SVHC in articles	Companies removing hazardous substances from articles due to “announcement effect	No. of hazardous substances removed from articles due to “announcement effect” No of companies/articles affected € per company/costs in total
Authorisation	Listing of SVHC on candidate list	Companies phasing out/replacing substances because of listing on candidate list	Decisions to phase out substances or to not-support uses because of listing on candidate list (predictive character of the candidate list) No. of substances replaced with alternatives Cost per replacement and overall cost
Authorisation		Cost to ECHA due to candidate list updates	
Authorisation	Applications for Authorisation	Companies applying for authorisation	No. of applications and typical cost

Drivers and enhancers	Pathway	Example types of cost	Potential indicators
			Costs of R&D triggered by need to consider alternatives
Authorisation		Cost to ECHA from reviewing AfAs	No. of AfA and typical cost
Restriction	Elaboration of a restriction proposal	Cost to ECHA or Member State authorities for elaborating restriction proposals	No. of substances proposed for restriction Cost per restriction dossier
Restriction		Cost to companies for providing input	No. of substances proposed for restriction Cost per restriction dossier
Restriction	Restriction	Companies replacing substances with alternatives or for which RMMs had to be put in place	No. of substances Cost to the industry per substance
Evaluation	Evaluation	Costs to ECHA and MSs for reviewing information	No. of substances evaluated Cost per substance evaluation
Evaluation		Costs to registrants for improving information	No. of queries by ECHA or MS to improve the information submitted Cost per substance
Inspection and Enforcement		Costs to ECHA & Member States from enforcement	No. of enforcements for non-compliance with registration requirements
Guidance and Support		Helpdesk	Cost of running the helpdesk per year

5.2 Overall cost of REACH

Table 20: Overall costs of REACH

Pathways	Indicators	Gaps in impacts considered
Requirements to be met for chemicals placed on the EU market	**Mentioned** Changes in costs of risk management at the manufacturer and downstream user level; some qualitative/semi-quantitative discussion but not in depth **Qualitative** Impacts on supply chains from rationalisation of product portfolios and substance withdrawal (including at the EU market level) – new supplier-search costs, lost revenues, changing inputs/processes **Monetised** Registration costs: € average cost per registration by tonnage band; € average costs of registration by company size, and range; € costs across all registrations for different registration deadlines Costs of elements of Registration: € costs of different testing requirements; € costs of updating eSDS; € costs of supply chain communication as part of substance registration Capital expenditure (testing, risk management, etc.) and R&D expenditure (where increased) Trade surplus: share of EU sales in the global chemicals market	• Impacts on international trade and EU competitiveness: Lack of proper quantitative indicator that can enable assessment of the effects of chemical regulations on international trade • More thorough sectorial analysis is needed to assess the performance of the EU chemicals market at the global level • Impacts on the structure of the EU chemicals market are not well understood, in part due to the lack of information on the actual split of chemicals production between small, medium and large companies • Limited quantification and no monetisation of employment effects, especially with respect to loss of SME manufacturers and potential shifts in production • Quantified impacts on downstream supply chains from portfolio rationalisation and substance withdrawal • Limited quantification of R&D expenditures across EU and the impacts on innovation from diversion of expenditure into meeting the costs of Registration, etc. • Diversion of new investment due to costs of registration obligations • Any systematic studies on changes in price level over time to assess impacts on EU-based companies' competitiveness • Systematic studies on changes in risk management at the company level and whether this has led to cost savings or cost increases, with consequent impacts on net profits and company viability

5.3 Registration

Table 21: Costs of Registration

Pathways	Indicators	Gaps in impacts considered
Chemical Assessment as part of the Chemical Safety Report	**Quantitative** No. of new tests required by ECHA as a result of substance Evaluation to bring dossiers into line; No of substances originally categorised as intermediates which had to be re-categorised as requiring full registration due to ECHA adopted definitions **Monetary** € administrative/SIEF related costs; € costs of substance ID determination or characterisation (e.g. for nanos); € costs of CSR preparation by tonnage; € costs of individual tests; € costs of preparing robust study summaries; € costs of using read-across and QSARS	• Test data may be outdated and the costs of elements such as preparation of Robust Study Summaries may be outdated (fee rates assumed in original assessments will be too low) • Validation of original assumptions on the number of new tests to be carried out and costs of bringing non-compliant dossiers into line, where ECHA require increased level of testing • Increased registration costs due to re-categorisation of some declared "intermediates", and associated impacts on production volumes and usage • Impacts of changes in ECHA's guidance which change requirements with respect to read across, use of (Q)SARS, and other information and reporting requirements
New classification and data quality	**Quantitative** No. of data sharing disputes; No. of substances changing classification based on original notifications to CLH and final registration data; Number of updates to dossiers (3) No. of substance evaluations started and concluded (3)	• Costs of resolving data sharing disputes not quantified • Costs of resolving differences in substance classification as notified to the CLH not quantified and monetised • Number of updates, the costs of making updates and cost sharing across dossiers • Costs to registrants of substance evaluations; costs to competent authorities of undertaking substance evaluation work.
Assessment of PBTs and vPvBs	**Quantitative** No of substances categorised as PBT/vPvB as a result of CSR requirements **Monetary** € costs of undertaking a PBT/vPvB assessment	• Impacts on markets for substances newly identified as PBTs and vPvBs, distinguishing between impacts due to REACH and impacts due to restrictions on the use of such substances under other legislation (e.g. Biocidal Products and Plant Protection Products)
Development of substance dossiers	**Qualitative** Accessibility of health and safety information (29);	• Reductions in future environmental damage costs due to the identification and intervention on PBTs and vPvBs

Pathways	Indicators	Gaps in impacts considered
	Effective use of the available information (29); Updated dossiers (29) **Quantitative** % of companies having experience with substance withdrawal (1); % of companies experiencing an increase in R&D activity (1)	• Limited quantitative data available. No monetisation

5.4 Information in the supply chain

Table 22: Information in the supply chain

Pathways	Indicators	Gaps in impacts considered
Safety Data Sheets and Communication through the Supply Chain	**Quantitative** Estimates of the number of SDS sent out per substance by tonnage; Number of updates (from work on CLP); Numbers of downstream users per substance by tonnage (for communication requirements) **Monetary** € cost of updating SDS, including into different languages € cost of IT systems for producing SDS€ cost of sending out SDS € costs of changing labels, including artwork, printing, disposal of old labels and containers, etc.	• Cost-benefit analysis of harmonising methodology to derive DNELs and IOELVs/BOELVs • Validation of assumptions on the number of downstream users per substance would allow better estimation of the costs of changes in eSDS requirements • Cost estimates for changes in labels and labelling requirements are based on few data points, and may reflect certain sectors more than the "average" (e.g. coatings and detergents)
Sharing information along supply chain	**Qualitative** Level of information available to chemical suppliers on uses of the chemicals (19)	• Data are poor on the amount of time spent by downstream users in communicating uses up the supply chain • Data are poor on the degree to which DUs undertake their own risk assessments due to the failure for M/I to adequately cover their conditions of use in the CSR
	Monetary	• Lack of validated data on information sharing costs for nanoforms

Pathways	Indicators	Gaps in impacts considered
	€ cost estimates based on time for manufacturers/importers of supply chain communication	
Knowledge on the options for substitution **Substance technical knowledge**	**Qualitative** Better awareness of the needs of upstream and downstream value chains, which should lead to cost savings (28) Information in a practical and easily applied form to enable adoption of new RMMs (28)	• Knowledge on options for substitution is not equally shared throughout supply chain, downstream users and product manufacturers seem to be benefitting less. This could be leading to unnecessary costs for some stakeholders, especially when faced with restriction or authorisation. • Limited data are available on the degree to which downstream users or product manufacturers have substituted or have adopted new RMMS due to increased information, or on the costs they have incurred as a result • Limited data are available on the increased costs faced by downstream users and product manufacturers due to the loss of recycling potential or the increased use of secondary materials.

5.5 Evaluation

Table 23: Costs of Evaluation

Pathways	Indicators	Gaps in impacts considered
Dossier and Substance Evaluation (including evaluation leading to risk management)	**Mentioned** - RMOAs launched as a result of evaluation (19); Proposals for regulatory risk management (19); Clarifications of concern without needing a formal decision (19); Cases where SEv triggered changes in company level risk management without need for EU wide regulatory risk management (19); Proposals for REACH-driven regulatory risk management (19); Proposals for other EU legislative risk management (19) **Quantitative** - No. of dossiers checked (4); No. of adopted decisions (4); No. of information requests (broken down by type) (4)No. of follow-up evaluations and reasons for their initiation (4); No. of candidates for CLH as a result of substance evaluation (4); Outcome of compliance checks (4); No. of cases flagged by ECHA for substance evaluation (4); No. of substances evaluated by Member States and no. of requests for further information (4); % of cases in which evaluating Member State concluded further regulatory risk management might be needed (4); No. of substances subject to a restriction(2); No of recommendations for inclusion in Annex XIV and included in Annex XIV (3); Testing proposals (4) **Semi-quantitative** - N. of substances evaluated: 82 decisions on substance have taken place, contrary to 448 expected (28) **Monetary** - Costs to ECHA of dossier evaluation; Costs to ECHA and MS of substance evaluation related activities, including secretariat and defending against legal actions	• Costs incurred by MS in undertaking substance evaluations and in preparing RMOAs, and the number of these that then go forward to REACH Restriction or Authorisation activities • Actions and costs arising from compliance checks • Costs to industry of feeding information into RMOAs, either directly as a result of consultation by the responsible MS or due to an industry led initiative • Costs to industry and to non-proposing MS of responding to Restriction proposals, together with data on unintended consequences when initial proposals are modified • Number of cases where SEv triggered changes in company level risk management without need for EU wide regulatory risk management and the level of cost savings achieved by such tailoring of risk management requirements • Key cost drivers of substance evaluation to authorities and the potential for improving the cost-effectiveness of the process for authorities and registrants • Costs of new testing requirements resulting from evaluation • Costs to all parties associated with challenges to evaluation decisions

5.6 Authorisation

Table 24: Costs of Authorisation

Pathways	Indicators	Gaps in impacts considered
Listing of SVHC on candidate list ("announcement effects") **Authorisation process:** **Adequate control route (threshold substances)** **SEA route**	**Mentioned** - An increase in the price of the SVHC (33); Conditions being imposed on safe handling and use of an SVHC (33); Competitive disadvantages for EEA based producers (26); **Qualitative** - Reduction in the number of suppliers of SVHCs (33); Reduced availability of SVHCs on the market (33) **Quantitative** - Review periods recommended by RAC and SEAC compared to those sought by applicants; Number of decisions with/without additional conditions/monitoring arrangements (3); Market data on sales and revenues of SVHCs and of alternatives (36, 33); Substitution of SVHCs – in particular, among SMEs (33, 36) **Semi-quantitative** Number of companies who adopted new RMMs (28) **Monetised** Costs of making an application for authorisation per applicant and use; Costs to ECHA of administering the authorisation procedure; Costs of MS authorities staff time spent in reviewing applications (rapporteur or otherwise) Potential costs of a refused authorisation; Spending on R&D (19, 33, 36)	• Limited information on the number of manufacturers/importers and downstream user companies who have decided to phase out listed substances • Little quantification on the level of R&D investments stemming from Candidate Listing • Lack of collated data on the extent to which conditions of use have changed and on levels of investment in additional risk management measures due to Authorisation • Costs of additional requirements placed on downstream users of Authorised substances, and extent to which these duplicate requirements under existing legislation, e.g. OSH • Assessment of the cost implications of the additional conditions / monitoring arrangements proposed by RAC and SEAC, together with information on the number of cases where the Applicant has contested the proposed requirements • Substitution • Uncertainty over the extent of regrettable decisions and its impact on the benefits delivered by REACH • EU level • Limitations in the data (PRODCOM, Eurostat) do not enable assessment as to whether REACH has led to a reduction in EU sales of SVHCs with suitable alternative substances or technologies • No quantitative estimate of the changes in R&D spending. • Costs to industry from delays in decision making at the EU level, e.g. due to an inability to commit to investment plans • There is only a qualitative assessment of the possible different impacts on SMEs as opposed to larger firms • International level • No extensive study on the share of imported goods from non-EEA countries that contain SVHC. No cost-benefit analysis of the effects of controls at the border

5.7 Restriction

Table 25: Cost of Restriction

Pathways	Indicators	Gaps in impacts considered
Reducing risks through controls/phasing out	**Semi-quantitative** No of restriction proposals Average no. of restrictions per year (3) No. of consumers and workers benefiting (3); Cost-benefit comparison of the restriction process (3); **Quantitative** Costs to MS of preparing restriction proposals **Monetised** Estimated costs to industry of restrictions Estimated costs of monitoring and enforcement	• Ex ante versus ex post comparison of the predicted costs versus the outturn costs of Restrictions • Foregone innovation benefits due to forced restrictions on the use of substances • Costs to industry associations and individual companies of submitting information into the restriction process • Lack of ex ante and ex post comparative assessment to establish how different outturn costs are compared to predicted costs (also applies to benefits) • Follow-up assessments to identify any indirect effects on markets due to restrictions, including on the price or availability of products to consumers

5.8 Guidance

Table 26: Guidance and support

Pathways	Indicators	Gaps in impacts considered
Guidance and support	**Quantitative** Number of guidance documents issued, including updates; number of translated versions at EU level or prepared nationally **Monetised** Costs incurred by ECHA and MS in producing guidance (budget lines available); Costs of developing IT systems; Costs of Helpdesk support at EU and national levels	• Costs of changes in guidance on industry, especially where the changes introduce new requirements, and which have not also been subject to impact assessments.

5.9 Inspection and Enforcement

Table 27: Inspection and Enforcement

Pathways	(Previous) Indicators	Gaps in impacts considered
Inspection and Enforcement	Data should now be available from activities by the Forum, but was not available from any of the documents reviewed	• No. of enforcements for non-compliance with registration requirements • Value of fines levied for non-compliance • Costs to industry of responding to requirements stemming from inspections (although could also be a proxy for benefits)

6 Summary

6.1 Summary of data availability on the benefits of REACH

Direct benefits from REACH result from the reduction of risks caused by hazardous substances on all impact groups (environment, consumers, workers, man via the environment), the withdrawal/restriction of hazardous substances and the reduction of environmental releases. The withdrawal/restriction of hazardous substances has been accompanied in many cases by a substitution of SVHCs with alternatives, although it is unclear to what extent this has occurred as a direct effect of the Regulation. For these types of benefits, some quantification and monetisation has been carried out but it is incomplete due to data limitations. In particular, reliable extrapolation from individual chemicals to other similar chemicals is limited and there is limited evidence on the combined impacts across a number of chemicals or interactions with other EU legislation.

Benefits in the form of costs savings and welfare gains for workers have also materialised owing to the adoption of new or improvement of RMMs, effectively promoted by many drivers within REACH (i.e. listing of SVHC on candidate list, authorisation process, safety data sheets and communication through the supply chain). However, the systematic analysis of these benefits has not always been carried out. For example, data from a semi-quantitative assessment of the RMMs adopted as a result of authorisations is available (i.e. number of companies with new or improved RMMs) but a more in-depth analysis is lacking.

It is clear that REACH, in particular the Registration and the Information in the Supply Chain requirements, has contributed to improving the quantity and quality of information on substances available to all stakeholders (i.e. manufacturers, downstream users, public authorities, general public and workers). However, a clear quantitative link between this information and a likely reduction in disease cases and health damages as a result of more stringent classifications due to new data is missing. Similarly, it appears that better knowledge on substances has also enabled the elaboration of more robust toxicity estimates. However, any changes to DNELs, PNECs, uses advised against, etc. have not been systematically analysed across a large number of relevant substances.

REACH has successfully promoted the sharing of information along the supply chain, which has led to increased transparency and awareness. However, all of the reviewed studies provide a qualitative assessment and focus on the type of information communicated rather than its practical impacts. It has also been noted that the knowledge of substitution options is not equally shared throughout the supply chain, with downstream users and end product manufacturers being at a disadvantage.

REACH has played a significant role in contributing to the creation of a large and integrated market for chemicals. Intra-EU sales increased considerably in the last decade and it appears evident that multiple drivers within REACH have facilitated the integration process by means of harmonising regulations and standards thus ensuring a level playing field for all the operators in the EU. These conclusions are supported by extensive trade data and, to a lesser extent, other market data. The creation of a well-functioning single market delivers several indirect benefits to the EU economy, such as lower prices, more competition, etc.

REACH has also played a levelling role in the international context by becoming in some circumstances a regulatory standard adopted by other countries (e.g. South Korea, China, Canada). This means that REACH has indirectly prompted other countries to implement similar measures to control hazardous substances and environmental emissions. At the same time, this can contribute to create a level playing field between EU and non-EU industry operators. However despite

the availability of trade data, there does not seem to be a quantitative comparison of the competing effects of a cost disadvantage for EU producers and the benefits of the so-called 'Brussels effect', i.e. REACH inspiring regulatory changes in other countries.

A competitive economy is usually conductive to more innovation and more efficient use of resources. Although data are limited, it appears evident that REACH has provided firms with incentive to invest more resources in R&D. However, in some circumstances it cannot be denied that increase in compliance costs may have diverted resources away from R&D. Data on R&D activity are available, together with monetised estimates of the corresponding health and environmental benefits.

Assessment of human health benefits appear to be more developed than the assessment of the benefits to the environment. There is limited quantification and monetisation of environmental impacts due in the first instance to a lack of environmental quality/monitoring data that could enable a thorough assessment of systemic risks. It also appears that there is a lack of relevant assessment methods, and in particular available valuations for use as part of an economic analysis, in particular for PBT and vPvB substances. It is also more difficult to differentiate between the impacts of REACH and the impacts of other environmental legislation (e.g. Water Framework Directive) and other drivers. More widespread collection of data on the presence of chemicals of concern in the environment or in environmental media would help in establishing baselines for future assessments, regardless of whether they are based on physical indicators or monetary valuation.

Some indirect benefits are linked to improved working conditions stemming from improved risk management, with a highlighted benefit being a reduction in productivity losses. Reductions in healthcare costs per effect of better management of risk, reduction of releases into the environment and substitution/withdrawal of hazardous substances are also identified among the indirect benefits of REACH regulation. These have, however, received significantly less attention than the direct impacts and often there has been little effort to produce aggregate estimates of these benefits for employers and for national governments. For instance, savings in healthcare costs due to better management of risks may be estimated and presented in restriction dossiers and AfAs, but there is a lack of research providing aggregate estimates. There are also no collated data on the potential efficiency gains (or losses) from REACH in terms of changes in resource use, energy demand and material losses. Some data on these aspects may be available from Authorisation dossiers in terms of the negative effects of moving to alternative substances or processes, however, the potential gains linked to improving the recyclability of products at a broad level have not been assessed.

6.2 Summary on the data availability on the costs of REACH

It is clear that costs arise from implementation of most of the main drivers within REACH. These include costs to those directly affected by REACH and its legal obligations, where this includes manufacturers, importers and downstream users of chemicals, but also MS Authorities, the European Chemicals Agency (ECHA) and the European Commission. Costs also arise indirectly as a result of REACH implementation. These include costs due to the need for downstream users to react to changes in the availability of information on the properties of chemicals and their safe use (including on risk management measures), as well as actions resulting from Candidate Listing, Authorisation and Restrictions, and requirements on the communication of information.

Quantitative / monetary estimates of the most significant direct cost elements were developed as part of the original impact assessments, and have been subject to ex post assessments as part

of the various evaluations. These include for example, costs of registration, testing, CSR preparation, PBT assessments, producing and updating eSDS, costs of labelling (and re-labelling), supply chain communication, costs of various activities carried out by ECHA, Authorisation application costs (applicant's, ECHA's and MS Authorities' staff time), and costs of the Restriction process for rapporteurs, ECHA, MS authorities as well as to affected industries/companies.

What has been covered less well are some of the costs which are much harder to model or predict, which arise at the national level as part of MS implementation (e.g. inspection related costs), and which arise from on-going implementation decisions which are not subject to IA requirements (e.g. changes by ECHA in guidance or in its implementation and enforcement, e.g. costs arising from compliance checks, substance evaluation and legal challenges to the outcomes of these). There is also inadequate attention given to the impacts arising from the conditions placed on granted Authorisations, for example related to specific conditions of use or additional monitoring requirements; these can be proposed/set with no consideration as to the real cost-benefit trade-offs involved, particularly where the risks are already assessed as being very low.

Other impacts that are poorly understood and poorly researched include impacts on trade specifically due to REACH and its implementation and impacts in terms of displaced or foregone investment and R&D by industry. In addition, there is a lack of data on the extent to which there are overlaps, synergies and antagonisms between what is being required under REACH Authorisation decisions with what is also required under e.g. the Carcinogens and Mutagens Directive. There is also a lack of data on the extent to which there may have been regrettable substitutions, as a result of SVHC substance withdrawals in general, the Candidate List, and REACH Authorisation. However, companies are also unlikely to be forthcoming with such information, limiting the potential for research in this area.

It is also important to note that although cost estimates may exist for many of the direct costs of REACH, these have not necessarily been validated through new/recent research. It is also the case that some of the original estimates were based on certain assumptions as to the implementation and operation of REACH. In practice, the final regulation varied somewhat from what was assumed during the impact assessment, but its implementation has also developed over time. The latter in particular may mean that some of the original cost estimates and assumptions may no longer hold.

6.3 Proposals for addressing key gaps in data

6.3.1 Addressing key gaps in benefit data

A comprehensive overview of the current data gaps is provided in Section 5 for each of the REACH drivers, with some examples highlighted in Section 6.1.

These gaps could be addressed in two ways:

1. **Greater and better use of already available data**: A more efficient use of available data would help to fill in some gaps and allow for more extensive quantification. Some suggestions in this regard include:

- Good data are often available for individual substances but robust extrapolations from individual chemicals to other similar chemicals is limited: research could explore whether it would be possible to develop criteria enabling extrapolation from individual chemicals to related groups or categories. This could involve, for example, the categorisation of chemicals (e.g. classification such as sensitisers, types of exposures, associated risks and health effects, tonnages), carrying out a review that looks at a representative sample of substances and on

that basis extrapolating to similar substances also used across the EU. The results of such an exercise could be compared to existing burden of disease studies, or more general incidence and prevalence data.

- SVHCs: Although Candidate Listing is recognised as leading to some level of substitution, the extent of such substitution is poorly understood. As a result, the benefits of the Candidate List and its impacts on substitution remain uncertain. There may be the potential for research to try and apply a read across approach (or an approach similar to that described above) to develop rough estimates based on the benefits arising from regulation of the substances that have gone through authorisation or restriction.

- An analysis of the changes in risk management and hence exposures due to increased information across a large number of substances on DNELs/DMELs, PNECs and uses advised against could help to establish a clear quantitative link between the improved knowledge on substance properties and their uses and related health effects. It is not clear whether some data could be extracted easily from the Registration database (e.g. as a result of updates to the original Registration dossiers) or whether they would have to be collected directly from companies.

2. Collection of additional data: allowing more extensive quantification and monetization of the benefits of REACH. To this end, we would recommend:

- The implementation of an EU wide system of biomonitoring in order to generate more reliable and comprehensive data across different stakeholder groups: workers, consumers, general public;

- Creation of time series (potentially including historical) data at the EU level on the number of workers exposed and changes in exposure level over time in order to better track the impact that REACH and changes in chemicals legislation are delivering over timeframe. It is of note that some of the databases on the number of workers exposed to carcinogens, CAREX for example, are now significantly out of date;

- Addressing the limitations in official databases (PRODCOM, Eurostat) in order to have up to date information on the level of sales within the EU market;

- More efforts to quantify R&D expenditures across the EU in order to better evaluate impacts of REACH on innovation, and assess diversion effects due to increased compliance costs;

- Systematic studies on changes in risk management at the company level and whether this has brought about significant reductions in exposures (e.g. below the DNEL/DMEL threshold or not), and whether this has led to cost savings or cost increases for companies, with consequent impacts on innovation and R&D, or net profits and company viability;

- More thorough sectorial analyses that look into the results of some specific EU industries in the global market are needed to assess the performance of the EU chemicals market in terms of global competitiveness; this would allow for a more accurate quantitative comparison of the competing effects of a cost disadvantage for EU producers and the potential benefits of REACH in driving the shape of chemicals regulation globally, the so called 'Brussels effect';

- Improvements in statistical sources to track imports of substances containing SVHCs and to see whether enforcement of REACH is reducing the presence of SVHCs in imported products.

Waste management sectors at the moment are not sufficiently involved in the information exchange processes, and could be more involved in these. This could help to gather more information and potentially address information gaps. This is particularly relevant with regard to the lack of data on the benefits of REACH Restriction and Authorisation for vPvB/PBT substances which are also subject to waste-related legislation such as the POPs Regulation. The SCIP database will become live in 2021 and should help waste management companies to access information on the presence of substances of concern in articles. The added value of this database, i.e. to what extent companies make use of this information and how easily they can access it, could be part of a monitoring and evaluation exercise in the future to guide how its use is developed into the future.

In relation to ecosystem services, assessing the value of changes in natural capital and the services it provides is fundamental to determining what more can be done to target specific problems and what benefits can be expected out of this. The limited availability of data (most importantly dose-response data) is a primary cause of the difficulties in assessing the impacts of chemicals on ecosystem services. However, there are still unsolved methodological issues that are being discussed by scholars in terms of how best to capture and assess effects, for example, at the meso or community level. Further research is thus much needed to progress the quality of such assessments, particularly if one is to assign monetary values to ecosystem services and systemic risks.

6.3.2 Addressing key gaps in cost data:

The key components of REACH which currently give rise to costs are expected to be related to the implementation of Substance Evaluation, Authorisation and Restrictions. Thus, we would see these as the priority for any further research specific to REACH. In particular, we would suggest that any further research be carried out on the following two topics, where there is the potential for changing aspects involved in the future implementation of REACH:

1. **Conditions placed on granted Authorisations**. It is clear that there is a role for the RAC and SEAC to ensure that the continued use of a substance subject to Authorisation is carried out in a manner which minimises risks to human health and the environment. Even so, where the socio-economic benefits of the continued use of a substance have been demonstrated, and the risks of that continued use have been assessed by the RAC as being low, then consideration could also be given to the proportionality of the impacts that may arise from any conditions of use, including monitoring requirements, proposed by the RAC and SEAC. These are not currently subject to any cost-benefit duty, but could place a significant burden on the Applicant which in some cases could be disproportionate to the benefits that would / could be created through the required actions.
   Research could be carried out to catalogue the conditions that have been placed on authorisations stemming from RAC and SEAC recommendations. It would review the conditions of use that have been placed on past applicants and their downstream supply chains to provide at least a qualitative assessment of their potential costs and the extent to which these are justified by the residual risks from continued, Authorised uses. It could also be extended to assess the added value of further monitoring requirements, where monitoring is already required under other legislation. Cost-effectiveness analysis or cost-benefit analysis could then be used to examine the issue of proportionality, taking into account the extent to which the proposed conditions reflected Best Available Techniques or measures beyond those. The study results may of course raise issues with regard to the need to modify the current RAC/SEAC decision-making processes (e.g. asking the application to estimate the costs of implementation of specific additional RMMs), which may not be feasible or desirable.

2. **Modifications to requirements which are not subject to assessment requirements**. For REACH to continue to be the world leading model of chemicals regulation, it must be implemented in an effective and efficient manner. From an economic perspective, both of these can be impacted by the introduction of changes in the way that the Commission, Caracal and ECHA operate and implement REACH. What has been highlighted here is the up-dating of guidance documents, but this could also translate to other decisions with respect to e.g. definitions that are not given in the regulation but which are agreed either between ECHA or Caracal and the Commission Services. This work could also be expanded to consider whether or not there are differences in the interpretation of the guidance across MS, leading to different cost implications for both authorities and industry.

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A Pilot case studies

A.1 Overview

The three studies listed below have been reviewed as part of the pilot with particular regard to the benefit indicators

Table 28: Pilot studies

Title of the Study	Year of Publication	Short description	Link
Study on the costs and benefits of Authorisation	2017	Assess the performance of the authorisation procedure of REACH, providing evidence to assess if it is working as intended and achieving its objectives in terms of progressive substitution of Substances of Very High Concern (SVHCs) by less hazardous alternatives and control of the risks.	https://ec.europa.eu/docsroom/documents/26847/attachments/1/translations/en/renditions/native
Eurobarometer survey on the perception of chemical safety	2016	Provide information on the general public's perception and understanding of chemical substances, as well as attitudes towards their safety and awareness of involving chemicals in daily products.	http://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2111
ECHA: Assessment of the current substance evaluation process under REACH (Amec Foster Wheeler)	2015	The purpose is to undertake an objective assessment of the functioning of the current substance evaluation process (i.e. effectiveness, efficiency, transparency, workability of the process).	https://echa.europa.eu/documents/10162/13628/sev_survey_2015_en.pdf

In selecting these three studies, the intention was to test how well the analytical framework works with different types of benefits; in the three studies, the benefits of REACH range from those that are relatively easy to discern as a result of authorisation, to those that occur as a result of conclusions on risk or wider perception of chemical safety. It was also expected that the information presented in these studies was likely to range from attempts at quantification to qualitative statements to reporting of public perceptions.

A.2 Impacts of REACH – Authorisation (Final Report)

- This study deals with the impacts of REACH authorisation. It builds on available information and is an attempt at generating quantitative estimates of the overall impacts of REACH authorisation. It involves a review of the existing literature and surveys with industry, NGOs,

the EC, ECHA and MSCA's. The results of the study have fed into the second review of REACH by the European Commission in 2017.

- ECHA has identified 103 registrants who have ceased manufacturing or importing a SVHC, 69 of which occurred to substances on the Candidate List (the remainder to Annex XIV substances).
- The main impacts observed by the respondents to the survey were:
  - reduction in the number of suppliers of SVHCs;
  - reduced availability of the SVHC for their use;
  - an increase in the price of the SVHC, and
  - conditions being imposed on safe handling and use of an SVHC.
- Limitations in the data (PRODCOM, Eurostat) do not enable to assess if REACH has led to a reduction in EU sales of SVHCs with suitable alternative substances or technologies. Reasons why PRODCOM data may not be suitable for the task:
  - substitution takes time before changes become visible
  - alternatives being tested may continue to prove unsuitable
  - increased demand and sales of SVHC after the sunset date for those substances that obtained a review period
- Partial evidence that relocation outside EEA is likely to be rare, possibly also due to the fact that all applications to date have been successful.
- Most respondents said REACH Authorisation had not had a significant net impact on sales revenue (to date).
- Partial evidence that REACH Authorisation pushed companies to invest more in R&D.
- The present study found that the Authorisation process leads to substitution where it is technically feasible, even if the cost of applying for Authorisation could have been cheaper. This report sets out several drivers for these substitutions, with numerous case study examples. In such instances, it is nevertheless difficult to determine what motives prompted companies to substitute, whether the Authorisation process, other aspects of REACH and so on.
- Survey results indicate that: those companies who switched to an alternative due to REACH Authorisation, indicated either a net loss in sales or no net change.
- The survey results indicate that the levels of exposure reductions and emissions reductions of SVHCs achieved by both applicants and those that substituted (i.e. did not need to apply for authorisation) seemed to be relatively small (see Section 7.3). This is not necessarily surprising since companies should have been reducing their exposure over many years/decades. While qualitatively it can be shown that REACH authorisation is having a positive effect, due to lack of detailed data, it is currently not possible to quantify these benefits.
- Despite being 10 years into the REACH process, this study suggests it is still too early to be able to quantify the benefits of REACH authorisation. To quantify the benefits, historical data on the number of workers exposed and changes in exposure level over time would be required. Some of these data does exist at Member State (MS) level as some Member States

have confidential databases (for their MS) containing historical values for worker exposure which the study team were unable to obtain. In the future, should applicants reapply for authorisation (i.e. review report) the monitoring data which is set as a requirement in some of the authorisation decisions could provide some additional data to assist in assessing the scale of reductions being achieved over time.

Table 29: Summary of REACH benefits in the Study on the costs and benefits of authorisation

Driver/Pathway	Indicators	Gaps in impacts considered
Listing of SVHC on candidate list ("announcement effects")	Decisions to phase out substances or to not-support uses because of listing on candidate list (predictive character of the candidate list)	• Market data: limitations of data (i.e. PRODCOM, Eurostat) make it hard to assess if there has been a reduction in sales of SVHCs and increase in sales of alternative substances. Uncertainties over the impact on sales and revenues
Authorisation process: Adequate control route (threshold substances) SEA route	No. of applications: adequate control route applications versus SEA route applications; number of approvals; number of exemptions in Annex XIV No. of substances replaced with alternatives No. of relocations outside EEA Reduction in exposure, emissions and waste. Improvement in RMMs Market data on sales and revenues of SVHCs and alternatives (trend in SVHC substances as compared to others, suppliers of alternatives) Increase in R&D spending Substitution of SVCH could result in reduced production costs (less need for control measures) and overall improved production efficiency (labour productivity, energy consumption) Improved communication networks of micro-sized companies	• There is only a qualitative assessment of the possible different impacts on SMEs as opposed to big firms • Only qualitative assessment about improvement in RMMs • No access to national databases on worker exposure to carcinogens makes it harder to estimate historical trends in exposure levels and draws conclusion on actual reduction of worker exposure • Uncertainty whether the main driver for reducing emission and exposure is REACH Authorisation or national legislations (national OELs) • No quantitative estimate of the changes in R&D spending • Uncertainty over the overall effects of relocation (limited cases of relocation were identified, companies unwilling to provide information) • Little data (limited sample) about the effects on employment • Not enough information (limited sample) about effects on quality, price and availability of products • No quantification of benefits from better information • Only one instance of SVHC that undertook authorisation process for environmental hazards. No information on direct impacts on the environment. In some cases where controls on human health have been optimised, benefits for the environment are supposed to have ensued as well.

Driver/Pathway	Indicators	Gaps in impacts considered
		• Reduction of risks for the environment remain thus largely untested, not quantified.
Generation of information	Better information available for authorities: they know more about remaining uses of SVHCs and their production sites, more data to support control of exposure and emissions	

A.3 Study on the substance evaluation process under REACH

The purpose of the report was to undertake an assessment of the functioning of the substance evaluation process (i.e. effectiveness, efficiency, transparency, workability of the process). Substance evaluation is seen as essential for clarifying whether a concern exists and whether it should be considered for risk management. The study has included a stakeholder survey.

Table 30: Summary of REACH benefits in the Study on the substance evaluation process

Driver/Pathway	Indicators	Gaps in impacts considered
Improved information/ identification of risk	Number of substance evaluations per year Clarity of information on ECHA website Creation of methodological reference cases	• Types of effects typically identified • Number of RMOAs launched as a result • Number of proposals for regulatory risk management
Evaluation leads to risk management	RMOAs launched as a result Number of proposals for regulatory risk management Number of clarifications of concern without needing a formal decision Number of cases where SEv triggered changes in company level risk management without need for EU wide regulatory risk management Proposals for REACH regulatory risk management Proposals for other EU legislative risk management	• Number of clarifications of concern without needing a formal decision • Number of cases where SEv triggered changes in company level risk management without need for EU wide regulatory risk management

A.4 Eurobarometer survey on the perception of chemical safety

The report brings together the results of the Eurobarometer survey on public opinion on chemicals in the 28 EU Member States. The aim of the survey was to shed light on EU citizens' awareness and perceptions of chemical products, including comparisons with similar surveys conducted in 2012 and 2010. There is some interesting information in the report, including:

- Increased knowledge of the public: Almost half think that chemical products are safe for human health and the environment, although perceptions of safety vary considerably between Member States. At the same time, half of respondents say that the current level of regulation and standards in the EU is not high enough and should be increased. Women are more likely than man to believe so, younger respondents are less likely. Controlling for financial situation, those who have more financial constraints are more likely to think that level of regulations and standards should be increased.
- Less than half of respondents feel well informed about the potential dangers of chemicals. People in Northern European countries tend to feel more informed.
- There are margins to improve people's awareness of chemical hazard pictograms (part of CLP): most relevantly, there is a decreased capacity to recognize the environmental hazard pictogram; also, comprehension of the exclamation mark pictogram is low.
- Main source of information used by the public on the potential dangers of chemical products are the media and product labels.

The information on public perception of chemical safety in this report is very general in nature and cannot be related to specific drivers/pathways in REACH or even REACH more generally. The relevant table has thus not been completed for this report.

B Other reviewed studies[4]

B.1 Monitoring the impact of REACH on innovation, competitiveness and SMEs

- The majority of respondents (80-85%) reported no changes as regards imports or exports as a result of the implementation of REACH.
- The majority of survey respondents (two thirds) identified no impacts as regards international competitiveness.
- Registration 2013: Total registration costs for the 2998 phase-in substances registered in 2013 have been estimated as in the region of €459 million.
- Some 30% of survey respondents (OBS) have experience of substance withdrawals. Where withdrawals have occurred, the most typical response has been to switch suppliers or reformulate.
- There has been an increase in R&D activity for some 26% of companies surveyed (CATI), although in the OBS, only 10% indicated that their R&D budgets had increased. For nearly half of the companies sampled, R&D resources were transferred to compliance activities, and there was an increase in resources devoted to compliance.
- The first authorisations have been processed and granted and more are in the pipeline. Costs of Authorisation have been estimated by ECHA to be in the region of €230k and declining as experience with the process is gained.
- Estimates of registration costs for 2018 for 1-10t substances appear to be in the range of the ExIA (€228m compared to the estimate of €295 million), but the total cost of registering 10-100t substances is estimated to be significantly higher than formerly estimated (up to €1,136 million as compared to €581million) if validation and acceptance of negative and positive QSARs and read across does not occur within the time frame first envisaged.

Table 31: Summary of the costs of REACH

Drivers and enhancers	Pathway	Type of cost	Indicators
Registration	Substance registration	Manufacturer or importer registering a substance	€ for all registrations in 2013 and estimate for 2018
Registration		ECHA checking registrations and publishing information	
Registration	New classification or change to severity of classification	Costs due to a new classification or changed classification category	
Registration	Substance withdrawal for hazard properties reasons	Companies substituting non-hazardous substances for hazardous substances	% of survey respondents that have experience with substance withdrawals

[4] Some of the studies listed in Table 7 (in the main text) have been considered to make general observations about the functioning of REACH and draw final conclusions but have not been assessed in the following section. In some cases we only reported the findings from the latest of the studies in a series (e.g. ECHA Evaluation Report 2017, REACH Baseline Study 10 years update).

Drivers and enhancers	Pathway	Type of cost	Indicators
Information in the Supply Chain	Safety Data Sheets and Communication through the Supply Chain	Companies in the supply chain implementing RMMs	
Information in the Supply Chain	Communication on SVHC in articles	Companies removing hazardous substances from articles due to "announcement effect	
Authorisation	Listing of SVHC on candidate list	Companies phasing out/replacing substances because of listing on candidate list	
Authorisation		Cost to ECHA due to candidate list updates	
Authorisation	Applications for Authorisation	Companies applying for authorisation	Average cost per applicant/use
Authorisation		Cost to ECHA from reviewing AfAs	
Restriction	Elaboration of a restriction proposal	Cost to ECHA or Member State authorities for elaborating restriction proposals Cost to companies for providing input	
Restriction	Restriction	Companies replacing substances with alternatives or for which RMMs had to be put in place	
Evaluation	Evaluation	Costs to ECHA and MSs for reviewing information	
Evaluation		Costs to registrants for improving information	
Inspection and Enforcement		Costs to ECHA & Member States from enforcement	
Guidance and Support		Helpdesk	

B.2 Study on the Calculation of the benefits of chemical legislation on human health and the environment

- Includes a literature review but most of the reviewed literature is old or already considered in WP2.
- Focuses on the benefits of chemicals legislation, not only REACH but also CLP
  - Key output indicators: Substances with harmonised classification and labelling implemented after the entry into force of the REACH and CLP Regulations per hazard class;
  - Change in self-classifications (per hazard class) since the entry into force of the REACH and CLP Regulations;
  - Restriction decisions implemented after the entry into force of the REACH and CLP Regulations per hazard class, PBT/vPvB profile and endocrine activity of the substances and groups of substances covered by the decisions;
  - Substances of Very High Concerns included in Annex XIV per hazard class, with a PBT/vPvB profile, or with clear evidence of endocrine activity.
- Key result indicators:
  - Change in the concentration level of selected chemicals in human body tissues
  - Change in the concentration level of selected chemicals in animal and plant tissues
  - Change in the concentration level of selected chemicals in air, water and soil samples
  - Change in emissions of selected chemicals in air, water and soil
  - Change in production volume of selected chemicals
- Key impact indicators:
  - Change in incidence, prevalence and mortality following a change in chemicals' exposure due to chemicals legislation requirements per disease group
  - Change in environmental impacts (defined on ecosystem services or number of species) following a decrease in exposure due to chemicals legislation requirements.
- Quantification: output indicators by hazard class, trends in biomonitoring data for key chemicals, incidence and prevalence of occupational skin diseases and occupational asthma.

Table 32: Summary of benefit indicators

Drivers and enhancers	Pathway	Previous Indicators	Gaps in impacts considered
Registration	New classification and data quality	Number of CLH Increase in no of self-classifications	
Authorisation	Listing of SVHC on candidate list	No of substances in Annex XIV	
Restriction	Restriction as a process for earlier realisation of benefits	No. of substances subject to a restriction	

B.3 ECHA Report on the Operation of REACH 2016

- Useful information on the benefits including monetary values but for limited timeframe only
- Most benefits quantified

Table 33: Benefits considered in ECHA 2016

Drivers and enhancers	Pathway	Previous Indicators	Gaps in impacts considered
Registration	New classification and data quality	Screening results 2010-2015 (percentage of dossiers that pass the automated screening); No. of data sharing disputes and their outcome No. of registration dossiers by type and year (NONS included) Total no. of substances registered New substances registered per annum Number of updates % of registration dossiers selected for a compliance check No. of substance evaluations started and concluded Concerns/hazards under investigation	Number of updates given but also noted that the current systems does incentivise spontaneous updates by registrants
	Assessment of PBTs and vPvBs	No of substances discussed in the PBT expert group 2012-2015 and the outcomes	
Authorisation	Listing of SVHC on candidate list	No of recommendations for inclusion in Annex XIV and included in Annex XIV Review periods recommended by RAC and SEAC with/without additional conditions/monitoring arrangements Monetary benefit of granted authorisation per applicant per use	

Drivers and enhancers	Pathway	Previous Indicators	Gaps in impacts considered
		(potential cost of refused authorisation) No. of applications: no. of uses, no. of applicants by March 2016	
Restriction	Restriction as a process for earlier realisation of benefits	Monetary value of health and environmental benefits linked to restrictions adopted since 2009 No. of consumers and workers benefiting Reduction of emissions of PBT and vPvB substances Cost-benefit comparison of the restriction process Summary of HH and EV benefits of specific restrictions (monetary value or no. of people benefiting) Benefit-cost comparison of the restriction process	
Guidance and Support		Data made available through the website's dissemination pages	

Table 34: Costs considered in ECHA 2016

Drivers and enhancers	Pathway	Type of cost	Potential indicators
Registration	Substance registration	Manufacturer or importer registering a substance	Application costs per applicant per use in 2013-2015 (broken down by ES, Fee, SEA, AoA)
Restriction	Restriction		Benefit-cost comparison of the restriction process

B.4 Evaluation Progress Report 2017

- The report summarises 10 years of experience from the evaluation activities
- It shows data for 2017

Table 35: Summary of benefits in REACH Evaluation Report 2017

Drivers and enhancers	Path-way	Previous Indicators	Gaps in impacts considered
Registration		No. of dossiers checked No. of adopted decisions No. of information requests (broken down by type) Outcome of compliance checks No. of follow-up evaluations and reasons for their initiation No. of candidates for CLH as a result of substance evaluation No. of cases flagged by ECHA for substance evaluation No. of substances evaluated by Member States and no. of requests for further information % of cases in which evaluating Member State concluded further regulatory risk management might be needed Testing proposals	

B.5 Scientific and technical support for collecting information on and reviewing available tools to track hazardous substances in articles with a view to improve the implementation and enforcement of Article 33 of REACH

- Assesses different tools for communication of hazardous articles in substances in supply chains and to consumers (complex IT solutions, generic materials databases, declarations of compliance, (M)RSLs, third party certification systems, communication standards and product marking).
- Evaluates these tools with regard to their potential contribution to circular economy and a non-toxic environment.
- In current practice, communication on SiA is usually limited to the identity of regulated substances, if present above defined concentration limits. Additional information, such as on the concentration of the substances in articles are only requested in specific cases, e.g. if an actor needs to check if he exceeds the tonnage threshold of 1 t/a per SVHC and if he should notify the content of an SVHC in his articles according to REACH Article 7(2). Communication of full material declarations are an exception.
- Currently information on SVHCs in individual articles contained in complex objects, as required following the recent judgement of the European court of justice, appears to be rarely communicated.

  A general lack of consumer awareness on their 'right-to-know' of SVHC in articles and safe use information, if relevant, is observed by several actors and has been illustrated in several reports.

Table 36: Summary of benefits in Oekopol/RPA 2017

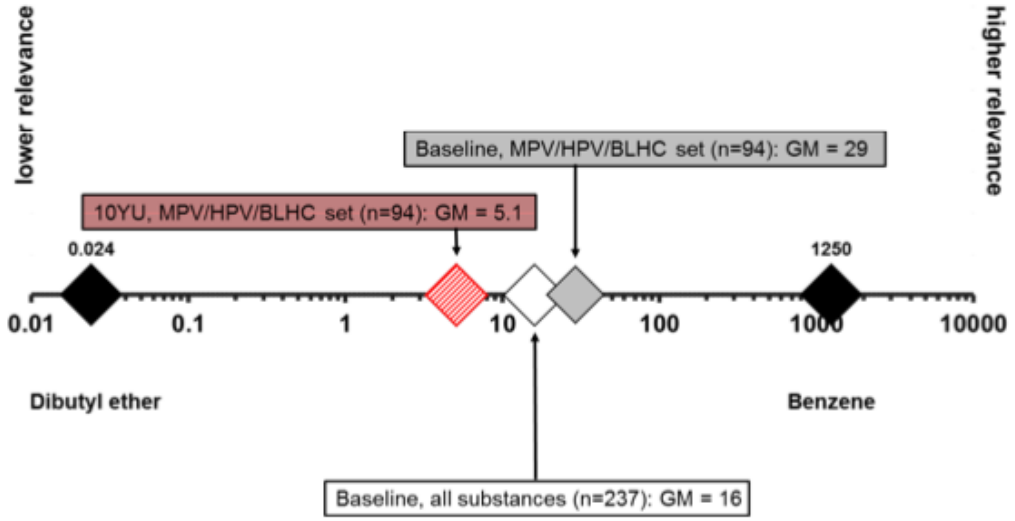
Drivers and enhancers	Pathway	Previous Indicators	Gaps in impacts considered
Information in the Supply Chain	Safety Data Sheets and Communication through the Supply Chain	Type of information communicated Usefulness of existing tools for supporting a non-toxic environment	
Information in the Supply Chain	Communication on SVHC in articles	Type of information communicated Usefulness of existing tools for supporting a non-toxic environment	

B.6 REACH Baseline – 10 years Update (2017)

- A CSR is only required for 15 of the 19 reference BLHC chemicals (79%). Three BLHC chemicals (16%) have an intermediate registration and one BLHC chemical (5%) is registered at a tonnage band of 1-10 t/a. In both cases, a CSR is not required according to the REACH Regulation. For the 15 BLHC chemicals with a CSR, an exposure estimate was available in the CSR. However, the situation is more complex for HPV and MPV chemicals;
- CSRs were not available for evaluation for 6 HPV and 6 MPV chemicals, because these only have an intermediate registration. In addition, a CSR is not required for 3 HPV chemicals due to the low tonnage;
- An exposure estimate (for workers) is available for the majority of substances that require a CSR. However, such an exposure estimate is not included in the CSR for 9 HPV and 7 MPV chemicals, almost exclusively due the fact that these substances are not classified. As a consequence, an exposure estimate is not required under the REACH Regulation.
- In the 5YU, the Reach Registration Deadline included BLHC and HPV chemicals. In the 10YU, BLHC, HPV and MPV substances are evaluated.
- Figure below shows the aggregated Risk Score the impact area of workers. For the 94 reference substances under evaluation in the 10YU (BLHC, HPV and MPV chemicals combined), the Risk Score for the baseline was 29[5]. 10 years on, the Risk Score for the 94 reference substances has reduced to 5.1, which is 18% of the baseline score. For comparison, this decline is similar that observed in the 5YU, when a decrease of the aggregated Risk Score from 42 to 8.7 (21%) was observed for the 62 reference substances.

[5] This value is higher than the aggregated baseline Risk Score of 16 for all 237 reference substances. This finding is not surprising since the fraction of BLHC chemicals (19/94, 20%) is higher than in the entire set (25/237, 11%) and Risk Scores are particularly high for BLHC chemicals.

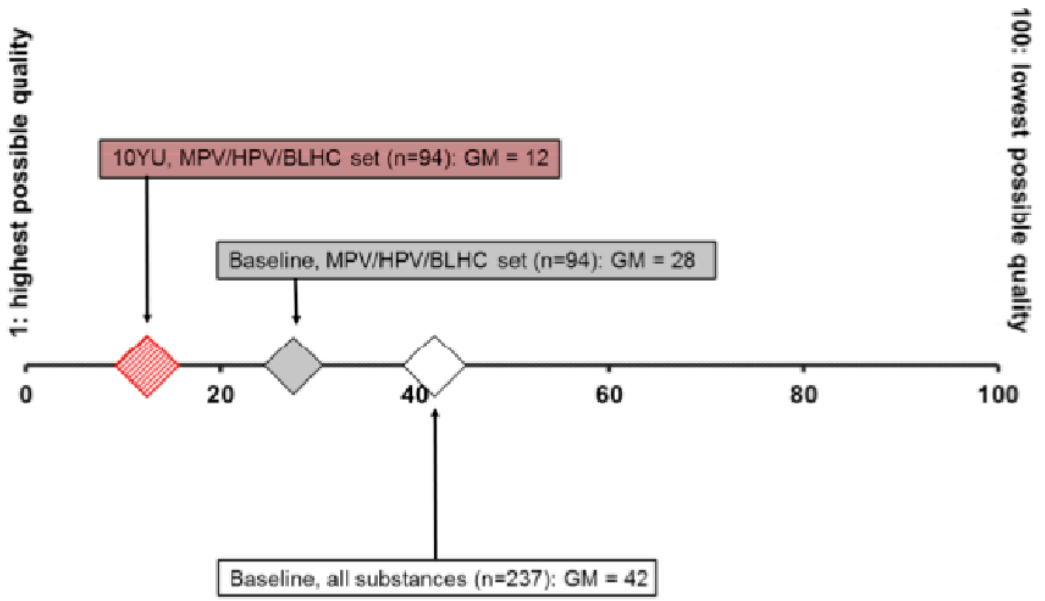
Figure 6: Aggregated risk (geometric mean, GM), for Workers



Source: Bunke D et al (2017): REACH baseline study – 10 years update

- The following Figure shows the aggregated Quality Scores. For the 94 reference substances under evaluation in the 10YU, the total baseline Quality Score was 28. This value reflects a better quality than the aggregated Quality Score of 42 for all 237 reference substances[6].
- In the 10YU, the aggregated Quality Score for the 94 reference substances declines to 12 (43% of the baseline value). This decline is somewhat stronger to the one observed in the 5YU, when a decrease of the aggregated Quality Score from 21 to 11 (52%) was observed for the 62 reference substances.

Figure 7: Aggregated quality score (geometric mean, GM), for Workers



Source: Bunke D et al (2017): REACH baseline study – 10 years update

[6] As before, this is not surprising since the fraction of BLHC and HPV chemicals in the 10YU sample (71/94, 76%) is higher than in the entire set (90/237, 38%) and BLHC and HPV chemicals can be expected to have more data than MPV and LPV chemicals. A similar pattern was also observed in the 5YU.

Workers

- In conclusion, there is a clear decline in the Aggregated Risk Score and an evident increase in the quality for the 94 reference substances evaluated in the 10YU, which reflects the fact that new data became available (DNEL not available at baseline). The trend of declining Risk Scores and Quality Scores is similar to the one reported in the 5YU, but it seems to be slightly more pronounced in the 10YU.
- No major changes occurred for BLHC and HPV chemicals from the 5YU to the 10YU. The most prominent changes are observed for MPV chemicals, thus highlighting a better quality of the data.
- Overall, the evaluations for the impact area workers show that the implementation of the REACH Regulation leads to lower Risk Scores and improved quality of the underlying data in the 10YU when compared with the pre-REACH baseline. Lower Risk Scores and better data quality are observed in the aggregated as well as the group-specific (BLHC, HPV and MPV chemicals) evaluations. For the impact area workers, the results of the 10 YU confirm the ones obtained in the 5YU for a larger set of chemicals. Compared to the decline in Risk and Quality Scores from baseline to the 10YU, the changes between the 5YU and the 10YU are small.

Environment

- The 10YU in the impact area environment confirms the trend observed for the 5YU (decreases in Risk Scores and RCRs as well as an improved quality) for a larger dataset of BLHC and HPV chemicals. MPV chemicals showed a very similar decrease in Risk Scores, RCRs and Quality Scores (improved quality) from baseline to the 10YU as the ones observed for HPV chemicals in the 5YU. It is also observed that the decrease in Risk Scores and Quality Scores is more evident in the 10YU compared to the 5YU for the BLHC chemicals.
- Overall, the evaluations show that the implementation of the REACH Regulation leads to lower Risk Scores for the environment and improved quality of the underlying data in the 10YU when compared with the pre-REACH baseline. It is observed that the toxicity estimate is of overall importance and that REACH appears to lead to an "improved toxicity", i.e. the eco-toxicity dataset for many substances has been improved leading to higher toxicity estimates corresponding to that the assessed toxicity has been decreased.

Consumer

- Registration dossiers brought useful information on:
  - uses: only 39% of evaluated substances are intended to be used by consumers in products or articles;
  - toxicity: DNELs for general population were provided in CSRs for 60% of the evaluated substances;
  - exposure: exposure estimates were provided for 62% of the used substances.
- The variations of the aggregated Risk and Quality Scores from baseline to the 10YU show a lower estimated risk (RS decline from 7.0 to 1.0) and a better quality of the data (QS decline from 50 to 17), with the same tendency for HPV and MPV chemicals.

- Between baseline and the 10YU, the toxicity estimates increased more than the exposure estimates, leading to a decrease of the Risk Characterization Ratio and the Risk Score. As a result, the number of substances with RCRs above 1 decreased from 23 at baseline to 11 in the 10YU among 32 "used" substances.

Man via the environment

- Among the 94 substances registered at the time of this evaluation, specific data on exposure for humans via environment is reported for 39 of them and 4 substances presented measured data. The data for the other substances are calculated by modelling.
- Decline in the Risk Scores and improvements in the quality of data.

General overview

- Correlation with substance evaluation: according to the data, inclusion of a substance in substance evaluation makes it more likely that the toxicity or exposure estimate has changed between the 5YU and the 10YU.
- Correlation with dossier evaluation: Substances with changes in toxicity or exposure estimates are more likely to have been covered by dossier evaluation. For example, 4 of the 5 BLHC chemicals that are included in the dossier evaluation process experienced altered toxicity or exposure estimates between the 5YU and the 10YU (80%). In contrast, only 4 of the 14 BLHC chemicals (29%) that are not in the dossier evaluation process experienced such changes. Again, the findings are similar for HPV chemicals.
- Correlation with soft measures: Evidence suggests that such measures initiated by ECHA did not generate significant results between the 5YU and the 10YU. The CSR was updated before the soft measure was mandated.

Main gaps identified:

- Tonnage information is extracted from ECHA – gaps depend on the limitations of the dossiers: E.g.: manufacture/import of given substance at different tonnages every year.
- Dossiers tend to report upper end figure for tonnages, which leads to overestimation

B.7 Restricted Success - EEB's appraisal of restriction under REACH

- This report focuses on shortcomings of the restriction process (as of 2017).
- Slow pace, narrow scope.
- Burdensome, unclear requirements.
- Too quantitative, as the study leaves out difficult or less quantifiable concerns and creates a false sense of certainty about the proposal.
- Dossier Submitter is held to a high standard but industry submissions are not held to the same standards.
- Too much focus on cost benefit, existence of alternative should be a sufficient reason to act.

Table 37: Summary of benefits in EEB 2017

Drivers and enhancers	Pathway	Previous Indicators	Gaps in impacts considered
Restriction	Restriction as a process for earlier realisation of benefits	No of restriction proposals No of restrictions entered into Annex XVII. Average no. of restrictions per year. Scope of restrictions. Benefits always represent a significant underestimate.	Data from 2017

B.8 Case study on "Announcement effect" in the market related to the candidate list of substances subject to authorisation

- Five hypotheses – 2 not supported, 3 supported
- Hypotheses supported:
  - Hypothesis 1: State of play – awareness
  - Hypothesis 2: Companies will look at the candidate list and consider it in their product development
  - Hypothesis 4: Importers, producers and professional recipients of articles would prefer articles without SVHC
- All considered qualitatively.

B.9 Health Impact Assessments of policy measures for chemicals

- The aim of this project was to quantitatively estimate the potential health gain resulting The aim of this project was to quantitatively estimate the potential health gain resulting from policy measures taken in the past (pre – 2008) and to be taken in the future (post – 2008) for chemicals in consumer products. In addition to REACH, the study summarizes the effects of the European General Product Safety Directive 2001/95/EC, Annex I of the Dangerous Substance Directive 67/548/EEC, and the Biocides Directive, the Preparation Directive (1999/45/EC) and the Limitations Directive (76/769/EEC).

Key points

- RIVM (2008) provides a summary of more than thirty studies that have been carried out in order to analyse the impact of REACH and considers different views on how, if possible at all, to value health benefits expressed in DALYs into monetary units.
- Some of the studies analysed the impact of REACH on society whereas other studies limited their scope to the impact of REACH on the business sector.
- It is important to note that any benefits listed below are potential future benefits as the study was undertaken in 2008, i.e. less than one year after REACH entered into force, and before it was fully implemented.

- RIVM (2008) concludes that impact studies prepared for the development of REACH are all based on a very small scientific basis, and therefore do not provide appropriate quantitative information that is directly applicable for the estimation of health effects due to chemical exposure from consumer products.

Table 38: Benefits considered in RIVM (2008)

Drivers and enhancers	Pathway	Previous Indicators	Gaps in impacts considered
Registration	New classification and data quality	Substances used in different kinds of consumer products should be more clearly identifiable in the future	Potential impact not quantitatively assessed – it's hard to quantify beforehand the size of any health benefits.
Restriction		Health benefits (expressed in DALYs) Reduction of specific disease cases per year	DALYs were not monetized because there are many conflicting views, based on methodological and technical as well as on practical and ethical grounds.

B.10 Environmental effects on public health (Koundouri, 2009)

- The paper looks at the available economic valuation techniques to quantify the impacts of environmental degradation on human health. Economic valuation studies can help to better shape public policies. The main approaches can be classified into revealed and stated preference techniques
- Revealed preferences method is based on the use of observable market information (i.e. prices) under the assumption that such information reveals individuals' valuation of certain aspects. Examples of this method include the cost of illness, hedonic pricing, QALY and so on.
- The stated preference technique makes use of questionnaire to build up a theoretical market evaluation of the good to assess. The most well-known stated preference methods are the Contingent Valuation Method (CVM) and the Choice Experiment (CE).
- In conclusion, the paper argues in favour of a deeper engagement of economists in setting out policies that seek to reduce environmental degradation. Economic analysis can also help to factor in long-terms effects with the appropriate discounting tools and include in the analysis matters of inter-generational equity.
- A more detailed explanation of these methods is also included in the paper. There is also a list of examples.

B.11 The costs of not implementing the environmental acquis

- Benefits of REACH based on the assumed share of illness caused by exposure to dangerous substances - uncertain estimate: €4-5 billion per year (€2011 prices)
- Phase-out of dangerous chemicals will have important environmental and health benefits. As part of the preparation for REACH, estimates ware made illustrating that the benefits could

be substantial. According to the Extended Impact Assessment, using prudent assumptions, the total health benefits would be in the order of magnitude of €50 billion over next 30 years. The annual costs are estimated to 4-5 billion EUR.

B.12 Assessment of the Health and Environmental Benefits of REACH

- Review of existing studies: RPA (2003): estimates of the benefits for occupational health between €18 billion and €54 billion; Extended IA: €50 billion
- Review of available information:

Table 39: Summary of benefits and studies where they were analysed

Benefit	Pathways	Studies discsussing benefit
Less environmental damage – less spending for environmental damage	Indirect: better information on substance properties and safe conditions of use Direct: safety assessment before marketing;(quicker) implementation of risk management measures; control of uses through authorisation	EC (2003): Extended Impact Assessment -qualitative RPA & BRE (2003): environmental and human health benefits –qualitative + examples Chemsec (2006): Developing countries –qualitative Chemsec (2005): Surviving REACH –qualitative DHI (2005): environmental and human health impacts ECORYS (2004): summary IA's –qualitative + example PCB clean-up
Reducing risk to the environment from SVHC	Direct: through implementation of RMMs; through conditions of the authorisation	EC (2003): Extended Impact Assessment –qualitative ECORYS: summary IA's –qualitative DHI (2005): environmental and human health impacts –quantitative
Less public spending to compensate damage	Indirect: better information through registration, authorisation and restrictions procedure	Chemsec: Developing countries –qualitative Pickvance et al. (2005): occupational health – quantitative RPA (2003): occupational health –quantitative UBA (2004): benefits in selected chains -qualitative
Less incidence of occupational diseases	Indirect: better information through registration	Pickvance S et al. (2005): occupational health – quantitative RPA (2003): occupational health –quantitative
Less public spending for public health damage	Direct: control of uses through authorisation Indirect: better information through registration (substance properties and RMMs)	RPA & BRE (2003): environmental and human health benefits –qualitative + quantitative example
Less incidence of public diseases	Direct: control of SVHC in consumer products through authorisation Indirect: better information through registration	UBA (2004): benefits in selected chains –qualitative + examples WWF (2003): social costs of chemicals -qualitative

Benefit	Pathways	Studies discsussing benefit
Reducing risks / exposure of the general public	Direct: control of SVHCin consumer products through authorisation Indirect: better information through registration (properties and safe use)	EC (2003): Extended Impact Assessment -qualitative DHI (2005): environmental and human health impacts –quantitative ECORYS (2004): summary IA's –qualitative UBA (2004): benefits in selected chains -qualitative

B.13 Study to develop EU enforcement indicators for REACH and CLP

- The objective of this study is to propose a set of indicators that can be used to monitor and measure the performance of the enforcement of the REACH and CLP regulations.
- The Forum is made of representatives from national enforcement authorities and is engaged in the effort to coordinate the enforcement of REACH and CLP in the EU.

Refer to the table below as an illustration of the link between the aim of the indicators and the intervention logic of REACH and CLP.

Table 40: Link between the aim of the indicators and the intervention logic of REACH and CLP

Indicator	Description
Objective	Key indicators should be ways to periodically assess the performance of REACH and CLP enforcement
Input	Indicators should help the Forum to measure their activities and help for a better fulfilment of their activities
Activities	Indicators should help to have better knowledge of the implementation and enforcement of REACH and CLP
(monitoring of) Output	Indicators should help to achieve a more harmonised and systematic approach concerning the collection of information and reporting at EU and national level
Outcome	Indicators should help Member states to use comparable data to evaluate their own enforcement activities

Indicators are proposed for three different levels:

- Member State
- Forum
- EU

Indicators are further divided into simple and complex indicators. Specifically, the Commission's Tender Specifications detailed that "the indicators should help to:

- *Have better knowledge of the state-of-play of the implementation and enforcement of REACH and CLP;*
- *The Forum for Exchange of Information on Enforcement ("the Forum") to measure the performance of their activities and help for a better fulfilment of their objectives;*

- *To achieve a more harmonised and systematic approach concerning the collection of information and reporting at EU and national level; and*
- *Member States to use similar data to evaluate their own enforcement activities"*

B.14 Service contract for technical assistance to review the existing Member State reporting questionnaire under Article 117 REACH, including the evaluation and configuration of an appropriate IT tool for the reporting

- The report provides a comparative analysis of the 2015 Member States reporting questionnaires under Article 117 of the REACH Regulation and Article 46 of the CLP Regulation. The questions touched upon several aspects of REACH and CLP Regulation.

B.15 Study on the cumulative health and environmental benefits of chemical legislation

- The focus of the study is on "cumulative" benefits delivered through the cumulative effect of various different pieces of legislation. The focus then is not exclusively on REACH nor does the report attempt to single out the benefits delivered through REACH regulation.
- The study concludes that there are a number of major uncertainties and data gaps in the information that is available to draw on in terms of impacts of chemicals on health and environment and benefits of the regulation. The level of information made available for the vast majority of hazardous chemicals in use across the EU is not detailed enough to allow for an adequate impact assessment. Besides, the process of disease development is "multi-factorial" so that the attribution of diseases to specific chemical substances is a challenge.
- To address the identified gaps, the report recommends targeted research and development, the implementation of an EU wide system of biomonitoring, refined methods to prioritise substances evaluation, and greater attention to so-called "cocktail" effects.

Various gaps are identified that future studies should seek to address to improve chemicals assessment in the future:

- In terms of benefits from avoided cancers, future analysis could widen the focus in order to differentiate impacts from genotoxic substances compared to those causing tumours through repeated-dose effects.
- For neurotoxic substances, the lack of a relevant hazard classification in current legislation is a limitation in identifying benefits, so this could be an area for further investigation. Similarly, further work to understand the issues of (clinical) thresholds and how these are used to evaluate the presence of adverse effects would be beneficial.
- There is a need for improved biomonitoring in Europe in order to understand the impacts of chemicals. More widely, biomonitoring covers known issues, and there is a need to better understand the less well known substances and effects.
- Further work is required on the valuation of benefits from reduced levels of PBT and vPvB substances, as this remains an area of significant methodological uncertainty.
- Further work is needed to determine whether it is feasible to extrapolate the findings on individual chemicals to other similar chemicals; this would help to provide an improved bigger picture and a total number of substances that are of relevance.

- The issue of boundary conditions and effects of major/catastrophic impacts on ecosystems is an issue that could be further taken into account in future benefits assessments.
- A need for further work on assigning monetary values to ecosystem services is recognised. Similarly, further research on how risk travels across systems (systemic risks) would be of benefit.
- The impacts of combined exposure to multiple chemicals remains an area where adverse effects (and hence benefits of legislation) are currently not very well researched, assessed and understood.
- There is a need for consideration of how to collect appropriate data on substances that are not already being prioritised for action (e.g. endpoints beyond those relevant for SVHCs under REACH).
- More could be done in future studies to assess the benefits achieved thanks to the fact that legislation now addresses pre-emptive actions.
- There is a lack of primary valuation studies.
- Related to the key data gaps e.g. for workers and carcinogens, where exposure data is missing, there may be further effort needed to attribute health impacts to chemicals exposure (e.g. in the case of cancers, there is a long lag time and cancers are only diagnosed a long time after the exposure, as doctors don't always ask patients about their past occupations, possible link with exposure to chemicals and the cancer might go undetected).
- Further work to match (e.g. cancer data matched with social security data and by extension identify occupations) could be considered, as a way of further attributing impacts to occupational exposure.
- On the face of a regulatory system set out to assessing exposures to single chemicals, the report also stresses the importance of not underestimating “cocktail effects”, i.e. the effects of combined exposures that could result in unexpected health problems.

In relation to environmental impacts:

- In general, it is recognised that there are limited studies that look at the impacts of chemicals regulation on the environment. Any estimates in the study is the result of a “bottom up” approach, whereby site-specific or Member State level data are extrapolated to have aggregate estimates at the EU level. The report does not report evidence of any study taking on a pan-European perspective.
- The report concludes that the inability to translate environmental benefits in monetary terms could lead to an underestimations of such benefits.

B.16 Commission General Report on the operation of REACH and review of certain elements

- This is the second Commission report on the operation of REACH. The evaluation has been carried out as part of the programme for Regulatory Fitness and Performance (REFIT) in accordance with the Commission's Better Regulation guidelines.

- The estimated scale of potential benefits for human health and the environment remains in the order of EUR 100 billion over 25-30 years.
- Further opportunities to improve and simplify have been identified, in particular for extended Safety Data Sheets, evaluation, authorisation and restriction. The issues requiring most urgent action are:
  - non-compliance of registration dossiers;
  - simplification of the authorisation process;
  - ensuring a level playing field with non-EU companies through effective restrictions and enforcement; and
  - clarifying the interface between REACH and other EU legislation, in particular that on occupational safety and health (OSH) and on waste.
- Authorisation

Based on the applications for 32 uses of 9 carcinogenic substances ECHA estimated that the cumulative socio-economic benefits of the authorised continued use of the substances, derived from the direct and the indirect compliance costs, are at least EUR 368 million per year, for the use of 8,400 tonnes of the substances per year. On the other side, the monetised risks, calculated from the modelling via dose-response function of the statistical cancer cases on workers and on the general population for each substance, were estimated to amount to EUR 7.4 million per year.

Table 41: Summary of benefit indicators (Commission Report on REACH)

Drivers and enhancers	Pathway	Indicators	Gaps in impacts considered
Evaluation, authorisation and restriction	National enforcement activities		Controls on imported goods – what is the effectiveness of controls at the border. Aggregate estimate of non-compliant products stopped at the border
Authorisation	Including substances in candidate list Substitution of SVHCs Relocation outside EEA	Substitution of SVHCs – in particular, among SMEs Comparison of substances listed for authorisation and applications actually submitted	No general consensus on the objectives of the Candidate List Limited quantification and monetisation. Not enough information on whether production reduction is accompanied by reduction of imports SVHCs in articles Not enough evidence available to assess how many companies relocated outside the EEA
Information through supply chain	Sharing information along supply chain	Level of information available to chemical suppliers on the properties and uses of the chemicals	There are still important gaps in the information passed down Flow of information happens but slower than expected: how many more benefits could be generated if this slowness is improved Lack of specific information about nanoforms

Drivers and enhancers	Pathway	Indicators	Gaps in impacts considered
		Information on long term endpoints	
Registration			Work is still needed to rectify important data gaps or inappropriate adaptations in registration dossiers for specific endpoints and for information on uses and exposure. The data gaps or data quality issues in dossiers hamper the identification of priority substances for SVHC identification or other regulatory action
Restriction	Reducing risks through controls/ phasing out	Health benefits for consumers and workers Reduction of releases to the environment Application of precautionary principle (4 substances)	Number of restrictions initiated annually is below than expected Cost-effectiveness of drawing on precautionary principle Impacts on EU producers facing restrictions in a comparison to non-EEA ones

B.17 Evaluation of ECHA

- ECHA has been entrusted with the implementation of a significant part of the technical, scientific and administrative aspects of REACH and CLP, complemented later with tasks related to BPR & PIC
- Overall, the evaluator considers that ECHA, during the review period, has been performing effectively and efficiently. It also showed evidence that the perceived transparency of the Agency is improved. Nonetheless, the evaluation revealed a number of improvement points.
- The study has reported evidence that the Agency's intervention is relevant to the societal needs in Europe and even beyond. By meeting the operational needs of the four Regulations, ECHA contributes to their overall objectives of taking into account health, consumer and environmental concerns, and the social and economic consequences that are relevant to citizens and stakeholders. As result of the evaluation, the overall ECHA's activities are aligned with the operational needs of REACH and CLP whereas the alignment to BPR and PIC is well on track but it is still ongoing.
- ECHA's role in seeking cooperation with other international partners is instrumental to the advancement and success of REACH at the EU and global level.

Table 42: Summary of benefit indicators (Evaluation of ECHA)

Drivers and enhancers	Pathway	Indicators	Gaps in impacts considered
ECHA	Listing of SVHC on candidate list	The need to deal with tasks of a technical and/or scientific nature, where decisions have to be taken	Influence on chemicals regulations outside EEA – how to assess whether and to what extent REACH has had an

Drivers and enhancers	Pathway	Indicators	Gaps in impacts considered
	("announcement effects")	on the basis of objective scientific criteria. The creation and management of networks encouraging the exchange of information and best practice. Higher degree of independence, which may increase the credibility of its data, findings or activities. Additional ways of involving stakeholders, thus increasing the quality and acceptability of its activities. Support to the Commission in its international cooperation activities.	influence on non-EU lawmakers, standards set by other agencies Thanks to ECHA dissemination activities, the level of awareness on EU chemical regulation is likely to have improved also among third countries' industry exporting to the EU – are there any economic benefits from this (i.e. international trade)

B.18 REFIT Platform Opinion

- The REFIT Platform Opinion focuses on the interplay of REACH and OSH regulations for what concerns the protection of workers in the workplace. REACH and OSH legislation work together to protect workers from the risks deriving from chemicals. Industry has voiced its concerns about the unnecessary burden imposed upon them by the overlapping of the two pieces of legislation, compliance to which commands significant costs. The document follows a case brought to the General Court of Justice on the question whether the OSH legislation can justify exempting certain uses of substances from the REACH authorisation requirement. The decision of the Court of Justice (which was at the time of the document subject to appeal) may limit the situations where OSH legislation is considered sufficient to control carcinogens in the workplace as a derogation to authorisation under REACH. The report notes:

  > *The Court decided that, as chromium trioxide is not specifically listed in CMD [or CAD], these directives do not constitute 'existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance' within the meaning of Article 58(2) of REACH.*

- Divergences between the two pieces of legislation can potentially arise in relation to "derived no effect levels" (DNEL) and "occupational exposure limit", which are respectively at the core of REACH and OSH; issues concern the respective methodologies to derive them, the application of appropriate RMMs. When the document was published, the Commission mandated the creation of task forces within RAC and SCOEL to analyse the reasons of such divergences and explore possible ways to remove the methodological differences.

- Exposure to the substance at levels lower than the DNEL but higher than the indicative OEL may be problematic. In this case, the role of ECHA, responsible for checking the compliance of the data provided by the companies with the obligations of the REACH regulation, is crucial to assess the validity of the risk management measures proposed by these businesses.

Table 43: Summary of benefit indicators (REFIT Platform)

Drivers and enhancers	Pathway	Indicators	Gaps in impacts considered
Safe Data Sheets	Exposure scenarios help companies to apply adequate RMMs	Effectiveness of two legislations in reaching their objectives: protection of workers from exposures and safety in the workplace Costs companies incur to comply with REACH and OSH Evidence of overlapping and unnecessary burden	Cost-effectiveness analysis: how the two regulations can be modified and simplified without impairing the capacity of the two regulations to deliver their benefits and reach their goals Cost-benefit analysis of harmonising methodology to derive DNELs and IOELVs/BOELVs

B.19 The EU Chemicals Policy: Towards Inclusive Governance?

- The paper looks into the level of inclusiveness achieved by REACH concerning the management of risk by all the involved stakeholders. Focus is on Authorisation since it is the piece of the Regulation in which the "public has the strongest interest in participating and where exclusion from decision-making is least justifiable".
- The analysis shows that the EU regulatory regime or chemicals control is more inclusive than what was in place before. Improvements have taken the form of a more participatory debate among stakeholders and enhanced transparency. Access to justice remains rather weak. However, the paper concludes that there is still a lot of work left to do before a full participatory and inclusive guidance is achieved and a more balanced interplay of public and private interests is also obtained.

Table 44: Summary of benefit indicators (EU Chemicals Policy)

Drivers and enhancers	Pathway	Indicators	Gaps in impacts considered
Authorisation	The entire regulatory process	Formal and effective involvement of all stakeholders in the chemicals management Balance between private and public interests Stakeholders attitudes, feelings and opinions	Effective ways to measure level of participation against benchmarks Little consideration is given to the question if and how more inclusion can be achieved in a cost-effective manner

B.20 SVHC in imported articles: REACH authorisation requirement justified under WTO rules

- The paper reports the conclusions on a legal appraisal on behalf of the German Environment Agency (UBA) in relation to the question whether extending the authorisation scheme to articles imported into the EU would violate WTO agreements. The conclusion is that such regulation would not constitute an unnecessary obstacle to trade, since the extended authorisation requirement would pursue a legitimate objective covered by the regulatory autonomy of the EU and, furthermore, the regulation would not be more trade-restrictive than necessary.

Table 45: Summary of benefit indicators (SVHCs in Articles)

Drivers and enhancers	Pathway	Indicators	Gaps in impacts considered
Authorisation	Listing of SVHC on candidate list	Competitive disadvantages for EEA based producers Quantity of goods imported from non-EEA countries containing SVCH substances N. of cases in which imported goods were inspected and found non-compliant with REACH and CLP	Extensive study on the share of imported goods from non-EEA countries that contain SVHC Cost-benefit analysis of controls at the border Effects of REACH Authorisation on non-EEA based companies – if and what is the extent of any "Brussels effect", convergence to EU standards

B.21 Strategy to promote substitution to safer chemicals through innovation

- Suitable datasets to quantify health and environmental benefits arising from a reduction in chemicals' exposure are largely missing and those that exist are representative for some national situations only. The scale of potential benefit of REACH remains as already stated in the 2013 REACH Review at least EUR 50 billion for human health by 2030 and EUR 50 billion for the environment by 2025
- A study compared the costs and the benefits of environmental regulation in the UK6. The environment ministry quantified the costs and benefits of 428 of its regulations affecting UK businesses, just over half of which were derived from EU or international legislation. Overall, the study estimated that with every £1 spent on compliance and enforcement returned £3 to society through economic, environmental and health benefits. This study has limited direct applicability to the benefits attributable to REACH, but it is relevant to the extent that it concludes that, referring more specifically to the UK chemicals legislation, which is almost exclusively based on EU regulation, a cost benefit ratio of almost 1 to 20 is achieved.
- Although validated and accepted alternative test methods are available for certain endpoints (notably skin and eye irritation), and these methods are frequently used in REACH Registration dossiers, there are still a significant number of recent in vivo tests submitted for those endpoints. The reasons for this need to be further explored in detail, but limited analyses point to regulatory requirements in third countries as an important driver for animal testing, highlighting the need to further work towards the international acceptance of alternative methods.
- General consensus is that REACH has had positive impact on health. Nevertheless, information on Health benefits resulting from a decrease in exposure is only available for occupational skin diseases and occupational asthma

Restriction process

- On the basis of the calculations by ECHA, it can be concluded that the health and environmental benefits of the restrictions adopted during the reporting period for this review have

outweighed the costs of their implementation, with human health and environmental benefits of more than EUR 380 million per year, and a reduction of about 70 tonnes of releases of substances of concern.

Table 46: Summary of benefit indicators (Innovation Strategy)

Drivers and enhancers	Pathway	Indicators	Gaps in impacts considered
Information through supply chain	Knowledge on the options for substitution Substance technical knowledge	Transparency about what knowledge is still missing and better awareness of the needs of upstream and downstream value chains Information is practical and easily applicable to promote new RMMs Increased recycling and uptake of secondary raw materials	Knowledge on options for substitution is not equally shared throughout supply chain, downstream users and product manufacturers seem to be benefitting less – Is this creating unnecessary burden on some categories of stakeholders? What is the cost for this? How can cost-effectiveness be improved? What other channels can be used to convey information to all categories of stakeholders? No quantification and monetisation about level of recycling and uptake of secondary raw materials per effect of information sharing. Unclear how waste management sectors could be more involved in REACH information sharing mechanism
Evaluation	Request of better information on chemicals	N. of substances evaluated: 82 decisions on substance have taken place, contrary to 448 expected	No quantification nor monetisation of costs/benefits
Candidate list and authorisation	Substitution effect Changes in Risk Management Measures	N. of substances added to the list: 36 between 2013-2017, slower rate compared to previous 5 years (due to more complex cases assessed, i.e. PBT, vPvB) N. of substances in Authorization list: 43 by June 2017, less than expected in baseline N. of companies who decided to substitute once substance is listed: evidence could be derived from listed substances for which no authorization has been submitted7 Number of companies who adopted new RMMs or improved upon them Investments on R&D	Limited information on the number of companies who have decided to phase out listed substances Uncertainty over the extent of regrettable decisions – how does this impact on the benefits delivered by REACH? Little quantification and scarce monetisation on the R&D investments per effect of substances being listed Not enough experience with regard to SMEs applying for authorisation in order to allow for a full assessment

[7] ChemSec: "The bigger picture" reports examples of companies that have decided to undertake substitution. Accessible at: https://chemsec.org/app/uploads/2016/02/The-bigger-picture_170509.pdf

Drivers and enhancers	Pathway	Indicators	Gaps in impacts considered
Restriction	Health benefits for consumers and workers	N. of consumers and workers positively impacted: Estimated to be ca. 81,000 Healthcare costs, productivity losses and suffering avoided	Little quantification and monetisation There is data collected only on limited substance restriction (i.e. restriction of chromium (VI) in leather articles
REACH 8 Multiple factors contributing	Data, information sharing (Since 2013 Review) Cooperation among MS authorities Free Circulation of substances in the internal market Health benefits Promotion of alternative methods to animal testing	Avoidance of animal testing. Introduction of alternative testing methods For occupational skin diseases and skin cancer: Benefits estimated to be ca. 1.59-1.87 billion and 249.9 million, respectively for the period 2004-2013.	No quantification or monetisation available No information on benefits/costs from these alternative testing methods There seems to be no evidence of the impacts and effects of EC investments to promote alternatives to animal testing Limited information available on health benefits. There is little attempt at quantifying and monetising
ECHA	Funding Information gatherer Technical support to companies Promotion of alternative methods to animal testing		Increased funding would be helpful – how much is needed? How can it help to deliver its objectives? How should MS and EU authorities coordinate public and private funding?

B.22 A study to gather insights on the drivers, barriers, costs and benefits for updating REACH registration and CLP notification dossiers

- The conclusions of the study highlighted a complex situation with multiple issues affecting the REACH registrant community. In particular, the parties affected by the Registration obligations have pointed out a lack of clarity over the functioning of the registration process. The requirements of Article 22 are acknowledged to be too generic and leading to confusion and uncertainties. Issues are highlighted by stakeholders when it comes to determining roles and

[8] Not specified further

responsibilities, i.e. who is responsible for updating which sections of the dossier and with the help of whom.

- During the interview phase it was clear that the respondents struggled to identify tangible benefits of updating dossiers which would add direct value to their business. However, some "softer" benefits identified range from improved understanding of the substances and enhanced visibility of the wide supply chain (downstream users in particular),
- SMEs raised concerns that REACH process places too onerous burden on them while favouring bigger companies.
- General opinion shared by registrants is that the dossier is the end of the process, which shows a failure to appreciate its role and ensuing benefits.
- Several actions that could act as a driver for greater benefits are recommended. They would take place with ECHA support and foresee a larger degree of involvement of industry, trade associations and possibly some policy measures. For instance, requiring mandatory periodic update of dossiers is expected to deliver an increased level of dossier update and improved confidence in effective management of risk to health and environment.

Table 47: Summary of benefit indicators (Updating REACH/CLP dossiers)

Drivers and enhancers	Pathway	Indicators	Gaps in impacts considered
Registration	Development of substance dossiers	Accessibility of health and safety information Effective use of the available information Updated dossiers	Limited quantitative data available No monetisation Several actions are recommended to increase awareness, smoothen the process in order to have more updated registration dossiers. There is little indication of the costs and benefits that would be achieved nor any attempt at assessing efficiency of suggested measures

B.23 Socio-economic impacts of REACH authorisations

The document is an overview of the applications for Authorisations submitted at the time the document was written.

B.24 Assessing the Health and Environmental Impacts in the Context of Socio-economic Analysis Under REACH

- The overall aim of this study was to provide scientific, economic and technical advice for the Commission in its preparatory work concerning regulatory decisions in the framework of REACH authorisations and restrictions which require the comparison of the impacts on health and the environment with other socio-economic impacts, such as the costs to businesses and consumers.
- The study also discusses methodologies that could be and are used in SEA to assess human health and environmental benefits respectively.
- In addition to REACH, the study summarizes the effects of the European General Product Safety Directive 2001/95/EC, Annex I of the Dangerous Substance Directive 67/548/EEC,

and the Biocides Directive, the Preparation Directive (1999/45/EC) and the Limitations Directive (76/769/EEC).

Key points:

- RPA et al (2011) provides a summary of more than thirty studies that have been carried out in order to analyse the impact of REACH and considers different views on how, if possible at all, to value health benefits expressed in DALYs into monetary units.
- Some of the studies analysed the impact of REACH on society whereas other studies limited their scope to the impact of REACH on the business sector.
- It is important to note that any benefits listed below are potential future benefits as the study was undertaken in 2008, i.e. less than one year after REACH entered into force, and before it was fully implemented.

Table 48: Summary of benefit indicators (SEA under REACH)

Drivers and enhancers	Pathway	Indicators	Gaps in impacts considered
Authorisation	Listing of SVHC on candidate lis	Monetary benefit of granted authorisation per applicant per use (potential cost of refused authorisation) Exposure of consumers to chemicals in non-food and food products	Few studies have been identified that have tried to quantify consumer exposures within a health impact assessment type of framework

B.25 Cost of inaction

- The key concept of the costs of inaction has been put forward by the Organisation for Economic Co-operation and Development (OECD) which defines inaction as the lack of development of "no new policies beyond those which currently exist" (OECD 2008).
- Inaction may also include failure to enforce existing national and regional policies on sound management of chemicals or to implement international conventions and protocols. Particular attention is required in defining inaction in developing country contexts, where awareness of risks from chemicals is very low, the magnitude of the problem is unknown, and policies to address sound chemicals management are limited or non-existent.
- Primary obstacles to the implementation of management laws, policies and institutions are barriers to mobilising political action.
- It is concluded that "a greater understanding of the economic costs and benefits of chemicals management can help to overcome these obstacles"
- Key gaps in knowledge are identified. Other than the often cited 2003 paper by the Commission of the European Communities concerning REACH, establishment of a European Chemicals Agency and regulation on POPs, no other studies were identified from the literature reviewed for this report that specifically report on quantified or monetized health, environmental and development planning effects of the POPs category of chemicals included in the Stockholm Convention, which was adopted in 2001 and came into force in 2004.

Figure 8: Summary of benefit estimates, Midpoints estimates of the cost impact of REACH (EURO mln) in a 30 year time horizon

Total Costs	Asthma	COPD	Dermatitis	Total
Without REACH	90,394	19,689	58,546	168,629
With REACH	45,428	9,572	22,678	77,678
Cost Savings	44,966	10,116	35,868	90,951

Source: Pickvance et al 2005

B.26 The impact of REACH on classification for human health hazards

- The authors compared information from REACH registration dossiers with harmonised classifications of 142 substances produced at very high tonnages and for which assessments were already carried out in the past. They found that 12 substances lacking a harmonised classification were classified in the registration dossiers submitted by the manufacturers/importers. Thirty-seven substances had stricter classifications and twenty-nine of these were classified for an additional end-point.
- These findings led the authors to conclude that REACH is improving the hazard characterisation even for those substances supposed to have a good data basis.
- Although the study does not point to any indicator in particular, it does reinforce the validity of some of the proxies that might be used as indicators of human health and environmental benefits, such as "number of companies that had to improve risk management measures as result of REACH" or "expenditure in risk management measures".

Table 49: Summary of benefit indicators (health hazards)

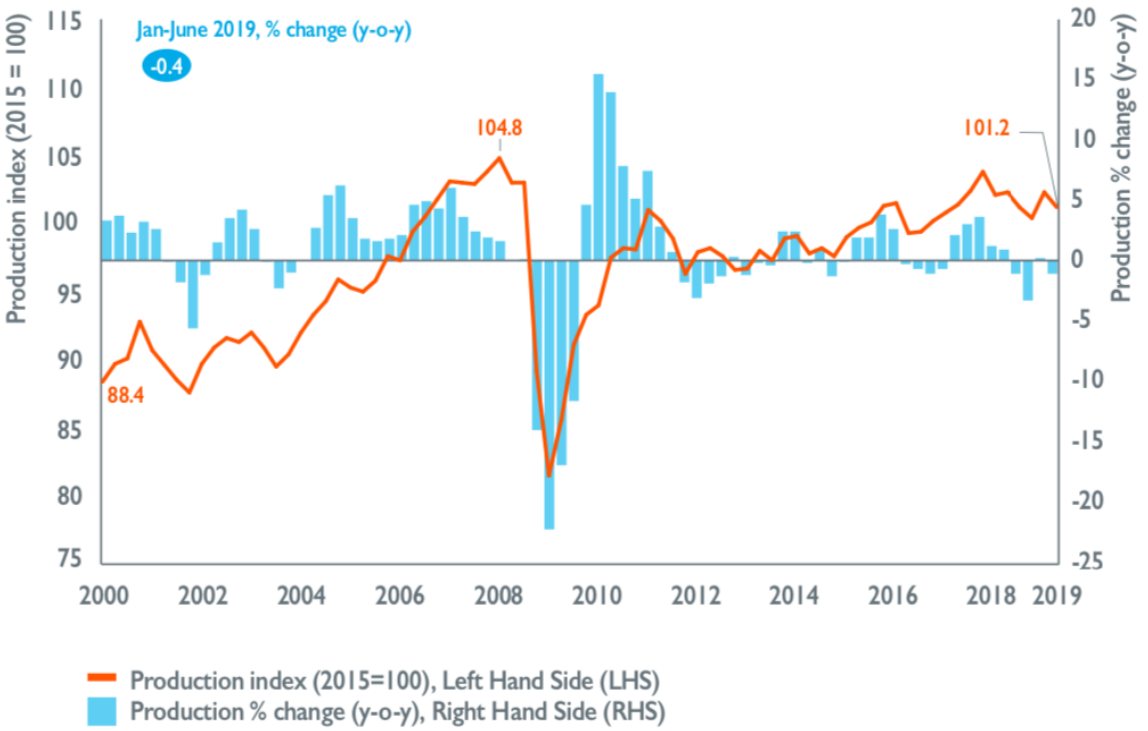
Drivers and enhancers	Pathway	Indicators	Gaps in impacts considered
Registration	New classification and data quality	Substances used in different kinds of consumer products should be more clearly identifiable in the future	Potential impact not quantitatively assessed – it is hard to quantify beforehand the size of any health benefits.
Restriction		Health benefits (expressed in DALYs) Reduction of specific disease cases per year	DALYs were not monetized because there are many conflicting views, based on methodological and technical as well as on practical and ethical grounds.

C General aspects: other reviewed studies[9]

C.1 Economic perspective

Figure below reports the production index as well as the annual change in percentage terms. It can be seen that chemicals output in the EU has not returned to the level it had before the financial crisis in 2008.

Figure 9: Level of production



Source: Cefic: https://cefic.org/app/uploads/2019/01/The-European-Chemical-Industry-Facts-And-Figures-2020.pdf

Europe has a large and integrated market made up of a customer base of over 500 million consumers and with chemicals sales worth EUR 519 billion in 2015. The importance of the internal market for chemicals is demonstrated by the fact that nearly 50% of all EU chemical sales in 2014 were intra-EU 'exports'.

Sale figures for the EU chemical industry remained broadly stable between 2007 and 2015, with figures of EUR 524 billion and EUR 519 billion respectively. Intra-EU sales increased from EUR 197.2 billion in 2005 to EUR 282.3 billion in 2015 – a 43.2 % increase during the last 10 years. How much this increase can be attributed to REACH is not certain, but these figures suggest that REACH is contributing to consolidating the internal market.

Intra-EU trade of chemicals has increased over the last decade, while the total EU chemicals sales remained relatively stable, though with some fluctuations. Moreover, as a result of a solid recovery after the economic crisis in 2008, the extra-EU trade balance showed clear signs of recovery, reaching over EUR 40 billion in 2015. This means that domestic (i.e. national market)

[9] The following sections put together a series of consideration and findings that could not easily fit the assessment framework presented above but might still be relevant for the purpose of this study. Some of the case studies missing from the list in Annex B are therefore referenced in this section.

sales have decreased while the increase in intra EU exports combined with an increase in exports to non-EU countries has led to an increase of the total chemicals sales over the period 2005-2015 (from EUR 458 billion to EUR 519 billion)[10] .

At the same time, the share of the EU industry on the global market has been decreasing over the past 20 years, representing as much as 32% in 1995 and declining to 15% in 2015. The extent to which this is related to REACH or global economic transformations (i.e. Chinese economic surge) is hard to determine.

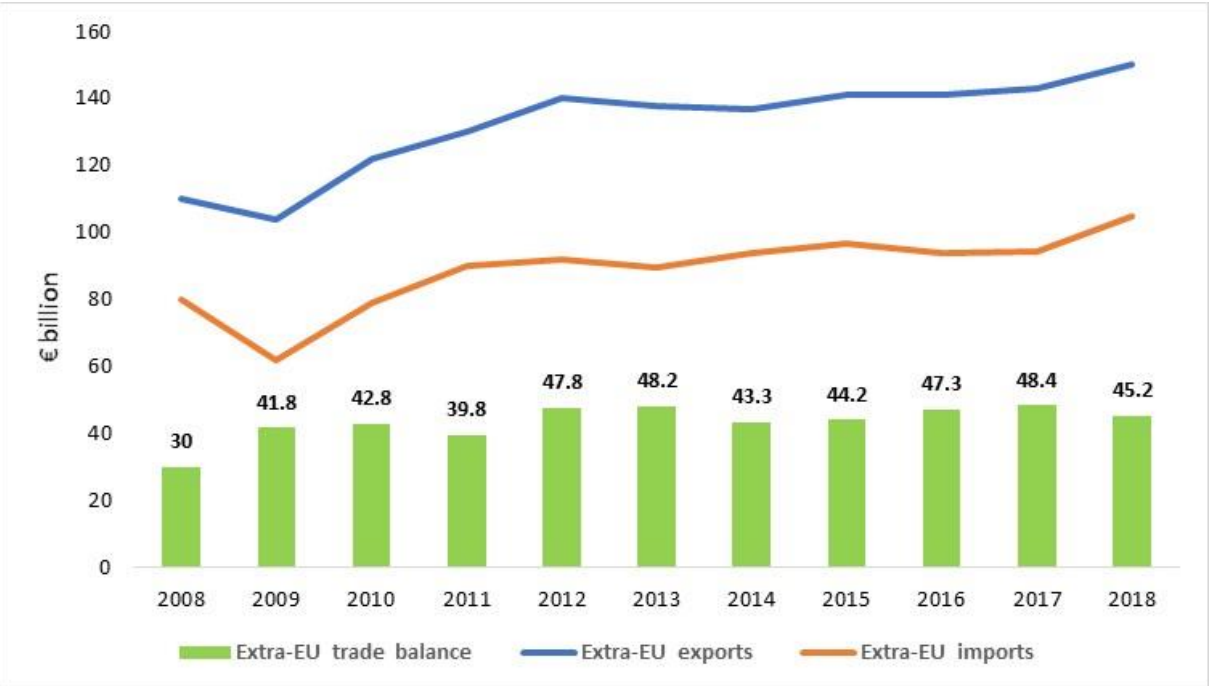
The net effect of REACH with this regard is hard to discern, but obviously the harmonization of regulations and standards has played a relevant role. It has contributed to avoid the fragmentation in the market and has brought in EU level rules that create a level-playing field for the economic operators in the EU market.

ECHA has recommended that to achieve a fair level-playing field throughout the single market, all Member States should consistently enforce ECHA and Commission decisions in their territory.

Trade surplus

The EU has maintained a significant surplus in its extra-EU trade balance in chemicals, as shows in the Figure 10 below. Looking at sectoral breakdown, it can observed that the largest part of the surplus came from specialty chemicals (58.2% in 2012), followed by consumer chemicals and polymers. In this perspective, it seems that the implementation of REACH regulation has not negatively impacted on the competitiveness of EU chemical companies in the international market. They have been able to preserve their level of sales outside the EU and level of imports has also remained substantially stable.

Figure 10: Trade balance



Source: Cefic Chemdata international, January 2019

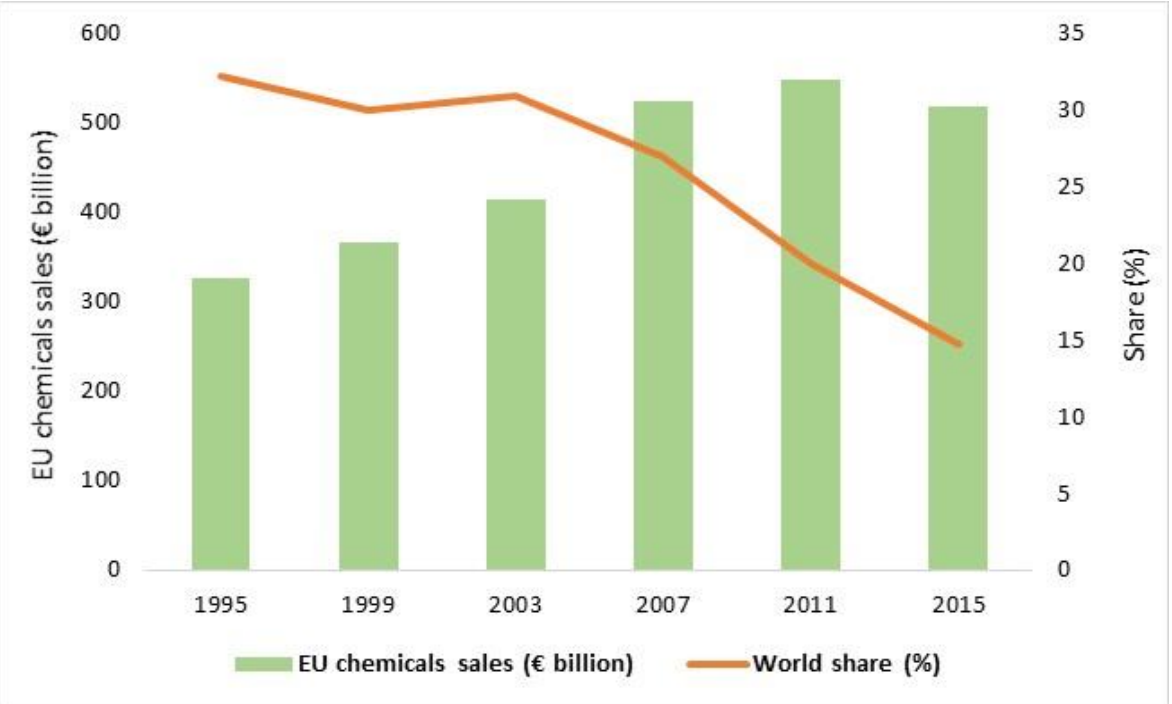
[10] CEFIC, Chemdata international 2015

On the other hand, the share of EU sales in the global chemicals market has been on a constant decline since 1995 (see Figure 11 below). However, in a study done by Oxford Economics it is also acknowledged that quantitative indicators measuring specific impacts of chemical regulation that could also allow for cross-country comparisons are not available. It is also noted that higher raw material and energy costs for EU companies in comparison to the USA and Middle East are putting them in a competitive disadvantage. On the contrary, in relation to China, relevant factors that hamper EU companies' competitiveness are high labour costs, capital and other fixed costs.

The loss of global market share is linked to the slow-down in exports in the petrochemicals sector[11].

These aspects are of relevance for the task of interpreting the effects of REACH regulation. As one of its intended benefits is to promote increased innovation, such efforts would be harmed if EU companies would not be able to compete with non-EU companies on a level playing field.

Figure 11: Share of EU sales in global market



Source: Chemdata international, January 2016

A quantitative modelling applied in the study of ECSIP suggests that REACH registration costs might have harmed the competitiveness of the chemical industry resulting however in a "negligible decline" of the EU chemicals exports in comparison to a baseline scenario without REACH. Results however are not conclusive.

Main gaps concern:

- Lack of proper quantitative indicator that can enable to assess effects of chemical regulations on international trade;

[11] https://www.mckinsey.com/industries/chemicals/our-insights/oil-price-shocks-and-the-chemical-industry-preparing-for-a-volatile-environment

- Uncertainty over the causes behind EU declining share in the global market, identified possible causes are higher energy and material costs, labour costs, other economic phenomena, and burdensome regulation; and
- More thorough sectorial analysis is needed to assess the performance of the EU chemicals market at the global level

The role of enforcement

Enforcement actions by Member States influence greatly the correct implementation of REACH requirements. Member State enforcement strategies are broadly in line with the strategy of the Forum and are an important prioritisation tool to focus activities on actual non-compliance risks.

There is a lack of attention on the costs and potential benefits not generated by a lack of enforcement by Member States.

Employment effects

On the other hand, there has been a gradual reduction in employment in the chemical industry from 2003 to 2013 (from 1.37 million to 1.16 million employees), with a bigger reduction during the period 2003-2008 than the period 2009-2013. Nonetheless, none of the studies reviewed identify any evidence of a correlation between the REACH Regulation and EU economic growth and employment in the chemical industry or downstream users.

There is some evidence that the entry into force of the REACH Regulation has increased the market of REACH-related consultancy (technical and legal) services as a result of activities outsourced by industry and public authorities but no figures are available to quantify those effects.

C.2 Impact on stakeholders

REACH is expected to increase confidence in chemicals of all involved stakeholders, such as consumers, investors, workers and the general public at large. It helps citizens to be more informed about the risks presented by chemicals and to make better informed decisions in their daily use of chemicals. Benefits that could come from this are hardly measurable. Eurobarometer surveys aim at delivering a picture of citizens' views and attitudes towards chemicals EU policies and regulatory frameworks.

Nevertheless, citizens are naturally unable to distinguish what comes from REACH or other pieces of legislation, so that results from such surveys cannot be directly applied to REACH.

In the REACH Review by the European Commission it is argued that REACH is able to engage with relevant stakeholders and take into account their relevant concerns throughout the decision making-process, although there is room for improvement concerning the dissemination of public consultations, the transparency about the consideration of the input gathered and the better communication between stakeholders and Member States.

Companies from the chemicals sector, as well as with their downstream users report no effects (neither negative, nor positive) on the trade of chemical substances within the EU/EEA due to the implementation of the REACH Regulation. While no discernible impact of REACH was identified, several companies expressed the view that REACH had made a significant contribution to the harmonisation of European chemicals legislation / integration of the Single Market. They also flagged the need for further efforts to make market surveillance and enforcement practices more aligned across the Member States by, among others, approaching the inspections and the relative resources (quantity and quality) allocated to ensuring compliance with REACH.

Interplay with other regulations

Further activities are needed to clarify the interface between REACH and other pieces of EU legislation; in particular work should continue on the interplay of REACH with occupational safety and health (OSH) legislation and with waste legislation Interplay with other regulations (i.e. OSH) and waste management

In addition to the direct link between CLP and restrictions for CMRs under REACH, there are more than 20 EU Regulations and Directives which currently refer to the existing rules on classification and labelling, covering wide policy areas such as consumer products, occupation health and safety, waste and end-of-life products and general legislation on control of dangerous or hazardous chemicals such as Seveso, Prior Informed Consent (PIC) and air and water quality Directives.

Other questions

Industry self-regulatory measures could be triggered by substance evaluation and information to supply chain. However, there is limited understanding of how to assess benefits of such self-regulation measures.

C.3 Innovation – Competitiveness

Innovation principle[12]

Innovation is at the core of the well-functioning of the internal market. Promoting innovation is key to guaranteeing sustainable growth and creation of jobs. Regulation can hinder or promote innovation. Thus, the innovation principle ensures that whenever the policy is designed its potential impact on innovation needs to be fully assessed. In this way the principle operates to ensure the effectiveness and efficiency of any regulatory initiative.

Possible ways by which regulation can be a driver of innovation are listed below:

- Standard setting directs producer toward specific goals and helps consumer by signalling quality and trustworthiness of products (the Porter Hypothesis); and
- Stringency of regulation provides certainty and guidance and could thus give impetus to research and innovation efforts

REACH

REACH encourages substitution by safer substances but it is difficult to attribute substitution effects only to REACH as substitution is also encouraged by other legislation (e.g. OSH) and supported by other drivers independent from REACH, such as consumer demands, market circumstances and initiatives such as e.g. the Substitution Support Portal (SUBSPORT) under the European Union's Life programme.

As resulted from CSES survey, no significant differences between large firms and SMEs have been identified, with the exception for the situation of substances that enter the registry of intentions. In this regard, more SMEs than large firms stated that they withdrew the substance.

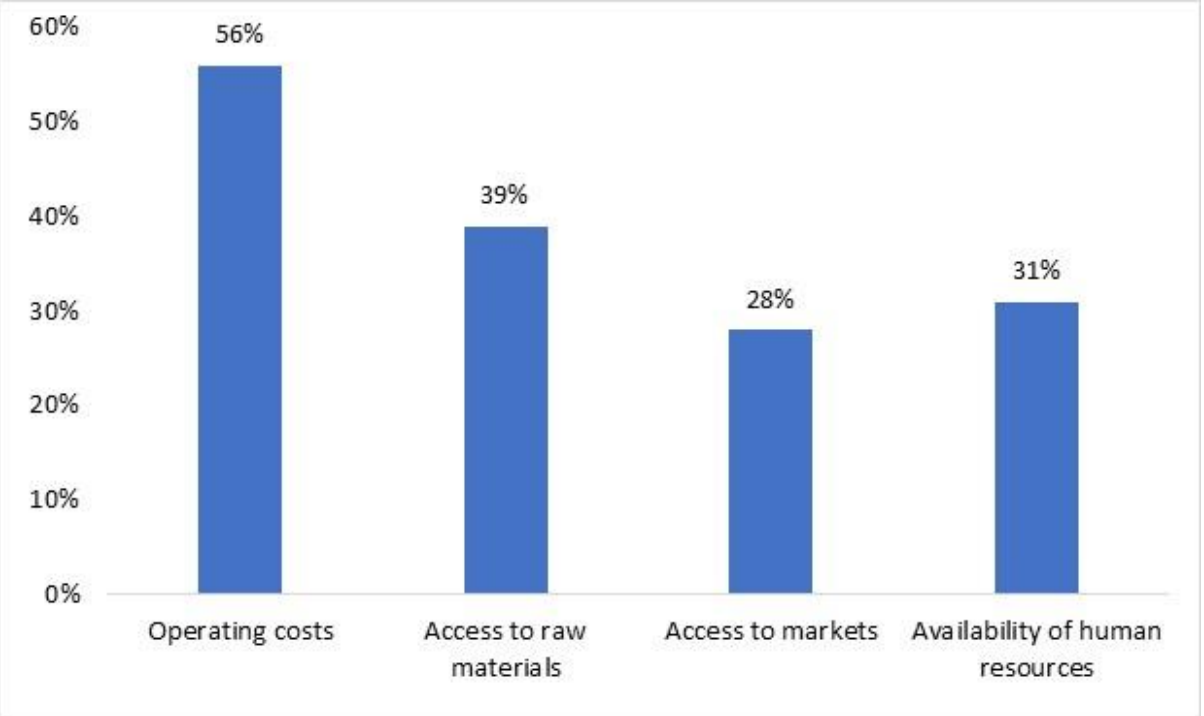
Innovation is clearly taking place and it has been facilitated by REACH. However, as observed in the REACH Review report by the European Commission (2018), there is more room for further initiatives, in particular to further engage SMEs.

[12] https://ec.europa.eu/epsc/publications/strategic-notes/towards-innovation-principle-endorsed-better-regulation_en#footnote4

Whether and to what extent REACH is encouraging directly and indirectly companies to direct their resources to their research programmes is unclear in the literature.

Find below the share of respondents to the business survey (CSES et al, 2015) on what are the factors associated with REACH Regulation that in their opinion are influencing their competitiveness with non-EU competitors.

Figure 12: Main factors influencing competitiveness according to respondents



Source: CSES et al, 2015

Responses vary by respondent's position in the supply chain. For instance, distributors tended to have the most negative view.

Substance withdrawal

Out of those companies that had faced a substance withdrawal, two thirds indicated that they were prompted to carry out research to identify an alternative substance. A third changed their manufacturing process to substitute the withdrawn substance (CSES et al, 2015).

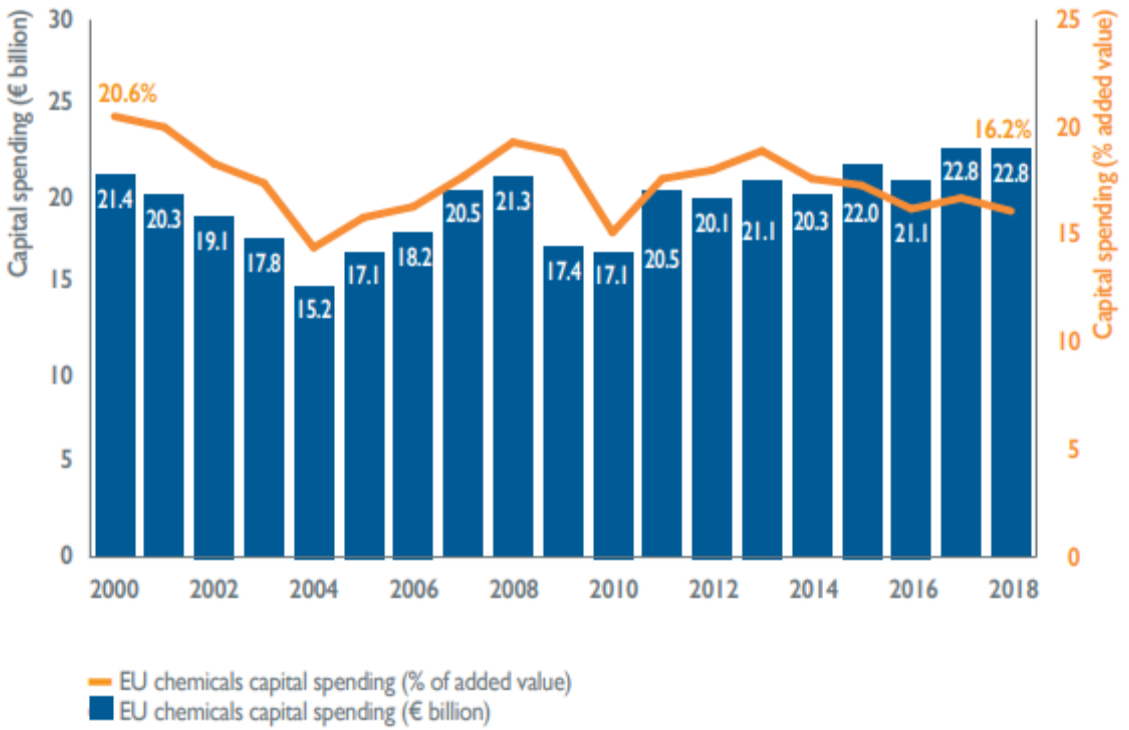
The most common response to a substance withdrawal was the identification of an alternative supplier, the identification of alternative substances (with the help of the supplier of that substance) or the change in the products design.

Results show that, as part of the registration process in 2013, companies may have revised their portfolios by withdrawing substances on the basis of economic considerations that were factoring in effects on profitability of registration costs and also undesirable hazard profile).

In the reports on the Impacts of REACH Authorisation, there were also 44 respondents providing 71 examples of no substitution not yet happened, but in the process of actively seeking to substitute and investment in substitution related activities. The report thus concludes that REACH Authorisation seems to be a major (but not the only) driver for substitution.

The Figure below shows how capital spending has evolved over time from 2000 to 2018. Spending in absolute figures has been relatively stable over time. The upward trend in capital spending that can be observed in 2004 and 2010 may have occurred because of REACH that has promoted businesses to invest in new RMMs and prepare for substitution to alternatives.

Figure 13: Capital spending in EU chemical industry



Source: Cefic, Chemdata International 2019 and Cefic Analysis 2019

There is some reason to believe that capital spending has not returned to the pre-recession level due to a shift of investment from the EU to countries outside the EU. Respondents to CEFIC Survey (CEFIC, 2016b) seem to support the view that EU chemicals sector has lost attractiveness to non-EU investors. The high cost of complying with European legislation is probably perceived as an obstacle by potential investors.

A report published by the European Competitiveness and Sustainable Industrial Policy Consortium (ECSIP, 2016) emphasises that the interviews with the European Automobile Manufacturers Association (ACEA), the European Tire and Rubber Manufacturers Association (ETRMA), the European Apparel and Textile Confederation (EURATEX) and the European Consumer Organisation (BEUC) revealed a general agreement that REACH has at most had a minimal impact on innovation.

This report notes that "innovation is driven by other parameters" (ECSIP, 2016: p.36) and that "innovation processes have been in place for a very long time" (ECSIP, 2016: p.36-37) before REACH. This is exemplified by the SAFERUBBER project from the rubber & plastics sector.

With respect to long-term investment, AmCham EU (2016) points out that REACH acts as a deterrent of long-term investment as the lack of predictability surrounding REACH means companies producing in Europe cannot be certain that a substance which is allowed now at a certain point in time will be available for use in three, five or ten years in the future – when a new product range is ready to go to the market.

Such obstacles may even stop some new products/technologies from coming to market.

Competitiveness, price level

The ECSIP (2016) report states that based on case studies and the results of quantitative modelling, REACH Regulation (not specifically the authorisation process) has had a minor negative impact on the competitiveness of the EU industry in relation to their third-country competitors.

More specifically in relation to the operation of REACH Authorisation, the ECSIP (2016) study concludes that the regulation has created a level playing field for EU and non-EU producers.

However, the authorisation requirement has the potential to harm competitiveness: insofar as EU article manufacturers may be at a competitive disadvantage since the requirement for authorisation of SVHCs does not apply to imported articles. The competitors producing outside the EU for export to the EU market thus do not have this cost element.

As reported by the CSES study, most surveyed companies stated that they absorbed registration costs rather than trying to recover them by increasing prices. Around 20% of them responded that they increased prices.

Possible gaps include:

- Any systematic studies on changes in price level over time;
- Competition in the global chemicals market is also a case of ensuring access to key imports of substances not available, or not available at competitive prices, in the EU, but there is little attention on this side of the question

Product and Process Oriented Research and Development notifications and registration of new substances

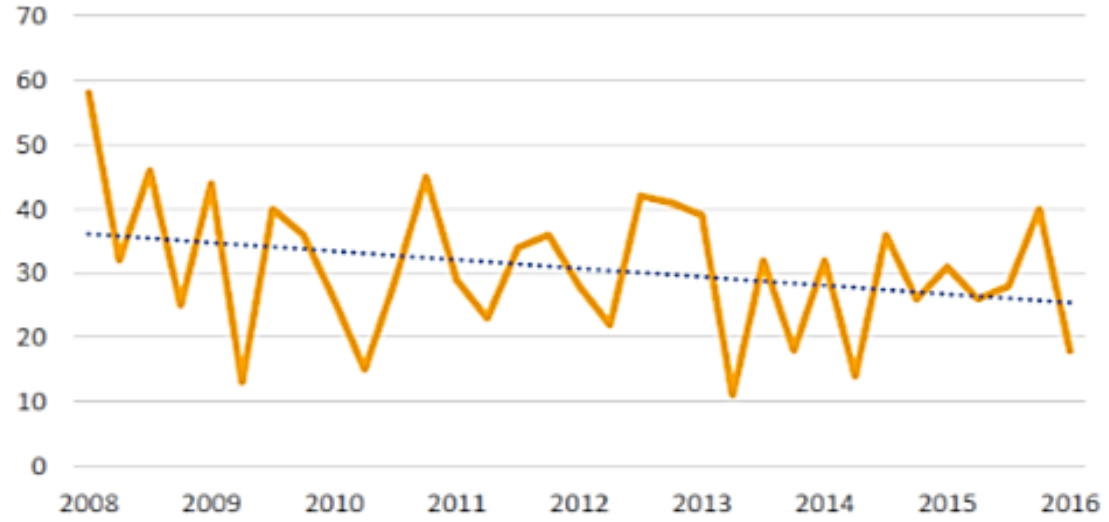
An indicator of innovation activity is provided by the number of new substances registered and the number of Product and Process Oriented Research and Development (PPORD) notifications (see Figure next page).

EU attractiveness

Stakeholders have raised concerns that high registration costs are creating barriers to entry of new innovative mixtures / substances and low volume research substances into the EU from non-EEA sources.

However, there is no sufficient evidence whether REACH Authorisation process, which is envisaged by the industry to create too much uncertainty, is weighing on the decision of non-EEA firms to locate and invest within the EU.

Figure 14: PPORD notifications for new substances



Source: ECHA, 2017

C.4 Indirect effect - "Brussels Effect"

When looking at the influence of REACH on other legislation outside the EU it is important to consider the policy influence (e.g. on the objectives set), the actual legislative influence and finally the influence of the REACH tools used to implement the legislation. Some examples include:

- South Korea has developed a legislation based on the model of REACH;
- REACH has influenced the legislation in China, developing a "REACH like" legislation, although differences in the scope and implementation are substantial (e.g. notification of new substances, proactive compliance practices by industry, prioritisation of chemicals); and
- There are common aspects with the Japanese regulation and regarding information requirements with Canada

Relevant differences remain between the US and EU, with the US placing the burden of proof on the authorities. As noted by the Commission[13]:

> *In the EU, with REACH, most chemicals are being assessed prior/during registration, i.e. since REACH came into operation already 17 000 unique substances were registered and therefore assessed by industry, which have the burden of proof for placing safe chemicals on the market. Other systems, e.g. that of the US Environmental Protection Agency (EPA) does these assessments only for a limited number of selected chemicals and the assessment is done by the regulatory authorities. By comparison, the 2012 Toxic Substances Control Act (TSCA) Work Plan for Chemical Assessments identified 83 chemicals for assessment by EPA as part of its chemical safety program, and the updated TSCA 2014 Work Plan had a total of 90 chemicals included, for which 4 assessments were concluded. In the last ten years, no new restrictions have been adopted in the US.*

[13] Commission Staff Working Document (2018): Commission General Report on the operation of REACH and review of certain elements

With the candidate list increasingly becoming a worldwide reference, REACH is likely to be playing a role in the promotion of innovation at the global level.

If only indirectly, REACH could then be seen as actively trying to foster international harmonisation in the implementation of chemicals policy.

C.5 The role of ECHA

Having an EU central body like ECHA produces cost-savings in terms of the time and resources needed by Member States e.g. as registration is done centrally and not at national level and provides increased visibility of EU activities in international fora (e.g OECD and UN).

ECHA has signed cooperation agreements with regulatory agencies in four countries: Australia, Canada, Japan and the United States of America. Activities are focused on exchanging information, best practice and scientific knowledge.

Animal testing

Because of the strong emphasis in the REACH text on the use of alternatives and the "last resort principle", REACH, together with the Cosmetics Regulation, is one of the principle drivers in the EU for the use of alternatives to animal testing.

Available information suggests that REACH enhanced the development, use and acceptability of alternative methods to replace, reduce, refine animal testing, but there are still areas of improvements regarding the use of adequate alternative methods. ECHA, which is putting a lot of effort into promoting new test methods through, among others, the update of guidelines on test methods stresses that the recognition of an alternative method by amendments under REACH and the Test Method Regulation takes considerable time. However, formal recognition of new testing methods through inclusion in the Test Method Regulation remains a challenge due to the inherent administrative processes and the time required for translation of the long and highly technical test protocols in all EU languages.

ECHA concludes in its third report on the use of non-animal test methods[14] that registrants generally made extensive use of existing information and adaptation possibilities before conducting new studies or proposing new high tier vertebrate animal tests, whereas regulatory requirements are updated to take up new reduction and replacement methods. The uptake and regulatory acceptability of the new methods in the EU also heavily stimulates validation and acceptance of alternatives in different jurisdiction

Until 31 December 2016, ECHA has taken decisions on 953 testing proposals, some of which concerned several studies that are already being or will be performed. 467 of the 953 testing proposals concerned prenatal developmental toxicity and 359 concerned repeated dose toxicity. 183 testing proposal decisions on reproductive toxicity are being finalised by the Commission.

On the one hand this means that less vertebrate animals than initially predicted have been used for testing, but on the other hand, hazard information has not been generated to the extent predicted either.

As reported in the Service contract for technical assistance to review the existing Member State reporting questionnaire under Article 117 REACH, 11 countries provided data on the overall public funding on national research and development of alternative testing, with 6 countries reporting expenditure of more than Euro 100,000 per year, and 2 countries (Germany and the

[14] ECHA (2016): Report on the Operation of REACH and CLP

Netherlands) of more than Euros 1,000,000. Around two-third of the countries do not record this information.

Overall then, there seems to be limited amount of quantitative evidence on the implementation at EU level of alternative testing.

In conclusion, it seems that REACH has succeeded at promoting a reduction in the use of animal testing, however evidence is scarce and inconclusive. Plus, as suggested in the REACH Review by the EC, effort at substituting traditional animal testing with alternative methods may have occurred at the expense of "delivering (hazard) information as for high-tier endpoints"

Possible indicators that would be useful in order to build a comprehensive assessment in qualitative and quantitative terms are the following:

- How many resources have been invested in R&D?
- How many new alternatives have been implemented?
- In what sectors and for what products have alternative methods replaced traditional animal testing