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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE
Commission General Report on the operation of REACH and review of certain elements
Conclusions and Actions

Annex 5

{COM(2018) 116 final}

Annex 5 – Horizontal issues

Contents

1 Human health and environmental benefits

1.1. Scope of this chapter

The intervention logic sets out the way in which the different actions can lead to impacts on the protection of human health and environment. Whilst those actions are part of the process that leads to impacts, the impacts themselves are difficult to quantify for a variety of reasons, such: latency periods, absence of a clear counterfactual, the challenges of analysing in a situation of risk and uncertainty and where the precautionary principle underpins REACH's provisions.

This chapter looks at all of these aspects in turn to identify the human health and environmental impacts associated with REACH.

1.2. Expectations before REACH adoption and conclusions of the 2013 REACH Review

The Extended Impact Assessment the Commission published with its proposal on REACH in October 2003[1] estimated the total implementation costs to be between EUR 2.8 and 5.2 billion over 11 and 15 years respectively and the human health benefits to be in the order of magnitude of EUR 50 billion over the following 30 years (both in net present value terms). This health benefit estimate was based on an illustrative scenario developed with the support of the World Bank and World Health Organisation. A series of further analyses and a Commission funded study[2] broadly confirmed these results.

In 2013, the additional benefits to the environment were expected to be significant but were not quantified[3]. In the same vein, the Commission launched a study to assess the impact of current chemical releases to the environment and the chemicals exposure to humans via the environment[4]. The long-term benefits of REACH were estimated to be up to EUR 50 billion over the following 25 years.

No quantification of the overall benefits of REACH in terms of protection of human health and the environment has been done since. Although the 2013 REACH Review contained partial conclusions on the stocktaking of the achievements of the Regulation until then, it was acknowledged that it was still too early to quantify the benefits and the report did not provide any general estimate, other than references to some of the observed initial trends, such as the improvement of the quality of the information, the implementation of more appropriate risk management measures or the observation that some first moves towards the substitution of SVHC through the supply chain had been undertaken.

[1] REACH Extended Impact Assessment, European Commission, October 2003
[2] Assessment of the impacts of the New Chemicals Policy on Occupational Health, RPA, March 2003
[3] The impact of the New Chemicals Policy on Health and the Environment, RPA and BRE Environment, June 2003
[4] The impact of REACH on the environment and human health, DHI, September 2005

1.3. Developments after the 2013 REACH Review

Singling out the health and environmental benefits that can specifically be attributed to REACH is challenging because REACH acts in concert with a whole suite of other Union chemical legislation in order to reduce human and environmental exposures from hazardous chemicals that are manufactured, placed on the market and used. For example, reductions in workplace exposures to carcinogenic substances are driven by a combination of CLP, REACH, and OSH-related legislations. Furthermore, assigning a particular attribution factor for a particular human disease outcome to chemical exposure remains challenging, as multiple causes can be attributed and the hazardous chemical exposure being one of these. Aside a number of data gaps and uncertainties, it is still very difficult to assess what portion of a particular health or environmental improvement can be attributed specifically to REACH, as opposed to other causes.

The main environmental and health benefit of REACH is that through data generation and industry self-regulation (i.e. through the introduction of risk management measures, information to downstream users on uses advised against), as documented in the registration dossiers, as well as through the actions taken by authorities in REACH, negative impacts are avoided. It is therefore inherently difficult, even with time, to collect direct measurements concerning these benefits – data is therefore at best indirectly measurable and must often be inferred. For example, the increased information on chemicals is measurable, as is the changes in classification and labelling that this causes. However, the accidents and avoided health impacts can only be inferred from the fact that knowing that a substance is hazardous triggers a behaviour which avoids or reduces the risk of damage.

As mentioned above, the 2013 REACH Review confirmed the original expectations that the health and environmental benefits of REACH implementation would take time to materialise. The Member States reports submitted in 2015 in accordance with Article 117(1) confirm that Member States share this view. Only 5 years have passed since the last Review and it is still less than 10 years since the entry into force of the Regulation. Overall, data gathering regarding quantification of health and environmental benefits of REACH has so far been limited but progress can be assessed on the basis of the outcomes so far, as described below.

1.4. Monitoring data availability and risk reduction resulting from REACH implementation

The so-called REACH Baseline study established a set of indicators to monitor the performance of REACH, in particular regarding risk reduction and improvement of the quality of data available for the assessment of chemicals, based on a methodology established in 2007 that calculates Risk and Quality indicators. Because of the accuracy of the methodology and the availability of data it is based on, the REACH Baseline study provides a robust indicator system to monitor progress towards the achievement of the REACH benefits.

The Risk & Quality Indicator system consists of an element assessing the nominal risk and an element assessing the quality of the underlying data. The resulting Risk Scores and Quality Scores are calculated for four impact areas: workers, environment, consumers and human health via the environment.

The risk score for a substance is a nominal value that indicates to what extent a risk could be associated with the use of the substance. In order to determine the risk score, an exposure assessment and a toxicity assessment have to be made. Both steps use data regarding the hazardous properties, the toxicological potency and the exposures. The quality of both of these data sets is characterised by the quality score.

The first baseline study was published in 2009 based on data available in 2007 before REACH entered into force, a five-year update study was completed in 2012 and a ten-year update study was concluded early 2017.

According to the 10-years' update of the REACH Baseline Study[5], the aggregated Risk scores show a clear decrease compared to the baseline. The decline in risk scores and the improvement in quality are evident in all four impact areas. The decrease in risk scores is similar to the one observed in the five-year update for High Production Volume (HPV) and Baseline High Concern Chemicals (BLHC), those correspond mainly to substances registered by the 2010 deadline, and is now observed for a larger dataset including HPV, BLHC chemicals and Medium Production Volumes (MPV), the latter corresponding mainly to substances registered by the 2013 deadline.

1.5. Overall benefits of REACH for human health and the environment

A number of illustrative pieces of information can be referred to when discussing the general benefits of chemicals and environmental legislation; some of these refer more generally to the benefits of broad environmental and/or chemicals legislation, others to specific REACH processes:

- A study compared the costs and the benefits of environmental regulation in the UK[6]. 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.
- Amec et al[7] found that the EU chemical legislation avoided significant costs to human health and the environment. Restrictions of certain uses of hazardous substances and the application of binding and indicative occupational exposure limits have resulted in significant reductions in exposure to carcinogens: when considering exposure to a group of 13 carcinogens since 1995, the authors estimate a total number of cancer deaths avoided (now and in the future) that may be in the order of 1.4 million deaths across Europe. The value of the reduction of the exposure to chemicals that may damage the development of children's brains has been estimated to be in the order of EUR 450 billion of avoided damage per year (in terms of higher life earnings potential).
- Another study by CSES[8] shows that around 53% of companies have improved their risk management measures because of REACH, with personal protection equipment and new safety instruction indicated with more frequency. This is an important finding and certainly constitutes a positive economic effect: various studies have concluded that expenditure on occupational safety and health is an investment that "pays off" and

[5] REACH Baseline study, 10 years update, Öko Institut et al, commissioned by the European Commission, November 2016

[6] The costs and benefits of Defra's regulations, Defra, 2015

[7] Cumulative health and environmental benefits of chemical legislation, Summary of provisional findings from the stakeholder workshop, Amec et al, 2017

[8] Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs, CSES et al, December 2015

calculated the Return on Prevention (ROP) to be 2.2[9] and the Benefit-Cost Ratio to be between 1.04 and 2.70[10].

In the absence of a clear quantification of the benefits directly attributable to REACH, a number of assumptions and intermediate results linked to the effects of the REACH processes (see intervention logic) can be drawn:

- The REACH Registration requirement leads to new and better physicochemical and (eco)toxicological information for the classification of substances, as well as to the introduction of risk reduction measures, the withdrawal of substances for which no appropriate data were available and the identification of safer alternatives
- The progressive Restriction of substances and groups of substances contributes to lowering human and environmental exposure
- The Authorisation mechanism leads to Substances of Very High Concern being progressively replaced by suitable alternatives and eventually phased-out and, while these are being used, the Authorisation process assures that the risks from them are identified, assessed and properly controlled
- The Evaluation processes (dossier and substance evaluation) are, in conjunction with the risk management option analysis (RMOA) by Member States, an essential part of the system, which allow to ensure its consistency and thus contribute to the achievement of the overall benefits of REACH

A study funded by the Commission provided indications on how harmonised classification and labelling (CLH) and self-classifications according to the Classification, Labelling and Packaging (CLP) Regulation have increased for substances and groups of substances across all the different hazard classes[11]:

[9] Calculating the international return on prevention for companies. Costs and benefits of investments on occupational safety and health, DGUV, 2013

[10] Socio-economic costs of accidents at work and work-related ill health, DG EMPL, European Commission, November 2011

[11] Study on the Calculation of the Benefits of Chemicals Legislation on Human Health and the Environment – Development of a system of indicators, RPA, April 2016

Table 5.1: Number of substances and groups of substances addressed by harmonised classification and labelling (CLH) and self-classifications

Hazard class – PBT/vPvB – Endocrine activity	Number of substances classified under harmonised classification (June 2008 – April 2016)	Changes in self-classifications (January 2005 – February 2016)[12]
Acute toxicity	80	1 077 *(+32%)*
Skin corrosion / skin irritation	30	2 196 *(+51%)*
Skin Sensitisation	37	1 192 *(+132%)*
Serious eye damage / eye irritation	30	3 340 *(+110%)*
Respiratory Sensitisation	1	1 118 *(+538%)*
Mutagenicity	13	1 731 *(+3 329%)*
Carcinogenicity	41	2 043 *(+284%)*
Reproductive toxicity	47	384 *(+229%)*
Specific Target Organ Toxicity	72	1 692 *(over 4 000%)*
Aspiration hazard	9	419 *(+251%)*
Hazardous to the aquatic environment	90	1 547 *(+40%)*
Hazardous for the ozone layer	0	12 *(+80%)*
PBT/vPvB profile	-	-
Endocrine activity	-	-

The number of substances in this table with harmonised classification and labelling and the changes of self-classifications provide an indication of how many hazards linked to substances have been identified, hence of how much the available level of knowledge on chemical substances, fundamentally from the information generated by REACH, is evolving (among public authorities, industry and the general public). It is particularly noteworthy the significant increase of self-classifications during the REACH period for all hazard classes. The table also shows that there has been a total of 450 harmonised classifications of substances in a legally binding way since the entry into force of REACH until April 2016, which means an average of circa 56 per year, to be compared to the 7 900 substances classified by Directive 67/548[13] during the 41 years previous to REACH, that is an average of 190 per year, hence today at a slower pace than before. It is worth noting that several reasons, not strictly related to REACH only, affect the trend observed, namely the fact that under CLP the focus is (by law) on CMRs and respiratory sensitisers (and pesticides and biocides), the higher level of scrutiny today for adopting harmonised classification (notably with the introduction with REACH of the Risk Assessment Committee) and the level of resources available for Member States in this field.

However, REACH (together with the plant protection products and the biocidal products regulations) seems to be enabling the generation of new and better information, which is resulting in a swelling number of classifications, in absolute numbers and per year, with RAC delivering approximately 30 opinions in 2012, up to around 50 at present (one opinion may

[12] The list of substances with self-classifications for human health and environmental hazard (around 98 000 substances at February 2016) was retrieved from the Classification and Labelling Inventory and compared with a list of substances with self-classifications retrieved from a 2005 extract of the IUCLID system, part of the European chemical Substances Information System (ESIS). The comparison resulted in the identification of 7 709 substances which appeared to be listed on both the IUCLID and CLI lists. The Risk-phrases from the IUCLID list have been translated into Hazard-phrases according to Annex VII of the CLP Regulation. The number of substances having self-classifications for one or more H-phrases has been counted and the distribution of H-phrases has been noted for all the 7 709 substances included in both lists.

[13] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

conclude on several classifications). It can therefore be assumed that REACH is still to attain its full potential in terms of resulting classifications per year, compared to the situation previous to 2008.

This same study[14] also made an estimation of the benefits of REACH referring specifically to two different endpoints. According to these estimations, the progressive reduction in the occurrence of occupational skin diseases and occupational asthma attributed to the exposure to chemical substances has resulted in total cost savings of, respectively, around EUR 1.59-1.87 billion and EUR 250 million for the period 2004-2013. Although these values, derived from two EU Member States only (Germany and the UK), have a limited representativeness for the whole of the EU, they provide an indication of the order of magnitude of the benefits. The accrued benefits are the likely result of multiple factors, such as an increased awareness on health and safety in workplaces, the pro-active adoption of better risk management measures, the restriction/withdrawal of some skin and respiratory sensitisers, the reduction of the workforce in sectors where workers are particularly exposed to skin or respiratory sensitisers and technological progress in the production processes. Nevertheless, the chemicals legislation is a determinant of many of these aspects and should be considered as having played a major role in reducing the number of cases of occupational skin diseases and occupational asthma. As a matter of fact, according to CSES et al (2015), because of REACH 53% of companies have improved their risk management procedures, with personal protection equipment and new safety instructions indicated with more frequency, and 39% have improved their management of environmental emissions and waste.

1.6. The benefits of the Registration process

REACH sets out duties and mechanisms to ensure a proper communication on uses and conditions of use up and down the supply chain. Such communication is necessary to ensure a proper description of the uses and the chemical safety assessment (CSA) at the top of the supply chain and that the end users of chemicals are adequately informed about the risk management measures that they need to take. Supply chain communication is done using safety data sheets (SDSs) that may also include exposure scenarios (extended or eSDS). Therefore, companies are now in a better position to implement risk management measures at their own work place and provide safety advice to their customers down the supply chain. The information generated in the registration process has in this manner contributed to building knowledge about chemical substances. There are indeed indications that REACH information has started to change risk management in the supply chains[15]. It has provided as well transparency about what knowledge is still missing and better awareness of the needs of the upstream and downstream value chains.

A report by RPA and CSES on the potential extension of the registration requirements for substances manufactured or imported between 1 and 10 tonnes per year[16] assesses the costs and the benefits of different options for the modification of the information requirements for substances registered in the 1-10 tonnes band. The study assesses the benefits, expressed in terms of damage costs avoided, on the basis of the avoidance of one incidence of 'disease' per year per substance identified with a human health classification and improvement in 1 km of waterbody for every substance identified with a classification for aquatic toxicity. The

[14] NEED TO SAY WHICH STUDY – not clear

[15] See for instance Impact REACH op MKB, Panteia, June 2013

[16] Technical assistance related to the review of REACH with regard to the extension of the registration requirements for substances manufactured or imported between 1 and 10 tonnes per year, RPA, March 2015

study concludes that the baseline scenario provides EUR 10.02 benefits for every EUR 1 of cost and that by increasing the information requirements, there is a roughly proportionate increase in benefit in terms of damage costs avoided.

1.7 The benefits of the Evaluation processes (dossier and substance)

By requesting better information on chemicals, the evaluation processes have improved their safe use. The European Chemicals Agency (ECHA) quotes in its report on the operation of REACH and CLP (2016)[17] several cases where the information generated has led to improved risk management at company level. For example, the registrant may have more severely self-classified their substance, applied further risk management measures, withdrawn or changed the conditions of use for the substance, or even ceased the manufacture or import of a hazardous chemical. Where the registrant has not taken appropriate action on their own initiative, ECHA has recommended for Member States to consider launching substance evaluation or proposing regulatory risk management measures such as harmonised classification. Evaluation has also increased the scientific knowledge and the understanding of substances and their hazards and risks.

1.8. The benefits of the Candidate list and the Authorisation process

The general report on the operation of REACH and CLP by ECHA points out that over 100 registered substances with a harmonised classification as CMR Categories 1A or 1B out of 300 have already been placed on the Candidate List. About one-third of the remaining substances are petroleum and coal derivatives and for these, ECHA is collaborating with Member States, the Commission and industry to address them in a systematic manner. The rest have been examined and found not to warrant identification as an SVHC at this stage. For many suspected PBTs and EDs work is on-going, but this can take substantial time due to the need for higher tier endpoint testing and the related decision-making timelines defined in REACH. Nevertheless, the common screening approach developed by ECHA has laid a foundation for efficient and effective identification of candidate substances for further information generation and assessment. The report also stresses that an increasing number of companies, in particular within the retail sector, are embedding within their strategies the need to reduce or avoid the presence of substances on the Candidate List in their products, what is resulting in an accrued pressure on their suppliers to provide information on the substances they use and to initiate further analysis of possible alternatives. As a matter of fact, Milieu et al found that 72% of industry stakeholders consider REACH as the main driver to substitute hazardous chemicals[18].

The Annual Report in 2017 on the implementation of the SVHC 2020 Roadmap[19] notes that all substances for which there was sufficient information on the hazard properties have already been addressed. Since the start of the implementation of the SVHC Roadmap in February 2013, 67 Regulatory Management Option Analyses (RMOAs) have been concluded and 92 are ongoing. Around half of the RMOAs concluded propose as a follow-up to identify the substance as being an SVHC. The other half of the RMOAs identifies either the need for other REACH regulatory risk management (e.g. restriction), the need for other regulatory risk management, such as the use of other regulations than REACH (e.g. CLP), or no action. This demonstrates that the SVHC Roadmap not only triggers the identification of substances to be

[17] Report on the operation of REACH and CLP, European Chemicals Agency (ECHA), 2016
[18] Study for the strategy for a non-toxic environment of the 7th Environment Action Programme
[19] Progressing together to identify substances of concern - Roadmap for SVHC identification and implementation of REACH risk management measures, European Chemicals Agency (ECHA), April 2017

included in the Candidate List but allows also identifying where there is need for restrictions or other regulatory action outside of REACH/CLP processes. Even though many RMOAs cover CMR properties, there is a clear increase of other properties (e.g. ED) compared to previous years. More substances with PBT and ED properties are being identified as SVHCs, indicating that the effects of the SVHC Roadmap implementation start to be more visible. This is a demonstration that in the light of more knowledge, there are greater reasons for concern, hence the need to further investigate.

According to ECHA's 2016 report on REACH and CLP, there is evidence that substitution is already happening as a result of a substance being listed on the Candidate List and the recommendation on priority substances for inclusion into Annex XIV:

- By March 2016, ECHA had received 90 applications for authorisation relating to only 21 substances out of the 31 substances that have been placed in Annex XIV (i.e. the Authorisation List), which may be an indication that substitution has taken place for at least some of the remaining 10 substances. For instance, originally 25 companies made a registration of DEHP, but only 3 manufacturers have applied for an authorisation; the EU's production of three phthalates (DBP, DEHP and DIBP) has also reduced by more than 50 % during the period 2010-2015. Other examples are diarsenic trioxide for which a substitute has been identified and the complete substitution of the flame retardant HBCDD by a polymeric (brominated) flame retardant, once it is available in sufficient quantities. ChemSec provides in the report *The bigger picture* a number of illustrative examples of companies that have decided to anticipate regulatory pressure and to undertake substitution[20], although not in direct relation with REACH.
- A big share of the submitted applications for authorisation that have been assessed requested the necessary time to substitute the SVHC with a safer alternative. These applications expressed a clear commitment to substitute within given timelines. Indeed, about a quarter of the opinions have concerned "bridging" applications, where the applicant has identified its substitution strategy and applied for a specific period identifying when the substitution would possibly take place.
- Although suspected, it is not known whether such substances are replaced by others of similar concern, what is often referred to as regrettable substitution. Indeed, Milieu et al found that 35% of companies have substituted at least one substance with a chemical alternative that was subsequently concluded to be of concern and therefore subject to regulatory and non-regulatory pressures. These cases of regrettable substitution, which result in an attenuation of the benefits, are often related to groups of substances with similar chemical structure, such as phthalates, bisphenols, brominated flame retardants and highly fluorinated substances.

Until the end of 2016, 111 applications were submitted by Industry, for which 60 ECHA had adopted an opinion. The socio-economic benefits of the continued use associated to those 60 applications amount to EUR 4.6 – 6.4 billion per year for an annual use of up to 366 metric tonnes of 17 different substances, to be compared to monetised health impacts in the range of EUR 230 – 340 million per year[21]. Even though the specific benefits and risks figures can vary substantially between substances and between uses of the same substance, which led to the case-specific approach as established by REACH, it seems obvious that the socio-

[20] The bigger picture, assessing economic aspects of chemicals substitution, ChemSec, 2016

[21] Socio-economic impacts of REACH authorisations – a meta-analysis of the first 100 applications for authorisation, European Chemicals Agency (ECHA), September 2017

economic benefits of continued use of the substances authorised so far clearly outweighs the monetised risks (i.e. by a factor of circa 14:1).

Whilst it is too early to quantify the overall benefits of the Authorisation process as a risk management option, a good estimate is given by the benefits associated to reducing the exposure to carcinogenic substances at work since occupational cancer concerns 91% of the 60 first applications received by ECHA (Arsenic oxides, Chromium (VI), dichloroethane, Lead Chromates and trichloroethylene). From a broad perspective, a report by the RIVM estimates the direct costs of work-related cancer to be at least EUR 4 – 7 billion per year in terms of healthcare and productivity losses, and the indirect costs as much as EUR 334 billion[22]. The 2017 Commission Communication "Safer and Healthier Work for All"[23] announcing the results of the REFIT Evaluation exercise of the OSH legislation concludes that occupational cancer caused by the exposure to carcinogenic substances is the first cause of work-related deaths in the EU, with 91 500 – 150 500 people exposed to carcinogenic substances at work having being diagnosed with cancer in 2012, and 57 700 – 106 500 cancer deaths attributed to work-related exposure to carcinogenic substances in that same year.

The Commission impact assessment accompanying the first and second amendments to the Directive on carcinogens or mutagens at work[24] provides quantified figures associated to specific carcinogenic substances. Accordingly, about 91 700 workers in the EU were exposed to Chromium VI compounds in 2006. The Commission proposal of an occupational exposure limit value of 0.025 mg/m^3 for all chromium compounds, which was expected to avoid 1 810 work-related cancer cases during the period 2010-2069, will provide estimated benefits in the range of EUR 591 million – 1.7 billion.

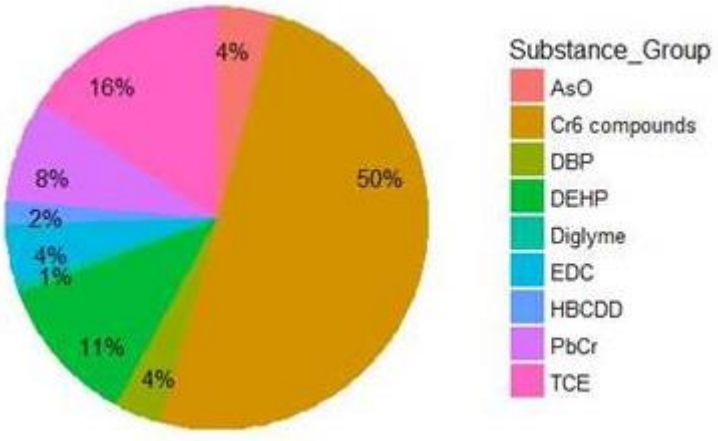
- Chromium VI compounds are listed in Annex XIV of REACH and manifold applications have been received for its use. As a matter of fact, 50% of the 60 first applications received by ECHA concern Chromium VI compounds, with an estimation of circa 186 000 workers and 60 000 locals exposed, and 73 excess cancer cases per year. The exposure limit values for the authorisation decisions adopted so far for Chromium VI compounds are set between 0.001 and 0.002 mg/m^3, 13-25-fold stricter than the occupational exposure limit value by the OSH regulation.
- For trichloroethylene (TCE), the occupational exposure limit value set by OSH legislation is 54.7 mg/m^3, with associated health cost savings expected to be EUR 118 – 430 million for the period 2010-2069. The exposure limit values for the authorisation decisions adopted so far for TCE, the second most numerous substance applied for, with 16% of all applications received so far, are set between 0.2-33 mg/m^3.

[22] Work-related cancer in the European Union: size, impact and options for further prevention, RIVM, Jongeneel W.P. et al, May 2016

[23] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "Safer and Healthier Work for All - Modernisation of the EU Occupational Safety and Health Legislation and Policy" COM/2017/012 final, January 2017

[24] Link to Directive 2004/37/EC

Figure 5.1: Distribution of the substances applied for (until March 2017)



Source: ECHA, 2016

These two substances alone account for 66% of the 60 first applications received by ECHA. It can thus be reasonably assumed that the more stringent limit values provided for by the REACH authorisation decisions will allow additional benefits in terms of protection of workers[25], through the reduction of occupational cancer cases alone. Also, some of the substances with carcinogenic classification are classified as well under other hazard classes (e.g. Chromium VI compounds are also classified as mutagenic 1B), so there may be further benefits.

The limit values set out in the individual authorisation applications, concern only those companies that have applied for and have been granted with an authorisation. It can be assumed that the rest of the companies (i.e. those not having applied or having been rejected the authorisation) have either ceased the use of the substances and/or replaced them by (non-classified or safer) alternatives, which would presumably signify further benefits.

There is also evidence that companies are improving their risk management measures as a result of the authorisation process, which is a clear direct indicator of the benefits of the Authorisation process.

1.9. The benefits of the 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[26] 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 for

[25] To consider that intermediate use is not covered by REACH authorisation but limit values are attributed under OSH

[26] This number includes restrictions submitted and adopted during the reference period (January 2011 - December 2016): Chromium VI in leather articles, Dichlorobenzene (DCB) in toilet blocks, lead in consumer articles, Nonyphenol ethoxylates (NPE) in textiles, cadmium in paints, ammonium salts in cellulose insulation materials, Bisphenol A (BPA) in thermal paper, DecaBromoDiphenylEther (DecaBDE) , PefluoroOctanoic Acid (PFOA) and its related substances

thousands of consumers and workers (compared to an estimated cost of about EUR 170 million per year) [27].

The two restrictions on the use of DecaBDE and PFOA and PFOA-related substances adopted in 2017 are of particular interest given their broad scope and their large environmental implications (the two substances are PBT). The Socio-Economic Assessment Committee (SEAC) assessed the proportionality of both restrictions based on the volumes of emissions they would avoid (4.74 and 40.9 tonnes per year respectively) and of their cost-effectiveness (the cost of avoiding the emission of one kilo was assessed to be of, respectively, EUR 464 and EUR 1 649), supplemented with a number of additional qualitative arguments, and concluded it was similar to that of previous restricted substances (e.g. Hg, Phenyl-Hg compounds), hence that they could both be considered as proportionate to the risk.

Another relevant example, given its direct effects on consumers, is the restriction of chromium (VI) in leather articles that applies since May 2015, which has been estimated to enable approximately 1.3 million people with chromium allergy to use leather articles without fear of symptoms and to avoid approximately 10 800 new cases of chromium allergy in the Union each year. The benefits, in terms of avoided healthcare costs, productivity losses (due to lost working hours) and avoided suffering (the willingness to pay for avoided allergy and symptom days) amounts to an estimated EUR 350 million per year.

Finally, the restriction of polycyclic aromatic hydrocarbons (PAHs) on articles for the supply to the general public, which was adopted in 2013 following the "simplified procedure" for restrictions (article 68(2) of REACH), is of especial significance for its main purpose was to prevent the exposure of children to these carcinogens.

1.10. Regulatory risk management measures for chemicals

In REACH, the restrictions adopted according to Article 68(2) are 'generic risk' based management decisions[28]. Based on the hazard assessment leading to the classification of a substance as a CMR category 1, Article 68(2) allows the Commission to propose restrictions addressing the use by consumers of the substance as such or in a mixture or in an article. The justification for such a restriction is based on the generic considerations that:

- in the EU there are 500 million consumers whose use of a substance is impossible to control and therefore gives rise to significant uncertainties about the level of exposure and the consequent risk;
- the CMR category 1 properties are the most severe concerning human health;

[27] Based on ECHA's Study 'Cost and benefit assessment in the REACH restriction dossiers' published on April 2016, the figures herein are adjusted to the nine adopted measures only. These figures include only the quantified and monetised benefits and costs, and thus do not represent the absolute value of the benefits and costs of the adopted restrictions. The benefits and costs figures presented in the ECHA report (benefits of over EUR 700 million, reduction of 190 tonnes of substances of concerns, and costs of about EUR 290 million) differ from the ones presented above as they also include restrictions outside the reference period, i.e. the four restrictions submitted before the reference period and restrictions processed by ECHA but still in the decision-making process of the Commission (NMP, Methanol in windshield washing fluids, D4/D5 in personal care products).

[28] The concept 'generic risk' was first introduced in the roadmap announcing the initiative to carry out an Evaluation and Fitness check on the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries, European Commission, May 2016

- the function of the consumer product containing a CMR will have alternative products without the CMR.

All the other individual risk management decisions are based on 'specific risk'[29], i.e. the chemical safety assessments in the registration, restrictions according to Article 69 and authorisations. The various priority setting mechanisms leading up to individual risk management decisions are either simultaneously combining hazard and exposure (e.g. ECHA's combined screening or the development of the Community Rolling Action Plan according to Article 44) or sequentially (e.g. Article 57 first establishes the hazard and Article 58 combines with exposure for Annex XIV listing).

The hazards of a chemical identified in the REACH registration dossiers are the starting point for all the regulatory work, both evaluation and the risk management action. In the light of the numbers regarding the actual tests conducted against the expectations in 2003, as presented in the Registration part of Annex 4, there is a significant number of chemicals where compliant hazard information may not be available, hence resulting in many situations where reporting on hazard does not enable adequate risk management. As a matter of fact, ECHA's 2017 annual report on the roadmap for the identification of SVHC notes that 540 substances are subject to further scrutiny (substance evaluation, compliance check and/or one of the PBT/ED expert groups) due to questions caused by shortage of related data and that, out of these, ECHA still needs to clarify whether 311 have PBT, ED and/or CMR properties.

Where there is sufficient data to establish the hazards, the risk management work under restrictions and authorisation works, though with the issues identified in the sections on restrictions and authorisation.

The outcome of the public consultation shows that the views are divided on whether the regulatory action should be generic or specific risk-based:

- **Industry respondents favour a risk-based (or specific risk-based) approach to risk management measures**

According to industry respondents, data on exposure and socio-economic considerations should be considered much earlier in the process, to reduce the time between the identification of a substance as an SVHC and the adoption of the risk management measures, avoid unnecessary measures and eventually increase the legal certainty for duty holders. Industry respondents are therefore very much in favour of integrating the RMOA as a compulsory step in the regulatory process.

- **Most non-industry respondents defend and wish to strengthen the current hazard-based (or generic-based) approach**

Non-industry respondents, in particular environmental NGOs, argued, on the contrary, that the inclusion of substances on the Candidate List should remain an independent step, exclusively hazard based, to ensure that all potentially hazardous substances are identified according to the objectives of the SVHC Roadmap. They oppose the RMOA process as they find it shifts the burden of proof back to authorities, and they blame this for the slowing down of SVHC listing and of the identification of PBT/vPvB substances, and called for abandoning

[29] The concept 'specific risk' was also introduced in the above-mentioned roadmap

it or at least not giving it more prominence. Member States did not provide any comment on this issue.

In conclusion, as all individual risk management decisions, except article 68(2), are based on a specific risk assessment and on the consideration of the socio-economic impacts, based on the current assessment there is no need to alter the present system of implementation. The action in the restrictions section concerning efficiencies between the application of Articles 68 and 69 will assess this allocation in detail.

1.11. The application of the precautionary principle

The application of the precautionary principle (PP)[30] in REACH can speed up the achievement of human health and environmental benefits. The PP enables the legislator to adopt a decision, in a faster manner than the standard practices would allow, in order to ensure the protection of human health and the environment when a potential risk has been identified, but cannot be assessed with the normal level of scientific certainty.

The study on the EU efforts to meet the World Summit of Sustainable Development (WSSD) Commitment[31], argues that the application of the precautionary approach under chemicals management needs to be tested in the way the EU currently deals with emerging risks, such as nanomaterials, EDCs and cocktail effects. The outcome of the decision-making process in these areas will indicate to what extent the EU is listening to "early warnings" and adopting precautionary measures. The study also considers that the extent of substitution of hazardous substances is an important element of testing the application of the PP in the context of REACH.

There are a number of different views on the application of PP, in particular:

- Based on a number of case studies the European Environmental Agency (EEA)[32] concluded that the application of the PP has been opposed by strong vested interests in the EU. The EEA calls for stronger public engagement in interpreting risk from emerging issues and greater humility in the face of uncertainty.
- There is no evidence of the PP currently being applied for emerging risks such as nanomaterials, EDCs and combined effects of chemicals. This view is shared by an article looking at the SVHC Candidate List, which considered that precaution plays a limited role in the implementation of REACH[33].

The PP does set out that the initial step, leading to a policy decision applying the precautionary principle, is one of a scientific assessment of the uncertainties in determining a risk. Within REACH, this scientific judgment is made by ECHA and the policy decision by the Commission, in consultation with the Member States in the REACH Committee. The scientific judgment of uncertainties is therefore part of the scientific assessments done at ECHA under:

[30] The PP is enshrined in the Treaty on the Functioning of the EU and its definition and scope are set out in the Commission communication (COM(2000) 1final)

[31] Interpretation of the WSSD 2020 Chemicals, Goal and assessment of EU efforts to meet the WSSD Commitment, European Commission, June 2013

[32] Late lessons from early warning: science precaution and innovation, European Environmental Agency EEA, 2013

[33] Risk and the Precautionary Principle in the Implementation of REACH: The Inclusion of Substances of Very High Concern in the Candidate List, Cristoph Klika, 2015

- Testing Proposal Evaluation
- Compliance Check Evaluation
- Substance Evaluation
- Authorisation
- Restriction

Under the first three, a consideration should be made as to whether there is a concern for the substance and, if so, whether addressing the concern can await the generation of the requested information. For authorisations and restrictions, in the absence of information, a similar consideration of weighing the concern, with the time it would reasonably take to obtain the information and the potential consequences of inaction, would be needed.

Although in the large majority of cases it would be expected that the uncertainties are limited, even though in authorisations and restrictions the risk and the socio-economic committees (RAC and SEAC) pay attention to identify them, there is no evidence that ECHA considers such uncertainties in all processes on a routine basis. In particular, the annual allocation of substances in the Community Rolling Action Plan (CoRAP) for substance evaluation is not ranked according to the level of concern.. It is therefore important to be able to communicate clearly and transparently the considerations given to the level of concern and the time needed to dispel it. Further to this, authorities will be able to make a decision on whether to apply the precautionary principle or not. .

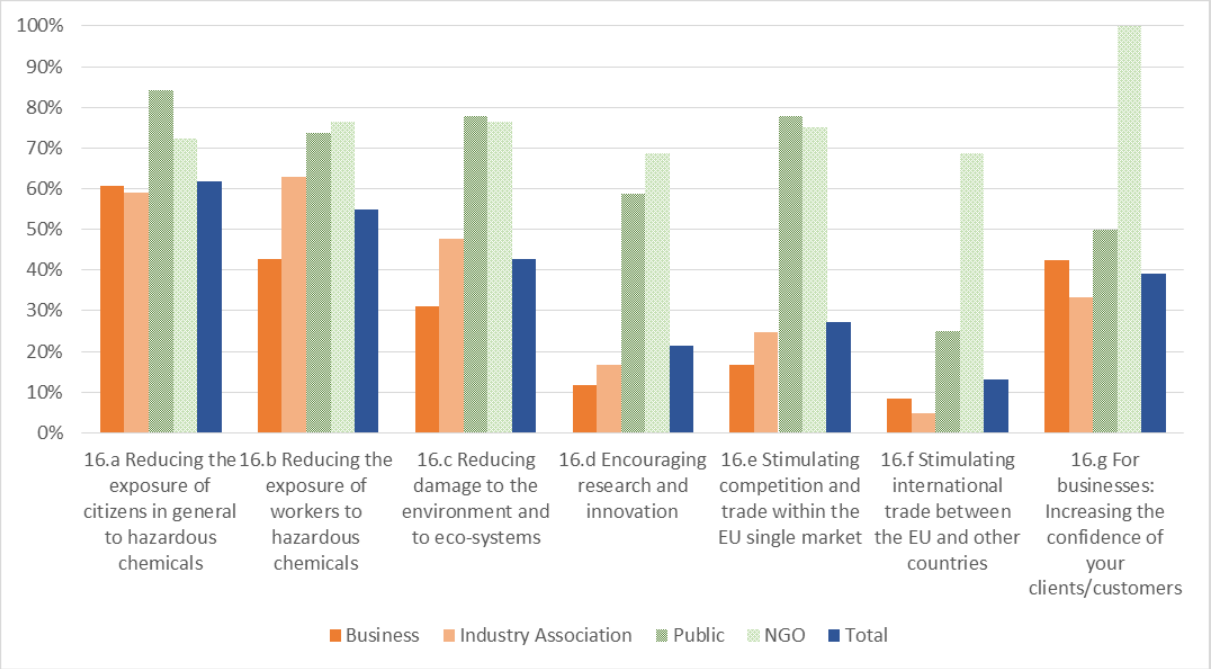
1.12. Results from the Public Consultation

The benefits of REACH are frequently mentioned in the position papers and comments of respondents to the open public consultation by stakeholders from all groups (i.e. industry, public authorities, NGOs, trade unions and other).

The increased knowledge about chemicals properties (i.e. hazards) and uses is the benefit most frequently mentioned. The increased communication in the supply chain is also seen as a benefit. The combination of both leads to increased awareness about chemicals in companies, more accurate choice of products and the adoption of risk management measures. Increased transparency and the dissemination of information on chemicals to the general public is also considered as a benefit of REACH, although mainly for substances as consumer associations and NGOs see a need to improve information to consumers on the safety of articles. Another benefit mentioned by several groups of stakeholders is how REACH has pushed companies to substitute substances of concern and therefore phase out SVHC from the market. Overall, this results in increased protection of human health and the environment, although stakeholders consider it is too early to draw firm conclusions, as evidence of concrete impacts is still not available.

Reducing the exposure of citizens in general to hazardous chemicals, reducing the exposure of workers to hazardous chemicals and reducing the damage to the environment and to the eco-systems are seen as significant benefits by most respondents. In general, trade unions, consumer associations, NGOs and public authorities are more positive than businesses and industry associations in the consideration of benefits generated by REACH.

Figure 5.2: answers to question 16: In your view, how significant are the following benefits generated for society by the REACH Regulation? (percentage of respondents ticking each of the options)



Source: Milieu, 2017

1.13. Conclusions

As foreseen in the Impact Assessment that accompanied the proposal for the REACH Regulation, and reiterated in the 2013 REACH Review, quantifiable benefits of legislation to human health and the environment are difficult to measure.

However, looking at the observable trends so far and extrapolating from current implementation of specific processes and measures (e.g. data availability from the Registration process, dossier and substance evaluations, identification of SVHC on the candidate list, individual restriction dossiers or authorisation applications) leads to the conclusion that the expected outcomes (e.g. generation of new information, introduction of risk management measures) leading towards those benefits are materialising, they are significant and, where quantification was possible, that the aggregated benefits of the legislation offset the costs by a significant margin.

The available evidence at present on the positive trend of classifications and change in self-classifications of substances, the observed gaps in the generation of hazard information, and the current lack of application of the precautionary principle, lead to the conclusion that the benefits of REACH could be further increased.

2 Internal market, competitiveness and innovation

2.1. Scope of this chapter

The changes in the internal market, competitiveness and innovation are all linked, and can be especially felt by SMEs. Strengthening the internal market through harmonisation allows for a more level playing field, lowers costs for businesses and allows for greater economies of scale. A stronger internal market is one of the positive factors for competitiveness, but REACH can also hinder competitiveness, for example, through increased costs for businesses. At the same time, REACH can affect the incentives to innovate, which in the long term underpins the chemical sector's competitiveness.

This chapter looks at all of these aspects in turn but also with an awareness of their interlinkages.

2.2. Conclusions of the 2013 REACH Review

The REACH Review 2013 acknowledged the need for a reduction of the overall costs related to REACH and their impact on SMEs, although industry recognised the positive economic effects for their business.

REACH harmonisation of the internal market was considered a driver for growth and competitiveness of the chemical industry. The 2013 REACH Review acknowledged the vulnerability and insufficient awareness of SMEs, recommending a reduction of the financial and administrative burden on SMEs in order to ensure the proportionality of legislation and to assist them to fulfil their obligations.

Increased communication in the supply chain and substitution of SVHCs were considered drivers of innovation, while the reorientation of R&D expenditure towards regulatory compliance was also noted.

2.3 Developments after the 2013 REACH Review

The REACH Regulation has among its purposes to ensure the harmonisation of the internal market and hereby to reduce the barriers for intra-EU trade. The following section aims to assess the degree of regulatory harmonisation achieved within the chemicals sector due to REACH and the contribution to intra-EU trade.

2.4. Internal market and competitiveness

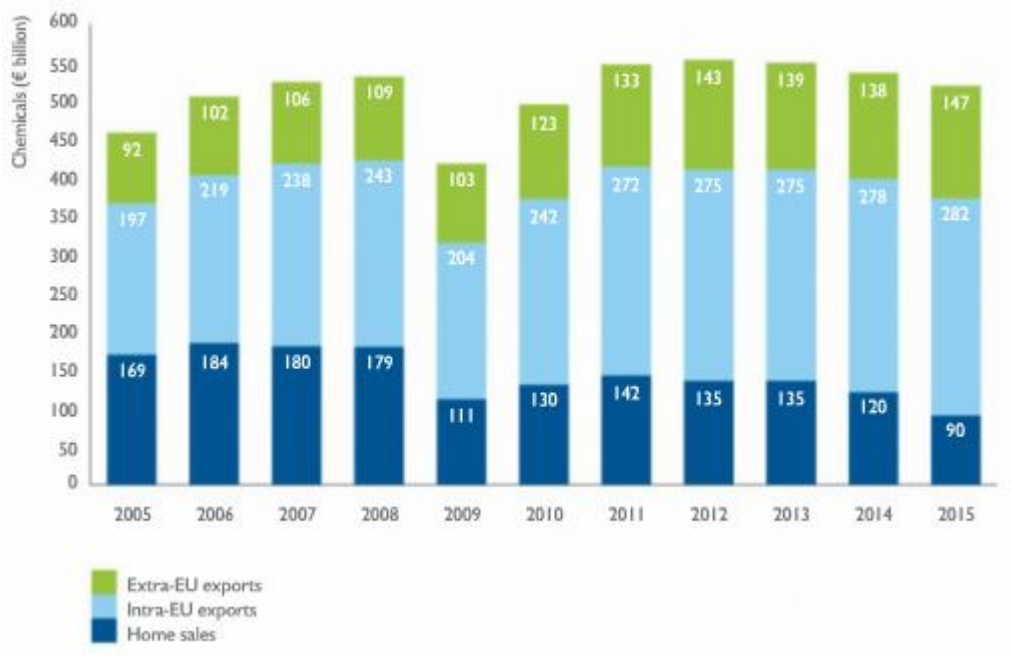
General observations

Europe has a large and integrated market with a customer base of over 500 million consumers. The importance of the internal market is demonstrated by the fact that nearly 50% of all EU chemical sales in 2014 were intra-EU 'exports'[34]. The data show a continuous increase in the intra-EU trade of chemicals over the last decade, strengthened by the removal of trade and non-trade barriers within the EU and the enlargements of the European Union in 2004 and 2007. Total EU chemicals sales were worth EUR 519 billion in 2015[35]. Over time, domestic (home) sales have decreased but a growth in total sales has come with increased exports to non-EU countries. Intra-EU sales (marked as "intra-EU exports" in the graph

[34] European Chemical Industry Facts and Figures Report, CEFIC, 2016, viewed 10 March 2017
[35] CEFIC, chemdata international, 2015

below) increased from EUR 197.2 in 2005 to EUR 282.3 in 2015 – a 43.2 % increase during the last 10 years. How much of this increase can be attributed to REACH or rather to a possible consolidation and diversification of the supply chain is not certain. However, the figures at least suggest that REACH is not hampering the internal market.

Figure 5.3. EU Chemicals Industry Sales



Source: Cefic, chemdata international, 2015

A large majority (80-85%) of respondents to a business survey conducted by CSES with companies from the chemical sector, as well as with their downstream users[36], 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 reported, several companies expressed the view that REACH had made a significant contribution to the harmonisation of European chemicals legislation / integration of the single market and important benefits could be gained from further harmonisation. The industry representatives also flagged in this business survey the need for further efforts to make market surveillance and enforcement practices more aligned across Member States. One of the main reasons for the perception of not fully effective enforcement, as identified by respondents, was a difference in approaches followed by Member States' enforcement authorities in terms of inspections and the relative resources (quantity and quality) allocated to ensuring compliance with REACH.

Effects from specific REACH processes

The Impact Assessment of the REACH Regulation anticipated concentration as manufacturers/importers removed some of their substances from their portfolios. Although 38% of respondents to the public consultation for the REACH REFIT 2017 Evaluation considered that the fees and charges for the registration of substances are adequate, according to the replies provided to the business survey (CSES et al, 2015), the overall registration costs

[36] Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs, CSES et al, commissioned by the European Commission, 2015

appear to be the main driver for withdrawals: almost one third of companies (including downstream users) reported being affected by a withdrawal of a substance from the market due to registration costs.

Inevitably, this situation has an influence on the R&D priorities and on the operational patterns of the concerned firms. Out of those companies that had faced a substance withdrawal, two thirds indicated that as a result they carried out research to identify an alternative substance, while a third of those companies changed their manufacturing process to substitute the withdrawn substance. The study (CSES et al, 2015) indicated a lower rate of withdrawal – approximately 16% of companies with downstream users' role have experienced withdrawal of substances from their suppliers. There are clear differences in answers depending on the position of companies in the supply chain and their role under REACH. The respective shares were 32% among formulators and much less among suppliers of articles (8.4%) and end users (5%). 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 of design of the own products.

These results show that, as part of the registration process in 2013, companies may have revised their portfolios by withdrawing substances based on economic considerations (after factoring in under their profitability the costs of registration, but also because of their undesirable hazard profile). The CSES study found that the substances withdrawn due to economic reasons were mainly specialty chemicals produced in small tonnages and with low profit margin. Although the surveys of industry show that individual companies may have been affected to some extent by the withdrawal of substances, there is no evidence of any major negative impact at EU scale resulting from the non-availability of substances.

The estimate of the total registration costs for the 2,998 phase-in substances registered in 2013 is EUR 459 million (CSES et al, 2015)[37], which is within the range predicted by the Extended Impact Assessment (ExIA) accompanying the REACH proposal[38]:

Table 5.2: Estimation of the total costs for the 2013 registration deadline

Concept	Cost (€ million)
Registration	248
Safety Data Sheets (SDS)	109
Testing / information	101
Total Costs	459

Source: CSES et al, 2015

The statistical average cost (per substance) of registering, testing and preparing the SDS was estimated to be around EUR 153,000 and the average per registrant around EUR 69,000.

[37] Registration costs include external costs such as ECHA fees, costs of participation in SIEFs/consortia, letters of access, consultants paid and any internal costs (e.g. wages and other human resources, travelling) directly linked with the registration process

[38] The impact of REACH on the environment and human health, DHI, commissioned by the European Commission, September 2005

However, the variation around these averages is wide[39], as costs depend on a number of complex factors, including the number of registrants, the properties identified, the additional testing required/waived, the amount of test information already available, the number and types of uses, etc.

The study by CSES found that most companies absorbed registration costs rather than increasing the prices to cover the costs. Altering the production (i.e. lowering the volumes rather than separating in smaller business entities) was also a minority response. Around 20% of companies increased their prices in order to recuperate their costs, which suggests that, overall, the REACH registration in 2013 is unlikely to have resulted in a wide ranging increase in prices across all registered substances as other factors, such as oil and gas prices, play a more important role.

As far as the downstream users are concerned, several stakeholders reported that the availability of data on substances has much improved and that the classifications are regarded as more trustworthy. However, the business survey (CSES et al, 2015) indicates that an important share of enterprises remains unaware of their current/impending roles, obligations and tasks under REACH, specifically with regards to the requirements concerning the communication throughout the supply chain[40]. Several gaps in information flow were identified, particularly compliance with the requirements for the Safety Data Sheets, the core communication tool under REACH.

The inclusions of SVHC in the candidate list or into Annex XIV are other important factors that trigger communication at all supply chain levels. About 39% of companies (21% of manufacturers, 42% of downstream users and 54% of formulators) (CSES et al, 2015) received a request from their clients to remove such SVHC from their products.

The Authorisation process is perceived by companies as having a marked impact on competitiveness, innovation and investment decisions. More specifically, the continuous process of including substances into Annex XIV creates regulatory uncertainty for the use of substances, what could be critical to some industrial processes or applications. The costs implied by the necessity to reformulate or implement an alternative could be associated with high costs. (see further details and key figures on direct costs in Annex 4, part on authorisation).

Finally, evidence of a tendency to move commercial activities outside of the EU as a result of listing a substance as SVHCs is rather limited. In the framework of the survey by CSES et al (2015), about 4 % of the suppliers of products with SVHC indicated they moved away from EU-production and a slightly higher share ceased the use of the substance in commercial activities (9%). According to CSES et al, a potential loss of business to the EU economy could be observed for 13 % of the concerned businesses, although it is likely that at least part of this was compensated by the use of alternatives or by moving resources to new business development. Furthermore, industry provided examples during the public consultation that denote their concerns related to the uncertainty and the recurring costs associated with the Authorisation process:

[39] Ranging from EUR 543 to EUR 666 000 (CSES, 2015)
[40] 28 % of industry associations said that the majority of companies are not aware of their REACH related responsibilities

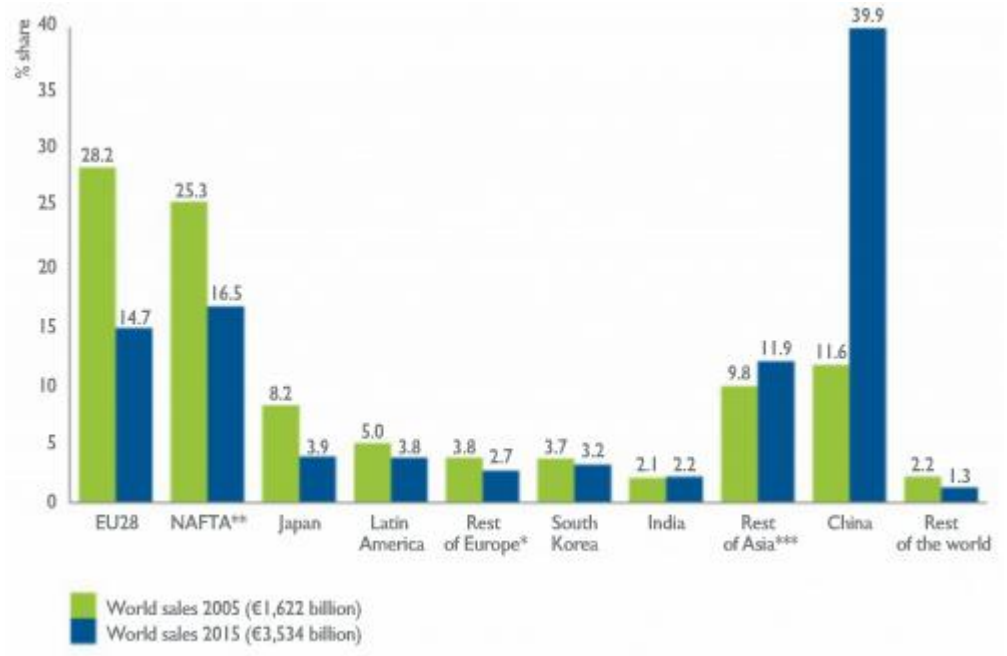
- Examples showing that it may be an important factor behind potential business decisions to relocate affected production activities outside the EU or behind the reluctance from international clients to source such products from the EU.
- In one example provided by industry, the lack of predictability associated with the Authorisation process was an important dissuasive factor for decisions of enterprises to invest in production locations within the EU.

2.5 External competitiveness

General observations

In 2015, China accounted for the largest share in global chemicals sales (40%), followed by the EU28 (28%) and the NAFTA (17%). Global chemicals sales are forecasted to reach EUR 6,300 billion by 2030. According to Milieu et al[41], this expansion will not be evenly distributed across geographical regions; instead, it will be primarily driven by emerging economies, such as China, India and Korea. In these emerging economies, the consumption and production of chemicals is growing faster than the global average.

Figure 5.4: Global chemicals sales: geographical background (2015)



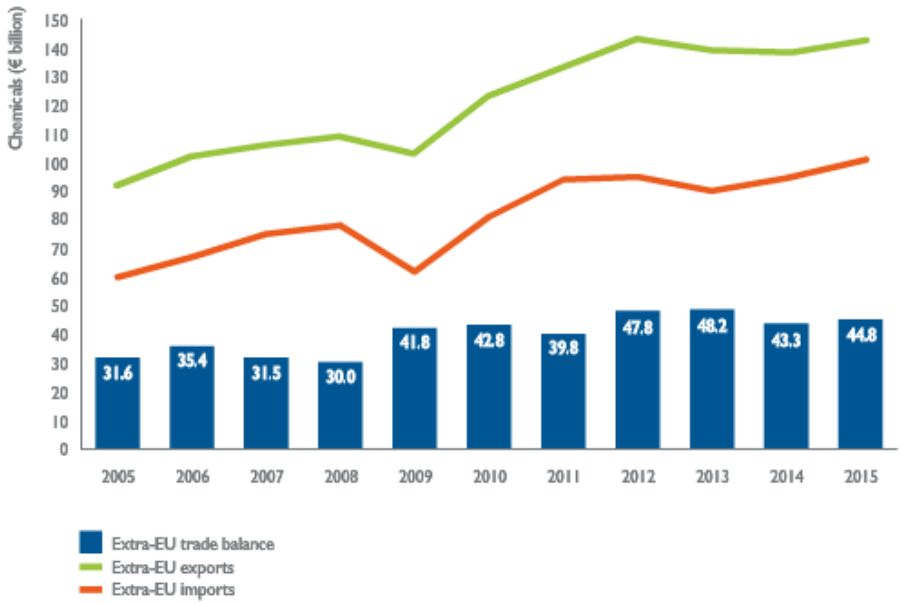
* Rest of Europe covers Switzerland, Norway, Turkey, Russia and Ukraine
** North American Free Trade Agreement
*** Asia excluding China, India, Japan, and South Korea
Source: Cefic, Facts & Figures of the European Chemicals industry, 2016

Over the last ten years, the EU chemicals industry has maintained a significant surplus in its extra-EU trade balance in chemicals. As a result of a solid recovery in the aftermath of the economic crisis in 2008, the trade balance showed clear signs of recovery, reaching over EUR

[41] Study for the strategy for a non-toxic environment of the 7th Environment Action Programme

40 billion in 2015. A sectoral breakdown indicates that the largest part of the surplus came from specialty chemicals (58.2% in 2015), followed by consumer chemicals and polymers[42].

Figure 5.5: Extra-EU trade balance with chemicals

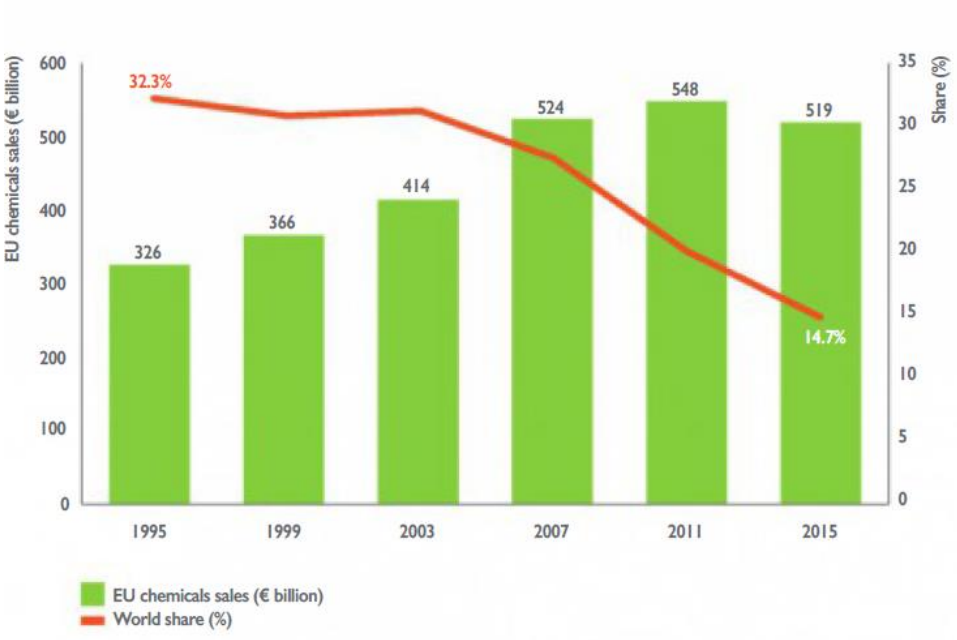


Source: Cefic, Chemdata international, January 2016

At the same time, the share of the EU on the global market has been decreasing over the past 20 years, as a consequence lower average production growth in comparison to other regions. Using a constant-market share analysis of chemical exports at the aggregate and subsector level for the EU and several other large countries that are significant chemical producers, a report by Oxford Economics[43] concludes that, until 2012, the extra-EU export market share has been decreasing over the past 20 years (i.e. including also 10 years before REACH) and that this is due to a declining overall competitiveness. No fundamental changes are expected since 2012 compared to today. The report however acknowledges that quantitative indicators measuring specifically the impacts of chemicals regulation and consistent across countries are not available. The evolution of EU share of global chemicals market over the period 2005-2015 (% of global sales) is illustrated in the chart below.

[42] Cefic, Chemdata international, 2016
[43] Evolution of competitiveness in the European chemical industry – historical trends and future prospects, Oxford Economics, commissioned by CEFIC, October 2014

Figure 5.6. EU share of the global chemicals sales



Source: Cefic, Chemdata international, January 2016

It is to be noted in this respect that the chemical industry is the most energy-intensive manufacturing sector in the EU, accounting for 12% of the total EU energy demand. Oil and gas are vital inputs for the chemical industry, not just as energy sources, but also as principle raw materials for final products. Therefore, raw material and energy costs put the EU at a disadvantage compared with the USA and the Middle East, while it is high labour costs, capital costs and other fixed costs that have the biggest impact on competitiveness in relation to China.

Looking closer at the global export competitiveness, it can be observed that the slow-down in exports may be due to the petrochemicals sector. Indeed, according to McKinsey & Company[44], changes in oil prices have immediate and significant impact on the cost structures of key chemical building blocks. The decline is thus closely linked to the oil refining industry, which has suffered hugely recently due to energy prices being driven by the supply of shale oil and gas in the US[45] and, more recently, by decisions taken by Middle Eastern producers to maintain very low prices in response to the growing shale oil and gas sector in the US.

Effects from specific REACH processes

The business survey (CSES et al, 2015) provides an indication of how companies perceive the broader impacts of costs associated with REACH on factors influencing their competitiveness vis-à-vis their non-EU competitors. Out of the sample of respondents, 56% reported a negative impact on their operating cost; somewhat lower shares saw a negative impact on the access to raw materials (39%), on the access to markets (28%) or on the availability of human resources (31%). On the other hand, the shares of respondents who identified a positive

[44] Oil-price shocks and the chemical industry: preparing for a volatile environment, McKinsey & Company, 2015
[45] "Will Europe's petrochemical industry follow the fate of oil refining?", by Nandita Lal, 10 January 2014

impact were significantly lower (less than 1-5% in all these categories). There were, however, substantial differences in perception depending on the role of the respondents under REACH. Examining the responses by role, distributors tended to have the most negative view, while article suppliers considered REACH more often as either not relevant or not having any particular effect. For example, with regards to the impact of REACH on external competitiveness, nearly three quarters of manufacturers and exporters of chemicals were of the view that the effects were negative, while 59% of the article suppliers considered them as (rather) positive.

These results should be interpreted in the context of the differences or similarities between regulatory regimes of the EU and its main trading partners. While the corresponding pieces of legislation in third countries (e.g. South Korea or China) have partly followed the EU pattern, REACH is considered (one of) the most advanced regulations in a global perspective and it tends to set the highest standards globally. A comparison with respect to the costs of registering new chemicals in different countries was provided in a thematic study comparing the impacts of REACH and corresponding legislation (ECSIP, 2016)[46]. The available evidence from this study shows that the costs of putting a new chemical on the market under REACH is somewhere in the middle of the cost range in the other assessed countries (i.e. South Korea, China, USA, Canada and Japan).

Apart from the Registration costs, the business survey (CSES et al, 2015) conducted among downstream sectors revealed that the biggest concern about external position relates to the control of SVHCs. The Authorisation mechanism often requires adopting costly changes in the production processes in order to allow for the use of alternative chemicals. This is perceived by EU Industry as a clear competitive disadvantage vis-a-vis the companies from third countries non-subjected to Authorisation obligations.

Another conclusion of the study comparing the impacts of REACH and the corresponding legislation in third countries is that European companies do not see compliance with REACH as a competitive advantage in global markets. Being compliant generally does not imply that less effort is required in other jurisdictions, since the standards and requirements are different (e.g. requirements for testing). This conclusion concurs with the results of the business survey (CSES et al, 2015), where only a minor share (3%) of firms indicated a positive impact of REACH in relation to the opening of new markets outside the EU, while in most cases REACH was not considered as having a particular impact.

With regards to the link between REACH and international trade, a quantitative modelling applied in the study of ECSIP indicates that the registration costs of REACH might have had some impact on the external competitiveness of the chemicals industry, most notably by potentially inducing a negligible decline of the EU exports of chemicals (-0.01% of the value of the sector's total exports), if compared to a situation where REACH would not have existed. However, due to the limitations of the quantitative modelling (difficulties to establish counter-factual scenarios), no firm conclusion could be drawn on the extent to which the recent development of external trade could be attributed to REACH. One of the reasons for difficulties with such an assessment is that the trade flows between chemical and downstream chemical user companies are driven by a wide range of factors other than REACH.

[46] Impacts of REACH and corresponding legislation governing the conditions for marketing and use of chemicals in different countries/regions on international competitiveness of EU industry, ECSIP, 2016

Furthermore, there might be significant differences between sectors in terms of the impact on the operational patterns due to the REACH legislation[47].

On the other hand, the survey among downstream users[48] provides an indication that REACH, especially in connection with the uncertainty associated with the listing of SVHC in the candidate list and Annex XIV, might have been among the factors affecting investment decisions of competitors from third countries, both for the chemicals sector and for the three downstream sectors (rubber and plastics, textiles and motor vehicles) included in the study. However, the observed relocation and investment trends could not be attributed directly or exclusively to REACH because, as the survey showed, the costs related to chemicals regulation were only one among many considerations.

2.6. Innovation

General observations

One of the key objectives of the European Commission is to ensure that 20% of the EU total GDP comes from industry by 2020[49]. The chemicals industry is one of the most R&D-intensive manufacturing sectors in advanced economies. As an input provider for other industries, it is indeed considered to be at the forefront of innovation and a solution provider for many societal and environmental challenges.

The effects of the REACH processes on innovation are complex. On the one hand, Regulation may have a negative impact on the resources that companies make available for R&D and innovation activities as illustrated below. For example, the business survey (CSES et al, 2015) shows that, from the specific viewpoint of companies, REACH would not provide an incentive for innovation, in the sense of improving their competitiveness in comparison to non-EU competitors. This can be illustrated by the finding that 35% of respondents perceive a negative impact of REACH on their capacity to innovate, compared to only 11% who perceive a positive impact.

On the other hand, according to the 'Porter hypothesis', stricter environmental legislative requirements may encourage companies to redirect their priorities to an increased allocation of resources to their research programmes, thus acting as a trigger for innovation towards sustainability, what may provide first movers with competitive advantages to the EU industry[50]. Indeed, although not directly attributable to REACH, the Danish industrial association Dansk Miljøteknologi claims that "the EU legislation is a driver for the countries' willingness to invest in new technology", thanks to which Danish companies are able to export between DKR 15-20 billions (circa EUR 2-3 billions) of environmental technology every year[51]. As a matter of fact, for about a quarter of respondents to the business survey (CSES et al, 2015), the implementation of REACH would have led to an increase in R&D activity and, for the industry stakeholders consulted in the framework of the study for a non-

[47] Operational patterns include e.g. decisions on localisation of production and on entering new markets

[48] Impacts of REACH and corresponding legislation governing the conditions for marketing and use of chemicals in different countries/regions on international competitiveness of EU industry', ECSIP, commissioned by the European Commission, 2016

[49] A Stronger European Industry for Growth and Economic Recovery Industrial Policy Communication, European Commission, 2012

[50] As acknowledged by Innovation in the chemicals sector and the new European Chemicals Regulation, World Wide Fund (WWF), 2003; Driving Innovation – How stronger laws help bring safer chemicals to market, Centre for International Environmental Law (CIEL), 2013; and Policy Brief on Green growth, Organisation for Economic Co-operation and Development (OECD), 2014

[51] "Dansk Miljøteknologi: Grønt diplomati kan øge eksporten", Jonas Fredsted Villadsen, 21 March 2017

toxic environment strategy (Milieu et al)[52]. The improved and increased communication in the supply chain required by REACH would have provided for the potential for more innovation, as it provides companies with new information on customer needs, on business development opportunities and more efficient and effective supply chain management practices in the longer term. In a similar vein, CIEL (2013) notes that the implementation of stricter measures with REACH has enabled significantly increased patenting of alternatives by major chemical manufacturers. Furthermore, the improved availability of information and transparency helps downstream users to make better informed choices when developing new or applying existing products, hence can contribute to their ability to innovate.

Effects from specific REACH processes

Among the REACH mechanisms, the Registration process can be assumed to affect the innovation activity in several ways. Firstly, companies may capitalise on the information and knowledge generated as part of the registration process. Secondly, the registration costs (in particular in terms of data generation and sharing) may affect the availability of substances on the market. And thirdly, the need of ensuring compliance with the registration obligations may lead to a re-allocation of resources in the concerned companies from R&D activities to compliance. These assumptions were largely confirmed by the results of the business survey (CSES et al, 2015).

- First, the information generated in the registration process contributed to building knowledge of chemical substances and it contributed to better awareness of the needs of the upstream and downstream value chains. As a result, a conceivable share of respondents (23% overall, with differences according to the role of the company ranging from 16% for manufacturers to 33% for formulators) reported having launched new products or services thanks to the knowledge gained through the compliance process.
- Second, about 54% of the companies that experienced a withdrawal from the market conducted R&D to identify alternative substances. On the other hand, several stakeholders also expressed concerns about the registration costs creating barriers to the entry of new innovative mixtures / substances and low volume research substances into the EU from non-EU / EEA sources due to registration costs.
- Third, the last effect of registration on innovation worked through the reallocation of R&D resources to the registration process. Nearly a third of the respondents reported having reallocated their R&D staff to ensure compliance with REACH, either on a permanent or on a temporary basis, which can be assumed to have reduced their capacity to innovate.

Another mechanism of REACH which affects the scope and focus of R&D activities is the Authorisation process. The results of the business survey (CSES et al, 2015) suggest that already the inclusion of substances into the candidate list and the Authorisation list (steps preceding the requirement to apply for an authorisation to be able to use a substance) work as a driver for research to find alternative substances or technologies. From the sample of respondents affected by the inclusion of a substance in the candidate list, about 9% launched initiatives to develop new substances and 30% launched initiatives to find an alternative formulation[53]. The response of companies to the inclusion of substances in the Annex XIV (Authorisation list) was broadly similar. Milieu et al concluded in the survey of member state

[52] Study for the strategy for a non-toxic environment of the 7th Environment Action Programme
[53] For the remaining 61%, no information is available

competent authorities, industry stakeholders and external consultants within the framework of the study for the setting of a non-toxic environment strategy that the legislative requirements are seen as the main driver of substitution, with respondents indicating that placing a substance on the candidate list for authorisation is the key mechanism that initiates the search for safer alternatives.

The industry stakeholders' survey by Milieu et all found however that, for 85% of the companies obstacles to substitution come from the lack of information on hazards and risks of some of the alternatives as well as the uncertainty concerning the regulatory requirements applicable to those alternatives. Also, some of the interviewed industry stakeholders (CSES et al, 2015) highlighted that the Authorisation process is slowing down the development of products and diverting resources from innovation, which otherwise would contribute to improving the competitiveness, towards the preparation and submission of applications for authorisation. Furthermore, during the workshop organised in June 2016 in the framework of the definition of a strategy for a non-toxic environment, it was highlighted that because the Authorisation process does not cover imported articles, it penalises European companies versus extra-EU, and that once the regulatory action has started, there may be insufficient time to identify and develop suitable alternatives. More generally, NGOs and some Member States pointed to unsatisfactory synergies between chemical legislative acts and to the lack of ambition and speed in the Authorisation process.

Nevertheless, there was consensus that a better enforcement of the legislation would ensure sufficient regulatory signals to investments in innovation and research of safer alternatives by reducing the chances of free-riders to continue operating in breach of legislation. In the same vein, the study of CSES collected some views that the candidate list and other communication instruments (PACT and CORAP list) are increasing the transparency and providing guidance for companies on research and development directions, which in turn may lead to safer and more environmentally friendly chemicals.

As described in further details in Annex 4, part on authorisation, the European Commission and ECHA are aware of industry concerns and have started to reflect on how to streamline and simplify the Authorisation process for specific areas where the Authorisation requirement might impose a disproportionate administrative burden on operators[54].

For instance, CSES et al mentions that substitution is also encouraged by the development of initiatives such as the Substitution Support Portal (SUBSPORT) [55], a project realised in the framework of the European Union's Life programme[56]. The portal aims to provide guidelines to compare and assess alternatives in order to promote substitution. There are also other initiatives focusing on providing assistance to companies (and especially SMEs) in exploring the possibility of substituting hazardous chemicals in products, for example:

- The Eco-innovation observatory[57] funded by the European Commission;
- Norden[58] – Nordic Innovation funded by the Nordic Council of Ministers;

[54] See the Authorisation chapter for further detail

[55] SUBSPORT is a free-of-charge, multilingual platform for information exchange on alternative substances and technologies, as well as tools and guidance for substance evaluation and substitution management

[56] LIFE is the EU's financial instrument supporting environmental, nature conservation and climate action projects throughout the EU

[57] The Eco-innovation observatory of the European Environmental Agency functions as a platform for the structured collection and analysis of an extensive range of eco-innovation information, gathered from across the European Union

- Substitu tion-cmr by Anses[59], the French Agency for Environmental and Occupational Health Safety.

The impacts of those projects have not been quantified.

This raises the question whether the REACH Regulation actually led to creation of new business opportunities. The business survey (CSES et al 2015), as well as a follow-up inquiry among the participating companies, suggested that up to now very few opportunities for business have been created thanks to REACH. Some business opportunities may however arise from increasing awareness of customers and business leaders of product safety. A survey carried out by TÜV Süd in China, India, Germany and the U.S. analysed the perception of product safety among consumers and business decision makers and outlined the trends between 2012 and 2016. The results show that consumers were placing increasing importance on safety when buying different products (children's products, consumer electronics, food and footwear). At the same time, the survey found an increase in awareness within the business community, as well as increasing confidence of business decisions makers that consumers were willing to pay more for a higher level of product safety. The businesses also reported decreasing costs to ensure product safety over time, but this comparison is however only available for the non-EU countries. This, when coupled with the confidence in consumers' willingness to pay a premium for safe products, points to possible creation of business opportunities.

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

Apart from costs and incentives, the length of time it takes from a product since it is conceived until it is available for sale (time-to-market - TTM) can be another critical aspect of the overall innovation process, particularly in creative sectors such as fashion, design, and Information and communications technology (ICT). About half of the respondents indicated that there were not any effects of REACH on the time to bring their products or services to the market, close to 20% found that it had increased TTM by up to six months and 15% reported that the TTM had increased by six months or more.

Another indication 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.

Data from the report on the operation of REACH and CLP (ECHA, 2016)[60] show that there was an increasing trend for the overall number of PPORDs. The PPORD exemption is well used by large companies and allows large-scale research and development without a heavy administrative burden, while ensuring safe use.

Further data from ECHA[61] show that between 5 and 20 new substances are notified every month under the PPORD process and that their number has overall remained constant over the period 2008-2016 (see chart 5.7). The share of PPORD submitted by SMEs is around

[58] Nordic Co-operation funds Nordic projects that boost innovation and competitiveness in the Nordic business sector and lead to commercial and sustainable development

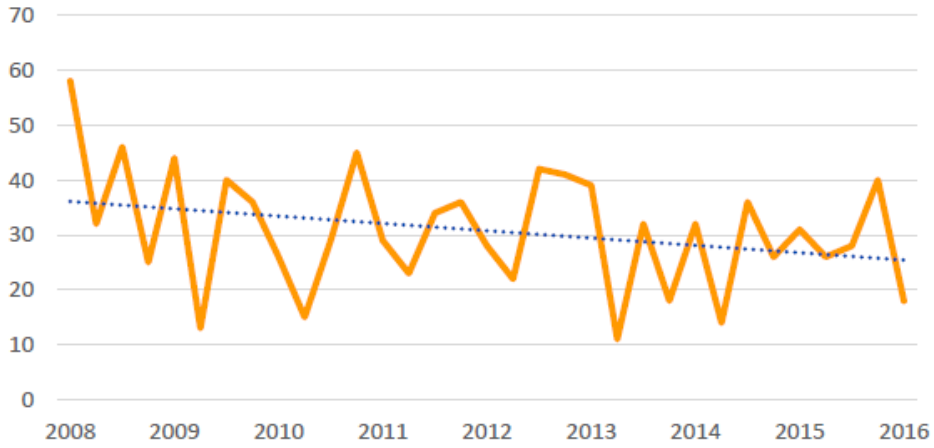
[59] Substitution-cmr website for the diffusion of initiatives, ongoing works and the status of research in the field of substitution

[60] Report on the operation of REACH and CLP, European Chemicals Agency (ECHA), 2016

[61] Monitoring innovation under REACH, European Chemicals Agency (ECHA), 2017

16%, which is comparable to the share of SMEs observed in the registration process, the majority are thus large companies. It should also be noted that, according to the results of the SME panel[62], PPORD is perceived as useful or very useful by nearly half of participating companies, while nearly a third was not aware of this mechanism.

Figure 5.7. PPORD notifications for new substances



Source: ECHA, 2017

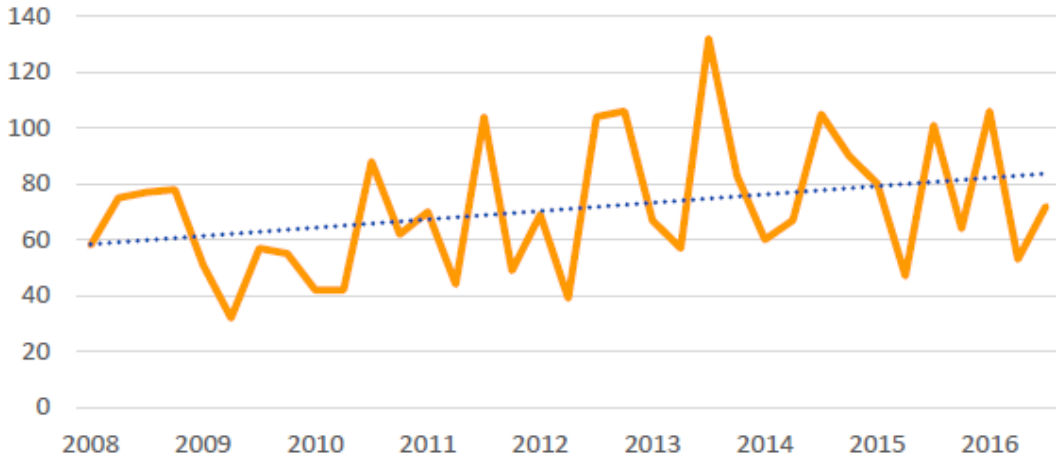
With regards to new substances placed on the market (i.e. substances not listed on the EINECS[63] or the ELINCS[64] inventories), data of ECHA indicate that those are continuously being registered with a steady upward trend. According to the registration statistics provided by ECHA, since the registration of non-phase-in substances under REACH came into force, 1745 non-phase-in substances were registered[65].This amounts to approximately 195 new substances brought to the market every year in quantities above 1 ton per company per year.
Data from ECHA (2017) show that 100 to 150 "new substances" in average have been notified in the C&L Inventory[66] every month during the period 2011-2016, representing about 20% of the total number of notifications. At the same time, data on the number of inquiries according to Article 26[67] suggest a gradual increase in the number of new substances over time (see chart 5.8 below). ECHA concludes that, in comparison with the flow of new substances notified under the previous Directive 67/548/EEC, there is no indication that REACH has negatively changed the previous trend[68].

It is important to note that the majority of PPORD notifications or inquiries for new substances are made by manufacturers (71% and 54% respectively). The proportion of manufacturers inquiring about any substance (whether new or existing) is lower (around

[62] https://ec.europa.eu/eusurvey/publication/REACHrefit
[63] European Inventory of Existing Commercial Chemical Substances
[64] European List of Notified Chemical Substances
[65] ECHA registration statistics (https://echa.europa.eu/regulations/reach/registration/registration-statistics), viewed March 2017. This number includes actually new substances, as well as "existing" substances, which have not been pre-registered. However, it is likely that the latter case is infrequent.
[66] This database contains classification and labelling information on notified and registered substances received from manufacturers and importers
[67] Duty of potential registrant, who have not pre-registered, to enquire from the Agency whether registration has already been submitted for the same substance
[68] ECHA notes however that these figures cannot be easily correlated (taking into account the differences in the tonnage band and in the process)

40%, clearly below the 54%), which would support the idea that manufacturing of new substances mainly takes place within the EU.

Figure 5.8. Article 26 inquiries for new substances



Source: ECHA, 2017

2.8. Perspective of Businesses/Perspective of SMEs

General observations

The main conclusion of the 2013 review concerning SMEs was that 'a significant number of SMEs were unaware about their role and obligations related to REACH, what implied the need for further action to support and guide these companies'. The past review also aimed to discern the impacts REACH registration had on downstream users, the majority of which are SMEs.

It is widely recognised that SMEs face a range of issues as compared to large firms in several fields: access to finance, access to skills and capabilities, access to markets, innovation, etc. The survey and interview conducted with SMEs by CSES et al suggests that there are some areas where SMEs might be differently impacted than larger firms by the requirements of REACH.

Effects from specific REACH processes

The registration costs[69] were estimated to be EUR 459 million for the 2013 deadline (CSES et al, 2015). When referring specifically to SMEs, these estimates show that their registration costs in 2013 (per substance per registrant) were somewhat higher than for large companies[70]. The breakdown also provided an overview of the average costs of the different components of registration. It follows from this analysis that the cost of liaising with downstream users and the costs of producing eSDS were moderately higher for SMEs compared to larger enterprises. This result seems consistent with other findings from the business survey (CSES et al, 2015) in respect of good practice tools and methods for gathering information (for

[69] Registration costs include external costs such as ECHA fees, costs of participation in SIEFs/consortia, letters of access, consultants paid and any internal costs (e.g. wages and other human resources, travelling) directly linked with the registration process

[70] In fact, the costs for SMEs were 5-25% higher than for large companies, depending on the tonnage band

example, it is known that some larger enterprises have developed and applied IT tools to facilitate the communication with their downstream users) and with respect to learning and getting familiarised with the production of extended safety data sheets (eSDS), where it is likely that larger enterprises gained more experience as part of the 2010 registration compared with the SMEs.

The work of companies towards the last registration deadline in 2018 (which will concern substances placed on the market in low tonnages) has started and is expected to involve many small enterprises, many of which will need to go through the learning experience, assuming that they did not yet have to submit registrations at the earlier deadlines. The most recent estimates of registration costs for 2018 for 1 to 10 tonnes substances appear to be in the range of the extended Impact assessment accompanying the REACH proposal (EUR 228 million, compared to the estimate of EUR 295 million). However, the total cost of registering 10 to 100 tonnes substances has been estimated to be significantly higher (up to EUR 1 136 million as compared to EUR 581 million). This may be partially explained by the fact that the estimation is a worst case scenario derived from the assumption that validation and acceptance of negative and positive QSARs[71], grouping and read-across[72] do not occur within the time frame first envisaged. Nevertheless, the registration costs, along with the related uncertainties about the supply and the withdrawal of substances, remain challenges for SMEs. In this context, the sub-sectors where SMEs are largely represented have been voicing concerns that due to their industrial structure (the large share of SMEs and the dependence on imports of low cost low volume substances), such enterprises are particularly vulnerable to REACH compliance costs. Such an example is the one of dyes for the textile and leather industry, where the industry signalled that the costs of registration (the price of the letter of access) are beyond what is affordable for small and micro firms[73]. For this reason, ECHA provided support to the sector on development of scientific methods (read-across and QSAR) that would help to reduce the registration costs. Furthermore, the Commission and ECHA supported development of industry-specific guidance documents for the sector of essential oils in order to clarify the registration requirements.

As regards the effects of the authorisation process, there has not been enough experience yet with regard to SMEs applying for authorisations to allow for a full assessment. The results of the SME panel indicate that some concerns are present among approximately one quarter to one third of SMEs. The preparation of an application for authorisation was seen as a slightly or moderately important challenge by 13% of participants and as a considerable/very important challenge by 19%, while the rest either had no view or did not see the Authorisation process as a challenge. In relation to the costs associated with the application, those are slightly or moderately important for 10% of respondents and considerably or very important for further 15%, while the rest had no view or did not see this aspect as a challenge. Also the business survey (CSES et al, 2015) suggests comparatively less experience of SMEs

[71] Quantitative structure-activity relationship are mathematical models that can be used to predict the physicochemical, biological and environmental fate properties of compounds from the knowledge of their chemical structure

[72] Grouping of substances and read-across is one of the most commonly used alternative approaches for filling data gaps in registrations submitted under REACH. This approach uses relevant information from analogous ('source') substances to predict the properties of 'target' substances. If the grouping and read-across approach is applied correctly, experimental testing can be reduced as there is no need to test every target substance

[73] This is supported by a 2014 study made by Dye-Staff, a group of (mainly Italian) SME dye manufacturers. The study voices concerns that SME dye manufacturers will need to register a very large number (sometimes hundreds per company) of small-volume dye chemicals for the 2018 registration deadline, and that may reduce their substance portfolio and/or put at risk their business viability. Source: Study on the socio-economic impact of registration of the dyes according to REACH Regulation for small and medium-sized Italian companies, Dye-Staff, 2014

with the process given that a bigger share of SMEs than large firms indicated that they had not been affected by the placing of substances on the candidate list.

Like in the case of registration costs, the question can be raised if and to which extent the Authorisation process could affect decisions of companies on their investment decisions or in their decision to relocate or shift part of their production of articles. While relocating and importing the articles without having to comply with the Authorisation requirements could be an option for some companies (specifically for those with manufacturing facilities outside Europe), there is no available evidence that would enable to fully assess the possible relocation of activities by SMEs outside the EU. However, there are examples indicating that the costs and uncertainty associated with the Authorisation requirements were an important factor for some SMEs active in international value chains in deciding to move the sourcing, manufacture or maintenance of specific components outside the EU.

As regards the restriction process, the feedback from the SME panel shows that it is a matter of concern for about half of the respondents (a slightly/moderately important challenge for 27% of the respondents and a considerable/very important challenge for further 23%). The costs (e.g. of replacing a restricted substance) incurred in relation to the Restriction process are slightly or moderately important for 20% of the respondents and considerably/very important for further 17% while the rest had no view or did not see this aspect as a challenge.

Concerning the impact on innovation, the survey identified no significant differences between large firms and SMEs, except for the situation of substances that enter the registry of intentions (RoI), which triggers the restriction procedure, where more SMEs than large firms stated to have withdrawn the substance in question. Similarly, with regard to business opportunities created by REACH, the results are similar as for larger companies, indicating that very few SMEs perceive such benefits for now.

The findings of the study of CSES however suggest that there are some other differences between SMEs and large companies, for example in terms of their perception of the broader impacts of REACH on competitiveness. SMEs tend to see the effects of REACH on the single market in a less favourable light than large firms, but are less concerned than larger firms about the effects of REACH on their competitive position vis-à-vis firms outside the EU. One possible explanation is that SMEs are on average less involved in international trade. Some smaller firms on the other hand might have benefited from REACH when EU-based downstream users switch their purchasing to EU-based REACH compliant suppliers.

Another difference identified is that more SMEs than large firms have very limited experience with eSDS and tend also to be less proactive as regards upstream communications on use mapping, which can be assumed to be due to limited resources.

Lastly, in terms of human resources, smaller firms tend to rely more on external training and external consultants to ensure compliance with REACH. At the same time, more SMEs consider it very difficult to find consultants with the right level of skills and experience (23% of SMEs compared to 13% of large firms).

2.9. Measures adopted to support SMEs

Since the REACH Review 2013, several support measures have been introduced to alleviate the burden on SMEs. Among those, the registration fees were revised and reduced for SMEs (an additional 5% compared to the earlier situation and applicable already for the 2013 registration deadline). Furthermore, an Implementing Regulation on data-sharing was adopted

and entered into force on 25 January 2016; SMEs were expected to benefit considerably from a more fair and transparent framework, as the actual costs of studies are requested to be itemised and disclosed to any potential registrant, and must be clearly separated from administrative and operational costs of a substance information exchange forum (SIEF). The data from the SME panel survey show that the reduction in fees of 2013 is perceived as useful or very useful by nearly half of the respondents (46 %), whereas a quarter was not aware of this measure. Similar feedback was given for the Regulation on data sharing.

Several studies that have been prepared for the Commission, ECHA and Member State authorities looked at the availability and usefulness of diverse support tools. In the run up to the last registration deadline, implementation of support initiatives continued via the implementation of the ECHA's 2018 registration roadmap. A dedicated website[74] with a toolkit to guide companies in the process towards the 2018 registration and a guide for SMEs ("Chemical safety in your business"[75]) have been developed in all EU languages, in order to provide readily accessible information and more user-focus guidance to companies, especially SMEs, about their role and obligations in relation to REACH. Furthermore, support in view of the 2018 registration has been provided to some sectors that are made up mostly by SMEs. Also, for the natural essential oils sector, ECHA and the Commission provided support to the development of two industry guidance documents that clarify registration requirements[76] and will thus help to prevent unnecessary costs and burdens. All those actions have received positive feedback from stakeholders (e.g. through the SME panel) although the impact cannot be assessed at this moment.

Furthermore, ECHA is developing its "Cloud Services", in order to deliver IUCLID functionalities from an ECHA-hosted and managed infrastructure. This will save SMEs resources, who will not have to install the software, organise backups and migrate their data in case of new releases. Moreover, it will enable the ECHA to provide integrated support and help functionalities to companies when preparing registration dossiers. ECHA has estimated that this measure may save over EUR 11 million per year across the industry.

The available support mechanisms have been widely disseminated**,** in cooperation with the Communicators network (Member State representatives) and the Enterprise Europe Network (EEN)[77]. The cooperation between the EEN and national Helpdesks has been reinforced with a view to make use of EEN direct contacts with companies in order to disseminate information about REACH and facilitate companies' access to the services of Helpdesks.

As regards availability and quality of information, the SME Panel shows that a majority of respondents are satisfied or very satisfied with the availability of information about REACH and how that affects their company (56%). However, a considerable share (40%) is not satisfied and only a very small share (3%) is very satisfied without providing further explanations.

The guidance published by ECHA is seen by SMEs as useful (33%) or very useful (49%). Concerning national helpdesks, the respondents were satisfied (42%) or neutral (39%) with the content of obtained replies without providing further details.

[74] https://echa.europa.eu/support/getting-started
[75] https://echa.europa.eu/support/small-and-medium-sized-enterprises-smes
[76] https://echa.europa.eu/support/substance-identification/sector-specific-support-for-substance-identification/essential-oils
[77] The Enterprise Europe Network helps small and medium-sized enterprises (SMEs) by providing them business expertise in and outside the EU

2.10. Conclusions

REACH has contributed to the harmonisation of the chemicals legislation in the EU, while at the same time is likely to have had only limited impact on the intra and the extra-EU trade.

The number of registrations by the 2013 deadline for substances above 100 tonnes, as well as the associated costs, appears to be broadly in line with the estimates included in the Extended Impact Assessment accompanying the REACH proposal. However, concerns about the vulnerability of SMEs to the registration costs remain, as well as concerns about the competitiveness of specific sub-sectors (with prevailing high numbers of SMEs) in view of the continuing withdrawal of chemicals from the market. Specific support by ECHA, the Commission and Member States has been assisting some sectors to mitigate those concerns and prepare for the next registration deadline.

SMEs are more vulnerable due to their limited resources available and therefore the registration obligations and the costs, along with substance withdrawals, remained the main issue for them. At the same time, benefits in terms of business opportunities / incentives to innovate may have not been created.

Overall impacts on innovation are complex. As observed in the REACH Review 2013, on the one hand, for some companies REACH leads to an increase in resources spent on R&D and to the use of the information generated for compliance with REACH for the conception of new products. On the other hand, the need to ensure compliance leads to diverting resources that would otherwise be available for other innovative activities. However, the increased availability of information of substances and the higher transparency enable the users of chemicals to make better choices in the design of products and in their use.

The listing of SVHC in the candidate list or in Annex XIV triggers communication across the supply chain, initiates substitution activities at all supply chain levels, and triggers considerations of reformulation for some products and of withdrawal for some others. The continuous inclusion of new substances in the candidate list and in Annex XIV is however associated with uncertainty and perceived as a challenge for international competitiveness. On the other hand, data confirm that, since the entry of REACH into force, there have been a continuous flow of new substances on the EU market.