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Commission General Report on the operation of REACH and review of  
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Conclusions and Actions

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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**

{SWD(2018) 58 final}

# 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

(Text with EEA relevance)

#### 1. INTRODUCTION

The EU's Regulation on the registration, evaluation, authorisation and restriction of chemicals (referred to as REACH)<sup>1</sup> entered into force in 2007.

REACH puts obligations on industry to collect chemical safety information, to use this information to develop and apply appropriate risk management measures, to communicate these measures to users of chemicals and, finally, to document this in registration dossiers submitted to the European Chemicals Agency (ECHA). ECHA or Member States evaluate if the safety information is sufficient and, if not, require additional information.

REACH also establishes two distinct EU risk management approaches:

- a) *Restrictions* enable the EU to impose conditions on the manufacturing, placing on the market or use of substances;
- b) *Authorisation* is designed to ensure that substances of very high concern (SVHCs) are used safely while promoting substitution by suitable alternatives.

One initial policy driver<sup>2</sup> for REACH was the slow progress in completing EU risk assessments and implementing the risk reduction strategies for existing chemicals<sup>3</sup>. In addition, only 20% of these substances had a publicly available data set allowing a minimum screening for risk assessment. In line with the polluter pays principle<sup>4</sup>, REACH shifted the burden of proof to industry, making it responsible for the safety of chemicals along the supply chain. In addition, authorities should focus on those risks which industry cannot or does not manage appropriately. Protection of the environment and human health was another initial driver for REACH, which was complemented by the objectives of ensuring the free circulation of chemicals in the EU, enhancing the competitiveness and innovation of EU industry and promoting non animal testing methods. The regulatory proposal was developed following a sequence of prior evaluation and impact assessment similar to the policy cycle now applied in the Commission's Better Regulation<sup>5</sup> guidelines.

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<sup>1</sup> Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) OJ L 396, 30.12.2006, p. 1. Corrected version in OJ L 136, 29.5.2007, p. 3.

<sup>2</sup> OECD (2015). Preliminary analysis of policy drivers influencing decision making in chemicals management. Series on Risk Management, No. 28. Document ENV/JM/MONO(2015)21. [Appendix 6 concerns REACH](#)

<sup>3</sup> 100 106 substances marketed in the EU before 1981. These substances are now called phase-in substances.

<sup>4</sup> Article 191(2) of the Treaty on the Functioning of the European Union (TFEU).

<sup>5</sup> [https://ec.europa.eu/commission/priorities/democratic-change/better-regulation\\_en](https://ec.europa.eu/commission/priorities/democratic-change/better-regulation_en)

REACH also contributes to the EU meeting the World Summit Sustainability Development 2020 goal<sup>6</sup>. REACH brought together and aligned the body of chemicals legislation established over the previous decades, replacing 40 different pieces of legislation with a single Regulation.

Member States, ECHA and the Commission are required to regularly report on the operation of the Regulation<sup>7</sup>. The Commission also has to carry out a number of reviews by different deadlines<sup>8</sup>. In 2013 the Commission presented the first report covering REACH's first 5 years of operation and including certain reviews<sup>9</sup>.

The present document is the second Commission report on the operation of REACH. The evaluation has been carried out as part of the programme for Regulatory Fitness and Performance (REFIT) in accordance with the Commission's Better Regulation guidelines<sup>2</sup> and is accompanied by a staff working document<sup>10</sup>. This report also includes three reviews: one on possible registration of polymers<sup>11</sup> and two on minimum information requirements for low tonnage substances (1-10 tonnes/year)<sup>12</sup>.

## **2. FINDINGS OF THE EVALUATION**

### **2.1. Achievement of REACH objectives**

Some 10 years after its entry into force, REACH is fully operational and delivering results towards achieving its objectives. Although progress towards the objectives is lagging behind initial expectations, it has steadily improved as experience was gained.

REACH provides a comprehensive data generation and assessment system for chemicals manufactured and used in the EU, designed to improve the protection of human health and the environment and positioning the EU as frontrunner in achieving the goal set for 2020 at the World Summit for Sustainable Development. REACH has also influenced legislation in third countries (e.g. Korea or China), although significant differences still exist and there is room to further exploit the potential of REACH to serve as a global model for chemicals legislation.

The main direct costs incurred under REACH so far are associated with registration and the communication of information along the supply chain. These are estimated at EUR 2.3-2.6 billion for the first two registration deadlines. Costs have been higher than anticipated (EUR 1.7 billion), in particular for the first registration deadline. Additional costs result from evaluation, authorisation and restrictions. The estimated scale of potential benefits for human health and the environment remains in the order of EUR 100 billion over 25-30 years. The overall costs seem justified by the results observed and the benefits, that are starting to materialise.

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<sup>6</sup> WSSD goal: "By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment".

<sup>7</sup> See REACH Article 117

<sup>8</sup> See REACH Article 138

<sup>9</sup> COM(2013)49 and SWD(2013)25

<sup>10</sup> SWD(2018)58

<sup>11</sup> See REACH Article 138(2)

<sup>12</sup> See REACH Article 138(1) and 138(3)

The evaluation has identified a number of shortcomings and key issues that hamper the achievement of REACH objectives<sup>13</sup>. A number of improvements in the efficiency of the REACH processes have been implemented or are being developed since 2013; nonetheless, further opportunities to improve and simplify have been identified, in particular for extended Safety Data Sheets, evaluation, authorisation and restriction. The issues requiring most urgent action are:

- non-compliance of registration dossiers;
- simplification of the authorisation process;
- ensuring a level playing field with non-EU companies through effective restrictions and enforcement;
- clarifying the interface between REACH and other EU legislation, in particular that on occupational safety and health (OSH) and on waste.

## 2.2. Industry responsibility

Manufacturers and importers responded to the registration obligations for existing<sup>14</sup> substances by completing their registration dossiers on time and with no major disruptions of the market. However, incentives are lacking for companies to update their registration dossiers and work is still needed to rectify important data gaps or inappropriate adaptations to testing. Measures to support SMEs regarding their registration obligations have been effective, though more could still be done.

Compliance with the information requirements by registrants is considered insufficient. This is related to two main causes: (i) the legal requirements to avoid animal testing may push registrants to use alternative methods to animal testing, even if not justified; and (ii) difference in the assessment of hazard between registrants and authorities. In addition, the current approach to evaluation, including ECHA's decision-making procedures, should be further improved.

There has been a continued increase in the information passed through the supply chain, though it needs to be made more efficient (e.g. reduce costs of producing and supplying Safety Data Sheets), especially for SMEs. Improvement is also needed in the ability of companies to develop specific exposure scenarios, in particular for mixtures, and in helping with implementing the obligation to notify substances of very high concern in articles.

REACH applies a tonnage triggered approach to information requirements where higher tonnage leads to more comprehensive testing. It has proven to be proportionate to address substances already on the market. However, evidence suggests that further assessment of the affordability of registration requirements for low tonnage substances and registration of certain polymers could be warranted<sup>15</sup>.

Compared to previous (i.e. pre-REACH) legislation, the broader exemption for research and development activities and the reduced information requirements for new substances below 10 tonnes per year have stimulated the development of new substances.

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<sup>13</sup> For further details, see SWD(2018)58

<sup>14</sup> Existing substances refer to "phase in" substances in accordance with article 3 point 20 of REACH.

<sup>15</sup> Further details see the SWD(2018)58

REACH enables citizens to ask companies whether the articles they supply contain SVHCs, but this provision has had limited use. Where it is used, companies struggle with its implementation.

Authorisation is meeting its objectives to ensure proper control and foster substitution, where economically and technically feasible alternatives exist. Implementation should further gain in efficiency and aim to further reduce the administrative burden and business uncertainty for companies applying for authorisation, in particular for SMEs.

The authorisation requirements could be harming the competitiveness of EU companies because articles imported to the EU are exempt from the authorisation obligations. A better coordination and synchronisation of actions when enacting authorisation and restriction could further improve implementation.

### **2.3. Action by Member States and the Commission**

Member States have used their right to initiate actions under evaluation, authorisation and restriction, but insufficient resources reduce their activities. This reduces the number of substances that are assessed and regulated and slows down the process. Member States should ensure a more effective and harmonised enforcement of REACH, whereas the Rapid Alert System (RAPEX) ensures consumer products safety. While improvements have occurred through concerted efforts in ECHA's Forum<sup>16</sup>, national enforcement activities should be reinforced, including controls on imported goods.

The work under the SVHC Roadmap<sup>17</sup> is progressing beyond expectations. Most of the substances with confirmed SVHC properties have now been assessed, for example those which are persistent, bioaccumulative and toxic (PBTs) and carcinogenic, mutagenic and toxic for reproduction (CMRs). Addressing data gaps from registration and improving substance evaluation will enable identification of new SVHCs; at the same time, applying assessment of groups of similar substances could further speed up the process.

The restriction procedure is generally working, though further improvements in efficiency are needed, as proposed in the actions below.

When analysing the coherence between REACH and other EU legislation, some critical elements have been addressed by the Commission<sup>18</sup> in the interface with the Directive on the restriction of hazardous substances (RoHS)<sup>19</sup> and the Regulation on persistent organic pollutants (POPs)<sup>20</sup>. The interface between REACH and OSH legislation calls for systemic solutions to address the main overlaps and discrepancies.

Information needs for nanomaterials are currently being addressed by proposed amendments to the REACH Annexes. Furthermore, the Commission supports research into development of alternative methods<sup>21</sup> and promotes the use of human biomonitoring in chemical risk

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<sup>16</sup> Forum for the Exchange of information on enforcement.

<sup>17</sup> [Roadmap on Substances of Very High Concern](#), February 2013.

<sup>18</sup> [http://ec.europa.eu/growth/sectors/chemicals/reach/special-cases\\_en](http://ec.europa.eu/growth/sectors/chemicals/reach/special-cases_en)

<sup>19</sup> Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

<sup>20</sup> Regulation (EC) No 850/2004 on persistent organic pollutants, implementing the obligations of the Union under the Stockholm Convention.

<sup>21</sup> Further details see Annex 4 of the SWD(2018)58

assessment and management through initiatives such as the European Human Biomonitoring Initiative<sup>22</sup> and the Information Platform for Chemical Monitoring<sup>23</sup>.

## 2.4. ECHA

ECHA has been instrumental in the implementation of REACH and has now built up a significant competence in chemicals management. ECHA has established a user-friendly website enabling stakeholders to easily access the world's largest database on chemicals. ECHA has also established scientific cooperation with the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA), as well as with other non-EU agencies, which should be further reinforced to ensure coherence and profit from synergies.

Around 2020, the fee income of ECHA will be substantially reduced<sup>24</sup> and the Commission will need to assess how to maintain ECHA's expertise and independence, including the scrutiny of working methods of the committees and mitigation of conflicts of interest.

## 2.5. Potential for simplification and burden reduction

Overall, the REACH evaluation has not identified unnecessary legal requirements and obligations given the needs and objectives pursued. There is a margin for simplification and burden reduction in the way those requirements are implemented and in particular for clarifying how they are to be fulfilled by the duty holders. However, simplification should not incur reductions in the level of protection of human health and the environment.

Some margin for further simplification has been identified in several areas in relation to the information requirements, the extended Safety Data Sheets, the process to apply for authorisation and the requirements for substances in articles. Appropriate actions are set out in the following chapter.

## 3. ACTIONS

### 3.1. Knowledge and management of chemicals throughout the supply chain

The lack of information on existing chemicals was one of the two main policy drivers triggering the development of REACH. Since the entry into force of REACH, more information on the properties and uses of chemicals (e.g. by December 2017, ECHA received 65 000 dossiers for approximately 17 000 unique registered substances) is available and being used for the assessment and management of chemical risks. In spite of this positive trend, the lack of compliant information in the **registration** dossiers hampers the functioning of other REACH processes and slows down the achievement of the REACH objectives for human health and environment.

The efficiency and effectiveness of the **evaluation** procedures, implemented by ECHA, its Committees, the Member States and the Commission, need to be improved. This will provide stronger incentives for companies to update and bring into compliance their registration dossiers as required by REACH.

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<sup>22</sup> HBM4EU

<sup>23</sup> IPCHEM

<sup>24</sup> Following the last registration deadline of 2018

**Action 1:** *Encourage updating of registration dossiers*

The Commission in collaboration with ECHA, Member States and industry will identify why registrants are not updating their dossiers and make proposals for improvements by first quarter 2019, as appropriate.

**Action 2:** *Improve evaluation procedures*

ECHA is requested to significantly increase the efficiency of the evaluation procedures by 2019 by:

- (1) identifying the main reasons for non-compliance of registration dossier and developing remedies;
- (2) where appropriate, applying the various evaluation procedures in parallel;
- (3) systematically implementing a grouping approach<sup>25</sup>, where this is possible;
- (4) improving work-sharing across evaluation activities with Member States; and
- (5) improving decision-making procedures.

REACH extended the already existing Safety Data Sheets by adding so-called exposure scenarios. This has led to improvements in **communication** and more transparency in the supply chain. However, many companies, in particular SMEs, find them too technical and burdensome. In addition, the poor quality of exposure scenarios is an obstacle to providing safety information for mixtures.

**Action 3:** *Improving the workability and quality of extended Safety Data Sheets*

- (1) The Commission encourages more industry sectors to develop and use harmonised formats<sup>26</sup> and IT tools that would provide more user-targeted information and simplify the preparation and use of extended Safety Data Sheets as well as facilitate their electronic distribution.
- (2) The Commission will consider including minimum requirements for the exposure scenarios for substances and mixtures in Safety Data Sheets and request ECHA to develop a methodology for Safety Data Sheets of mixtures.

The need to better track chemicals of concern in materials and products in order to facilitate recycling and improve the uptake of secondary raw materials is discussed in the chemical product waste communication<sup>27</sup>, one of the deliverables of the Circular Economy Action Plan. Such tracking could also address the current difficulties for actors in the supply chain to fulfil the requirements for SVHCs in articles<sup>28</sup>.

**Action 4:** *Tracking substances of concern in the supply chain*

The Commission will gather evidence and assess options to address the challenges related to substances of concern, as discussed in the chemical product waste communication. The assessment will consider, among others, whether and how a tracking system could contribute to improve the workability of information requirements for SVHCs in articles.

<sup>25</sup> Assessment of groups of substances with similar properties instead of individual ones

<sup>26</sup> As those developed by the Exchange Network on Exposure Scenarios (ENES)

<sup>27</sup> Options to address the interface between chemical, product and waste legislation COM(2018) 32 final and SWD(2018) 20 final

<sup>28</sup> Articles 7 and 33 of REACH



### 3.2. Enhanced risk management

The slow progress of risk assessment and implementation of risk management for existing substances was another main driver triggering the development of REACH. Improved risk management measures have been introduced in companies as a result of the registration and authorisation requirements. The restriction and authorisation processes still need to be implemented more efficiently and with quicker decision making.

The implementation of the SVHC roadmap and early assessment of possible regulatory measures through a voluntary regulatory management option assessment (RMOA) is proving an effective tool to ensure that, by 2020, all known relevant SVHCs are identified, along with possible regulatory measures. The focus of SVHC identification is moving towards substances that require a case-by-case assessment of the equivalent level of concern condition<sup>29</sup>. The Commission, together with ECHA and Member States, will ensure that criteria for such identification are developed and applied in a consistent manner.

Moreover, the authorisation process is seen as an effective driver for substituting SVHCs along the supply chain, although efforts must be stepped up to promote substitution of SVHCs, in particular among SMEs.

#### **Action 5:** *Promote substitution of SVHCs*

The Commission, ECHA and Member States will step up support activities to facilitate substitution of SVHCs. Such activities may include the promotion of capacity building and collaborative networks and promoting R&D investment (EU, Member States resources) in sustainable chemicals and technology innovations.

As **authorisation** has become operational, a number of practical challenges and concerns have emerged that needed to be addressed. The ongoing efforts to simplify the authorisation process should continue with a view to clarifying the requirements and make the process more workable and more predictable for applicants.

When carrying out a RMOA, evidence is necessary to understand the practical workability of possible regulatory measures (authorisation or restriction) to inform the decision-making process. This includes available socio-economic information such as the known uses, number and size of actors involved in the supply chains as well as available information about technical and economic feasibility of possible safer alternative substances or technologies.

#### **Action 6:** *Simplification for a more workable authorisation process*

The Commission will continue to make the application for authorisation process more workable for operators, including for SMEs by:

- (1) simplifying the applications for continued use of SVHCs in legacy spare parts<sup>30</sup> and further considering the case of low volume applications in 2018;
- (2) closely monitor and address difficulties related to applications for authorisation covering multiple operators;

<sup>29</sup> In accordance with Article 57(f) of REACH

<sup>30</sup> Uses of SVHC to produce legacy spare parts for repairing articles no longer produced after the sunset date (e.g. aircraft and motor vehicles)

(3) reducing fees for applicants in joint applications for authorisation while balancing the fee levels per use in order to better reflect the workload for ECHA committees in 2018.

**Action 7:** *Early socio-economic information for possible regulatory measures*

ECHA in co-operation with the Commission and Member States will consider options to further develop and use available socio-economic information for consideration at the RMOA stage.

The number of new **restrictions** has so far not met the original expectations. Although the process has improved as a result of the actions initiated after the 2013 REACH review, there is room for further improvement in particular to identify relevant candidates for restriction and to increase Member State involvement.

**Action 8:** *Improve Restriction Procedure*

(1) ECHA is requested to clarify the information needed from the public consultations, including the minimum information to be submitted by industry when requesting derogations (time-limited or not) from restrictions.

(2) ECHA is requested to identify relevant cases for restriction as part of its regular screening activities, considering also substances for which only national legislation exists.

(3) The Commission will continue its efforts to identify suitable cases for restricting CMR substances in consumer articles through a simplified procedure, according to Article 68(2).

**Action 9:** *Further enhance Member State involvement in the restriction procedure*

The Commission and ECHA will work with Member States to further simplify the requirements for submitting a restriction dossier and to increase Member State capacities to develop dossiers for new restrictions and provide constructive solutions such as encouraging joint dossiers prepared by several Member States and/or in cooperation with ECHA.

**Action 10:** *Frame the application of the precautionary principle<sup>31</sup>*

ECHA's Risk Assessment Committee and Socio-Economic Assessment Committee should ensure that their opinions indicate when scientific data do not permit a complete evaluation of risk. This should include what information is needed to address the uncertainties, the timeline for generating such information and provide an assessment of the potential consequences of inaction to enable the Commission to consider if action is warranted on the basis of the precautionary principle, underpinned in the legal text of REACH.

The interplay between **authorisation and restriction** is enshrined in REACH. It foresees that for substances subject to authorisation, ECHA should consider after the sunset date whether the use of such substances in articles poses risks to human health or the environment that is not adequately controlled and, if so, should start a restriction procedure. There is a need to expedite the assessment of the need for restrictions on imported articles containing substances subject to authorisation<sup>32</sup> in order to ensure a level playing field between economic operators in and outside the EU. It should be explored if and how applying the authorisation procedure for the non-restricted uses of SVHCs to achieve comparable risk management and substitution more efficiently and predictably.

<sup>31</sup> COM(2000)1 on the precautionary principle

<sup>32</sup> According to Article 69(2) of REACH

**Action 11:** *Interplay between authorisation and restriction*

(1) ECHA is requested to consider systematically the preparation of a restriction dossier before the sunset date of each substance that is subject to authorisation and present in articles in accordance with Article 69(2).

(2) The Commission, ECHA and Member States will assess the interplay between restriction and authorisation to achieve a comparable risk reduction more efficiently through risk management and substitution.

**3.3. Coherence, enforcement and SMEs**

Further activities are needed to clarify the **interface** between REACH and other pieces of EU legislation; in particular work should continue on the interplay of REACH with occupational safety and health (OSH) legislation and with waste legislation<sup>33</sup>.

**Action 12:** *Interface REACH and OSH legislation*

The Commission will propose the following concrete steps to remove the overlaps and clarify the interface between REACH and OSH:

(1) How to use REACH tools (e.g. exposure scenarios, Safety Data Sheets) to enhance the effectiveness of OSH legislation.

(2) Improve the coordination of national enforcement authorities of REACH and OSH legislation.

(3) Align methodologies to establish safe levels of exposure to chemicals at the workplace by first quarter 2019.

(4) Enhance the role of ECHA's risk assessment committee (RAC), involving also social partners, to provide scientific opinions under the OSH legislation while respecting the role of the Advisory Committee on Health and Safety at Work.

Strengthening the **enforcement** of the obligations on all actors, including registrants, downstream users and in particular for importers, is necessary to ensure a level playing field, meet the objectives of REACH and ensure consistency with the actions envisaged to improve environmental compliance and governance<sup>34</sup>. Consistent reporting of Member State enforcement activities will enable a better assessment of this important aspect of REACH.

**Action 13:** *Enhance enforcement*

(1) The Commission will consider by first quarter 2019 further measures (such as recommendations, guidance documents, training and pilot projects), under the relevant legislative instrument, to clarify and enhance the role of REACH enforcement authorities as well as customs authorities in the enforcement of REACH.

(2) ECHA's Forum and Member States are requested to establish comparable parameters on enforcement. On the basis of those parameters, Member States should report annually to ECHA for the purpose of monitoring enforcement activities by Member States.

<sup>33</sup> Addressed by action 4 above.

<sup>34</sup> COM(2018) 10 EU actions to improve environmental compliance and governance

**SMEs** remain more vulnerable to the effects of REACH than large companies due to limited financial and human resources, especially in view of the 2018 registration deadline, where many more SMEs are expected to be involved than in previous registration deadlines as well as the challenges of downstream users.

**Action 14:** *Support compliance by SMEs*

ECHA and Member States are requested to step up efforts to develop, with input from voluntary actions by industry organisations, tailored guidance and support instruments focused on the needs of SMEs. Such instruments may include collection of best practice, generation of sector specific solutions and publication of documents in national languages.

### 3.4. Fees and future of ECHA

A well-functioning and efficient implementation of all REACH processes needs long term financial and resource stability so necessary competences can be maintained and efficiency gained, while taking account of budgetary constraints. ECHA's funding after 2020 needs to be considered and Member States participation to ECHA work needs to be reinforced. Over the period 2007 – 2020, ECHA funding has been coming from fees (70%) and from a balancing subsidy (30%). After 2020, the income from fees (in particular from registration) is expected to drop sharply. The sustainability of ECHA's financing therefore needs to be re-assessed.

Over the next years, it is expected that ECHA will become a European and global reference centre for the sustainable management of chemicals, capable of serving implementation of more pieces of EU legislation, should the Commission make proposals in this respect.

**Action 15:** *Fees and the future of ECHA*

(1) Bearing in mind that budgetary constraints will remain also in the post 2020 Multiannual Financial Framework, the Commission will explore ways of guaranteeing ECHA mission and independence and to assess all possible options for financing in a context of projected reduced fee income, including by containing expenditure.

(2) ECHA is invited by 2019 to:

i) reallocate staff to other areas of work following the completion of the registration process for phase-in substances to enhance the scientific and technical expertise related to the safety of chemicals as well as the evolving methodologies for their assessment;

ii) continue to identify efficiency gains and propose targets.

(3) Given the constraints identified above, the Commission will carefully assess whether to assign further tasks to ECHA and the associated resources.

### 3.5. Need for further assessment

The reviews related to registration requirements for low tonnage substances and polymers (Article 138) identified the necessity to assess affordability of additional registration requirements for the companies involved, especially given the number of SMEs who might be affected.

**Action 16:** *Review of registration requirements for low tonnage substances and polymers*<sup>35</sup>

<sup>35</sup> Review according to article 138(1), 138(2) and 138(3) of REACH.

The Commission will further investigate information necessary to assess the affordability of additional information requirements for low tonnage substances or to identify relevant polymers that could be subject to registration.

The Commission will continue to monitor the impacts of the 2018 registration obligation on SMEs, looking at overall incurred costs, availability of chemical substances and possible structural changes on the EU market.

The Commission will examine various options to fill data gaps and to improve data quality, robustness and transparency in the context of REACH. This is part of a broader discussion on the EU approach on transparency, quality and independence of data<sup>36,37</sup> on which risk assessment and risk management decisions are based.

For CMR substances for which no safe exposure levels exist, there is no consensus in the EU on what level of risk could be considered as acceptable. Furthermore, the rules to establish appropriate risk management measures for such substances in REACH do not include the concept of acceptable risk. Reflections will continue on acceptable risk levels, and whether they can have a role in the relevant REACH processes.

#### **4. CONCLUSIONS**

The REACH Evaluation concludes overall that REACH is addressing today's citizens' concerns about chemical safety<sup>38</sup>.

REACH is effective but opportunities for further improvement, simplification and burden reduction have been identified, which can be achieved by delivering the actions outlined in the report. Those should be implemented in line with the renewed EU Industrial Policy Strategy<sup>39</sup>, Circular Economy Action Plan<sup>40</sup> and the 7<sup>th</sup> Environment Action Programme<sup>41</sup>.

REACH is found to be generally coherent with other EU legislation concerning chemicals and delivers the international goals as intended.

Implementation is still on-going in all areas, with some key milestones, such as the last registration deadline, still to be completed by June 2018. Many of the costs of REACH have been incurred and benefits are starting to materialise.

The REACH evaluation has concluded that the legal requirements and obligations are well tuned to achieving the needs and objectives pursued. While this communication has identified a number of actions that will further improve REACH, there is currently no need to change its enacting terms.

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<sup>36</sup> C (2017) 8414final –Communication on the European Citizens' Initiative related to glyphosate

<sup>37</sup> Roadmap on Transparency and sustainability of the EU risk assessment model in the food chain

<sup>38</sup> [Eurobarometer survey on chemical safety](#)