COUNCIL OF THE EUROPEAN UNION

Brussels, 6 February 2013

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COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	6 February 2013
to:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No Cion doc.:	COM(2013) 49 final
Subject:	**General Report on REACH** **Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions in accordance with Article 117(4) of REACH and Article 46(2) of CLP, and a review of certain elements of REACH in line with Articles 75(2), 138(2), 138(3) and 138(6) of REACH** (Text with EEA relevance) {SWD(2013) 25 final}

Delegations will find attached Commission document COM(2013) 49 final.

Encl.: COM(2013) 49 final

EUROPEAN
COMMISSION

Brussels, 5.2.2013
COM(2013) 49 final

General Report on REACH

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

in accordance with Article 117(4) of REACH and Article 46(2) of CLP, and a review of certain elements of REACH in line with Articles 75(2), 138(2), 138(3) and 138(6) of REACH

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(Text with EEA relevance)

1. INTRODUCTION

Designed to ensure a high level of protection of human health and the environment, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation and to shift the responsibility to manage chemical risks from public authorities to industry, the REACH Regulation[1] (hereinafter REACH) entered into force on 1 June 2007. At the time of adoption REACH raised major challenges and questions for all the stakeholders involved. REACH required new forms of cooperation to share information among companies, enhancing communication along the supply chain as well as developing tools to guide and assist companies and public authorities in the implementation.

Five years after REACH entered into force, key milestones for its implementation have been accomplished. The first registration deadline in 2010 was a success, industry met its obligations with 24,675 registration dossiers submitted, corresponding to 4,300 substances. In result, the quality of data available for risk management has been significantly improved resulting in a marked decrease of the nominal risk for the registered substances. The authorities played their role, for example responding to thousands of questions, the majority coming from SMEs, through the network of Helpdesks, available in all Member States. Founded in 2007, the European Chemicals Agency (ECHA) is now fully operational. In the same period, the Commission made available € 330 million to fund research and other activities to develop alternative methods to animal testing.

A number of reporting and review obligations fall on the Commission five years after the date of entry into force; this Report meets these obligations. In addition it provides a platform for the Commission to report on findings from some more general assessments of the operation of REACH. An accompanying Staff Working Document[2] provides further details of the findings used for the conclusions and recommendations in this Report.

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1 OJ L 396, 30 December 2006, p. 1–849.

2 SWD(2013)25

In accordance with REACH[3], the Commission must report on the experience acquired with its operation and on the funding made available by the Commission for the development and evaluation of alternative test methods. REACH also calls upon the Commission to review the requirements relating to registration of low-tonnage substances, to report on the need, if any, to register certain types of polymers, to assess whether or not to amend the scope of REACH to avoid overlaps with other relevant Union provisions and to carry out a review of ECHA.

2. GENERAL CONCLUSIONS ON ATTAINMENT OF THE REACH OBJECTIVES

2.1. Human Health and Environment

REACH was adopted with the aim of ensuring a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. REACH is a key element of the EU's commitment towards the implementation plan adopted at the 2002 World Summit on sustainable development which aims to ensure that, by 2020, chemicals are produced and used in ways that lead to minimisation of significant adverse effects on human health and the environment.

REACH establishes a systematic registration of substances. The registration should document safe use of substances, by including information on the hazards of the substance enabling registrants to classify and label them and identifying risk management measures, and communicate this information down the supply chain. For substances above 10 tonnes, registrants must perform a chemical safety assessment to identify if additional risk reduction measures are required.

REACH improves the control of individual substances. Restrictions are designed to control risks not adequately controlled by industry. With respect to health and environment, the authorisation process aims to ensure that risks from Substances of Very High concern (SVHC) are controlled and that those substances are progressively replaced by suitable alternatives where these are economically and technically viable.

Although meeting those aims would require the use of animals in laboratory experiments, REACH sets out a number of detailed obligations aiming to reduce animal testing and provides incentives for the use and development of alternative methods for hazard assessment.

In short, the health and environment objective of REACH is expected to be achieved through (1) better knowledge on the properties and uses of substances resulting in better safety and control measures, reducing exposure and hence, the negative impacts on human health and the environment; and (2) the use of less dangerous alternative substances or technologies to SVHC.

[3] Articles 75(2), 117(4), 138(2), 138 (3) and 138 (6).

2.1.1. Expectations from REACH

The potential health and environment benefits (hereinafter "benefits") were assessed in the 2003 REACH impact assessment[4]. Benefits of REACH arise from the application of appropriate risk reduction measures – by industry in the first instance and mandated by authorities in the second – enabled by a systematic collection and generation of information on hazards and uses of chemicals.

The impact assessment provided an illustration of the potential scale of the expected long term health benefits due to these risk reduction measures. The positive effects of REACH on public health were assumed to start to occur 10 years after the start of REACH implementation, i.e. 2018, and would be fully observed after another 20 years, with total health benefits due to REACH in the order of magnitude of EUR 50 billion over the 30 years period (after discounting). The long-term benefits of REACH on the environment were estimated by another study to be up to EUR 50 billion over the 25 years period (after discounting)[5]. Notwithstanding the methodological difficulties the overall conclusion was that the benefits of REACH were expected to far outweigh the costs.

2.1.2. Findings

As expected, five years after the entry into force of REACH, it is still too early to quantify the benefits. Instead the Commission has looked at initial trends based on the examination of qualitative information and a representative set of quantitative indicators.

The Commission reviewed those key drivers which are already operational and of particular relevance to the generation of the benefits, namely: registration, information in the supply chain, authorisation and restrictions. Measures that help realise the benefits, such as dossier evaluation, provision of guidance, inspections and enforcement activities were also examined.

The Commission notes that:

– Increased information is resulting in changes in classification, with the majority becoming more stringent. The quality of the information available for risk assessment has already improved if compared with the pre-REACH situation.

– Increased information in the supply chain and improved safety data sheets is resulting in more appropriate risk management measures, thus contributing to the observed reduction in nominal risk, and has benefited end-users, such as article producers.

– Increased obligations on SVHC through the Candidate listing and Authorisation provisions have led to increased moves towards the substitution of those substances through the supply chain.

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4 *Commission Staff Working Paper [REACH] Extended Impact Assessment*, European Commission, 29.10.2003, {COM(2003)644}.

5 Study*: The impact of REACH on the environment and human health*, DHI, commissioned by the European Commission, September 2005.

Progress towards meeting the human health and environment objective of REACH is therefore materialising. This trend is expected to accelerate as the remaining key benefit drivers become fully operational. However, the Commission notes some key shortcomings which may hinder achievement of the benefits:

– many registration dossiers have been found to be non-compliant, including with regard to substance identity, as reported by ECHA;

– insufficient assessments by registrants of persistent, bioaccumulative and toxic (PBT) and very persistent, and very bioaccumulative (vPvB) properties, as reported by ECHA;

– problems with regard to the content and format of the extended safety data sheet, as reported by industry.

Therefore, the Commission:

(a) asks Industry to improve the quality of registration dossiers first, by focusing on the elimination of any non-compliance and by promptly updating them when needed;

(b) encourages ECHA and Member States to increase efforts towards compliance with the information requirements for the dossiers;

(c) encourages ECHA and Industry to address the problems related to compilation, communication and use of extended safety data sheets and therefore to promote them as a central risk management tool;

(d) in liaison with ECHA, will gather further practical evidence on how to improve the basis for the identification of substances and determination of "sameness". If appropriate, the Commission may propose measures, including implementing legislation;

(e) in cooperation with Member States and ECHA, will increase its efforts to identify relevant SVHCs building on the Risk Management Option (RMO) framework;

2.2. Internal market and competitiveness

From 1999 to 2009 the EU chemical industry grew slightly higher than the average rate for all manufacturing sectors, and has largely recovered from the crisis of 2008. The industry generates a positive trade balance and is particularly well-performing in high margin sectors of specialty chemicals.

In 2003, when REACH was proposed, the EU was the world's largest chemicals market with approximately 30 % of the global chemicals sales. Today it amounts to about 21 %, with China now being the largest chemicals market. However, the EU chemicals industry remains the world's largest exporter and its turnover has increased in absolute terms.

The internal market is a key driver for growth and competitiveness for the chemicals industry and REACH has further harmonised it. The industry acknowledges the

positive economic effects for their business even if some barriers remain. In this context the Commission reminds Member States of the need for a consistent and harmonised interpretation of all REACH provisions, notably the 0.1% concentration threshold of substances of very high concern in articles[6]. Without prejudice to the Commission's interpretation of these provisions and any pending proceedings against Member States for failing to fulfilling an obligation under the Treaties, the Commission invites Member States and other stakeholders to quantify potential environmental or health impacts, if any, of the current REACH provision.

The cost of REACH registration has discouraged some companies from competing on certain substances' markets, which in these cases have increased market concentration and prices. A potential positive effect is that greater specialization amongst chemical suppliers and new business models (like chemical leasing) may increase safety. The need to restructure some supply chains opens opportunities which, due to financial and organizational constraints, SMEs are less likely to exploit unless properly supported.

The registration has impacted also downstream users who are, in general, less aware of their role in REACH. Their situation has to be monitored further, especially in the context of future registration deadlines. In particular, attention has to be paid to the situation of article producers and to the costs related to the administration of REACH. Given that great majority of downstream users are SMEs, they should be a focus in improving the implementation of REACH

It is believed that a significant number of SMEs are unaware about their role and obligations related to REACH, and those who are aware, may have a false impression of the exact scope of their duties, which calls for further action to support and guide these types of companies. The Commission's concern over the impact of REACH on SMEs is reinforced by the recent survey showing that REACH is considered by SMEs as one of the 10 most burdensome pieces of EU legislation[7].

Therefore the Commission:

(a) will explore ways to reduce the financial impact of the Regulation, in particular for SMEs, inter alia, by reviewing the distribution of registration fees to grant greater reductions to SMEs and by asking ECHA to provide more specific guidance on transparency, non-discrimination and fair cost sharing; more specific recommendations from the Commission to reduce the impact of the Regulation on SMEs are presented in an annex to this report;

(b) encourages ECHA and Industry to address concerns about transparency, communication and cost sharing in the Substance Information Exchange Forum (SIEF), to intensify collaboration on streamlining procedures and to develop user-focused guidance, all with special attention to the SMEs and costs;

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6 Concentration of 0,1% weight by weight referred to in Articles 7 and 33

7 Public Consultation: "Which are the TOP10 most burdensome EU legislative acts for SMEs?" held by the European Commission from 28.09.2012 to 21.12.2012.

(c) notes that some countries are adopting certain principles of REACH in their chemical legislation; acknowledges that the regulatory discrepancies between EU and key markets remain, which may have an impact on the EU's external competitiveness; will continue to promote REACH-compatible legislation internationally.

(d) Acknowledges the challenges faced by many enterprises (including downstream users) that will be first time subject to registration and related obligations in 2013 and 2018. Therefore will use available means to monitor the preparedness of the industry ahead of the next registration deadlines. In addition, encourages Member States and ECHA to strengthen efforts in relation to prepare the industry for these crucial milestones.

2.3. Innovation

REACH aims to enhance innovation. Communication in the supply chain provides chemical companies with new information about their customers and their needs. Many companies state a positive impact of that information on innovation. Information generated for the registrations provide inspiration for the innovative use of existing substances.

REACH has had a positive impact on research into new substances, due to generally equal treatment of new and phase-in substances. The number of registrations of new substances has increased in line with the expectations before REACH was adopted.

Another innovation incentive in REACH is the product and process orientated research and development (PPORD) exemption from registration. This has been welcomed by the industry in general, but the Commission notes that only few SMEs have used PPORD so far.

In conclusion, REACH fulfils its objective with regard to innovation even if as regards for example R&D intensity an innovation gap with regard to the US and Japan still exists and pressures from the emerging economies are increasing. The Commission will continue to monitor the effect of REACH on innovation, in particular in new technological areas and will report by 1 January 2015.

3. GENERAL REPORT ON THE EXPERIENCE ACQUIRED FROM THE OPERATION OF REACH

3.1. Member States' reports on the operation of REACH

Article 117(1) required Member States to report by 1 June 2010 on the operation of REACH in their respective territories.

All Member States nominated competent authorities. In total, there are 40 competent authorities operating in the EU and EEA Member States, as 7 Member States have more than one authority.

Competent authorities play an important role in all REACH processes. Effective communication and collaboration between them as well as with the Commission and other stakeholders is a key success-factor for smooth and unified implementation of

REACH. The Member States' reports show that most of them consider the cooperation as a positive experience.

The reports also point out that competent authorities consider the resources and skill sets available to them for the purpose of their tasks as limited.

Enforcement is the sole responsibility of the Member States and all of them have nominated enforcement authorities. The Member States' inspection activities so far have covered manufacturers (37% of inspections), importers (23%), only representatives (3%) and downstream users (36%). To ensure more consistent enforcement at the EU level, REACH established within ECHA the Forum for Exchange of Information on Enforcement. This forum was recognized as a useful collaboration platform.

The Commission:

(a) will assist the competent authorities in enhancing in-house skills, e.g., by developing and sharing tools for the assessment of the impacts on the innovation and competitiveness;

(b) calls on Member States to maximise the effectiveness of the available resources through better coordination and knowledge sharing. With regard to enforcement, focused actions and synergies with other EU legislation should be sought;

(c) will develop enforcement indicators in liaison with the Forum and calls on Member States to monitor the effectiveness of the enforcement;

(d) will improve the reporting template and will clarify the role of customs authorities in the enforcement of REACH.

3.2. ECHA report on the operation of REACH and CLP

The first ECHA report was submitted in June 2011 in accordance with Article 117(2). It shows that regulators as well as industry have, in essence, met their obligations and that REACH is working well overall. Nevertheless, there are lessons to learn from the experience so far.

ECHA identified three broad areas for improvement in the operation of REACH and CLP:

– Industry needs to take full ownership of its registration dossiers and proactively work on their quality, even after submission to ECHA.

– Effective communication through the supply chain of information on substances and how to use them safely needs further attention. Means to achieve it must be strengthened and tools to facilitate it must be developed or improved.

– Limited resources demand effective prioritisation of substances for further consideration in the REACH and CLP processes. Further use of registration

information should be facilitated in order to best focus authorities' resources towards safe use of substances.

Issues in all REACH areas have been found, some can be solved through optimising implementation while others would require the Commission to consider proposing amendments to REACH. ECHA concludes that industry now primarily needs stability and predictability, and does not advocate changing REACH in the short term.

3.3. Animal Testing

The key findings from ECHA's Article 117(3) report on alternative methods to testing are:

– 90 % registration dossiers have been submitted jointly and there is good progress with the sharing of data;

– registrants have extensively used available provisions to waive tests;

– the quality of the justifications for not conducting animal tests is of concern;

– registrants in general did not propose unnecessary testing;

– the procedure of providing testing proposals works well;

– fewer testing proposals than expected were received, although in part due to the inappropriate adoption of alternative approaches; and

– 107 higher tier animal tests seems to have been conducted without a testing proposal

Overall, €330 million has been allocated by the Commission to support the development and evaluation of alternative methods in the period 2007-2011. Nine Member State Competent Authorities reported expenditure of more than €100,000 each per year. The breakdown in spending is reported in the staff working paper. Efforts should continue since there are still gaps in providing alternatives for some complex toxicological endpoints. Additional attention should be paid to the regulatory use of the results and to the education of users.

The Commission recommends:

(a) ECHA to continue efforts on dossier evaluation, improve guidance and communication with industry to enhance the quality of the submitted justifications for use of alternative methods; and

(b) ECHA to evaluate the effectiveness of the process of public consultations on testing proposals, these public consultations should further focus on alternative approaches and generate new relevant information.

(c) Member States to enforce compliance with testing proposal requirements

The Commission will oversee the spending of research funding on alternative methods to encourage their development in line with the relevant section of the

Commission Communication on the combination effects of chemicals[8], taking into account the need for regulatory use. The Commission will also coordinate internationally and across sectors, where relevant.

3.4. Review of the requirements for registration of 1 to 10 tonnes substances and on the need to register certain types of polymers

The registration requirements for substances in quantities of 1 to 10 tonnes have been assessed for their adequacy to identify hazards to human health and the environment. The assessment includes consideration of the identification of any human health or environmental classification endpoint sufficient for classification under CLP and identification of appropriate risk management measures. The Commission confirms that the information requirements are less than those of an OECD Screening Information Data Set (SIDS) dossier which is consistent with the absence of a requirement for a chemical safety report.

The Commission has at present insufficient information on the impact on innovation and competitiveness to propose changes to the information requirements for substances produced in low tonnages.

Similarly, the Commission is reviewing the need, if any, to register certain types of polymers. At present, more information is necessary to conclude on that need and feasibility.

Given the potential benefits whilst also considering the costs, the Commission will continue to work in these areas in co-operation with Member States and other stakeholders and come forward with a proposal, if appropriate, by 1 January 2015.

3.5. Classification, labelling and packaging (CLP)

The CLP Regulation[9] sets the rules for classification, labelling, and packaging of chemical substances and mixtures at EU level. Its main objectives are to determine whether a substance or mixture displays properties that lead to a classification as hazardous and to harmonise the standard symbols, phrases and packaging conditions that should be used to inform users. For substances this is reported in the REACH registration dossier.

The enforcement of CLP is closely related to the enforcement of REACH, both facing similar challenges. Member States pursue their CLP inspections often as a part of REACH inspections. Furthermore, the Forum for exchange of information on enforcement, managed by ECHA undertakes its tasks with regard to both Regulations. A strong and harmonised approach towards enforcement of CLP and REACH throughout the EU is vital for delivering their objectives.

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8 *Communication from the Commission [...] The combination effects of chemicals Chemical mixtures*, European Commission, {COM/2012/0252}, Section 5.2 (4) (i) and (ii).

9 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directive 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p.1).

Article 46(2) of the CLP Regulation requires Member States to report regularly on the results of official controls and other enforcement measures taken. The first reports submitted covered the period January 2009 to June 2011. Overall 26 Member States submitted reports which showed large variations in the level of detail and the issues addressed.

Most Member States co-operate, co-ordinate, and exchange information and have appropriate sanctions in place to enforce the CLP Regulation. Most also have an enforcement strategy in line with the strategy developed by the Forum. The total number of inspections concerning particular products and individual duty holders has steadily increased over the last three years. In terms of issues identified where further improvements are necessary, compliance with the legal requirements could be substantially improved (generally the compliance rates amounted to 70%), and the reporting by Member States needs further harmonisation.

Compared with situation before the CLP Regulation was adopted, the Commission and all Member States are now - due to the reporting obligation - regularly updated on enforcement activities and compliance rates. This will allow to target enforcement activities on problematic areas and to further develop joint enforcement strategies. However, Member States might have to dedicate additional resources to enforcement and to the regular reporting to fully profit from the experience gained across the EU.

It is expected that further development of the enforcement strategy of the Forum in relation with CLP will also have a positive effect on the effectiveness of enforcement in improving the rate of compliance. The strategy should include harmonised and targeted enforcement projects, and an element of awareness raising particularly focussed on SMEs.

4. REVIEW OF ECHA

The Commission has examined ECHA's:

– Effectiveness: the extent to which objectives set are achieved;

– Efficiency: the extent to which the desired effects are achieved at a reasonable cost;

– Economy: the extent to which resources are available in due time, in appropriate quantity and quality at the best price.

The Commission also assessed ECHA's role, added value, acceptability by stakeholders and location.

The review encompassed the start-up of ECHA, two major REACH deadlines and a key CLP deadline. However, substance evaluation activities had not started, nor had any authorisation applications been received.

ECHA had a successful start-up, contributed to by a swift and performing recruitment policy, the strong commitment of staff and management alongside the support of the Finnish authorities.

ECHA met most of its key objectives and can therefore be considered as effective with most stakeholders noting that ECHA performed well. The Agency was set up, handled pre-registration and registration effectively, and laid down the foundations for its tasks under authorisation and restrictions. It also delivered most of the required guidance documents, initiated the activities of the network of REACH and CLP national helpdesks and the Forum. Dissemination of data, usability of search tools on the ECHA website, provision of the data to Competent Authorities and the Commission, and communication and transparency in general, could have been more effective.

Delivering the expected outputs was ECHA's clear priority in the starting years. This meant ECHA coped with unexpected circumstances. In addition, ECHA conducted activities not strictly required by REACH to support industry's compliance with its obligations, for example, a campaign about Substance Information Exchange Forums (SIEF) formation and organisation, and participation in the Directors' Contact Group[10]. The Commission acknowledges that overall efficiency was reduced by the complementary activities but agrees that this focus on delivery was the right choice for ECHA to make as it contributed to the overall effectiveness.

ECHA's strong engagement with industry stakeholders triggered some criticism that ECHA appeared to favour industry over other stakeholders. However, it is indisputable that the effectiveness of ECHA and the measure of success of REACH depend on the ability of individual companies to fulfil their obligations and on the commitment of industry as a whole. The Commission is convinced that ECHA's approach in this regard is another example of a justifiable focus on effectiveness in the start-up phase. Fully aware of the diversity of its stakeholders and their often conflicting expectations, the Commission is confident that ECHA will continue to strike the right balance between independence and stakeholder engagement taking into account that it is now to be considered an agency at cruising speed.

ECHA showed its ability to be flexible. The budget planning and forecasting were adequate. Operational adaptability was displayed in responding to new situations through a risk management approach, re-allocation of resources where necessary and willingness to learn and adapt.

The Commission considers that ECHA should now play its central role in the technical and administrative management of REACH. In view of the evidence gathered by the ECHA review, the Commission invites ECHA to:

(a) enhance efficiency and economy by e.g. further prioritization of tasks and improved cooperation between ECHA bodies ;

(b) continue and enhance stakeholder engagement activities, including SMEs as a separate target group taking into account their specific needs;

(c) improve the sharing of information and data with the Commission and Member States' authorities where possible and compatible with confidentiality rules.

[10] Information on these activities is provided by ECHA in its annual General Reports available on ECHA website: www.echa.europa.eu

The Commission recommendations should be put in place with the existing resources already allocated to the agency therefore they will not entail a budgetary impact over and above the appropriations already foreseen for the years to come.

5. REVIEW OF THE SCOPE OF REACH

The Commission has analysed links between REACH and more than a hundred pieces of other EU legislation with a view to identifying and assessing overlaps between them.

Overall, the Commission is of the view that the scope of REACH was set well and no major overlaps with other EU legislation have been identified. Nonetheless, some minor overlaps or potential overlaps were identified. In this context, the term overlap was understood as encompassing situations where two pieces of EU legislation regulate the same situation which may lead to instances of legal uncertainty or where legal requirements lead to unnecessary burdens on duty holders.

In the registration area few minor overlaps or potential overlaps have been identified. These will be addressed on a case by case basis. In the restrictions area, where a number of EU sector-specific legislations lay down restrictions of substances or categories of substances, some minor overlaps were identified. Taking into account the existence of various EU legislation containing substance restrictions, the Commission considers useful to invite ECHA to develop an inventory of all existing restrictions in EU legislation on an individual substance basis.

The Commission will strive to minimise or avoid overlaps or potential overlaps through

(a) inviting ECHA to change guidance, if appropriate; and

(b) implementing legislation under REACH or other EU sector-specific legislation in particular when considering future restrictions and substances subject to authorisation.

In the event of REACH or other relevant EU legislation being open for revision in the future, the Commission will address any remaining areas where overlaps were identified.

In addition to overlaps, the Commission also identified certain areas where information generated under REACH processes could be used in the context of EU sector-specific legislation requirement. By the same token, the information generated for the purpose of EU sector-specific legislation could be useful for REACH purposes[11].

6. NANOMATERIALS

The Second Regulatory Review on Nanomaterials concluded that; "*Overall the Commission remains convinced that REACH sets the best possible framework for the*

[11] Examples of synergies between REACH and other EU legislation are listed in SWD, Title 1.1.

risk management of nanomaterials when they occur as substances or mixtures but more specific requirements for nanomaterials within the framework have proven necessary. The Commission envisages modifications in some of the REACH Annexes and encourages ECHA to further develop guidance for registrations after 2013".

The Commission will make an impact assessment of relevant regulatory options, in particular possible amendments of REACH Annexes, to ensure further clarity on how nanomaterials are addressed and safety demonstrated in registration dossiers. If appropriate the Commission will come forward with a draft implementing act by December 2013.

7. CONCLUSIONS

Based on the above findings the Commission considers that REACH functions well and delivers on all objectives that at present can be assessed. Some needs for adjustments have been identified, but balanced against the interest of ensuring legislative stability and predictability, the Commission concludes that changes to the enacting terms of REACH will not be proposed.

Within the current framework, however, there is a need to reduce the impact of REACH on SMEs. The annex to this report sets out the measures that will contribute to this goal.

There are many other opportunities for further improvement of the functioning of REACH by further optimizing the implementation at all levels, as set out in this Report and further described in the Staff Working Document. To achieve this, strong commitment of all the actors involved is necessary; therefore, the Commission undertakes to continue to work jointly with Member States, ECHA and stakeholders towards a successful implementation of REACH.

Annex

List of specific recommendations from the Commission with the aim to reduce the administrative burden of REACH by SMEs while maintaining their ability to fulfil all REACH obligations

- ECHA is encouraged to provide more specific guidance on transparency, non-discrimination and fair cost sharing in the framework of SIEF formation and operation. The review has identified specific problems in relation to the powers of lead registrants which role is more frequently exercised by larger companies. These powers could materialize in imposing flat fee on 'letters of access' and charging disproportionate amounts for the administration of SIEF. The incentives to ensure an economically efficient SIEF administration must be made stronger..

- The Fee Regulation is currently being reviewed taking into account the results of the overall REACH review, in particular, those related to costs of REACH and its impact on competitiveness and innovation. A main objective of the revised Fee Regulation is to lower the costs for SMEs.

- ECHA and industry should develop more user-focused guidance, with special attention to SMEs. The review has identified a specific problem in relation to the vast amount of guidance developed to support the implementation of REACH. Only a fraction of the existing guidance is targeted to specific groups of companies. REACH is applicable to many different types of companies through the whole supply chain which has led to often rather complex guidance documents.

- ECHA in collaboration with the industry should improve the guidance for protecting intellectual properties in the context of mandatory exchange of information in the value chain. In the context of joint registration a specific problem has been found with the disclosure of important business information, which in some cases constitutes the foundation of specific companies. More specific guidance is needed to disseminate best practices among the industry on which information should be protected, and how best to achieve satisfactory protection.

- Similarly, ECHA should develop better guidance, especially targeting SMEs and less experienced companies, in the use of the Use Descriptor System. Currently SMEs often need external support driving up their compliance costs. Improper use of the system may result in significant differences between suppliers of the same substance in the required conditions for its use which limits the possibility to change supplier; leads to higher costs and reduced stability of supplies.

- ECHA and national REACH Helpdesks are called upon to develop specific activities and guidance on integrating REACH processes early into the R&D and other innovation processes. Some innovative companies have expressed concerns over regulatory uncertainty. While a number of innovation-friendly mechanisms are present in REACH and a lot of information is being produced by ECHA and disseminated on the internet on the exact obligations, these mechanisms and information sources need to be well advertised among innovating companies.

- The Commission will make further use of Enterprise Europe Network (EEN) to increase awareness of REACH along the supply chain and to improve the communication within

the supply chain. REACH concerns a wide variety of companies and a significant proportion of businesses in Europe qualify as downstream users. It is believed that a number of SMEs are unaware about their role and obligations related to the Regulation, and those who are aware, may have a false impression of the exact scope of their duties. For this reason wider communication and awareness raising activities will be pursued using established platforms of EEN and national REACH Helpdesks.

- Finally, the Commission will continue to monitor the administrative costs of implementation of REACH by SMEs and the quantity and quality of technical and legal support for SMEs provided by responsible implementing institutions.