ORGALIME

Position Paper

Brussels, 27 January 2017

ORGALIME RESPONSE AND POSITION PAPER
PUBLIC CONSULTATION REACH REFIT EVALUATION

EXECUTIVE SUMMARY

Orgalime welcomes the Commission's public consultation on the REACH REFIT evaluation on the effectiveness, efficiency, relevance, coherence and EU added value of this critical piece of legislation.

In the context of the REACH Regulation 1907/2006, Orgalime represents a major EU downstream user (DU) industry of chemical substances and mixtures, as well as EU producers and importers of articles, whether final or components for further manufacturing in Europe or abroad, and whether for use by private consumers or professional customers. The EU engineering industries are clients of the chemical industry and suppliers of capital goods to all other industry sectors, including the energy sector, automotive, aerospace, chemical, food or textile industries as well as to the health and environment sectors. Our industry is also subject to sector specific chemicals legislation, namely Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Notwithstanding the fact that there is a certain room for improvement, we consider the REACH Regulation as generally fit-for-purpose and do not see the need to amend it at this stage. Efforts should be dedicated to improving its implementation, which in our view is both, possible and necessary, as we explain in this document.

REACH has in our view shown **clear added value for the EU:** the introduction of REACH as a Regulation has set rules directly applicable in all EU Member States and a fully harmonised framework for the management of chemicals in the EU. Thanks to REACH, diverging national initiatives are no longer possible in areas covered by its scope. Harmonised rules across the EU guarantee the functioning of the EU internal market, which is one of the four freedoms of the EU and one of the EU's greatest achievements to the benefit of consumers, the environment and industry alike. This benefit could not be generated at national level. Nevertheless, Member States still adopt measures on substances outside the REACH framework, and sector specific EU chemicals legislation, such as Directive 2011/65/EC (RoHS), do not always live up to the explicit legal requirement of having to be consistent with REACH.

REACH is also showing its first positive results in terms of **effectiveness:** it is promoting the generation of data on chemical substances, which is increasingly positive for realising the objective of protecting the environment and human health. A common knowledge base and understanding of chemicals throughout the EU is being built, which is a fundamental precondition for proper risk management measures in support of industry's competitiveness as REACH implementation continues. Additionally, more communication on chemicals substances in the supply chain is also being generated by REACH. As implementation progresses, the effectiveness of REACH will, in our view both, broaden and deepen.

Concerning REACH **efficiency**, it is perhaps too early to draw a final conclusion. Important milestones still lie ahead after this REFIT exercise, and the effect of some of the processes established by REACH, such as registration and authorisation, are yet to be fully apparent.

Notably, 1st June 2018 is an important date for DUs as it sets the deadline for the registration of a high number of low volume substances, above one tonne per year, manufactured or imported.

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Registration of these substances is crucial to avoid disruptions in our supply chains, which would negatively impact our innovation capacity and competitiveness. Securing the maximum portfolio of substances to remain available for product innovation in Europe should be a shared priority for further REACH implementation as it supports the Commission's jobs and growth agenda and the competitiveness of EU industry. How REACH will be further implemented, will clearly determine the assessment of the efficiency of REACH in terms of costs and benefits generated.

REACH has definitely shown **relevance:** it provides a comprehensive framework to address the management of chemical substances in the EU.

Finally, whilst REACH is **coherent** amongst its different chapters, further strengthening coherence of sector specific legislation, notably the RoHS Directive, with REACH is in our view necessary, especially to better support the Circular Economy. We highly appreciate the existing CARACAL Common Understanding Paper on the Interface between REACH and RoHS, which clarifies several important issues. However, despite the provisions explicitly required by RoHS, we are still lacking a substance evaluation methodology for the setting of new restrictions under RoHS that would be coherent with REACH. We advocate for setting in place and applying one common substance evaluation methodology fully consistent with REACH for any further REACH and RoHS implementation on our sector. Future possible Member States' new RoHS restriction proposals should equally be consistent with REACH, as legally required.

We further on provide our detailed responses and comments to the individual questions of the stakeholder questionnaire. These aim at providing Orgalime's motivation and justification to all our answers given to the individual questions raised, and also include our recommendations regarding further REACH implementation priorities in the concluding section:

ORGALIME DETAILED RESPONSE TO THE PUBLIC CONSULTATION IN RELATION TO THE REACH REFIT EVALUATION

Introduction: the online evaluation questionnaire is available here and structured as follows:

- Part I – General Information about respondents (compulsory)
- Part II - General Questions for respondents interested in REACH, but who may not be familiar enough with the legal text and provisions to answer more detailed questions (compulsory)
- Part III – Specific Questions which require more in-depth knowledge and experience in dealing with the REACH Regulation (optional)
    - Effectiveness
    - Efficiency
    - Relevance
    - Coherence
    - EU added value
- Part IV – Additional Comments

Part II - General Questions:

QUESTION 6: to what extent do you think REACH is achieving the following objectives?

	1 Not at all	**2 Slightly**	**3 Somewhat**	**4 Substantially**	**5 Very much**	**Do not know/not applicable**
a) Improve protection of consumers				X		
b) Improve protection of workers				X		
c) Improve protection of the environment				X		
d) Free circulation of chemicals on the internal market (Reduce barriers to trade in chemicals across borders within the EU)				X		

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e) Enhance competitiveness and innovation						X
f) Promote alternative methods to animal testing for hazard assessment of chemicals						X

Orgalime comments related to question 6:

- A general remark is that REACH has yet to reach its full potential. This is due to the fact that only high volume substances have been registered so far. By 1st June 2018, substances manufactured or imported in volumes between 1 and 100 tonnes a year will still have to be registered. Improving the quality of data regarding substances registered so far is still work in progress, too.
- The process of authorisation of substances has only just begun. Substitution of substances of very high concern, therefore, is also in the first phase. We can expect that after this REFIT exercise, the effect of REACH will be broader (as a higher number of substances will be registered) and deeper (if the quality of the dossiers meets the REACH requirements) than today.
- Regarding points a) and d), ensuring that exposure scenarios and assessments in the context of registration dossiers do indeed include the substance's effects during the waste phase is a precondition for REACH to deliver its objectives, especially in the light of Circular Economy. Checking the quality of registration dossiers and completing them also in this respect should be prioritised.
- Related to point *e) Enhance competitiveness and innovation,* competitiveness and innovation are different issues. Innovation has improved with, for example, the push stemming from REACH for substitution in case of reliable alternatives being available. We have doubts whether REACH has achieved the objective of improving the competitiveness of the European industry, since it limits imports of chemicals from outside the EU and thereby can trigger price increases for chemicals. Also, the discriminatory effects of European companies against their non-EU competitors stemming from REACH authorisation are becoming increasingly evident. Finally, the competitiveness impacts of article 33 and 7.2 will strongly depend whether or not authorities will see fit to ensure a proportionate implementation in the future. Overlaps with other legislation regarding product information must in any case be avoided.

QUESTION 7: to what extent do you think REACH is delivering the following results?

	1 Not at all	**2 Slightly**	**3 Somewhat**	**4 Substantially**	**5 Very much**	**Do not know/not applicable**
a) Generation of data for hazard/risk assessment				X		
b) Increase in information on chemicals for risk management				X		
c) Increase in information exchange in the supply chain				X		
d) Improvement in development and implementation of risk management measures				X		
e) Shifting the burden of proof from public authorities to industry					X	
f) Fostering innovation (e.g. substitution of SVHCs, development of new substances)			X			
g) Promoting the development use and acceptability of alternatives to animal testing						X

h) Implementation of the 3Rs (replacement, reduction and refinement) in relation to the use of animal testing						X
i) Dissemination of information on chemicals for the general public			X			

Orgalime comments related to question 7:

A general remark is that REACH has yet to reach its full potential. This is due to the fact that high volume substances have been registered so far. By 1st June 2018, substances manufactured or imported above one tonne per year will still have to be registered. Improving the quality of data on the substances registered so far is still work in progress, too. The process of authorisation of substances has only just begun. Substitution of substances of very high concern, therefore, is also in the first phase, which particularly explains our response to point f). We can expect that after this REFIT exercise, the effect of REACH will be broader (as (hopefully) almost all substances will be registered) and deeper (if the quality of the dossiers meets the REACH requirements) than now. Regarding a) and d), ensuring that exposure scenarios and assessments in the context of registration dossiers do indeed include the substance's effects during the waste phase is a precondition for REACH to deliver its objectives, especially in the light of Circular Economy. Checking the quality of registration dossiers and completing them, especially also regarding waste phase aspects, should be prioritised.

QUESTION 8: the various processes of REACH (e.g. registration, evaluation) are expected to generate data that can be used by public authorities to adopt adequate risk management measures under REACH or in other EU legislation. To what extent do you think that the data generated are adequate for adopting the following measures?

	1 Not useful at all	**2 Slightly useful**	**3 Somehow useful**	**4 Substantially Useful**	**5 Very useful**	**Do not know/not applicable**
a) REACH authorization			X			
b) REACH restriction			X			
c) Consumer protection legislation concerning chemicals in articles (e.g. cosmetics, toys, food packaging)			X			
d) Environmental legislation (e.g. Seveso, Industrial Emissions Directive)			X			
e) Harmonized Classification & Labelling			X			
f) Occupational Exposures Limits (OEL) in the context of worker protection legislation			X			

Orgalime comments related to question 8:

The potential of REACH to be a source of reliable data is evident and very much appreciated. However, the quality of the data must improve as the adequacy of the data generated depends on the quality of the data submitted in the registration dossier to ECHA (see also our comments to questions 6 and 7). The ECHA 'Evaluation report 2015 "of February 2016 states that only 18% of the verified registration dossiers were compliant, with no further action needed by the registrants. This means that 82% of the other verified registration dossiers were not compliant. It is the obligation of the registrant to file a compliant registration dossier and to keep it up to date. It is the obligation of authorities to request the completion of registration dossiers where these are incomplete, including for waste phase aspects.

Incomplete, incorrect, unreliable and therefore non-compliant registration dossiers have a tremendous effect on downstream users who have to comply with REACH and other obligations related to other pieces of EU legislation:

- Downstream users need the registered chemicals and require correct information (for example, reliable safety data sheets) to be able to use chemicals without harming the environment or human health.
- Downstream users need to substitute SVHCs either used as a chemical or present in articles with chemicals that translate into environment improvements, thus that have a lower risk for the environment and human health. If registration dossiers cannot be trusted, companies make wrong decisions based on unreliable data of these dossiers.
- Correct and high quality data are also key for Member States to underpin their decisions to propose new measures on chemical substances.

We strongly call for high quality of data and of registration dossiers and encourage ECHA and Member States to strengthen compliance and implementation efforts toward this fundamental goal for REACH to deliver.

QUESTION 9: to what extent do you agree with the following statements in relation to the European Chemicals Agency (ECHA)?

	1 Strongly disagree	**2 Disagree**	**3 Neutral**	**4 Agree**	**5 Strongly agree**	**Do not know/not applicable**
a) ECHA has handled the registrations of chemical substances effectively (i.e. support for registrant, access to IT tools)						X
b) ECHA has established a strong and trustful relationship with its stakeholders				X		
c) ECHA has contributed to reducing the impact of REACH on SMEs				X		
d) ECHA's activities and guidance have facilitated an innovation-friendly framework			X			
e) ECHA has been successful in facilitating the implementation of the last resort principle concerning animal testing						X

Orgalime comments related to question 9:

- Regarding point *d) ECHA's activities and guidance have facilitated an innovation-friendly framework*, the industry does not expect ECHA to stimulate innovation. According to our experience, ECHA translates REACH legislation into practical guidance. Also, our further evaluation depends whether or not ECHA will adopt a proportionate approach in the final ECHA Guidance on Substances in Articles, which is currently revisited following the related ECJ ruling of September 2015.

Part III – Specific Questions which require more in-depth knowledge and experience in dealing with the REACH Regulation

III. A

EFFECTIVENESS

The following questions explore the extent to which the objectives of the REACH Regulation have been met, and any significant factors which may have contributed to or inhibited progress towards meeting those objectives.

QUESTION 10: in your view, to what extent have the REACH Regulation and its various chapters been implemented successfully?

	1 Not at all	2 Slightly	3 Somewhat	4 Substantially	5 Very much	Do not know/not applicable
Registration			X			
Data-sharing and avoidance of unnecessary testing						X
Information in the supply chain			X			
Evaluation - dossier	X					
Evaluation - substance		X				
Authorization			X			
Restriction			X			
Overall implementation of REACH			X			

Orgalime comments related to question 10:

- Our answers are primarily motivated by downstream users' experiences.
- Downstream users are usually not registering substances themselves, but their registration by the chemical supplier is crucial for continuing their own activities and manufacturing operations, notably in Europe. Similarly, when it comes to authorisation, in most of the cases our industry expects to be impacted by the authorisations granted or rejected in the value chain, rather than facing authorisation obligations directly. For implementing proper risk management measures, DU depend on reliable, easy to understand, overall good quality Safety Data Sheets.
- REACH has not yet reached its full effect in all areas.
- The availability and reliability of alternatives and socio-economic impacts of possible risk management should be taken into account in the assessment of risk management measures.

QUESTION 11: do you agree that the REACH legal text presents requirements regarding the following chapters in a clear and predictable manner?

	1 Strongly disagree	2 Disagree	3 Neutral	4 Agree	5 Strongly agree	Do not know/not applicable
Registration			X			
Data-sharing and avoidance of unnecessary testing						X
Information in the supply chain			X			
Evaluation – dossier			X			
Evaluation - substance				X		
Authorization				X		
Restriction				X		

Orgalime comments related to question 11:

Notwithstanding certain possible clarifications, the REACH legal text presents overall requirements in a clear and predictable manner. We would like to highlight the following:

- The effects of these requirements in practice can be very complex. For example, substitution of a substance A of very high concern is difficult when the dossier of alternative substance B is not complete, unreliable or the substance has not been registered yet.
- The same is valid for articles 33 and 7(2). Their implementation following the Ruling of the European Court of Justice from September 2015 needs to be workable and proportionate by limiting them to the necessary and at appropriate level of detail to be communicated in order to allow the safe use of the article.
- Implementation of sector specific legislation needs to be much more consistent with REACH (see previous remarks on RoHS Directive and parallel substance evaluation methodology despite RoHS being required to be consistent with REACH, see article 6 RoHS).

QUESTION 12: in your view, to what extent are the following elements of REACH working well?

	1 Not well at all	**2 Rather not well**	**3 Neutral**	**4 Rather well**	**5 Very well**	**Do not know/not applicable**
Transparency of procedures			X			
Speed with which hazards/risks are identified				X		
Speed with which identified risks are addressed				X		
Time to allow duty holders to adapt		X				
Predictability of the outcomes		X				

Orgalime comments related to question 12:

- In relation to the "*time to allow duty holders to adapt*", our comment is that too frequent reviews of the Candidate List are a serious challenge for industry to adapt in a timely manner. Our industries produce highly complex products and have multi-tiered supply chains and therefore need realistic timelines and sufficient stability of regulation to adjust. Instead of two updates per year, one should suffice for the purpose of implementing REACH objectives.
- Related to the "*predictability of the outcomes*", our comment focuses on the authorisation process. The inclusion of substances from the Candidate List to Annex XIV and subsequently the granting of an authorisation is not fully transparent or sufficiently predictable in terms of timing or final result. This uncertainty has a negative impact on the economic planning of a company. Also, in view of the 2018 registration deadline, DU are left in legal limbo until the last moment as to whether a substance will indeed be registered or not. In any case, REACH does not allow to withdraw a substance for economic reasons alone. This should be particularly looked at during further implementation and enforcement.

QUESTION 13: please identify unintended effects of REACH, indicating whether you consider those to be positive or negative. Please provide evidence to quantify such effects or a qualitative description (max. 5.000 characters)

Orgalime comments related to question 13:

- Examples of positive unintended effects of REACH:
  - As REACH implementation progresses, the links, complementarities but also the inconsistencies and contradictions of other EU legislations with REACH became both, clearer and more visible. This promotes a higher level of awareness and information and also potential and political will for remedying identified inconsistencies. For example, the Commission's initiative of a Common Understanding Paper of the Interface between REACH and RoHS has been supported by CARACAL, which we highly welcome.
  - Applying without prejudice to worker safety legislation, REACH clearly generates benefits for workers. The relationship of REACH with worker safety legislation is also an area where more convergence and coherence would be beneficial.
  - Communication between different stakeholder groups, industry, NGOs, consumer organisations or authorities increases and strengthens mutual understanding, the finding of solutions and their acceptance.

- REACH encourages enterprises to substitute (earlier) substances of very high concern in cases where alternatives are available, even if no legal restriction or authorisation has yet been adopted.
- REACH clearly shows spill over effects to other regions of the world that are equally debating whether to adopt similar regulation.
- REACH provides all the necessary information (including data on nanomaterials) and should also be the relevant legislative tool for nanomaterials.

- Examples of negative unintended effects of REACH:
  - These in our view primarily arise in areas of the Regulation relating to downstream users, and mainly in terms of costs and administrative burden, which have not been assessed to be so high during the adoption process of REACH. Impacts on DUs and article manufacturers are more considerable than initially assumed.
  - When it comes to registration and authorisation, we see a risk for downstream users to be exposed to withdrawal of substances should these not be registered in 2018. Similarly, we risk facing supply disruptions should critical substances not be authorised, in the absence of an appropriate, available and reliable substitute.
  - REACH can in practice limit the capability of DU companies to import chemicals from outside the EU (full registration would be too cumbersome for them).
  - Authorisation in practice turns into an advantage some manufacturing activities outside Europe (for example Chromium VI, etc.) where environment and human health standards are usually lower than in the EU. While a case by case assessment of the most appropriate risk management measure is always necessary, restrictions, as a tool, generally speaking can provide a fairer level playing field for manufacturers of articles, as they apply both to articles manufactured in the EU and to those manufactured outside the EU. Where restrictions are to be set, industry needs available, reliable alternatives, sufficiently long compliance deadlines and a workable exemptions mechanism, as is provided for under the RoHS Directive.
  - The adoption of REACH after some product specific legislations, such as the RoHS or Ecodesign Directives is leading to overlaps and inconsistencies. Whilst the Common Understanding Paper between REACH and RoHS addresses some of these concerns, we are still confronted with different methodologies for the setting of new substance restrictions for electrical and electronic equipment (EEE) under REACH and/or RoHS (see previous comments).
  - Articles 7.2 and 33 have more far-reaching consequences on a high number of enterprises than initially thought. The Ruling from the European Court of Justice of September 2015 made compliance more challenging for the industry. A workable, proportionate future implementation through the ECHA Guidance matters.
  - A conflict with Circular Economy objectives of keeping products in use for as long as possible arises, since the “repair as produced” principle is not sufficiently acknowledged by REACH. Also, if recycled materials may benefit from streamlined REACH authorisation requirements, it is essential to ensure that article manufacturers can further on comply with their specific chemicals legislation, such as existing RoHS restrictions in electrical and electronic equipment.

QUESTION 14: in your view, to what extent are the following elements of REACH enforcement satisfactory?

	1 Not at all satisfactory	**2 Rather unsatisfactory**	**3 Neutral**	**4 Rather satisfactory**	**5 Very satisfactory**	**Do not know/not applicable**
Overall REACH enforcement in the EU			X			
REACH enforcement at Member States level			X			
REACH is enforced uniformly across the EU			X			
Prioritization of enforcement activities at EU level (by Forum)			X			

Communication on enforcement activities from Member States and Forum			X			

Orgalime comments related to question 14:

- The different Enforcement Authorities should continue exchanging and coordinating their national practices on REACH enforcement. The better the coordination of enforcement authorities, the more efficient their enforcement of the REACH Regulation for an improved level playing field amongst market operators. This will avoid negative impacts on the competitiveness of legitimate manufacturers.

QUESTION 14.1: If you answered 3 or less for any of the above, please explain how the relevant aspect of REACH enforcement could be improved.
(max. 5.000 characters)

Orgalime comments related to question 14.1:

- The different Enforcement Authorities should continue exchanging and coordinating their national practices on REACH enforcement. The better the coordination of enforcement authorities, the more efficient their enforcement of the REACH Regulation for an improved level playing field amongst market operators. This will avoid negative impacts on the competitiveness of legitimate manufacturers.
- Databases as an enforcement tool cannot replace active market surveillance. Only physical checks by market surveillance authorities are effective and should therefore be the preferred tool.

QUESTION 15: have you, in the past 5 years, experienced a REACH inspection/control or have your products been controlled for REACH compliance? - To be answered only by companies (REACH duty holders).

Yes	
No	
I don't know	

Orgalime answer for question 15:
Not applicable to Orgalime given that we are a European trade association.

EFFICIENCY

The following questions explore the costs and benefits of implementing the REACH Regulation. The legislation was designed to deliver benefits in terms of protection of human health and the environment, better functioning of the EU internal market (facilitating the free movement of goods between EU Member States) and fostering competitiveness and innovation of EU industry (such as better and safer chemicals). Costs can relate to costs for businesses, public authorities and society as a whole.

QUESTION 16: in your view, how significant are the following benefits generated for society by the REACH Regulation?

	1 Not significant at all	2 Rather not significant	3 Neutral	4 Rather significant	5 Very significant	Do not know/not applicable
Reducing the exposure of citizens in general to hazardous chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.			X			
Reducing the exposure of workers to hazardous chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.				X		
Reducing damage to the						

environment and to eco-systems and, therefore, avoiding the costs of treating contaminated water, restoring impacted fisheries, cleaning-up contaminated land, etc.			X			
Encouraging research and innovation, generating new jobs, and improving the competitiveness of EU manufacturing industry by encouraging/supporting a shift towards green, sustainable chemistry and a circular economy				X		
Stimulating competition and trade within the EU single market		X				
Stimulating international trade between the EU and other countries		X				
For businesses: Increasing the confidence of your clients/costumers in your products			X			

Orgalime comments related to question 16:

- The benefits generated for society by the REACH Regulation of reducing the exposure of citizens in general to hazardous chemicals and, therefore, avoiding healthcare costs, lost productivity, etc. need to be considered in combination with the effect of other legislation, because safety of products is achieved through other safety regulations (such as General Product Safety Directive, Low Voltage Directive) and not REACH.
- The benefits generated for workers by the REACH Regulation of reducing the exposure of workers to hazardous chemicals and, therefore, avoiding healthcare costs, lost productivity, etc. are rather significant. Information on chemicals gained through the registration process ensure safe handling through the supply chains, as long as information is of good quality.
- The benefits generated for society by the REACH Regulation of encouraging research and innovation, generating new jobs, and improving the competitiveness of EU manufacturing industry by encouraging/supporting a shift towards green, sustainable chemistry and a circular economy have to be split, because innovation and competitiveness are different issues. For example, when companies spend more money for complying with REACH they spend less money for innovation and therefore they are less competitive. To support the Circular Economy, further REACH implementation should ensure minimum quality requirements for secondary raw materials and the possibility of manufacturers to comply with existing restrictions, notably RoHS and REACH restrictions applying on electrical and electronic equipment.
- REACH can in practice influence the capability of DU companies to import chemicals from outside the EU, which could trigger price increases for chemicals and therefore could impact the competitiveness of EU manufacturing industries.
- Authorisation gives an advantage to manufacturing activities outside the EU (for example, Chromium VI).
- The benefits generated by the REACH Regulation for businesses - increasing the confidence of your clients/costumers in your products - are difficult to evaluate considering the parallel existence of other legislation, such as the RoHS, Ecodesign or WEEE Directives and of course industry's own driven continuous improvement of the environment performance of products.

QUESTION 17: in your view, to what extent are the costs linked to the following REACH chapters (for society, companies, public authorities, etc.) proportionate to the benefits (for society, companies, public authorities, etc.) achieved?

	1 Not at all	**2 Slightly**	**3 Somewhat**	**4 Substantially**	**5 Very much**	**Do not know/not applicable**
Registration						X

Information in the supply chain (e.g. eSDS – extended Safety Data Sheets)						X
Evaluation – dossier						X
Evaluation – substance						X
Authorization						X
Restriction						X
Requirements for substances in articles						X

Orgalime comments related to question 17:

- The question is too ambiguous to be answered: Impacts and costs on DU will depend on many still open implementation issues. Also, split incentives can occur (costs arise for one or two players, benefits for others). Some examples:
  Because of the high costs linked to the REACH registration, we expect that some SMEs and trading companies will not register on time before 1st June 2018 and their products will vanish from the EU-market for economic reasons.
  Related to the REACH costs for information in the supply chain (for example eSDS – extended Safety Data Sheets), we refer to earlier studies about the cost effects of REACH for SMEs. In all these studies, it was pointed out that SMEs consider REACH costs and the administrative burdens as too high. We would like to remind that Safety Data Sheets (SDS) are a tool to improve safe working conditions for downstream user companies. It seems that SDS became too voluminous and complex documents due to extended SDS scenarios that were included. Due to this many SDS now consist of more than 100 pages and are not understandable and readable for most workers and so are not useful in practice. Therefore, we call for developing summaries, for example "Work Instruction Cards" to be used by workers. Another concern is the poor quality of SDS. Incomplete, incorrect, unreliable and therefore non-compliant registration dossiers have a tremendous effect on the downstream users who have to comply with REACH and other pieces of EU legislation. Therefore, we call for continued efforts to ensure their improved quality. We also call for accurate data to avoid that ineffective measures are implemented and workers not protected, or that measures that are not needed and only a burden for companies are in place. Too low protection is a harm for the safety of workers and excessive protection is a burden for workers and additional unnecessary costs for companies.
- Regarding the costs of REACH authorisation, a lot depends on variable factors, such as if it will be possible to distribute the significant REACH authorisation costs over a reasonable number of years or not. In addition, the development and implementation of alternatives are related to high costs due to various levels of testing, collaboration with the suppliers and/or the costumers, process adjustments, up to replacement of installations, legal procedures (such as for permits of a product) etc.
- Regarding the costs linked to the REACH requirements for communication on substances in articles (Art. 33), a lot will depend on its proportionate implementation in the future. The frequent update of the Candidate List results in higher flow of information to be managed and subsequent costs. In addition, the Ruling from the European Court of Justice from September 2015 results in more complex and detailed information and therefore in a higher administrative burden for companies, while the benefits of too detailed information are at least unclear, at worst not realised.

QUESTION 18: is the level of the fees and charges paid to ECHA as provided by the Fee Regulation Commission Regulation (EC) No 340/2008), still adequate?

	Yes	**No, it is too high**	**No, it is too low**	**I don't know**
Fee for registration				X
Fee for authorization		X		
Fee for appeal				X

QUESTION 19: do you believe that there are areas where the REACH Regulation could be simplified or made less burdensome?

Yes to a large extent	
Yes but only to a minor extent	X
No	
I don't know	

If yes, you may provide ideas, preferably substantiated with quantitative evidence or qualitative information, at the end of the questionnaire.

Orgalime comments related to question 19:

- Better implementation of REACH is the solution.
- We welcome the Commission, ECHA and Member States efforts to simplify applications for authorisation for low volume substances and to streamline the authorisation process as a whole. Regarding simplified authorisation of secondary raw materials, we wish to remind the Commission that article producers need to remain in a position to comply with product specific legislation, such as existing RoHS restrictions or ecodesign requirements. Also, streamlining must not result in shifting responsibilities down the chain.
- We call for the integration of the "repair as produced" principle when it comes to authorisation and restriction implementation.
- SMEs have to be supported even further to meet their requirements under REACH.
- Requirements for communication on substances in articles need to be implemented in a way that they are proportionate, workable and feasible for companies.
- Less frequent updates of the Candidate List would help legal certainty.
- Better screening of applications for substances to be included in the Candidate List (for example application in material or articles) during the preparation of Risk Management Option Analysis (RMO-As) by Member States before deciding how to regulate substances.
- Through this analysis Member States should be able to decide whether REACH is the right instrument to address the concern linked to the substance assessed or if another piece of legislation is more fit-for-purpose. This should be the case for example in situations where only a limited number of workers is affected by substances of very high concern and work conditions can be controlled.
- When it comes to our sector and new restrictions in electric and electronic equipment, we call to apply one common substance evaluation for REACH and RoHS implementation based, inter alia, on risk, the availability of reliable substitutes and technical feasibility of substitution. Restricting an undesired substance in one sector "only" will be of limited effectiveness as the same substance will continue to enter material cycles via other applications, improper waste treatment processes and due to pre-REACH realities. This would hamper the Circular Economy. Also, realistic compliance deadlines are a prerequisite that industry can successfully handle substance restrictions.

RELEVANCE

The following questions explore the extent to which REACH is consistent with current needs.

QUESTION 20: do you believe that the REACH Regulation addresses the key issues in relation to the management of chemicals?

Yes to a large extent	X
Yes but only to a minor extent	
No	
I don't know	

If you answered no, you may provide detailed comments at the end of the questionnaire.

Orgalime comments related to question 20:
Self-evident.

QUESTION 21: how suitable do you consider REACH to be to deal with the following emerging issues?

	REACH is the most suitable EU legal instrument to address the issue	**REACH should only play a secondary role and the issues should be addressed by specific legislation**	**REACH is not a suitable instrument and should not address the issue at all**	**Do not know/ Not applicable**
Nanomaterials	X			
Endocrine Disruptors	X			
Substances in articles		X		
Combination effects of chemicals	X			
Extremely persistent substances	X			

Orgalime comments related to question 21:

- In our view REACH is the most suitable EU legal instrument to address the issues of nanomaterials, endocrine disruptors, combination effects of chemicals and extremely persistent substances.
- Regarding substances in articles we believe that REACH should only play a secondary role and the issues should be addressed by specific legislation. More often than not case by case solutions will be required in this area.
- Regarding the instrument on restriction (Annex XVII) we stress that as regards electrical and electronic equipment, the RoHS Directive exist in parallel, which restricts the use of currently ten substances in such appliances. The Common Understanding Paper REACH-RoHS clarifies important aspects of the interface of REACH and RoHS restrictions.
- Related to the Article 33, we believe there is room for improvement of implementation. The Ruling from the European Court of Justice from September 2015 made compliance even more challenging for the industry. Including Article 33 turned REACH into product legislation affecting many more enterprises than intended.
- Regarding combination effects of chemicals, assuming that it is about combination effects of chemicals and mixtures and the obligation related to safety data sheets (SDS), our comments are the following:
    - Chemicals when combined have an effect but which is very difficult to assess. It requires a case by case approach.
    - The problems with Safety Data Sheets (SDS) encountered by several companies are the following:
        - Distributor did not hand over the current SDS that would have been available from the producer
        - Producer did not update the SDS
        - SDS on a mixture did not contain information on all substances present in the mixture
        - CAS-number used that represented a mixture, without indicating the components of this mixtures, one of them being a substance of very high concern.

COHERENCE

QUESTION 22: please tell us to what extent you agree or disagree with the following statements:

	1 Strongly disagree	2 Disagree	3 Neutral	4 Agree	5 Strongly agree	Do not know/not applicable
The different chapter (e.g. registration, authorization, restriction) in REACH are applied in a coherent manner (e.g. there are no contradictions, inconsistencies…)				X		
The different chapters in REACH (e.g. registration, authorization, restriction…) are applied in a coherent manner (e.g. there are no contradictions, inconsistencies, they are complementary…) in relation to other EU legislation (e.g. worker protection legislation, consumer protection legislation, environmental legislation)		X				
The implementation of the SVHC Roadmap, including the Risk Management Option Analysis /RMOA) contributes to coherent implementation of authorization and restriction under REACH				X		
The implementation of the SVHC Roadmap, including the RMOA, contributes to coherent implementation of REACH in relation to other EU legislation (e.g. there are no contradictions, inconsistencies, they are complementary…)				X		

Orgalime comments related to question 22:

- We agree that the different chapters (registration, authorization, restriction) in REACH are applied in a coherent manner (there are no contradictions, inconsistencies…).
- We disagree that the different chapters in REACH (registration, authorization, restriction…) are applied in a coherent manner (such as that there are no contradictions, inconsistencies, they are complementary…) in relation to other EU legislation (such as worker protection legislation, consumer protection legislation, environmental legislation). The reasons are the difficulties encountered with the RoHS Directive, which, despite required by article 6 RoHS, is not consistently implemented with REACH. The common understanding between REACH and RoHS is a good start but has not yet been implemented fully. In addition, we call for a commonly accepted scientific and technical evaluation for establishing restrictions which is valid for both REACH and RoHS. When it comes to new restrictions in electric and electronic equipment, one common substance evaluation for REACH and RoHS implementation should be developed and applied. This methodology should be based, inter alia, on risk, the availability of reliable substitutes and technical feasibility of substitution.
  Restricting an undesired substance in one sector "only" will be of limited effectiveness as the same substance will continue to enter material cycles via other applications, improper waste treatment processes and due situations existing in practice prior to REACH realities. Also, realistic compliance deadlines are a prerequisite for industry to successfully handle substance restrictions.
- In addition, the implementation of different REACH chapters impacts other EU policies and objectives, such as the industrial policy, waste policy or resource efficiency policy.
- We agree that the implementation of the SVHC Roadmap, including the Risk Management Option Analysis /RMOA) can contribute to coherent implementation of authorisation and restriction under REACH.
- We agree that in principle the implementation of the SVHC Roadmap, including the RMO-A, can contribute to coherent implementation of REACH in relation to other EU legislation (meaning in particular that there are no contradictions or inconsistencies, or that they are complementary…). In general, it goes in the right direction even though coherence is not always guaranteed case by case.

- We welcome that there is now a systematic use of RMO-As by the authorities. We call for enhancing coordination amongst Member States to avoid that same substances are assessed in parallel by different Member States.

QUESTION 22.1: if you disagree with one or more of the statements above, where do you consider coherence should be enhanced?
(max. 5.000 characters)

Orgalime comments related to question 22.1:
More coherence of other legislation with REACH, notably of RoHS with REACH, should be enhanced.

EU ADDED VALUE

QUESTION 23: to what extent do you consider that taking action through the different chapters of REACH has added value above what could have been achieved through action by Member States alone at national level? (1= no value, 5= a very high value)

	1 No Value	**2**	**3**	**4**	**5 Very high value**	**Do not know/not applicable**
Registration					X	
Data-sharing and avoidance of unnecessary testing					X	
Information in the supply chain					X	
Evaluation – dossier					X	
Evaluation - substance					X	
Authorization					X	
Restriction					X	

Orgalime comments related to question 23:

- We strongly believe that taking action through the different chapters of REACH has added very high value above what could have been achieved through action by Member States alone at national level. Harmonised rules under REACH in all EU Member States are a must for our industry because they guarantee the functioning of the internal market which is one of the EU's greatest achievements. Fragmentation of the EU internal market has to be avoided by all means.

Part III. B

QUESTION 24: in your view, how satisfactory are the following mechanisms and procedures of the REACH Regulation?

	1 Not at all satisfactory	**2 Rather unsatisfactory**	**3 Neutral**	**4 Rather satisfactory**	**5 Very satisfactory**	**Do not know/not applicable**
Awareness raising for duty holders on key obligations and deadlines			X			
Support for preparation of registration dossiers						X
Participation in substance Information Exchange For a (SIEFs) – data sharing						X

Dossier submission – IT tools						X
Communication of information along the supply chain			X			
eSDS – extended Safety Data Sheets		X				
Notification of SVHCs in articles		X				
Information concerning presence of SVHCs in articles			X			
Assessment of testing proposals						X
Dossier compliance check		X				
Enforcement/follow-up of compliance check decisions		X				
Substance evaluation activities by Member States			X			
Identification of relevant SVHC's for the candidate list			X			
RMO-A (Risk Management Option analysis) process				X		
Prioritization of SVHCs for authorization			X			
Amendments to the list of substances subject to authorization			X			
Substitution of SVHCs			X			
Support for applicants for authorization			X			
Assessment of applications for authorization by ECHA		X				
ECHA public consultations (e.g. in restriction or authorization)			X			
Consideration of the availability and feasibility of alternatives		X				
Decision making by Commission on applications for authorization			X			
Preparation of Annex XV dossiers to propose new restrictions			X			
Assessment of proposals for new restriction				X		
Decision making by Commission on new restrictions				X		
Exemptions for R&D			X			

activities						
Reduction of fees for SMEs		X				
Guidance by ECHA				X		
Guidance by national authorities			X			
Guidance by industry associations				X		
Support provided by Helpdesks				X		
Operation of the Board of Appeal						X
Inspections by enforcement authorities						X

Orgalime comments related to question 24:

- The identification of relevant substances of very high concern for the candidate list should be more rigorous and based on solid data collected during the RMO-A phase.
- Related to ECHA public consultations (for example during the restriction or authorisation process), the consultation periods are extremely tight compared to the time required for the industry to collect data. We would very much welcome longer consultation periods.
- Guidance by national authorities, if any, need to be fully consistent with the ECHA Guidance and should not add on complexity or new requirements considering that REACH is a Regulation and fully harmonises requirements in the EU.
- Regarding Article 33, implementation could be more efficient so as to reduce the administrative burden. For example, we call for reducing the speed of the process. An annual instead of bi-annual frequency of the update of the candidate list would make the process less burdensome for companies.
- In addition, we ask for a better screening of alternative substances before being added onto the Candidate List. Substitution must result in environment improvement and translate into benefits.
- Regarding restriction, we would like to stress the importance of consistency of legislation and of avoiding double legislation. The parallel implementation of REACH and RoHS regarding the restriction of the use of certain substances in electrical and electronic equipment is a prominent example in this respect: we refer to the pending ECHA restriction proposal on four phthalates, which are already restricted by RoHS, and which, so far, fails to exclude RoHS products from its scope. The agreed Common Understanding Paper explicitly states that in such cases, REACH should not create double legislation. We call for the systematic application of this common understanding throughout REACH implementation. In addition, we reiterate that one commonly accepted scientific and technical evaluation for establishing restrictions under either RoHS or REACH would benefit the environment, human health and industry as well.

Part IV – Additional comments

QUESTION 25: if you have any additional comments relevant to this public consultation, please insert them here. You may also upload position papers.
(max. 5.000 characters)
Please upload your additional document(s) (one by one, any format)

Orgalime has published a position paper on the REACH Refit Evaluation, which includes all our responses and comments to the individual questions of the stakeholder questionnaire in more detail. These comments aim at providing Orgalime's motivation and justification to all our answers given to the individual stakeholder questions and it also includes our recommendations regarding further priorities for REACH implementation.

QUESTION 26: are you interested in being contacted in the context of the ongoing study on the impact of authorisation?

YES	X
NO	

CONCLUSIONS

Based on above considerations, Orgalime considers **an amendment of the REACH legislation as premature at this stage.**

We believe that **continued and enhanced implementation of REACH** is the best option for strengthening its impact on the ground. In particular, we suggest focusing implementation efforts on the following areas:

1. **Quality of data on registered substances and registration dossiers:** The potential of REACH to be a source of reliable data is evident and very much appreciated. However, the ECHA 'Evaluation report 2015 "of February 2016 states that only 18% of the verified registration dossiers was compliant.
   Incomplete and incorrect registration dossiers have a tremendous negative effect in the entire supply chain, and on DUs in particular:
   - DUs require correct information (such as reliable safety data sheets) to be able to use chemicals without harming the environment or human health.
   - DUs need to substitute SVHC used as a process chemical or present in articles with substances that have a lower risk for both, the environment or human health. If data stemming from REACH registration are not of sufficient good quality, companies will lack the necessary and indispensable information for taking appropriate risk management decisions.

   Correct and high quality data are also essential for authorities, including Member States, to underpin their decisions to propose new measures on chemical substances.
   - ⇨ *We call for enhancing and ensuring the high quality of registration dossiers, including high quality dossiers in 2018.*
   - ⇨ *We call for continued ECHA and Member States' support to achieve this objective, including through requests to complete incomplete dossiers and through surveillance and enforcement.*
   - ⇨ *In particular, the existing ECHA Guidance on information requirements and chemical safety assessment, chapter "R.18: Exposure scenario building and environmental release estimation for the waste life stage", version 2.1 of October 2012, needs to be fully implemented during the REACH implementation process.*

2. **Continue the good practice of conducting Risk Management Option-Analysis**
   We welcome the systematic preparation of Risk Management Option Analysis (RMO-As) by Member States before deciding on how to regulate on substances in a specific case.
   Through this analysis, regulators are in the position to identify whether REACH is the right instrument to address the concern linked to the substance in question, or if another piece of legislation would be more fit-for-purpose. This increases the efficiency and effectiveness of REACH as it concentrates resources of all actors on areas and means where real benefit can be generated. Double regulation is avoided, which in return strengthens legal certainty and competitiveness of the industry.
   Should REACH be identified as the most appropriate tool, then the RMO-A should carefully consider whether the identification of a substance as SVHC and its inclusion in Annex XIV or rather an Annex XVII restriction would be the most appropriate measure.
   Additionally, RMO-As should thoroughly evaluate socio-economic consequences of the regulatory options considered. These considerations should be linked with an in depth analysis of available alternatives. If existing alternatives have the same properties and risks as the substances to be potentially authorised or restricted under REACH, there will be no benefits for the environment and human health, while unnecessary costs for industry arise.
   - ⇨ *We call for a better screening of alternatives for substances assessed by Member States or ECHA before they are proposed for addition to the Candidate List or for restriction.*
   - ⇨ *We call for enhancing coordination amongst Member States to avoid that the same substances are assessed in parallel by different Member States.*
   - ⇨ *Member States potential new RoHS restriction proposals should be consistent with REACH, as article 6 RoHS requires the following: "The review and amendment of the list of restricted substances in Annex II shall be coherent with other legislation related to chemicals, in particular Regulation (EC) No 1907/2006, and shall take into account, inter alia, Annexes XIV and XVII to that Regulation. The review shall use publicly available knowledge obtained from the application of such legislation."*
     As REACH implementation goes on, we call for improving RoHS implementation so that it will indeed be consistent with REACH.

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RMO-As are also the best means to identify if the REACH Regulation or the RoHS Directive should be used for further restricting the use of substances in electrical and electronic equipment.

3. **Make identification of Substances of Very High Concern and Annex XIV substances more efficient** to reduce the administrative burden for companies.
   - ⇨ *We call for an annual instead of bi-annual frequency of updating substances of very high concerns on the candidate list. This would help make the process less burdensome for companies.*
   - ⇨ *We welcome the introduction by the Commission of new stakeholder consultations on socio-economic impacts, in parallel to ECHA consultations on their draft recommendations for the addition of new substances in the Annex XIV.*
     If data gathered during the consultation show that there would be a disproportionate economic impact while only limited health and environmental gains, and the unavailability of alternatives, those substances should not be included in the Annex XIV and other risk management measures should be selected.
     This would avoid forcing European companies into costly and burdensome authorisation procedures and discriminating them against their non-EU competitors.
   - ⇨ *We also request the Commission's support for ensuring a balanced application and implementation of REACH articles 58.2 and 56 REACH. So far, in ECHA's recommendations for the prioritisation of substances to be included in the Annex XIV, the application of these legally granted exemption mechanisms has in our view been too narrow. Where RoHS grants an exemption, REACH article 58.2 should be applied.*

4. **Restriction and Authorisation of Substances of Very High Concern**: restriction and authorisation are processes aiming at substitution and minimisation of the use of substances of very high concern.
   Given their far-reaching effects, the RMO-A phase should assess whether these two processes are indeed the most suitable risk management measures. There may be cases where other pieces of legislation allow to address the concern linked to a substance and avoid unnecessary costs for industry, such as in the case of Chromium VI.
   Regarding authorisation, as stated earlier, DUs rarely face authorisation obligations directly. In most of the cases we expect to be impacted by the authorisations granted or rejected through knock on effects in the value chain. Industry fully supports substitution when reliable alternatives are available and if appropriate compliance deadlines and an exemption mechanism are granted. Should alternatives not be available, authorisation for the continued use of an Annex XIV substance should be granted.
   Industry finds it challenging to manage the uncertainties linked to the Commission's final decision on the length of the authorisation period that will be granted. This period needs to be sufficiently long to ensure smooth industrial operations.
   It is also to be noted that despite the fact that these periods can be renewed, the uncertainty related to the length and final outcome of any renewal request raises questions at customers' and suppliers' level. Experiences also show that the work to demonstrate the non-availability of alternatives is highly demanding. ECHA should scrutinise third parties' claims regarding the existence of alternatives as thoroughly and as rigorously as the applicants' analysis of alternatives.
   Therefore:
   - ⇨ *We call for accurate and thorough RMO-As as a first step in the process.*
   - ⇨ *We call for maintaining and making the authorisation process ever more clear and transparent, to limit the uncertainties for industry as highlighted above.*
   - ⇨ *We welcome and call on the Commission, ECHA and Member States to keep up efforts to streamline the authorisation process and simplify it when needed and justified. In the case of streamlined authorisation for recycled materials we underline that this must not result in a shift of responsibilities down the value chain. Producers of electrical and electronic equipment must remain in a position to comply with sector specific legislation, and RoHS restrictions in particular.*
   - ⇨ *We also call for a systematic implementation of the "repair as produced principle" in the REACH authorisation and restriction process, to ensure the availability of spare parts for repair, reuse, remanufacturing or refurbishment of appliances in line with Circular Economy objectives. This will avoid that appliances legally turn into waste while still repairable.*
   - ⇨ *We call for a better clarification of definitions and terms used in the Annex XVII in guidance documents (such as" prolonged or short-term repetitive contact with the human skin or the oral cavity" - entry 27 on nickel).*

5. **Focus on effective and meaningful communication across the supply chain that is necessary to allow the safe use of substances**
   Safety Data Sheets (SDS) are *the* key tool for communication in the supply chain and to ensure safe working conditions in downstream user companies. DUs experience shows that many SDSs have inconsistencies in the SDS classification when compared with existing REACH registration dossiers and CLP notifications, and other sections of the SDS itself. These errors create issues for DUs, including SMEs, which do not have the capacity and the resources to verify the quality of SDS. Additionally, SDS have become too large and complex documents due to extended SDS scenarios. Many SDS are now consisting of more than 100 pages, are hardly understandable or readable and are, as a consequence of limited use in practice.
   - ⇨ *We call on ensuring the proper implementation of REACH requirements related to Safety Data Sheets and to make ensuring their quality a top priority.*
   - ⇨ *We understand that long Safety Data Sheets are needed for legal reasons by chemical companies but we call for developing summary "Work Instruction Cards" to be used by workers in downstream user companies, as really required by SMEs.*

   Secondly, when it comes to communication related to Substances of Very High Concern in articles, the **implementation of articles 33 should be proportionate**.
   - ⇨ *We call for a proportionate and workable implementation of article 33. As laid out in Article 5 of the EU Treaty, measures are to be limited to what is necessary to achieve the given objective. The objective of Article 33 REACH is to allow the safe use of articles. Sub-articles (components) of complex products are often deeply integrated, assembled or joint together into the final article with no exposure under reasonable and foreseeable conditions of use. To allow the safe use, it would therefore in our view not be necessary to require a complete breakdown of a complex article into all of its components.*

6. **Continue efforts of the different Enforcement Authorities to exchange and coordinate their national practices on REACH enforcement.** The better the coordination of enforcement authorities, the more efficient their enforcement of the REACH Regulation for an improved level playing field amongst market operators. This will avoid negative impacts on the competitiveness of legitimate manufacturers.

7. **REACH costs and administrative burden** for companies, and in particular for SMEs, are very significant and not always justified and proportionate to the benefits.
   - ⇨ *We welcome the Commission's efforts to simplify and streamline processes under REACH (such as a simplified authorisation for low volume substances) and we call for keeping up these efforts. As previously mentioned, streamlining must not compromise manufacturers' ability to comply with other legislation, such as RoHS.*
   - ⇨ *We call for continued efforts and support for SMEs to meet their REACH obligations.*

8. Regarding the interface between **REACH and RoHS,** we call for:
   - ⇨ *the systematic application of the agreed Commission and CARACAL Common Understanding Paper.*
   - ⇨ *for potential Member States' RoHS restriction proposals to be consistent with REACH, including being consistent with the RMO-A.*
   - ⇨ *for one commonly accepted scientific and technical evaluation for establishing restrictions which is accepted for both, REACH and RoHS implementation. This methodology should be based, inter alia, on risk, the availability of reliable substitutes and technical feasibility of substitution. Restricting an undesired substance in one sector "only" will be of limited effectiveness as the same substance will continue to enter material cycles via other applications improper waste treatment processes and due to pre-REACH realities. Also, realistic compliance deadlines and a functioning exemptions' mechanism are a prerequisite for industry to successfully handle substance restrictions.*
   - ⇨ *Where data and information gaps exist for RoHS implementation, REACH should be the primary vehicle to fill them.*

Europe's engineering industries continue to fully support the objectives of REACH and other sector specific legislation, such as the RoHS Directive 2011/65/EU and remain committed to its proper compliance in the EU to the benefit of the environment and human health and in support of our competitiveness and innovation capability at EU and global scale.