ORGALIME

Position Paper

Brussels, 18 July 2014

Risk Management Options (RMO) Analysis following the SVHC Roadmap to 2020

EXECUTIVE SUMMARY

The European engineering industries represented by Orgalime are fully committed to the responsible use and risk management of chemicals in their manufacturing processes, a proper supply chain management and the development of sustainable products, systems and technologies in overall respect of environmental and human health objectives.

We particularly support the objectives of the EU´s chemicals policy acquis, including the REACH Regulation or the sector specific RoHS Directive, as well as the objectives pursued by several other critical pieces of EU legislation, such as the WEEE or Ecodesign Directives.

For the purpose of ensuring timely and proper compliance with all EU legislation, however, our industry depends on regulatory predictability, stability and legal certainty. These requirements are at the same time key factors for stimulating industrial re-investment in Europe that will allow the manufacturing sector to continue adding value with a strong prospect of jobs and growth in Europe.

In practice, however, our industries often experience the opposite, including in the area of chemicals policy: we face, for example, frequent inclusion of substances in the REACH candidate list, numerous reviews of sector specific legislation, insufficiently coordinated legislative or implementation activities on new and/or existing EU measures. Indeed, the engineering industries face more and more overlaps in the interface between REACH and RoHS that risk upsetting the overall consistency of the EU chemical legislation. This is not helpful for companies in terms of recovering the investment made in innovative products, nor for their global supply chain management, nor for their overall competitiveness.

Therefore, Orgalime welcomes the Commission's commitment to improve "planning", "predictability" and "communication", as provided in the Roadmap on Substances of Very High Concern (SVHC) to 2020, which is aligned to the stated objective of the REACH Review. We also welcome the Commission's SVHC Roadmap, in conjunction with ECHA's Implementation Plan as a first promising step towards a proper implementation of the REACH Review recommendations. Orgalime industries strongly support its core element, namely the proposal for carrying out the Risk Management Options (RMO) analysis on a regular basis. The SVHC Roadmap is in our view the occasion to implement the main principles of the wider EU Industrial Policy. A transparent, clear and predictable process should be ensured, while keeping the administrative burden, costs and workload to the minimum level necessary.

Orgalime, the European Engineering Industries Association, speaks for 40 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 23 European countries. The industry employs some 10.3 million people in the EU and in 2013 accounted for some €1,800 billion of annual output. The industry not only represents some 28% of the output of manufactured products but also a third of the manufactured exports of the European Union.

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Nonetheless, the ECHA Implementation Plan on the SVHC Roadmap will in our view require further substantiation to deliver its stated objectives and to successfully operate in practice. Orgalime particularly seeks regulators´ support for several critical follow up steps and measures, including the following:

1. Providing an overview of potential uses of substances scrutinised and notifying the potential affected industry sectors (via European industry associations) on an automatic basis;
2. Setting up a harmonised prioritisation mechanism for the substances to be scrutinised under the RMO analysis;
3. Involving industry at an early stage and under realistic timelines to allow industry to properly contribute throughout the RMO process;
4. Establishing regular, comprehensive and publicly available updates of the prioritisation of all SVHCs included in the Candidate list in view of further possible inclusion in Annex XIV;
5. Re-assessing the Candidate list substances in using the RMO analysis in the mid to long term;
6. Introducing more transparency in the process of filling the Candidate list and throughout the implementation of the SVHC Roadmap (the envisaged "Activities Coordination Tool" PACT is a promising step);
7. Striving for a common understanding throughout the 28 EU Member States, the Commission and ECHA on the criteria for identifying a SVHC as "relevant";
8. Making the criteria upon which Member States choose a SVHC as relevant and upon which Member States will assess such substances publicly available;
9. Providing regularly updated, public information on the state of Member States´ activities and procedures, including on envisaged timelines for the assessments of substances for identification as SVHC as well as other regulatory measures;
10. Adding information regarding the sectors that use a certain substance to the current ECHA database – the ECHA website should also allow for a search per industry sector as a starting point, rather than "only" per name of the substance
11. Developing a Commission guidance document on the RMO process to provide:
    - a common understanding of the different possible RMOs (including REACH and other relevant EU legislations, such as sector specific chemicals regulations, waste, industrial emissions policy measures or core work place occupational health and safety policy measures) and which option would be generally considered more appropriate in what case,
    - a recommendation of a three step RMO analysis, including evidence of risk, thorough evaluation of risks, demonstration and justification of the need for regulatory action and the chosen the RMO as well as an assessment of impacts of the suggested measures to the relevant industry sectors, and
    - key information to be gathered in RMO reports;
12. Reinforcing cooperation with Europe´s main trading partners, in terms of providing early warning on substances to be put on the candidate list, especially if such a substance is only produced outside Europe, in order to facilitate the complex management of global supply chains for European industry.

These Orgalime´s suggestions are derived from its experience as a major client industry of the EU chemicals industry (thus a major REACH "downstream user"), while representing producers and importers of final articles and their components that will be supplied to all sectors of the EU economy, including the automotive, aerospace, chemical, food, textile, energy generation, transmission or distribution industries, as well as private consumers. Our industry is a strong, competitive and innovative industry: we are the enabler of the green, low carbon energy and resource efficiency economy through the products, systems and technologies that we produce.

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Orgalime provides hereafter the detailed reasons for its belief in and call for support for the RMO process and harmonised implementation of the SVHC Roadmap, as well as its detailed recommendations for its further implementation.

1. INTRODUCTION

The SVHC Roadmap together with its Implementation Plan are in our view helpful tools to come forward with a pragmatic approach for tackling the very large number of potential substances to be analysed by 2020.

In addition, they are important for pathing the way towards a better harmonisation of current practices in the 28 EU Member States, the Commission and ECHA, especially through providing a common understanding of what constitutes a "relevant SVHC" under the fully harmonised EU REACH Regulation.

Two elements attract Orgalime´s particular attention: the implementation of the proposal to carry out Risk Management Options (RMO) analysis, and the future involvement of stakeholders, including relevant industry experts, in this process, which should in our view be mandatory for each Member State and for ECHA.

2. WHY IS A THOROUGH RMO PROCESS NEEDED?

Orgalime sees multiple benefits arising from a proper RMO process for all different actors involved:

2.1 Improved efficiency of procedures and reduction of costs for all actors involved

Carrying the RMO analysis includes an additional step in the risk management procedures. We acknowledge that in certain cases this can make the regulatory procedures lengthier and, perhaps, more complex in the beginning. However, if applied thoroughly, the RMO analysis offers a potential of increasing the overall efficiency of regulatory procedures and reducing costs.

The RMO analysis provides clarification whether an implementation measure under chemicals policy (such as a REACH restriction, RoHS restriction, REACH authorisation) would be appropriate rather than other EU environment policy measures or workplace occupational health and safety policy measures. It consequently facilitates a consistent application of such decisions by all regulators leading to a more efficient use of resources at EU level, but also at national and industry level.

2.2 Improved overall coherence and consistency of EU legislation

The RMO analysis appears to us as a key instrument to improve coherence in the application of the different EU legislative tools. Indeed, the RMO process should avoid parallel REACH authorisation and restriction procedures, but also REACH and sector specific risk management measures, such as RoHS restriction, on the same substances.

Today, European engineering industries face parallel legislative requirements that are not sufficiently coordinated, such as REACH, RoHS, WEEE, or Ecodesign. Indeed, the ever more complex body of the EU legislation is increasingly of concern to industry, especially for integrated multifunctional products. The different pieces of EU environmental legislation act in isolation from each other, whereas different safety, health and environmental parameters can influence and also conflict with each other. In addition, the use of different frameworks to assess the use of the same substance in the same product (for example, REACH Authorisation and RoHS Restrictions/ Exemptions) may result in inconsistent judgments on the need and way to further regulate a substance.

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Taking into consideration legal measures under REACH and beyond, the RMO analysis helps regulators to objectively choose the best legal instrument to protect human health or the environment from a holistic perspective. This contributes to a mutually reinforcing implementation of the various pieces of EU legislations that each stands alone but not in isolation from the others.

2.3 Improved transparency in the EU decision making process and gathering all available expertise at the earliest stage possible

So far, the consultations on the identification of SVHCs showed that the involvement of downstream users (DUs), especially SMEs, is a challenge mainly due to the short timelines given in consultations and the complexity of our supply chain. However, better transparency can foster a more effective and active contribution of stakeholders that facilitates the RMO activities, even beyond the REACH scope. Indeed, gathering available expertise very early will help to build a complete picture of the scrutinized chemical substance and a mapping of its uses. Collecting information that is not available from usual sources (that is registration dossiers and evaluation) helps Member States authorities' to minimize unintended and undesirable consequences on end users, including European manufacturing industries.

Furthermore, better transparency and proper communication will have wider positive effects, notably an increased acceptance of final decisions on regulation of chemical substances and, timely preparations for compliance with communication requirements (Article 33 REACH), and thereby on EU environmental and human health policy objectives.

2.4 Improved regulatory predictability and legal certainty for European industry

The competitiveness of our industries depends on various key elements, including the availability of a broad and as diversified as possible a portfolio of reliable, high performing chemical substances for innovation and product quality. Indeed, our clients expect our sectors to provide innovative products with a high degree of reliability, safety and fitness for purpose.

To develop new products, technologies or even entire production lines, producers need sufficient legal certainty and predictability on the substances they can rely on in the future, which is not necessarily the case today. This would facilitate our companies' continued investment in new technologies and keep Europe in the lead in many areas of engineering technology.

The RMO analysis appears to us as a key instrument to provide such legal certainty and predictability in the EU´s substance management policy and so planning security for companies.

Orgalime's industries are producing complex products with hundreds and thousands of different components, which are sourced around the globe. The time needed to develop or re-design a product differs from case to case, but significantly depends on the degree of complexity of supply chains and differing company structures. Some of our products have very long development cycles, while products need to be submitted to testing and conformity, assessment procedures to meet all relevant market and legislative requirements.

From an industry perspective, clarity on the planning of ongoing substance assessments in the EU helps certainty and predictability also for the identification, evaluation and testing of economically and scientifically viable alternatives and available substitutes. Therefore, the implementation of the SVHC Roadmap to 2020, especially the RMO analysis, should reconcile continuous improvement of the environmental performance of our processes and products with the reality of complex supply chains and highly competitive global markets.

Our industries are committed to substitute hazardous substances where reliable better alternatives substances or technologies are available without compromising other essential product parameters.

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However, too frequent and substantial updates of the REACH Candidate list and the lack of long term planning on future substances subject to authorisation or restriction, as well as parallel legislative actions on same substances used in our products, just create confusion, legal instability and uncertainty for companies.

3. ORGALIME SUGGESTIONS TO ACHIEVE A SUCCESSFUL RMO PROCESS

3.1 A transparent process of substance identification and selection for assessment

We acknowledge that stakeholder consultation is currently part of the REACH implementation, such as the SVHC identification process, which we appreciate. However, in the light of first experiences, we face too short deadlines, too frequent consultations and updates of the Candidate list as well as complex procedures. The current REACH implementation makes effective contributions to consultations and compliance with requirements challenging for the engineering industries, as a whole and especially even more challenging for SMEs. Given the complexity of our supply chain, gathering the requested information is at best a complex process that requires human resources and time. As a consequence, this results in high costs and creates legal instability and uncertainty for article suppliers without substantial benefits for human health or the environment.

To provide better predictability and transparency on the substance identification and selection for assessment, Orgalime suggests the following measures**:**

- **A prioritisation mechanism of scrutinised substances**

The SVHC Roadmap foresees the publication of certain information, which is a good step towards transparency and should help improve predictability on scrutinised substances. To implement this commitment, the ECHA Implementation Plan announces the publication of annual reports summarizing activities carried out in the past months and outlining activities planned for the following year. This is generally welcome, but insufficient with respect to activities planned for the future. Given the long development cycles of our complex products, an outline of activities should clearly go far beyond 12 months.

Therefore, Orgalime suggests a clear identification of the substances which are prioritised and therefore likely to be assessed up to 2020. A harmonised ranking of the substances to be scrutinised (for example red-orange-yellow) should be built according to their priority for detailed assessment (RMO analysis) and a clear timeline for the assessment should be given. Such a “prioritisation mechanism” would divide the list of substances into three priority groups according to the potential need to address risks for human health and the environment. Indicating on which substances to focus first would provide better predictability for the industry, while not hampering the sound and thorough assessment or the outcomes.

- **An accurate and timely prioritisation of substances already included on the Candidate list**

In the light of first experiences, we realise that the authorisation procedure covers the whole supply chain, from chemicals manufacturers to complex article manufacturers, and may result in knock-on effects on the whole supply chain. The first step of the authorisation process is the inclusion of substances on the REACH Candidate list: a waiting line, for “*eventual inclusion in Annex XIV*” (Article 59 REACH). As a consequence, it triggers notification and communication requirements (Articles 7.2 and 33 REACH), but also uncertainty on the future on these substances that may negatively impact the whole supply-chain.

We recognise that candidate substances are assessed on a regular basis to prioritise some substances for further inclusion in Annex XIV REACH. However, currently, the results of such a prioritisation assessment assign a priority level (that is low, medium or high) to assessed substances in the context of a particular “prioritisation round”.

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It does not provide a clear picture on **all** evaluated substances whether they will be subject to authorisation in the future and, if it is case, when it will be recommended by ECHA.

Orgalime believes that the prioritisation mechanism should assess all substances of the Candidate list (rather than only the new ones) at each "round" on a regular basis (for example once a year), giving thus a consolidated picture on the real priorities.

It will contribute to improving predictability and avoiding unexpected consequences on manufacturing industries. Such an assessment, indicating whether these substances are likely to become subject to authorisation, would be very beneficial. A clearer communication will fully tie in with the RMO process. We therefore fully support the newly adopted ECHA commitment that "*in subsequent prioritisation rounds, each substance that is not already included in Annex XIV will be reassessed, taking into account any new information relevant for the prioritisation*".[1]

- **A re-assessment of Candidate list substances in the mid to long term**

For the time being, we admit that the REACH Regulation does not foresee any mechanism to reassess and consequently withdraw substances from the REACH Candidate list. However, in the longer term, Orgalime supports settling this shortcoming in the legal framework of REACH directly.

Some SVHCs have been identified without the full RMO analysis. In the light of new information or a deeper assessment (such as adjustments of classifications), it may appear that the inclusion of some substances in the Candidate list as potential candidates for the authorisation list is not the best approach to handle the given risks. We remind regulators that the consequences of authorisation are severe for European industry competing globally and result in knock-on effects on the whole supply chain. In addition, authorisation applies to the manufacturing process of articles produced in the EU, but not to those outside Europe. This results in an unbalanced situation for European manufacturing industries.

Therefore, we urge regulators to carry out the RMO analysis for substances included in the Candidate list and the set of substances currently under the SVHC identification process. This would help to clarify whether the authorisation is indeed the most appropriate risk management option.

- **Reinforced cooperation with major trading partners**

While some substances are only manufactured outside Europe, the regulation of such substances in the EU risks impacting the entire supply chain, including EU end-users.

This is the case, for example, for ADCA (azodicarbonamide) that is a foaming agent widely used in the plastics industry, which enabled high levels of technical product innovation, safety and environmental gain. For example, ADCA is used in the manufacturing process of power, telecommunication and data cables to ensure highly protective insulation. Notified in the ECHA Registry of Intentions in August 2012, ADCA has been then included in the candidate list and recommended for inclusion in the authorisation[2] list within 18 months. However, such a short period did not provide EU downstream users and non EU chemical manufacturers with sufficient time to react adequately. It could impact the availability of such a key substance from the market. As a consequence, our industrial processes and supply chain could be seriously disturbed and the environmental and safety performance of our products could decrease. These potential supply chain interruptions may negatively impact jobs, exports and competitiveness of our industries.

[1] *Prioritisation of SVHCs for inclusion in the Authorisation List (Annex XIV)*, ECHA, 10 February 2014

[2] 5th recommendation for further inclusion of SVHCs in the authorisation list (Annex XIV), February 2014. http://echa.europa.eu/documents/10162/13640/5th_a_xiv_recommendation_06feb2014_en.pdf.

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We believe it is of utmost necessity to better raise the awareness of other regions of the world in order to facilitate the complex management of global supply chains for European industry. Non EU actors face difficulties in understanding European requirements and EU regulatory procedures. The Commission, ECHA and Member States should contribute towards spreading information to major EU trading partners on REACH requirements and the implementation of the EU chemical management policy, including, for example early warning on substances to be put on the Candidate list.

3.2 A comprehensive Risk Management Option (RMO) analysis

Once a substance has been selected for further scrutiny, according to Article 57 REACH, Orgalime recommends three key steps that should be applied for a successful Risk Management Options process.

- **Step 1: Determine and evidence whether there are risks to be managed or not,** following:
  - **a risk based approach** for all substance evaluation based on scientific and technical evidences;
    Indeed, the EU Court of Justice (case T-456/11, judgement of 14.11.2013 on Commission Regulation on the restriction of cadmium in plastic materials) has recently stated that: "*if it is not to adopt arbitrary measures, which cannot in any circumstances be rendered legitimate by the precautionary principle, the Commission must ensure that any measures that it takes, even preventive measures, are based on as thorough a scientific evaluation of the risks as possible, account being taken of the particular circumstances of the case at issue*".
  - **a life cycle approach**, including the waste phase;
  - **a case by case assessment of substances** (although the grouping of substances based on properties and uses might be relevant, each substance should be subject to the RMO analysis on an individual basis);

  This step should result in **a conclusion on whether there is need for further regulatory action or not**, which should be made publicly available. To come to such a conclusion, possible already **ongoing risk management processes should be taken into consideration**. Indeed, the outcome of ongoing risk management processes, under REACH, or other legislation such as RoHS, on a given substance should be taken into account to confirm whether or not there is a need for additional measures to regulate residual risks.

- **Step2: Demonstrate the need for regulatory action, in particular that the risk is not yet addressed in any EU measure, either under the chemical regulatory framework or other.**

- **Step 3: Analyse the possible regulatory options to handle the identified risks appropriately,** comprising at least the following:
  - **an automatic assessment of all various options to regulate substances** and the identification of the most appropriate instrument to address the concerns;
    The range of risk management measures options to be assessed should go far beyond the REACH Regulation and include legal measures, but also non-legal measures. The range of options to be assessed should include risk management measures under the REACH/CLP Regulations (that is authorisation or restriction) and those outside the scope of REACH through sector specific legislation (for example, RoHS, Packaging, Batteries and Accumulators Directives), but also measures under other EU environment and waste acquis, such as the Seveso, Waste Incineration, Industrial Emissions or WEEE Directives. In addition, workplace occupational health and safety measure (such as binding and indicative occupational exposure limits (OEL) under the Chemical Agents at Work Directive or the Carcinogens or Mutagens at Work Directive) should also be part of

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the RMO analysis given their potential to effectively reduce risks without jeopardizing further the competitiveness of the EU industry.

- **an assessment of impacts of risk management measures on Downstream Users**, especially SMEs;
- **an assessment of necessary exemptions** for any risk management measure;

In order to carry out steps 2 and 3, a common understanding of the possible risk management options and what option would be more appropriate in a given case appears an essential prerequisite to us.

Such a common understanding is urgently needed considering the increasing overlaps and inconsistencies arising from an insufficiently coordinated implementation of the horizontal REACH Regulation and other pieces of legislation, such as the sector specific RoHS Directive today. **We therefore welcome the Commission's initiative for developing a common understanding on the interface of REACH and RoHS, which should be applied under the RMO process[3].**

In addition, we invite the Commission to extend this initiative for developing such an understanding also for the interface of REACH and other RMOs, including the above mentioned policy instruments.

Along the whole process, **a proper involvement of European stakeholders must be ensured, including relevant industry experts, on an automatic basis (see entry 3.4).** It should start **at the early stage, when the RMO(s)** are being selected in order to avoid decisions that risk having major and unpredicted consequences on the entire supply chain. Otherwise, it is unfair that, depending on which country is proposing a substance, industry may or may not have the possibility to contribute its knowledge.

Finally, transparency along the whole process must be ensured, from the criteria used to select substances subject to the RMO analysis, to the criteria upon which assessments will be carried out up to the results of the analysis and envisaged next steps. The RMO analysis should also provide an estimated timeline for the implementation of the most appropriate measures: this provides predictability for the industry and facilitates timely compliance. The ECHA Implementation Plan appears as a good step forward and we fully support the ECHA's intention to launch the "Activities Coordination Tool (PACT)".

To ensure certainty and reliability of the process, we strongly believe that binding procedures are necessary. We support the Commission's Roadmap on SVHC to 2020 and ECHA's Implementation Plan, which built the framework for the Risk Management Options (RMO) process. However, at long term, the RMO analysis should be integrated in the REACH legal text.

3.3 An RMO analysis report that provides the relevant information

Orgalime identified some key information that should be gathered in a report, and made publicly available, at the different steps of the Risk Management Options process:

- **<u>Step 1</u>: To determine whether there are risks to be managed or not:**

[3] Orgalime has developed a specific position paper on the Complementarity RohS-REACH, including concrete recommendations to ensure a truly complementary, coherent and consistent implementation of REACH and ROHS2 (http://www.orgalime.org/sites/default/files/position-papers/PP_Complementarity_REACH_and_RoHS_Mar13.pdf). In addition, Orgalime has issued, in cooperation with EUROMETAUX and CEFIC, detailed comments on the Commission 's initiative for a Common Understanding on the implementation of the REACH Regulation and the RoHS Directive (add link)

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- information on substance REACH status (such as registration data), its harmonised classification, if available, additional information from any prior previous RMO analysis carried out;
- information on risks for the environment or human health: evidence, data, exposure, uses and life cycle stage of concerns.

➢ **<u>Step 2</u>: To determine whether there is need for further regulatory action or not:**
- information on risks for the environment or human health not adequately controlled (evidences, data, exposure, uses and life cycle stage of concerns);
- existing legal provisions related to the targeted substance under REACH (that is existing restriction or authorisation), other EU legislation including worker and waste legislation but also policies relating to critical raw materials and manufacturing), legislation and standards at national or international level;
- proposals for legislation under development.

➢ **<u>Step 3</u>: To determine the most appropriate (set of) risk management measures(s):**
- identification of the existing measures (different options) under REACH and other legislation that may lead to adequate control of identified risks;
- identification of the measures considered as most appropriate and reasons supporting the choice of these specific measures;
- an estimated timeline for the implementation of such measures;
- evaluation of measures against key criteria, such as effectiveness, proportionality, enforceability, regulatory consistency;
- in case of authorisation or restriction: assessment of alternatives substances or technologies as well as evidence of their benefits.

3.4 A process that gathers all available expertise at the earliest stage possible

We strongly believe that the RMO analysis should involve stakeholders to ensure a proper REACH implementation in line with its objectives. We suggest gathering all available expertise, including downstream users' expertise, as early as possible in the RMO analysis process, but also along the whole process, on a mandatory basis for all Member States.
Orgalime suggests consulting of impacted downstream users, especially on aspects that are not part of a registration dossier, such as:

- evidence and data on how risks related to the use of a substance are avoided ;
- inputs on detrimental impacts on economic, environmental and human health aspects, including diversity of sectors and technologies likely to be impacted and if certain substances are considered critical, for example substances contributing to lowering CO_2 emissions;
- if further action is necessary, advice on the procedure(s) considered to be most appropriate for the control of targeted risks, such as REACH restriction, RoHS restriction, REACH authorisation, RoHS exemption, measures under other EU environment and waste acquis (the Waste Incineration, Industrial Emissions or WEEE Directives), occupational or consumer legislation;
- where the exposure is related to workers safety, proposals for the establishment of an EU-wide occupational exposure limits (OEL) or other specific worker health and safety measure before an authority submits a substance for authorisation;
- in case of authorisation or restriction, assessment of impacts and suitable alternatives;
- and identification of necessary exemptions and transition period (on basis of investment and design/production cycles).

To facilitate downstream users' participation, Orgalime suggests that ECHA provides an overview of potential uses of substances scrutinised on an automatic basis. We also propose to notify the industry sectors using the scrutinised substance (for example, through European industry associations), which can be potentially affected by any follow up of the RMO analysis.

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This would help downstream users, especially SMEs, to focus on core substances and actively contribute to the assessment procedure.

In addition, to facilitate the assessment of substances, a general database delivering information on substances uses in the different industry sectors is needed.

To avoid leading to additional burden in the industry sector, information should be sourced from registration dossiers and notified information to ECHA. While such information is already available on the ECHA website using the name of the substance as a starting element, it should also be possible to make a similar search in using the industry sector as a starting point.

4. CONCLUSIONS

Orgalime's industries support a European legislative framework ensuring a high level of protection of human health and the environment, while enhancing competitiveness and innovation.

As European engineering companies are facing a lack of regulatory predictability and legal certainty due to continuously changing and insufficiently coordinated legislation, the RMO analysis appears to us as a key opportunity to improve planning security for companies in the area of the substance management policy within the wider EU environmental policy acquis.

In addition, the RMO analysis is expected to improve the efficiency of procedures and thereby reduce costs, both for the Member States and the industry, as well as the overall consistency of EU legislation. Furthermore, from an industry perspective, it will improve security for the evaluation of economically and scientifically viable alternatives and available substitutes.

To deliver its full potential, the RMO analysis should however follow a commonly accepted understanding and practices throughout the 28 EU Member States, the Commission and ECHA, which should involve relevant industry experts on a mandatory basis throughout the process. Providing better transparency to stakeholders on current and future assessment activities, including through a prioritisation mechanism, is a key aspect that Orgalime promotes. In addition, the RMO analysis should be carried out at the early stage and assess all options, regulatory and other, available to manage an evidenced risk, within or beyond the REACH Regulation, such as through waste or work place occupational health and safety policy measures.

Finally, the option identified as the most appropriate one to manage a demonstrated risk needs to be consistent with other EU policies, including measures intending to mainstream all policy and regulatory measures with a view to promoting the competitiveness of European manufacturing industry, thereby revitalising much needed European manufacturing investment in Europe: this is essential to enable the manufacturing sector to continue adding value with a strong prospect of creating jobs and growth in Europe.

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