Position Paper

Brussels, 20 March 2013

Commission's General Report on REACH (COM/2013/49)

EXECUTIVE SUMMARY

In the context of REACH, Orgalime represents a major EU downstream user industry of chemical substances and preparations as well as EU producers and importers of final articles including many of their components for both, professional customers and private consumers. The EU engineering industries are clients of the chemical industry and supplier of capital goods to all other industry sectors, including the automotive, aerospace, chemical, food or textile industries as well as to the health and environment sectors.

Orgalime welcomes the Commission's General Report on the REACH Regulation and its main recommendation to not change the main terms of the REACH Regulation in order to provide stability. We fully support this commitment towards legislative stability and predictability. In line with the EU industrial Policy, we believe that regulatory stability is necessary to allow the manufacturing sector to continue adding value with a strong prospect of jobs and growth.

In addition, unexpected impacts on the EU's manufacturing industries have to be monitored carefully, as suggested in the REACH Review report. Indeed, we strongly believe that REACH implementation should neither result in unaffordable costs, nor negatively impact the competitiveness of the engineering industry.

We support the Commission's approach to improve REACH through its implementation. Indeed, a better application of the REACH Regulation is needed, in particular in the following areas:

- The coherence with sector specific legislation, such as the RoHS2 Directive.
- Communication in the supply chain, including on nanomaterials, where a more effective flow of information is needed.
- The functioning of the internal market, undermined by national legislation restricting the use of specific substances in some products.
- The full harmonisation of REACH provisions, such as the implementation of the 0.1% threshold triggering communication and notification requirements (Articles 33 and 7.2 REACH).
- The risk management procedures (authorisation and restriction procedures), where a more balanced approach and further consideration of socio-economic impacts on the EU manufacturing industries are necessary.
- The inclusion of a Risk Management Options (RMO) analysis in the preparation of an Annex XV dossier, as a standard basis, and the involvement of stakeholders.

Orgalime, the European Engineering Industries Association, speaks for 39 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 23 European countries. The industry employs some 10.2 million people in the EU and in 2011 accounted for some €1,666 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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Proper implementation of REACH is indeed, in our view, crucial to the EU wide horizontal framework for chemical management. The horizontal Regulation should, in our view, set the principles and provide all relevant information on substances needed for a proper implementation of REACH itself but also of sector specific legislation, including the RoHS Directive and the various EU Waste, Waste Incineration or Industrial Emission Directives. In addition, we ask for a clear guidance on what risk management procedure (e.g.: REACH authorisation, REACH restriction, sector specific restriction via RoHS2, measures under the Waste Incineration or Industrial Emissions Directives) applies in what case.

Our industries remain available to provide input and information available in its role as downstream users and article manufacturer. We are committed to contribute to shape a successful, meaning truly consistent implementation of the EU chemical management policy especially both, REACH and RoHS, in our industry sector.

Orgalime substantiates its position hereafter:

Introduction

Orgalime welcomes the Commission's General Report on the REACH Regulation and, in particular, its main conclusion that "*changes to the enacting terms of REACH will not be proposed*". We support that necessary adjustments identified in the REACH Review can be achieved through improving REACH implementation.

Orgalime fully supports the Commission's commitment towards regulatory stability and predictability. These are, in our view, key factors in welcoming industrial investment back into Europe that will allow the manufacturing sector to continue adding value with a strong prospect of jobs and growth. The legislative stability for implementing such a complex and critical piece of EU legislation is essential to ensure predictability to the EU industry, at least, in the field of chemicals management. In addition, EU sector specific legislation should be fully consistent with the EU wide harmonised tool for chemicals management, namely the REACH Regulation.

We appreciated the Commission's approach to carry out the 2012 REACH Review, in particular the several thematic studies that assessed the implementation of the Regulation beyond the legal requirements. As a main result, the General Report and its accompanying staff working document provide a fair picture of the implementation, including impacts on downstream users.

In view of upcoming EU institutions' discussions on the REACH Review, Orgalime would like to contribute to the debate with the following comments on the key issues tackled in the Commission's General Report on REACH:

1. Internal market, competitiveness & innovation

- **Unforeseen impacts on Downstream Users to be monitored further**

We support the overall objective of REACH that is to ensure a high level of protection of human health and the environment as well as the free circulation of substances on the internal market, while enhancing competitiveness and innovation.

However, REACH implementation should not hamper the competitiveness of EU manufacturing industries, especially in the context of the difficult economic situation our industries are currently facing. The engineering industries provide solutions aiming at improving the environment, for example equipment for the promotion of renewable energies and for the treatment of air and waste.

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We offer the technological solutions needed to achieve the political goals of becoming more energy and resource-efficient. The REACH implementation should, therefore, not results in unaffordable costs for our industries and for our customers.

Today, positive impacts remain unclear. It is premature to assess the effectiveness and efficiency of different REACH procedures as well as the overall impact on innovation and competitiveness. However, unexpected negative impacts down the supply chain have been identified. Indeed, the General Report mentions the increase of substances' markets concentration and prices as well as costs and administrative burdens. These may result in the withdrawal of key substances from the market without sufficient warning, insufficient registration of some SVHCs or only as intermediate (even though they are used more than as such) and reformulation of some preparations without notice. This may lead, as worst case scenario, to disturbances in the supply chain that would negatively impact environmental and safety performance of our products, besides growth and competitiveness of our industries.

Therefore, we support the Commission's recommendation to carefully monitor the situation, especially in the context of future registration deadlines, since these unexpected consequences may hamper competitiveness and innovation of EU engineering industries.

- **A necessarily harmonised implementation**

The General Report highlights the benefits of harmonisation provided by the internal market and the REACH Regulation. Today, the EU industry faces diverging interpretation, by some Member States, for example, as regards the 0,1% (w/w) concentration threshold referred to Article 33 and Article 7.2 of the REACH Regulation.

As main consequences, these diverging interpretations risk hampering the competitiveness of EU engineering industries and the functioning of the internal market, but also creating legal uncertainty and confusion for companies. In addition, such different enforcement practices will hamper benefits bring forward by REACH and prevent it to act as the EU wide harmonised tool for chemicals management.

In this context, we fully support the Commission's call for "*a consistent and harmonised interpretation of all REACH provisions, notably the 0.1% concentration threshold of substances of very high concern in articles*".

REACH is a complex and demanding piece of legislation. It requires industry to dedicate many resources to comply with requirements so as to achieve and obtaining thus the benefits of REACH for health and environment. However, some Member States are still adopting national legislation on chemicals, often as restrictions on the use of certain substances in certain products. This is undermining REACH and moreover hampering the competitiveness of industry and the functioning of the internal market without necessarily contributing to the improvement of health and environment.

We therefore support that the Commission should highlight to Member States the importance of REACH as the EU wide and central tool for chemicals management and to pursue the legal supremacy of the REACH Regulation.

2. Challenging communication requirements for manufacturers of complex products

Orgalime industries are producing complex products with hundreds and thousands of different components, which are sourced around the globe. Gathering the requested information to comply with REACH communication requirements (Article 33) is an intense process, which also requires human resources and time.

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The immediate application of communication requirements, when a substance is included on the candidate list, makes compliance with communication requirements challenging for articles manufacturers. Moreover, the requirement applies on articles at the date of supply, instead of at the time of production or import. Manufacturers consequently face difficulties to comply for articles produced or imported before a substance was included on the candidate list, but supplied after the substance is included. This is especially relevant for equipment with long storage time, such as medium voltage equipment and spare parts.

In addition, the current REACH implementation increases the difficulty with, in our view, too frequent updates of the candidate list (twice a year). This creates legal instability and uncertainty for article suppliers.

Extremely tight time schedules and frequent candidate list updates make the compliance even more challenging for our industries. We therefore support an effective flow of information through the supply chain. Given the challenges we face, we also call for a balanced implementation of Article 33 REACH communication requirements.

3. Scope and overlaps with other EU legislation

The General Report states that "*no major overlaps with other EU legislation have been identified*". However, the Review points out minor overlaps with EU sector specific legislation, especially in the restriction area. We support the Commission's intention to "*minimise or avoid overlaps or potential overlaps*" through a set of actions, for example in setting up an inventory of all existing restrictions in EU legislation or amending guidance, if appropriate.

Nevertheless, details on how to improve implementation remain of utmost importance for manufacturers since they have to comply with the requirements stemming from both, the REACH Regulation and the sector specific legislation. This is the case for the RoHS2 Directive. Indeed, overlaps risk upsetting overall consistency of the EU's chemicals legislation and hampering the competitiveness of EU engineering indsutries. We therefore call for a common understanding for the implementation of REACH and RoHS2 as well as a consistent application of both legislative instruments.

With this in mind, Orgalime suggests the following concrete recommendations to ensure a truly complementary, coherent and consistent implementation of REACH and RoHS2:

- Use one commonly accepted scientific and technical evaluation per substance that is valid for both, REACH and RoHS implementation.
- Include Risk Management Options (RMOs) on a standard basis in Member States´ preparations of REACH Annex XV dossiers as well as any Member State's proposal for RoHS substance restrictions following article 6 RoHS - we support that RoHS restriction proposals should equal a REACH annex VX dossier.
- Implement existing guidance documents properly, notably chapter "R.18: *Exposure scenario building and environmental release estimation for the waste life stage*" of the ECHA Guidance document on information requirements and chemical safety assessment, and amend it, if necessary, to minimise or avoid overlaps between REACH and RoHS, as suggested in the REACH Review report.
- Base any new restrictions on a risk approach and life cycle approach, which include the waste phase.
- Require a scientifically based and structured preparatory evaluation process before setting up any new substance restrictions by:
    - Taking into account the opinions of the REACH Committees (RAC and SEAC) in the preparatory process of potential new RoHS2 restrictions.
    - Applying Article 58.2 REACH and not requiring REACH authorisation for the specific uses and applications exempted under the sector specific RoHS2 Directive, during the granted duration time of the RoHS exemption.

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- Gather information from the REACH framework for implementing the RoHS2 implementation in case of missing information, especially substance aspects arising at the waste stage
- Provide sufficiently lengthy timelines for industry to prepare for compliance with a new substance restriction

Our suggestions are summarised in the annexed flowchart. The details and full set of concrete suggestions for establishing a common understanding and truly complementary and consistent implementation of REACH and RoHS2 are given in Orgalime's additional Position Paper

4. Risk management: authorisation and restrictions procedures

- **A balanced approach for the authorisation procedure to not hamper EU manufacturing industries competitiveness**

The authorisation procedure applies to the manufacturing process of articles produced in the EU, but not to imported articles. This may result in an unfair situation for European manufacturing industries.

For example, the proposed inclusion of chromium trioxide in Annex XIV REACH illustrates this: although the industry is proactively working on a substitution strategy, uses of chromium trioxide are technically essential for some specific uses to provide the required high level of quality and safety. For some uses, the substance is used in the manufacturing process but is not present in the final article, such as in chromating of articles or in the conversion layer before powder coating of aluminium. In such cases, consumers are not exposed. The EU's manufacturing industries are faced with significant administrative and financial burdens as well as legal uncertainty, whereas imported articles are not concerned. Our industry will be forced to source its components outside Europe in future. Therefore, going this way, not only will have a negative impact the competitiveness of the EU industry, but will also impact the environment.

The EU's chemical policy needs to be consistent with other EU policies, including measures intending to revitalise the European industry. Consequently, regulators should avoid as much as possible major impacts on the competitiveness of manufacturing industries. Therefore, when considering including a substance in the Annex XIV REACH (authorisation list), we call upon regulators to:

- properly balance socio-economic impacts against health and environment protection;
- take into account further the criterion of economic and technically viability for the substitution of substances (Article 55 REACH);
- and, implement in a more balanced way REACH requirements, especially Articles 58.2 and 56, to grant necessary exemptions.

- **A Risk Management Option (RMO) approach as a standard basis**

The Commission has announced it is increasing its efforts to "*identify relevant SVHCs building on the Risk Management Option (RMO) framework*", which we support.

Today, REACH procedures do not foresee an appropriate and balanced mechanism allowing stakeholders, with specific expertise in a given field, to participate in the preparation of an Annex XV dossier. Therefore, beyond the identification of SVHCs, we encourage the Commission, Member States and ECHA to use the RMO approach when considering any future authorisations and restrictions, to be established via Annex XVII REACH or specific sector legislation (i.e. Annex II RoHS). It will help to identify the most adequate procedure under the REACH Regulation or other EU sector-specific legislation, thus avoiding any possible future overlaps or inconsistencies in the EU chemicals legislation.

We believe that the RMO analysis should take place as soon as possible, and preferably before the preparatory process of an Annex XV dossier is launched. The lack of transparency in Member State's preparatory work to submit an Annex XV dossier may lead to misguided conclusions. In addition, local national health and environmental interests may prevent assessing actual risks on basis of an EU harmonised approach. On the contrary, a well-structured and coordinated consultation of stakeholders in all EU Member States is, in our view, necessary. Our industry is committed to providing the necessary information to authorities in order to support their work and facilitate the RMO activities, even beyond the REACH scope.

- **A better communication in the supply chain so as to contribute further to risk management procedures**

In the areas of SVHCs identification, authorisation and restrictions, the increasing number of substances assessed raises our concerns. We acknowledge the consultation of stakeholders, including the industry, which we appreciate. However, in the light of first experiences, we realise that the authorisation procedures cover the whole supply chain, from chemicals manufacturers to complex article manufacturers. Short given deadlines, the frequency of consultations and the complexity of procedures make it very challenging for the engineering industries to provide effective contributions. As a consequence, these procedures may result in conclusions which are misleading and on knock-on effects on the whole supply chain.

Our industry, especially SMEs, often do not have the resources to provide the necessary information on risks and benefits. Indeed, the assessment of chemicals properties placed in the supply chain is not the core expertise of engineering companies. We therefore support more transparency and an effective flow of information through the supply chain.

5. Nanomaterials

Orgalime is satisfied to see the confirmation of the Second Regulatory Review on Nanomaterials' conclusions on how to best handle safety of nanomaterials taken up in the REACH General Review Report. We support the Commission's approach to work with the existing legislation and adapt it where needed rather than introducing new EU legislation.

We strongly support that the REACH Regulation as the best possible framework for a harmonised risk management of nanomaterials, thereby avoiding double regulation and conflicting requirements. Where assessed as necessary, any specific requirements for nanomaterials can be specified in REACH's Annexes and guidance documents. However, it is of the utmost importance to avoid increasing administrative burdens on companies when clarifying how REACH applies and / or using REACH in the context of nanomaterials.

In addition, we acknowledge that increasing and improving information on nanomaterials in the supply chain is necessary. REACH provisions offer, in our view, the necessary tools, especially through the Safety Data Sheets, to increase transparency in the supply chain.

Orgalime's views on the Commission's Communication on the Second Regulatory Review are summarised in a specific position paper.

6. Stakeholders' involvement and awareness

In addition to the consultation of stakeholders foreseen in risk management procedures, we strongly support the open dialogue with EU institutions, including the Commission and ECHA, as well as the involvement of stakeholders in various forums, such as the DCG, CARACAL, and ECHA enforcement Forum. This is, in our view, essential to achieve an efficient implementation of an as complex and critical piece of EU legislation as the REACH Regulation.

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Annex:

CONSISTENCY RoHS-REACH from the perspective of REACH

Step 1: Registration

- Registration dossiers (Chemical Safety Reports, Exposure Scenarios) to properly implement ECHA Guidance R.18, and its results to be taken into account under RoHS2
- The RoHS article 6 Methodology shall specify, which information would be needed to ensure a proper RoHS implementation; this information should be generated via REACH
- Objective: **One common scientific conclusion per substance**, which will be relevant for REACH and RoHS2 implementation

Step 2: Evaluation

- Where data and information gaps should exist (especially on susbstance aspects in the waste phase, including on the information required by article 6-RoHS methodology), these should be filled by REACH, including during evaluation process
- Objective: **one common scientific conclusions per substance**, which will be relevant for RoHS2 and REACH implementation

Step 3: Authorisation

- Annex XV dossiers (and their preparation) to include Risk Management Options
- Commission guidance document to explain what procedure should apply in which case (REACH restriction, RoHS restriction, REACH authorisation, RoHS exemption, other EU environment/waste policy measures, i.e.: Waste Incineration, Industrial Emissions or WEEE Directives)
- Where RoHS2 grants an exemption, article 58.2 REACH shall be applied
- Prior to setting any authorisation requirement, the opinions of RAC and SEAC need to be sought

Step 4: Restriction

- Annex XV dossiers to include Risk Management Options
- On the basis of Commission guidance document (what procedure in what case) whereby:
- In case of an existing RoHS2 restriction - RoHS2 as lex specialis sets relevant restriction (no REACH authorisation to apply following article 58.2 REACH; no new REACH restriction to be set for Electrical and Electronic Equipment)
- In case of setting a new restriction - either in RoHS2 (if case specific) or in REACH annex XVII (but not twice);
- Where RoHS2 grants an exemption, article 58.2 REACH shall be applied
- Prior to setting any restriction, under RoHS or REACH, the opinions of RAC and SEAC need to be sought
- Sufficient timelines for industry to ensure compliance with any new restriction

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