Position Paper

Problems for SMEs arising from the implementation of REACH after two years of its entry into force

The REACH Regulation entered into force on 1 June 2007. After two years of implementation and the pre-registration phase finished, UEAPME is presenting its first summary of this complex piece of legislation. This paper shows the major conclusions and identifies seven areas for action with a view to optimizing implementation.

1) Significant reduction concerning financial burden

REACH requirements have proven to be a very time- and resource-consuming process. The complexity of the REACH system has forced many companies and mainly SMEs to manage their responsibilities with a consultant, resulting in substantial additional costs. The financial impact on companies will drastically increase in the coming years especially because of costs associated with animal testing and registration fees.

During the pre-registration 150.000 different substances where notified. More than 2.7mio dossiers from over 65.000 companies were submitted. The EC predicted 30.000 different substances and also calculated the fees based on the assumption. The miscalculation is obvious. Since the calculation of fees was based on wrong assumptions, a correction is necessary. As registration fees are part of administrative burdens they should be reviewed in light of the outcomes of the first registration wave. We also suggest a payment of fees by installments in cases where necessary.

For example: assuming that only 10% of the 2.8 million pre-registrations lead to registrations, this may generate registration fees of at least €1.4 billion (280,000 registrations x €5,000 (average of all registration fees categories) = €1.4 billion).

The payment of registration fees under REACH is an example of where costs on companies can be reviewed, without jeopardizing the whole process.

2) Share of costs and cooperation in SIEF and consortia must be fair, non – discriminatory and transparent

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In practice it is quite complicated for SMEs to get the right information out of the SIEF. Especially because of the high number of participants in many SIEF it is impossible to manage and to generate the information properly. For this, the registrants can join a consortium in which normally one company is in the lead. For most SMEs a consortium is the only feasible way to fulfill all the information obligations demanded by REACH. The costs – especially fees - for numerous consortia are disproportionally high, fees starting from 25. 000 up to 50.000 Euro are no exception. On top of this the members must also pay extra research costs which are as good as not predictable. Also the annual fees as the research costs are shared by the members in the consortium. The number of members per year is also not predictable. Very often SMEs in practice do not have any choice as to accept every contract given by the leading bigger companies in a consortium. The bottom line is, for SMEs it is often impossible to predict the costs, to plan for the future and to have a fair and transparent access to consortia. The price of the registration regime is for the majority of SMEs so high that they are threatened by bankruptcy, only because of the high unforeseen costs of this regime. To be clear, these costs were not included in the impact assessment.

The EC wants the SIEF to be a market driven exchange information forum under supervision of ECHA. Fair, transparent and non discriminatory cooperation was an essential condition for a good practice of REACH. Nevertheless the registration-costs are seriously increasing because of the untransparent behaviour of many consortia. The registration-regime creates a situation of unfair competition in which the consortium has a very dominant position.

Legal aspects of consortia, working in SIEF, data sharing, cost sharing, competition law and similar matters are very complex and for most SMEs not feasible because of too few resources and knowledge. It is the duty of the EC to provide those companies more useful support and a clearly stronger protection. A better training for SMEs is needed. To guarantee fair conditions for those companies the EC should organize workshops and provide more SME-friendly guidance. The EC should also give a stronger concern to aspects of competition law especially in consortia, e.g. screening of existing consortia-contracts, SME-helpdesk for consortia issues.

3) Consistent European chemicals legislation

REACH is replacing about forty different European legal-acts. The aim is to provide a European-wide fully harmonised framework for the management of chemicals. Overlaps or inconsistent Community rules on related areas must be avoided. Such inconsistencies will lead to disruption in highly complex global supply chains, legal uncertainty, unnecessary duplication of administrative burden and costs. Those aspects are now even more damaging since complying with REACH requires a lot of time, considerable investments, coordinated efforts and resources from all actors and especially by SMEs in the supply chain.

A number of recent examples illustrate missed opportunities to establish a consistent EU legislative framework.

Example 1:
Restriction of substances should be an instrument of Title VIII of REACH. The review of the RoHS-directive (2002/95/EC) is in some aspects taking account of that fact and using some main REACH-instruments for restriction. This is especially the expertise of the REACH-committees RAC, SEAC and the forum (art. 85 REACH). The scope of RoHS should not be expanded in future. Furthermore all present restrictions from RoHS should be transferred to Annex XVII of REACH. Future necessary restrictions for electrical and electronic equipment should be implemented directly according Title VIII of REACH. This existing duplication of regulatory-instruments must be refused in the spirit of better regulation and governance. Such legal fragmentation also lowers legal-security significantly. This is considering all existing legal requirements especially a problem for SMEs, which could be avoided very easily with our recommendation.

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Example 2:
The newly revised Eco-label Regulation will cause duplication of legislation. An Eco-label will not be awarded to goods containing certain dangerous substances or mixtures. Introducing a pure hazard-based approach, not moderated by the risk-based approach, is in contradiction with the REACH philosophy. REACH ensures the safe use of chemicals and the Eco-label should focus on its main purpose: labelling products that demonstrate environmental excellence.

Example 3:
The Cosmetics Directive (76/768/EEC) imposes a marketing ban on cosmetics produced from substances tested on animals in a phased approach that began on 11 March 2009. Many new cosmetics substances however will also be used in other non-cosmetics applications covered by REACH and are therefore subject in many cases to mandatory animal testing. This naturally creates problems for companies.

The objective of consistent European chemicals legislation needs to be addressed seriously.

4) Harmonised application of REACH at national level

Besides ensuring a high level of protection of human health and the environment, the REACH Regulation should ensure the free movement of chemicals. Therefore we expect that the huge efforts caused by REACH result in better health and environment but also in eliminating barriers to trade and leveling out differing requirements throughout the EU.

A number of Member States are experiencing difficulties in removing existing legislation and also the enforcement activities are quite different. In some cases Member States do not stick to the outcome of the final REACH adoption procedure, resulting in different interpretations of the rules. A number of concrete examples are outlined below.

Example 1:
Examples of dubious enforcement activities, especially for imports, have been reported from some Member States. There should be a stronger pressure on Member States for a more harmonised approach of national REACH enforcement schemes and the avoidance of national provisions, which go beyond the Community requirements and give raise to additional administrative burdens. Representatives of SME-organizations could be involved also as invited experts according article 86 (1). In many aspects, as for example communication in the supply chain, SMEs will be the main parties involved.

Example 2:
Notification requirements for substances in articles apply, inter alia, if a certain substance is present in the article above a concentration of 0.1% of the weight of the entire article. The same threshold applies for information requirements according to article 33. Nevertheless, six Member States (Austria, Belgium, Denmark, France, Germany and Sweden) are challenging this legal requirement of REACH, which can only result in negative effects on the internal market and disturb the urgently needed level playing field for companies.

Example 3:
In regard to the link between REACH and waste legislation, it will be of key importance that once end-of-waste criteria are established and approved for a certain waste stream at EU-level, they are also implemented in a consistent way by all EU Member States. Inconsistent application would lead to the loss of the benefits of the end-of-waste status, but would also lead to a duplication of legislative, administrative and financial burdens.

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For companies genuinely harmonised rules are of utmost importance. The Forum – a network of Member States' competent authorities responsible for enforcement – is a key player in relation to uniform enforcement.

There is also a need for a clear way forward on further harmonisation of national legislation where this is a barrier to free movement of chemicals in the internal market. In the meantime national differences must at least be better highlighted and the most important differences should be eliminated. We are especially concerned that companies may not be informed about existing more stringent restrictions maintained in some Member States on the manufacture, placing on the market and use of certain dangerous substances (article 67.3 of the REACH Regulation).

5) REACH-IT

REACH-IT – ECHA's online platform to submit data and dossiers on chemical substances – is the crucial instrument for communication between companies and ECHA. It is also the cornerstone for cooperation within the Substance Information Exchange Forum (SIEF), which requires mandatory exchange of data between companies, particularly on data related to animal testing. REACH-IT must therefore be reliable concerning workability and data protection. In many aspects it is the only official form for submissions under REACH.

After a troublesome start of REACH-IT, many technical improvements have already been made. To avoid the dissatisfactory situation during the pre-registration-phase the stability of the system must be guaranteed in the further process of REACH.

Considering special needs of SMEs, better guidance for users in all official languages have to be provided. Since the REACH-IT is an official form for submission of data it also must be provided in all official languages. This is a basic right of all citizens of the member-states. But it will also be necessary especially because of notifications as, for example, uses through downstream users, and the classification-inventory according the CLP-regulation or concerning SVHC in articles.

In the future we highly recommend an offline completeness-check software-tool. That will take much pressure from the very tight timeline for companies and authorities.

Especially for questions concerning technical aspects and the content of registrations dossier there should be a concrete contact person. An anonymous e-mail address is not citizen-friendly and does not raise confidence into ECHA. Experience shows that in a personal discussion many problems can be solved best and most efficiently. That saves time and creates confidence in an institution.

6) Legal uncertainties about obligations through REACH

Companies face numerous legal and interpretation uncertainties about their obligations under REACH. The Commission, ECHA and the Member States have provided guidance and workable solutions to industry. The Technical Guidance Documents (TGD) have proved to be suitable instruments for reducing the number of uncertainties. They are based on studies and input from all stakeholders.

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However, in a number of cases companies are still left in uncertainty regarding their obligations. This is for example the case in many Member States, where companies in the production chain require each other to attest the "REACH conformity" of their products by filling in corresponding documents. These declarations of conformity should be avoided, since they are not foreseen by the REACH Regulation and, therefore, they only create red tape without ensuring compliance with the prescribed information obligations. Another example is the absence of TGD on the substances exempted from registration (Annex V of the REACH Regulation). When there is no TGD, national helpdesks intervene. Very often they opt for a "precautionary approach" which increases the administrative burden. This precautionary approach has led to a huge number of double and probably redundant pre-registrations.

Nevertheless ECHA-guidance documents are often too time-consuming and complicated for the needs of SMEs and cannot provide them with an in-depth answer to all their practical questions. We recommend a better involvement of SME organisations in the elaboration of guidance documents in the Partner Experts Groups (PEG). Good guidance has potential to ameliorate the REACH governance and reduce administrative burdens consequently. Also a translation of TGD into all EU languages is seen as a very important aspect for supporting SMEs. Moreover, support material focusing on the evaluation of exposure as well as on communication in the production chain should be available with practical examples easily understandable for everybody.

7) Transparency and stakeholder involvement

All the different Committees of the European Chemicals Agency (ECHA) have started their activities. The request from ECHA for interested stakeholders resulted in a long list of interested stakeholders in order to be appointed as observers. Observers are invited and participate on a regular basis in the different Committees. The first impression is positive.

The fact that the Forum opens its sessions to stakeholders more than once a year is interesting. So far we appreciate the transparency of the Agency, and the first invitation for the Partners Experts Groups (PEG) indicates that this continues to go in the good direction.

SME representatives should play a much more important role in the REACH Helpdesk Correspondents' Network (REHCORN). They could give input on practical implementation as well as on anticipating issues. Better involvement of this sector, particularly at an earlier stage, should be beneficial for the helpdesks and also for companies having practical problems with the implementation. In order to enhance transparency and a better consideration of SME-problems in the REHCORN-process we recommend for example an earlier access to questions addressed within the network.

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Recommendations in a nutshell:

1) Significant reduction concerning financial burden

- Payment of fees by installments
- Revise fees downwards based on the experience gained from the first registration wave (December 2008 – November 2010).

2) Registration in a SIEF must be fair, non –discriminatory and transparent

- EU research into the practices of the consortia.
- An impact assessment about price and the administrative burdens effect of REACH.
  EC must provide more training and support for SMEs concerning SIEF, Consortia, data sharing, cost sharing, competition law, e.g. workshops, guidance, helpdesk

3) Consistent European chemicals legislation

- Make sure that EU legislation dealing with substance aspects fully ties in with the REACH Regulation. Avoid legal fragmentation, overlaps and conflicting requirements.

4) Harmonised application of REACH at national level

- The Forum should play a key role for consistent and coherent enforcement of REACH throughout Europe. Representatives of SME-organizations should be involved as experts.
- Apply REACH legal requirements with regard to the 0.1% threshold value for articles strictly. Guidance document must not go beyond legal requirements.
- Harmonise implementation of the end-of-waste criteria that are currently under development for specific waste streams at EU level.
- Review REACH-related requirements where national differences still apply (for example, more stringent restrictions according to article 67.3 of the REACH Regulation) and set-up a work plan for eliminating them.

5) REACH-IT

- Ensure the stability of REACH-IT.
- Provide REACH-IT and supporting documents in all EU languages.
- Provide offline software for the completeness-check.
- Better technical and more personal support by ECHA.

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6) Legal uncertainties about obligations through REACH

- Ensure strong representation of SME-representation in the revision-process for TGD´s. Provide TGD´s on time and improve their clearness and accuracy to avoid misinterpretation.
- Structure TGD´s in a way to provide practical examples easily understandable by everybody.
- Provide translations of TGD´s in all EU languages.

7) Transparency and stakeholder involvement

- Enhance the involvement of SME observers in the REACH Helpdesk Correspondents' Network (REHCORN), for example by giving them early access to the questions addressed within the network.

Brussels, October 2009

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