BUSINESSEUROPE

POSITION PAPER

27 May 2009

SEVEN PRIORITIES FOR OPTIMISING IMPLEMENTATION OF REACH: LESSONS LEARNED FROM THE FIRST TWO YEARS

Executive summary

Two years after its entry into force, BUSINESSEUROPE has carried out a first assessment of the implementation of REACH with a view to drawing the attention of European and national authorities to European industry's experiences, successes and difficulties encountered so far.

BUSINESSEUROPE has identified seven priority areas for action:

1. The financial burden on companies should be reduced. Phased payment of registration fees first and lowering of fees in the longer term is required.

2. Consistent European chemicals legislation needs to be guaranteed. Chemicals rules must be set using uniform criteria and consistently in one place. REACH must be this place.

3. The quality of guidance about industry's REACH obligations should be improved to avoid legal uncertainty. A strong and timely representation of industry in Partners Experts Groups and translation of Technical Guidance Documents into all EU languages will help improve the situation.

4. Truly harmonised REACH rules across Member States should be ensured, especially in terms of enforcement activities. Attention should be given to industry's practical experiences.

5. The efforts of the European Chemicals Agency (ECHA) and the Commission to involve industry are much appreciated. The REACH Helpdesk Correspondents' Network should involve industry better.

6. Impacts of REACH on international trade should be looked at very carefully. Clarity about non-European companies' obligations and full compliance with WTO rules must be ensured with a view to a real level playing field.

7. ECHA's online platform to submit data and dossiers on chemical substances (REACH-IT) must be fully operational. Making the system available in all EU languages is worth close consideration, especially for facilitating SMEs' work.

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SEVEN PRIORITIES FOR OPTIMISING IMPLEMENTATION OF REACH: LESSONS LEARNED FROM THE FIRST TWO YEARS

The REACH Regulation entered into force on 1 June 2007. After two years of implementation, with the pre-registration phase completed – companies submitted about 2.8 million pre-registrations by the deadline of 1 December 2008 – and the first stage of registrations on-going, European companies have acquired important experience with the implementation of this extremely ambitious and complex piece of legislation. BUSINESSEUROPE has undertaken an assessment on implementation of the REACH Regulation. This paper presents key findings and identifies seven areas for action with a view to optimising implementation.

Industry has engaged in an unprecedented effort involving mobilisation of considerable company resources to fulfil REACH obligations. Efforts by the European Chemicals Agency (ECHA), the Commission and Member States' competent authorities to come to workable solutions have been much appreciated.

However, it is essential to adopt the most cost-effective implementation measures and ensure a stable EU legislative framework to safeguard the competitiveness of European industry.

The following areas have been identified as priority actions:

1) Significant reduction in financial burden on European companies

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

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 fact that the fees have to be paid by each separate legal entity also creates a heavy burden for large companies, especially where many legal entities exist.

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

Rates for registration fees have been set on the basis of assumptions about substances to be registered. Experience with the pre-registration phase has shown that the number of substances pre-registered was significantly underestimated. ECHA received about fifteen times more pre-registrations than expected. It is foreseen that the same may be true for the successive registration phases.

Future implementation of the REACH Regulation needs to take account of these situations. In the short term, phased payment of the fees would ease the situation of companies facing financial difficulties. Instead of payment of the full fee at the time of

registration, the fee could be paid in three or four instalments. It could save around €200 million for producers and users in the first years of registrations. In December 2010, fee rates should be revised downwards based on the experience gained from the first registration wave (December 2008 - November 2010).

BUSINESSEUROPE recommends:

In order to reduce the financial burden on companies

1. *From now until November 2010: phased payment of registration fees. Split the fees into parts whereby only the first part needs to be paid upon registration. Further instalments could then follow in two or three instalments. This measure could save around €200 million in the first years of registrations.*
2. *In December 2010: revise fees downwards based on the experience gained from the first registration wave (December 2008 – November 2010).*

2) Consistent European chemicals legislation

By replacing about 40 pieces of EU legislation, REACH aims to provide a fully harmonised framework for chemicals management across the EU and covers substances on their own, in preparations and in articles.

Overlaps or inconsistent Community rules on related areas should be avoided. Inconsistency will only lead to disruption in highly complex global supply chains, legal uncertainty, unnecessary duplication of administrative burden and costs. This is all the more damaging since complying with REACH requires a lot of time, considerable investments, coordinated efforts and resources from all actors in the supply chain.

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

Example 1:
The Commission's recast proposal of the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipement (RoHS) 2002/95/EC does not take full account of all REACH criteria and procedural elements for establishing any further substance restrictions in electrical and electronic equipment.

Example 2:
The newly revised Ecolabel Regulation will cause duplication of legislation. An Ecolabel 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 ecolabel 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 legistation needs to be addressed seriously.

BUSINESSEUROPE recommends:

In order to establish consistent European chemicals legislation

1. *Make sure that EU legislation dealing with substance aspects fully ties in with the REACH Regulation so as to avoid overlaps and conflicting requirements. For instance, sector-specific Directives should fully implement all criteria and procedural elements of the REACH Regulation instead of developing additional approaches on regulating chemicals in specific articles or products.*

3) Legal uncertainties about REACH's obligations

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.

However, in a number of cases companies are still left in uncertainty regarding their obligations. This is the case for example with 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.

Industry believes that the quality of guidance provided and its timeliness should be improved. A strong representation of industry in the Partners Experts Groups (PEG) and a translation of TGD into all EU languages are seen as two conditions for improving the situation.

BUSINESSEUROPE recommends:

In order to improve the quality of guidance provided to industry

1. *Ensure strong representation of industry in the Partners Experts Groups (PEG) which aims at revising the Technical Guidance Documents (TGD). The overall objective is to provide TGD on time and to improve their clearness and accuracy to avoid misinterpretation.*
2. *Provide translations of TGD in all EU languages.*

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 substances, on their own, in preparations and in articles. Industry, therefore, expects this huge REACH effort would result in bettering health and environment but also in eliminating barriers to trade and levelling 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:
Enforcement activities must be harmonised as much as possible. Examples of dubious enforcement activities, especially for imports, have been reported from some Member States. Furthermore, the penalties in Member States differ widely. In some countries the legislation gives a clear indication of the penalties connected with the different types of offences, while others are quite general.

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.

For industry, genuinely harmonised REACH 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. For example, industry is concerned that it 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).

BUSINESSEUROPE recommends:

In order to achieve truly harmonised REACH rules amongst Member States

1. *The Forum – Network of Member States' competent authorities responsible for enforcement – should play a key role for consistent and coherent enforcement of REACH throughout Europe.*
2. *Use industry's experiences when discussing enforcement issues at EU and national levels.*
3. *Apply REACH legal requirements with regard to the 0.1% threshold value for articles strictly. Any guidance document must not go beyond REACH legal requirements.*
4. *Harmonise implementation of the end-of-waste criteria that are currently under development for specific waste streams at EU level.*
5. *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) 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. Industry is given the opportunity to participate actively.

The fact that the Forum opens its sessions to stakeholders more than once a year is interesting.

So far industry appreciates 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.

In the REACH Helpdesk Correspondents' Network (REHCORN), industry representatives could play a much more important role. Industry could give input on practical implementation as well as on anticipating issues. Better involvement of industry, particularly at an earlier stage should be beneficial for the helpdesks, and hence for the companies having some practical problems with the implementation.

BUSINESSEUROPE recommends:

In order to enhance transparency and stakeholder involvement

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

6) Impacts on international trade

The international dimension of the implementation of REACH must be considered in light of its compatibility with WTO rules and its impact on the competitiveness of European manufacturing. Decision-makers must therefore first avoid discrimination between European and non-European companies in the operation of the regulation to avoid difficult questions at the WTO. They must also ensure the minimum negative impact on the competitiveness of European companies in the EU and international markets as they compete against partners not exposed to the same regulatory burdens.

Over recent months, the numerous discussions in the WTO's Technical Barriers to Trade Committee illustrate difficulties faced by non-European companies. This relates for example to:

- the *Only Representative* (OR) system by which non-European manufacturers must appoint a natural or legal person in the EU for communicating with ECHA. Non-European distributors are not allowed to employ an OR. This provision is seriously impeding the trade of many well established and legitimate non-European trading companies.
- trade partners have also expressed concerns about a lack of clarity in terms of the registration process and how it applies to certain products such as cosmetics ingredients.

On the other hand, European companies foresee already impacts which could hamper their competitiveness.

The REACH process could encourage the manufacturing of articles outside the European Economic Area. European manufacturers of articles are subject to challenging REACH rules, which may imply a loss of competitiveness in comparison with non-European counterparts. European manufacturers of articles are therefore not on a level playing field with non-European companies.

In addition, due to the complex and costly REACH system, foreign suppliers might consider turning their backs on the European market altogether. The low interest and knowledge of REACH among some non-European suppliers cause fear among those European industries depending on these imports.

BUSINESSEUROPE recommends:

In order to minimise negative impacts on international trade

1. *Provide more clarity to non-European companies on their obligations.*
2. *Ensure full compliance with WTO rules.*
3. *Keep under review impacts of REACH on the competitiveness of EU companies on both EU and international markets. As a short-term action, the Commission's on-going REACH Baseline Study aimed at measuring REACH implementation and effectiveness should also look at the competitiveness issue.*

7) 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.

Since the system went online, there have been numerous problems and breakdowns. Industry has patiently accepted these during the pre-registration phase, although the work in REACH-IT was constantly interrupted and impossible to plan. At the end of the pre-registration phase, ECHA was faced with a totally unexpected situation with huge number of pre-registrations justifying emergency and temporary measures. Industry now needs a fully operational IT system in order to be able to respect the deadlines of the Regulation.

Having REACH-IT in English only is a huge problem, especially for SMEs. Making the IT system and related guidance available in all EU languages is worth close consideration. It could significantly facilitate communication between companies and ECHA for the registration process as well as future legal requirements such as notifications for the classification and labelling of substances. Such possible adaption of REACH-IT should not result in more unwieldy systems of communication and internal cooperation within industry.

Numerous difficulties are also faced by industry regarding the SIEFs. These relate to the very high number of members in SIEFs, the role of the SIEF formation facilitator (SFF) or access to information.

Example:
Participation of the recycling and recovery companies in SIEF is difficult because of restricted access to information. In most cases, they are automatically given a "dormant" status, which prevents them from receiving communications besides mandatory data sharing. Consequently, they might have restricted access to information needed for exemption from registration as provided for under article 2.7 d.

BUSINESSEUROPE recommends:

In order to improve the workability of REACH-IT and SIEF

1. *Give close consideration to the possibility of making REACH-IT and related guidance available in all EU official languages.*
2. *Make available at short notice the software for the Technical Completeness Check to allow a check by companies prior to submitting the dossier.*
3. *Guarantee that "dormant" participants in SIEFs are granted access to information that enables them to prove sameness of substances in accordance with article 2.7 d.*

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