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Is REACH going well?

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1. REACH in 'still waters'?

Little is heard these days about REACH, the new EU Regulation on the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emical substances.[1] For the general public and non-specialised EU observers, the ongoing implementation of what is perhaps the biggest EU regulation ever undertaken appears to be proceeding in serene tranquillity. What a contrast with the turmoil and hectic debates that raged between mid-2003 and December 2006, when this new EU chemicals regulation (of some 850 pages) was finally enacted.

Remember the European Parliament finding itself in need of fitness training? The MEPs had to stand up and sit down again every time each of the 1,039 amendments had to be voted on (first reading), and this was repeated 350 times in second reading. Remember the fierce and widespread lobbying on REACH, even before the first preliminary RIA (regulatory impact assessment) of May 2003? And the drastic adaptation of the proposal and the final RIA only 5 months later? Remember the public letter sent by three Prime Ministers (of France, Germany and the UK) to European Commission President Romano Prodi to reconsider REACH? Or the 41(!) RIAs published by lobbying groups, countries, regions and NGOs, causing an unprecedented intensity of debate on what is a highly technical piece of EU legislation? Or the massive hearing in the EP in January 2005, with every one of the 1,000 seats of the EP hall (+ balcony) occupied the entire day, and many hundreds of spectators standing before the monitors in the corridors and the EP café? Not to speak of the serious concerns of WTO partners like the US or Japan.

The silence and 'still waters' are remarkable. It would be more than surprising if such complex and controversial EU legislation, with such radical features, would enjoy smooth, timely and effective implementation. True, implementation might be regarded as relatively easy in case of EU regulations (and REACH is an EC regulation) compared to directives. No long delays of transposition into national laws, no preoccupations over divergences of interpretation or about 'gold-plating' – adding additional features for one country's benefit only. But the absence of these headaches does not imply that the implementation of REACH is smooth, timely and effective. The Regulation has a number of unique properties that render implementation exceedingly difficult and burdensome. Close observation of the current process confirms that proper and timely implementation is a very tall order indeed.

This CEPS Policy Brief discusses the milestones of REACH and the difficulties of its implementation in a non-technical fashion. Discussing these issues in circles beyond the chemical sector is important because REACH is not targeted only or even primarily at chemical enterprises. Via the value chain and the REACH obligations which come with different positions in the value chain, REACH implementation affects virtually every industry in the EU, including imports. And as a consequence of its ambitious health, safety and environmental objectives, it is of interest to workers, consumers and citizens throughout the EU, if not beyond.

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

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Section 2 will sketch out the main properties of REACH, the ensuing obligations and ECHA, the European Chemicals Agency in Helsinki. We attempt to do this in a reader-friendly fashion. Section 3 will survey the present status as far as observations by outsiders make this possible. We shall demonstrate that the REACH Regulation suffers from overly ambitious deadlines and a number of technical and administrative uncertainties that currently show up in a higher burden of implementation for companies and the ECHA than expected. Section 4 attempts to look one or two years ahead and discuss crucial issues for this short run. Section 5 comprises some reflections on the complicated cost/benefit structure of REACH which can only be appreciated when assuming a long-run perspective. The implementation process affects the cost-benefit picture. Section 6 concludes.

2. Reminders about REACH and its implications

Two leading objectives of REACH are the promotion of EU public health and the environment insofar as these are endangered by chemicals, without adversely affecting the industry's competitiveness. Of course, before REACH there was already extensive EU chemical legislation in place, but this legislation had less broad objectives.

The point of introducing REACH was and is that existing legislation suffered from a number of serious drawbacks which rendered it insufficiently effective and complete, as well as unnecessarily costly (in some respects).[2] The greatest drawback was undoubtedly that regulation of specific chemicals before REACH often lacked risk assessment.[3] The hazards and risks associated with numerous chemical substances were not known. Nevertheless, certain categories of 'dangerous' chemicals have been identified and restricted in use (or forbidden) without or with partial knowledge of health and safety properties. Innovation suffered from a penalty in that the existing stock of chemical substances registered before 1981 had not been tested except in cases where severe risks had been detected, whereas new, innovative chemical substances (after 1981) had to undergo costly risk assessment and some form of risk management. For the globally competitive European chemical industry, such a penalty amounted to a perverse incentive, prompting excessive reliance on existing chemicals even though their risks were (often) not known while losing promising options to create more effective or less risky chemicals.

The EU swing to REACH at first seemed to be an overreaction, based on the precautionary principle applied to all chemicals, even though in many cases decades of use had not indicated the slightest suspicion of a risk to health or environment. However, in the end the application of the principle was more measured and the system set up turned out to be far less hazard-driven.[4]

REACH therefore amounts to a consistent and all-encompassing system that aims at controlling risks of chemical substances in the EU, produced or used in quantities above 1 tonne a year. It aims to do so in order to serve health, safety and environmental objectives while explicitly promoting the competitiveness of the EU chemical industry via the avoidance of unnecessary costs as well as the facilitation of innovation. Since these two types of objectives can conflict, it is essential to carefully design REACH as a system and its cost/benefit structure over time.

The 3½ year battle in Brussels over REACH boiled down to a struggle to maintain the consistency and wide coverage of the system (so as to accomplish a complete mapping of risks of all substances above 1 tonne) while containing its costs. We shall not go into an assessment of the REACH system in this contribution. The present Policy Brief focuses on the ongoing implementation of REACH.

A simplified flowchart on how REACH works is provided in Figure 1. It is based on the principles that a) only 'registered' substances can be produced and marketed and b) industry (including importers) – and not ECHA or national authorities – is responsible for risk assessment. Producers and importers first 'pre-register' all substances they might later 'register' with technical dossiers[5] before specific deadlines (Figure 2); this 'pre-registration' should have been done by 1 December 2008.

[2] Readers interested in getting some notion of the heavy-handed and multi-layered chemicals regulation before REACH, spread over more than 40 EU regulations and directives, yet without being swamped by technicalities, are advised to read Maglia & Rapisarda Sassoon (2000) and KPMG (1997).

[3] Risk is the relationship between intrinsic properties of chemical substances (hazard) and actual exposure of humans or the environment to the substances.

[4] A hazard is only a necessary but not anywhere near a sufficient condition for risks to be important enough for regulatory action. Proper risk assessment must check the dose/response relationship, verify the expected exposure (or ranges of it) – which depends normally on use – and only then can the risk be determined. Many hazards do not imply risks of any importance because the quantities are minute or the exposure is next to zero.

[5] These are called 'phase-in substances', the ones already included on an EU list by 1981. The ones developed after 1981 and accepted by authorities are called 'non-phase-in' substances. They have more generous deadlines. Entirely new substances innovated now or in future also fall under such a regime.

Figure 1. REACH implementation

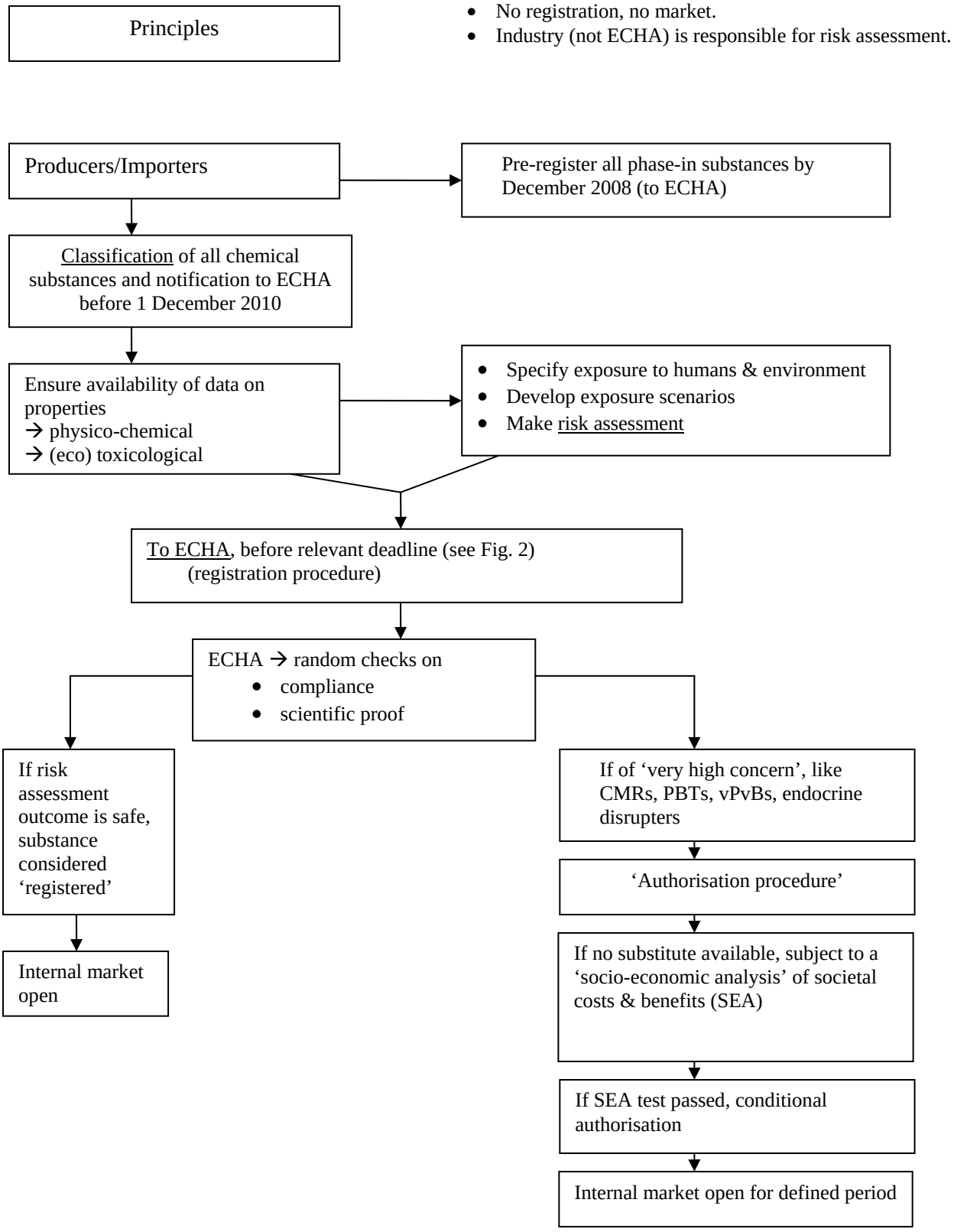
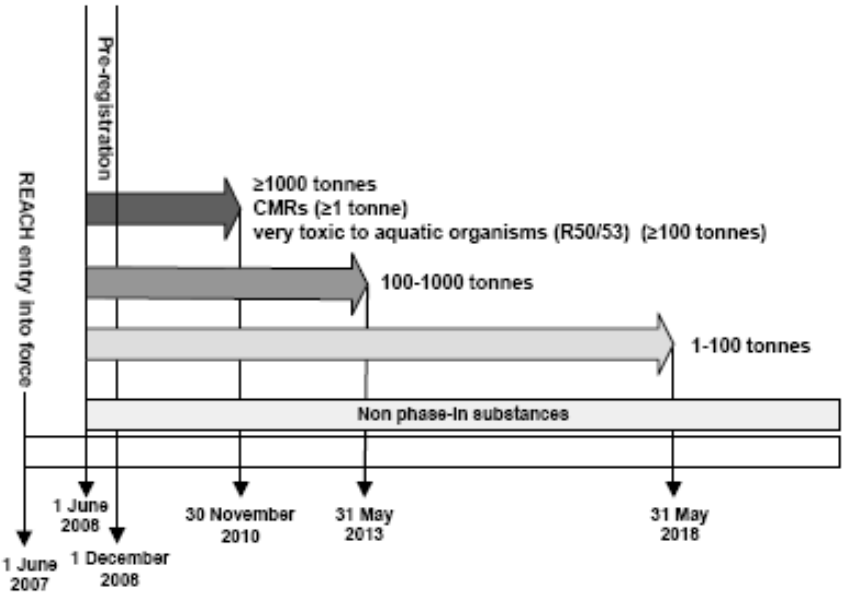


Figure 2. Implementing REACH: The deadlines



Source: European Commission.

Figure 1 shows that producers/importers should classify all substances,[6] address the properties of the chemical substance by test reports or other data available and write a risk assessment based on an exposure scenario (description of expected 'exposure' to humans and the environment). All this is then submitted to ECHA before the relevant deadlines, which differ according to suspected risk, as defined by tonnage produced or by concerns already known to some degree. ECHA will, in close collaboration with the Commission and member states, distinguish two routes. First and most frequently, if the substance is 'registered', it is considered safe to be used as described in the risk assessment. This enables the company(ies) to operate in the internal market. Second, if concerns remain, the company(ies) cannot operate in the internal market. In specific cases, substances will be restricted (banned from the market) or authorised for a specific period for a specific application (under very strict management conditions). This is done via separate procedures and on the initiative of the member states and other stakeholders.

For the time being, REACH is mainly about generating and sharing risk information, little else. For a period of no less than 11 years (until 2018), a series of deadlines applies, as shown in Figure 2, for a total of some 30,000 substances listed by 1981. For the production or marketing of chemical substances in quantities in excess of 1,000 tonnes/year and some dangerous substances, the registration deadline is 30 November 2010, which is very tight as we shall show below. For smaller tonnages, it is respectively 31 May 2013 and 31 May 2018.

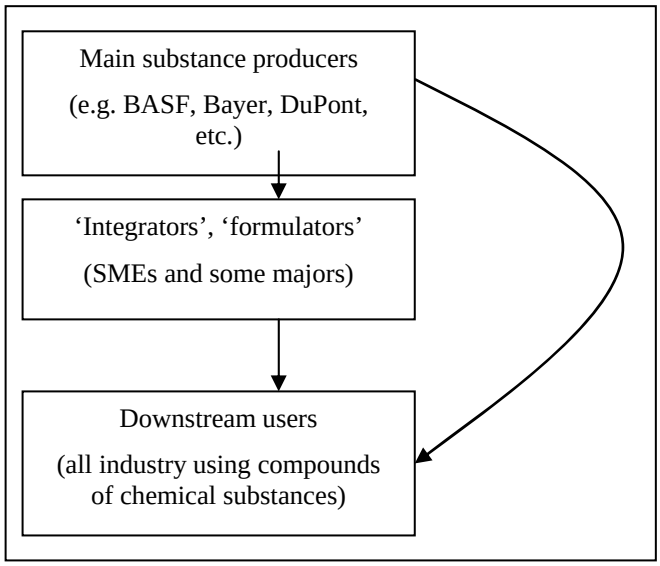
The 'chemical safety reports' (required for substances used in quantities of 10 tonnes and higher) are demanding. For example, for substances classified as dangerous, the exposure scenarios must include operational conditions and appropriate risk management measures ensuring adequate risk control for all identified uses. In order to reduce costs for the Agency, other authorities and industry, part of the registration should be jointly submitted on the basis of cooperation between companies producing or marketing identical substances. The pre-registration before December 2008 was also meant to bring together producers and importers of the same substances and to initiate exchange of information between all applicants on what substances they were interested in. All companies dealing with substance X could then find one another and form a SIEF (Substance Information Exchange Forum). SIEFs can usefully exchange information but must share existing vertebrate animal testing data and agree on the generation of new test data. It does not take much imagination to appreciate that many thousands of SIEFs have to be organised in a very short period of time. A crucial characteristic of REACH is the consistency down (or sometimes, up) the value-chain.

The chemical industry consists essentially of two layers: primary substance producers – such as BASF, Bayer, AKZO-Nobel or DuPont – and the extremely diversified second layer of so-called 'integrators' or

[6] Thus not only those produced or imported in quantities of over 1 tonne per year. With some 100,000 chemical substances already known in 1981, this is absolutely essential.

'formulators' (many thousands of SMEs, plus the majors) making intermediate products by blending substances and innovating incrementally but incessantly. Both layers, but mainly the second one, sell to the downstream users and these include practically all sectors of industry. This is illustrated in Figure 3.

Figure 3. Chemicals value chain



Downstream users are fully part of REACH. Information relating to health, safety and environmental properties, risk and risk management measures is required to be passed down or up the value chain[7] with the help of safety data sheets (SDS). SDSs exist since 1991 but for dangerous substances only.

Obviously, downstream users have to make their uses known up the value chain so that 'identified uses' include their applications.[8] Downstream users comprise an incredibly diversified and sizeable 'group' of sectors and subsectors, from furniture-makers or computer manufacturers to ceramics, oil derivatives, cars, textiles, paper, shipbuilding, home appliances, building products or cosmetics, and others. Much of the consternation in the legislative preparation of REACH had to do with the concerns and uncertainty of downstream users.

What costs would it imply for them and when would they know for what substance(s) over this lengthy period of 11 years? What about substitutes, whether introduced for cost reasons or due to reduced risks? Would these substitutes equally well fit their requirements? What about their costs? What if formulators would 'withdraw' some substances, thereby affecting the quality or characteristics of intermediate products supplied to downstream users? It is these concerns that prompted lobbyists to suggest astronomical cost figures in the early phases of decision-making in Brussels. It is now clear that these suggestions amounted to wild exaggerations, but it is nonetheless a matter of some concern to the numerous downstream users.

3. The present status of REACH implementation

Originally, it was anticipated that ca 30,000 phase-in chemicals would require registration during the period 2010-2018, but the first phase of REACH has shown that this figure was a large underestimation.

The REACH regulation has been in force since 2007. The first year was spent on development and implementation of the administrative structure and guidance. The impact on industry was still limited. REACH actually started on 1 June 2008 with half a year available for pre-registration for substances already present on the EU market (phase-in substances). These substances benefit from an exemption from registration until 2010, 2013 or 2018, depending on the tonnage produced or imported. This pre-registration has been less problematic than anticipated by the sector. In general, REACH IT, the IT system developed to allow pre-registration and registration, functioned well. There were, however, some accessibility problems due to the very large number of pre-registrations (see below). Since December 2008, the first execution phase of REACH started. SIEFs were set up and the first registrations submitted to ECHA. The first deadline for dossier submission of December 2010 is now fast approaching. New substances on the EU market need to be registered immediately and the work on the phase-in substances has been initiated. Many companies have prepared themselves extensively during the last two to three years. The European Chemicals Agency (ECHA) in Helsinki has begun to function and produced thousands of pages of guidance.

Despite the enormous efforts of various stakeholders, however, the 'REACH world' is in many cases less well accessible than expected. At this moment numerous companies are experiencing serious problems in their efforts to meet the (first) registration deadlines.

A number of issues related to REACH are set out below in order to show the complexity of the situation experienced by the chemical industry in Europe. REACH has serious consequences for all companies

[7] Commercially sensitive information is not required to be exchanged.

[8] There are opt-out possibilities but this implies a separate chemical safety assessment by the downstream user, if above 1 tonne a year.

putting substances, preparations or articles[9] on the EU market. The principle is: no data, no market. As noted, REACH influences companies that are considered typical representatives of the chemical industry, but large numbers of companies in other markets and even retailers are affected as well.

Pre-registration

The pre-registration period was closed on 1 December 2008. The 30,000 substances used on the EU market were expected to result in some 200,000 pre-registrations. How different it turned out to be. In total, 14 times as many, namely 2,750,000 pre-registrations were submitted to ECHA by 65,000 companies. The number of substances was an unexpected 146,000. Part of the avalanche was caused by ambiguities in the legislative text of REACH. ECHA issued some guidance on how to read the text only in October 2008, barely six weeks before the deadline. Pre-registration was considered necessary also for re-imported substances, recovered substances, monomers in polymers and substances intended to be released from articles. This caused a huge surge of additional pre-registrations in November 2008.

Only Representatives

In order to allow non-EU manufacturers of chemicals to influence their own registration and to relieve the burden on importers, REACH foresees the establishment of 'Only Representatives' (ORs). These are legal entities within the EU, taking over the responsibility of the importers from a non-EU manufacturer for compliance with REACH. At this moment it is not clear how many entities act as ORs, but it is known that some take care of hundreds or even thousands of chemicals on behalf of their clients (non-EU manufacturers). Among the ORs, one finds consultants, legal firms and EU affiliates of non-EU producers, but also companies specially set up to deal with OR services. ORs had to submit the pre-registration, keep track of volumes imported and take care of the communication in the supply chain.

The quality and especially knowledge among ORs can differ substantially. For pre-registration, not much knowledge was necessary, but during the present phase of SIEFs, the OR represents its client in discussions on substance 'sameness' and other technical SIEF tasks. Engaging with a low-quality OR can endanger compliance with REACH as well as continuation of exports to the EU market. The non-EU company itself may have limited knowledge of REACH and will rely on information coming from his OR. The ORs are liable for REACH (non-) compliance of their non-EU clients, but the awareness of their legal position seems less than satisfactory.

Substance Information Exchange Forum

The Substance Information Exchange Forum (SIEF) is a forum formed of pre-registrants of the same substance with the task to assess substance 'sameness', start the sharing of (vertebrate) data and reach agreement on Classification and Labelling. Many SIEFs have been formed after 1 December 2008 and are trying to arrange their cooperative tasks. This cooperation is a novel element in REACH. Competitors are forced to work together and to exchange information. The SIEF idea is part of the legislative text of REACH, but nowhere is there the slightest rule or recommendation for SIEF organisation and management. This omission is costly and creates much uncertainty.

The discussions in the SIEF might lead to the exchange of confidential business information as well as infringement of EU competition law. Companies are allowed, if not forced, to share what is necessary under REACH, but have to respect Articles 81, EC (on prohibited collusion and anti-competitive agreements) and 82, EC (on abuse of dominance, possibly collectively). Such discussions may lead to tricky situations. Larger companies are aware of these risks and train their representatives, but SMEs might violate competition law without intending to do so. CEFIC, the chemical lobby in Brussels, has launched an awareness campaign on precisely this danger.

In some cases the formation of and work in the SIEF led by industry run smoothly, but there are failures, too. For example, SIEFs may not start at all. Other SIEFs have merely communicated a standard inquiry letter and are waiting for a formal start. It is not surprising to find that competing companies have difficulties initiating the process of data-sharing, but few anticipated the trepidation or lack of action that currently characterise many SIEFs. This is a serious problem, because the process needs to be completed rapidly, especially for the many substances to be registered by December 2010. There are several IT tools available to assist the SIEF process, but these are not standardised and in some cases are very expensive. Therefore, only a limited number of the SIEFs use these tools.

There is a need for standards and for solutions to force mal- or non-functioning SIEFs to start, but legal instruments to enforce this are lacking.

Enforcement

For a large and ambitious legislation like REACH to become successful, strict enforcement is critical.

[9] A technical term defined in Art. 3.3 of the Reach Regulation as "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition".

Enforcement is assigned to the national level. National authorities (19 countries in September 2009) have enacted enforcement rules: they now check imports and perform on-site inspections. However, the rules and penalties related to violation of REACH differ strongly among EU countries. In some, it may lead to imprisonment, while in others only financial penalties will apply. A forum of ECHA (The Forum), with designated national coordinators as its members, addresses enforcement, but is only endowed with advisory, coordinating powers. The Forum has published and initiated REACH-EN-FORCE-1, the first enforcement project concentrating on pre-registration, registration and safety datasheets.

Registration

By September 2009, ECHA had received some 1,200 registration dossiers (half of these on intermediates). These dossiers first undergo a completeness check (this has left over ca 500 dossiers) and in some cases they might be evaluated for compliance.

The technical completeness check is performed to ascertain that all elements required are in the dossiers and the registration fee is paid. Of the dossiers submitted, those on substances that are under product- and process-orientated research and developments (PPORD) passed more easily. A Technical Completeness Tool will be ready by the end of this year, so that companies can check completeness before submitting their dossiers.

At present limited experience with dossier evaluation is available.

ECHA has indicated that the main issues with the dossiers are related to substance identification (also of test material used in studies), inadequate justifications for waiving, poor quality of the robust study summaries in the dossier and non-compliance of studies with Good Laboratory Practice. It needs to be stressed that reasoning and documentation of arguments are essential points to satisfy the evaluation criteria of ECHA.

Small and Medium Enterprises and REACH

Awareness of REACH among Small and Medium Enterprises (SMEs) in Europe is increasing, but still companies find out that they 'forgot' to pre-register or failed to pre-register the correct substance. In addition, discussions about the status of products being an 'article' or a 'formulation' or a substance of UVCB[10] are ongoing.

SMEs are relatively strongly affected by the REACH regulation. In general, they lack human and financial resources to deal with REACH. Many SMEs are believed to be downstream users, but they might have additional roles (manufacturer/importer) as well. SMEs that are downstream users face complicated work when their use is not incorporated in the dossier submitted by their supplier. In that event, they have to compile their own dossier, which is highly specialist work.

Costs/benefits

No thorough cost-benefit analyses have recently been conducted on REACH. The available larger studies date from the period when early proposals on REACH were being discussed. REACH was altered considerably before the EU enacted it. Moreover, these studies were criticised as poorly documented and vague on the benefits.[11] REACH supports the protection of human health and environment, while enhancing free movement in the EU internal market and competitiveness. This ambition is very general and can only be supported. It is, however, difficult to substantiate.

What valuable work there is on cost and benefits could not foresee the high numbers of (pre-) registrations now witnessed. Does this mean that the costs of REACH will increase proportionally or are the newly expected numbers of genuine registrations an over-estimation (and how large is this over-estimation)?

4. REACH issues in the short run

Many questions regarding the further development of the implementation of the REACH Regulation remain open. What can we expect during next year and how realistic are the deadlines? Will industry manage to comply with REACH? Will substances be phased-out (temporary) because of tight deadlines? Will REACH actually lead to innovation?

Will REACH improve the transparency of the chemicals market? Will REACH indeed have a positive effect on human health and environment?

Making the 2010 deadline

Industry. The 2010-deadline is approaching rapidly. Many SIEFs do not function at all and others struggle with legal issues related to data- and cost-sharing. CEFIC has published a standard SIEF agreement to assist SIEFs in these matters. In view of the deadlines, agreement needs to be reached as soon as possible, since only then will the actual work begin. Activities are not limited to the building-up of the dossier, but

[10] Unknown or Variable Composition, Complex reaction products or Biological materials.

[11] Ökopol (2007).

may well include complicated and time-consuming tests necessary to ascertain the properties as well as the development of exposure scenarios leading to safe use. Vertebrate tests that might be unavoidable include tests which take 6 to 9 months. Full development of an exposure scenario requires extensive discussions in the supply chain. This can last for many months. In short, registrants that do not obtain agreement in their SIEF may be running out of time to finish their dossiers before the deadlines.

Guidance and tools. Work on generic exposure scenarios and electronic tools to assess such scenarios, is in a starting phase and needs to be completed before registrations can be done. Currently, updates of the guidance on registration, guidance on the guidance by authorities and industry organisations and explanatory notes are published on a regular basis, so that the final picture of the requirements for registration is being adapted all the time. Fortunately, very recently, new tools have become available.[12]

Number of substances. The number of substances to be registered by the 2010 deadline is now expected to amount to 55,000 (originally anticipated 3,000-4,000). It is not clear how realistic these figures are, but the increase augments the anticipated workload of both ECHA and the national authorities substantially. One wonders how ECHA will deal with this.

In September 2009, the EP still had to rescue ECHA from an ill-considered EU budget cut by adding €4.5 million for 2010, as fees will start coming in later. Of course this enormous number of substances also multiplies the efforts of the chemical industry. All this is likely to cause delays or to lead to difficult choices on prioritisation of substances within companies.

Authorisation/replacement/innovation

Substances that are considered of 'very high concern' will fall under authorisation, i.e. under very strict conditions will these substances be allowed to be used for a distinct period. Candidate substances for authorisation can be suggested by the EU member states. At this moment, 18 chemicals are present on the first candidate list of which seven have been prioritised to become subject to authorisation. An additional list of 15 proposed substances became available in early September 2009. The EU expects the candidate list to grow with 25 substances per year. Two non-official 'black lists' of substances of very high concern have been published by different NGOs: the SIN list (www.sinlist.org) and the TU list (www.osha.europa.eu). To include all 267-306 substances on these lists in the candidate list will take more than ten years if the suggested 25 substances per year that can be handled is realistic. However, few observers expect that all substances on these lists will be subject to authorisation in the final analysis. On the other hand, these two lists do not contain all candidate substances for authorisation. Many of these will be identified during the REACH registration process when data on hazardous properties and exposure information will become available.

The phase-out of substances of 'very high concern' and a proposal for replacement with less dangerous alternatives is part of the authorisation process. It seems unlikely that proper replacements can be found for all substances on the available lists within a defined period. Replacement and innovation can take years of research, entailing large investments. In certain industries, e.g. aerospace, replacement of a single substance in a product can take up to 10 years.

Nevertheless, in the longer run, REACH will stimulate innovation and substitution. An additional problem in times of economic recession is the reduction of research budgets. There are examples of innovation induced by more strict EU legislation, e.g. on fluorinated compounds, but so far these successes are still rare.

Supply chains

It was expected that REACH would provide insights into the supply chains within the chemical industry, yielding concomitant advantages for control and safe use of chemicals. 'Supply chains', however, seldom exist. Companies are each others' clients and/or suppliers and can have different roles in a single 'supply chain'. In most cases a 'supply web' is a more appropriate term. Supply webs do not stop at the EU borders and, without REACH obligations outside the EU, it is even more difficult to obtain insights into the webs abroad. Information exchange in supplier-client relationship is often likely to entail the exchange of confidential, critical business information on e.g. the composition of products or specific uses. This may be less of a problem in well-controlled supply chains like the automotive industry, but more so in loosely organised and complicated webs like the textile industry or the paint industry. In addition, in the absence of legal obligations, the willingness to share data is expected to be limited. Therefore, the expectations about a boost in transparency seem to have a weak basis in global business conduct. Many non-EU players will have insufficient awareness and complex supply webs are difficult to assess for enforcement purposes.

In order to fulfil their REACH obligations, chemical manufacturers in the EU will cover their downstream

[12] For the specialists: a CSR10 tool, able to extract data from the technical dossier in IUCLID5 to the templates for the registration dossier, is the most important one. This tool will allow experts to work more efficiently to build up the dossiers.

use (as far as it is more or less easy to assess). Beyond this, companies (down stream users) will be left on their own and asked to prepare their own dossiers. No doubt, this will affect especially the smaller companies with limited knowledge and resources.

5. Benefits and costs of REACH, once again

The sharp contrast between the 2001 consensus among all stakeholders on the REACH principles and the bitter battle on the actual REACH proposal starting in May 2003 was caused by the deep concerns about the benefits and costs as well as their lopsided structure over time. The Commission's RIA of REACH spent little effort and just a few lines (on the very last page) on an extremely rough 'guesstimate' of the benefits for public health, whilst declining to express any guess on environmental benefits. The Commission's text gave the strong impression of doing the calculation of benefits as an afterthought. However, very considerable efforts were invested in order to come to grips with the expected costs, both direct and indirect. Thus, the REACH debate and decision-making process was deeply flawed from the beginning. 'Better (EU) Regulation' must be based on the benefits first. Why regulate if not for the benefits of health, environment as well as innovation?

Indeed, the costs matter too, but they can be seen in perspective if, and only if, the benefits are at the very least well understood, if not (roughly) quantified over some reasonable range. One can suggest two main reasons why the benefits of REACH were difficult to come to grips with.

First, the early design of REACH was based on the precautionary principle, but it was applied indiscriminately to all chemical substances instead of a subcategory where at least some suspicions might have been researched (as the precautionary principle suggests one should do; see European Commission, 2000). With the wholesale application of the precautionary principle, one cannot – almost by definition – describe the scope and magnitude of the benefits due to a lack of knowledge. It is precisely in the disciplining of the application of the precautionary principle that 'good regulation' begins.

Second, the benefits would only follow from a very lengthy period of testing and 'registration' based on risk assessment of all chemical substances. In other words, the benefits were to be reaped in the distant future whereas the costs had to be incurred upfront for many years. Such a time structure of benefits and costs is a nightmare for (elected) politicians. Although the chemical industry grossly exaggerated its lobbying on costs at first it remains undeniable that their concerns about the immediate costs and distant as well as unknown benefits were not without foundation. But the point about benefits can be sharpened still further: only the net benefits over and above those already gained from existing restrictions of chemicals should be counted. What (currently unrestricted) substances might yield these net benefits, was and is still unknown, but it would be pretty extreme to assume that their number would exceed (say) 2,000 or perhaps 3,000, not anywhere near 30,000.

Against this background it is of some interest to discuss the possible consequences of the ongoing implementation on benefits and costs.

A well-performed investigation into the benefits seems essential to enhance the motivation to support the further implementation of REACH by industry, consumers and other stakeholders.

REACH is unknown to the general public. No extensive television campaigns were initiated to let the European public know that this legislation is in place and that individual consumers have the right to ask questions about the safety of non-food products they are buying in retail shops. The legislation affects thousands of companies and millions of people.

The consequences of REACH for the entire European (non-chemical) industry were poorly recognised and many questions remain unanswered. Help-desks are available and function well on standard questions, but remain silent on the more difficult ones. ECHA is trying hard to perform its enormous task properly, but the agency is still understaffed. Guidance documents of thousands of pages are produced, which now need explanatory fact sheets. The guidance is still incomplete and is updated almost on a daily basis. IT tools are available for some tasks, but others still need to be developed. For the management of the SIEFs, no legislative provisions are available. Industry competitors have to organise themselves and solve legal issues related to confidential business information and competition law, as well as IT solutions to communicate in SIEFs of thousands of members. How can industry keep track of all of this?

Industry is responsible for the registration under REACH. A dossier will not be formally approved by the ECHA. There might be an evaluation that leads to questions and even to an authorisation, but in the end industry is responsible for the safe use of substances. This is a U-turn as compared to the previous system and is unique in the world. Industry cannot hide behind an approval, but faces full responsibility. This might prompt the phase-out of production or use of certain substances by the chemical industry on a voluntary basis. Companies assuming responsible care as a leading principle in their corporate strategy are expected to do this. In addition, there are reports on shifting production of dangerous chemicals to non-EU

countries, which is only a transfer of problems at the peril of others and not a sustainable solution.

Regarding the costs, no new estimates are available at present. The number of substances to be registered turns out to be much larger then envisaged and this will influence the overall costs of REACH substantially. Every task related to registration is still a learning-by-doing experience and costs are difficult to estimate. SIEF duties take much time and significant resources. In times of economic recession it is difficult for companies to find and allocate resources to tasks that seem either poorly defined or changing in magnitude on a regular basis. There are already serious delays in many businesses and perhaps also inside ECHA. It seems almost impossible to keep to the extremely tight 2010 deadline (see Figure 2).

Making choices seems unavoidable. Companies may decide to focus on fewer substances or take a less active role in the registration process.

Resources are scarce and are sometimes found in-house (production personnel filling in the dossiers?). One should not expect ECHA to postpone its deadlines. This is understandable, as the deadlines are included in the REACH Regulation. Amendments are not impossible,[13] but such changes would imply a time-consuming process. Therefore, the relevant query is which steps ECHA is willing to take without violating the REACH regulation.

The lack of qualified resources to deal with REACH is another issue that causes delays. The numbers of toxicologists, eco-toxicologists, chemists and occupational hygienists with knowledge of REACH is limited and it is difficult to find these experts. Many consultancy companies have found the 'world of REACH', but experience difficulties hiring competent people. These employees need to have not only good knowledge of a huge regulation of considerable complexity and many technical annexes, but also the experience to solve complicated matters of hazard and risk assessment. REACH provides incentives to companies and testing houses to replace animal tests by non-animal testing, e.g. *in vitro* testing (testing in cells and tissues) and *in silico* testing (so-called QSARs, computer models simulating such tests (see Annex XI of the Regulation). These alternatives are in some cases more costly and time-consuming than the original tests. Worse, they are very often not yet officially validated.

Therefore, qualified toxicologists are indispensable to interpret the results of the alternatives and their usefulness as a substitute.

Exemptions from REACH include the following: active substances in pesticides and biocides, co-formulants in pesticides, cosmetics for human use only, veterinary and human medicinal products and several other classes. Nevertheless, REACH will influence the industries dealing with these regulated chemicals, e.g. raw materials and intermediates in the production process might be subject to REACH. For cosmetics, the situation is even more difficult. Most of the ingredients of cosmetics will need to be registered under REACH (although the consumer use of cosmetics is excluded in the REACH dossier) and thus will be tested in animals. The Cosmetic Directive,[14] however, no longer allows animal testing on ingredients (first deadline March 2009, second 2013).

This would mean that many substances tested under REACH will no longer be permitted as ingredient of cosmetics. This might well entail drastic consequences for the EU cosmetics industry.

6. Conclusions

The implementation of REACH was always expected to be a huge effort on the part of ECHA and business throughout the value chain, inside as well as outside the EU, chemical companies as well as downstream users. However, it now turns out to be a process with still more complications and hiccups due to unforeseen details and lingering uncertainties with respect to some technical aspects. The SIEFs lack an overall 'governance' system, which should preferably be run by ECHA, as this would provide badly needed certainty and early information at the Agency level about the weaknesses and incipient failures of (many) SIEFs. The hiccups have the unfortunate effect of delaying or overburdening the current preparations for the December 2010 deadline.

The 2010 deadline appears to be too tight now that difficulties and uncertainties have emerged or lingered during the actual practice of implementation. Creative solutions for bottlenecks are essential. Current indications are that a very considerable number of SMEs and importers will simply not be capable of registering in time or will submit with gaps and omissions causing other delays. The authors would not expect ECHA to be able to answer all the questions raised, but some pragmatic ideas on how to meet the deadlines are nonetheless urgently required. The authorities in the capitals, Brussels and Helsinki

[13] Already today a number of amendments have been adopted by the Commission, such as those to Annexes IV and V, and later on to Annexes XI and XVII; a new EU regulation by the EU legislator on classification [1271/2008] is, so far, the only one involving the Council and the EP fully.

[14] The 1976 Directive (76/768/EEC) is under review. However, the seventh amendment to Directive 2003/15 seeks to phase out animal testing. Detailed timelines can be found in SEC (2004) 1210 of 1 October 2004.

cannot close their eyes to what is (not) happening in the REACH process and merely state that the deadlines will not be postponed. Many examples of how to work on REACH in time and cost-efficient and effective ways are available. These can be most helpful for others, but it takes learning and organisational time to initiate the effective and fully-compliant implementation in the complex REACH environment. Can one really pursue the course when such large numbers of 'drop-outs' are at risk? A slight delay in the start of the REACH train can be justified in order to allow everyone to catch it in the end.

However, timing is not the only problem. Questions concerning such issues as enforcement, the processes in supply chains, or better 'supply webs' and costs and benefits are perhaps even more important.

Enforcement will differ between EU member states, both with respect to controls and to the penalties for non-compliance. The Forum has only an advisory status and cannot impose rules or harmonise approaches. The chain of REACH is as strong as its weakest link and enforcement might be the weakest link. It would be unacceptable if industrial activities or ORs are moved to EU countries known for their lax enforcement policy. The notion of supply chains proves to be somewhat academic for REACH obligations which are demanding. We employ the term 'supply webs' which exemplifies the diverse and multi-functional links between chemical companies in various layers of value-added as well as downstream users. No one can know for sure how (im)practical the REACH obligations of passing on sufficient and well-structured information on substances will be outside the traditional bounds of the chemical sector and outside the EU more generally. But for numerous EU companies, it might put their business at risk even though their efforts in obtaining the relevant information have been energetic and sincere.

Finally, the lingering problems – not to speak of the unexpectedly high numbers of pre-registrations – tend to further raise the unprecedented upfront costs of REACH. These increased costs and uncertainties have to be appreciated given the absence (so far) of any new indications of benefits of a similar magnitude to European society. The authors therefore urge a much closer attention to what benefits might actually result from REACH. Good regulation requires first and above all, a solid understanding of the benefits of regulation. Otherwise, why regulate? And why at such huge up-front costs? We do appreciate the recent REACH Baseline study as a worthwhile attempt to begin monitoring whether indeed REACH will yield the benefits the EU has long hoped for (see EUROSTAT, 2009).

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