Chemicals regulation: REACH and innovation

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Content

Summary

This paper investigates the implications of the new REACH regulation on innovation. REACH is not yet finally developed and implemented, and the present paper shall be seen as a contribution to the discussions of improving the regulation, its implementation, and of supplementary and complementary activities and initiatives. It is important to remember that the adaptation of the regulation, which will take place June 2007, the concurrent establishment of the new European Chemical Agency in Helsinki, and new procedures for contact and interaction between suppliers, users, and authorities, will not be the end of the process of improving the working of the European chemicals regulation.

Innovation may take very different shape depending on where and how we look. In the paper we develop an approach to innovation that is sensitive to the different nature of innovations carried out at different sites of the production-chains, i.e. from producer of basic chemicals to end-user, and we discuss how this work together with the new European chemicals regulation.

Introduction

To talk about innovation and REACH is like stirring up a hornets' nest. REACH was made exactly because it was feared that substances that ought to be regulated and restricted was freely marketed and used – that the use of some substances was to be phased out, and that new solutions to meet demands and needs was to be developed. Doing this will inevitable make those who produce substances likely to be phased out unhappy. Therefore, one of the major discussions of REACH has been about the impacts of the regulation, and hereunder innovation, competitiveness, and employment. The 'deal' in REACH has been to counterbalance the expected phase out of some existing substances with eased requirements towards the testing of new substances, i.e. raise the threshold for registration from 10 kg to 1 tonnes.

There has been made a number of impact assessments and especially those made by RPA for the UK government and the European Commission and by Arthur D. Little for the Federation of German Industries have been sources for widespread attention (RPA 2002, RPA 2003, ADL 2002). These impact assessments has been widely criticised for overestimating the costs of REACH and underestimating the benefits (Berkhout et al. 2003; Ackerman & Massey 2004; German Advisory Council on the Environment 2003; UBA 2003). As an important part of this criticism it has been pointed out that the innovation concepts employed is embedded in a static context, which leaves no room for examining the dynamic interrelationship there is between (environmental) regulation and industrial innovation, which elsewhere has been documented as being of high importance for innovation in industry (Thomas 1994, Porter & Vanderlinde 1995, EPA network 2005). Therefore, there exists a need for developing and refining a concept of innovation in the context of chemicals regulation and REACH in specificity, which is much more sensitive towards the whole range of innovation dynamics that emerges when engaging the full range of players involved from cradle to grave.

Innovation

When we turn to the father of the modern concept for innovation (in economy), innovation is defined as processes involving or introducing new products, processes, markets, supply-chains and forms of organization (Schumpeter 1934). Schumpeter distinguishes innovation from invention and diffusion, i.e. innovation is not the process of fostering new ideas, nor is it the dissemination of innovations into society. Furthermore is the differentiation of innovation in the terms of the 'rate' and 'direction' important for the discussion and evaluation of innovation (Freeman & Soete 1997). The rate of the innovation is the quantity of innovations produced during a given time, and the direction of innovation is the quality of the innovation i.e. the kind including its beneficial or damaging consequences.

The rate of innovation is measured indirectly through a number of indicators such as R&D intensity (the ratio between R&D expenditure and turnover), Co-operation (with other enterprises/public institutions), number of publications, number of patents, etc (OECD 2005). Interpreting these proxies for the rate of innovation one has to be careful, as the data may reflect other variables, such as contextual traditions for taking out patents etc that may hamper comparisons across nations or sectors.

Capturing the direction of innovation with measurable indicators is seemingly much more difficult which is illustrated by the absence of guidelines towards the assessment of this dimension of innovations in the OECD Oslo manual (OECD 2005). The reason is quite obviously that assessing the qualitative character of innovation involves judgement of what is desirable or not, and that creating unambiguous indicators for comparison may be difficult, especially if no guidelines for good or bad exists, which is the case in the economic guidelines from the OECD. It is commonly known to be a dictum of the dominating neoclassical economic paradigm that it should be left to the market to guide the directions of innovations. But this is exactly where regulation of chemicals has a role to play. But we *can* differ between good and bad, and this should have impact on the directions of innovation, and this is where the regulation of chemicals must go hand in hand with innovation. And it is known from pharmaceutical industry that such regulations may have positive effect on both quality of innovations and competitive performance, where Thomas (1994) found that the regulations of safety, pricing, basic research and foreign direct investment resulted in UK firms developing a range of skills and capabilities.

In the work by OECD on innovation, there is a clear tendency to increase the scope of innovation from a focus on technological product and process (TPP) innovation in manufacturing, to include innovations taking place in service sectors (OECD 2005). In this paper we take a step further by including innovations taking place downstream of the production-chain, drawing on approaches to environmental improvements from the field cleaner technology, eco-design, and alternatives assessments (Røbke 1992; Brezet 1997; Lassen, Løkke, & Hansen 1999).

The key term here is the radicality of the innovation, and as will become clear from the following, moving down the downstream of the production chain gives possibility for large improvements of environmental and health performance.. The conceptualisation has grown out of a reflection on the development of environmental policies going from dilution and end of pipe solutions towards solutions going upstream of the product-chain as can be seen in Figure 1 as the levels one to five. These five levels of radicality for the improvement of environment and health are further extended with three levels of solutions that transgress the perspective of the single product life cycle. At the fifth level, the product may be substituted by another product that can provide a corresponding service.

The three product oriented levels may be exemplified with approaches to substituting brominated flame retardants (Lassen, Løkke, & Hansen 1999): (level 3) The brominated flame retardant can be replaced by another flame retardant without changing the base-polymer. (level 4) The plastic material, i.e. the base polymer with flame retardants and other additives, can be replaced by another plastic material. (level 5) The product can be replaced by a different product, or the function can be fulfilled by the use of a totally different solution. At the sixth and seventh levels we include a societal perspective on consumption and need, and the innovation involves incremental or fundamental changes in social systems which shall improve environmental performance.

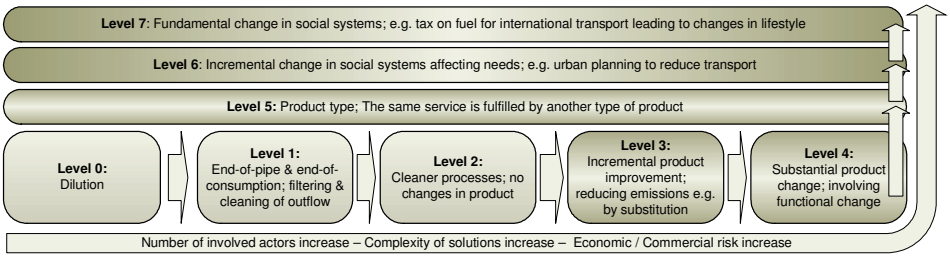


Figure 1 Levels of radicality for environmental improvements. Based on Røpke (1992). The first three lighter grey levels are characterized as production innovations not involving any product modifications, the three

mid levels involves product changes, and the last two levels involve change in social systems targeting consumption patterns.

The spread of radicality should not be seen as exclusive phases. Radical changes at the highest level will often require innovations at lower levels as part of the technological system that enables more dramatic improvements in environmental performance, be it human toxicity or energy consumption. Further, it is noteworthy that the levels should not be mistaken as a grading of alternative solutions; most people would agree that preventive strategies is better than cleaning up, and increasing radicality will often but not necessary lead to better environmental solutions. Environmental problems differ greatly and hence, solutions may be found at different levels depending on concrete evaluation and problem analysis.

The radicality model is organised in a bottom row that includes innovations that can be undertaken within the company. When we move from the left to the right at the bottom (Figure 1) more actors becomes involved within the company, and at the third and fourth level may also downstream users be influenced or be able to experience the change. The changes will be brought about by the companies themselves, but in increasing cooperation with other companies and actors such as consultants, authorities, university departments, financial partners etc. (see e.g. Rasmussen et al. 2000 or Remmen 2001 for a discussion of this in a Danish context).

When we move from the bottom to the top we involve still more actors, and most importantly, the prime actors are not necessarily the company producing the 'conventional' product. At the fifth level the services might be based on technology or materials originating from a different branch, e.g. from petrochemical to organic fibre, which may lead to resistance both within the branches producing the 'conventional' solution and among downstream users that tend to stick to the known and proven solutions (Lohse et al. 2003). At the sixth level the perspective has moved away from the companies producing the goods and services, ad towards changes in the societal arrangements and social systems that frames the patterns of consumption and thereby indirectly the patterns of production. At the sixth level these changes are incremental, such as changes in urban planning influencing the transport patterns between home and work, without influencing traditional lifestyles, whether at the seventh level change is of a fundamental character leading to radical changes in lifestyle.

The increasing radicality also involves increasing risk which partly can be read from the debates of the consequences of REACH, as noted in the introduction. It is obviously more risky for a company to make product-changes than to install filters, as the technical risk will be accompanied with a commercial risk, and which has been stressed, and according to some been exaggerated, in the evaluations issued by commercial interests. Within this framework, the critique of REACH as being to costly to industry could therefore to be understood as a critique of REACH as be-

ing too radical. It should be noted that in the debates the most radical suggestions has been related to requirements for substitution of hazardous substances with less hazardous, which corresponds to or leads to pressure for level three and four of radicality in solutions, and that implicitly in the discussions, the industry position has been that phased out substances should be substituted with substances that functionally should be replacements. One example of such a level three innovation is the resent achievements by DANISCO in developing a vegetable oil-based alternative for the conventional plasticisers such as the phthalate DEHP used in soft PVC-products. However, higher level innovations also be furthered, such as constructive changes in electronic products rendering the use of chemical flame retardants unnecessary (B&O ex), or downstream users developing solutions delivering the same service but based on alternative technologies. These types of solutions obviously imply high risks for some upstream producers and new business opportunities other.

At this point it is relevant to look at the time perspective of such changes. Below, a crude model illustrating the relations between the 5 highest radicality-levels and the time required to develop and implement these types of solutions is depicted. The model was developed in relation to the UNEP work on eco-design, and hence it is targeted broadly at product design and on improving the overall performance of the product in a life-cycle perspective. The model tells us, that the best performance is most likely to be found in the most radical types of innovations. This is not in conflict with the idea above – that the appropriate level of solution to a problem depends on a specific assessment – but rather that large improvements in eco-efficiency will depend on a combination of technology- and system-innovations. The model also reminds us, that improvements in relation to chemicals cannot or should not be seen out context of overall product performance. Finally, the model gives us an indication of the time perspective necessary for radical innovations.

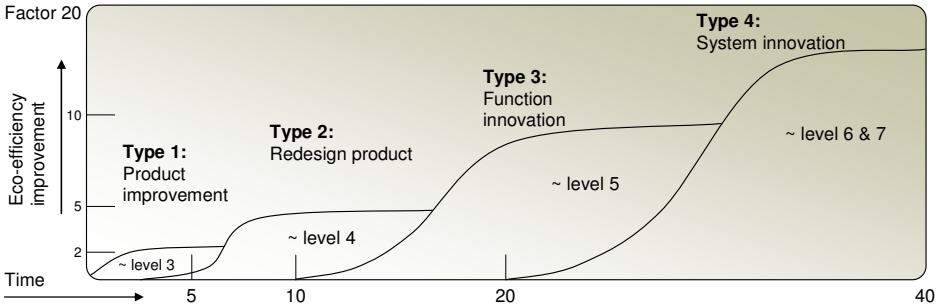


Figure 2 Eco-efficiency-factor and time-factor, effect and radicality of innovations, after Brezet (1997).

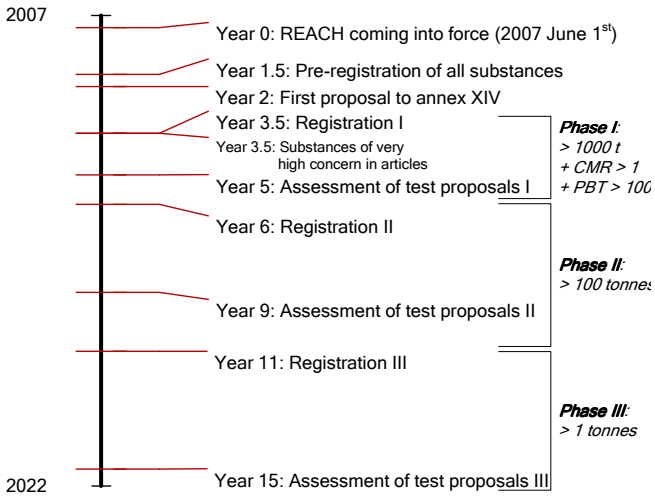
As a consequence of this expanded perspective on innovation the downstream user perspective becomes much more central. Innovation cannot be left for chemists alone, but has to be made from at multi stakeholder perspective, including an enhanced communication and a combination of push and pull mechanisms to guide the direction of innovation.

REACH and innovation

In this section we combine the innovation concept developed above with the mechanisms and prospected workings of REACH. First we resume the basics of REACH and discuss the immediate innovation impacts the regulation has been foreseen to provide. Next we discuss how the extended innovation concept may be used to guide further development of the regulation of chemicals. The new European chemicals regulation has been through a long cumbersome process starting in 1998 with the Ministers' Council request to the Commission for a review (KEMI 1998) and succeeding with the final vote in the European Parliament December 13th 2006 and the Councils final adoption December 18th. The compromise was reached on basis of amendments from the European Parliament to the Common Position adopted by the Council (Council of the European Union 2006) and the Commission.

The Basics of REACH

Basically, the purpose of REACH is to replace the existing European chemicals regulation based on risk assessment, with a new strategy also based on risk assessment. The regulation we go from was based on a division of the chemical universe into 'existing substances' and 'new substances'.



The three steps of the new strategy is

- Registration of certain chemicals (by industry)
- Evaluation of registrations and test results

- Authorisation of chemicals with special attention to effects of concern

These three steps will be carried out in three phases as depicted in the figure above, starting with high volume substances and the most problematic substances in year three from the passage and implementation of REACH which presumably will be 2007. The following two phases will run from year 6 and year 11 respectively.

Registration will apply when production or import exceeds 1 tonnes pr year per producer or importer. In this case there must be produced a technical dossier with increasing detail with increasing volume. The technical dossier will be registered in a database, containing 1) information on company identity and substance identity, manufacture and uses (guidance on safe use, classification and labelling, and exposure information if applicable), 2) study summaries, robust study summaries and proposals for testing, and 3) various statements. From 10 tonnes pr year there must also be produced a Chemical Safety Report (CSR) which includes 1) mapping of uses, including consumers & end of life of the chemical, 2) exposure scenarios, and 3) proposals for tests (Article).

Evaluation will be performed by the new Chemicals Agency in Helsinki in concordance with the member states. The Agency will perform spot check of minimum 5% of the dossiers, and evaluation of test proposals before the initiation of industry-performed testing

Member states and the agency will then evaluate the results of the tests, with the possibility of three generic types of conclusions - no further information is needed, more data needed, substances should undergo further regulation (authorisation).

A number of substances will be exempted from registration, including polymers and unaltered naturally occurring substances (Annex V & VI).

Authorisation will apply to substances of high concern (Council of the European Union 2006: 129-130) defined by:

a) carcinogenic substances category 1 or 2,
b) mutagenic substances category 1 or 2,
c) substances toxic for reproduction category 1 or 2,
d) persistent, bioaccumulative and toxic substances (PBT),
e) very persistent and very bioaccumulative substances (vPvB),
f) other effects, e.g. endocrine disrupting, or effects of equal concern as those above (a-e)

Substances that fulfil one of the six criteria above will be listed on a *candidate list,* which will be public. From this list the Agency shall prioritise substances to be added to the Annex XIV, starting in year two, taking into

account 1) PBT and vPvB proporties, 2) wide dispersive use, and 3) high volumes.

Annex XIV is the central tool that will enlist all substances which are prohibited or which use is restricted and allowed with an authorisation.

Three criteria are in place. Firstly, authorisation is given automatically if *adequate control* can be documented. Secondly, this will not apply if there cannot be determined a threshold for the substance, i.e. or if the substance meet the criteria d) or e), i.e. PBT and vPvB. Thirdly, if it is shown that the socio-economic benefits outweigh the risk to human health or the environment, then an authorisation may be granted anyhow.

All applications for authorisation must include "an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution, and including information about any relevant research and development activities by the applicant, if appropriate." (Article 61(4)(e)). Furthermore, where the analysis "shows that suitable alternatives are available […] [shall the application include] a substitution plan including a timetable for proposed actions by the applicant" (Article 61(4)(ea)).

Furthermore, third parties, e.g. other market agents, downstream users, authorities, and NGO's, may also post alternative substances and technologies. However, all information on uses, volumes, and downstream users is kept confidential to protect the commercial interest (Article 63(2) and 117(2)), which may make it difficult for third parties to target the alternatives.

Reach and Innovation

As it will be clear from the brief description above, there are a number of ways in which the new regulation will have impact on substitution of hazardous substances with less hazardous ones. The immediate mechanisms fall in three types. The first is costs related to the registering, testing and authorisation, the second is information about side effects related to health and the environment, and the third is the direct requirements for substitution-analysis build into the authorisation procedure.

Cost

The costs are due partly to fees payable at registration and authorisation, partly to obligations to investigate the substances.

It is expected that the registration will act as a drive for substitution. The demands for information may require testing which may lead to increased

costs: “In order to avoid this, industry will look for safe and well-tested alternatives to replace potentially problematic substances” (Questions and Answers on REACH August 2006: 27). The structure and amount of fees are to take account of the tonnage range of the substance being registered and of foreseeable expenses at the registration phase.

Furthermore, it is expected that the requirement for the substances of highest concern to be authorised will also promote substitution: “Applications for authorisation are costly (if the risks of the use of the substances cannot be adequately controlled, a company has to demonstrate that the socio economic reasons outweigh the risks; the application may then be granted by the Commission. The strict conditions for authorisation and the related costs will encourage companies to invest in research to find safer substitutes to avoid having to go through the process.” (Ibid).

Information

Increased information flow is a key characteristic of the new chemicals regulation. It is known from innovation research that up and downstream information will give impetus to innovation through at least four types mechanisms:

- close contacts with customers;
- accessing external sources of knowledge;
- having effective internal communication; and
- being able to recruit educated people who are linked into wider knowledge networks

(Freeman and Soete 1997, Berkhaut 2003)

It will be of high importance that the regulation is implemented in a way that will support these effects.

- Downstream producers may chose alternative substances or technologies if the safety data sheet (SDS) is encumbered with troublesome remarks, e.g. CMR or PBT.
- Upstream producer may choose to redraw substance if safer alternatives exist (in their portfolio).
- The candidate lists for authorisation may come to work as the Danish List of Unwanted Substances, which has been shown to speed up downstream users phase out of before strict regulation (DN 2005).

Left is how to assess what ‘safer alternative’ means. This is a discussion which we will return to below.

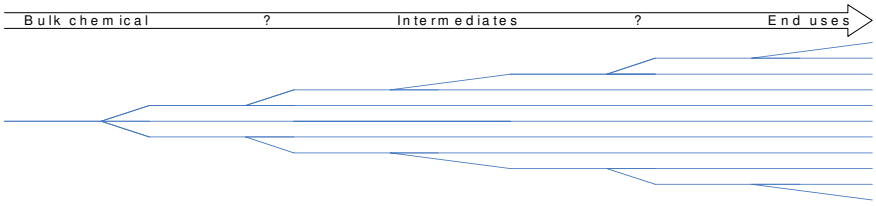
Duty to perform Alternatives Analysis

The duty to perform alternatives analysis, or rather analysis of substitutions, has been central in the final negotiations of REACH, and this has become obligatory for the most problematic substances i.e. for those that will require an authorisation.

The innovative potential of this mechanism is highly depending on the possibilities to suggest safer alternatives, which relates strongly to the long-established discussion on functional units in the world of LCA (see e.g. Weidema et al. 2004). It is obvious that the framing of the alternative analysis in terms of functional units has deep impact on the the types of alternatives that are relevant. The narrower the function definition, the lower radicality will be the result of the innovation process.

REACH and alternatives assessment – a role for LCA?

In the new regulation the responsibility has been extended to the whole lifecycle of the product: in the TGD's definition of the risk assessment procedure all likely use-scenarios must undergo a risk assessment. In this sense, the RA and the LCA approaches have opposite perspectives; from one substance to multiple uses and from one (or more if comparative) functional unit, back to multiple substances and processes, and forward to disposal (see also Christensen & Olsen 2004; Flemström, Carlson, & Erixon 2004).



LCA may come to play a role in the alternatives assessment that often is referred to as the assessment of substitution possibilities. In any way should REACH make it easier to perform LCA's. Firstly, the number of substances on market should go down as producers decide to phase out where easy substitutes exist, and as downstream users decide not to use substances that will require extended precautions. Secondly, the number of evaluated substances should go up as a consequence of the no-data-no-market principle

A number of methods have been suggested for assessing and developing better alternatives. Interesting, the requirement for establishing substitution assessments has a lot of similarities with requirements for replacing or supplementing risk assessment with alternatives assessment.

Conclusions

To achieve higher level innovations it is important to involve and activate all the capabilities and interests that are involved in the full cradle to gate chain of production. This is shown through examples of innovations that this is thinkable only from certain points in the production-chain, and which is only thinkable with what has been termed broad types of functional units within research into LCA. Furthermore it is important to stress the importance of choice of method and boundary conditions. We are talking about a combined stakeholder and lifecycle approach. This approach connects to the terminology of user-driven innovation.

Static assessments of impacts underestimate ability to innovate by stressing the rate of innovations over the direction of innovations.

REACH will enforce information requirements in the product-chain; whereby key parameters such as CMR, PBT & vPvB will give direction of innovation, as will the candidate list.

REACH will probably tend to enforce focus on lower level innovation; more radical innovations at function and system level will require creative and broad discussions; LCA's with broadly defined functional units constitutes a possible path.

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