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Contents

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Letter from the Editor

Lessons learned or business as usual?

Chemical and pharmaceutical companies are breathing a sigh of relief as the great crisis seems to be over. Customer industries, like automobile or construction, are sending slight signs of revitalization. Although recovery will be a long and slow process, more and more experts are looking optimistically into the future. But what will come after the crisis? Did our world change? The Obama Administration is criticizing Wall Street bankers as they are torpedoing reforms and paying large bonuses again. Speculators boost resource prices again by gambling at the stock markets. So, business as usual? Regardless of whether these developments will continue or not, the global megatrends will remain. Moreover, governments might exert more influence in the future. This issue of the Journal of Business Chemistry deals with some of these aspects, like sustainability or the impact of regulatory frameworks.

In their commentary "Mergers & Acquisitions (M&A) in the pharmaceutical industry: The wheel keeps on turning", Matthias Hornke and Sven Mandewirth give an update on Matthias Hornke's commentary of January 2009, also published in the Journal of Business Chemistry. They compare the evaluation made in 2009 with the actual events coming to the conclusion that most parts of the forecast held true. In contrast to low M&A activities in general, transactions in the pharmaceutical industry were quite high. In this light, the authors also give an outlook on M&A activities in 2010.

Elina Kähkönen, Teemu Hirvonen and Katrina Nordström present new insights on the development of active substances in the field of biocides. In their article "New biocide active substances: needs and challenges in the EU as viewed by industry" they interview industry representatives in order to identify some of the present drivers and challenges of new active substances development in the different biocide application areas. Additionally, the authors discuss the impact of EU regulations, especially of the Biocidal Product Directive.

The first contribution to our Practitioner's Section also discusses EU regulations, namely REACH. In their article "REACH implementation costs in the Belgian food industry: a semi-qualitative study", Genserik Reniers, Hanne Geelen, Emilie Goris and Amaryllis Audenaert evaluate the costs of the Belgian food industry induced by the REACH regulatory framework. The authors find no indication of REACH compliance significantly hampering the competitive position of Belgian food industry.

A second practitioner contribution is connected to Matthias Hornke's commentary dealing with the pharmaceutical industry. In their study, Gunter Festel, Alexander Schicker and Roman Boutellier combine industry interviews and desk research to shed more light on the outsourcing behavior of incumbents and emerging companies in that industry. Their article "Performance improvement in pharmaceutical R&D through new outsourcing models" presents a completely different behavior of the two company types.

The last article of this issue "Sustainability in the chemical and pharmaceutical industry - results of a benchmark analysis" presents a study on sustainability activities and commitment of large German and international firms. Jürgen Peukert and Karin Sahr discuss specific fields of strengths and weaknesses in the chemical and pharmaceutical industry as far as sustainability is concerned. Additionally, they identify three different groups of companies referring to their implementation of a sustainability approach.

Now, please enjoy reading the second issue of the seventh volume of the JoBC. We would like to thank all authors and reviewers who have contributed to this new issue. If you have any comments or suggestions, please do not hesitate to send us an email at contact@businesschemistry.org.

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Journal of Business Chemistry

Commentary

Mergers & acquisitions (M&A) in the pharmaceutical industry: the wheel keeps on turning

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A prediction was made here in January 2009, that the market for company mergers and acquisitions in the pharmaceutical industry would continue to reach a high level in 2009, even after the announced cases of large M&As (e.g. Novartis/Alcon, Roche/Genentech, Teva/Barr Pharma) in 2008. This forecast was attempted even though it was clear that the so-called 6th M&A wave was drawing to a close after encountering increasing problems in raising outside capital, especially after the collapse of Lehman Brothers in September 2008. And indeed, when considered as a whole, the M&A year 2009 – and the first months of 2010 are not showing any considerable improvement – was a weak M&A year: the global M&A transaction volume fell from approx. US$ 4.200 bn in 2007 (2006: approx. US$ 3.400 bn) to a mere US$ 2.500 bn in 2008, to then only accumulate a volume of approx US$ 1.300 bn in 2009. This decline is even more distinctive at a European level and thus shows that US and Asian companies are increasingly setting the tone for M&A transactions. Furthermore, the global share of financial investors in purchase volume took a plunge from 26% in 2006 to 8% in 2009. Companies - so-called strategic investors - must therefore stem the remaining low M&A volume on their own.

Pharmaceutical M&A remain at a high level in 2009

In retrospect, the prognosis for a strong M&A year 2009 for pharmaceuticals was quite accurate: In January 2009, Pfizer announced they would be taking over their competitor Wyeth for US$ 68 bn. Shortly after, Merck & Co. followed suit with their report on the acquisition of Schering-Plough for US$ 41 bn. Other examples of further large-scale M&A cases in the pharmaceutical sector were the takeover of the Czech generics manufacturer Zentiva by Sanofi-Aventis (approx. US$ 2 bn), the acquisition of the US skin-care specialist Stiefel Laboratories by GlaxoSmithKline (approx. US$ 2.9 bn), the complete takeover of the joint venture Merial (animal health) by Sanofi-Aventis from Merck & Co. (approx. US$ 4 bn) and the takeover of the pharmaceutical sector of Solvay by the Belgian company Abbott Laboratories (approx. € 4.5 bn).

In March 2010, both the announced US$ 5.3 bn takeover of Millipore by the German Darmstadt-based company Merck and the takeover of Ratiopharm by Teva (approx. € 3.6 bn) show that the M&A market wheels are still running smoothly in the pharmaceutical industry. The M&A community is increasingly seeing cases such as Merck/Millipore as an indicator or guiding light for a general re-ignition of the M&A market. What is causing this exceptional situation in the pharmaceutical M&A market and what are the probable developments for 2010 and 2011? Why does the generics business appear to raise interest again even though major pharmaceutical companies had a tendency to part with it in the last decade?

Global weak economic phase promotes consolidation

Generally, it can be said that the worldwide financial crisis is not only influencing the amount of drugs being sold but is also increasingly pressurizing the pharmaceutical industry's pricing. The demographic development of economically advanced nations is leading to a steady increase of health costs - with simultaneous national budget deficits. Pressure is therefore mounting to minimize the costs of the health system by means of regulatory measures. In addition, the drug pipelines are quite low and many blockbuster drugs with bn. US$ turnovers will soon be disappearing as a source of revenue for the pharmaceutical giants.

Generic drug manufacturers such as Teva, Mylan or STADA are growing and are also in the middle of a consolidation process (e.g. Merck Generics being acquired by Mylan in 2007, takeover of Ratiopharm by Teva). Pressure is building up immensely for the group of research-based pharmaceutical companies who were pampered by success so far. They rapidly have to increase their efficiency by tapping into synergies in e.g. R&D, procurement or administration.

Generic drug manufacturers are becoming more attractive

When on their shopping spree, research-based pharmaceutical companies no longer shy away from taking over generic drug manufacturers and thus acquiring a „turnover base line" – even if the margin is not enormous – which they use as a value argument when presenting to their shareholders. One example is the huge interest Pfizer showed in taking over Ratiopharm: the patent protection for several Pfizer drugs will be expiring in the coming years and Ratiopharm would have been a good opportunity to generate further efficient growth. Shortly after the takeover of Wyeth, Pfizer followed high increase in efficiency objectives by closing down sites, for example. It remains to be seen if high takeover prices can be justified, such as the US$ 41 bn paid by Merck & Co. for Schering-Plough and the thus acquired drug pipeline. It is currently hard to predict the transaction value of the approx. 20 phase III drugs that Merck & Co. acquired with the deal.

Biotech as a major driver of pharmaceutical consolidation

Apart from the drivers „Synergy by economies of scale" and „Purchase of drug pipelines", there are increasing signs that pharmaceutical companies are placing their bets on producing biological blockbusters alongside small molecules. Next to the general risk reduction coming along with a product portfolio diversification biotech investments contain a "copy protection" which results from high financial and know-how requirements to copy biotech products. Biotech as a driver for M&A or the intensification of cooperations was probably the motivation driver for the following M&A deals: MedImmune/AstraZeneca (in 2007 for approx. US$ 15 bn), Merck/Serono (in 2006 for about € 10.1 bn), Merck/Millipore (in 2010 for approx. € 5.4 bn) or Astellas Pharma/OSI Pharmaceuticals (offering US$ 3.5 bn in 2010). Takeovers of especially small biotech companies are simplified by the high financial need for product development or market entry. Since these required loans are not available through banks or financial investors, it offers a perfect investment opportunity for large financially sound pharmaceutical players.

Justifying high acquisition prices by efficiency improvement in difficult markets

In conclusion, not only increasing efficiency pressure but also dried-out pipelines will increase the consolidation pressure on the pharmaceutical sector in the near future. In addition, biotech will „mature" and by doing so, will become an integral part of larger pharmaceutical companies. It will become important for the success of pharmaceutical M&A cases to justify the often high acquisition prices with future turnover in partially difficult markets or through cost savings. This is where it calls for the merging partners to implement a high quality post merger integration and in doing so to sufficiently take into consideration the particularities of national clients and also the cultural differences of the own workforce.

Journal of Business Chemistry

Research Paper

New biocide active substances: needs and challenges in the EU as viewed by industry

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Emerging regulatory initiatives in the EU are driving towards more environmentally safe chemicals, used as such or in a wide range of products and applications. The aim of the regulations is also to foster and support the emergence of new or safer alternatives and to drive innovations thereof. Biocides are chemicals, which are used in a vast and steadily growing number of applications in order to preserve product safety and quality, however, the number of the Active Substances (AS) used in biocides is decreasing in the EU concurrent with the implementation of the Biocidal Product Directive (BPD). Accordingly, the present study attempts to elucidate views of representatives of the biocide industry in order to identify some of the present drivers and challenges of new AS development in the different biocide application areas, with emphasis on the economic feasibility of safer biocide development in the future. Notably, the costs of vertebrate testing are a major factor in development of new AS. Therefore, an evaluation of the costs of such tests and their total proportion of total AS development costs is also discussed. Industry expectations for the implementation of the BPD and impacts thereof are presented.

Biocidal products are Active Substances (AS) and preparations containing one or more AS, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means (EC, 1998). Biocides are used in a vast and steadily growing number of applications from foodstuffs to paints and marine construction (e.g. Waterman et al., 2005; Raczek, 2005). However, despite the growing number of applications the number of available biocide chemistries i.e. Active Substances (AS) is decreasing in the European Union (EU) concurrent with the implementation of the Biocidal Product Directive (BPD) 98/8/EC (EC, 1998; EC, 2003). Moreover, other restrictions due to the acknowledged toxicity and/or eco-toxicity of AS such as Tri Butyl Tin (TBT) in antifouling products or Copper Chromium Arsenic (CCA) for wood preservation have created voids on the biocide market (Bruns et al., 2005). Currently, safer replacements for the out-phased AS are screened for from the existing selection of AS or from the use and development of alternative non-biocidal approaches. Thus, on one hand demands for eco-efficiency may render product raw materials more susceptible to biodeterioration, whereas on the other hand, there is increased concern of development of resistance of target organisms to the existing selection of AS (Maillard, 2002). Accordingly, current trends pose significant challenges to the development of new AS, where profitability and costs due to EU regulation is also a major issue (Bruns et al., 2005).

Current EU regulatory initiatives aim at driving the chemical industry towards more environmentally friendly, sustainable and safe products and processes as well to concurrently foster innovations within the EU markets (EC,

2006; EC, 1998). The role of regulations as drivers of innovations in the chemical industry is evident (Frohwein and Hansjürgens, 2005), and e.g. initiatives such as the Montreal protocol have boosted the development of more environmentally safe product alternatives (Bonnet and Lacroix, 2006). Moreover, the presently implemented EU directive 2004/42/ EC on paints, sets ambitious targets for striving towards the development of low Volatile Organic Compound (VOC) paints (Mast et al., 2008). On the other hand, in many areas of innovative technologies, regulatory initiatives lag behind technology development (Nieminen et al., 2004). This may lead into situations in which the prevailing technologies are out phased due to regulatory risk reduction although safer replacements are not yet available, e.g. decades after the ban on DDT, no successful replacement for all usages is available to date (Coleman et al., 2008). Such may also be the case with formaldehyde and its derivatives, which are widely used biocides with excellent efficacy properties (Power, 1997), but with risk classification as toxic, potential carcinogen and irritant (EC-JRC, 2009). Hence, it remains to be seen whether they will remain as AS of biocides in the EU market as the implementation of the BPD is completed. Overall, the views and response of the industry to emerging regulations is difficult to anticipate when evaluating the possible benefits be gained by a new regulatory instrument (Pearce and Koundouri, 2004). This is clearly a critical issue as development of safer chemistries and substitution with less hazardous alternatives is an industry decision and choice.

The biocide industry, i.e. suppliers of biocides and biocide AS, has stated that the development of new AS is not economically feasible, due to the regulatory demands which pose strict requirements for product safety and efficacy testing (Lindner, 2005; Bruns et al., 2005). Accordingly, the aim of the present paper is to elucidate the most significant obstacles and possibilities for product development of new AS by clarifying whether the industry views AS development as technically feasible, what kinds of AS's are needed and, more specifically, what are the drivers for new AS development as seen by the industry? Moreover, the study evaluated whether regulatory issues have prevented the development of the desired AS's and more specifically, can define demands of the BPD be identified as obstacles of the development? Furthermore, the cost structure of possible new AS product development was evaluated, for which no previous published data is available. The present study also strives to identify the approximate magnitude of costs that may be viewed as intolerable for new AS development within the EU in accordance with previous statements by the industry (Bruns, 2005), and to present an estimate of the cost level which could be tolerable to the industry.

Theoretical Background

Chemical regulations e.g. REACH aim at reducing the environmental and health risks associated with, or due to, chemicals. Benefits of regulatory actions are primarily aimed at reducing health expenditures caused by chemical exposure (EC, 2006; Pearce and Koundouri, 2004). On the other hand, we argue that, in the case of biocides, reduction of risk of the chemical substance is tied to increasing in risk of product spoilage or biodeterioration by unwanted organisms. Clearly, such results will constitute a financial risk for the industry but may also cause health risk to industry workers or consumers (Ludensky, 2005; Scholtyssek, 2005). These factors emphasize the complex repercussions of reduction of chemical risks. Moreover, the BPD also states "[...] when properly used for the purpose intended, they are sufficiently effective and have no unacceptable effect [...] such as resistance development [...] no unacceptable effect on the environment and, [...] health."(EC, 1998). Hence, reduction of the chemical risks of biocides may not be acceptable if it results in reduced efficacy towards unwanted organisms.

Consequently, the risks of; 1) over regulation of a substance with minor hazards or 2) under regulation of a notably hazardous substance (Koch and Ashford, 2006) is clearly a very relevant issue with reference to biocide regulation and risk management. Accordingly, we also present that the hazard of a biocide must be evaluated with reference to the balance sought between acceptable of tolerable chemical vs. biological risk. Undoubtedly, the industry will need to approach such an evaluation based on economic sustainability. Moreover, development of resistance of the target organisms is a specific risk which is only associated with the biocidal chemical. Notably, as the target organisms are continuously exposed to the same of similar chemicals at a steady concentration, i.e. chemical risk is constant, the risk of development of resistance to the chemical will increase (Maillard, 2002).

Avoiding or mitigating such an increased risk of resistance development could, however, be avoided by development of new AS. The new AS may even be equivalent to chemical risk of current AS, but would offer an alternative for reducing the biological risk. It is therefore within this context that we will approach the question of enhancing innovation and new product development and current stagnated new AS development. Our theoretical framework therefore supports the arguments of Frohwein and Hansjürgens (Frohwein and Hansjürgens, 2005), who demonstrated that the Porter hypothesis for regulation as a driver of innovation and new product development may not be directly apply to the chemical industry.

Methods and Approach

The data was gathered by interviewing 14 representatives of the International Biodeterioration Research Group (IBRG) in 2008. The IBRG is an organization founded under the Organisation of Economic Co-operation and Development (OECD), in 1968 (IBRG, 2009). Its members are representatives of industrial users of biocides, biocide manufacturers, testing laboratories from both the private and government sector and academic institutions. A total of ten IBRG experts participated in an oral interview, of which 2 gave answers jointly, giving a total of 9 complete interviews. These ten experts represented companies with a market share of over 50 % of the global biocide market (Anon, 2008a). Moreover a questionnaire was filled in by 4 other IBRG members. These replies to questionnaires were obtained from a global biocide company (1), a small/medium sized European biocide company (1), a European microbiological service provider (1), and a European research institute (1). All interviewees described their roles in the organization by defining how much their work is related to microbiological testing, biocide development, EHS/ biocide regulations and customer support (figure 1.)

The nine biocide supplier interviews were composed of (i) direct questions, (ii) statements and semi-quantitative questions and (iii) a table to fill in during the interview. For analysis of data, the answers to direct questions (n=6) (oral and written) were expressed as numbers of similar answers/total number of answers. With reference to statements such as e.g. "Implementation of BPD will lead to the following", interviewees were instructed to reply whether they agreed or disagreed by choosing from the following: 0 = not at all; 1 = to minor extent; 2 = to some extent; 3 = completely. Seven statements were presented, of which 3 focused on comparing biocide applications in antifouling, treated wood, process waters, masonry coatings, cosmetics, plant protecting agents, foodstuffs and disinfection (and other areas, if needed). It is evident that some of these application areas are not within the scope of the BPD, i.e. cosmetics, foodstuffs and plant protecting products (EC, 1998). These areas are under different regulations, however, analysis of such regulations were beyond the scope of this paper. Consequently, these areas of application were only included from the point of view of the possibility that a concerted effort towards new AS in these application areas could have significance as a driver for the development of a new AS also in applications within the scope of the BPD.

The results were summarized as a) the number of replies for naming each application and b) the value given (0-2). Answers on applications were expressed as a number of replies / total number of answers in all the applications. Finally, the interviewees were also requested to fill in a table of the development costs of a new AS's and of new biocidal product development. The estimates were given either as direct cost (€ or $) or as proportion of the total cost (%). Cost evaluation for vertebrate testing in accordance with BPD was calculated independently from the interviews. The calculations are based on data obtained from an international testing services company (Anon, 2008b). The lowest cost alternatives for the tests were used for different means of administration (dietary, gavage, dermal). Moreover, the price for one exposure concentration (instead of 3 concentrations) was used for acute inhalation toxicity. Cost of preliminary tests as well as costs of tests for finding the preliminary dose range were omitted form the calculations as they are not included in direct test requirements (EC, 1998). Costs for mutagenicity studies were also not included assuming that prior studies in vitro give adequate result. Costs were converted to Euros (1 GBP = 1.253 €, 24.10.2008).

Limitations of the Study

The structure and the approach of the present study set certain limitations. First, the number of interviewees is limited and can not

be stated to represent the whole biocide supplier industry. On the other hand, the data collected represents views of major actors of the EU biocide markets and the individuals interviewed had an average of at least 20 years experience in the field in many areas of experience and responsibility (figure 1).

Therefore, the data presented in this study may be viewed as an indication of leading industry perspective with relevance to current and future trends in the EU. Moreover, as these trends are not the topic of scientific publications in general, very little previous data is available for such an industry perspective. Second, an estimation of the economic feasibility of new AS development does not take into account potential revenues. This decision was made, as the aim was to focus specifically on the structure of the development costs and on the share of the costs related to the regulatory requirements, which have been identified as a major obstacle for new AS development (Bruns, 2005). Moreover, we have addressed the issue of development of new AS profitability (EU) in a previous study (Soirinsuo, 2009). Thus, taking the above limitations into account, the present study offers an industry based perspective on the drivers, challenges and trends of development of new AS in the framework of EU regulations, with specific reference to the implementation of the BPD.

Results and Discussion

Drivers of New AS Development

Fulfilling the technical requirements on new biocide AS is a challenge as they should be harmful to living organisms, but at the same time, be safe for humans and the environment (EC, 1998). However, regardless of this dilemma, all the interviewees agreed either mostly (7/13) or fully (6/13) that it is technically possible to develop new and better AS's. Regulatory costs were the most notable arguments against new AS development (4/13).

With regard to the need for new AS's for different applications, the majority stated that there is a need for new AS development (table 1). Only a small proportion answers indicated "no need" (5/92) and the majority indicated some need (45/92) or a clear need (42/92). Moreover, the majority saw a clear need for new AS development in antifouling products (9/12) and in plant protecting agents (8/10). The interviewees were also asked to describe the kinds of specifications that new development should strive for. Based on the answers it became evident that improved safety (without loosing efficacy) is clearly the most important driver for development of new AS's (11/24). Improvement of efficacy, avoiding the emergence of resistant strains, and widening of the available biocide selection was of equal importance respectively (3/24). A few interviewees also stated that price performance and consumer acceptance are of importance (2 /24 for

Figure 1 Level of expertise and areas of responsibility as indicated by interviewees

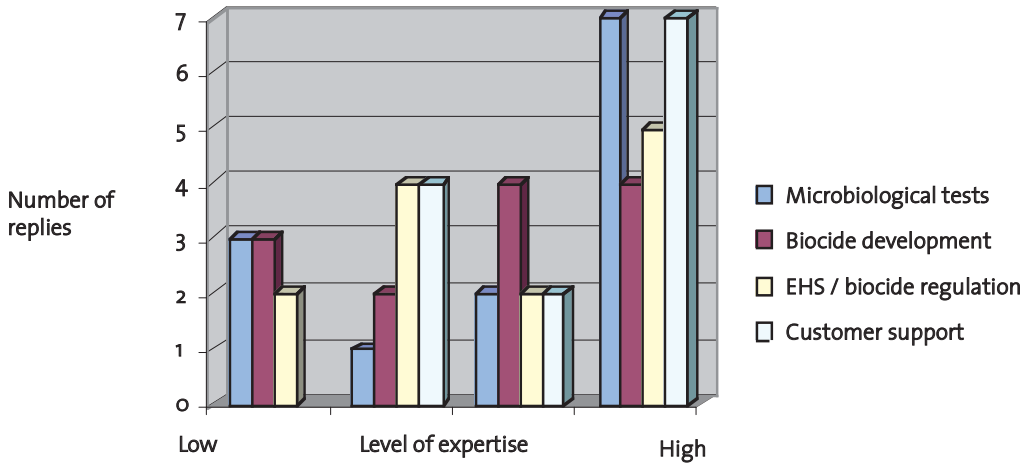

Table 1 Need for a new AI development in different applications

Application	0	1	2	Total	Examples of the developement specifications (number of replies)
Antifouling		3	9	12	Safer than TBT (1) / Cu (1)
Treated wood		7	6	13	Replacement for CCA (1) Safer than DCOIT[a], Cu (1)
Process waters	2	8	2	12	Safer than CIT/MIT[b], phenolics (1)
Masonry coatings		6	5	11	Safer than diuron, terbutyryn (1) Alternatives for algicides / in high pH coatings (2)
Cosmetics	2	6	4	12	Safer than parabens, CIT/MIT, FD[c] (1) More efficient than parabens (1) Approved by consumer (2) Alternatives in creams (1)
Agents		2	8	10	Safer than glutaraldehyde, FD (1)
Foodstuffs		6	4	10	More efficient than benzoic acid, sorbic acid (1)
Disinfection	1	7	4	12	More efficient than QUAT[d] (1) Efficacy against resistant strains (1)
Total	5	45	42	92	Specifications in general: More efficient (1) Price performance (1) / in organic fungicides (1) Improved safety (2) / compared to IT[e] (1) Avoiding resistant strains (2) Multifunctional (1)

0 = no need, 1 = some need, 2 = clear need

each). Accordingly, based on the above data, it is evident that development of a new, safer biocide is considered important and also technically feasible. Non-chemical means for control of biodeterioration were not perceived as viable alternatives nor as significant competitors for traditional AS based chemical biocides.

Regulatory demands and BPD: Present challenges

The EU biocide industry is inherently tied to the BPD. A central goal for the BPD is simplification of the national biocide regulations in the EU, none of which covers all the biocide application included in BPD (OECD, 1999; EC, 1998). Other aims include the harmonization of biocide regulations in the EU, enabling free circulation of biocidal products, minimizing vertebrate testing and minimizing the Environment, Health and Safety (EHS) risks of biocide usage (EC, 1998). It is therefore evident that the present status and future expectations related to BPD implementation and impacts thereof play a pivotal role in new AS development. Accordingly, the present study focused on elucidating expectations of the industry as to how well such aims will be accomplished via the implementation of the BPD (table 2).

The minority of interviewees were of the opinion that implementation of the BPD would lead to simplification of biocide regulation (5/13) and only a few regarded harmonization as being completely achievable (4/11) or to take place at least to some extent (5/11). All the interviewees expected that the free circulation of biocidal products would be enhanced at least to some extent after the implementation of

a) DCOIT = 4,5-Dichloro-2-n-octyl-isothiazolin-3-one.
b) CIT/MIT = Chloro-2-methyl-4-isothiazolin-3-oni / 2-methyyli-4-isotiazol-3-oni.
c) FD = Formaldehyde Donor.
d) QUAT = QUATernary ammonium compounds.
e) IT = Iso Thiazolone.

Table 2 Outcomes of the BPD implementation

Outcome	0	1	2	3	Total	Comments
Simplification of biocide regulations in the EU	3	5	4	1	13	
Harmonization of biocide regulations in the EU	1	1	5	4	11	Harmonization not complete because member states are sticking to national interpretations (2)
Free circulation of the biocides in the EU	0	4	3	4	11	
Minimizing the number of animal tests	3	1	3	5	13	Minimization due to data sharing (2) Minimization only after the implementation process (2)
Minimizing the EHS risks of biocide use	1	6	5	1	13	Risk reduction due to out phasing of some hazardous substances (3)
Total	8	17	20	15	61	

0 = not at all, 1 = to minor extent, 2= to some extent, 3 = completely
Comments were given without further questions

BPD. Only some of the interviewees believed that the BPD would lead to a slight reduction in the number of animal tests (3/13), whereas a more significant reduction was predicted by others (5/11) "No reduction at all" replies (3/13) may reflect views on the situation during the ongoing implementation of the BPD, whereas other interviewees may have referred more to the expectations after the implementation. Two interviewees stated that number of the animal tests will reduce only after the review process. Half of the general comments on BPD described the BPD as "complicated" or by similar terms (6/12). It was also emphasized that in-house expertise (3/12) and advice from the authorities (5/12) will be imperative for successful management of BPD implementation at company level. On the other hand, a few stated that communication with the authorities is often not successful (2/12) and one interviewee concluded that currently also the authorities are part of the learning process. It is to be expected that as both authorities and industry proceed in this learning process during the implementation of the BPD, understanding of the regulation will improve, and the perceived complexity of regulation may decrease.

Impact of the BPD Implementation on Available AS on the Market

Impact of the implementation of the BPD on the AS selection on the market was evaluated by asking interviewees to name important or interesting AS that are likely to be removed from the EU market due to the implementation of the BPD. Many of the replies to this question (4/7) identified formaldehyde and/or formaldehyde donors (FD). These chemistries are used in numerous applications such as in-can preservation of different products such as polymer dispersions and paints as well as in process fluid preservation e.g. in the pulp and paper industry. "Safer than FD" was also given as one specification for new AS development (table 1). No other out-phased AS chemistries were named as important or interesting by more than one respondent.

Cost Structure of AS and Biocidal Product Development

The cost of implementation of regulatory demands has been named as one of the main reasons for stagnant development of new AS (Bruns et al. 2005). Therefore, the aim of this part of the interview was to arrive at a numeric value for what is considered an intolerable cost level for new AS development and what kind of cost estimates would be tolerable. It is

to be noted that unlike new AS, new biocidal products are being developed and thus it may be argued that the costs of biocides development are tolerable. The cost structure of the development of a new AS was based on an analysis of data from the oral interviews and the 7 tabular cost estimations given by respondents (table 3). Four of the estimates were given by interviewees as costs (€/$) and three as proportions (%). It is evident (table 3) that the difference between the tolerable cost structure of biocidal products and the intolerable AS development costs is vast (table 3). Interviewees estimated the total cost of a new AS development and a new biocide as being in the range of M€ 2.7- 3.8 (3/4) and M€ 0,1 and 0,6 respectively (4/4). In both cases, the majority of interviewees allocated the main share of the costs to regulatory requirements such as EHS risk evaluation, dossier composition and the registration fee 7/7 for AS and 4/7 for biocidal product development). For new AS development the majority (3/4) estimated the cost as being between M€ 2.2 and 3.5 for EHS risk evaluation including the dossier composition. This falls in the same range as the earlier results obtained by Gartiser et al. (Gartiser et al. 2007). The one exception of the interviewees estimated the cost as being even higher. During the present study, independent of the interviews, we calculated that vertebrate testing would be in the range of M€ 2.4 (Anon, 2008b), for AS testing to fulfill requirements of the BPD. Clearly, these regulatory demands become a major cost factor. Interviewees estimated the costs related to EHS risk evaluation and dossier composition of new biocidal product development as either € 50,000 (2/4) or € 300,000 (2/4). These regulatory issues are also inherently tied to vertebrate testing, with a cost estimate of € 40,000. It may thus be concluded that as the main costs of new AS development are directly linked to EHS risk evaluation testing, a critical challenge is how to redu-

Table 3 Cost structure of the development

Action	Proportion (cost when available)							
Active substance	**% (1000 €)**							**Average**
Development	20 (600)	3 (72)	10 (2,000)	1 (50)	5	15	25	11
EHS risk evaluation	70 (2,100)	82 (2,160)	75 (15,000)	93 (3,500)	50	60	25	83
Dossier composition	5 (150)	1 (36)	<5 (1,000)		20		25	
Registration fee in the EU	5 (150)	<1[a] (7)	<5 (1,000)	5 [b] (200)	10		25	
Other (manufacture)		13 (360)						6
Other (not specified)					5			
Other (customer work and method development)						25		
Total cost for AI (1,000 €)	**3,000**	**2,635[c]**	**20,000**	**3,750**	**-**	**-**	**-**	**3,150[d]**
Biocidic product	**% (1000 €)**							**Average**
Development	25 (150)	15 (72)	10 (50)	8 (9)	20	50	50	25
EHS risk evaluation tests according to regulations	25 (150)	8 (36)	50 (250)	48[e] (55)	30	50	50	60
Dossier composition	25 (150)	2 (7)	10 (50)		40			
Regestration fee in the EU	25 (150)	n. a.	<5 (<25)	43 (50)	10			
Other (manufacture)		76 (360)						14
Other (marketing)			25 (125)					
Total cost for biocidial product (1000 €)	**600**	**475**	**500**	**115**	**-**	**-**	**-**	**422**

a) The registration fee in the US.
b) The original data was given as 82 - 320,000 €, of which average is presented.
c) The original values were given USD and converted into Euros (1 USD = 0.72 €).
d) The clearly differing value (20 M€) was left out of the average calculation.
e) The original data was given as 50 - 60,000 €, of which the average is presented.

ce these costs without the subsequent increase of the EHS risks which the evaluation specifically strives to control.

Avoiding Possible Stagnation of AS Development

The interviewees stated that simplification of the regulation is almost as important as cost reduction in enabling new AS development. Harmonization of different regulations or extended permanence of the chemical risk classification (R-phrases, warning labels), were not considered as important. Other regulatory issues that interviewees also stated as supporting interest in new AS development were improved Intellectual Property Rights (IPR) protection (1) and reduction in data requirements in accordance with reduced volumes as implemented under REACH (Regulation (EC)) No 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals) (1).

In order to shed light on the more concrete direction on the kinds of regulatory changes that the industry is calling for, the interviewees were asked to name an example of a satisfactory registration procedure of biocides or other chemicals, which also provides adequate safety and environmental information. Interviewees responded by naming the U.S. Environmental Protection Agency (EPA) biocide registration as a sole positive example of such procedures (5/8) as it is considered as being better understood and communicated by both the authorities and the industry (3/8). The other positive aspects of the EPA biocides procedure were better protection of Intellectual Property Rights (IPR) and being based on risk assessment instead of the precautionary principle. This principle comprises a model of anticipatory to protect humans and the environment against uncertain risks of human action (UNESCO, 2005). One comment summarized the EPA procedure as being "more straightforward" as it has been in operation for a longer period of time and thus is better comprehended. Of the respondents who mentioned EPA as the positive example, 3/5 were US-based and the rest (2/5) were based in Europe. Nevertheless, the stagnation of new AS development is also a concern in the US even though the regulatory process may be considered more acceptable.

As the simplification of the regulation was

Table 4 Changes in the regulatory network necessary for facilitating development of new AI and the importance of the basic research for promoting such development

		0	1	2	3	Total
Changes in regulatory network	Simplified market entry with the new biocidic products	0	0	4	9	13
	Cheaper process for market entry	0	0	3	10	13
	Harmonization of the requirements between the different directives on biocides (plant protecting agents, cosmetics, foodstuffs, BPD)	1	1	6	5	13
	Extended permanence of a chemical risk classification	3	3	4	2	12
	Other changes proposed (number of comments): Reduced test requirement along with reduced volumes (1) Improved IPR protection (1)					
Basic research area	Determination of biocide efficacy		1	2	10	13
	Determining biological activity and mechanisms of the biocides		2	7	4	13
	Determination of biocide toxicity and ecotoxicity	1		2	10	13
	Determination of microbial succession in biodeterioration and biodegradation	2	3	4	3	12
	Other areas considered important (number of comments): Exposure scenarios (1) Cost efficiency (2) Biocide & non-biocide combinations to reduce contamination (1)					

0 = not important at all, 1 = very little importance, 2 = quite important, 3 = very important

considered a priority for new AS development, the BPD's objective to simplify EU biocide regulation is well in line with such demands. Presently, however, this has not been accomplished, as the industry considers the BPD complicated. Moreover, the expected future simplification, via learning by experience as the implementation proceeds, may be seriously hindered by adhering to national interpretations (table 2).

Cost Reduction – Minimizing Toxicity Tests

Reduction of costs was ranked as the most important factor for promoting development of new AS (table 4) where cost reduction is directly influenced by requirements for toxicity testing (table 3). Consequently, basic research in toxicity should be considered equally as important as biocide efficacy itself, which is the most essential and inherent property of biocides. Notably, in the present study, only one interview indicated "no importance at all" for toxicity and eco toxicity research. At the same time this particular respondent ranked exposure scenario research as important, which supports the view on the importance of chemical risks assessment as such.

The clear majority of the interviewees expected a reduction of animal tests to take place after the implementation of the BPD (table 2). Surprisingly perhaps, only one reply suggested similar tonnage trigger structure permitting reduced data requirement with reference to smaller volume as stipulated by REACH (EC, 2006). In conclusion, more targeted toxicity testing research and transparent data on such testing is an important driver for new AS development.

Conclusions

The ultimate goal for new AS development is a "safer than" chemistry of that of an existing AS. The present study indicates that biocide suppliers view the development of such new AS as technologically feasible and there is a definite need for new AS development in many application areas. However, to enable such development simplification of biocide regulation and tolerable development costs are essential. Although simplification of the placement of biocidal products on the EU market is also an important aim of the BPD, industry representatives interviewed in this study were doubtful on accomplishing such a goal. Simplicity of a regulation involves also fluency of communication between the authorities and the industry as exemplified by the functioning of the EPA procedures, with emphasis on direct communication between the parties. In the EU, however, such communication and interaction poses a challenge, as a vast number of national authorities of 27 Members States, are trying to harmonize their work and agree on a common agenda for the interpretation of the regulations (Gartiser, 2007). Consequently, national authorities are largely responsible for the implementation of the regulations and thus play a dominant role in the subsequent communication between all players in the field. According to the present study, it appears that the authorities are considered to be in a learning stage with BPD practices and thus their support for the industry may not be adequate at this time. It remains to be seen what impacts the recent simplification of the registration and centralization of part of the process under the European CHemical Agency (ECHA) will have in the future (COM, 2009).

The costs of toxicity testing on vertebrates according to regulatory requirements were named as the most demanding requirements of new biocides development and basic research in this area was called for. The present study arrived at a cost estimate of 2,400 000 € for vertebrate tests, which represents a major share of the approximately 3,000,000 € of the total cost of development. Although these estimates are only approximations, it is evident that such cost structure together with the ethical considerations gives strong support for the goals of minimizing of vertebrate testing as stipulated by both the BPD and REACH. However a dilemma still exists as, on one hand, both the BPD and REACH consider these tests as the best and most reliable method for evaluating toxicity and eco toxicity, and few alternatives to such testing are currently available. On the other hand, the test requirements for the highest tonnage substances in REACH are reduced compared to the requirements for AS in the BPD. For example REACH defines the chronic toxicity studies on one species as being adequate, while the BPD requires testing in a rodent and a non-rodent species (EC, 1998 and EC, 2006). A step forward has, however, been taken as both BPD and REACH strongly guide data sharing of vertebrate tests in order to avoid multiple testing. According to the interviewees in the present study, such guidance via the BPD were also expected to result in concrete actions of mini-

mizing animal tests. In the case of REACH, the implementation of the obligatory data sharing is verified by centralized control by the European Chemicals Agency (ECHA) of the substances registered. Other data holders than industry may also share the relevant data after the preregistration. Moreover, the possibilities of using alternative test methods or omitting test usage are emphasized in the case of REACH as the Annex XI addresses on the alternatives such as read across of similar substances, Quantitative or Qualitative Structure-Activity Relationship ((Q)SAR) and in vitro testing and recommends their use wherever applicable. Furthermore, complete omission of testing is also acceptable in cases where prior data on human exposure results is available, or the likelihood of only limited exposure can be demonstrated. In the case of BPD similar listing is found in a Technical Guidance Document (ECB, 2000). Finally, in REACH, the reduction of the test requirements accompanied by reduced market volumes of the substances serves the same objective and is equally important in permitting new, small volume chemicals to be brought onto the EU market (EC, 2006).

In conclusion, concise and economically feasible chemical regulation without increasing EHS risks with reference to use of chemicals may not necessarily be a "Mission Impossible", even though by first glance it certainly appears to be. Active communication between the authorities and industry is a powerful tool for simplifying emerging regulations and their implementation. Decreasing the cost effects of the regulatory demands is a major hurdle, as it calls for development of methods for replacing the most expensive toxicity tests. Thus, research and development of alternative, less expensive test methods is pivotal for the development needs of the chemical industry at large. A number of assumptions have been made in the present study and the trends that we have identified are open for anyone to challenge. As stated also by Pearce and Koundouri (Pearce and Koundouri, 2004) clearly more superior assumptions can be generated, as the methodology, the data and the limitations of the present study have been made transparent. On the other hand, even as the results of the present study carry merely indicative value, our arguments are very much in line with recent views by Hartung (2009) on the need for development of new testing methods. Hartung (2009) calls for concrete actions in the form of substantial funding for academic and non -governmental organization for the development of such new methods. This underlines the global importance of REACH in exploring an arsenal of tools to reduce the number of vertebrate tests and pushing forth alternative test method development. Consequently, REACH has set the stage for development of tools for the biocide industry for enabling economically sustainable development of safer biocides.

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Practitioner's Section

REACH implementation costs in the Belgian food industry: a semi-qualitative study

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In this paper we discuss how companies in the Belgian food industry are affected by the REACH legislation and whether their competitiveness is weakened as a result. The study has been carried out through an extensive literature study, an electronic survey, in-depth interviews and a case-study. No indication is observed of REACH compliance significantly hampering the competitive position of Belgian food industry. The overall cost burden seems to be relatively low. In contrast with the chemical industry, large food companies bear the highest costs, whereas the financial impact on small and medium-sized food companies remains limited.

1. Introduction

REACH concerns European legislation dealing with the Registration, Evaluation and Authorization of CHemical substances in the European Union. The main goal of REACH is an improved protection of human and environmental health within the context of sustainable development and without compromising competitive strengths of businesses subject to the legislation. The underlying principle of REACH is that companies themselves should thoroughly assess the risks of chemical substances they use, process, or store (ECA, 2008).

The regulation applies to chemical substances produced within, imported into or placed on the European market, where they are further used or sold. These substances can be pure chemical substances as such, as well as chemical substances in mixtures, e.g. in paints or inks, as well as materials in articles such as packages. Chemicals excluded from the legislation include medicines, radioactive substances or cosmetics. Chemical substances directly used in food are excluded as well (Watson, 2008).

REACH discerns between companies' roles as regards handling the chemicals: manufacturers, importers and downstream users. According to the role a business takes on, different obligations originate.

Manufacturers and importers have to register their substances when the production or import of these substances surpass the threshold of one tonne annually. Registration is the most important obligation within REACH and might give rise to significant costs for businesses. The registration process includes companies gathering information required to better manage risks with regard to chemical substances and making this information available to the authorities and to other companies. Required information may differ depending on the concerning volume and hazardous properties of the substance. Registration dead-

lines differ depending on the tonnage band of the substance and its hazardous properties. Since the number of existing substances is particularly high (some 30,000 chemicals are envisioned), the registration is divided in phases over a period of eleven years. As the tonnage or the risk of the substance is higher, the deadline for registration will be earlier. New substances will have to be registered immediately when brought onto the market. Besides registration, other important obligations include authorization, notification, classification, labeling, developing Safety Data Sheets, advanced communication, etc.

Downstream users are formulators of preparations, users of chemicals in industrial processes, professional users or producers of articles. They basically buy substances from EU-based suppliers. Such companies are not required to register the substances they use, since these substances have already been registered at a particular point upstream in the supply chain. Downstream users' obligations include amongst others verification of the Chemical Safety Sheets, passing on information throughout the supply chain, authorization and putting in place appropriate risk control measures (ECA, 2008; Koch, 2006).

To summarize, the European REACH legislation brings about a number of obligations. In order to meet with these obligations, companies have to incur expenses. As an example, for gathering the required information demanded by REACH, companies may need to carry out laboratory tests for which the costs may be substantial. Meeting the obligations also requires a considerable amount of administration (and its accompanying costs).

Furthermore, not only the chemicals sector may experience a strong impact of REACH, other sectors that use chemical substances may be financially affected as well. These sectors are referred to as 'downstream sectors'. The food industry is an example of such a sector. Examining the cost impact of REACH implementation on industrial companies active in the Belgian food industry is therefore highly relevant. This study thus investigates whether the competitiveness of the Belgian food companies will not be affected by this new European regulation.

2. Approach

To obtain an understanding of the contents of REACH and its implementation implications, an extensive literature study on REACH was carried out. Furthermore, the Belgian food industry was analyzed. In-depth interviews with managers from Belgian food companies and with a representative from the Federation of the Belgian Food Industry (FEVIA) were carried out and academic and professional literature was employed to acquire a general idea of the Belgian food industry. Subsequently, a literature study on costs following the implementation of REACH in the chemical industry was performed. The costs identified for the chemicals sector were then used to obtain an apprehension of those for the food sector. At present, no information is available on aggregated REACH-related costs directly from the Belgian food industry.

To empirically assess our literature-based findings and to obtain concrete figures from the Belgian food enterprises, an electronic survey was carried out and questionnaires were send to more than 700 companies active in the food sector. In this survey, amongst other questions, companies were asked whether they were knowledgeable of REACH and whether they could identify their role under REACH (i.e., manufacturer, importer or downstream user). If these companies had already incurred any expenses in consequence of REACH, they were asked to make an indication of the size of these costs.

Afterwards, a case-study was carried out by means of an in-depth interview. A compliance manager from a major Belgian food company was interviewed to validate our empirical deductions and to comment on the research results.

3. Literature study

The Belgian food industry is referred to by its Federation as the "Small and Medium-sized Enterprises (SME) sector par excellence" (Bosch, 2009). A company is categorized as an SME when it employs at most 250 Full Time Equivalent (FTE) employees and has a yearly turnover of maximum 50 million Euros. Table 1 illustrates the Belgian food industry's composition based on the numbers of FTEs. More than 50% of the companies are so called micro-companies that employ less than 5 employees. The number of large companies (>500 FTE) is very small. The Belgian food industry is therefore considered as an SME industry that is characterized by a very small amount of large companies (Bosch, 2009, De Schutter & Kielemoes, 2007).

In 2007 a total turnover of 36,931 million

Table 1 Composition of the Belgian food industry based on the number of FTE employees

Number of employees per company	*Number of Belgian companies*	*% Belgian food companies*
< 5	3,272	55.12
5 - 9	1,270	21.39
10 - 19	652	10.98
20 - 49	414	6.97
50 - 99	149	2.51
100 - 199	108	1.82
200 - 499	59	0.99
500 - 999	18	0.17
> 1000	2	0.03
total	5,936	100.00

Source: FEVIA, 2009

Euros was generated in the Belgian food sector (FEVIA, 2009). Approximately half of this turnover was generated on the Belgian market and the other half was generated by export. Approximately two third of the export is sent to France (21.7%), the Netherlands (19.3%), Germany (14.7%) and the United Kingdom (11.0%). A total of 85% of the export is intra EU while only 15% is destined for the rest of the world. The most important destinations outside Europe are Russia, the US and Japan. Given that REACH creates a disadvantage only for those companies that export to countries outside the EU, this disadvantage thus only applies to the 15% of the food companies exporting to non-EU countries (and consequently at first glance only these plants may suffer from a weakened competitiveness).

As already mentioned, chemical substances used in food are in general excluded from REACH. Companies that use these chemical substances for non-food purposes can however be subject to the legislation, for example when a certain production process creates a by-product of which the destination is a non-food purpose or when one certain substance can simply be used for various purposes. Chemicals may for example be detergents for cleaning machines or lubricants for smearing machines. Packaging may also contain chemical substances.

It should be noted that until present a very limited amount of costs has already been made by food companies due to REACH. Actual costs will thus become ever more transparent during the next decade as the registration deadlines for the different categories (amounts of chemicals processed, used, imported, etc.) stipulated by REACH will fall successively.

In order to estimate the extent of the costs resulting from REACH, a list of potential costs was made up (using the chemical industry as a guiding sector).

Costs arise when manufacturers and importers meet their registration and other obligations. They can be divided in three categories: direct, indirect and hidden costs. Direct costs are a result of gathering required information, testing, administration or they result from rationalizing the product portfolio.

The most important costs directly related to registration are laboratory test costs. In the case where not all required information is present, tests may have to be carried out to acquire all the necessary data. Costs for these tests may be considerable. For this reason, companies often form consortiums. This brings about a number of advantages, yet it is not obligatory. In such consortiums, companies may jointly perform certain tests and therefore split certain high costs among the various members. Furthermore, given that companies do various tests together, these tests have to be done only once and double testing is avoided since companies can share the obtained results. In case of testing on animals it is even compulsory by REACH to avoid double testing. The formation and management of these consortiums is an example of indirect costs that may arise. Other indirect costs include personnel training and increased communication with customers and suppliers (Heughebaert, 2008).

Rationalization of the product portfolio may occur for two reasons. First, it is possible that the authorities encounter certain substances as too risky or too dangerous for human and environmental health. Consequently, these substances may no longer be authorized, and as a result companies producing or importing these substances may no longer be permitted to do so. If this is the case for a company, rationalization of its product portfolio is obligatory. Second, it is possible that certain companies evaluate the registration costs as too high. These companies doubt the profitability of continuing to produce or to import these substances. In this case, the companies themselves choose to no longer produce or import the substance. Rationalization leads to high costs

for the former importers or manufacturers because these have to cut parts of their portfolio or substitute these substances in their products for tolerated (authorized) alternatives which requires considerable time and money for research. (Van Gennip & Van Geel, 2004; Angerer et al., 2008; Danneels, 2009).

Hidden costs are for example increased costs for managing suppliers, replacement of critical substances or rationalization of the supplier base.

In the Belgian food industry, we are obviously mainly interested in downstream user costs. Although downstream users might not need to register any substances and therefore avoid the significant registration costs, due to REACH compliance, they may be confronted with increased costs due to the various obligations they do have to meet. Potential costs may arise due to administration, increased communication and drawing Safety Data Sheets. Other important costs for downstream users may arise in case their suppliers rationalize their product portfolio. In case this rationalization is decided by the supplier himself and not imposed by the authorities, downstream users may have to find and negotiate with (new) suppliers still delivering the desired chemical substance(s). Converting to new suppliers often demands significant investigation and thus requires a considerable amount of resources. In case rationalization is indeed enforced, downstream users will need to reconsider product designs that contain the substances that are no longer authorized. They either need to substitute such unauthorized substances for other substances that are still permitted, or they have to completely eliminate them from the design. Redesigning products may require a considerable amount of research resources, being a time and money consuming activity. Furthermore, such research implies a large part of the budget for R&D to be taken up for this purpose, and hence less resources are available for R&D, e.g. in function of innovation. The impact of REACH implementation on innovation is however not unambiguous, because it incites innovation as well by delivering an incentive for cost reducing alternatives (Wolf & Delgado, 2003). Downstream users may furthermore be confronted with increased prices for chemicals if suppliers roll of a great share of their increased costs on their customers. They will be more willing to bear higher prices than to switch over to suppliers outside the EU who are not confronted with higher costs due to registration. If they would switch over, they would then no longer be downstream users but importers and would have to incur the high registration costs themselves (EC, 2002; Maeckelberghe, 2009).

Moreover, companies not complying with REACH obligations risk to be heavily fined. In Belgium, fines may be monetary penalties amounting up to 4,000,000 Euros in case of a major offense and up to 1,200,000 Euros in case of a minor offense, or they may translate into custodial sanctions for company CEOs (Hamblok, 2009).

An obvious conclusion of our literature study is that REACH-induced costs may influence the competitiveness of Belgian food companies. Competitiveness is determined by whether the costs made by a company are competitive compared to its competitors as well as by its product portfolio (and thus indirectly by e.g. innovation). To study the impact of REACH on organizations' competitiveness, a distinction needs to be made between large companies and SMEs and between whether the destination of the export is intra- or extra-EU.

REACH pressure on company competitiveness is not evenly distributed among the companies. Observing REACH implementation in the chemicals sector, small and medium sized enterprises experience a far stronger pressure on their competitive positions compared to large companies: large chemical companies produce or import large quantities of substances and costs can be spread over much larger volumes. SMEs often produce or import a larger variety of chemical products in somewhat smaller quantities (although generally still surpassing the 1 tonne per year tier). Consequently, large companies are able to obtain much lower costs per tonne than SMEs.

Furthermore, a distinction must be made between intra-EU or extra-EU export. On the one hand, REACH discourages extra-EU export, since those companies selling their products on the global market will no longer be able to compete with non-EU companies on that market. Two arguments explain this observation: (i) importers or manufacturers within the EU facing test and registration costs may roll off their increased costs on their customers leaving these companies with a competitive disadvantage compared with non-EU competitors, and (ii) the manufacturers and importers themselves suffer lower profit margins compared with non-EU competitors. On the other hand, REACH favours intra-EU export, since

European companies buying chemical substances or products containing chemicals will prefer to buy these products from suppliers within the EU this way avoiding registration costs. Hence, REACH can be considered as a technical trade barrier which enforces competitiveness amongst European companies selling products on the European market.

In the chemicals sector, only 23% of chemicals sales are exported outside of the EU area (Cefic, 2009). The EU chemical industry comprises 29,000 enterprises, 96% of which have less than 250 employees and may be considered as SMEs. Only 4% of the EU enterprises employ more than 249 employees and generate 72% of total chemicals sales. Most of the chemical companies are thus SME downstream users.

In the chemical industry, REACH frustrates the competitive position of SMEs compared to the competitive position of large companies due to the costs per tonne. Although not as high volumes of chemical substances are produced or imported by chemical SMEs compared with large chemical enterprises, most of these companies produce or import a diversity of substances with relatively high amounts, and are therefore immediately subject to registration and REACH regulations for each of these substances. Thus, registration costs due to REACH implementation in the chemicals industrial sector are distributed over a large number of companies. The question arises whether the same conclusions can be drawn with respect to the Belgian food industry.

4. Empirical research

4.1. Survey

An e-survey was sent to 712 companies active in the Belgian food industry. Companies were asked to indicate their role with relation to REACH. In case a respondent indicated to be a downstream user, he was also asked identifying the company's suppliers. Respondents were furthermore asked whether their companies complied with all REACH obligations at the moment of filling in the questionnaire, and, if not so, to indicate which obligations they did not comply with. Companies were asked for their REACH related costs, to give an indication of the nature of these expenses and to quantify them. The questionnaire was sent out in February 2009 and the deadline for filling in the e-survey was set on the end of April 2009. A response rate of approximately 4.5% was obtained. This is an acceptable rate given the fact that response rates for academic studies have been known to show a general decline in recent years (Griffis et al., 2003).

To limit the workload for the respondents (and also to increase the response rate of the survey), the selected companies were asked to identify a single informant. Checking his/her function within the company validated the competence of this informant. For more information and suggestions on selecting key informants, reference is given to Kumar et al. (Kumar et al., 1993). In our survey, respondents can be considered to be sufficiently knowledgeable such that the results are not tainted by informant bias: all respondents indicated to be either compliance managers or environmental managers.

A mix of large companies and small and medium-sized enterprises responded to the survey. As regards company activity types (i.e., breweries, bakeries, milk producing companies, candy producing plants, meat enterprises, chocolate companies, etc.), the participating plants also have a very diverse product portfolio. The representativeness of the sample can therefore be regarded as sound.

As regards the participating companies' roles under REACH, 9.1% of the respondents were upstream users (manufacturer or importer), whereas 42.4% were downstream users. One third of the respondents (33.3%) either were not subject to REACH at all, or were unaware of these regulations. Apparently, 15.1% of the participating food companies explicitly mentioned to be ignorant as regards REACH. These figures are comparable with our observations in the chemical industry, where the largest group consists of downstream users as well (Danneels, 2009). It should however be noticed that within the food industry the amounts or the range of chemical products are usually rather limited (and generally lower than the 1 tonne per year tier, hence leading to non-exposure to REACH compliance).

Companies were further asked to give an indication of the costs they already made or they were expecting to make due to REACH implementation. Upstream user estimations range between 100,000 Euros and 300,000 Euros yearly.

Downstream users assessed their REACH implementation costs to amount to maximum 2,500 Euros yearly. As mentioned before, downstream users may however be confronted with significant costs in case their sup-

pliers rationalize their product portfolio. From the survey it is obvious that food companies consider this possibility as very unlikely. The reason for this stems from the fact that chemical substances used in food and beverages are very unlikely to be considered as risky and therefore will (most likely) not be forbidden in the future. Hence, suppliers of downstream users will probably not be confronted with forced rationalization.

Using the survey results for manufacturers or importers and for downstream users, total cost impact for the Belgian food industry is estimated. To this end, manufacturing or importing companies' estimated costs are aggregated and are added to the estimated aggregated costs for downstream users in the Belgian food industry. In this industry, 5,936 companies are active (FEVIA, 2009). Based on our empirical results, we estimate some 540 companies are upstream users and thus need to register. This is a conservative estimate, since a number of food companies are not yet aware of REACH and of their role in this new legislation. The total costs for this small upstream user group will then vary between 54 and 162 million Euros yearly. The survey results further indicate 42.4% of the food companies are downstream users. Total costs for downstream users can therefore conservatively be calculated to approximately 6.3 million Euros. Total cost impact of REACH implementation for the Belgian food industry can thus conservatively be estimated to vary between 60.3 and 168.3 million Euros yearly.

Furthermore, the Belgian food industry generates an annual average turnover of 36,931 million Euros. Hence, REACH implementation costs represent 0.1% to 0.5% of total turnover of the Belgian food sector. Angerer et al. (2008) indicate that in the chemicals industry, REACH costs amount to approximately 0.13% of total turnover.

In both the chemical industry and the food industry, costs thus remain rather limited compared with total turnover. However, there is a difference between both industrial sectors: unlike in the chemical industry, the spread of the costs in the foods sector is highly uneven. A large part of total costs is borne by a very small group of food companies requiring to register, whereas a very small part of total costs is carried by a large group of downstream users. Large food companies fall mostly into the category of manufacturer or importer, experiencing the strongest pressure. Food downstream users are mostly SMEs for which the impact remains limited. The latter observations are in contrast with the chemical industry, for which mostly the SMEs experience a large pressure on their competitive position and are sometimes no longer able to compete with the larger companies.

Furthermore, given that REACH favors intra-EU export and discourages extra-EU export and given that only 15% of Belgian export is extra-EU, the competitiveness impact of REACH on food companies remains limited in this regard as well. Once again, the large companies are globally active and export extra-EU, thus face possible negative impacts on their competitive position.

It follows thus from the empirical data that REACH affects the food industry in a fundamentally different way than it affects the chemical industry. To evaluate and to interprete these findings, a case-study in a major Belgian food enterprise was carried out.

4.2. Case-study

One of the respondents of the e-survey was the compliance manager of Citrique Belge, an upstream user company belonging to the Belgian food industry. He welcomed an in-depth interview in which costs and implications of REACH could be discussed. As an instructive document for the interview, a list of guiding questions was prepared in advance.

Citrique Belge is one of the worlds' largest manufacturers of citric acid and produces approximately 100,000 tonnes of citric acid every year. Consequently, the company falls within REACH's highest tonnage category and is subjected to registration requirements. In case of Citrique Belge, the registration deadline was November 30th, 2007.

REACH-related estimated costs for Citrique Belge are divided into direct, indirect and hidden costs. This company was formally part of a larger multinational company, Hoffman-La Roche, which executed toxicity studies and exposure safety studies. Meanwhile, the company has been taken over by DSM, a chemical multinational, which is now the parent company of Citrique Belge. Due to its past, the company did not have to incur expenses for testing. Compared with other food companies requiring to register, this may be considered as an exceptional situation in which Citrique Belge is able to avoid significant costs.

As indicated in section 3, companies take part in consortia in order to cut costs. For this reason, Citrique Belge founded a consortium

for citric acid. The consortium consists of a limited number of manufacturers of citric acid. Citrique Belge does not have complete knowledge about REACH and has therefore hired consultants to lead the consortium. The costs to the company for further developing the consortium is estimated to amount to 25,000 Euros yearly.

Indirect costs made by Citrique Belge are for instance costs to inventorize all the substances followed by the identification of substances that need to be registered. These costs are borne by the parent company DSM. Citrique Belge did establish essential systems and procedures for REACH itself and gathered the data required for preregistration. This required a considerable amount of personnel costs (via personnel time). Other indirect costs follow from the required adaptation of Safety Data Sheets.

Citrique Belge assumes that all suppliers will register their products and that authorization for citric acid and its components is unnecessary. In this scenario none of the substances of Citrique Belge needs to be substituted. Hidden costs are thus estimated to remain zero.

Total costs are estimated by the company to range between 100,000 and 200,000 Euros yearly until the deadline expires on 30 November 2010. REACH related costs thus possibly amount to maximum 600,000 Euros in total for Citrique Belge.

The compliance manager of Citrique Belge further recognized our empirical findings on REACH implications in the Belgian food industry and fully agreed with them. Additionally, he emphasizes there is a lot of room for interpretation of REACH legislation and it appears that various parties are insufficiently informed. The company's respresentative therefore recommends that REACH communication between all stakeholders (companies, authorities, etc.) is substantially improved.

5. Conclusions

REACH is often considered as novel European legislation only applying to the chemical industry. Although mainly the chemicals sector is indeed subject to it, REACH should also be followed up by other industries using chemical substances (mainly in downstream activities), e.g. the food industry. Downstream companies frequently wrongfully assume that they have no connection to REACH whatsoever, despite using e.g. products containing chemical substances, detergents, etc.

A survey in the Belgian food sector clearly confirms the need for further communication about the existence and the importance of REACH to downstream sectors.

The impact of REACH implementation on the Belgian food industry cannot be compared with its impact on the chemical industry. As opposed to the chemicals sector, in the food sector a very limited number of companies bears nearly all costs and an overwhelming majority of companies, the downstream users, bears little costs. A number of downstream users even indicates to make no expenses at all. This is however unlikely and possibly due to the fact that these companies are not sufficiently aware of their REACH obligations. An in-depth interview with the compliance manager of a major Belgian food company backs up our empirical conclusions and indicates an urgent need to enhance REACH awareness and knowledge amongst downstream user sectors.

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Practitioner's Section

Performance improvement in pharmaceutical R&D through new outsourcing models

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The stimulation of innovation in the pharmaceutical industry through outsourcing of research and development (R&D) activities within the drug discovery and development process is analysed. The empirical data were collected through interviews with experts of pharmaceutical companies and service providers between 2002 and 2005. Additionally, in 2008, the outsourcing behaviour of the already interviewed and additional companies was analysed through desk research.
The results show that the outsourcing behaviour of traditional and emerging pharmaceutical companies is completely different. Whereas the make-or-buy decisions of traditional companies are mainly competency or know-how driven, that of emerging companies are primarily capacity or cost driven. Nevertheless, for both types of companies the cooperation model of "strategic partnership" offers access to high-level expertise while reducing fixed costs and complexity. Within this model, external providers are temporarily integrated into internal R&D teams and thus able to support R&D projects flexibly and more timely.

Introduction

Increasing pressure on the pharmaceutical industry

Global competitiveness is becoming increasingly important for the pharmaceutical industry. Companies are exploring options to enhance the efficiency of the resources they are using at all stages of the whole value chain from discovery research to production and logistics as well as sales and marketing. Especially innovation is recognised as the cornerstone for competitive advantage and is fostered by strong investments in R&D (Achilladelis et al., 2001). Rising costs of pharmaceutical R&D coupled with increasing pressure of stakeholders demanding steady growth lead to increasing pressure on the output of the innovation pipeline.

But drug development and commercialisation is an expensive, lengthy and risky process. Studies published in 2003 report an average pre-tax cost of approximately US$800 million to bring a new drug to the market (DiMasi, 2002; DiMasi et al., 2003). It is estimated that by the time a medicinal product is placed on the market, an average of 12-13 years will have elapsed since the synthesis of the new active substance. Thereby, on average, out of every 10,000 sub-stances synthesised in laboratories, only one or two will successfully pass all the stages to become marketable medicines (EFPIA, 2008).

Performance improvement by outsourcing

The current pressure to increase the output

of R&D has created new needs for specialised technologies with the potential to reduce lead times and streamline the drug discovery and development process. Cockburn, Henderson and Stern (Cockburn et al., 2000) have shown that drug discovery productivity is dependent on the internal organisation of R&D. For these reasons, pharmaceutical companies have been forced to reassess their mode of R&D operation including outsourcing activities (Quinn, 1999; Quinn, 2000).

Outsourcing, traditionally thought of as a short-term strategy for demand realisation, could be considered to lever the core competencies to increase performance in pharmaceutical R&D. There are good arguments to stress the complementarity between in-house R&D and external know-how (Arora et al., 1990; Arora et al., 1994; Cassiman et al., 2002; Cockburn et al., 1998). For example, Arora and Gambardella examined the complementarity among sourcing strategies of large companies in the biotechnology industry. The access to external know-how may leverage the productivity of internal R&D activities if the organisation exhibits a willingness to absorb external ideas (Veugelers, 1997; Veuglers et al., 1999). An important task in innovation management, therefore, is to integrate internal and external knowledge within the innovation process, in order to benefit from positive effects each activity has on the other.

But outsourcing R&D also bears potential risks due to project complexity und loss of flexibility. Studies to clarify the comparative effect of outsourcing in relation to internal improvements within manufacturing processes showed that internal enhancement of manufacturing capability made it much easier to predict improvements in operating performance than outsourcing (Dabhilkar et al., 2008). Generally, outsourcing leads to negative effects when used only as a cost reducing strategy to improve short-term performance. The consequence may be the loss of internal know-how and expertise as well as higher total costs in the long-term. There are numerous examples where insourcing prevented the negative effects caused by bad outsourcing decisions (The Economist, 1996).

Figure 1 Analysed and interviewed companies

Interviews: pharma companies		Additional analysis: pharma/biotech companies		
Aeterna Zentaris	Orion Pharma	4SC	Dolorgiet	OSI Prosidion
Bayer Shering	Pfizer	Actelion	Engelhard Arzneimittel	Ratiopharm
Bionorica	Roche	Addex Pharmaceuticals	ESBA Tech	Respiratorius
Böhringer Ingelheim	Sanofi-Aventis	Alsachim	Evotec	Sandoz
Eisai	Speedel	Amgen	GlaxoSmithKline	Santhera Pharmaceuticals
GlaxoSmithKline	Stada	Antisense Pharma	Grunenthal	Sirtris Pharmaceuticals
Lichtwer Pharma	Wyeth	Apogenix	Heidelberg Pharma	Solvay Pharmaceuticals
Meda		Apogepha Arzneimittel	Idenix	Spirig Pharma
Merck Serono		Astex Therapeutics	Janssen Cilag	Stada Arzneimittel
Merz		AstraZeneca	Jerini	Syncom
Novartis		Basilea Pharmaceutica	Johnson & Johnson	Takeda Pharma
Nycomed		Berlin Chemie	Lilly Pharma	Tocris Bioscience
Interviews: service providers		Biofrontera Pharmaceuticals	Lipideon Biotechnology	U3 Pharma
Accovion	Focus Clinical Drug Development	BioGenerix	Medice	Ugent
Avecia	Genedata	Biovertis	Medigene	Wilex
Clariant	Lonza	Bristol Myers Squibb	Micromet	
Dottikon Exclusive Synthesis	Solvias	Celgene	Midas Pharma	
DSM		Cellzome	Mologen	
Dynamit Nobel/ Novasep Synthesis		ChemBridge	Morphochem	
Eurofins Medigenomix		Coley Pharmaceuticals	Morphosys	
Evonik Degussa		Decode	MSD Sharp & Dohme	
		Develogen	Neurotune	
			Noxxon	
			Oncalis	

Research question and methodology

This paper discusses how the challenges facing the pharmaceutical industry are shaping "make-or-buy" strategies within pharmaceutical R&D. Pharmaceutical industry includes also the biotechnology industry which is strongly linked to the pharmaceutical industry. The discussion of outsourcing will use the example of chemical synthesis offered by specialised service providers within the drug discovery and development process. This example is chosen as it covers an important part of the drug discovery and development process and represents the outsourcing mentality in pharmaceutical very well.

The empirical data have been collected through desk research and interviews with managers and experts of 19 different pharmaceutical companies and 12 pharmaceutical service providers in different rounds between 2002 and 2005 (Figure 1). An interview guideline with a reference set of questions was developed to secure the comparability of the answers and to leave enough room for spontaneous answers, which gave a semi-structured nature to the interviews. Each interviewee was interviewed in sessions of approximately 60 minutes, whereby most of the interviews were conducted face-to-face and only a few by telephone.

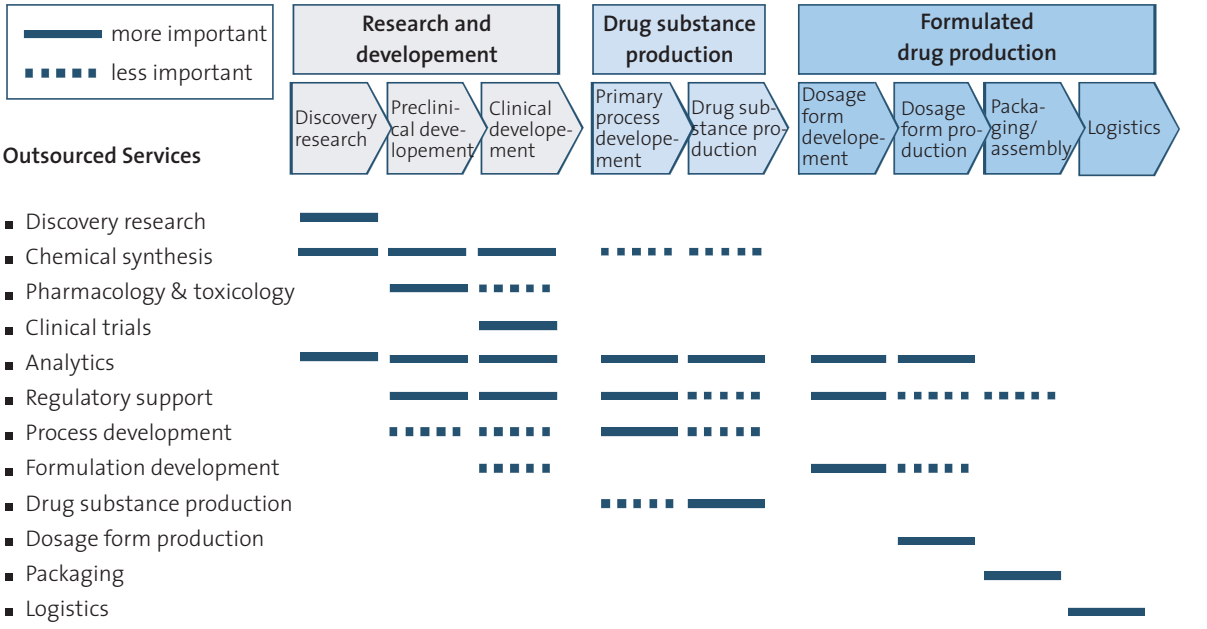
Additionally, in early 2008, the outsourcing behaviour in the field of chemical synthesis of the interviewed companies and 61 additional pharmaceutical and biotechnology companies was analysed through desk research using different public sources (e.g. business databases) and company disclosures (e.g. websites and press releases). Additional telephone calls with persons responsible for chemical synthesis clarified open questions, which could not be answered using other sources.

Results of analysis and interviews

Outsourcing behaviour of pharmaceutical companies

Outsourcing activities are well established along the whole pharmaceutical R&D and production value chain from discovery research to packaging and logistics (Figure 2). Most of the outsourced services are used in one or more process steps of the value chain. The analysis and interviews showed that the differentiation between traditional and emerging pharmaceutical companies is of importance. Traditional pharmaceutical companies, which could be large ("big pharma") or mid-sized companies, normally cover the whole or most of the pharmaceutical value

Figure 2 Outsourcing activities along the pharmaceutical R&D and production value chain



chain from drug discovery/development up to production and marketing/sales. A widely used term for this kind of company is "Fully Integrated Pharmaceutical Company" (FIPCO). In contrast, emerging pharmaceutical companies are focused on selected stages of the pharmaceutical value chain (Van Arnum, 2008). Most of the biotechnology start-up companies or other technology driven companies with their roots in R&D are part of this group.

Most traditional pharmaceutical companies have their own in-house capacities and the openness for outsourcing is significantly lower compared to emerging companies (Figure 3). They are less interested in buying services due to sufficient in-house capacities. Also cost reduction (reducing fixed costs or reducing people on the payroll) is not so important for outsourcing of services than always thought. These companies have a high interest in additional, external know-how which is not available in-house or too expensive, if it was to be built up internally. Expanding in-house capabilities by external expertise is seen as the most important advantage of using external services. Discovery research and clinical trials are good examples and show the highest outsourcing degree. Within these areas the major requirements in cooperating with services providers are:

- Leading edge equipment and know-how of the provider while adhering to the highest possible technical standards.
- Clear competence profile of the chemical provider focused on specific segments while being unique and innovative.
- International presence and availability of experts to support the customer worldwide.
- Highly standardised co-operation model covered by general agreements with precise definition of the ownership of intellectual property.

Compared to traditional companies, the outsourcing level of emerging pharmaceutical companies is generally rather high and in some categories 100% due to low or missing internal resources. These companies see outsourcing as an effecti-

Figure 3 Percentage of companies using outsourcing differentiated between traditional and emerging pharmaceutical companies

Outsourced services	Traditional pharmaceutical companies	Emerging pharmaceutical companies
Discovery research	↑	↑
Chemical synthesis	↗	↑
Pharmacology & toxicology	→	↗
Clinical trials	↑	↑
Analytics	↘	→
Regulatory support	↓	↗
Process development	↗	↑
Formulation development	→	↑
Drug substance production	→	↗
Dosage form production	→	↑
Packaging	↘	↑
Logistics	↘	↑

↑ high → medium ↓ low

ve method to capture capacity and expertise without investing much money in in-house resources. In particular, many start-ups lack experience and expertise around drug development, which consequently forces them to relay on external service providers. In doing this, they have the following requirements.

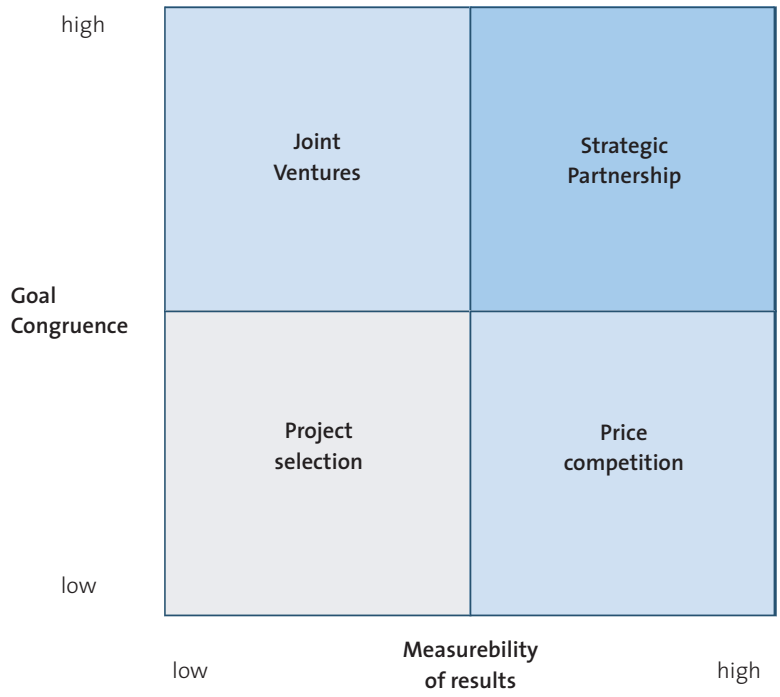
- Lean and flexible development capacities on the side of the providers, easily adaptable to smaller demands.
- Full service range and know-how around chemical synthesis with capabilities for the support of project management.
- Transparent and flexible cost structures, similar or equivalent to own in-house structures to avoid additional administrative resource burdens.

Cooperation models for outsourced services

In the areas of pharmaceutical R&D and production, four different co-operation models between pharmaceutical companies as customer and service providers as vendors have been established, depending on goal congruence and measurability of results. There is a simple correlation: the higher the goal congruence, the more trust between the two partners, and the higher the measurability of results, the closer the relationship comes to a traditional customer-supplier relationship (Figure 4).

- Project selection: Selection of service providers on a project-by-project basis from a core list of preselected service providers. The service providers are engaged according to the fit of their core competence to the specific project requirements (e.g. the choice of the best-fitting clinical research organisation for the management of clinical trials in a special therapeutic area and/or a special phase of the drug development process).
- Price competition: Long list of service providers systematically put into competition in order to secure lowest purchasing prices. This model is less strategically oriented, but rather serves to achieve the demand for the most cost-efficient fulfilment (e.g. purchase of standardised analytical services for routine analytical tasks within drug development or quality management). It can be applied successfully only if the outcome can be measured easily.
- Strategic partnership: Strategic links with a handful of preferred service providers who are given preferential "right of first refusal".

Figure 4 Different types of cooperation models for outsourced services



A framework contract covers all the relevant services (e.g. contracts with full-service drug discovery service providers like Albany Molecular Research).

- Joint venture: If the results depend on both parties, but contribution cannot be easily attributed, a 50-50 joint venture is a good choice. This approach has not been observed between a pharmaceutical and a service provider. It is a well-known approach in other industries, e.g. in fuel cells, or high-tech in general.

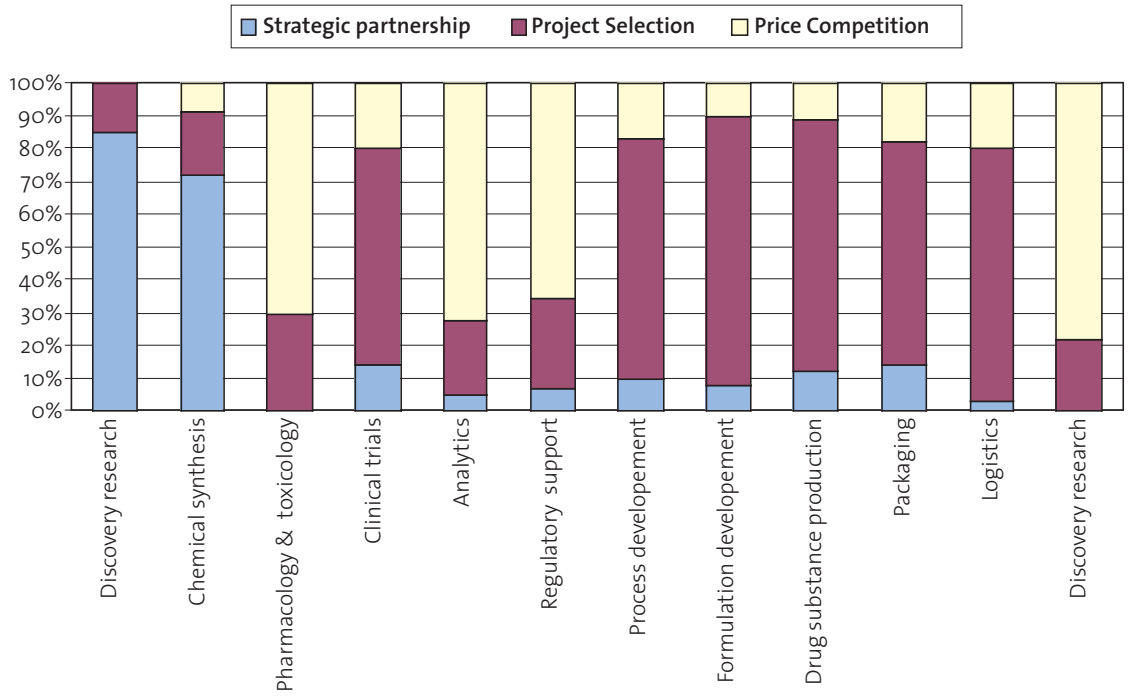
The pharmaceutical industry invests high management capacity in choosing appropriate service providers and to commit them to the company to achieve goal congruence. Stringent inspection of the supplier's facility, quality, best practices, trained staff and certified processes is crucial in the selection process (Findlay, 2007). Assessment of the service provider's financial stability is imperative during the selection process. As these suppliers work with various projects from pharmaceutical companies, it becomes crucial to ensure there is no backlog of projects due to financial constraints.

Analysing the relevance of the cooperation models for the different outsourcing areas shows that the most often used cooperation model is "project selection" (Figure 5). The "strategic partnership" model is used mainly in the areas of discovery research and chemical synthesis. "Price competition" is mainly used for services in the area of pharmacology & toxicology, analytics, regulatory support and logistics, fields where the deliverables are easy to control. The "Joint venture" model between pharmaceutical companies and service providers is more of theoretical nature, as it not often found in practice. But there are some joint ventures between service providers, especially to cover emerging markets. A good example is the formation of the joint venture Evotec-RSIL in India between Research Support International (RSIL) and Evotec to design, synthesise and manage compound libraries as a service. The joint venture combines Evotec's expertise in library design, synthesis, analysis, purification and project management with RSIL's synthesis expertise coupled with a low cost structure in India.

Chemical synthesis services as example for strategic partnerships

The "strategic partnership" model is analysed more in detail as it is perceived that this model has the potential to improve the performance of pharmaceutical R&D significantly. For a better

Figure 5 Relevance of the co-operation models for the different outsourcing areas



understanding of the "strategic partnership" model, the field of chemical synthesis should serve as an example.

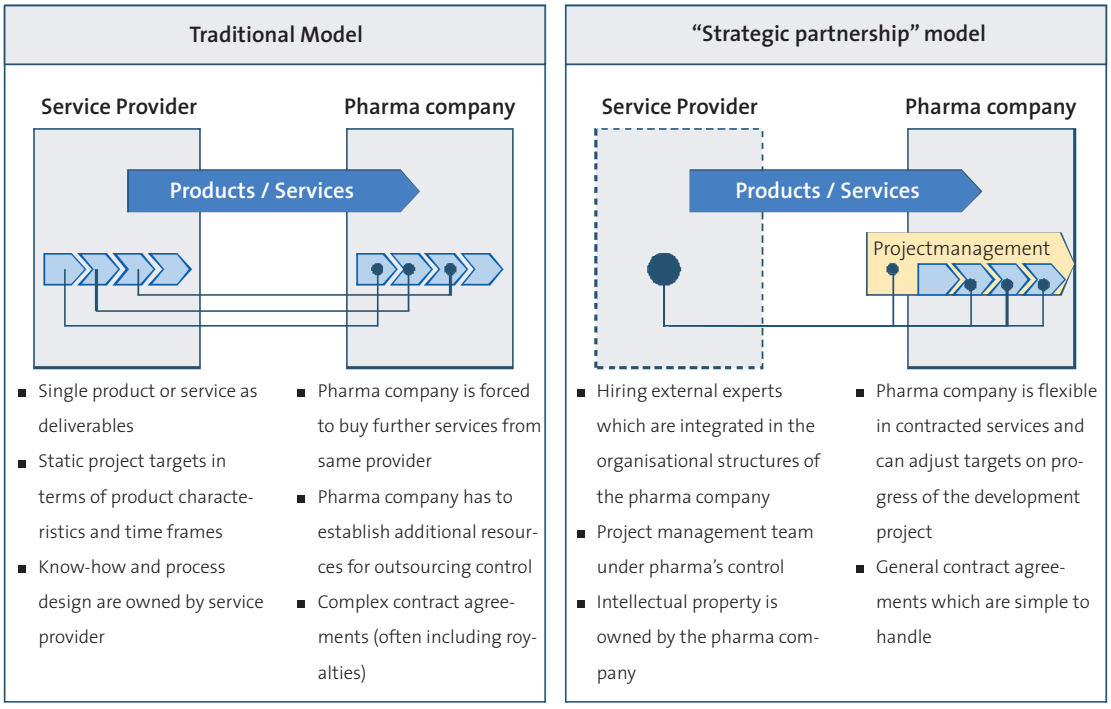
Traditional outsourcing concepts within chemical synthesis are focused on single product or service. Only the product (e.g. lead compound or class) is sold exclusively or semi-exclusively to the customer with the provider remaining the owner of the synthesis know-how and process design. Contracts have been rather complex in the past due to opposing views on intellectual property and rigid customer provider relations. Therefore, both partners are forced to think and act much more result-oriented than react within existing organisational boundaries. Service offerings in outsourcing need to be adapted, while interfaces between customer and service provider, reduced and redefined. A solution is "body leasing": integrating external experts into internal R&D teams to support R&D projects more flexibly and more timely within pharmaceutical companies. Many "strategic partnership" models are based on service providers hiring out their employees with specialised skills and leaving intellectual property rights in the ownership of their pharmaceutical customers (Figure 6).

This represents a switch from isolated service offerings to an integrated platform of support within the customer's processes and structures. This means that pharmaceutical companies hire in experts for a defined period and integrate them into their in-house R&D structure. Hired experts use either their own in-house infrastructure or facilities inside the customer's organisation. A project management team for which the customer is responsible guarantees success of the development project as well as the intensive know-how and expertise transfer. A highly standardised project management is important to ensure success. This addresses pharmaceutical industry concerns of minimising third party activities for critical path activities through highly standardised processes.

Experiences and learning effects

Cost, time and innovation are the levers to improve R&D performance and R&D outsourcing could give the mentioned levers a positive impact. The positive effects of outsourcing are enhanced if the supplier is used to supplement existing core competencies (i.e. to free resources in order to invest in higher internal capability). Besides limiting fixed costs, service providers can often provide the expertise and know-how in a more flexible and cost-effective way than internal resour-

Figure 6 "Strategic partnership" model as outsourcing concept



ces. Furthermore, the complementarity between in-house R&D and external know-how creates additional benefits regarding the quality of research and services. Therefore, the right strategic partner could not only offer cost advantages, but also quality improvement and innovation, and the "strategic partnership" model guarantees a high internal competence level in the long-term.

But nevertheless, some aspects like perceived (or real) difficulties to transfer know-how and issues with intellectual property situation are seen as major obstacles for outsourcing. Service providers should react to the concerns of pharmaceutical customers with a best practice approach which includes the following aspects.

- Complexity and efficiency: definition of highly standardised and transparent processes and contracts.
- Co-operation and communication: project management in close vicinity to the pharmaceutical company and not only offshore lab resources (e.g. in China or India).
- Costs and invoicing: establishing full cost transparency and easy invoicing process.
- Flexibility and quality: high flexibility regarding project execution with stringent quality control.
- Exclusivity and secrecy: clear and transparent rules regarding the engagement in projects of direct competitors.
- Intellectual property: cooperation agreement leaving all critical IP at the pharmaceutical company.

If these aspects are handled properly, the professional market for highly specialised services and the flexible structures within the services networks make pharmaceutical research more efficient. In the future, highly specialised research service providers will play a more important role and integrative part of the processes in the pharma industry. The result is that there has been an increase in drugs introduced to the market over the past years, after the number reached a low point shortly after the turn of the millenium.

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Practitioner's Section

Sustainability in the chemical and pharmaceutical industry - results of a benchmark analysis

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Growing awareness of sustainability

The awareness of sustainability as a main issue of companies' performance has considerably grown over the last years. The reasons for this development are manifold. On the one hand, global megatrends such as climate change, demographic challenge, global growth of population, etc. have led to growing concerns about the future of nature and the survival of people, especially in developing nations. On the other hand, misleading developments in management of a large number of globally acting companies have caused mistrust and a discussion regarding the importance of values and ethics as part of good and sustainable corporate governance.

The discussion of sustainability more or less started in 1972 when the Club of Rome published its first report "The Limits of Growth" which "explored a number of scenarios and stressed the choices open to society to reconcile sustainable progress within environmental constraints".

"The international effects of this publication in the fields of politics, economics and science are best described as a 'Big Bang': over night, the Club of Rome had demonstrated the contradiction of unlimited and unrestrained growth in material consumption in a world of clearly finite resources and had brought the issue to the top of the global agenda." (The Club of Rome, 2010).

As a consequence, the United Nations started to establish a platform for a structured dialogue about the ecological challenges the global society is facing. Among others, in 1982 the World Commission on Environment and Development (WCED) was founded, leading to the highly recognized report "Our Common Future" in 1987 (better known as Brundtland Report - named after the Chair of the WCED, the former Prime Minister of Norway, Gro Harlem Brundtland). The report marked the beginning of a definition of sustainability as a

"Development that meets the needs of the present without compromising the ability of future generations to meet their own needs" (United Nations, 1982)

and it highlighted three fundamental pillars of sustainable development:

(1) environmental protection,
(2) economic growth and
(3) social equity.

This so-called "triple bottom line" has become the frame of reference for most all further discussions about sustainability. Especially the sustainability approach of companies often aims at ensuring a balance of their economic, ecological, and social ranges of responsibility.

Sustainability has attracted companies' growing attention within the last couple of years. And against the background of a public opinion looking increasingly critically at the way companies are doing their business, sustainability has turned out to be a substantial contribution to ensure their so called "license to operate".

The current global economic crisis has given further breeding ground to this development. On the one hand, national governments and global regulating authorities (European Union, International Monetary Fund) have undertaken strong efforts in order to develop substantial and successful recovery plans. On the other hand, a discussion about how to realign rules and ways of responsible – sustainable – corporate governance has been gaining momentum. Politics and the

global public in general are asking

- for more transparency of companies' decisions,
- for a more long term planning horizon and - as a further consequence -
- for a new performance bonus system for executives being linked strictly to a long term business success and
- for ways to ensure their contribution to both a successful national and global economic development as well as a world being economically, ecologically and socially in balance.

Sustainable corporate governance seems to have become synonymous with good corporate governance which is at least aiming at a recovery of the credibility of business and their commitment to contribute to global welfare.

The development described above may serve as proof that sustainability or corporate responsibility (CR) is far more than a buzzword. It has become a rather substantial part of companies' risk or even opportunity management systems, especially as far as reputation, global procurement, health, safety, environment (HSE) as well as talent management are concerned. What has started as being a more or less soft subject for business has meanwhile evolved into a hard success factor whose negligence may lead to substantial reputational damage and accordingly result in high cost effects. Furthermore, global standards and global non-financial reporting systems have prepared the ground for giving sustainability a frame for higher commitment and accountability. Against that background there seems to be no doubt that sustainability will remain on the agenda of companies.

Ernst & Young: Sustainability in the Chemical and Pharmaceutical Industry - A benchmark analysis

Ernst & Young has a long lasting experience in dealing with sustainability as a strategic product offering on a global basis (Ernst & Young, 2010). We are convinced that sustainability will become a substantial part of the corporate governance of a company. Against that background, it is our understanding that

"Sustainability is about creating long-term shareholder value by embracing opportunities and managing risks derived from social, environmental and economic factors. As with any business issues, sustainability risks and opportunities will be different for each individual company." (Ernst & Young – Definition of Sustainability).

However, the exposure of companies to sustainability rather depends on their product portfolio and their stakeholder environment. The chemical and pharmaceutical industry has quite a long tradition in dealing with sustainability issues. Coming from a claim to protect the environment, sustainability has meanwhile become a question of health and safety standards. And, it now seems to be defecting to a holistic management approach, covering all main management functions as part of the mission statement and good corporate governance.

This is the summarized result of a sustainability research in the Chemical and Pharmaceutical Industry which has been conducted during the last months by the Climate Change and Sustainability Services Team of Ernst & Young in Germany. So far, we have had a look at about 20 Chemical and Pharmaceutical companies in Germany and at about 17 further global players within the sector.

The objectives of our research were

- to get an impression of the leading chemical companies' intensity of activities and the commitment to sustainability
- to identify specific fields of strengths and weaknesses in the Chemical and Pharmaceutical Industry as far as sustainability is concerned
- to identify points of improvement
- to get a deeper insight into future developments and expectations.

We compiled a list of criteria and indicators which we considered to be significant for conveying an impression of the commitment and the activities the selected companies are dedicating to sustainability items. The criteria we identified referred to form and content:

- Sustainability Reporting:
  - Does the company publish a sustainability report regularly?
  - Does the sustainability report refer to the Global Reporting Initiative (GRI) criteria?
  - If not, is CR/Sustainability presented in the annual report or does the company at least publish reports on special CR issues, e. g. environmental reports?
  - Is the sustainability report externally verified?
- Corporate Governance and Sustainability Strategy:
  - Does the company have a written mission statement (or core values, vision statement etc.) that refers to sustainability/CR?

- Does the company have guidelines or policies that concretize how sustainability issues should be put into practice (e. g. Code of Conduct, CR Policies, Code of Ethics etc.)?
- Does the company have clear CR objectives or targets – and are these quantified and have a clear timeline?

- CR Organization and Management
  - Does the company have a CR team or a person responsible for sustainability issues?
  - Are other departments involved in the CR/sustainability processes (e. g. matrix organizations, Cross-company CR teams)?
  - Is the top management directly involved in CR/sustainability?
- Environment
  - Do the production sites have a certified environmental management system (ISO 14001 or Eco-Management and Audit Scheme - EMAS)?
  - Does the company have clear environmental objectives?
  - Does the company collect and publish environmental data?
  - How active is the company in the areas of resource protection and savings, compared to others?
  - How active is the company in the areas of environment and climate protection, compared to others?
  - Does the company produce environment-friendly products?
- Employees
  - Does the company commit itself to meeting international social minimum standards (e. g. Human Rights Declaration, International Labour Standards (ILO) conventions)?
  - Does the company have clear Human Resources (HR) objectives?
  - How strong is the company, compared to others, in the areas of:
    - Training and Development?
    - Health and Safety at the workplace?
    - Diversity?
    - Work Life Balance?
  - Does the company conduct employee surveys?
- Supply Chain/Procurement
  - When choosing its suppliers, does the company consider social and environmental criteria and does it give information about its concrete requirements?
  - Does the company regularly audit its suppliers and monitor the suppliers' compliance with the company's requirements?
- Corporate Citizenship
  - Is there a guideline about the handling of donations?
  - How strong is the company in the area of Corporate Citizenship, compared with others?
- Other Aspects
  - Does the Risk Report pay attention to sustainability risks?
  - Is the company included in important sustainability indices?
  - Does the company cooperate with universities, Non-governmental Organizations, political or social institutions?
  - Does the company actively conduct a strong stakeholder dialogue?
  - Is the company member of the "Responsible Care" initiative?
  - Is the company member in other relevant industry or business initiatives about sustainability issues?
  - CR communication: How comprehensive, transparent, consistent and easily accessible is the information about CR on the corporate website?

Based on the sustainability information which has been made available to the public (Sustainability Report, Annual Report, homepage and further publications) we developed a sustainability ranking by awarding credits for each criterion and indicator the company actually meets. Perhaps it is worthwhile mentioning that it is not intended to publish the results of the benchmark in the sense of yet another "good company ranking". Due to a very heterogeneous data basis (both quantitatively and qualitatively), the benchmark is not meant as an objective ranking – but rather as a first assessment and basis for further discussion.

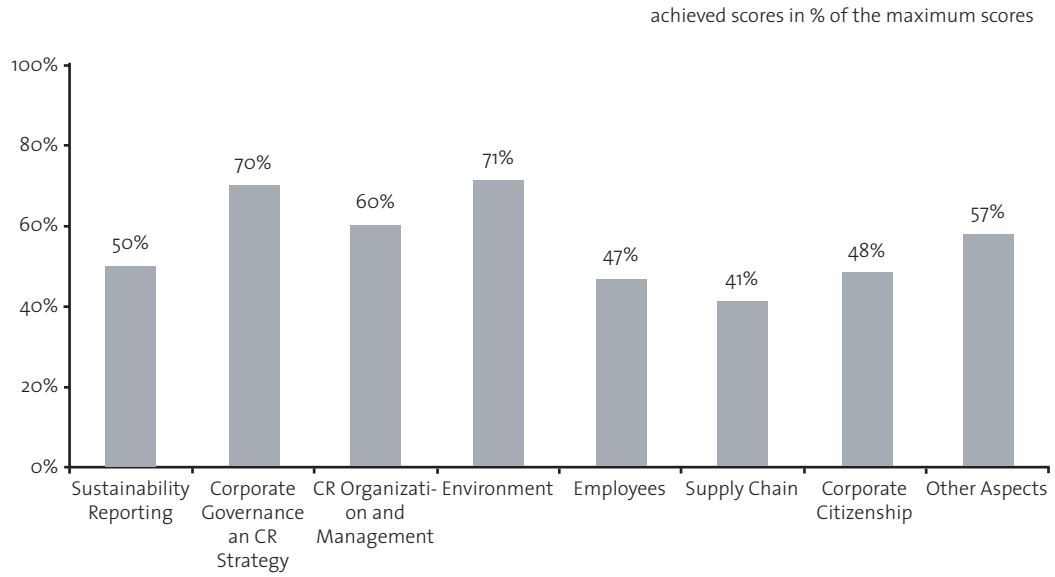
Main Results

A first overall assessment shows main strengths of the analyzed companies in the field of environmental activities, whereas main weaknesses have to be stated with regard to supply chain and global procurement. Therefore, this paper will in the following lay a stronger focus upon those two issues whereas further criteria which had been analyzed will be summarized more briefly.

Environment

As already mentioned above, the Chemical and Pharmaceutical Industry has long experience

Figure 1 Ernst & Young sustainability benchmark analysis – average score of the 8 main benchmark criteria



in the field of sustainability and gave way to a systematic companies' approach. Several environmental accidents have led to greater concern about safety operations of the Chemical and Pharmaceutical Industry. Especially, the "Seveso disaster" in July 1976 in the region of Milan/Italy resulted in the highest known exposure to Dioxin (TCDD) in residential populations and led to studies and standardized industrial safety regulations. As an example, the EU industrial safety regulations are known as the Seveso II Directive which imposed much harsher industrial regulations.

Since then, governments and multilateral organizations around the world have undertaken active initiatives to protecting the environment. Especially in Germany and on a European level a rather extensive environmental legislation process has been implemented during the last decade. Initiatives like the Emission Trading Scheme (ETS), REACH (Registration, Evaluation, Authorisation and Restriction of Chemical substances), voluntary programs, carbon or energy taxes, and standards on energy efficiency are just a few examples of respective efforts which have gained impact on companies' processes, not only in the Chemical and Pharmaceutical Industry.

Hence, it is not surprising that environment issues soon became a main focus of the companies' compliance activities. And, even less surprising, our analysis underlines the relatively high level of activities in the environmental field as well. The 37 inspected companies achieved two thirds of the total points available on average.

However, new challenges are arising and more and more national governments have just decided to put the protection of the environment on their political agenda. Even latecomer China has started becoming a more active participant in the global climate change talks and other multilateral environmental negotiations, and claims to take environmental challenges seriously. President Obama, too, announced higher concern with climate change and plans to become a constructive player in global discussion on how to prevent climate change.

Those developments were seen as a promising indicator for the UN Climate Summit in Copenhagen in December 2009. The Summit was supposed to lead to a new climate strategy and to replace the Kyoto Protocol from 1997. However, things went differently. The outcome of the conference was more than disappointing as it uncovered the gap especially between the Member States of the European Union on the one hand and countries like China, the United States of America, South Africa, India, Brazil, on the other hand in their commitment in dealing with the Carbon Dioxide matter. The Copenhagen Accord which was drafted by countries such as Brazil, China, India, South Africa, and the United States did not become accepted by the participants of the conference as a legally binding agreement. They just agreed "to take note" of it. Hence, it cannot be considered as an appropriate successor to the Kyoto Protocol whose validation will end in 2012 (United Nations Framework Convention on

Climate Change, 2009).

Anyway: Climate Change is and remains the main environmental topic on the global agenda of business and of global and national politics as well. Driving force behind this development is a growing awareness and public discussion of climate change, its consequences to human living and the demand for providing transparency on carbon foot print of operations, product life cycles, etc. National governments and global regulatory bodies are of course main forces in giving those activities a main frame of reference. But also global multi-stakeholder organizations challenge politics and business to providing more transparency and more speed on CO_2 management.

Just to name a few prominent examples:

The **Carbon Disclosure Project** (CDP) is an independent not-for-profit body and maintains the largest database of primary corporate climate change information in the world. It consequently follows up the goal to disclose CO_2-emissions. A growing number of organizations all over the world use this database in order to measure and disclose their greenhouse gas emissions and climate change strategies. And it is the explicit goal of the CDP to "put this information at the heart of financial and policy decision-making." (Carbon Disclosure Project, 2010).

In order to meet reporting requirements, the Greenhouse Gas (GHG) Protocol Initiative, founded in 1998, developed internationally accepted GHG accounting and reporting standards and promotes its use worldwide. The GHG Protocol Initiative says:

"It was designed with the following objectives in mind:

- to help companies prepare a GHG inventory that represents a true and fair account of their emissions, through the use of standardized approaches and principles
- to simplify and reduce costs of compiling a GHG inventory
- to provide business with information that can be used to build an effective strategy to manage and reduce GHG emissions
- to increase consistency and transparency in GHG accounting and reporting among various companies and GHG programs" (The Greenhouse Gas Protocol Initiative, 2010[a])

Today, the GHG Protocol Corporate Standard is the relevant standard for businesses as far as measuring and reporting of the six Greenhouse Gases (carbon dioxide (CO_2), methane (CH_4), nitrous oxide (N_2O), hydrofluorocarbons (HFCs), perfluorocarbons (PFCs), sulphur hexafluoride (SF_6)) as listed in the Kyoto Protocol is concerned. Next steps and challenges are still ahead as there are currently high efforts underway to further expanding the scope of GHG-data collection. So far, the instrument covers all direct emissions, i.e. owned or controlled by a company (Scope 1) and all indirect emissions from use of electricity, steam, heating and cooling (Scope 2). The next step will be the Scope 3 Standard, which will, for the first time," allow companies to look comprehensively at the impact of their corporate value chains, including outsourced activities, supplier manufacturing, and the use of the products they sell. Since January 2010 so called "road testers" of the Product Standard representing 17 countries from every continent and more than 20 industry sectors measure the climate change impact of products." (The Greenhouse Gas Protocol Initiative, 2010[b]).

And the next environmental challenge is already under discussion: Water. Its availability is first of all crucial for the survival of human being and furthermore a main resource for business operations. Due to this outstanding importance there is growing demand that organizations and business operations should approach water similar to their CO_2 management. This would among others include mapping the water footprint according to 'direct, 'indirect' or 'virtual' water impacts and calculating water risks. The World Business Council for Sustainable Development (WBCSD) launched a Global Water Tool at World Water Week 2007 in Stockholm. It became updated in 2009 for the 5th World Water Forum in Istanbul. According to this tool leading questions to assess exposure to water risk are:

- How many of your sites are in extremely water-scarce areas? Which sites are at greatest risk? How will that look in the future?
- How many of your employees live in countries that lack access to improved water and sanitation?
- How many of your suppliers are in water scarce areas now? How many will be in 2025? (World Business Council for Sustainable Development, 2010)

The responsibility for protecting the environment is a far reaching challenge for businesses and operations. The discussion about main points of activities will go on, as elaborations above might have shown. Especially for the Chemical and Pharmaceutical Industry it is a subject of high concern and conjures up main reputational risk factors. But, of course, it also comprises the chan-

ce of becoming a first mover (for example in the field of Water) and moderating this process proactively. Therefore, a strategic and systematic approach to assess and monitor environmental challenges is highly recommended.

Questions companies often ask in this regard are:

- What is the right response to climate change and water shortage for today and the future?
- How do I identify, articulate and weigh the implications and impacts for my organization?
- Am I adequately educating the people in my organization to take action about climate change and water shortage and its implications?
- How important is a climate change strategy to my organization?
- What changes are occurring in different locations where my organization operates?
- What are the implications of inaction?
- What are my competitors and peers doing?
- Does my approach provide competitive advantage?
- Is my strategy helping my organization innovate? How do we keep up with changing risks and opportunities?
- How will implications of climate change and/or water shortage develop over the next few years?

Those questions help to pave the way to develop a tailor-made environmental company profile including elements such as assessment of risks and opportunities, definition of goals and Key Performance Indicators (KPIs), reporting on progress, assessment of reliable data, management guidelines. They are necessary efforts to develop environmental management systems being transparent and accountable.

Sustainable Supply Chain and Global Procurement

Compared to environmental issues that are already paid rather high attention by analyzed companies, the awareness of potential sustainability opportunities and risks coming up from supply chain management have not yet been sufficiently developed. However, several studies have shown that sustainable supply chain management is an instrument to protect reputation, to reduce risks and costs and to enhance revenue growth (Ernst & Young, 2008[a]).

Efficiency and sustainability are two sides of the same coin. For example coming back once again to CO_2 this means in more detail: When there is carbon, there are costs. Hence, knowing the Carbon Footprint of suppliers and building up a carbon orientated logistic strategy would directly serve to increase cost efficiency. And there is a clear perspective on market regulations for limited resources. As such the ETS of the European Union has implemented trading periods for carbon allowances. The next period starting in 2013 already foresees the development to auctioning off of those allowances so that CO_2 will soon turn out to be an additional currency companies will proactively start dealing with.

Beside environmental challenges, supply chain and global procurement also touch varying labour standards worldwide. There is growing concern of the global public community about how companies are dealing with social standards and obligations such as working conditions, children's work or even animal testing. According to the wide range of socially relevant questions there is also a growing number of legally binding regulations on the one hand and a variety of standards companies may comply to voluntarily on the other. Critical incidents of irresponsible handling of social matters within the supply chain have shown a highly sensitive reaction of consumers and the public in general which have repeatedly led to a high damage of companies' brand reputation. But, well managed sustainable supply chain may also serve to further shaping companies' profiles and to develop a business advantage compared to competitors.

Supply chain can make or break corporate reputation. Supply chain management and global procurement have always been crucial to companies' business success. All global companies, chemical and pharmaceutical companies in particular, are aware of the vital importance of their supplier. Traditionally the choice of supplier has mainly been driven by product quality, price, timely and reliable delivery. But the more the public has demanded that products are socially and environmentally responsible, the more those criteria get translated into global procurement decisions. From the perspective of drivers of sustainability, sustainability supply chain management is a kind of litmus test which shows as to whether a company's commitment to sustainability is just "green washing" or whether it is put into practice. The crucial point in this context is, how a company is treating and developing its global suppliers. Questions here are: Is business at least in line with local standards? Or does the company do even more by transferring fundamental working standards of the western world to partners or sites in

the developing world?

When it comes to sustainability, it is necessary to perform a shift in traditional supply chain management. Global procurement and supply chain management have to be expanded on ethical and environmental matters and to be included into established processes. According to that spirit, a sustainable procurement has to include (among others)

- clear standards – socially, ecologically,
- transparent sustainability guidelines
- sensitizing purchasers and suppliers to sustainability expectations
- selection, evaluation and control of suppliers according to those standards and expectations
- appropriate and clear penalty and
- global coverage.

In achieving these goals the development and implementation of a code of conduct for the sustainable supply chain management is highly recommended. Substantial elements of a sustainable supply chain and global procurement management are:

- training of global purchasers and suppliers,
- strengthening the performance of suppliers in NON-OECD countries,
- individualizing suppliers network and training,
- benchmark with procurement settings in competing branches,
- deciding on compliance with ecological and social standards,
- developing an transparent escalation strategy for non-complying suppliers
- developing transparent evaluation and controlling tools,
- defining clear responsibilities in the supply chain – centralized and decentralized.

Sustainable supply chain management is more than a non-binding add-on to the general supply chain management. It has become a crucial point for a company's risk and reputation management. And, it is foreseeable that this development will gain even more momentum all the more sustainable standards and expectations will get an inherent part of supplier contracts. According to the growing interest in ecological and social product life cycles and management standards, a sustainability strategy will no longer be successful without a sustainable global procurement and supply chain management.

Above all: A coherent sustainable Corporate Governance and Management System

In our sustainability analysis there is a companies' average of about 68 % of total points in the field of Corporate Governance and the existence of a clearly defined Sustainability Strategy. The interesting message here is that in fact many of the companies we focused on already have sustainability strategy and corporate governance systems in place. However, most of those initiatives have not yet been aligned to a coherent concept. A closer look at the single guidelines, be it the code of conduct, the risk management policy or any ethical standards, shows that all of them had been developed and implemented with different purposes. Hence, the challenge now lies in revising those policies and putting them in line with one main objective. This might be oriented towards a clearly defined understanding of sustainability as part of good corporate governance. A systematic approach as such would definitely help bringing transparency and credibility into the companies' reputation and help underlining and supporting its "License to Operate".

Almost 60 % of the points available have been achieved for organizational structure and management systems in the field of sustainability. Best-practice examples show that a well organized sustainability management is usually affiliated to a representative of the managing board. This helps to underline that sustainability is of high priority and that it is far away from any kind of arbitrariness. It is a signal which is mostly important towards external as well as internal stakeholders. With regard to the internal companies' world very often inconsistency in commitment towards sustainability has to be noticed. On the one hand there are people highly dedicated to the issue and on the other hand there are others without a deep understanding of the importance and the potential impact the subject may have on business, reputation and sales success. However, it is mostly recommended to close this gap and to supply sustainability in form and content with a cross-functional management approach. One main step on this way is to establish a kind of so called "steering group" with the clear assignment to develop and follow-up a tailor-made sustainability agenda. In that context it is of course necessary to cover all main business and working fields, to map local and global dimension of the business and hence to include all relevant people into this working process. In any case one person should be nominated to coordinate and monitor the process and to be the main con-

tact person for all questions which may be raised internally or externally.

Sustainability Reporting

50 % of the total points have been achieved on average in the field of sustainability reporting. There is a clear development of a growing number of sustainability reports being published on a regular basis, either annually or every second year. The reporting standard having been published by the GRI (Global Reporting Initiative, 2010) more and more turns out to be a substantial guideline and orientation frame in terms of form and content of those reports. The achieved standardization all the more gives liability, accountability and comparability to the non-financial reporting universe. There is no doubt that during the last years non-financial reporting has made a real leap in quality. Feedbacks from financial analysts confirm that information given by sustainability reports is more and more referred to as an additional source to the financial reporting system. Furthermore, a growing number of companies ask for the provision of an independent assurance service in relation to their Sustainability Report. Most of those companies are starting with a so called limited assurance on the HSE - performance data and the HR-related performance data included in the report. In addition, assurance on a number of defined topics and the reporting process is possible. Assurance of the full report is mostly considered to be an option for future years.

There seems to be a growing attention of the financial market towards sustainability reporting and socially responsible investment (Ernst & Young, 2008[b]). Especially, in the process of company evaluation a growing number of so called non-mainstream analysts refer to non-financial data provided by those reports. Non-financials may turn out to be one distinctive feature in the evaluation tool. Furthermore, they may also serve as signal for a long-term strategy of a company and a broader view on potential business risks. Against the background of growing criticism towards a short-term business orientation which the actual financial crisis disclosed to be a misleading perspective, middle- and long term goals would help round off the picture of a sustainably successful and responsibly acting company.

Employees and HR Management

HR Management is of growing concern and is becoming more and more of a business case. According to latest studies, talent management is ranking under the ten main business risks of globally acting companies. Furthermore it becomes evident that the young manager generation has made a substantial shift regarding their criteria for selecting a potential employer (Ernst & Young, 2009). In this context, it is worth mentioning that money and short term career development can no longer be seen as sufficient to attract high-potentials. It is even more necessary to disclose the attitude of a company on how to live up to expectations regarding the companies' responsibility for local infrastructure, environment or even more social balance, locally and globally. Employer branding is an inherent part of reputation management and plays a crucial role in attracting talents and therefore ensuring productivity.

Sustainable leadership, open-minded and transparent leadership communication, responsiveness to employees' concerns, upward feedbacks, credibility of leadership proven in a "walk the talk"-culture and a diversity of cultures and gender are the current success criteria of a sustainable HR Management.

Corporate Citizenship

The engagement of a company for its local surrounding or for global burning issues (such as access to medicine, nutrition, etc.) has a long tradition. Companies are free to decide on how their engagement should look like. However, there is a tendency that these engagements help underline special competence and profile of a company. This would help to further sharpening reputation and is a question of credibility. Against that background, more and more companies have started identifying projects and subjects they plan to focus on and have begun developing a guideline on how to have this engagement put into practice.

Three different stages of sustainability implementation

The management of single sustainability criteria – as elaborated above – is only one result of the Ernst & Young Sustainability Benchmark Study. It also discloses a broad range of levels of an overall sustainability management approach having been adopted and incorporated in the analyzed companies so far.

There are three more or less well-defined groups:

Group One – the lower level

Companies on the lowest level still have not yet developed their own approach to sustainability. Even if a deeper look at the companies' process may disclose single initiatives especially in the field of HR Management, environmental activities such as waste management or, last but not least, activities in the field of corporate citizenship, there is no rounded sustainability picture yet.

Against the background of sustainability becoming more and more important to employees, investors, customers, and other stakeholders, it is highly recommended to get an impression of the potential risks and opportunities. A systematic assessment of current sustainability activities and challenges is a necessary first step to get a picture of the specific risks and opportunities the company is facing with regards to sustainability.

Middle-Ranking Group

A second group of companies has basic understanding of the impact of sustainability on their own business. Coming from a focus on environmental protection, a broader approach that also covers health and safety issues has meanwhile been developed. The so called HSE or HSEQ (Health, Safety Environment and Quality) Groups are taking care of the respective items in the management process by developing goals and KPIs, by arranging audits and certifications, and by developing a reporting system. The HSE(Q) systems mostly cover the main global sites. But, systems often remain partly intransparent and are not incorporated into main management functions, such as Corporate Governance, Global Procurement, Risk Management, Internal Audit, and/or HR. However, for success and credibility it is crucial to practice sustainability throughout the company, top-down as well as bottom-up.

High-Level Group

Companies represented on the highest level already have a broad understanding of sustainability which is reflected in the code of conduct, management principles, etc. Sustainability is seen as a business case which means that the current and future megatrends mentioned above are a main part of the companies' innovation cycle and product development. There are only a few shortfalls worth mentioning, which are most likely in the field of talent management and global procurement. Companies in this group are the main benchmark and forefront of the further sustainability development in general.

Further prospects of sustainability

The future of sustainability remains to be seen. Its discussion has not yet come to an end – neither in the global community in general nor in politics or companies. There are many interests driving sustainability. Most of them spring from ethical expectation to protect global survival and to enable welfare and social development. With regards to politics there will be further discussions necessary about how to draw the global bow and to set a regulatory framework helping to ensure the challenges of a sustainable world.

The expectations regarding the role companies may play in this global setting have become more or less clear: Business should account for responsible manufacturing and trading processes: responsible meaning both socially and ecologically. Companies are answering this new ethical attitude by implementing respective structures and processes into their management, by developing goals and reporting efforts and achievements, accordingly. Even if ways of treating sustainability expectations have already led to quite high acceptance and incorporation of sustainability into management thinking, these actions remain to be reactive. However, the more the discussion of sustainability reaches politics, legislation, standard setting bodies and the financial world, the more it becomes an element for the creation of business value. This development seems to gain momentum and will make a paradigm shift necessary that will turn sustainability into a basic part of companies' strategy and in so far into a business case.

Designing sustainability to a business model will be far more than identifying, evaluating and reporting relevant KPIs of the management process. It will have go beyond focusing on the reduction sustainability risks in the global manufacturing, on implementing sustainability into buying, selling and management processes. Sustainable business is a long term business model. As such it will need to have an impact on market and product development. It will influence innovation processes and will get more management groups of a company and even its controlling bodies involved. Against that background sustainable management should not only be concentrating on the companies' adherence to social and ecological standards and reflecting them in code of conduct and management behaviour. Sustainable management approaches should also turn the question right the way round by asking for

the contribution, that sustainability (social and ecological criteria in particular) may give to business development and value creation. If sustainability succeeds in becoming a business driver the reservation and latent criticism towards the gap between business thinking and "green washing"-communication might disappear. And more importantly, touching the heart of business, sustainability will be a criterion for innovation, product development and the evaluation of business success.

As far as the chemical and pharmaceutical industry is concerned sustainable business strategies will have to meet with both: new challenges in the industrialized world, such as lifestyle diseases or demand for "eco-products", and the need to help overcome current global challenges, such as hunger, global nutrition, global access to medicine, water shortage and climate change. There will be no doubt that in the future companies will be further commissioned to political goals (e. g. Millennium Development Goals), financial markets expectations and the acceptance of a further diversified global consumer community. Stakeholders will furthermore represent virtual expectations of consumers in developing countries who are not able to raise their voice and to articulate their claims. The crucial question will be whether companies will be able to turn a moralized global market and political environment into business success.

Sustainability becoming part of business modelling will have to build on at least five more or less well defined steps:

(1) awareness and management of sustainability risks,
(2) identification and management of opportunities deriving from sustainability,
(3) analysis of future scenario regarding sustainable regulatory and market developments
(4) integration into innovation, business life cycle management and product development and
(5) changed market appearance, stakeholder management and reporting.

Ernst & Young as a multidisciplinary solution provider could be the partner with whom to face this new challenge and to accompany companies on their way to a value creating sustainable business model.

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