CHEManager EUROPE

5/2007 June

THE NEWSPAPER FOR THE CHEMICAL AND LIFE SCIENCES MARKETS

Markets & Companies

Doing business in China can be challenging and rewarding

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Chemicals

It's ChemSpec time! Can the show live up to expectations?

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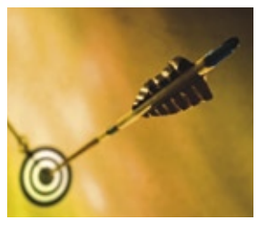


Newsflow

According to Bloomberg reports, Saudi Basic Industries Corp. (Sabic) will will buy General Electric's plastics unit for about US-$11 billion. The acquisition is the largest ever in the Persian Gulf and the price is above the US-$8–10 billion estimated by some investors. GE placed the plastics unit, where profit last year slipped 22% to US-$674 million, on the block in January. GE and Sabic declined to comment.

▶ www.sabic.com
▶ www.ge.com

Rhodia announced the completion of the sale of its 50% stake in Nylstar to a third party agent acting on behalf of a consortium of Nylstar's credit banks on 14 May. SNIA, Rhodia's partner in this joint venture, has also completed the sale of its 50% stake. This sale forms part of the financial restructuring of Nylstar.

▶ www.rhodia.com
▶ www.nylstar.com

Akzo Nobel has announced that Dr. Jörg Spiekerkötter, CFO and member of the board of management of its subsidiary, Organon BioSciences, will leave the company. Organon BioSciences CEO Toon Wilderbeek will continue to lead Organon BioSciences until the deal is closed.

▶ www.akzonobel.com

John P. Jones, chairman and chief executive officer of Air Products, will retire as CEO on 1 October, after 35 years with the company. The board of directors has appointed John E. McGlade, currently president and chief operating officer, to succeed Jones as CEO. McGlade also has been elected a director of the company effective immediately. Jones will continue as chairman of the board until 31 March to provide for an orderly transition of responsibilities.

▶ www.airproducts.com

Celanese announced that a second public offering of 22.1 million Class A shares had been completed.The selling stockholders, funds affiliated with the Blackstone Group, told Celanese they completed a registered public secondary offering of 22,106,597 shares of the company's Series A common stock under Celanese's universal shelf registration statement filed in May.

▶ www.celanese.com

Reach Is Here

ReachCentrum Helps Companies Untangle the Legislation Web

ReachCentrum, a 100% subsidiary of Cefic, was set up one year ago with the goal of supporting companies throughout the Reach process. Since then, the organisation has provided workshops, newsletters and individual training for companies. Now that Reach will officially go into effect on 1 June, Cefic's executive director Thomas Jostmann has been busy making sure companies know the basics of what's to come. Brandi Schuster spoke with him about the new legislation and concerns he's been hearing from companies.

Thomas Jostmann
Cefic's executive director

CHEManager Europe: Mr. Jostmann, first of all, happy birthday. How have ReachCentrum's first 12 months been?

T. Jostmann: We've started with general Reach workshops and in depth training sessions, which have been very successful thus far. We have recognised a real need for general information; the many questions that have been raised during these workshops have indicated that there's a huge demand for getting more hands-on experience and for more information on how to implement Reach. We've also started these services in order to enable networks of national associations that represent companies throughout Europe providing the same kind of services. This will help organisations to deal with Reach by providing necessary tools and support to facilitate the cooperation of companies.

What else do you offer?

T. Jostmann: One of the key success factors for companies to successfully cooperate is an effective consortia management. We provide management support, guidance throughout the Reach process, help with reviewing the dossiers which

▶ Continues Page 15

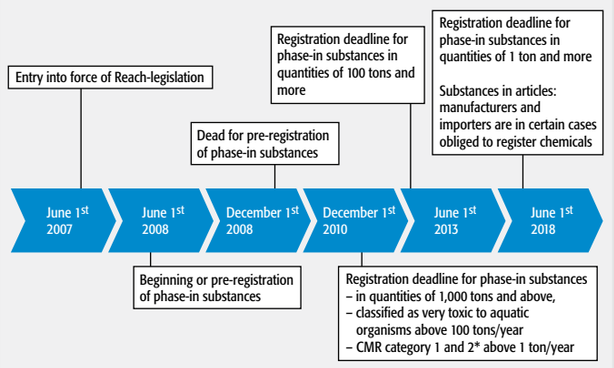
MARKET REPORT

Calculating the Full Impact of Reach

By Dr. Michael Fahrbach, KPMG

Chemical companies and their downstream users are bracing themselves for the impact of Reach, the new regulation for Registration, Evaluation, Authorization and Restriction of Chemicals in the European Union that will replace existing legislation in June. Concern over compliance is widespread, given the huge nature of the task. Ensuring product safety will require widespread changes to organisational structures, operational procedures and communication lines up and down the supply chain, plus an increase in risk management activities. To date,

Reach – Time table **Figure 1**



* CMR = carcinogens, mutagens and reprotoxic

Source: KPMG © GIT VERLAG

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Investment In Quality

Helsinn is Fully Dedicated to cGMP Production

Helsinn is a developer and manufacturer of active pharmaceutical ingredients and high-potency active ingredients. The privately owned Swiss-based group delivers cGMP products for clinical trials from small quantities for early phase up to tens of tons for commercial supply through its subsidiaries Helsinn Chemicals and Helsinn Advanced Synthesis. The latter, with a new plant in Biasca, Switzerland, on stream since October 2001, has enabled the group's chemical operations to enter the field of HPAI and strenghten API manufacturing. CHEManager Europe asked Giorgio Calderari, Ph.D., Helsinn's chief operating officer, about the beginning and the development of his company's cGMP production and their commitment to the highest standards of quality.

Giorgio Calderari Ph.D.
Chief Operating Officer of Helsinn

CHEManager Europe: Dr. Calderari, how have Helsinn's chemical operations grown and arrived at the actual stage? When did Helsinn start cGMP production?

Dr. G. Calderari: The Helsinn Pharmaceutical Group started activities in 1976. From 1983 several investments where done in the group's chemical operations that grew from a total capacity of 17m³ in 1984 to today's total production capacity of 117 m³. This total production capacity includes classical intermediates and APIs, but more and more high-containment technology for the production of high-potency active wingredients and APIs with special handling requirements. cGMP production in Biasca started from the very beginning back in March 1984 after a cGMP inspection from the Swiss authorities. The production of other, non-pharmaceutical chemicals in the multipurpose plant was performed

▶ Continues Page 14

Logistics For China

Talke Teams up with Kerry Logistics

In the fall of 2006, Talke Logistic opened its first office in China. The company has since strengthed its presence and activities on the Chinese market through a joint venture with Kerry Logistics, which is located there. This new constellation should enable Talke to offer onsite services such as warehousing and processing on production sites of customers from the chemical industry active in the Chinese market. CHEManager Europe asked Richard Heath, Alfred Talke's chief business development officer and Vincent Wong, Kerry Logistics' joint managing director, about the current situation on China's logistics market and about the two companies' plans for chemical logistics in China. The interview was conducted by Dr. Sonja Andres.

Richard Heath
Chief business development officer for Talke

Vincent Wong
Joint managing director for Kerry Logistics

CHEManager Europe: How does the logistics market in the Chinese chemical sector look today?

V. Wong: The Chinese chemical sector has predominantly managed its own logistics in the past. Logistics and material handling activities are mainly done in-house and third parties are used for transportation

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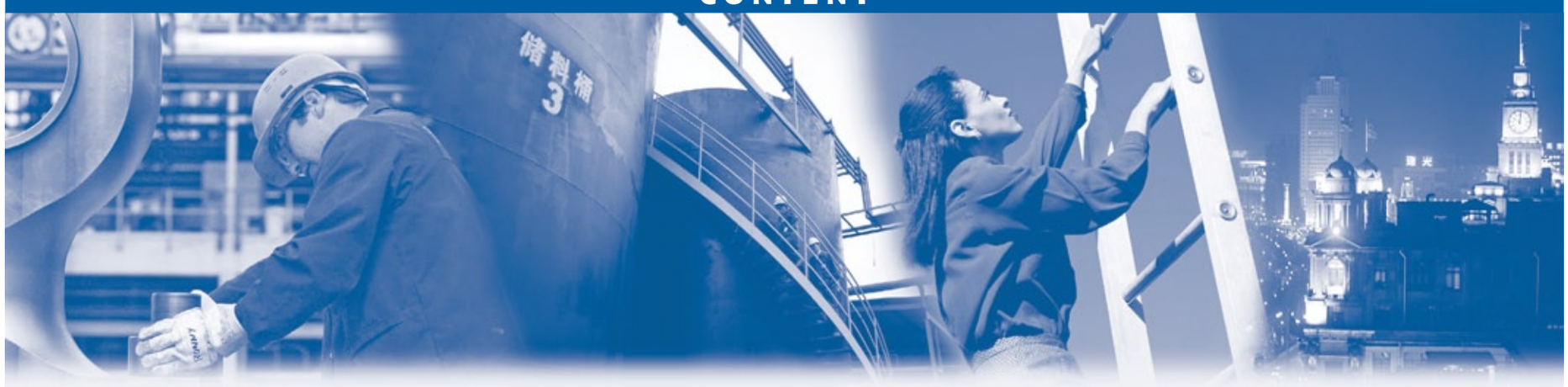


Rhodia Reports Strong First Quarter

Rhodia has reported that its net sales were up 4.7% to €1,260 million in the first quarter of 2007. The company's recurring EBITDA was up 27% to €205 million, versus €161 million in the first quarter 2006. Operating profit jumped 88% to €130 million from €69 million in the first quarter 2006. The company has also reported a net profit of €59 million, versus a €36 million loss in the first quarter 2006. The company said highlights included solid demand levels and strong pricing at the beginning of the year ; the closing of Silicones and Rhodia Organics' Sulphuric products divestments with significant capital gains recorded in the first quarter; and continuing refinancing efforts resulting in significant reduction in future interest costs.

Jean-Pierre Clamadieu
Rhodia CEO

"Rhodia is progressing along its route to profitable growth."

"The first quarter 2007 marks a solid start to the year. Operating performance has continued to progress," said Chief Executive Officer Jean-Pierre Clamadieu. "Rhodia is progressing along its route to profitable growth by building on the businesses in which we enjoy solid leadership positions."

▶ www.rhodia.com

Clariant Sells Custom Manufacturing Business

Clariant said it has sold its Custom Manufacturing Business to International Chemical Investors Group (ICIG) for an undisclosed transaction value. The company said that the sale is the latest step in its strategy to focus on its core competencies in colours, surfaces and performance chemicals. Clariant's Customer Manufacturing Business supplies a wide range of intermediates and actives ingredients for the agrochemicals, pharmaceuticals and polymers industries.

At closing, the new autonomous entity will be one of the world's leading suppliers to the agrochemicals industry with production sites in Germany and the U.S. In 2006, the Custom Manufacturing Business had sales of around CHF 217 million and about 490 employees. Clariant said it expects to record a book loss of approximately CHF 70 million. The transaction is expected to close by mid-year after fulfilment of local transfer requirements such as approval of all relevant authorities. All assets and personnel will be transferred to the buyer.

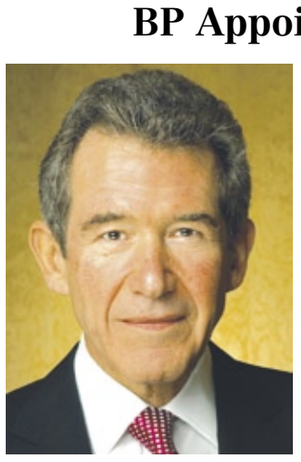
Jan Secher
Clariant CEO

"It is a major step in focusing our business portfolio."

Jan Secher, Clariant's CEO, said: "As an independent entity supported by a committed investor, the Custom Manufacturing Business has an excellent opportunity to improve its performance in the future. It is a major step in focusing our business portfolio on colours, surfaces and performance chemicals."

▶ www.clariant.com
▶ www.ic-investors.com

BP Appoints Tony Hayward as CEO



Lord John Browne

Tony Hayward

Following a decision by Lord John Browne to step down as the company's CEO, the board of BP has appointed his designated successor, Dr. Tony Hayward, as new CEO with immediate effect. Lord Browne resigned after the lifting by the UK courts of a legal injunction preventing the publication of details of his private life. Lord Browne said: "In my 41 years with BP, I have kept my private life separate from my business life. I have always regarded my sexuality as a personal matter, to be kept private. In particular, I deny categorically any allegations of improper conduct relating to BP."

BP chairman Peter Sutherland said that Lord Browne had informed the company of allegations relating to the limited use by Jeff Chevalier of BP computer and staff resources. Sutherland said: "At John's explicit request, the board instigated a review of the evidence. That review concluded that the allegations of misuse of company assets and resources were unfounded or insubstantive."

▶ www.bp.com

Galapagos Announces Agreement with EPA

Galapagos announced that its service division BioFocus DPI has entered into a multi year compound management agreement with the U.S. Environmental Protection Agency. BioFocus DPI will provide chemical procurement and compound management services as part of the EPA's ToxCast Program (Prioritisation of Environmentally Relevant Chemicals). The contract covers a period of up to five years and has a total value of up to €6.3 million.

Under the agreement BioFocus DPI will acquire, analyse, store, format and deliver specific compounds to a variety of sites selected by the EPA. The total size of the collection will be determined at the EPA's discretion.

▶ www.glpg.com

EU Commission OKs Statoil, Hydro Merger

Statoil and Hydro have received clearance from the European Commission for the announced merger between Norsk Hydro ASA's petroleum activities and Statoil ASA. The European Commission has declared that the merger is compatible with the common market pursuant to Article 6(1)(b) of the EC Merger Regulation. The clearance represents a major step forward for Statoil and Hydro in order to complete the planned merger. Merger clearances are still in the process of being obtained in other jurisdictions as required by applicable laws.

▶ www.statoil.com
▶ www.hydro.com

Doing Business In China

Opportunities and Challenges for European Companies

The growth of the Chinese economy is well known and well documented. The compound growth since 1995 has been 9%, with an impressive rate of 10.7% in 2006. Now China's overall GDP ranks sixth in the world, and the country has the world's second-largest foreign exchange reserve. Furthermore, it is a very popular destination for forward direct investment, taking in some one billion dollars a week.

Ting Zhang
China Business Solutions CEO

With about the same land area as the U.S., but with four times the population, China provides potentially the world's greatest internal market. The Chinese economy is also becoming substantially more sophisticated and advanced technologically, and this tendency is also evident in the patterns of its own internal market. Take the information communication sectors for example, China is the world's largest market for mobile telephones, with over 450 million users by the end of 2006, while it is issuing licences for third-generation operations during 2007. It is the world's largest market for semiconductors. It is the second-largest market in the world for personal computers and also for internet services, with 123 million users as of the end of 2006. The Chinese software industry is usually regarded as lagging that of India, but this also is developing rapidly.

These more advanced developments proceed against a background of continual development in more traditional industries such as steel and cement, where China is by far the largest producer and consumer in the world as it continues to develop its housing, its industrial plants and its infrastructure. A large part of the new industrial development is concentrated in number of powerful municipalities of Beijing, Tianjin, Shanghai, Guangzhou, located in the Bohai Rim, Yangzi Delta, Pearl River Delta respectively.

No Longer a Cheap Sweatshop

Although it is popular in the West to depict China's economic development as one driven by an endless supply of cheap labour, with figures like €2 a day being frequently cited for manual workers, China is less and less a low-wage-cost country. Social costs are substantially higher than in most other Asian countries, while increasing labour shortages, and especially shortages in skilled operatives, are driving up production costs. At the same time, however, the efficiency of the productive apparatus is increasing with such rapidity as to more than compensate for these increases in labour and associated costs. The attractions of a more highly skilled and better-educated workforce, allowing research and development also to be localised and even outsourced and off-shored, together with the associated high quality of outsourced manufacturing and its close proximity of the rest of the Asian market, continue to make China a most interesting proposition for business investment and development.

When Chinese cost structures are seen in relation to those of UK, it is clear that the lower wages (and then only in exchange rate terms, these being much higher in purchasing-power terms) can be counter-balanced by the higher levels of knowledge encapsulated in such areas as automation and process control. But then cost is not the only driver, and indeed much of the attraction of China today resides in the higher efficiencies of many of its supply chains. These are in turn often associated with a rapid increase in the number and variety of research and development centres in China.

Emerging S&T Power

The country is emerging as a strong science and technology (S&T) base. About 250 000 engineering students are currently enrolled in higher education every year and China is increasingly becoming competitive in advanced technologies, with new technology standards being created by Chinese for China. Sophisticated local taste and preference are strong drivers for a Chinese way of technology approach and development. The Government is keen to encourage S&T as a driver of the new economy. For example, the Chinese Ministry of S&T launched S&T funding programmes worth €10 billion in 2005, the lion part of which is dedicated to high technology R&D, but key basic research gets its fair share as well. R&D intensity has more than doubled from 0.6% of GDP in 1995 to just over 1.34% in 2005. In 2007 two-thirds of Chinese research spending is expected to come from industry and one-third from the government. In the meantime the number of foreign R&D centres in Shanghai, Beijing, and Chengdu are steadily increasing, reaching over 720 by the end of 2006.

China's goal for S&T is coming from a big nation going to a strong nation based on an innovative society. Even though currently only 5% of patents filed by Chinese nationals are on inventions, the country focuses on technology development for scientific and technological independence, in a well-promoted drive known as "self-innovation."

At the same time as these internal transformations are proceeding, China is itself becoming a major overseas investor. The investments cover a wide field, ranging from securing sources of industry-strategic raw materials to such purchases as that of IBM's PC business by Lenovo.

Key Areas For Development

Looking forward, the Chinese economy is expected to grow at an annual rate of 8% during the period of the 11th Five-Year Plan (2006–10). Accelerated industrialization and local governments' strong desire to develop their economy will be the backbone of future economic growth. The per capita income of urban and rural residents grew by annual averages of 9.2% and 5.2% from 2001 to 2005.

This improved standard of living allowed for increased spending on healthcare, transportation, telecommunications, education, entertainment and housing, rather than just food and clothing. The urban population of 450 million, largely housed in 34 cities with more than a million inhabitants, includes a rapidly emerging and developing middle class. The upgrading of the consumption structure will cause an upgrading of the industrial structure.

However China will continue to face a number of obstacles in the course of its future economic development. The nation's resources and the environment are coming under greater pressure as China strives to maintain sustainable development. China's market economy is far from perfect, resulting in poor quality growth. The gaps between different regions, and rural and urban areas, and the income gap between different groups will also have an impact on social stability.

The key areas for economic and social development in China for the next 15 years include:

- Manufacturing & information industries – to master core technologies for global competitiveness
- Agricultural S&T – to promote comprehensive productivity capabilities & ensure food safety
- Energy – exploration, energy saving technology and clean energy
- Environment – major cities & industries to set up technological development modes for a recycled economy
- Healthcare – disease prevention & management. Development and manufacture of new drugs, medical equipment and industrialisation
- New technologies – nanotechnologies and convergence of technologies
- Natural resources – water and natural resources from mining to distribution
- Communication & Transport – include equipment for building & maintenance of infrastructure; new energy automobiles

Along with China's integration into the global economy, the nation will further increase the levels of capital, advanced technology and management expertise introduced from developed countries, to expand its development.

Challenges

Clearly China has a lot to offer to Europe, especially in the areas of science and technology, and their relations to a variety of markets. Europe in return also has much to offer China, and indeed also in these areas, but then these originate within very different social and cultural contexts. It will therefore be useful to review the pragmatics of this relationship, beginning with the most common issues, as follows.

Among the most commonly cited difficulties for Europeans when trading and working with Chinese are the barriers to effective communication that arise through differences of language and culture. Although the extraordinary statistic that 300 million Chinese are currently learning English, the overall English speaking level is still very low, particularly within mid-aged management level.

The next-most cited issue when trading in China is the lack of knowledge of the market. This is often closely related to the cultural issue but the market also still has legacy from the previous planned economy with complicated regulatory issues for different industries. The difficulty experienced in recruiting and retaining local staff of a suitable quality is another issue that often arises. Due to a huge influx of foreign investment into China and also the rapid growth of the Chinese economy, the market for skilled labour is very competitive and some foreign companies have reported over 20% annual staff turnover, particularly related to high and new technologies.

Issues that are more widely shared – and the pain from which is more evenly spread – are those of over-administration, bureaucracy and corruption.

The last major issue and one that is often not taken seriously enough, has to do with lacunae in the rule of law, in particular on intellectual property rights: obtaining some kind of justice in the first place and enforcing any resulting court orders subsequently. These are problems that require excellent partners who are able to find their way through the system – but then such problems are by no means limited to China, and indeed many European companies have also experienced similar problems in the U.S.

Success Factors

- There must be a commitment from the leadership of the company to a long-term, value-building perspective. China is a market that requires ongoing sponsoring and support from the top executives and decision makers.
- The technologies brought into play must be the 'best in class', and supported by a sound understanding of their sociotechnical environments.
- Proper attention must be given to training and education in Chinese culture and business practices.
- Considerable effort must be put into identifying and securing a good local business partner.
- The ability to recruit and retain best people. Local staff should be motivated by promoting their all-round development and by consequent promotion.

For European companies with drive, flexibility and innovation, there are enormous opportunities to be discovered in China. And there is no better timing that now to start doing business in China.

Ting Zhang is the founder and CEO of China Business Solutions Ltd, a China specialist firm based in Cambridge, UK. The company provides a whole range of consulting and research services as well as China recruitment and executive search.

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Global Biotechnology Makes Historic Advances

Ernst & Young's 2007 Global Biotechnology Report

Strong product pipelines and product success, record-breaking financing totals, unprecedented deal activity and impressive financial results mark historic industry advances, according to Beyond Borders: Global Biotechnology Report 2007, Ernst & Young's 21st annual report on the biotechnology industry.

"The industry in the U.S. has never been stronger, and we're seeing its success story spreading to other parts of the world – particularly Europe," said Glen Giovannetti, Ernst & Young's global biotechnology leader. "Time will determine whether these trends will be sustained, but there's reason for optimism. Innovation is being rewarded with record revenues and unprecedented premiums in M&A transactions."

Multi-faceted Success

By virtually every performance indicator, the global biotechnology industry showed robust growth in 2006: Deal values soared, with alliances involving U.S. companies totalling US-$23 billion – an all-time record – while high premiums (the difference between the price per share paid by a buyer and the company's share price before the deal was announced) drove the value of mergers and acquisitions (M&A) to the second-highest level in the industry's history.

Capital raised by the world's biotechnology companies grew by 42% to US-$27.9 billion. Venture capital (VC) reached US-$5.4 billion, an all-time high.

Global public company revenues grew by robust double-digit rates and crossed the US-$70 billion threshold for the first time. Double-digit revenue growth was achieved in Canada (22%) the U.S. (14%) and in Europe (14%).

Net losses of publicly traded companies fell by 37% in Europe and 43% in Canada, creating momentum toward profitability. While the U.S. sector saw increased net losses, this was due primarily to large transaction-related charges in a year of unprecedented deal activity; in the absence of these, the U.S. industry would have been profitable in aggregate for the first time, and the global industry would have had its lowest net-loss ever.

U.S. product approvals increased from 33 in 2005 to 36 in 2006. New drug application (NDA) and biologic license application (BLA) approvals grew from 21 to 25. In Europe, product pipelines of public companies grew significantly.

The Year of the Deal

Intense competition, particularly among pharmaceutical buyers, created a robust deal environment in 2006. The average premium in M&A transactions with values over US-$500 million increased to 60% in 2006, more than twice the average M&A premium from 2003 to 2005. Several companies in the U.S. were acquired for premiums in the 50% range, with some crossing the 100% threshold. In a reversal of recent trends, pharmaceutical buyers gravitated towards early-stage platforms and technologies.

"In many ways, 2006 was the year of the deal – but this is all the more remarkable because there was no one deal of the year," said Giovannetti. "In prior years high deal-value totals were typically driven by a single mega deal, but in 2006 we now have widespread recognition among buyers of the potential value in biotech's platforms and pipelines. That's remarkable, and a testament to the tremendous innovation of the global drug development industry."

U.S. Strong and Approaching Profitability

The U.S. had another strong year for product approvals with 36, including 25 NDAs and BLAs. This compares favourably with 2005, when the industry secured 33 approvals, including 21 NDAs and BLAs. Capital raised increased by 38%, fueled by some of the largest financings in industry history. U.S. revenue grew by 13% among public and private biotech companies to US-$59 billion, and the industry made a truly historic move toward profitability. In the absence of over US-$4 billion in acquired in-process research and development charges related to the year's unprecedented deal activity, the U.S. publicly-traded sector would have shown an aggregate net profit, for the first time in its history. Notably, the largest revenue growth companies in the U.S. included "mid-tier" firms with recent product launches and rapidly growing sales.

"We predicted profitability in the U.S. industry before the end of the decade," said Mike Hildreth, Americas biotechnology leader, Ernst & Young. "Only a strong deal year with high charges for in-process research and development kept the industry from reaching that goal this year."

Sustained Progress in European Recovery

The European biotech sector sustained the recovery it had begun in 2005, with revenue growth of 13% – more then twice the 2005 growth rate of 6% – contributing to revenues (for public and private biotech companies) of €13.3 billion (US-$16.6 billion). 2006 marks a four-year turnaround, from the 12% revenue decline recorded in 2003. Financing increased by a robust 45% to reach €4.7 billion (US-$5.9 billion). VC financings reached an all-time high of €1.5 billion (US-$1.9 billion). The pipelines of publicly traded companies grew an impressive 30%, bringing the overall pipeline to almost 700 compounds, plus 27 in registration and awaiting regulatory approval. In addition, Europe's privately held biotechs have nearly 800 compounds in their pipelines, and 12 compounds in registration.

"Last year, there was cautious optimism in the European biotech industry – as the sector emerged from a prolonged period of restructuring," said Siegfried Bialojan, Germany biotechnology leader, Ernst & Young. "This year, double-digit revenue growth – and sustained success across multiple measures – prove Europe's biotech sector has bounced back."

Emerging Solutions for Asia-Pacific Challenges

In Asia-Pacific, governments and companies are moving aggressively to make the transition from competing on cost to developing home-grown innovative pipelines. Businesses are adopting creative models to overcome capital constraints and other hurdles. Firms are reinvesting revenues from services to develop innovative pipelines, and are entering deals to accelerate commercialization efforts, drive economies of scale and increase global competitiveness. Conglomerates are entering the fray, making investments in the growing sector.

"Asian biotechnology companies face critical challenges in their efforts to accelerate the transition to become enterprises driven by research and development," said Utkarsh Palnitkar, India biotechnology leader, Ernst & Young. "Companies are leveraging the Asian advantage in bio-manufacturing and the contract services arena and utilising them to drive the growth story in drug discovery and research."

Outlook: Challenges of Success Will Drive Deals

With the biotech industry maturing in more regions, an increasing number of companies will have to deal with the challenges of success. This year's report features results of an Ernst & Young survey of over 400 biotechnology CEOs, at small, mid-sized and large biotech companies, which found that some of the fastest growing challenges facing their companies are issues facing maturing companies: ensuring regulatory compliance for sales forces, dealing with pricing pressures, expanding globally, and managing global operations. Survey respondents also were resoundingly optimistic. Ninety-four percent of respondents indicated they plan to hire new talent in the next two years, and 68% indicated plans to introduce new products within two years.

These challenges of success will drive even more deal activity in the years ahead according to survey respondents: 99% of Americas CEOs and 87% of European CEOs plan to enter deals in the next two years, with "sales and marketing assistance" being the most popular reason for entering alliances; and 52% of CEOs plan to partner to bring new products to market, up from 29% of products that are currently marketed with the help of partners.

"Maturation brings greater responsibilities, including greater regulatory challenges and heightened investor scrutiny," said Giovannetti. "Despite these challenges, the biotechnology sector still holds great promise for innovative companies and is comfortably on track to become a US-$100 billion revenue industry before the end of the decade."

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Kemira Acquires Coagulant Business

The agreement between Kemira and Dalquim Industria e Comercio, Brazil has been confirmed. Kemira Water Solutions Brasil acquires the shares of two companies conducting the coagulant business of Dalquim Industria e Comercio. Dalquim is a manufacturers of aluminum based coagulants in the South of Brazil. The revenue of the coagulant business is approximately €12 million.

The target companies are located in the south of Brazil and have two production units. Main customer base is the paper industry and municipalities for potable and wastewater treatment. The company will be targeting the fast expanding paper industry and potable and waste water treatment sector in the southern states of Brazil.

▶ www.kemira.com

BYK-Chemie USA Acquires Bergen Materials

BYK-Chemie USA, the U.S.-subsidiary of BYK-Chemie, member of Altana, acquired the business of Bergen Materials, a U.S.-based additives supplier serving customers in the paint and plastics industries. Net sales of Bergen Materials is approximately US-$3 million. BYK-Chemie will take over the activities of the company, including all client relationships and production assets.

▶ www.byk-chemie.com

chemanager@gitverlag.com

Lanxess: CEO Pushes for Degussa Takeover According to reports, Lanxess is continuing to push for a takeover of Degussa. CEO Axel Heitmann is offering €4–6 billion for the speciality chemicals producer, exclusive of debt and pension obligations, as an alternative to a planned stock launch of Degussa's parent, German energy group RAG. A merger of the two chemical and plastics companies, with a complementary portfolio, would represent "a historic chance" to create a second major German player, behind BASF, Heitmann remarked.

▶ www.lanxess.com
▶ www.degussa.com

Dow Polyurethanes Acquires Hyperlast Dow Polyurethanes, a business group of The Dow Chemical Company, has completed the acquisition of British Vita's polyurethane systems business, Hyperlast. The Hyperlast acquisition includes elastomer systems enterprises in the UK and North America as well as Autothane, a manufacturer of advanced automotive suspension components.

▶ www.dow.com
▶ www.hyperlast.com

Arkema Sells Specialty Amines Business Arkema said it has sold its specialty amines activity produced in the Riverview (Michigan, U.S.) facility to Taminco. Part of the Thiochemicals business unit, this activity generates sales of some US-$72 million. This divestment is part of Arkema's strategy for a selective management of its asset portfolio. Arkema said the deal is part of the transformation drive initiated at the time of its creation, and represents a further step in its portfolio re-centering process.

▶ www.arkema.com
▶ www.taminco.com

GS Capital Partners to Acquire Myers Industries Myers Industries announced a definitive agreement to be acquired by GS Capital Partners (GSCP) in a transaction valued at approximately US-$1.07 billion including the assumption or repayment of approximately US-$276.0 million of debt. Under the terms of the agreement, GSCP will acquire all of the outstanding shares of Myers Industries' common stock. Shareholders will receive US-$22.50 per share in cash for each share of common stock they hold.

The board of directors of Myers Industries, on the unanimous recommendation of a special committee, has unanimously approved the transaction and will recommend that Myers' shareholders approve the proposed sale. The transaction is subject to certain closing conditions, including the approval of Myers Industries' shareholders, regulatory approvals, and the other customary conditions of closing. There is no financing condition to complete the transaction.

▶ www.myersind.com

BASF to Sell Chemische Fabrik Wibarco to Hansa Chemie BASF has signed an agreement to sell its subsidiary Chemische Fabrik Wibarco to Hansa Chemie International (HCI), Zurich, Switzerland. Both companies have agreed not to disclose the transaction price or other financial details. The transaction, which is subject to antitrust approval, is expected to close in July 2007.

Wibarco, located in Ibbenbüren in northern Germany, mainly produces linear alkylbenzene (LAB). LAB is a starting material for linear alkylbenzene sulfonate (LAS), a key component of most modern detergents. Hansa Chemie International will take over the Ibbenbüren site with a workforce of approximately 80 employees.

▶ www.basf.com
▶ www.hansachemie.eu

Akzo Nobel Acquires Ceilcote Business Akzo Nobel has strengthened its leading position in the global protective coatings market after signing an agreement to acquire the worldwide Ceilcote business from the German-based KCH Group for close to €12 million.

"This deal underlines our strong commitment to delivering on Akzo Nobel's ambitious growth strategy," explained CEO Hans Wijers.

Established in Cleveland, Ohio, in the U.S. in 1926, Ceilcote – which employees 36 people – is a global operation, with a regional sales office situated in Singapore. Last year, the company relocated its main manufacturing facility and headquarters to a new facility in Berea, Ohio.

▶ www.akzonobel.com
▶ www.ceilcotecc.com

Syngenta to Take Stake in Sanbei Syngenta said it agreed to take a 49% minority stake in Sanbei Seed, a Chinese corn seeds company headquartered in Longhua, Hebei Province. The transaction is subject to the required approvals from the Chinese authorities. Further details of the transaction have not been disclosed. Established in 1998, Sanbei is one of the larger high-value corn seeds companies in China. More than 90% of Sanbei's sales are generated by corn seeds. In 2006, the company reported sales of approximately $30 million. Sanbei has around 500 employees.

▶ www.syngenta.com

Merck KGaA Sells Generics Business Merck KGaA said it will sell its generics business to Mylan Laboratories, Canonsburg, Penn. (U.S.). Merck and Mylan have signed a share purchase agreement whereby Mylan will acquire all Merck Generics companies throughout the world for €4.9 billion. The divested generics business represents €1,802 million of sales in 2006. The agreement is subject to regulatory approval. Closing of the transaction is expected in the second half of 2007.

▶ www.merck.com
▶ www.mylan.com

Symrise Profit Up 81% German flavor and fragrances company Symrise has reported an 81% rise in first-quarter net profit, on high growth in both its main divisions and effective cost management. Net profit to the end of March was €29.2 million, up from €16.1 million a year ago, and beating analyst expectations of €27.8 million. First-quarter earnings before interest, taxation, depreciation and amortization came in at €73.5 million, up 20% from the €61.1 million reached a year ago.

▶ www.symrise.com

MARKET REPORT

Calculating the Full Impact of Reach

▶ Continued Page 1

predictions for financial consequences have mainly centred on direct costs of registration, estimated to be between €1.7 and €3.3 billion. However for most companies the full business impact will certainly be greater.

To assess the total impact of Reach compliance across the value chain, it is vital to look beyond the direct costs of data collection and dossier preparation. Whilst these will be substantial, one must also consider the impact that will be seen across all operations and business lines. This is particularly difficult to calculate as Reach and related activities focus on individual substances whereas business impact is measured via individual cash generating units (e.g. business units, product groups or single products). As most of these units will probably rely on a number and combination of substances, assessment can become extremely complex, especially if the business is part of a conglomerate. Most current cost estimates do not include such factors, despite the fact that they were a major concern raised during the drafting and negotiations of the Reach directive. Factors impacting on revenues and costs may come in a number of forms: a few examples are offered below.

Dr. Michael Fahrbach
KPMG

Passing Along Costs

The simplest factor to calculate is that of manufacturers and importers passing their Reach costs along the supply chain. As the cost of registering a substance will eat into its contribution margin, all manufacturers will look to recoup what they can. Where a substance is supplied by one company only, it is most likely they will be able to pass their increased costs on to customers. Downstream users will therefore need to ascertain whether any of their business lines depend on such substances.

Manufacturers and importers may find registration requirements too onerous, and either abandon production or choose not to register a substance for a particular use, especially with substances of "very high concern" (including those that are carcinogenic, bio-accumulative or highly toxic), as these may require authorisation. Where particular substances are no longer available, downstream users would have to make extensive changes to their operations, perhaps to their manufacturing processes or product formulations (due to substitution of substances). Unexpected new requirements might include research and development or the creation of new client specifications. It is also likely that potential substitutes were not originally chosen because they are harder to work with or more expensive – both possibilities that would increase costs for that business line.

Concerns For Downstream Users

Different uses of a substance must also be considered: for example, a paint ingredient might attract a greater risk when applied as a spray. For this reason, Reach requires that all intended uses must be registered. Downstream users will find they cannot continue to use substances as they have in the past if their supplier does not register that use, giving rise to the same issues and costs as if the substance had been withdrawn. Related issues for suppliers include the costs of ensuring they have complete usage information from all their clients, although it is possible that these costs are offset or exceeded by the value of the information gathered. For example, valuable cross-marketing opportunities for selling new uses of substances to other customers may be uncovered.

Under Reach, all downstream users of a substance have the right to inform the supplier of their intended use for it, but not to enforce inclusion of that use in the registration dossier. If a supplier will not register such a use, the downstream user must weigh the possibility of registering it directly, with all the attendant costs.

Registration and substitution of substances are not the only possibilities to consider. Registration data requirements vary depending on the volume placed on the market per year; but some manufacturers produce a large volume of chemicals, of which only a small proportion is destined for sale and use within the EU. Such manufacturers might find it more profitable to relocate that production outside the EU, or at least the part destined for sale there.

Business Impact Analysis

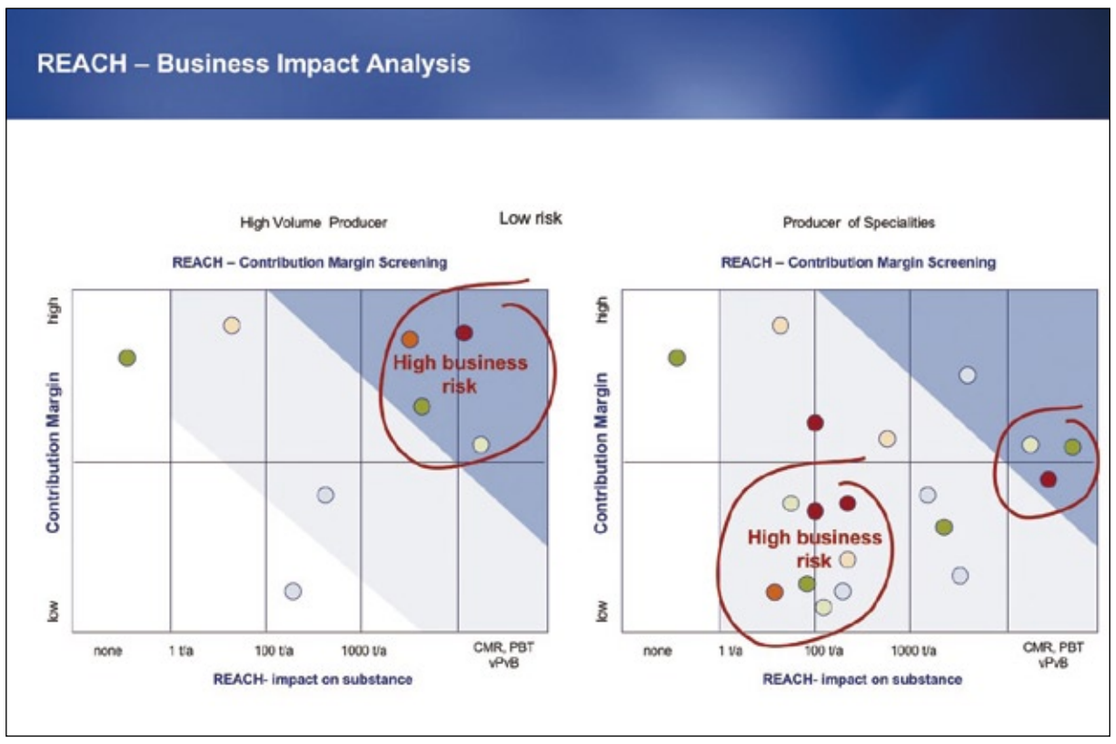
Such potential issues and costs can be flushed out by a company-wide investigation based on business impact analysis. This will help optimise market demands against regulation demands by uncovering and analysing the risks that exist throughout the value chain, and discovering the best way to compensate for them.

Identification of substances throughout the value chain with the highest Reach risk potential is the first step towards identifying business areas and product lines with high business risk for the company. Once substances with a risk potential are identified, the options for risk management can be developed. Broadly, these are: registration; substitution; relocation (as a whole or partly) outside of the EU; or abandoning a business line. However, close analysis of all the operational factors may uncover other solutions.

These considerations can be used to create a model for monitoring factors affecting contribution margins during Reach implementation. It might also be useful to develop a cash-flow analysis for specific options. Such a wide-reaching and methodical analysis requires a tool that is easy to use, easy for everyone along the value chain to understand, and easy to update.

KPMG's Business Impact Analysis Methodology

KPMG experts in the chemical industry have been analysing the potential impact of Reach on a range of businesses in several European countries since 2005. Their work has been the basis for developing a specific business impact analysis methodology for Reach implementation. This methodology focuses on business-critical substances and cash generating units that require substantial data compilation to become Reach-compliant. It supplies a basis for strategic decisions on the most cost-effective and efficient way to comply.



KPMG's methodology is a four-step approach to developing a clear understanding of how key performance indicators, such as contribution margins and cash flow, will be affected by Reach compliance. The first stage is a screening (e.g. contribution margin/Reach or supplier basis/Reach screenings) to determine the substances with the highest risk potential. In the next two stages the data is collected and the strategic options are assessed. This assessment results in the production of clear action plans in stage four. Analysis can be performed once as a basis for future decision-making or on a regular basis to allow monitoring of ongoing Reach implementation.

The underlying assumption is that there will be an impact on the contribution margins of chemical products, which will vary depending on the strategic options implemented. The methodology covers all business areas including operational and organisational structure, direct costs of Reach, assessment of strategic options, and identification of Reach-related risks in non-core areas of business:

- Identifying direct Reach costs by identifying those substances most affected, then calculating the expected financial costs for documentation and data collection. This includes identifying any costs that can be avoided or minimised.
- Estimating when these expenditures should be expected, to create a time line for financial forecasting and a framework for internal allocation and treatment for accounting purposes.
- Identifying strategic options for all affected substances/products. Deciding which criteria are relevant for deciding on options. Identifying which costs and investments are necessary for the implementation of these options.
- Assessment of the subsequent business development plan.
- Identifying any Reach-related risks in the sales and supply chains and whether there are any new internal or external communication requirements. As a result, a model and key indicators that allow management to monitor the business impact on an ongoing basis can be agreed.
- Ensuring full communications across the business

The key to understanding the full impact of Reach is discovering its effect on every element of the value chain and incorporating relevant interdependencies within conglomerates. It is crucial that information uncovered by a company's Reach implementation efforts is available and comprehensible to management and operations teams. It is also important that those responsible for direct work on Reach understand how their work impacts on the rest of the business.

KPMG's methodology simplifies and clarifies the process for determining the best Reach-compliance options. It offers an integrated approach to evaluation, facilitating communication and strategic and operational decision-making, including procurement, distribution and key account management. It is easy to integrate with existing Reach implementation projects, offering flexible scalability in the scope and level of analysis. The action plans and supporting information produced can be used for internal controls and reporting during both implementation and follow-on business activity, and the internal allocation of Reach costs.

Analysing the full business impact of Reach to define and execute the right strategic options affects every business line and requires their support to minimise costs and disruption. Companies impacted by Reach need to make sure they control this process from end to end.

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Altana: New Supervisory Board

The Supervisory Board of Altana, which will operate as a specialty chemicals company in the future, newly constituted itself following the annual general meeting. Dr. Fritz Fröhlich, chief financial officer of Akzo Nobel until 2004, was appointed new chairman of the supervisory board. The other new board members are Dr. Helmut Eschwey, chairman of the board of management of Heraeus; Werner Spinner, member of the management board of Bayer until 2003; and Dr. Carl Voigt, division head of Degussa until 2006. Susanne Klatten remains deputy chairwoman of the supervisory board; and Dr. Klaus-Jürgen Schmieder, member of the management board of Air Liquide, remains chairman of the audit committee.

Justus Mische, Altana's former chairman of the supervisory board, as well as Dr. Ernst-Uwe Bufe, Prof. Wolfgang A. Herrmann, and Prof. Heinz Riesenhuber resigned from their Board mandates.

▶ www.altana.com

Schwarz Pharma: Sales Down

Detlef Thielgen
Schwarz Pharma CEO

"We are satisfied with business development in the first quarter of 2007."

The Schwarz Pharma Group achieved sales of €232.1 million in the first quarter of 2007 (–6.2%). Due to the decline in sales and a lower gross margin following a changed product profile, the operating result in the first quarter of 2007 fell to €9.9 million (–12.7%). The net result amounted to €3.2 million (previous year: €2.2 million) as a result of a declining tax burden.

"We are satisfied with business development in the first quarter of 2007. The implemented restructuring measures, the continuing excellent launch of Neupro and the planned filing for three more indications are the best conditions for a successful year," said Detlef Thielgen, CEO of Schwarz Pharma.

▶ www.schwarzpharma.com

Aker Kvaerner, Praj: Bio-fuels JV

Photo: Pixelio

Praj Industries and Aker Kvaerner will create a joint venture (JV), for the European market. Aker Kvaerner has approved the implementation of the JV, and this consent joins the Praj Industries' Board approval wherein Praj will hold a 60% share of the JV and Aker Kvaerner will hold 40%. The JV shall combine Aker Kvaerner's execution capabilities and extensive European market knowledge with the technological expertise of Praj.

The JV will offer European customers access to the complete scope of services required for license, plant design and construction, with seamless integration and application of the Praj technology. Praj has been active in European markets for bio-ethanol technology solutions. In 2006, Praj and Aker Kvaerner entered into an alliance for strategic cooperation on bio-ethanol projects in Europe. Based on market interest in the alliance and the fact that Europe will follow a binding guideline of 10% bio-fuels blending by 2020, thereby expanding the market opportunity for bio-fuel plants, the two companies have decided to extend their association by forming a JV.

▶ www.akerkvaerner.com
▶ www.praj.net

Ashland, Cargill Form JV

Ashland and Cargill have agreed in principle to create a new joint venture devoted solely to the development and production of biobased chemicals. The parties intend for the new stand-alone entity to become a leading global supplier of chemicals from renewable sources. The venture's first product will be propylene glycol (PG). Using both licensed and proprietary technology, the joint venture will produce high-grade propylene glycol from glycerin, an abundant co-product of biodiesel production. The joint venture expects to provide global manufacturing and marketing of biobased PG, starting with a 65,000 mt/y at a yet-to-be-finalised location in Europe.

With a 50:50 ownership structure, Cargill and Ashland will bring to the new venture their unique technology, innovation and expertise in bioprocessing, along with chemical formulation, supply chain management and market analysis. The venture anticipates a combined initial capital investment in the range of US-$80-100 million. Details on the name, leadership and development plans are expected to be announced later in 2007.

▶ www.ashland.com
▶ www.cargill.com

AstraZeneca to Acquire MedImmune

AstraZeneca has entered into a definitive agreement to acquire MedImmune in an all-cash transaction. Under the terms of the agreement, which has unanimous MedImmune board support, AstraZeneca will acquire all of the fully diluted shares of MedImmune common stock at a price of US-$58 per share, for a total consideration of approximately US-$15.6 billion (including approximately US-$340 million net cash).

The acquisition of MedImmune shall significantly accelerate AstraZeneca's biologics strategy. The combination of MedImmune with AstraZeneca's wholly-owned subsidiary Cambridge Antibody Technology shall create a fully integrated biologics and vaccines business within the AstraZeneca Group with critical mass in research, development, regulatory, manufacturing and global sales and marketing reach. The deal is expected to close in June.

▶ www.astrazeneca.com
▶ www.medimmune.com

Ciba Improves Profitabilty

Ciba has reported CHF 1.66 billion in sales for the first quarter of 2007, 3% higher in Swiss francs and local currencies than the first quarter of 2006 (2006: CHF 1.62 billion). The company said growth in Europe was good, particularly in Germany and Eastern Europe; and Asia was very strong, with China continuing to show double digit growth. Sales in the U.S. were lower, with weakness in the construction, paper and automotive industries affecting demand; however, the decorative coatings and industrial paints markets showed good growth. Central and South America also achieved good sales growth.

Armin Meyer
Ciba Chairman and CEO

"We will continue to streamline our operations and drive profitable growth."

Armin Meyer, chairman of the board and chief executive officer, comments: "The year has started off well, with good sales growth across the business and improvements in profitability, particularly net income. We will continue to streamline our operations and drive profitable growth with our strong, focused portfolio and market leading positions in plastic additives, coating effects and water & paper treatment."

▶ www.cibasc.com

Air Products Earnings Up

Air Products reported net income of US-$228 million, or diluted earnings per share (EPS) of US-$1.02, for its second fiscal quarter. On a continuing operations basis, net income increased 16% and diluted EPS was up 19% compared with the prior year. Record second quarter revenue of US-$2,473 million was up 11% from the prior year on strong volumes across the company. Operating income of US-$325 million was up 15% versus the prior year.

John Jones
Air Products Chairman and CEO

"This was another excellent quarter, capping off a great first half to our fiscal year."

John Jones, chairman and chief executive officer, said, "This was another excellent quarter, capping off a great first half to our fiscal year. We again delivered strong volume performance, with our Merchant Gases, Tonnage Gases, and Electronics and Performance Materials businesses leading the way, and we drove productivity to our bottom line. Most importantly, we again made a meaningful improvement in our return on capital versus last year. We also announced a strategic acquisition in Poland to build our resources and capabilities in a high growth region."

▶ www.airproducts.com

Lonza Acquires S.A.M. Assets

Lonza has acquired the assets of S.A.M. Electron Technologies based in Shawinigan Canada. The acquisition of these assets is concurrent with an exclusive worldwide license for a cerium mediator electrochemical technology (CeTech) from Hydro-Québec and lease agreement with the City of Shawinigan.

The plant has a nominal production capacity of 400 t/y for vitamin K-3 derivatives and can be quickly expanded to achieve much higher capacities. The Shawinigan operations are anticipated to provide jobs for approximately 20 people locally. The acquisition closed on 2 May and is a wholly owned and operated subsidiary under Lonza Canada.

▶ www.lonza.com

EU's Reach: Language Requirements

The Reach regulation, which comes into effect in June, will require a registration, over a period of 11 years, of some 30,000 chemical substances. The registration process requires the manufacturers and importers to generate data for all chemicals substances produced or imported into the European Union above one tonne per year. The registrants must also identify appropriate risk management measures and communicate them to the users. Amongst the myriad controls and regulations facing chemical companies will be a requirement to take cognisance of the multiple language dimension of the European Union. In particular Reach requires that, when it comes to labelling or documentation relevant to the chemical substance, companies ensure:

- The inscription must stand out clearly from its background and shall be in a language which is understood in the territory where it is being used.
- The labelling of articles containing asbestos shall be in the official language or languages of the Member State(s) where the article is placed on the market.


Photo: Pixelio

- The safety data sheet shall be supplied in an official language of the Member State(s) where the substance or preparation is placed on the market, unless the Member State(s) concerned provide otherwise.

Chemical companies wanting to sell their products in within EU will have to translate into 23 official EU languages. These are Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Irish, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovene, Spanish and Swedish.

▶ www.europa.eu

NNE Pharmaplan Launched as Joint Company

NNE's acquisition of the German engineering company Pharmaplan which was completed on 31 March. According to the company, Pharmaplan supplements NNE with know-how in delivery of turnkey facilities, validation and key pharmaceutical processes, whereas NNE supplements Pharmaplan in areas such as biotechnology, cleanroom and automation.

"We will now start integrating the two companies, while maintaining focus on the daily business of supplying high-quality engineering and consultancy services to the pharmaceutical and biotechnological industries," said Hans Ole Voigt, president of NNE Pharmaplan. "The purpose of the merger is to utilise the business synergies and future growth potential which will be released by unifying two companies with complementary market presence and competences."

Today, NNE Pharmaplan has five offices in the U.S. market. In the growing markets of India and China the company has 60 employees in offices in Delhi and Bangalore and 130 employees in Tianjin, China. Europe and the rest of Asia are covered by 12 offices, as well as the corporate headquarters in Copenhagen, Denmark, and a significant German hub in Frankfurt.

▶ www.pharmaplan.com

Dowpharma Licenses Pfenex Expression Technology

Dowpharma contract manufacturing services, a business unit of The Dow Chemical Company, has licensed its Pfenex Expression Technolog to VGX Pharmaceuticals. Under this non-exclusive global license, Dow's technology will be used to produce a proprietary VGX therapeutic protein indicated for cancer therapy. Compared to traditional microbial fermentation techniques, the Pseudomonas fluorescens-based Pfenex Expression Technology produces increased yields of soluble, correctly folded therapeutic proteins. Dowpharma is able to screen hundreds of expression strains, enabling rapid identification of a strain capable of producing high yields of properly folded, active protein. The soluble protein expressed is easier to handle, enables a clearer path through the purification process and avoids a refold step which dramatically reduces the overall cost of goods. This makes Pfenex Expression Technology an obvious choice for the growing number of drug candidates that require complex folding.

▶ www.pharma.dow.com
▶ www.vgxp.com

Bachem, Immatics Expand Cooperation

Bachem said it will further expand its close co-operation with Immatics in the production of peptides for Immatics' clinical development program. Corresponding supply agreements have been closed recently. Over the past two years, Bachem has supported Immatics by manufacturing synthetic peptides for IMA901. IMA901, a combination of ten different peptide antigenes, is Immatics' first cancer vaccine for the treatment of renal cell carcinoma that successfully completed phase 1 development in 2006 and will enter phase 2 development this year. For IMA901 Immatics has been granted orphan drug status in March by the European Medicines Agency (EMEA) with the consent of the EU Commission. This gives Immatics exclusive rights and favours faster approvals in all EU member countries.

▶ www.bachem.com
▶ www.immatics.com

Gene Bridges, BASF Sign Collaboration Agreement

Gene Bridges said that it has signed a collaboration agreement with BASF to use Gene Bridges' Red/ET recombination technology alongside BASF´s expertise in biotechnology, process development and product application.

Under the terms of the agreement, Gene Bridges will provide bio-molecular engineering for strain optimisation and in return, BASF will be responsible for subsequent screening and product and process development. The new agreement is a significant expansion of previous service projects successfully carried out by Gene Bridges for BASF.

▶ www.genebridges.com
▶ www.basf.com

Kemira GrowHow Sells Part of Chemicals Business

Kemira GrowHow said expects to sell its Danish hydrochloric acid, sulphuric acid and canning businesses to Gropa, part of Parcongroup. Kemira GrowHow will continue to provide its nitric acid and ammonia based products in Denmark. If the sale is effected Kemira GrowHow will support Gropa in the supply chain process to guarantee deliveries to the customers for an interim period. The expected sale of this business is part of the restructuring of Kemira GrowHow's Danish business and securing the long-term competitiveness of Kemira GrowHow in its core activities

▶ www.kemira-growhow.com
▶ www.parcongroup.com

Schering-Plough: FTC Requests Info in Organon Purchase

Schering-Plough said received a Request for Additional Information (Second Request) from the Federal Trade Commission (FTC) regarding its planned acquisition of Organon BioSciences, the human and animal health care businesses of Akzo Nobel. A request for further information is typical in a transaction of this size. Schering-Plough said it will continue to cooperate fully with the FTC in its continuing evaluation. Schering-Plough continues to expect the transaction to be completed by year-end 2007, and it remains subject to certain closing conditions, including regulatory approvals and discussions with works councils.

Schering-Plough announced in March that it would be acquiring Organon BioSciences for approximately €11 billion in cash.

▶ www.schering-plough.com

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Chemical Distribution

This years's FECC congress will adress key issues

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Chemicals

Navigating legal obligations through Reach

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Play Hard or Go Home

For Chemspec Europe, Time Has Come to Prove Its Quality

ChemSpec Europe has been a leading European fine and speciality chemicals event on the annual calendar for 21 years. The 2007 edition in Amsterdam on 27–28 June will, according to the organisers, again draw some 6,000 attendees and deliver networking opportunities for over 400 companies who attend as exhibitors.

However, this year's Chemspec Europe will be crucial for the future of this event and the European chemicals conference schedule. With the menacing competition from Informex Europe, slated for launch in 2008, ChemSpec exhibitors will critically survey the course of the two-day convention and the quality of attendees.

Informex, already a well-established brand in the U.S. with an offshoot in China, is trying to gain a foothold in Europe. And ChemSpec Europe in the last couple of years had to meet with criticism from many of the exhibitors who were questioning the event's concept being too focussed on pharma chemicals and losing sight of other speciality chemicals segments.

The organisers of ChemSpec Europe, however, state that exhibitors and visitors alike cover the whole spectrum of fine and speciality chemicals from sectors such as pharmaceuticals; agrochemicals; biotechnology; coatings; contract and toll manufacture of all kinds; cosmetics and personal care ingredients; electronic chemicals; dyestuffs and colours; biocides; surfactants; and water treatment.

Chemspec Europe also features a host of associated features, including ChemSource, a show for the outsourcing of contract services, the associated RSC conference, the Colours Village, the BioZone Village and the national pavilions representing China, India, the U.S., Korea, Russia and the UK.

Also, the organisers of ChemSpec Europe won't allow doubting the quality of visitors, although they say that it gets harder every year to do new business via trade shows in general. According to them, attendees at Chemspec Europe conduct real business: 84 % of the visitors surveyed at the last show held direct purchasing responsibility and 66 % stated that they definitely intended to place orders as a result of attending.

This, above all else, is the reason why companies come to ChemSpec Europe. A few key buyers can make all the difference between a successful show and an unsuccessful one. Therefore, ChemSpec Europe again features a Meet the Buyer section that should become an integral part of the convention. The organisers fly in a selection of buyers, carefully vetted for having a large budget and responsibility for purchases in areas of direct relevance to the exhibitors, and set them up in special meeting rooms on the show floor.

The buyers commit to holding a specified minimum number of meetings with exhibitors while also having the time to wander the show floor. For a small fee, exhibitors can secure half-hour, one-on-one meetings with the buyers they think most relevant to them.

We will know by the end of June just how successful this admittedly interesting idea proves to be.

Michael Reubold

▶ www.chemspeceurope.com

Winds Of Change

Can Profitability Be Restored to the Global TiO_2 Industry?

Global expenditure on titanium dioxide (TiO_2) passed the US-$10 billion mark for the first time last year, and it is forecast to continue to rise at around 3 % per annum over the next 10 years. Thus, TiO_2 will consolidate its position as one of the world's top five inorganic chemicals – behind ammonia, caustic soda, chlorine and phosphoric acid, but comfortably ahead of sulphuric acid, carbon black and the rest of the field.

TiO_2 is mainly used for its pigmentary properties, though consumption is also increasing in some of the niche non-pigment areas, such as synthetic fibre delustrants, sunscreens, catalysts and self-cleaning glass. The ideal pigment should fulfill two key objectives: opacifying, i.e. hiding or obliterating the substrate and imparting colour (including black or white) to the material in which it is incorporated. Thanks to its high refractive index and to the fact that it can be manufactured with a narrow particle size distribution (around half the wavelength of "normal daylight"), TiO_2 is an excellent opacifier. It also offers brilliant whiteness, it is essentially inert to acids, alkalis, solvents and redox agents and it is thermally stable up to 1,825 °C. Pigment-grade TiO_2, with a particle size of 200–300 nanometres is not toxic, fibrogenic, carcinogenic or allergenic. Commercial offerings of nanoparticulate grades of TiO_2 have only been introduced in recent years, so there is not much long-term epidemiological data on working with them. The best advice is to adopt the same health and safety precautions when handling nanoparticulate TiO_2 as for other nanoparticulate materials.

TiO_2 pigment really established its place as the opacifier and white pigment of choice onwards from the early 1950s, displacing toxic white lead. While TiO_2 has excellent technical properties, it is also rather expensive – even in the prevailing climate of historically low prices. Pigment extenders (such as calcium carbonate, talc and calcined kaolin) are fairly good opacifiers or fairly good brighteners that are much cheaper than TiO_2, so when used in conjunction with TiO_2 they can enable the paintmaker or plastics processor to achieve adequate performance at a reasonable cost.

Quality-of-life Product

World consumption of TiO_2 pigments was 4.99 million t in 2006, accounted for by a wide variety of end-uses. Three sectors have always predominated: paint, plastics and paper. The paint industry accounts for nearly 60 % of TiO_2 pigment consumption worldwide, the plastics industry for 23 % and the paper industry for just under 10 %. These and other TiO_2 end-use sectors turn out products that are essentially "consumer-oriented": paints for houses, cars and domestic appliances; quality printing papers and inks for books, magazines and brochures; plastic products for packaging, etc. Hence, although TiO_2 is just a component of the paint or paper, it counts as a product that typically enhances the quality of life.

Not surprisingly, in view of TiO_2's role as a "quality-of-life" product, the affluent industrialised countries (members of the OECD) are the major consumers of TiO_2. They account for over 70 % of Global usage. The most rapid growth rates in TiO_2 consumption during the 1980s and 1990s were witnessed in the newly industrialised countries, such as South Korea and Taiwan. China has shown quite spectacular TiO_2 demand growth, increasing from less than 40,000 t in 1991 to more than 800,000 t in 2006.

Plotting per capita gross domestic product (GDP, in US-$) against per capita TiO_2 consumption indicates a fairly good correlation between the two parameters. For the OECD countries, average consumption of TiO_2 in 2000 was 116 kilos per million dollars GDP. Some countries – notably Belgium, the U.S., the Netherlands and Taiwan – consume significantly more TiO_2 per capita than would be predicted on the basis of a 100 % universal GDP correlation. Other countries – such as Japan, Switzerland, Denmark and Norway – consume significantly less.

Most of the end-user industries that comprise the customer base for TiO_2 pigment suppliers have seen intense merger and acquisition activity in recent years. The top 30 consumers now account for about 25 % of global TiO_2 pigment consumption. Nevertheless, there are still a lot of relatively small TiO_2 consumers. For example, in Europe, there are about 1,500 paintmakers altogether. Certainly, the major companies (Akzo Nobel, ICI, BASF) are major TiO_2 consumers, but the smaller enterprises together account for a substantial tonnage of TiO_2 consumption, representing at least 20 % of the sector total. Fragmentation of the customer base is slightly less in North America, but is much more pronounced in Japan and other Asia/Pacific markets.

Not an Easy Industry to Enter

There are relatively few producers of TiO_2. There is a great deal of proprietary technology in several areas of TiO_2 manufacture, especially at the pigment-finishing end (particle sizing and applying surface coatings to ensure good dispersion, etc.). Hence, it is not an easy industry to enter and most aspiring new entrants seek collaboration and assistance from established experts. But at the present time, there are no companies actively searching for licensees for chloride-process or sulphate-process technology.

▶ Continued **Page 11**

Reach Consortia

How to Successfully Establish and Manage Them

During the last months, we have seen the final milestones passed on the way to enforcement of Reach, the new European chemicals legislation. The new regulation will now enter into force in June; the pre-registration phase for Phase-In Substances (PISs) will end on 30 November 2008.

Generating toxicological and physico-chemical information on an estimated 30,000 PISs is one of the key tasks of Reach. However, this task must be achieved by performing vertebrate animal tests only as a last resort and by avoiding any duplication of other tests. The number of tests may be reduced by sharing existing data and by jointly generating new study data. To control this process, Reach requires that all registrants share the data generated from vertebrate animal tests, and, if requested by other members of the Substance Information Exchange Forum (SIEF), also data from other tests. Similar rules apply to registrants who register new substances.

Reach does not give guidance on the actual form of data sharing and leaves this open to the general principles of economy and law, in particular, contract and company law. Reach strongly supports a joint registration by several parties (One Substance, One Registration – OSOR principle). The formerly used term "consortium" has disappeared from the legal text and Article 11, as published now in the Official Journal of the EU, only stipulates that a lead registrant shall perform the registration on behalf of all registrants with an interest in the same substance.

Bearing this in mind, consortia may provide one potential platform for joint registration and also for data sharing. However, there will be no mandatory participation within a consortium and, if deemed feasible, data could also be shared by granting usage or transferring ownership, i.e. signing a two- or multi-party contract. In addition, it is possible that more than one consortium is formed for a specific substance. Intellectual property protection (IPP) and compliance with competition law are critical issues during the registration work within a consortium. Article 11 of the Reach regulation provides that, for instance, uses of substances have to be filed individually, chemical safety reports may be filed separately, and (Robust) Study Summaries may be filed separately for economic or other reasons. Articles 81 and 82 of the EC Treaty prohibit all actions that may adversely affect competition within the common market of the EC member states or that may represent an abuse of a dominant position.

This concept may force consortium members not only to non-disclose specific information on prices and business conditions but also to accept members that do not have any alternative for data sharing – a situation particularly likely in small or homogenous product markets. Potential members may also include downstream users. Currently "Guidelines on the Applicability of Article 81 to Horizontal Cooperations" do only provide limited orientation under Reach and more Reach-specific guidance is needed. The due RIP 3.4 on data sharing will hopefully clarify these aspects.

Experience And Expectations

Experience in joint data collection/generation may be drawn from the OECD/ICCA Program and the U.S. Environmental Protection Agency's (EPA) high-production volume (HPV) Challenge Program, where companies have voluntarily cooperated in consortia and still do so. Test requirements are lower there than under Reach, the number of substances on the working lists is much lower (amounting to about 1,400 and 2,800, respectively), and success, determined as the extent of consortia formation within individual substance markets, is very high. Less frequent formation of consortia seen in the biocide area in Europe may be explained by the highly company specific and proprietary nature of formulations.

Several projects have tried to shed some light on the benefits and problems of consortia formation under Reach. During the Strategic Partnership on Reach Testing (Sport) Project various critical aspects were identified, ranging from protection of intellectual property and other confidential data to cost sharing and late entry into the consortium. Members of the project committee of the Human and Environmental Risk Assessments (HERA) Project found that achieving a common position in data and assessments helps to streamline discussions with the authorities and to deliver harmonised information to the downstream users.

Environmental Resource Management estimated that direct costs of Reach to the upstream industry in Ireland may drop by 71% in the event that consortia formation increases from 25% to 100%. Cefic views consortia positively, but also emphasises potential conflicts with competition law. Due to concerns about inadequate IPP, large manufactures are often more reluctant to participate in a consortium than SMEs and importers.

In summary, strong arguments support cooperation within a consortium. These may include a unified and better substantiated position of the registrants, synergies in intellectual and financial resources, and significant cost reductions for data generation and dossier preparation, not to forget a reduced registration fee (currently a 33% discount is proposed). However, much effort has to be put in to consideration of potential pitfalls and on the efficient organisation of daily consortium work.

Participation Within A Consortium

Each company has to evaluate individually the pros and cons of participation within a consortium and, as the case may be, to decide on the appropriate timing and contribution. Registrants of PISs exceeding 1,000 t/y or those of very high concern have to register within a period of 3.5 years after enforcement of Reach. Waiting for official access to the SIEF data base, allowed 18 months after enforcement, will often leave insufficient time to approach other registrants, to negotiate, to set up appropriate structures (e.g. consortia), to evaluate and to share existing data, to generate new data, and to prepare the dossiers. Consequently, many parties have already made first steps into consortia. Others are strongly recommended not to waste useful time now and to run short of time later.

Therefore, it should be in the interest of large tonnage-companies and those dealing with substances of very high concern to initiate in a timely manner joint Reach activities with registrants concerned with the same substance, i.e. to be proactive prior to the opening of their subject SIEFs. Market research shows that companies frequently believe they know all or most of their competitors, but for those companies operating in highly fragmented markets or with individual main activities focussed on different regional markets, this belief often proves wrong. The use of professional market research may therefore help to identify and establish a dialogue with potential consortium partners as early as required. If appropriate a Third Party Representative (acc. to Art. 4) can expedite this process in order to avoid disclosing the identity of the client.

Prior to participation within a consortium, alternatives and related costs should be examined. Based on relevant experience, RCC has developed several cost scenarios for consortia, spanning the entire process from formation to registration. These scenarios analyse the implications of payments from up to 15 parties, the time of entry, the quality of data owned / provided, and the type of use granted. Results obtained under realistic model conditions indicate that data-owning parties founding the consortium can expect re-imbursements during the entire project to be about 20 times higher if five late registrants pay 50% of study costs for data access only, compared to becoming full members contributing on a proportional basis. Non-data owners joining earlier also profit, but to a much lesser degree. Costs for parties not joining but accessing data at a late stage were about 4-fold higher than costs for full data access under proportional conditions.

According to the rules of finance, future payments have to be adjusted using a discount rate, so they are comparable to current values. Small tonnage-companies that consider registration in alliance with other consortium partners within the 3.5 years-time window, but that do not have to do so coercively, should evaluate a possible reduction of their financial burden in case they decide to register at the end of the 11-year window and postpone payments accordingly. Based on a market interest rate of 6 and a delay in payment of 7 years, they may decrease financial burdens by 30%, i.e. the absolute value of the negative Net Present Value.

Essentials Of Consortia Work

Effective work within a consortium requires consideration of strategic, scientific/regulatory, organisational/managerial, economic and legal aspects. Identification and establishment of a consortium core cell may be a highly sensitive strategic task that necessitates a sound understanding of the subject branch and is often initiated by the market leader.

One of the first steps should be to agree on the substance, i.e. the focus of the consortium. This entails inclusion and exclusion of specific companies. Extension of the founding team has to comply with competition law but will in praxis never be free of psychological aspects and business interests. Regulatory aspects comprise the whole pre-registration, registration, and, as the case may be, authorisation process. Evaluation of existing studies from a scientific, but also economic, point of view is a key task. Managerial aspects may range from organisation of general consortium activities and technical work to budget administration and commissioning of subcontractors.

During preparation of registration dossiers, support from an independent party having the role of a trustee is essential to safeguard non-disclosure of sensitive information to the other consortium members. Economic aspects may involve all decisions on financial liquidity and payments made by and to the consortium and/or individual members. Under Reach, sharing of all costs among consortia members can be freely negotiated as long as not immoral or conflicting with other general legal principles. In principle, past and new costs as well as direct and indirect costs may be shared. While cost allocation per capita is simple, other considerations, for instance based on sales, production volume or market share, would require support by the independent trustee to avoid conflicts with competition law.

As soon as the due guidance on cost-sharing becomes available from the agency this may also be drawn upon. If no agreement can be achieved on cost sharing of existing or new studies, Reach requires equal cost sharing between owner and buyer or among commissioning consortium members.

Finally, legal aspects include those that are routine for all types of cooperative contracts and those that are specific for consortia under Reach. The legal and economic features of a consortium may be tailored according to the needs of the participants and can meet the legal form of either a partnership or an incorporated company that has to be entered in the register of companies. General contract elements may comprise, but are not limited to, the purpose, the process of founding (e.g. individual interests and contributions), of admission and withdrawal of members, and of termination, the rights and duties of representatives and management, the decision making process (e.g. by a steering committee), measures to be taken in case of non-performance of members, and measures for settlement of disputes.

Contract elements specific to the consortium situation under Reach should, for instance, specify rights in data, the confidential supply of sensitive data, e.g. via trustee services, and late entrance conditions. Often cooperation starts with closing a pre-consortium contract that lays down the intention to form a consortium and details the intent as far as deemed appropriate. While this does not normally provide any legal obligation to join the consortium, signing it represents a highly important psychological step towards any serious cooperation.

Drawing upon experience gained during several years of international consortia work and allocating specialists from all disciplines required (including support by one of RCC's neutral international law partners), RCC offers a comprehensive one-stop service package known as the RCC Umbrella Consortium Management Model. Alternatively, clients may be supported according to the RCC Peer Management Consortium Model, where management tasks are shared with a law firm, an association or any other qualified party.

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Winds Of Change

Can Profitability Be Restored to the Global TiO_2 Industry?

Continued Page 9

There are two conventional technologies for making TiO_2 – normally described as the "sulphate process (SP)" and the "chloride process (CP)." There has been a lot of debate over the past 30 years as to the relative merits of the two technologies and much of the debate has been oversimplified by the protagonists for the purposes of competitive propaganda. There are environmental and manufacturing costs, and product quality issues attached to both sulphate and chloride processes.

The installation of acid recycling and by-product recovery facilities at SP plants enables such plants to move nearer towards realising the "pollution-free/closed-loop" concept, but it does mean more capital investment. In terms of capital costs alone, it would currently be 10–20% cheaper at a greenfields site to build a CP plant rather than an SP plant plus the necessary acid-treatment facilities.

On the other hand, ample merchant supplies of sulphuric acid are generally available in every corner of the world and acid can be fairly easily transported, whereas the same is certainly not true of chlorine. Producers that have built new CP plants in Mexico, Saudi Arabia and Australia have been more or less forced to have small chloralkali plants built alongside their TiO_2 plants, thus increasing overall capital and operating costs and creating the problem of finding outlets for the co-product caustic soda and any surplus chlorine output.

TiO_2 Manufacturers Fail to Earn the Real Cost of Capital

Over the past 35 years, there have been several peak/trough/peak cycles in TiO_2 pigment prices (in real terms), but underlying the year-to-year movements up or down, there has been a long-term decline. During the second half of the 1980s, TiO_2 pigment was in short supply, and all manufacturers were running their plants flat out to try to keep pace with the demand boom. The average annual US pigment price reached US-$2,240 in 1989, equivalent to a peak of US-$3,646, in terms of 2006-dollars. The long-term average over the 20 years between 1970 and 1990 was just above US-$3,200, in terms of 2006-dollars. In the early 1990s, a number of new plants and capacity expansions came on-stream, while the hoped-for widescale retirement of older plants failed to materialise. In a climate of overcapacity, TiO_2 pigment prices fell steeply, with a few short-lived respites, reaching a trough of US-$1,985 (in terms of 2006-dollars) in 2004. Drastic cost reductions were implemented, but they could not stop the erosion in profit margins. Most TiO_2 manufacturers were failing to earn the real cost of capital during the 1990s and early 2000s. TiO_2 prices began to turn up again in 2005 and this trend is expected to continue, as the increase in global demand continued to outpace the net expansion in global capacity.

The industry is a highly competitive oligopoly. The top five producers – DuPont, Millennium, Tronox, Tioxide and Kronos – now control 63% of world capacity. After the top five multinationals, there are 15–20 medium-size global TiO_2 pigment suppliers, most of whom have just one plant. These medium-size suppliers account for more than 20% of total global capacity. At the top end of this category this category are Ishihara Sangyo Kaisha (Japan and Singapore), Kemira (Finland) and Rockwood/Sachtleben (Germany). Some of the more important Chinese producers – such as Chongqing YuGang, PanGang Jinzhou, Sichuan Lomon and Zhenjiang InterChina Chemical – have joined the ranks of the medium-size global players in recent years. Altogether, the 60 or so Chinese producers now account for 15% of world capacity.

More Changes in Corporate Ownership Anticipated

There have been a lot of changes in corporate ownership within the TiO_2 industry in recent years. The first wave of rationalisation was triggered initially by DuPont's plan to take over from ICI all of Tioxide's TiO_2 assets outside North America. The agreed takeover was aborted in January 1999, after a lengthy examination by US anti-trust authorities. Six months later, the entire Tioxide business was sold by ICI to Huntsman, a completely new entrant to the pigment industry. Like ICI, Bayer and Rhône-Poulenc quit the TiO_2 pigment industry, while Kemira downsized its business, selling its foreign TiO_2 manufacturing assets. Millennium and Kerr-McGee were actively acquiring TiO_2 pigment assets in the 1997–2001 period. Rationalisation of ownership led to some rationalisation of capacity. Millennium closed an SP plant at Baltimore (U.S.) and wrote-down to zero value its SP plant at Le Havre (France); Kerr-McGee closed SP plants at Antwerp (Belgium) and Savannah (U.S.); Huntsman reduced its Global capacity by 10%, with cutbacks at Grimsby (UK) and Umbogintwini (South Africa).

A second wave of industry rationalisation began in December 2004, when Lyondell (a petrochemical and oil refining company, based in Houston) acquired Millennium. In November 2005, Kerr-McGee floated off its TiO_2 and other chemical businesses as a separate entity – Tronox. Kerr-McGee itself became a "pure-play" oil and gas company, but the name disappeared altogether its subsequent absorption by Anadarko. NL Industries also floated off its TiO_2 business as a separate entity – Kronos Worldwide Inc. – but majority control of Kronos remains with the family of Mr Harold Simmons (the Texas billionaire) and his Contran group. Towards the end of 2005, it looked as though ownership of Tioxide was about to change again as the Huntsman family was seriously considering offers from various private equity funds to buy the entire assets of the family-controlled Huntsman Corp., which would have probably led to restructuring and the sale or hiving-off of Tioxide. In the end, the offers were rejected as inadequate and Huntsman subsequently implemented its own restructuring, including the sale of its petrochemical assets to Sabic, Koch Industries and others.

The most important development so far this year was announced in February: the agreed sale of Millennium's TiO_2 business by Lyondell to Cristal (aka the National Titanium Dioxide Co. of Jeddah, Saudi Arabia). The transaction, which should be completed before the end of June, involves the payment of US-$1.05 billion as cash plus the assumption of about US-$ 150 million worth of debt and liabilities. Cristal entered the TiO_2 industry in 1991, with the commissioning of a three-line chloride-route TiO_2 plant at Yanbu, on the Red Sea coast of Saudi Arabia. This plant now consists of five lines, with a total nameplate capacity of 120,000 t/y. The acquisition of Millennium's 670,000 t/y. of capacity from eight plants in Australia, Brazil, France, the UK and the U.S., will raise Cristal to the status of the world's second largest TiO_2 producer, with a global market share of 14%. Cristal had been planning to install two more lines at the Yanbu plant, raising capacity here to 180,000 t/y. Presumably these plans will be suspended while the company digests its new acquisition.

Other major changes in the industry are imminent. DuPont is determined to retain its position as the world's leading TiO_2 supplier and it is making good progress with its project to build a 200,000 t/y. TiO_2 plant at DongYing (China). This will be the first modern chloride-route plant in China and its commissioning in 2009 is likely to precipitate the closure of a number of small-scale sulphate-route plants with inadequate provisions for pollution control. Meanwhile, DuPont is also planning to expand its existing plant at KuanYin (Taiwan) to 150,000 t/y. Tronox has declared that it is considering selling-off its 107,000 t/y. sulphate-route plant at Krefeld (Germany). Sachtleben, which already has a 100,000 t/y in nearby Duisburg, would be an obvious purchaser. And finally, questions about the future of Tioxide have emerged again recently following remarks by John Huntsman at a recent investors' seminar in New York. He said: "In the TiO_2 industry, there needs to be a 'big three' and not a 'big five.' If we can play a role in the industry's consolidation and generate US-$200–300 million in synergies, we would look at that opportunity."

Given that the TiO_2 industry generates a product with fairly well assured long-term demand growth in line with GDP growth and with no real technical substitutes and given that the capital and technology barriers to entry into the industry are quite high, it is really quite amazing that this has not been a very profitable business over the past 15 years. Perhaps this is about to change.

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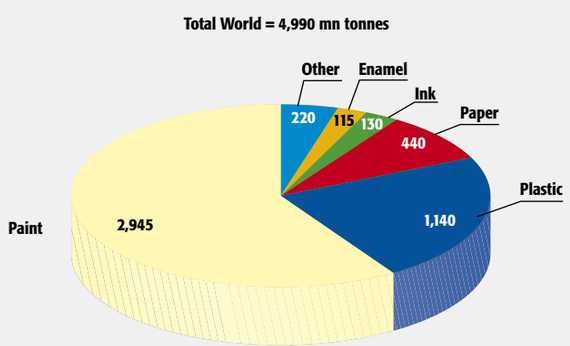
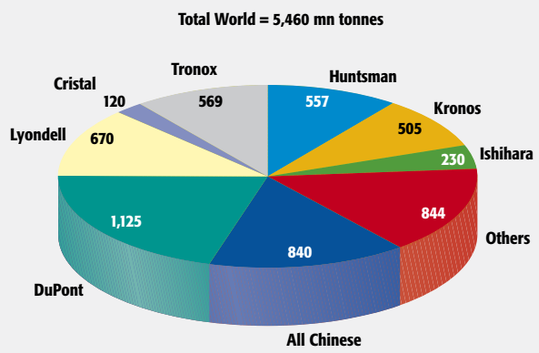
World: TiO_2 Pigment Demand, 2006
by end-use sector ('000 tonnes)



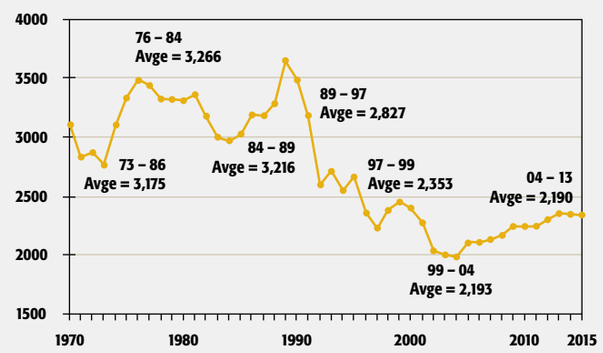
Source: Artikol, 2007 © GIT VERLAG

World: TiO_2 Pigment Capacity
End-2006 ('000 t.p.a. pigment)



Source: Artikol, 2007 © GIT VERLAG

U.S.: TiO_2 Pigment Price
(US-$/tonne, constant-2006 dollars)



Averages are for Trough-to-Peak & Peak-to-Trough

Source: Artikol, 2007 © GIT VERLAG

Supply Chain Dialogue

A Key Success Factor in Reach

Reach is the European Union's (EU) new chemicals regulation, which is effective from June. It has a broad scope, covering manufacturers and users who work with chemicals. Reach requires the chemical industry to have an appropriate level of knowledge of the properties of these chemicals, their uses, and to manage risk through the supply chain. Robust mechanisms will be required for information to flow both up and down the supply chain. While a complicated task, this will be facilitated by effective supply chain dialogue.

Reach is another example of broad-reaching EU environmental laws that have significant extraterritorial impacts. The nature of the global economy means that when a major market, such as the EU, imposes product content requirements, those requirements reverberate throughout the global supply chain. The scope of Reach is broad, covering chemical manufacturers, importers, suppliers as well as downstream users. How each of these will be affected will depend upon their chemical usage, supply chain and how they wish to manage their intellectual property. For the entire supply chain, this will require that industry has an appropriate level of knowledge of the properties of these chemicals, their uses, and to manage risk throughout the supply chain.

Information Requirements

For Reach to be successful, a significant amount of information will need to be generated and exchanged among supply chain partners and with the European Chemicals Agency (ECA). The key tool used for communicating hazard and risk management information in the supply chain will be an enhanced Safety Data Sheet. Successful communication within the supply chain will need to be iterative and follow a flexible process that takes account of differing market sector needs and levels of sophistication. For chemicals suppliers and distributors – some with product portfolios in excess of 10,000 items and many with a similarly large number of customers – care will be needed to ensure that required supply chain polling is both efficient and cost effective. A questionnaire developed with input from chemicals manufacturers and distributors has been issued recently (fig. 1). It is hoped that this will form the basis of a common supply chain template.

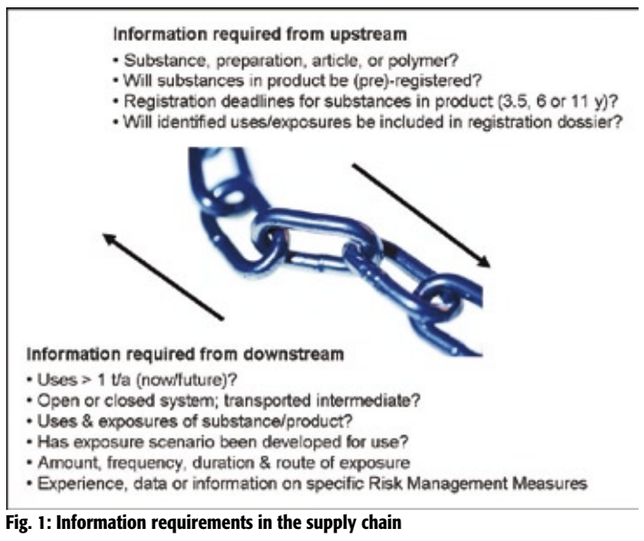


Fig. 1: Information requirements in the supply chain

Informaton Flow

Most industry sectors have engaged in supply chain polling – typically from downstream customers to upstream raw material suppliers – requesting confirmation that certain "substances of concern" are either not present in products supplied or systematically declared if present above certain defined limits. The listed substances often vary – both qualitatively and quantitatively – between markets and even between customers in the same market sector. While recent efforts have focused on standardising these lists, the absence of a consistent supply chain expectation and the need for dialogue to put the supplied information in the correct context can cause misunderstandings and delays with approvals. Many predict Reach will become the global reference standard regarding substances of concern, which should simplify expectations in the supply chain. In addition, this may accelerate a move toward convergence of global markets and regulations relating to the substances used in products.

It is clear that a downstream user will need to carefully evaluate the benefits of electing to have his use included in the registration of a substance made by his supplier versus the potential intellectual property loss suffered by providing such information upstream. These are real concerns in many supply chains. Several of the impact assessments conducted during the drafting of Reach acknowledged the costs and efforts incurred in identifying uses. The business risks are real, as users must give suppliers sensitive information on usage; this could seriously affect their market position. Reach has provisions to allow downstream users to register their use of a substance independently should confidentiality considerations be deemed critical.

Exposure and Use

Chemicals manufacturers and distributors often have a broad understanding of the uses of their products. However, the detailed application, use, emission and exposure information is often specific to a particular market sector, or even, to a particular customer. In order for the downstream customers use to be included within the registration dossier, information will need to be passed back up the supply chain. It is this two-way supply chain communication that marks one of several differences of Reach and the legislation it replaces.

Data Exchange and Supply Chain Performance

So how should these data exchanges occur within the supply chain? Within some sectors – primarily electronics and automotive – requirements to meet EU extended producer responsibility directives have driven the need for a systematic exchange of environmental data between supplier and customer. While relatively simple compared to Reach, these directives have caused significant supply chain disruption; the resulting materials declaration challenge left many in the supply chain avidly chasing data without the means to process or manage them effectively. Many have sought to install or develop Product Lifecycle Management (PLM) systems to address their product portfolio management needs.

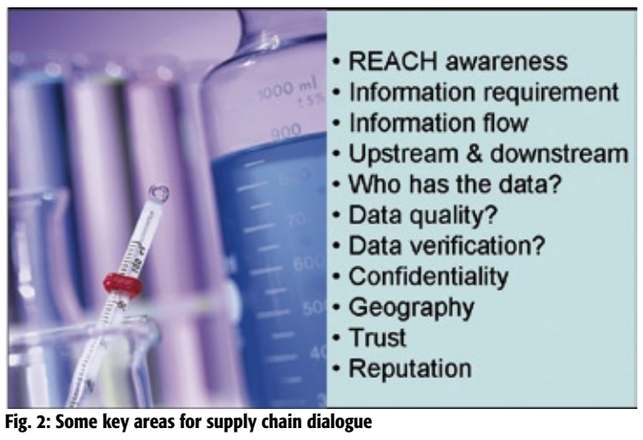


Fig. 2: Some key areas for supply chain dialogue

Similar approaches may be helpful in managing aspects of information exchange under Reach, but clearly revisions to existing approaches will be required. The likely development of a common framework within the chemical industry – in order to respond to their compliance requirements in Reach – will ensure the need for cross compatibility between the systems operating in the major supply chain sectors. Most companies have in place processes to rate supplier performance as well as some form of needs management and customer distinction. These processes can be further utilised as a basis for data verification of responses obtained from supply chain partners, since not all responses will be of the same quality or degree of completeness. This is not a simple "check box" approach, unfortunately. The received responses will need to be assessed by staff that has the right skills to judge, for example, that an exposure scenario provided by a downstream customer is appropriate for a particular use of a substance. Options for recycle will need to be built into the process accordingly.

Trust and Reputation

With an increased importance being placed on the exchange of information in the supply chain to meet many of the challenges of Reach, intangible attributes like reputation and trust will also play a part. Supply chain relationships based upon cooperation and improved dialogue should serve to encourage this. Elements that reinforce trust include established product stewardship programmes, where companies seek to ensure that their products can be used safely and responsibly throughout their lifecycle. Key features include: familiarity with applicable regulatory requirements; experience with risk management practices; proven capabilities in managing hazard and exposure databases; improving risk communication to clients, and providing chemical safety compliance and advisory services.

Conclusions

Reach has established new expectations for information exchange within global supply chains. There will be some significant hurdles both for large and smaller-sized companies. An iterative process of polling and response is envisaged, together with a mechanism to capture, manage and verify the obtained information (fig. 2). The prospect is for an increasingly rapid move to establish information management tools that will enable suppliers to meet the developing supply chain requirements without introducing significant operational costs.

The dual challenges of increased information sharing along the supply chain – typically creating with it attendant intellectual property concerns – together with active targeting and de-selection of listed materials will create strategic issues for all but the best-prepared companies. In doing so, Reach presents manufacturing supply chains with an unprecedented opportunity to establish and nurture effective communication approaches that will serve to strengthen relationships based on improving trust and cooperation.

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Specialised Separation Technology for Chemical Industries

Crystallization by evaporation followed by drying, purification by sublimation, concentration by evaporation with subsequent drying, solid-solid reaction or other type of heterogeneous reactions are common unit operations in the chemical industry. These processes are characterised by multiple phase change. They are heat transfer controlled, but also diffusion limited unit operations, and commonly developing large vapour volumes. Evolution of large volume of vapors is not rare. The presence of viscous phases impede the agitation and all related results thereof. Conventionally such processes are realised in several distinct steps. The related space requirement, investment and operating costs are high. In today's competitive market environment the industry seeks for new solutions. Solutions that reduce capital and operating expenditure, and maximises revenues.

Specialised separation technology introduces unique solutions to:

- The crystallization by evaporation followed by drying;
- The realisation of heterogeneous reactions in the absence of solvents or in the presence of low solvent concentration;
- The evaporative concentration with subsequent drying of any material irrespective of its consistency and flow characteristics;
- The purification and separation of products by continuous sublimation;
- The combination of several unit operations with simultaneous multiple phase processing in a single unit.

The characteristic features of the specialised separation technology for the chemical industries are:

- Intensive mixing and kneading in all phases

- High interface renewal frequency
- Large free sections for vapor disengagement
- Heavy design
- Large self-cleaning heat exchange surface
- Large installed volume
- Closed design
- Units for batch or continuous operation

The unique combination of mechanical, chemical and thermal operations in a single unit guarantees process optimisation and economy. The following extract of representative applications from the chemical process industries, make apparent the capacities and potentials of the solutions provided from the specialised separation technology:the production of xanthates, hexamethylolmelamine, CMC, phosphates, phthalocyanines etc; vacuum drying of plant extract; continuous selective sublimation under vacuum or with carrier gas stream; evaporative separation of toluene diisocyanate from distillation residue with subsequent drying; vacuum drying of additives and stabilizers.

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Ubichem Catalyzes Research

Scientists from the Ubichem Research facility in Budapest, Hungary, are amongst the authors cited on two papers that describe advances in the use and understanding of the catalytic formation of carbon-carbon bonds. Organocatalytic work on the asymmetric Michael addition – that describes how newly discovered thiourea catalysts efficiently promote the reaction of nitromethane with chalcones with high levels of enantioselectivity – has stimulated much new research in the field. This groundbreaking research was sponsored by Ubichem and published in The American Chemical Society's Organic Letters. The paper, co-authored by Ubichem scientist Tibor Soós, was the journal's most cited article of 2005.

A second report, co-authored by Ubichem's Andreás Szabó and József Répási and published in the Journal of Organic Chemistry, describes exciting results obtained in scale-up of Sonogashira chemistry. The group's findings suggest that by using supported palladium in coupling reactions, chemists may be able to exploit the benefits of homogeneous catalysis but retain the ease of heterogeneous catalyst separation.

Ubichem Research – established in 1995 and based at two locations in Budapest, Hungary – provides a comprehensive range of services in support of pharmaceutical development. From process research, through development and manufacture of active pharmaceutical ingredients (APIs) under cGMP ICHQ7a guidelines, Ubichem works with its customers all the way from discovery to market.

▶ www.ubichem.com

EU Regulations for Homeopathy: Facing GMP?

COMPANY PROFILE Two new high-performance liquid chromatography devices facilitate identification of unknown compounds in ChemCon's analytical labs. One of the devices is equipped with a mass spectroscopy detector. This recent investment means quick and more efficient in-house analytical support both for cGMP/ICH-compliant API production as well as for contract R&D. In only a few branches, success is depending on a quick launch of new products that much like in pharmacy. Patents are expiring just too soon. Generics hardly ever gain market shares if the competitors are already established.

Designed to work under full GMP and ICH compliance right from the start, ChemCon offers an integrated concept of services for all stages of new "small molecules" (organic or inorganic) drug development. Expertise covers classical scientific problems such as chemical patent claims verification or target molecule synthetic route development and optimisation. Parallel synthesis capabilities facilitate the building of compound libraries and speed up process optimization and scale-up. Class C and D clean rooms, audited by the US FDA, can be used for production of APIs in "injectable grade."

Today, the company also offers fully documented, high-quality, GMP-compliant drug synthesis in small scale suitable for homeopathy. At least in regard to GMP requirements, EU regulations are going to treat homeopathic medicines essentially like conventional drugs. Especially, this applies to stability testing and strictly traceable and well–documented origin of raw materials. Typically, commercially available inorganic or organic fine chemicals lacking full GMP documentation do not qualify for those requirements even with guaranteed purity. On the other hand, chemical synthesis is not supposed to be within the core competency of homeopathic pharmaceutical manufacturers.

▶ ChemCon GmbH
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A Chance for Innovation in the EU

The New Chemicals Regulation and the New Research Framework

The new chemicals regulation in the EU, Reach, was published in December 2006 and comes into force on 1 June. This regulation will have a major impact on the chemical industry worldwide. The Seventh Framework Programme for Research (FP7) was adopted on 30 November 2006 and is the EU's main instrument for funding scientific research with a budget of more than €54 billion over its seven-year life.

Dr. Irene McGrath
Rivendell International

The basic elements of Reach are registration, evaluation and authorisation of chemicals. The legislation is based on the idea that industry itself is best placed to ensure that the chemicals it manufactures and puts on the market in the EU do not adversely affect human health or the environment. Reach will create a single system for both what are currently described as new and existing substances. Substances are now described as non-phase-in substances (i.e., those not produced or marketed prior to the entry into force of Reach) and phase-in substances (those substances listed in the EINECS, or those that have been manufactured in the EU, but not placed on the EU market, in the last 15 years or the "no longer polymers" of Directive 67/548/EEC).The European Chemicals Agency (ECA) will manage the technical, scientific and administrative aspects, aiming to ensure that Reach functions well and has credibility with all stakeholders.

Registration and Evaluation

Reach requires the stakeholders to obtain and submit relevant information on their substances for registration. There are two phases: pre-registration and registration:

Pre-registration

Each potential registrant of a phase-in substance in quantities of 1 t or more per year shall submit the required information to the agency to pre-register the substance.

Registration

- Substances: Any manufacturer or importer (M/I) of a substance, either on its own or in preparations, in quantities of 1 tonne or more per year shall submit the required information for the registration.
- Substances in articles: Any M/I of articles shall register any substance contained in those articles, if the substance is present in quantities totalling over 1 t per M/I per year; and the substance is intended to be released under normal or foreseeable conditions of use.

Every potential registrant of a non-phase-in substance or potential registrant of a phase-in substance who has not pre-registered during the established period shall inquire from the agency whether a registration has already been submitted for the same substance.

Evaluation

The evaluation process is divided into dossier evaluation and substance evaluation. The dossier evaluation is undertaken by the agency to evaluate testing proposals or to check compliance with the registration requirements. The substance evaluation will be coordinated by the agency and the competent authorities. This evaluation may be used later to prepare proposals for restrictions or authorisation.

Authorisation Of Chemicals

The aim of authorisation is to assure that the risks from substances of very high concern (fig. 1) are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies.

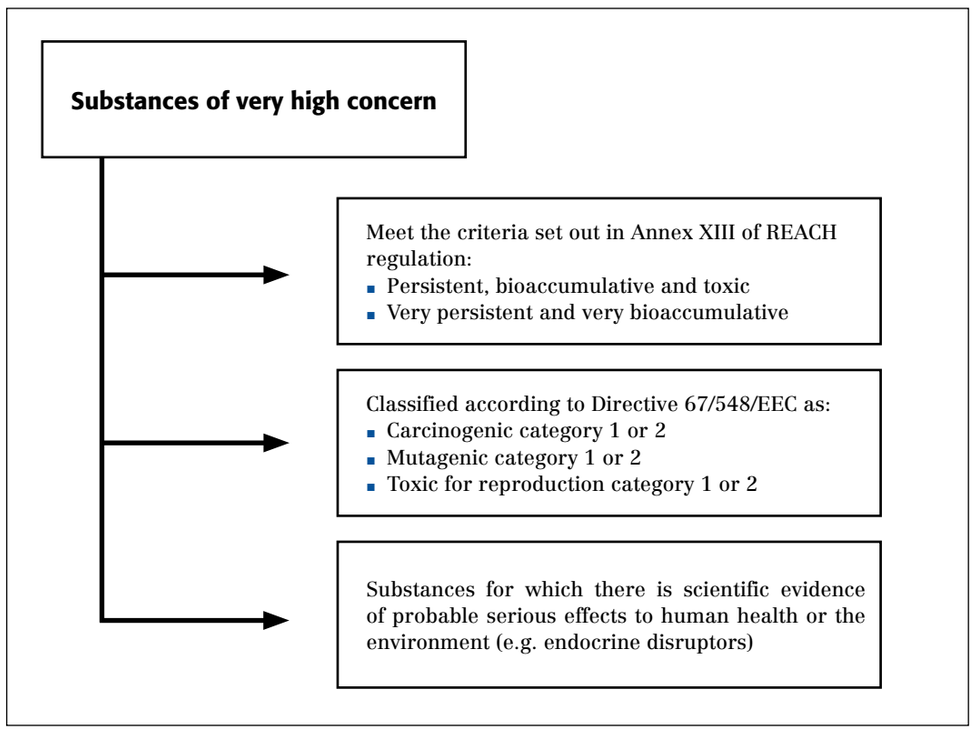

Figure 1: Substances of very high concern

The substances subject to authorisation will be included in Annex XIV of the Reach regulation. Applicants will have to demonstrate that risks associated with uses of these substances are adequately controlled or that the socio-economic benefits of their use outweigh the risks. Applicants must also analyse whether there are safer suitable alternative substances or technologies. If there are, they must prepare substitution plans. If not, they should provide information on research and development activities, if appropriate. The commission may amend or withdraw any authorisation on review if suitable substitutes become available.

The fees related to the applications for authorisation are estimated at €50,000. Therefore, this process has been designed to encourage companies to invest in research to find safer substitutes to avoid having to go through the authorisation process. Exemption from the general obligation to register for products and process orientated research and development (PPORD)

Registration shall not be required for a period of five years for a substance manufactured in the community or imported for the purposes of PPORD by a M/I or producer (P) of articles, by himself or in cooperation with listed customers. A notification will be required. A decision to extend the five-year exemption period by a further maximum of five years could be taken upon request if the M/I/P can demonstrate that such an extension is justified by the research and development programme.

For further information, please, visit the following websites:
www.ec.europa.eu/research/fp7/www.cordis.europa.eu/fp7/

The EU Seventh Framework Programme (FP7)

FP7 is the EU's main instrument for funding research in Europe, which runs from 2007–2013. This Framework Programme provides new impetus to increase Europe's growth and competitiveness, recognising that knowledge is Europe's greatest resource. The programme places greater emphasis than in the past on research that is relevant to the needs of European industry, to help it compete internationally and develop its role as a world leader in certain sectors. A priority will be to make participation in the programme simpler and easier, through measures addressing the procedures, plus a rationalisation of instruments.

Participation in FP7 is open to a wide range of organisations and individuals:

- Research groups
- Companies intending to innovate
- Small or medium-sized enterprises (SMEs)
- SME associations
- Public or governmental administration
- Early-stage researchers (postgraduate students)
- Experienced researchers
- Institutions running research infrastructures of trans-national interest
- Organisations and researchers from non-EU partner countries
- International or civil society organisations

Specific Programmes Under FP7

The core of FP7, representing two thirds of the overall budget, is the cooperation programme. Research will be carried out in ten key thematic areas, one of them being the environment. A series of activities are listed under this thematic area, many of which are directly relevant to policy needs.

Examples of these activities that could be relevant when looking for safer suitable alternative substances or technologies to comply with the Reach regulation are:

Environment and health: Interaction of environmental stressors with human health including identification of sources, links to indoor environment, and impact and emerging risk factors; integrated risk assessment methods for toxic substances including alternatives to animal testing; quantification and cost-benefit analysis of environmental health risks and indicators for prevention strategies.

Environmental technologies for observation, prevention, mitigation, adaptation, remediation and restoration of the natural and man-made environment: related to water, climate, air, marine, urban and rural environment, soil, waste treatment, recycling, clean production processes and chemicals safety.

Cooperation

- Collaborative research across Europe and other partner countries through projects by trans-national consortia of industry and academia
- Ideas in contrast with the Cooperation programme, there is no obligation for cross-border partnerships. Projects are implemented by "individual teams" around a "principal investigator"
- People provides support for researcher mobility and career development, both for researchers inside the European Union and internationally

Capacities

Strengthens the research capacities that Europe needs to become a thriving knowledge-based economy

Nuclear Research

Comprise research, technological development, international cooperation, dissemination of technical information and training

Summary

Both the Reach regulation, through the exemption of registration of PPORD substances, and the FP7, as the main instrument for funding scientific research in Europe, encourage innovation to find safer alternative substances to those of very high concern. Therefore, it may be possible for industry to make use of the FP7 to fund research into finding safer suitable alternatives under the Reach regulation.

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Securing Knowledge in the Maintenance Field

At Chemserv, the term IH-Schule (maintenance school) stands for internal transfer of knowledge and experience. Generally speaking, this maintenance school organises the systematic transfer of knowledge from senior to junior staff. Providing basic vocational training and, particularly, Further training to our staff is of vital importance for our service-based company. This is generally pursued along two different paths: apprenticeship or further training.

For further training, our employees, basically, have a number of different tools available.

By founding an internal maintenance school, we have laid the foundations for "nuts and bolts" training in accordance with industrial requirements. The basic idea is to systematically collect, document and transfer the experience of senior and more experienced staff to junior and inexperienced staff through internal hands-on training.

Currently, the following training blocks are available:

- Fitting engineer (for manual, control and safety fittings)
- Pump engineer
- Paper mill engineer
- Electric motor technician
- Instrumentation and control engineer

Every year, new educational topics are added to the educational programme.

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VWR International to Acquire Remaining Stake in KMF

VWR International has acquired the remaining approximately 76% interest in German-based scientific laboratory supply distributor KMF Laborchemie Handels GmbH (KMF) effective April 1, 2007, that it did not already own. KMF has 70 employees, all based in Germany, with annual revenues of approximately US-$45 million.

Manuel Brocke-Benz, senior vice president and managing director of VWR's European operations, said, "We are very pleased that VWR now has a 100% stake in KMF, a key European distributor for the Company. The very customer-centric approach of KMF, together with the strength of VWR's logistics network and service capabilities in Germany and across Europe – will enhance our value proposition to our combined customer base. Our suppliers will also clearly benefit from having an even stronger partner in one of the major European markets. We look forward to integrating the KMF team to support our growth plans in 2007 and beyond."

▶ www.vwr.com

Warm-hearted Instead of Ice-cold

PRODUCT Environmentally safe, highly functional, inexpensive – since the early 1960s, powder coatings have developed into a mature technical alternative to liquid coating systems. Recently developed highly reactive systems allow applying powder coatings on temperature sensitive substrates like wood, plastics or preassembled composites. Unfortunately this high reactivity comes along with a limited storage stability leading to the necessity to store these powders in a fridge.

Now for the first time highly reactive powder coatings are available which are storage stable even at 40°C. Using a sophisticated catalyst system combined with an appropriate formulation know-how Degussa was able to develop innovative powder coating formulations, based on their own Vestagon BF polyurethane hardeners. These formulations combine all desired properties: emission free, highly reactive and storage stable at the same time. Thus the application range of this environmental compliant technology will be enhanced significantly.

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Chemical Distribution Up Close and Personal

This Year's FECC Congress Set to Address Key Issues

The chemical distribution sector has been experiencing important transformations that will have impact both on the structure and on the performance of the market. The on-going consolidation trend, the influence of private equity investors, the emerging role of Asia and the compliance with the new Reach regulation are key factors that will determine the picture of the chemical distribution in Europe in the coming years. The new scene of the chemical distribution is also reflected in the development of FECC. The growth of our membership, along with wider access to high-level decision makers and increased representation in different international fora, illustrates the successful performance of FECC.

The 2007 FECC Annual Congress takes place in Paris, on 10–12 June, and we expect to welcome over 350 senior industry players. This year's theme is "Market transformation – overcoming challenges: chemical distribution in the 21st century," focusing on the latest market changes and upcoming challenges for the chemical distribution industry in Europe. Throughout the congress, several key business players will present the latest developments on the market changes and expectations. In this context, the role of the private equity investors and the growth opportunities in new markets will be important topics of discussion during the Congress.

Hendrik Abma

In addition, the European Commission will deliver a keynote speech on the new European Chemicals Agency that will play a key role in the imminent implementation of Reach.

Reach Will Make Distributors Play A Key Role

FECC is pleased that Otto Linher, Head of Sector in the Reach Unit of DG Enterprise and Industry in the European Commission will be one of the keynote speakers at the Paris congress. He will introduce the new European Chemicals Agency in Helsinki, which will – as an independent body – manage the technical, scientific and administrative aspects of Reach such as the management of registration dossiers, or the technical and scientific advice on chemical issues. Linher will also address the issue of the industry's preparation for the new Reach regulation. Companies are currently preparing the pre-registration. Potential registrants are encouraged to pre-register their substances during the indicated period (June–December 2008) in order to be able to join the Substance Information Exchange Forum and benefit from the transitional periods for the registration.

FECC has been advocating the interests of its membership under the scope of Reach, already during the legislative process and currently with regard to the guidance documents for the industry, and the upcoming regulation on fees. In this context, FECC advocates that the requested fees are reasonable, in particular for SMEs, which already count on restricted resources due to the implementation of the new Reach requirements. Our advocacy work will continue in order to defend the views of the Members during the numerous reviews that are already planned for the coming years.

FECC is also focused on the facilitation of the compliance with the new Reach requirements to the FECC membership and assist its members with the preparatory activities. The development of guidelines for companies on how to prepare, and a number of other initiatives are in place in order to help companies to successfully implement the new legislative requirements. FECC has also a close cooperation with the European Institutions on the development of Guidelines for industry in the context of the Reach Implementation Projects (RIPs) to ensure that the guidance documents are workable for companies, in particular SMEs.

Among others, FECC is actively involved in the Reach Implementation Project (RIP) on data sharing. Reach will make European manufacturers and importers of the same chemical substance cooperate in a data sharing process in order to ultimately achieve a joint registration of the substance. FECC advocates the introduction of a fair cost sharing system in the data sharing process, which sets a proportionate share for small companies. The different aspects of the consortia formation process will also be an interesting topic in the Congress.

Summary

FECC has remarkably improved during the last years both in terms of membership and effectiveness. A large number of companies as well as two new national associations have recently joined FECC resulting in a strengthened network and an enhanced representation, particularly in the Central and Eastern European countries. FECC is constantly involved in initiatives with the EU Institutions where input from the European Chemical distribution sector is required. FECC has contributed not only to the Reach discussions, but also to the upcoming Globally Harmonised System of Classification and Labelling of Chemicals (GHS), updated provisions for the transport of Dangerous Goods, the increasing Security provisions, the future Directive on Good Manufacturing Practices for certain excipients, the guidelines on Drug Precursors, and the recent debate on Explosive Precursors.

FECC will continue to be actively involved in the EU legislative process, contributing constructively to the debate and ensuring that the chemical distributors' needs and sector specifics are taken into account. FECC will also continue to communicate its members' views to all interested parties.

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Investment In Quality

Helsinn is Fully Dedicated to cGMP Production

▶ Continued **Page 1**

similarly to advanced intermediates but always with high quality in mind.

When did Helsinn decide to dedicate the production solely to cGMP? What triggered the decision at that time?

Dr. G. Calderari: The regulatory approach changed quite drastically in the early 1990s when several concepts used for drug product manufacturing were also introduced and asked for drug substance manufacturing: process validation, cleaning validation, batch release, to name only the key changes. In the mid 1990s, we realised that it would be quite difficult to have a mixed production of cGMP and non-cGMP in the same plant. It was also a strategic business decision: working in Switzerland with the first indications of pressure on price, we decided to move to high-quality and, therefore, to a global value concept and offering. The offer for non-cGMP fine chemical production in Europe was already important and competition from Far East was not yet so present like it is today. Helsinn's management, therefore, decided to make the big step abandoning the "fine chemicals" production in Switzerland and dedicating itself to "pharmaceutical chemicals" following the new stringent regulatory requirements, but also anticipating the actual needs of the pharmaceutical companies.

In the mid-1990s, you were Helsinn's R&D Director and personally involved in the idea to dedicate the chemical production to cGMP.

Dr. G. Calderari: Yes, as always there is the need of a catalyst that initiates the idea. The catalyst was a conference on Drug Product and Drug Substance manufacturing future authorities requirements held in Amsterdam in 1994 which I attended. Coming back from that course enthusiastically, I shared the information and my thoughts with Paolo Guainazzi who, at that time, was Helsinn's Director of Production. He recognized that, in fact, it was not possible to work with so many compromises caused by the mix of GMP and non-cGMP production. The internal discussions with Helsinn's management, then confirmed that this would be an important step in order to have a clear positioning with a real investment in quality.

Formally, the function of Quality Assurance was created and I took over this responsibility myself. The quality policy, quality system and quality committee were created in 1995. This, definitively, was good timing since by the time Helsinn received the call from the Swiss authorities confirming that the FDA would come and inspect Helsinn, the system was in place and running.

Being in charge of R&D in 1995, how did you cope with the quite opposite concepts of R&D creativity and a highly regulated system with standard operating procedures?

Dr. G. Calderari: In fact, it was very positive because I was creating a new system and not controlling it. The challenge was to create a system able to solve technical/organizational/scientific issues by maintaining a certain flexibility and mainly using the cGMP rules in order to better manage the company – from the technical but also organizational point of view. The vision has always been to create a QA system as a tool for helping to manage a company and not only to fulfil regulatory requirements.

Since the introduction of the QA system in 1995, several audits from authorities and Helsinn's partners for contract manufacturing took place. Looking back at the last 12 years, what is it that has most impressed you?

Dr. G. Calderari: There are several positive aspects that have impressed me. First of all, the pioneering approach of a small chemical company that has anticipated the times and has also added some new ideas to contract manufacturing. Big pharma and large manufacturers were certainly already following the trend, but not so the small and medium-sized fine chemicals companies. Certain concepts that are standard today, back in 1995 were new and not yet completely understood.

Also, at Helsinn we see the audits as training opportunities. Every audit from authorities or partners is considered verification and a fine-tuning event. The inspection performed by an expert who has seen other realities and has a long-term experience brings this to our personnel with new ideas or a different way to see the same thing.

In fact, there are no limitations to introducing changes if realistic and correct. The only limitation has to be given in order to avoid an exaggeration of introducing SOPs at all levels, even for really basic things. Trying to reach a perfect system also bears the risk to become very slow, not flexible at all and unaffordable. The art is to find the right way to have an excellent system with highly motivated people that make the system. Easy to say, but it is a process that takes a long time, and I believe we have reached this level based on the audit reports we have received from last year's inspections.

Do you think that the current system runs the risk of becoming overregulated and inefficient?

Dr. G. Calderari: I actually do see a negative side of the current general situation where bureaucratic people have denatured the original quality concept I believed in and I still believe in: substantial quality that enables to manage both, technology and the company. Too many rules have been introduced creating the so called Great Mountain of Paper – the ironical definition of GMP – that is difficult if not impossible to manage sometimes. In fact, this doesn't really come from the legislator but from the system itself, encouraged by consultants and clients that want the 100 % certainty. The challenge of the upcoming years will be to maintain an excellent quality system by speeding-up certain operations, by revisiting it and by using supportive tools like software. The goal is to have the managers not loosing the vision on the product quality, while loosing time in closing unwise deviations that are not critical to the product quality.

Back in 1998, Helsinn Advanced Synthesis started the project of a new plant for the production of HPAIs and also APIs, introducing a new containment concept not required at that time. How did the idea arise?

Dr. G. Calderari: The bay concept of Helsinn Advanced Synthesis was already there in the middle of 1994, with the "Box 2000" idea. The initial dream was to have an isolated production bay with three small reactors able to produce products with lower dosages and higher therapeutic activity. Also, the idea to avoid any possible cross contamination with other products while producing in a closed and dedicated space was part of this vision. The new Helsinn Advanced Synthesis plant is the evolution of this single-box "small scale" into a large construction having three isolated productions areas for HPAI and five production bays for the production of APIs including isolation. Still today, in 2007, it is recognized that we anticipated the times with this multi-purpose plant as contract manufacturer.

Which were the key points that Helsinn had to face in order to be able to produce HPAIs?

Dr. G. Calderari: The first point was to recognize that the product for which the plant had to be built, Palonosetron, was an HPAI. In 1998 the concept of HPAI was not so clear like it is today. Based upon that, the understanding that it was not possible to manufacture the compound in the traditional way without having big issues from the HSE point of view as also possible cross contamination when considering the production in a multi-purpose plant. The third step was to identify the equipment and SOPs that would enable the production of HPAI. What followed was the presentation of the plan to Helsinn's top management and the approval of the investment required, and last but not least, have Helsinn's Biasca mixed team of R&D, Production, Engineering, QA staff support and follow through the project from basic design, trough plant installation and qualification while continuing the routine production with high motivation and enthusiasm.

Looking back on what we did, I would also reiterate that first of all everybody from top management to the operator has to believe in the system at all levels in order to become successful.

Do the chemical operations also benefit from being a part of a pharmaceutical group?

Dr. G. Calderari: Indeed! The know-how acquired from the activities for the Helsinn Healthcare group is used to improve the services to our partners. In fact, being part of a pharmaceutical group and being involved in the development and commercialisation of new chemical entities – including the Drug Product manufacturing business of Helsinn Birex Pharmaceuticals in Ireland – have provided the chemical operations with certain speciality skills in the management of the CMC part that are offered as "free-of-charge" consultancy while implementing a new project for third parties.

Acknowledgements

The interview was initiated and supported by Gabriel Haering, Ph.D., Head of Helsinn Business Development Manufacturing Operations, and backed up with technical expertise by Paolo Guainazzi, Ph.

Gabriel Haering

Paolo Guainazzi

▶ http://manufacturing.helsinn.com

The Linde Group to Supply Equipment for LNG carriers

Cryostar, a subsidiary of the Linde Group, has won an order from Samsung Heavy Industries totalling over US-$50 million. As part of this order, Cryostar will supply on-board boil-off gas reliquefaction plants for five LNG tankers to be built by 2008. The modern membrane carriers with a cargo capacity of 265,000 m^3 will be the largest ever built and are destined for LNG trade between Qatar and the U.S.

The larger the vessel, the more important the boil-off gas management for the LNG. It is stored on board at –163 °C, in order to ensure that the maximum cargo is delivered. Cryostar, who provide both the reliquefaction process design and the majority of cryogenic equipment, developed the plant's unique low power consumption technology. The on-board reliquefaction of boil-off gas on LNG tankers with slow speed diesel propulsion makes these carriers highly economic for long distance travel. Thanks to its low CO_2 emission, this propulsion concept is also more environmentally friendly than conventional steam propulsion, where the boil-off gas is burned together with heavy fuel oil in boilers.

▶ www.cryostar.com
▶ www.shi.samsung.co.kr/eng

Perten Instruments, Newport Scientific Agree

Newport Scientific and Perten Instruments announced that Perten Instruments will be the exclusive distributor of Newport Scientific in Sweden, Denmark, Finland and Norway beginning 1 June.

Rod Booth, Managing Director of Newport scientific said, "This is a perfect opportunity to build on the synergies between the product lines of the two companies. We believe Perten Instruments is able to enhance the support and services needed in the Nordic countries to further penetrate the market. Perten Instruments has the local know-how and has many years of experience working with customers in grain, flour, food and feed industries."

▶ www.newport-scientific.com
▶ www.perton.com

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Reach Is Here

ReachCentrum Helps Companies Untangle the Legislation Web

Continued Page 1

will be generated under the new legislation. This provides companies with quality assurance, which in turn raises confidence in the dossiers developed by the consortia.

So it's been a busy year.

T. Jostmann: We have been quite busy with raising awareness for Reach, developing guidance support for companies and supporting tools to start with the practical implementation and making sure that everything is in place and helping companies come together.

How many non-EU companies have approached ReachCentrum?

T. Jostmann: We don't distinguish between the two in the way they approach ReachCentrum as we are offering our services to all companies which have to play an active role in the processes under Reach. Some non-European companies came to us with piles of information about their substances and said, "Please finish the registration for us." Of course, that is not something that is really straightforward because there are many obligations which would require an active contribution of these companies. You have to consider the company cooperation all over the world, both European and non-European, there's a need to make people aware of their own responsibilities under Reach as manufacturers or importers and how they can cope with it.

What's on the top of the list of worries for non-European companies?

T. Jostmann: A big issue for non-European companies is getting represented within Europe. Within the Reach legislation, such companies are obligated to nominate a sole representative. We from ReachCentrum have clearly indicated that it cannot be our role, because that would put us into a compromising position in our consortium management service.

Where are these companies from?

T. Jostmann: They are spread throughout the world. We have our counterparts in the United States and we support organisations like the American Chemistry Council in conducting workshops to provide necessary information. We also have close contact with individual companies; however, we still need to consolidate our efforts.

You mentioned a need for more basic information on the part of companies. What are other concerns companies have about Reach?

T. Jostmann: The main concern is the complexity of the legislation. Many companies don't understand what they have to do; they would like to have a kind of "cookbook" to guide them through Reach. Once we provide an overview and more in-depth training, people get even more worried. There are literally thousands of pages of material that need to be digested before companies can get to work. That is when people really begin to see the complexity of Reach being the major challenge.

How do you help companies get through the legal jungle?

T. Jostmann: Our approach is different than many of the help desks out there. Usually they address what must be done, but not how it must be done. We, on the other hand, are compiling ideas on how to comply with Reach. We share the hands-on experience we've gained so far as well as what can be implemented on the company level to find the right way to cope. There are a lot of different strategic decisions to be made. Then there's the question of doing all of this in practical terms. This needs to be in context with the guidance being developed in the RIP projects that are partially still running. These Reach Implementation Projects, which are governed by the European Commission and provide guidance for companies and authorities, have yet to be finalised. This makes it difficult if a company wants to prepare itself in due time. We need to somehow bridge this gap by giving advice on what can be done already in practical terms to prepare the company for Reach.

Have you encountered different concerns within different sectors?

T. Jostmann: There are different levels of awareness. For example, some downstream users are very advanced in their thinking; many are taking a more consolidated approach to preparation. Other downstream areas further down the value chain are not really aware of Reach and think that they don't have to play a role in the legislation, which is sometimes a misperception. There needs to be an in-depth discussion to identify uses along the supply chain, to describe conditions of use and how to do a chemical safety assessment based on that information. There is a broad range of how advanced different companies are in terms of Reach awareness and preparation.

In our workshops, we have seen that questions coming from downstream users are very fundamental ones. They ask about what their responsibility is, how they can provide information and how they can protect their confidentiality. Of course, some companies also have concerns about their competitiveness compared to other regions of the world and how they have to comply with Reach regarding inclusion of non-European competitors. It is really the business side of things that people have in mind when they raise complaints about Reach.

Is it too late to begin preparing?

T. Jostmann: I wouldn't say that it's too late, but it's certainly high time. There are a lot of things to do to make sure that a company is prepared before Reach goes into effect. Companies can still do plenty to prepare themselves, such as market and product screenings as well as taking a look at the customers supplied. Companies can take into consideration data they already have in-house. Now is also the time to consider who might be a potential cooperation partner in a consortium. Companies should also look at what they will have to invest in testing substances and what the intrinsic properties of their substances are. There is plenty that companies can be doing right now to get things started – there's no reason to wait.

What hurdles are up the road for companies with chemicals to register?

T. Jostmann: Companies must be aware of internal organisation hurdles. In the past, companies usually had one person who took care of compliance issues. But with Reach, there is a need for integrated responsibility. A multi-disciplinary team must be involved with people from all areas of the company. A lot of data will have to be provided: how the substance is used; what is workplace exposure or a potential emission into the environment; what is the customer's profile; what is the substance going into, etc.

There are many business-related decisions that must be made in order to develop a strategy for the various substances. Companies should ask themselves if it is worth registering a substance or if it would be better to remove the substance because the costs outweigh the benefits.

Companies must also consider their own internal legal structure, which can be something that creates more snags internally. In the end, there are certainly a lot of hurdles for companies, but this also isn't exactly rocket science – it's basic, fundamental work that companies have to consider.

With all of those hurdles in mind, how can an SME compete with a major player when it comes to Reach compliance?

T. Jostmann: The portfolios make a difference. Many times, large and small companies are similar in terms of organisation. However, even then, smaller companies might lack certain expertise. I'm not sure that every small and medium-sized enterprise has toxicological experts; there they would have to look for external help and have to participate in consortia in which they can share expertise with other companies. Also, SMEs are sometimes quite tied up with formulations using hundreds of different substances; they have to make sure that their provider will continue providing such substances. They have to have market clarity as to whether they will still have access to their substance.

Will Reach mean the end for some smaller companies?

T. Jostmann: It will be a challenge for some smaller companies to manage their entire list of substances within a short timeframe, and they would be well-advised to focus on their good substances first. Considering the limited financial and human resources that most small companies have, they might have to reshape their product portfolios as some of the substances might not justify the financial investment. Having said that, some highly attractive niche markets will need special treatment of confidential business information which isolates the SMEs from sharing efforts with others but and complying with Reach is vital for companies to maintain access to these special markets . That is the real challenge, but also an opportunity for substance providers, because they can prove that they will stay on the market because they have done their job. This then reflects well on a company's market share and product portfolio.

What kind of companies have been taking advantage of the ReachCentrum?

> ***"There is plenty that companies can be doing right now to get ready – there's no reason to wait."***

T. Jostmann: Under Cefic's roof, we have roughly hundred different industry sector groups which have a long lasting experience in industry cooperation and have to prepare for Reach anyway. These sector groups are comprised of both large and small companies. When new companies come to ReachCentrum for getting some assistance or guidance on how to prepare for Reach, we can build on this extraordinary experience with having a large representation of the entire chemical industry. Also, there really is no difference between big and small companies, because they all have to cooperate on the substance level.

Reach is still being eyed with criticism from the industry – too high costs; too bureaucratic. How do you see the legislation?

T. Jostmann: The old chemical legislation didn't work well, and there was a definite need for a new regulation which helps re-building confidence in the products of the chemical industry. We shouldn't underestimate the concerns coming from the downstream industry and the end consumers regarding the safe handling of substances. Ensuring proper management of chemicals throughout the value chain and providing more information will guarantee the safe management of chemicals. So if that has been handled properly, companies can benefit from Reach. This is forward thinking and taking responsibility – it is just a question of how efficiently the legislation can be implemented and enforced at the member state level to ensure a level playing field . On the other side, uncertainty was a huge challenge for companies; now that Reach is on the table, the uncertainty is gone and we can all look forward to getting it implemented.

Some companies are complaining that they are no longer competitive. This is a legitimate concern, because some of the substances will probably disappear. However, legislation similar to Reach is being considered in several parts of the world, and here European companies can gain competitive benefits in being one of the first to tackle such reforms.

Does the Reach legislation have any positive sides for the chemical industry?

T.Jostmann: If you talk about confidence in our products, then yes indeed. If a substance has gone through all the testing, then we know it can be managed safely. Once that comes back to the market place, we won't have to have in-depth discussions about single substances anymore. That's our hope. If you can demonstrate safe use, no one should argue afterwards. The communication about how substances are used within the value chain and how exposure can be limited or eliminated is a good benefit.

▶ www.reachcentrum.com
▶ www.cefic.org

Choppy Waters

How to Navigate Through Reach's Legal Obligations

After an intense period of lobbying and debate, Reach has finally been agreed up on and affected companies need to be planning and implementing their compliance strategies. We examine below some of the particular legal and practical issues to be aware of, particularly when preparing for the early stages of pre-registration and registration.

In very broad terms, Reach affects companies which operate in, or import products into, the EU. Reach affects a wide range of sectors to differing degrees; from the obvious large chemical and raw material manufacturing companies; to sectors as diverse as automotives, paints, detergents and clothing. The main obligations are on manufacturers and importers, but there are a number of requirements on product re-formulators and professional users further down the supply chain (referred to as downstream users). Distributors and retailers may also be affected by product changes or the ceasing of production of certain products.

What Does Reach Cover ?

Reach covers both existing substances that are on the market now (estimated at 30,000) and new substances as they are introduced by industry. It is important to note that Reach applies to substances, not products. Substances can be on their own, within preparations (mixtures of substances), or in articles (items that have a particular shape or design which determines function).

A small number of substances are totally excluded from Reach, such as radioactive substances and waste. A larger group of substances are excluded from the registration and/or authorisation processes, notably, food additives, cosmetics, medicinal products, biocides, pesticides and polymers (monomers are not excluded). Therefore, the first step for companies is to determine whether their chemicals and/or articles will fall under Reach and determine what particular obligations they will have.

Legal Duty Of Care

Industry will be pleased to hear that the final text of Reach does not include a specific legal duty of care, which was present in earlier versions of the legislation. However, there is still a general obligation to ensure that the manufacturing, placing on the market, importation or use of chemicals does not adversely affect human health or the environment. Companies will need to consider the impact on their risk management strategy and put in place mechanisms to deal with this, for example, by considering contractual mechanisms with suppliers and customers.

Registration

Companies that manufacture or import substances caught by Reach, in quantities of 1 t or more per year, must register with the new European Chemicals Agency (ECA). Substances in preparations must also be registered, but in general terms, substances in articles only need to be registered if they are present in the article in quantities greater than 1 t/y and are intended to be released under reasonable foreseeable conditions of use. Failure to comply will mean exclusion from the EU market.

Registration requires detailed technical dossiers to be compiled (requirements increase with tonnage and/or hazardous nature). Users of chemicals further down the supply chain will also need to ensure that their specific uses are registered and provide additional information back up the supply chain. The ECA will make a large amount of information submitted under Registration publicly available on its website. However, when submitting the data, companies can request that some of it be kept confidential, where disclosure may harm the company's commercial interests.

Pre- Registration & Consortia Membership Issues

Due to the large numbers of substances and sectors affected by Reach, there is a transitional period for registration of substances already on the market (called phase-in substances). To facilitate this process, there is a pre-registration period between June and December 2008. The information to be submitted for pre-registration is fairly straightforward (for example, substance name, CAS/EINECS name/number, name of registrant and tonnage band). If a company takes advantage of this, it will have much longer to compile the detailed technical dossiers required for full registration. Full registration deadlines then depend on tonnage and/or hazardous nature and are phased in at 2010, 2013 or 2018.

For companies that pre-register, it is mandatory for them to get together into substance groups. These are often referred to as consortia, but are technically called SIEFs (Substance Information Exchange Forums). Other entities, such as downstream users or companies that hold information on substances, can choose to pre-register so that they can also take part in the SIEF. These groups must share existing animal test data on substances to minimise any further testing that may be needed for registration. There is a general obligation for companies to register substances together, using one company as a lead registrant (although some data must still be submitted separately). There are opt-outs available if a company does not want to register jointly, but it cannot opt out of sharing its data.

Companies have the ability to be compensated for the data that they share. However, the provisions setting this out are not at all straightforward. Any cost sharing must be "fair, transparent and non-discriminatory." If the group cannot reach agreement on sharing of costs, they shall be shared equally. If a company refuses to share its data, it will not be able to proceed with its own registration.

During this data sharing process, a company will need to take care not to infringe competition law. Reach is still subject to all the normal competition rules, at both national and EU levels. Failure to comply with competition law can lead to civil penalties and under some national laws even to criminal penalties, with fines of up to 10 % of group worldwide turnover.

The aim of Reach is to be sharing technical data necessary for the dossiers and not market sensitive information, such as prices, sales volumes etc. It will be clear for certain types of data that it should not be shared, but in other cases this will not necessarily be so obvious. Given the significant possible penalties that companies may face, great care should be taken to ensure competition compliance; both in respect of the actual data that is shared; and the conduct of parties within consortia when discussing issues concerning the data.

Practical Preparation

There are a number of steps a company can be taking to prepare for pre-registration and registration. The consortia groups will require contractual agreements to properly set out each members' rights, liabilities and obligations. For example, with respect to: membership, costs sharing, confidentiality, dispute resolution and competition. As an illustration, a company will need to take care not to prevent a new company from joining a consortia group, or include price sharing arrangements that unfairly penalise companies. Some sectors are setting up such consortia now to share data and prepare for registration.

Companies will also need to identify and evaluate the data they currently hold on substances and where applicable, collate evidence of commissioning costs of that data. Companies will also need to assess whether they hold the appropriate legal rights to charge other registrants for access to that data.

Challenging Decisions Under Reach

It is also worth remembering that a limited number of ECA decisions can be appealed before a board of appeal, including decisions concerning certain aspects of registration. There is also the possibility of taking legal action in the form of judicial review before the European Court of Justice, both against decisions of the board of appeal and also, where no right of appeal exists against the board of appeal, against decisions of the ECA. Companies should be putting in place good data management in case it needs to use these avenues of redress.

Summary

Reach therefore presents a number of challenges for companies, both through the detailed internal management of information necessary for compliance and the wider strategic impact and costs of Reach. However, with appropriate preparation and planning, the most successful companies will be able to avoid being caught out by Reach.

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Intelligent Distribution Enhances Opportunities

Partners Support Marketing and Serve as Trend Scouts

In 2000, Wacker Chemie created the "Distribution Management" department to closely interlink internal activities with those of distributors as partners. As a result, the group can serve fragmented markets cost-effectively and collaborate more efficiently within networks.

Axel Schmidt is Director of Distribution Management at Wacker Chemie AG, Munich.

Like in any other field, there are many different views on marketing. Brian Norris, an American marketing expert, considers it to be an ongoing process of moving people closer to buy something. His colleague, Philipp Kotler, defines marketing as a human activity directed at satisfying needs and wants through exchange processes. And Al Ries, chairman of the US-based marketing consultancy firm Ries & Ries, views marketing as simply a war between competitors.

As a globally-active chemical company, Wacker has a holistic approach to marketing which is oriented toward customers and their needs. This is not confined to any single function, but rather is a basic mindset to have a working process in place which satisfies customer needs and therefore influences the decisions of customers to buy. A marketing partnership is therefore seen as a collaborative process between a chemical company and a chemical distributor that is based on contractual agreements and basic principles. The collaboration's aim is to influence end-customers' purchasing decisions and to satisfy their needs via joint activities and knowledge transfer.

Mutual Win-Win Situation

A key factor in selecting a sales channel is the distinction between direct customers and distribution customers. Some 2,000 to 3,000 Wacker customers are classified as direct customers due to their business volume and international market presence. These are joined by key partners, particularly in domestic markets, with whom new technologies are developed.

In the case of distribution management (channel management), the primary question is which sales channel is best suited toward optimally serving customers, suppliers and all other associated parties. In terms of indirect sales, Wacker has two channels: The sales and logistics subsidiary Drawin, as well as specialised transregional or local distributors which, for example, serve as catalog companies for pharmaceutical labs or offer a broad range of chemicals for the cosmetics or electronics industries.

However, traditional chemical distributors are still our most important sales partners. Beside commodities, they distribute our specialty chemicals either at a local level in a country or transregionally, spanning entire continents. For example, the cooperation with Brenntag is very successfully in the Americas and in Eastern Europe, and with the IMCD Group as a partner for Western Europe. In addition to these large distributors, further partners also include, among others, Reda in the Middle East, Ipiranga in Brazil and Amtrade in Australia. Since no chemical distributor currently serves all regions, we aim to collaborate with the strongest partner in each region.

Collaboration with Distributors Offers Numerous Advantages

The main reason for collaboration with distributors can be summarised as follows:

- Distributors enable the group to serve fragmented markets cost-effectively.
- They usually have their own pool of customers, which results in additional business potential. Plus, these customers can also be supplied with so-called complementary goods.
- Distributors have local warehouse facilities and thus offer partners the possibility of fast and flexible delivery.
- Distributors protect against credit risk and have local influence and contacts.
- Distributors also function as market trend scouts and support the Group's marketing strategy.

Here, we differentiate between service partners and market-access partners. The latter are particularly important in Asia. These functions are now supplemented by those of the marketing partner. A partnership of this sort can take very different forms depending on the market segment and region. The range spans from the further enhancement of local services to intensive sales collaboration with the aim of jointly developing and serving not just smaller customers, but also entire markets together.

The criteria shaping a marketing partnership include, among others, regional and economic factors. Wacker differentiates between mature, developing, and emerging markets such as China, India and Southeast Asia. Since the primary goal in these countries is market access, the Group also maintains close contacts with regional players. This also includes collaboration with diverse types of distributors, such as traders and agents.

In developing markets such as Eastern Europe and Latin America, collaborations exist with globally-active partners, and the most important goal is local market development. The focus in mature markets is on the services of a distributor, with whom the marketing-partnership model is particularly valuable. In this case, we collaborates with a strictly limited number of partners. In mature markets, collaborations with specialist distributors are confined to niche segments, in which allrounders do not have the necessary technical expertise.

As part of distributor training, Wacker also offers web-based training programs. (Photo: Wacker Chemie AG)

Marketing Mix: It's the Mixture that Counts

Even the best marketing strategy is worthless without a balanced and synergetic combination of marketing instruments. This is why Distribution Management particularly considers the right marketing mix when planning marketing partnerships. The focus is on the following operational instruments:

Product Development: Sales partners play a key role at this early stage. Their tasks include devising market surveys and suggestions for new products or applications. Primarily, however, the partner must serve as a market trend scout to enable early detection of market trends that can be taken into account when developing new products. As a multiplier, the sales partner ensures that our product innovations and solutions reach market maturity and become well-know more quickly.

The sales partner also plays a vital role as a multiplier for sales and distribution policies (placement). For this reason, sales partners were sought who also distribute other chemical companies' products.

In terms of promotion, we strives to establish a joint market presence with each partner, covering joint advertising, product literature, tradeshow appearances and customer events, etc.

Another key instrument is pricing. In the distribution business, it is determined by the market price level above all. We do not define final prices, but rather support our sales partners in select cases with "price supports" (i.e. special transfer prices for individual transactions). The size of commissions paid to our distributors depends on the extent and quality of the services provided.

Distribution Management ensures smooth collaborations with all distributors. Its tasks include regular reviews, sales reports and contractual auditing. E-business is also an important topic. In the U.S., there is a support center for distributors, which offers them technical support. However, the key task is to coordinate the distribution activities of all business units and business teams to ensure that processes are as effective as possible.

Personell as a Success Factor

However, the key success factor for sales is staffing. Without motivated and qualified employees, any marketing partnership is destined to fail. Therefore, targeted training programs are used to progressively build and strengthen relationships with distributor employees. Marketing-partner training begins with a general internet course, followed by an introduction to sales tools, such as product information and data sheets. Moreover, training includes specialty sessions – which also fulfill mentoring and coaching functions – for advanced employees or joint customer visits.

In summary, we have very clear ideas of what we expect from sales partners and what we intend to achieve together. Trust and fairness between us and our partners are vital and form the basis for our joint success. Whoever thinks like this does not view distributors as potential threats, but rather as partners who make a major contribution toward successfully and sustainably implementing business strategies and visions.

Wacker's Distribution Strategy at a Glance

- Optimal balance between direct and indirect business.
- Global and transregional partners receive a clear commitment and preferential treatment.
- Balance between traditional chemical distributors and specialized distributors.
- Supplementing the distributors' services and market-access functions via joint market developments.

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Production
FACILITIES · PROCESSES · TECHNOLOGIES

Production
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Logistics
Need for cold-chain logistics on the grow
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Ubichem Extends Production Capacity

Ubichem said it is investing in additional production capacity in its facilities in Budapest, Hungary. Four additional 3,000 l reactors (glass and steel) and increased drying capacity are planned to be online in the second half of 2007. The company said this will greatly increase the total output of the plant and support current development projects as they move up in scale. New quality control laboratory facilities also form part of the expansion in Hungary, which were operational at the end of March.

▶ www.ubichem.com

AstraZeneca to Build R&D Expansion

AstraZeneca has begun construction on a US-$100 million R&D expansion at the company's Waltham, Massachusetts (U.S.), facility. According to AstraZeneca, the expansion of the research facility will accommodate up to 100 additional researchers who will join the more than 450 existing employees focused on discovering treatments for infectious diseases and cancer.

▶ www.astrazeneca.com

Agrium to Build Nitrogen Facility

Agrium said that it and its project co-owners are proceeding with the construction of a world scale nitrogen facility to be located in Damietta, Egypt, with completion expected in 2010. The plant will be designed and built by Uhde and consist of two ammonia and urea trains with a combined capacity of 1.3 million t of urea and 100,000 t of net ammonia.

Agrium will have a 60% interest in the EAgrium joint venture. Egyptian government owned entities EChem and EGAS will hold a 24% interest in the joint venture, and Gasco, the national operator of the gas distribution grid, will hold a nine percent interest. The Arab Petroleum Investment Corporation (APICORP) will hold the remaining seven percent interest. Agrium is to be the exclusive marketer of the nitrogen products exported from this facility.

The lump sum turn-key project was scheduled to commence by mid-May, with the first train expected to be complete the first half of 2010 and the second train to be complete by the end of 2010. The construction cost of the facility and related infrastructure is forecast to be approximately US-$1.2-billion. The majority of the project is expected to be financed through non-recourse debt, with the remainder funded by equity contributions from the co-owners. The project is conditional on a lender financing commitment.

▶ www.agrium.com
▶ www.uhde.biz

Solvay Solexis Expands Production Capacity

Solvay Solexis said it will increase the production capacity for this specialty fluoropolymer. The new capacity expansion will increase Solvay Solexis' existing PVDF capacity at its plant in Tavaux (France) by some 30% and is scheduled to come on stream early in 2009.

▶ www.solvaysolexis.com

Basell to Expand Polypropylene Capacity

Basell plans to expand capacity at its Bayport, Texas site by restarting a polypropylene plant that has been inactive since 2001. The company currently operates two Spheripol process plants at Bayport with a combined annual nameplate capacity of 530 kt. The plant to be restarted also uses the Spheripol process and has a nameplate capacity of 220 kt. This plant will be fully refurbished and upgraded with state-of-the-art innovations. Start-up is scheduled for the second quarter of 2008.

▶ www.basell.com

Akzo Nobel to Invest in Chinese Chemicals Plants

Akzo Nobel said it will spend €250 million on building two chemicals plants in China–the first confirmed investments in a new multi-site being established by the company in Ningbo. As announced last October, a 50 hectare plot has been reserved within the Ningbo Chemical Industry Zone (NCIZ) and the two new facilities – for the manufacture of ethylene amines and chelating agents – will be the first to be constructed on what will be one of the biggest sites for the company's activities in the world.

Work will begin once the relevant approvals have been obtained from the Chinese authorities. Both plants – which will create several hundred new jobs – will utilise state-of-the-art technology and will meet high, self-imposed standards for eco-efficiency. The chelating agents plant is expected to start up in 2009, followed by the ethylene amines factory in early 2010.

▶ www.akzonobel.com

On Track for the Intelligent Factory

Pictures of the Future in Automation and Control

On track for the Intelligent Factory" – automation is an example of how Siemens consistently sets technology trends to create sustained benefits for its customers. Let us all take a look into the future: How will industrial automation develop? What are the general conditions and challenges which will govern this development? And to what extent does Siemens live up to its claim to be a trendsetter in this technology? The following is an excerpt of Prof. Klaus Wucherer's presentation during this year's Hannover Messe fair.

Prof. Klaus Wucherer, Siemens

With our innovation approach, we have also taken a look ahead into the future of our business segment Automation and Control. We believe that five trends will largely determine the future of this complex field of technology: Standardised platforms, micro-system techniques, mechatronic solutions, the growing performance of IT and industrial communications, and the convergence of product life cycle management (PLM) and automation.

Platform Strategy: Totally Integrated Automation

With the launch of Totally Integrated Automation (TIA) in 1996, we succeeded in advancing the integration of engineering, data management and communications to unprecedented levels of performance. TIA has remained the benchmark generally applied to the world of automation, meeting customers' requirements to increase their productivity on the one hand and reliably protecting their investment on the other. TIA is a unique approach to automation which covers all levels of the automation pyramid. All components interact; they are interconnected through high-performance communications with the main aim of cutting engineering costs on the one hand and reducing life cycle costs on the other – always bearing in mind the overall automation task. Thanks to TIA, we are the sole supplier capable of providing integrated and reliable solutions for converging factory and process auto¬mation in the form of hybrid automation.

We are poised to forcefully drive TIAs further development. This means bringing new technologies into the automated world and linking production systems with product design and merchandise management systems. In a highly fragmented industrial software market we are the ones who, by placing the emphasis on extending our portfolio in the field of PLM and MES (Manufacturing Execution Systems), are again setting the trends. What our customers require is consistent solutions and the integration of the most diverse software technologies into a meaningful and lasting solution.

Micro System Technology

Another key area for the future of automation is in micro-scale and nano-technology. In combination with software and microchip technology, it uses micromechanical components, thus driving major technological developments.

Microsystem technology is based on the manufacturing process of micro-electronics. New products are being developed, beyond electronic and opto-electronic components, including micro-sensors, micro-actuators and even micro-reactors which can be applied in process technologies. Reactors in micro size can be made in modular units and switched in multiple parallels which is a great advantage in such industries as pharmaceuticals and fine chemicals. The corresponding automation is due to follow these concepts of size and distribution in the medium term and become an integral part of micro-system technologies. As soon as we get there, this will open up entirely new saving scales.

Micro-reactors are used to optimize lab processes, making it easier to transfer them to the industrial manufacturing process. Once a production process has been certified at pilot-scale and is multiplied thanks to a standardised process, both the capital expenditure and the time-to-market are bound to drop dramatically for the user. Moreover, it suits individual requirements in small batch production as is the case with active pharmaceutical ingredients. If the production output is to be increased, standardised components are multiplied and run in parallel. "Number up" instead of "scale up."

Bio-sensor systems are used in in-vitro diagnostics, in large volume screening or bio-detection systems, and in miniaturised sample preparation in bank card format. In the autumn of 2004, researchers at Fraunhofer, Infineon and Siemens were selected for the German Future Award given by the German Federal President for a project called "Laboratory on a chip – electrical bio-chip technology."

All these new technologies create the basis for the next step in intelligence distribution. As a vision one could imagine networks of self-monitoring, self-configuring components, with each component dealing largely independently with the task assigned and sharing the information gained with all other components within the network.

Innovative Mechatronic Combinations

Mechatronics is not a new trend, but a consistently important one which shows to what extent consumer habits are reflected in production technology. Since consumers are increasingly asking for more personalised goods and products, manufacturers must be able to cope with production on demand and real-time production planning.

In technological terms this is achieved via smart modular mechatronic systems which can be quickly and easily exchanged whenever required. Mechatronic systems are changing the conventional form of mechanical engineering. Machine functions which used to be defined by mechanical components will now be realized through an interplay of mechanics, electronics, and software – in short "mechatronics." It allows the development of new machine designs at considerably less cost and much greater performance and efficiency. Such systems can also be used to analyse existing machines; based on a well-founded optimization of control loops, we can make the most of such equipment.

Moreover, software tools and services supporting a machine's entire life cycle are gaining importance. They assist in the mechanical engineering and automation design, in optimising and commissioning the machine, as well as during operation and service at the facility of the end-users, who are getting involved in the early design phase where the machine's properties and functions are virtually determined. This allows to predict, already during the design phase, how a prototype will behave, for example by using kinematic models which simulate its motions for collision control.

Enormous development, material and cost savings can be made if machine maker, end-user and automation partner work closely together throughout the entire design process, from the initial idea, through simulation to the finished machine. Benefits to the user extend from faster machine design and verification of user software to ensuring the proper processing time of the machine later on. Major benefits are also manifest in the form of a safe start-up, risk-free program optimisation, and first run training activities.

Information and Communication Technologies

IT software and industrial communications are dominating base technologies which are also playing an increasingly important role in automation. In about 40% of our Siemens business sectors we design components containing software. We generate almost 60% of our sales with products, systems and applications for which we develop the necessary software ourselves. Over 30,000 Siemens engineers worldwide are engaged in the development of software.

The functionality of our products, especially our embedded systems, is increasingly realised by means of software. The improvement of software and engineering processes provides the key to better quality, shorter development times and increasing productivity. Some of the challenges of automation which we are tackling together with our customers include the transition from proprietary systems to open systems and the reduction of high maintenance and further development costs caused by inflexible system architecture.

The trend towards networking, distributed intelligence and powerful engineering tools has made the share of software development grow rapidly among all automation producers. With a view to reversing the increase in R&D expenditure, manufacturers are taking a variety of measures, such as improved software development processes and clearly organised stable long-term software platforms such as Simatic IT, our rapidly growing MES proposition.

Networked production environments require powerful and stable communication networks capable of providing the required information at any point in time. These networks must be designed to cope with future requirements in order to better organise growing data volumes arising from the convergence of both office and automation environments.

The communication channels required for successful business reach a high degree of complexity. To make all partial processes interact in a fully functioning and economically meaningful network, these processes must be analysed first; and communication by fieldbus and ethernet must be well thought out and carefully planned.

CIM – A Vision Gets Back On Track

The dream of every factory designer and automation specialist is the Digital Factory. In the same way as a product and all

▶ Continues Page 23

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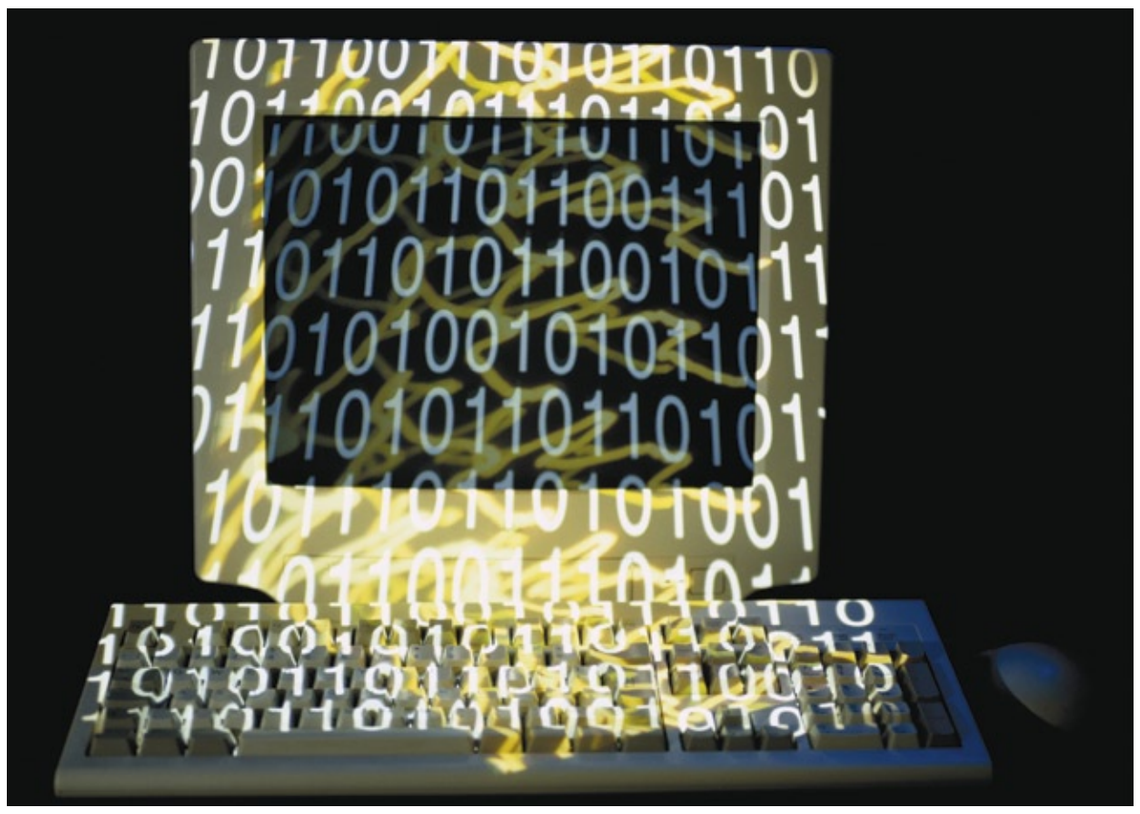
FDT Group and EDDL Cooperation Team

Agreement to Develop Unified Solution for Device Integration

The EDDL Cooperation Team (ECT) and the FDT Group said they have reached agreement to combine efforts and work toward a unified solution for device integration that is compatible with both technologies. The two companies said this would satisfy one of the most frequent customer requests.



As part of this agreement, the FDT Group will join the ECT as its newest member. FDT and ECT representatives agree to work together to finalize this solution and achieve a common framework that meets the requirements of all parties. Future developments will use a subset of the OPC UA technology within a client-server architecture. In addition, both parties have agreed to incorporate the advantages of FDT and EDDL technologies.

"This new cooperation follows our targets of openness and freedom of choice for the benefit of end users and is strongly supported by our members," said Flavio Tolfo, managing director of the FDT Group."After much discussion, we reached commitment to work together and protect the investment of each technology for the benefit of end users. The FDT Group is looking forward to bringing to bear its broad experience of integrating software applications in conjunction with device descriptions by joining the EDDL Cooperation Team to solve end user needs."

Hans-Georg Kumpfmueller, chairman of the ECT, said, "This agreement, once brought into reality, is a major step forward for device integration in several areas. It eliminates double efforts for customers and vendors, and preserves backward compatibility and operating system independence. It is based on the upcoming OPC UA technology, providing EDDL based integration with the possibility for integrating software applications for highly complex OPC UA (Unified Architecture) is a technology of the OPC Foundation requirements. Our agreement is the natural technical evolution based on the most up to date, open, and flexible technologies. The ECT welcomes the FDT Group as a new member to shape the future."

Frequently Asked Questions

Why did the ECT and FDT Group decide to work together even though each claims to have the better solution for device integration?

Currently, there exist two technologies which are offered to end users. On the one hand they overlap to some extend, on the other hand they have a different scope of application. Unfortunately, existing market dynamics forces users in some cases to choose one of these two and offers no migration path from one to the other. Because this approach is unacceptable for end users, there is a need for a single unified solution. Additionally, manufacturers are currently investing in parallel development efforts to support two technologies. For these reasons, we decided to join efforts and develop a common Future Device Integration (FDI) architecture.

Is there already a solution for the common device integration visible?

There is not yet a solution for a common approach. There exist ideas and concepts that have to be discussed in the technical teams, who will then have to define the architecture for a common device integration solution based on use case requirements. A white paper published by itm describes a device integration concept that combines the advantages of EDDL with those of FDT, i.e. it makes use of a textual description for basic integration and allows for advanced application needs to use software based integration.

What is the goal of this new agreement?

Our goal is to develop a unified path forward for device integration that is based on use case requirements, incorporates the best aspects of each technology and eliminates redundancies where they may exist.

What is the scope of the joint technical development?

The architecture will be developed with the following guidelines:

- a client server architecture
- platform and operating system independent
- host system independent
- compatible with existing EDDL and DTM based device descriptions
- applicable to any field device communication technologies
- applicable for hierarchical and heterogeneous network topologies
- an open specification and become an international standard

How will the project be organised? How will it be staffed?

The FDT Group will join the ECT and become part of its steering committee. A joint working team will be responsible for the technical development.

What is the timing for implementation?

The technical work team shall meet shortly and detail the scope of work, resource requirements and a product roadmap. Our intention is to proceed as fast as possible and our first milestone is to have draft specifications and prototypes in place no later than the end of 2008.

What will happen with the installed base of existing EDD's and DTMs?

It is the individual responsibility of the ECT and the FDT Group to develop migration strategies for their installed base using the common FDI. The intent is to ensure backward compatibility with existing EDDs and DTMs.

Will this specification become an international standard?

It is our intent that the FDI model is an open specification and an international IEC.

What about the requirements in Factory Automation?

FDT covers applications in factory automation and process automation. EDDL is used mainly in process automation and for some device descriptions in the factory automation market. It is the intent to develop FDI in a way that it could be used for factory automation devices.

What will be the impact on current developments? Will current projects be delayed?

This common development is an addition to existing technology development and standardisation efforts that each organisation has planned and budgeted. Current projects will continue in concert with this development effort.

Who will own the specification and who will be responsible for its maintenance and development?

In future the FDI model specification will be owned collectively by all members of the ECT. When it becomes an international standard, the technology will be available under the rules of IEC. The ECT will be responsible for its maintenance and development.

How will you position this announcement in the market? Will you market it jointly?

Our intent is to jointly announce this agreement to the market. For now, the ECT, along with the FDT Group, will begin to highlight the benefits of an FDI model through their marketing channels. For the future, we will develop together a common set of supporting communicat ion material that promotes the benefits of the unified solution.

Is there an existing framework for the FDI model?

The final FDI architecture will be developed by a joint technical team. The basis for this solution is the concept from the German based institute itm as outlined in its White Paper v 1.1 as well as the FDT and EDDL specifications.

Will the common FDI be operating system independent?

Yes, one of the primary goals of the solution will be to ensure the FDI model is operating system and host system independent.

When will a specification be available?

Our plan is to have a specification completed by the end of 2008.

What are the next steps?

The technical team will work out a detailed solution based on common use cases and common requirements and will develop the technical specification based on these use cases and requirements.

Which protocols will the common FDI cover?

The FDI model shall be applicable to any field device communication technology; e.g. Hart, Profibus, FF, Profinet, etc. The architecture will be available for adoption by other fieldbuses.

How can it be made sure that Host and Device suppliers will comply with the new specification?

Conformance tests will assure that components or files are developed according to the FDI model.

It looks like FDI works like a printer driver in Windows. Is that a good analogy?

A better analogy would be to say that FDI should work like web pages using a web browser on Internet.

Can FDI be used to provide externally accessible information, or does it only display values on the screen?

FDI will support both. The host can use the information about the data to present the data as well as making it available through to other applications, for example through an OPCUA server.

Is FDI only intended to display data in computer workstations or will it support handheld communicators as well?

FDI is intended to be platform independent supporting software and sophisticated device management systems on Windows workstations as well as embedded devices such as handheld field communicators. Data servers such as for OPC will also utilize FDI to build name space etc. Thus FDI will provide a single universal solution.

Will FDI only work for simple instruments like temperature transmitters, showing diagnostics as brief text messages?

There will be no draw back. FDI is intended to apply to simple as well as sophisticated devices including, for example, valve positioners or multivariable transmitters.

How will future versions of Windows and its regular service packs affect the compatibility of FDI?

FDI is will be platform independent, e.g. independent of a computer hardware or operating system. Therefore the technology will not be affected by changes in operating systems. The investment in the system is protected.

Do I need to complement FDI with FDT/DTM and EDDL?

No. FDI will handle all aspects of the device and system life cycle from configuration and commissioning to advanced diagnostics and performance analysis. FDI will be compatible with existing FDT/DTM and EDDL installations.

Devices from different vendors should be displayed consistently. Does FDI technology help to ensure that?

Yes. FDI gives the device vendor complete freedom to define the content on device pages to give access to all device functionality. The style (look & feel) will come from the host while the device vendor will have the freedom to write applications for specific functionality.

Over the life time of the system there will be many versions of devices used as failed devices are replaced. How does FDI prevent conflicts between different versions of a device?

One of the major requirements to FDI is that the addition of a new device or version shall not remove or overwrite existing device descriptions or software components. A new version shall not conflict with an old.

Will FDI meet the requirements of Namur NE 105?

Sure, this is a must. It is of course the major interest of the involved organisations to meet the requirements of a group of important customers.

▶ www.ftdgroup.org
▶ www.eddl.org

Borouge Awards Two Major Contracts

Borouge awarded contracts valued at approximately US-$3 billion for Borouge 2, the major expansion project at the company's production facilities in Ruwais, Abu Dhabi in the United Arab Emirates.

The two contracts compromise:

- A contract worth approximately US-$1.855 billion for the construction of three new Borstar technology polyolefins units and associated material handling facilities, laboratory facilities and marine works to Tecnimont. of Italy, awarded on a lump sum turnkey basis
- A contract for an estimated value of US-$1.234 billion with Tecnicas Reunidas of Spain, awarded on a convertible lump sum basis to construct the offsite and utility facilities for the expanded plant.

The contract with Tecnimont S.p.A. Italy will see the development of two Borstar polypropylene plants with a combined annual capacity of 800,000 t and a new Borstar Enhanced PE plant with an annual capacity of 540,000 t to complement the existing 600,000 t/y unit. Preliminary work on the polyolefins unit will begin mmediately and is scheduled to be completed in 2010. The contract with Tecnicas Reunidas S.A. will see the supply of utilities to all the associated EPC packages for the Borouge 2 project. Preliminary work will begin immediately and is also scheduled to be completed in 2010.

▶ www.borouge.com

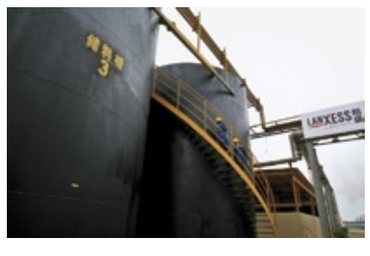
Dow to Expand DVB Capacity

The Dow Chemical Company announced plans to expand its global-scale divinylbenzene (DVB) plant, located at the company's Michigan operations manufacturing site. Scheduled for completion in the fourth quarter of 2007, the expansion will increase Dow's capacity for DVB by approximately 3 million pounds per year (1,350 mt/y). The amount of the investment was not disclosed.

▶ www.dow.com

Lanxess Opens New Plant in China

Lanxess has opened a new plant in Shanghai as part of its Asia strategy launched in 2006. This is the group's second production facility for inorganic pigments in China. The plant with an annual capacity of approximately 20,000 t will be operated by the Inorganic Pigments business unit to supply raw materials for the production of inorganic pigments in Shanghai, which started in 1996. Lanxess had previously sourced these raw pigments from suppliers.



▶ www.lanxess.com

Borouge Launches Gulf Plastics Pipe Academy

Borouge announced the launch of the Gulf Plastics Pipe Academy (GPPA), of which it is a founding member. The GPPA, formally launched by Harald Hammer, CEO, Borouge, at Dubai PlastPro, is set to play an important role in increasing the use of high quality plastics pipe systems in the Middle East.

The GPPA is an independent, non-profit organisation that has been formed to promote the use of specified plastics pipe systems and good installation practices in the greater Middle East region. A unique organisation, the GPPA represents all stakeholders in the plastic pipe value creation chain – such as polymer producers, pipe and fittings producers, pipe system designers and contractors, pipe installers and utility providers. The goals of the organisation have been discussed with many other companies in the Middle East and beyond, and the response to this initiative has been very positive in every case.

The GPPA is committed to raising the knowledge and skills required to develop high quality plastics pipe systems. This will be achieved through developing education and training programmes, promoting standardisation and certification and by encouraging best practice in health, safety and environmental matters.

▶ www.borouge.com

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High-throughput Formulation R&D

Automated Workflows for the Development of New Products

For some time now, high-throughput methodologies have been applied to various research areas, such as catalysts, polymers and electronic materials. Recently, more academic and especially industrial interest has also been seen in the area of high-throughput formulation research.

For a number of reasons, formulations research is well-suited for the application of high-throughput technologies: Typical formulations can easily consist of 10–15 active components. The nature and concentration of these components need to be carefully optimised for the target application. Additionally, the application and the performance testing of the formulations may each involve many adjustable parameters. Altogether, this presents an incredibly large experimental field. Moreover, many formulations have short product cycles, which increases the need for new developments and shorter commercialisation periods.

A general representation of a typical formulations research workflow, embedded in the required informatics infrastructure, is shown in figure 1. From a number of liquid and solid components formulation libraries are prepared. Then, the formulations are applied, e.g. as coatings, followed by several performance testing and characterisation steps.

The implementation of a high-throughput workflow for the development of new formulations has the following advantages:

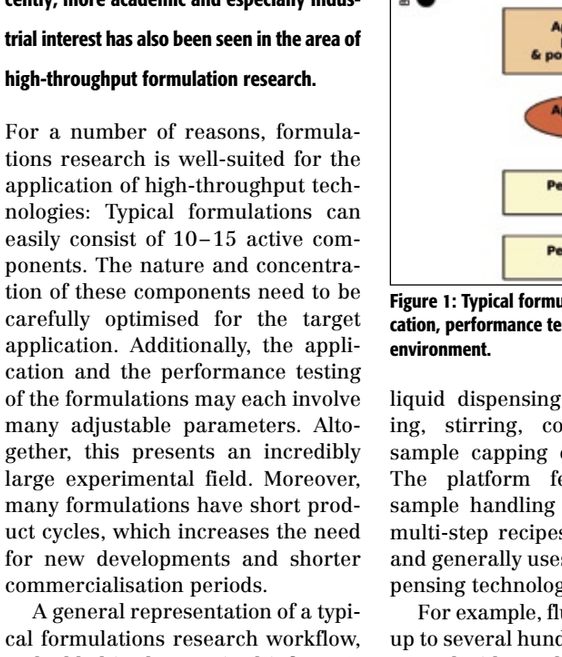

Figure 3: Fpro Formulator, hte's new workstation for modular high-throughput formulation workflows.

- Systematic, fast and controlled execution of R&D programs
- Reduction of development times and development costs
- Productivity increase in R&D
- Faster reaction to customer requests and legislation changes
- Excellent reproducibility of results
- Common database for recipe information and results data
- Generation of structure-property relationships, better understanding of formulation properties

Available Platform Designs

The major design goals for our formulation systems are modularity, flexibility and extensibility, as the demands of high-throughput experimentation projects tend to vary significantly over time requiring important changes to the initial workflows. Individual modules can be exchanged or re-grouped around the robotic handling system and new modules performing different functions can also be added which makes future extensions to the systems possible.

Figure 2 shows an example of a large-size robotic platform for the high-throughput preparation of formulations for diverse applications. Around a central articulated-arm robot on a linear track the different functional modules such as viscous liquid dispensing, powder dispensing, stirring, coating application, sample capping etc. are arranged. The platform features individual sample handling allowing complex, multi-step recipes for every sample and generally uses weight-based dispensing technology.

For example, fluids with a viscosity up to several hundred Pas can be dispensed with our dispense technology. Our proprietary dispensing algorithm automatically controls all necessary dispensing parameters and acquires the dispensed amounts in real time from a high-speed scale with a resolution of 0.1 mg. The corresponding dispense amounts range from 1 mg to 50 g or more. The dispense accuracy in reproduced experiments is generally less than 1 %. For very small dispense amounts, a special piezo-based dispensing technique has been developed, that can also be used for fluids with very high viscosities (> 100 Pas) which may additionally contain particles, such as pigment pastes.

Our latest development, the Fpro Formulator, is shown in figure 3. It combines the functionality of the large-size platform on a significantly smaller footprint. The system features a wide range of modularity and can be equipped with up to three robotic arms and tool changers for very complex formulation and application recipes. Additionally, several systems can be combined within larger workflows.

Furthermore, a broad range of characterisation instruments such as viscosity, pH, colour measurement, stability measurements, and film characterisation such as ellipsometry, electrical measurements and FT-IR, can be integrated into the automated workflows.

Software Integration

The operation of the formulation platforms is fully supported by our advanced software tools, namely myhte for experimental design, data management, data analysis and workflow integration, and hte Control for process control, scheduling and monitoring.

Within myhte, the scientist translates the recipe structure of the formulations into a so-called template consisting of a series of process steps (dispense, mix, apply, dry etc.). The variable parameters of these process steps can then be filled by means of the implemented Design-of-Experiments algorithms, generating a recipe matrix. Libraries of recipes can then be arranged into jobs. The job is retrieved from the database by the operator on the platform's computer. Next, hte Control assists the operator in equipping the platform with all necessary substances and materials, followed by fully automatic execution of the job, thus generating a library of formulations or coatings. hte Control also dynamically schedules the processing steps for the different samples between the various modules of the platform. Finally, all relevant process control data (actual dispense data, time stamps, barcode assignments etc.) is transferred to the database and can be analysed and visualised by the scientist with myhte.

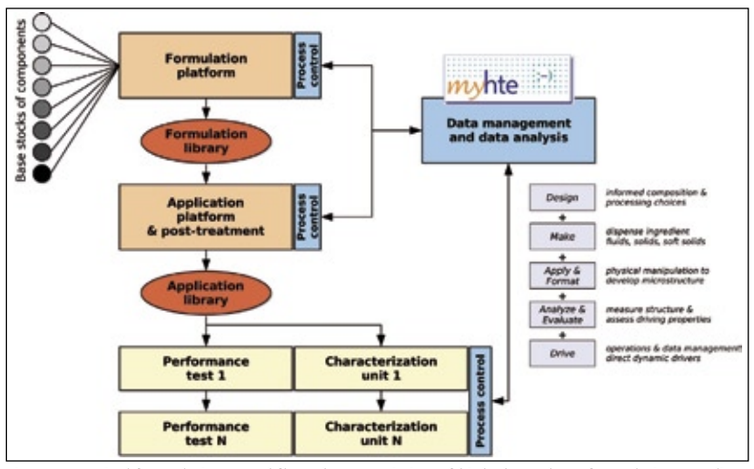

Figure 1: Typical formulations workflow chart consisting of high-throughput formulation, application, performance testing and characterisation, integrated into a suitable data processing environment.

Figure 2: Partial view of a high-throughput formulations platform, showing the articulated arm robot on linear track and the viscous fluids dispensing stations.

In general, the software environment definitely determines the overall productivity and efficiency of a high-throughput workflow. This fact is still very often underestimated. In the end, the data is important, not the robot.

Applications

The area of formulation research is very diverse with regard to the nature and the amounts of the starting formulations, which of course may be even more important for high-throughput formulations research, as high-throughput experimentation projects tend to vary significantly over time requiring important changes to the initial workflows.

Our prime design goal was therefore to create multi-purpose systems that offers flexibility and extensibility in order to meet future requirements. Accordingly, the platform modules can easily be exchanged or extended, and the dispense amounts and component viscosities both cover a range of several orders of magnitude. Additionally, the platforms are very flexible with regard to the size of the individual formulation samples. The typical amount of one prepared formulation is in the range of 5–100 g, which in most cases is enough material even for standardised application tests and characterisation using conventional equipment. All samples carry a unique barcode allowing re-arrangements of the samples to different array formats for subsequent application and characterisation steps.

The systems can be used for a broad range of applications, such as the optimization of lacquers, paints, inks, films and coatings, adhesives and lubricants, agrochemical and cosmetic formulations, or even chocolate as well as catalytic reaction mixtures, with a throughput of 100–200 samples prepared, applied and characterised per day.

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Logistics For China

Talke Teams up with Kerry Logistics

Continues Page 1

and to some extent for warehousing. The transportation market is highly competitive with a strong focus on low prices.

Unfortunately the pressure on prices often leads to cutting corners in areas such as safety and it is difficult to develop a different mind-set as a result.

Within the manufacturing sites, the logistics related activities such as warehousing and packaging are sometimes handled by third parties, but these tend to be manpower providers rather than logistic service providers. The coordination and management is still done by the manufacturer and there is still only limited understanding of the concept of outsourcing the entire logistics activities.

What hurdles exist?

R. Heath: One of the biggest hurdles is the licensing of activities in China. A company requires a multitude of licenses for the activities to be done and these can be difficult to acquire, particularly in areas such as dangerous goods, or DG. Furthermore, there are additional licenses required for different regions, even in transportation.

Which are the biggest differences between Europe and China in the logistics sector?

V. Wong: Europe is clearly a mature market where things have developed throughout the years and logistics has gone through many phases of sophistication. China is still going through some of these phases and whilst the country is developing at a tremendous pace, there are still some changes in mindset that need to take place.

R. Heath: Whilst it cannot be said that Europe has an ideal regulatory set-up, it is possible to move goods under the same conditions without being faced with different regulations or licenses. Transport licensing coupled with complications of not being able to combine bonded and non-bonded warehousing make it challenging to set up efficient supply chain solutions.

To develop the Asian market, Talke established a JV with Hong-Kong Kerry Logistics. Which partner took the initiative to develop the Chinese and the European markets, respectively?

R. Heath: The two companies have varying drivers which lead to a mutual interest in setting up the JV.

Talke is specialised in chemical logistics, and the move to China was driven by two main elements. Firstly, the requirement to provide the clients with complete supply chain solutions, encompassing Talke's other markets in Europe and the Middle East. Secondly contacts with major multinational chemical and petrochemical producers who are the usual clients of Talke, showed an interest in having reliable, experiences service providers to support their developments in China.

Kerry Logistics is an Asia-based company with a focus on business evolving around China. Kerry is developing a global network of freight forwarding competence around the heart of their business in China. Chemicals are one area of Kerry's activities, and they saw the need to introduce specialist know-how by means of a partner such as Talke.

What differentiates the two logisticians Talke and Kerry from each other? In what areas do they complement one another?

V. Wong: Kerry is an LSP handling a wide range of products, whilst Talke is a specialist service provider for chemicals and petrochemicals. Kerry also offers a global freight forwarding network that is not part of Talke's usual business. The combination of the two provides a strong combination for the benefit of the chemical manufacturers.

What is the benefit of the JV Kerry-Talke for Talke ?

V. Wong: Local knowledge and connections in China, together with an extensive network of distribution and offices.

Kerry has already a network with offices and logistic facilities in China. Which benefits does the JV generate for Talke?

V. Wong: The presence of the network enables Talke to offer a distribution network throughout China. Local presence will be advantageous when setting up specific operations.

Which kind of logistic services can Kerry-Talke provide to companies in the chemical industry that want to gain ground or to develop their business?

R. Heath: Essentially, Kerry-Talke will offer a full range of logistics services in China. Newly developing companies can profit from the possibility to receive a full package of services, thus eliminating the need to develop their own department to handle their logistics requirements. This not only reduces the hassle on a daily basis but also takes away the requirement to develop human resources in this area.

Are there already projects planned?

V. Wong: Kerry-Talke is in discussions with major industry players and there is a growing interest for outsourcing. Additionally, the JV is presently in the process of acquiring land for warehousing and material handling activities. The first phase will be in Eastern China and details will be announced once the purchase is finalised.

Is there a possibility to adapt European logistic solutions for chemicals or hazardous materials onto the Chinese market?

V. Wong: There are always local differences, but it is the aim of Kerry-Talke to introduce best practices to the growing chemical industry in China and for this purpose many years of experience are required. Companies go through various cycles of development and whilst the evolution in China is very rapid, it can often be seen that the business models essentially develop in the same way, albeit at a different speed.

You've had the possibility to work in the polymer sector in the Middle East. How was your experience?

R. Heath: The move to the Middle East was on the basis of the enormous growth in production in the region. Growing quantities lead to new logistical challenges and higher requirements for flexibility. A major part of this development was to introduce the concept of outsourcing site logistics, i.e. within the perimeter of the production facility. Talke was able to launch this concept successfully and is now in the process of creating extra flexibility by means of specialised polymer handling terminals. Developing on this region, the move to China will enable clients to develop best-in-class concepts to export to Asia from the Middle East.

What can we understand from the term "Multi-User-Platform"?

R. Heath: This is a facility that is constructed in strategically interesting locations for the industry as a whole, be it close to production facilities or close to ports for import and export capabilities. The platform can be used by a multitude of clients, as and when they require. This can be on a purely spot basis or linked to short or medium-term agreements. The flexibility and cost effectiveness is achieved by means of catering for several clients at one location.

Kerry had already JVs with Talke and the British contract logistician Wincanton. Are there plans for JVs and partnerships with other European logisticians? What is the aim?

V. Wong: These are the currently partnerships that Kerry has been working on in Europe. Kerry also welcomes any potential partnership that has business synergy to strengthen the service offered and the global network.

How do you assess the global development of the logistics market for chemicals and chemical products?

V. Wong: The logistics market will continue to be of enormous importance as manufacturers look for best value feedstock regions which are often far from the consumption areas, particularly for commodities. Major manufacturing regions such as China will be important production regions, not only for their domestic consumption but will also be the source for other parts of the world requiring competitively priced products. Costs will continue to place pressure on the industry and areas such as Europe with high manpower costs will be challenged.

▶ www.talke.com
▶ www.kerrylogistics.com

Accelrys, Johnson Matthey and CMR: Consortium

Accelrys, a provider of scientific business intelligence software and services, together with CMR Fuel Cells and Johnson Matthey, announced the formation of a UK-based Research Consortium. Funding has been awarded through DTI's Technology Programme competition. The DTI will award the consortium a total of £1.15 million over the duration of the three-year grant to offset research expenses. The partners will pool their respective research and development expertise in the areas of catalyst science, materials modelling, workflows and databases to develop predictive methods for the development of advanced low-cost catalysts. The Consortium plans to develop and validate a unique set of predictive tools based upon the latest scientific understanding of how electro catalysts function. In doing so, it aims to accelerate the progress towards commercial applications for fuel cells and provide fundamental advancement of catalyst research.

▶ www.accelrys.com
▶ www.cmrfuelcells.com
▶ www.matthey.com

Honeywell Partners with MOL Group

Honeywell announced it has established a strategic business relationship with MOL Group, the Hungarian national oil and gas provider, to provide automation solutions for MOL facilities in central Europe. The companies said goal of the strategic business relationship is to reduce production costs and increase yields at MOL's plants in central Europe. To do so, Honeywell will implement 10 UniSim Operator Trainer Simulator projects at MOL's Duna and Slovnaft refineries over the next three years; upgrade five existing Honeywell TDC 3000 control systems; and extend the current Integrated Service Agreement by five years, to 2014. Additional projects will be defined each year according to MOL's budgets and business priorities.

▶ www.honeywell.com
▶ www.mol.hu

ExxonMobil Drills World-record Well

Exxon Mobil Corporation said its subsidiary, Exxon Neftegas Limited (ENL), has completed drilling of the Z-11 well, the longest measured depth extended-reach drilling (ERD) well in the world. Located on Sakhalin Island offshore Eastern Russia, the record-setting Z-11 achieved a total measured depth of 11,282 m or over seven miles.

The multiphase Sakhalin-1 Project includes the Chayvo field which is located 8–11 km offshore. The Z-11 was drilled to the Chayvo reservoir from the Yastreb rig, the world's largest land-based drilling rig. Overall, the Chayvo field reached its peak production rate of 250,000 barrels (34,000 metric t) per day in February after an on-schedule startup in October 2005. The Z-11 is the 17th ERD producing well to be completed as part of the Sakhalin-1 Project.

▶ www.exxonmobil.com

Honeywell Increases Nylon Resin Capacity

Honeywell Resins & Chemicals announced that is has increased its nylon resin availability by 10% through a series of productivity improvements. The company also announced it has also gained capacity to supply higher viscosity resins used for packaging with the end of an existing swap agreement with BASF. The company realised the increase in resin capacity through a series of productivity improvement efforts at its Chesterfield, Va. facility, which is its main production facility for nylon resin.

The company also said its nylon resin swap agreement with BASF terminated 1 May. As a result of the termination, Honeywell will have a greater supply of high-viscosity resins, which are more suitable for packaging applications. Those resins had previously been subject to the swap. The agreement had been in effect since May 2003 as a part of the transaction in which Honeywell sold its engineering plastics business to BASF in exchange for BASF's nylon fibre business.

▶ www.honeywell.com

BASF: More Polyisobutene from Ludwigshafen

BASF has started its expanded plant for medium molecular weight polyisobutene (MM PIB) in Ludwigshafen, Germany ahead of schedule. The facility has increased capacity by 6,000 mt of MM PIB per year. The company now has a total MM PIB capacity of 18,000 mt, which is marketed by BASF worldwide under the Oppanol trademark.

▶ www.basf.com

Arkema Enhances Product Range

Following research and development work, Arkema said plans to launch a new Evatane grade combining high Vinyl Acetate content – 40% – and a low Melt Flow Index (MFI below 3). Standard 40% EVAs normally feature high fluidity. However, in most cases this type of product does not comply with the minimum thresholds demanded by the cable market regarding elongation at break and tensile strength.

Currently undergoing testing under the test name Evatane X0601, the new grade is scheduled to be launched on the market at the end of 2007. The main market targeted by this grade is oil-resistant crosslinked cable and flexible cable. Evatane resins are ethylene copolymers with a high vinyl acetate content (18% to 42%). More of an elastomer than a polyethylene, they are easy to process and are compatible with a large number of polymers. Evatane copolymers are used in many industrial applications, including hotmelt glues, cable, multilayer packaging film, encapsulating film for solar panels, in-car soundproofing, shoe soles, petroleum additives, bitumen, masterbatches and ink.

▶ www.arkema.com

Profisafe Goes Wireless

Product PI (Profibus & Profinet International) has specified ProfIsafe for wireless networks. The new version of the Profisafe profile (Version 2.4) describes the conditions for the functionally safe transmission of data via WLAN and Bluetooth. The concept has been assessed and approved by the BGIA and TÜV.

The company said the publication of the specification of Profisafe on Profinet IO – and thus on Ethernet – in 2005 was a success, simultaneously confirming the compatibility, in principle, of Profisafe for wireless networks. It was then simply a case of defining the details in respect of the issue of security; in other words, access protection for safety-relevant data. The new Profisafe profile Version 2.4 specifies the security issues involved in the configuration of wireless components for secure cyclic data exchange. First applications with Profisafe for wireless are already proving their worth in practice. PI members can download the profile for free from the PI website (non-members have to pay a fee of €150).

▶ www.profibus.com

Agilent Opens China Campus

Agilent Technologies announced the official opening of its China headquarters campus, including the launch of the Agilent Open Lab & Solution Centre and the Life Sciences & Chemical Analysis Centre of Excellence. The new campus is located in Beijing Wang Jing Science Park and combines Agilent's Beijing-based R&D, sales, marketing, technical support and after-sale functions in one location.

Agilent's Open Lab & Solution Centre provides electronic measurement customers with a full range of test and measurement services, including a professional testing environment and technical consulting services. It is Agilent's second Open Lab for electronic measurement in China.

Agilent plans to leverage the China headquarters to help drive the development of the local industries – particularly in the key areas of energy, environmental protection, agriculture, food safety, information and basic biological research in life sciences -and become a true strategic partner in Chinese enterprises' development toward globalisation.

▶ www.agilent.com

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Temperature Control In Demand

Need for Cold-chain Logistics in Pharma, Biopharma Increasing

Pharmaceutical and biopharmaceutical companies invest heavily in the development of products, from research to actually getting the product to market. Not to mention additional costs of ensuring that products meet regulatory standards as imposed by various enforcement agencies such as the World Health Organisation (WHO), the U.S. Food and Drug Administration (FDA), or the U.S. Department of Agriculture (USDA). It is important for companies to ensure that resources initially spent to develop products are not lost in transit. There are optimal conditions set for each product and regulatory standards specific to handling, storage and the distribution of products. It is important that after a product becomes ready to ship, regardless of its stage, whether in development, trial, or directly to market; companies need to ensure that careful measures are taken to reduce the risks, especially in transit. Whether transporting product domestically or globally, it is imperative that the quality and integrity is maintained, ensuring that products are still viable upon reaching their destination.

Under the guise of each product specification, using cold-chain logistics allows pharma and biopharma products to be transported with confidence that transit will not compromise the shipment. From high value to highly sensitive, having an integrated cold chain logistics provider presents added security in ensuring the product maintains integrity. This sector is becoming an imperative need for pharma and biopharma companies to ensure their investments are protected, monitored and assured to maintain quality.

With the increased amount of temperature sensitive products entering the pharma drug and research market, the emphasis shifts on keeping the structure of the product in tact from the manufacturer to the customer, and at every stop in-between. Studies have shown that 19% of the world's best selling pharmaceuticals are temperature-sensitive and clearly require complete temperature controlled settings, even in transit. This translates to one in every five products in the total pharmaceutical market representing a temperature-sensitive product. Unlike chemical based pharmaceuticals, biologicals are expected to grow in the double digit range; as a result, temperature-sensitive products are likely to increase as well. Deviations from the optimal normative temperature of products can reduce effectiveness of products and/or render products useless. Increased regulations may now require any deviation to be filed with local agencies to further deem products use in the marketplace, if applicable.

Experienced Logistics Provider Crucial

Having an experienced and dedicated logistics service provider should be an integral part of moving products. Life science products have special transportation needs and should not be handled as general cargo. Therefore, it is integral to ensure logistics providers are an expert not only in the life sciences industry but also at ensuring temperature-sensitive products are monitored and maintained. Dedicated and expert logistics providers have to have staff who understands the regulatory environment, who are dedicated to the industry and who know and can anticipate unforeseen issues regarding customers' shipments.

A logistics provider dedicated to the life science industry should be more like a strategic partner, where they are proactive, able to keep customers up to date and integrate new practices and more efficient ways of managing sensitive products. An integrated supply chain can produce a single point of contact for complete end-to-end transportation reducing the risks associated with transport. When products need to have exception management such as controlled-temperature settings, an integrated logistics service provider becomes much more important to ensure companies do not expose themselves to further risk. In some cases working with a proven logistics provider can reduce insurance premiums, especially when moving high value products.

Things To Consider

There are many circumstances to consider when choosing appropriate transport means to move product. Pharma companies need to understand what their needs are and evaluate providers based on their ability to monitor, track and take corrective action when moving product. Some shipments can be easily transported without compromising integrity and end use; however, the majority of pharma and biopharma products need special attention guided by shipment profiles and integrated process mapping. The majority of vaccines and over half the products sold by biotech companies need to be stored and transported between 2–8°C.

Finding routing for lanes or developing tailor-made standard operating procedures (SOPs) can prove to be difficult for any global forwarder. Further complicating the process are instances that are inevitable, but likely to be reduced with consistent and committed interaction with transport suppliers. It is not uncommon that shipments are offloaded, temperature readings are hard to obtain, and tracking shipments with multiple suppliers at any given point can be a handful for logistics, quality, or product managers to gather over multiple shipments and products.

At this point it becomes beyond necessary for companies to choose a single point of contact ensuring they have a liaison that increases their productivity and provides solutions. Corrective action is necessary after business hours, on weekends or over holidays, dedicated monitoring by an integrated logistics service provider reduces the risk that shipments are mishandled and then subjected to extreme conditions, damaging products rendering them useless.

Cost Considerations Important

It is truly beneficial to weigh the total costs when choosing to transport high value products, pharma companies need to account for research, development, capital and time input into products to make them available in the market. A loss on a high value shipment can set sectors of the life sciences industry back millions of dollars and years of development, when a true solution could have been provided and implemented at a fraction of the costs.

Companies in the life sciences industry include pharmaceutical, biotech and healthcare enterprises and benefit considerably from seamless end-to-end logistics service from a single provider. The integration of standardised processes and systems provided will result in a higher level of delivery performance and reduction of preventable service failures for temperature-sensitive products. LifeConEx is a true expert in the life science industry, qualified with the expertise necessary to transport sensitive products. The company's services offer a higher level of delivery performance in exception management, ultimately reducing the assumed risk when transporting temperature-sensitive products.

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Yara and Praxair to Establish JV in Industrial Gases

Yara International and Praxair have signed a Heads of Agreement with the intention of establishing a joint venture to further enhance development opportunities for Yara's industrial gases business. The planned joint venture would be owned 50% by each partner and comprise Yara's existing industrial gases business located in Norway, Denmark and Sweden.

The companies said the intention is to establish the new company during third quarter 2007, with completion of the transaction subject to certain conditions and obtaining regulatory approvals. The venture would operate under the name Yara Praxair AS and would be based in Oslo, Norway. It would be headed by Per Kværum and the Board of Directors would consist of representatives from both companies and the employees. The agreement would result in a one-time net income for Yara of more than NOK 700 million, which is expected to be booked in the third quarter. Yara and Praxair will review the strategy to expand the industrial gases business further into new product segments and geographical areas. In 2006, Yara's existing industrial gases business had sales of NOK 940 million. Yara's CO_2 business in Europe will continue as a wholly owned business unit in Yara. Yara will continue to further develop its European CO_2-activity, and will supply the new joint venture with CO_2 and argon in Scandinavia.

▶ www.yara.com
▶ www.praxair.com

Chemists Drive for a Greener Future

Cardiff University is working with industry to find valuable uses for a major by-product of the renewable fuel source biodiesel. One concern regarding biodiesel production is what to do with the major by-product, glycerol. A global glut of glycerol is occurring as industrialised nations move to substitute fossil fuels with more sustainable alternatives. Glycerol production in the United States already averages more than 350,000 t/y and in Europe production has tripled within the last ten years. Currently disposal of surplus glycerol is by incineration.

Now researchers in the University's School of Chemistry working with Vertellus Specialities UK, a global supplier of chemical specialties, have won a grant to investigate the possibility of converting glycerol to high-added value speciality chemicals. The £60,000 project, with £40,000 financial support from the Department of Trade and Industry-led Technology Programme will allow the research team, led by Professor Graham Hutchings, School of Chemistry and Brian Tarbit, Vertellus Specialities, to ultimately improve the environmental benefits and economic viability of biodiesel manufacture.

▶ www.theglycerolchallenge.org

Elementis sells Global Pigments Business

Elementis announced that it has agreed to sell its global pigments business headquartered in East St. Louis (U.S.) to Rockwood Specialties Group for a cash consideration of approximately US-$140 million on a cash free, debt free basis.

Elementis Pigments is a producer of synthetic iron oxides and complementary products. In the year ended 31 December 2006, Pigments' reported operating profit, before exceptional items, was £6.1 million on sales of £94.2 million with net assets of approximately £42 million, excluding cash and debt. Gross assets were approximately £61million. After taking account of transaction costs and estimated net assets at the time of completion, Elementis expects to record a pre-tax gain on sale of approximately £20 million. This gain will be recorded as an exceptional item in the 2007 financial statements.

The price represents an attractive multiple of 2006 operating profit (earnings before interest and tax) of 11.5 times. In addition, the transaction is expected to have no material impact on the group's 2007 earnings before exceptional items, and provides an opportunity to further strengthen the Group's balance sheet to support growth in the Specialties business.

Completion is subject to regulatory approvals, including a filing under the Hart Scott Rodino Act in the U.S., and is expected to take place before the end of 2007. Net proceeds from the sale will initially be used to reduce net borrowings, but the Board is reviewing other potential uses and will provide an update before completion.

▶ www.elementis.com
▶ www.rockwoodspecialties.com

chemanager@gitverlag.com

Lurking Risks

The Competitive Position of Chemical Park Operating Companies

The operating industry for chemical and industrial parks in Germany finds itself caught up in a new departure and in a process of re-identification at the same time. Opinions are divided on whether to expand or streamline the portfolio, on whether to expand into external markets or to concentrate on essential, mainly site-related operator tasks. Often ideological worlds lie between the different points of view. Yet at the same time, the operating companies need to follow a joint path for the benefit of Germany as a location, in order to strengthen this location against international competition.

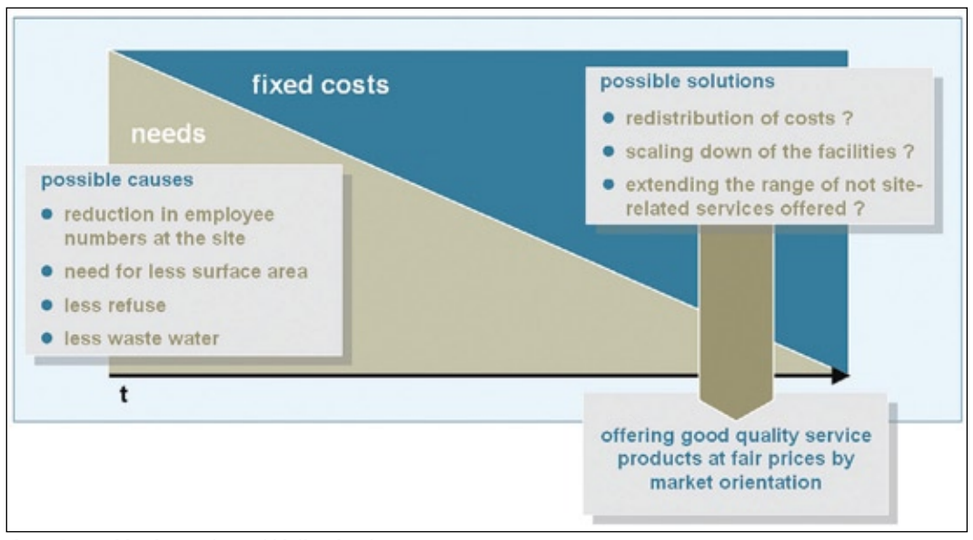

Fig. 1: Competition is complex and bi-directional

Frank Duscheck
Arisma

Benjamin Fröhling
Arisma

The operating company landscape of the German chemical and industrial parks is marked by many different features. On the one hand, most of the companies owe their origins to the few large German chemical companies that were already established in the country at the beginning of the 20th century. On the other hand, the sales, mergers and divestitures of the past decade have ensured that, as a result, today's operators have very different basic prerequisites. As a consequence, corporate strategies and philosophies are extremely varied and the service units of today have been aligned more or less with market requirements.

Nevertheless, regardless of whether an internal service unit, shared service or hived off company, the economic goals of an enterprise must always remain those of growth and profitability. On their way to reaching these goals, which can only be achieved through competitiveness, service companies pass through various stages of maturity. These stages of maturity correspond to the development phases of the service companies. Thus, in the beginning, an in-house service unit usually continues to provide all the services required by the production departments, without really paying attention to the costs whilst doing so. With progressively more maturity, an innovative service portfolio develops that is controlled by the operating figures and, as a rule, only continues to provide those services that ensure an economic benefit to the service company in the long term.

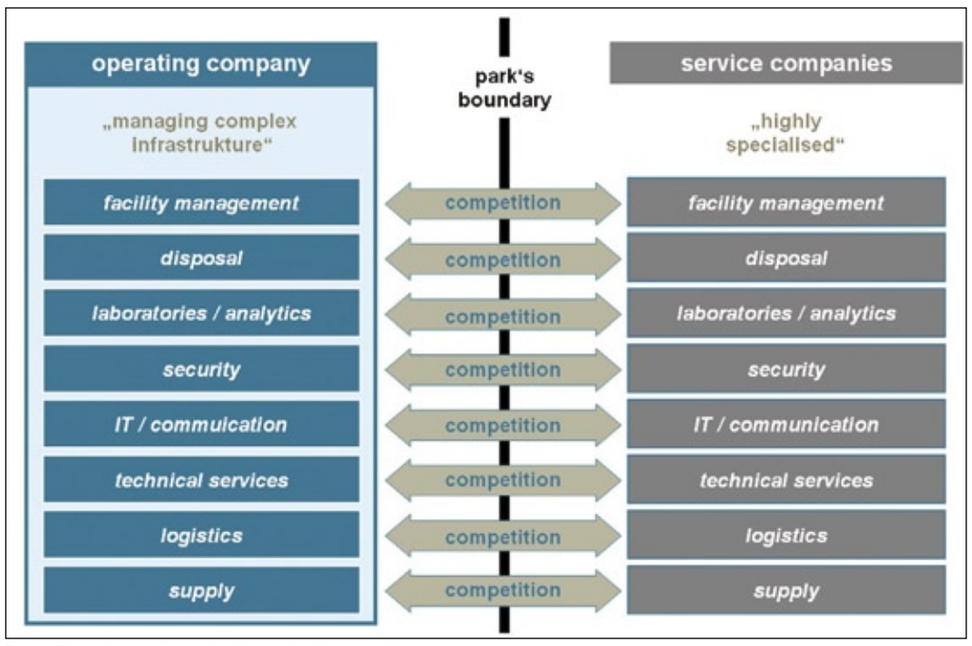

Fig. 2: The risk of being left with residual fixed costs.

A strong portfolio with marketable service level agreements and competitive prices, however, is not only a must for every company whose declared goal is to participate in markets beyond its own site in order for that company to grow or to dilute fixed costs. Today every company attached to a site finds itself in competition. For there are numerous service companies that have been operating in the open market for years and that provide services outside of self-serviced sites. With the increasingly extensive relations between group companies and service subsidiaries, pressure is growing from external service providers, who are forcing their way into self-serviced sites from the outside.

Market Orientation Only for Diluting Fixed Costs?

Through a loss of business, there is a risk of being left with residual fixed costs for maintaining current resources and reserve capacity. For this reason, an operating company has to be in a position to at least defend itself in its own market on the basis of a competitive service portfolio. The migration of companies from the site, as well as increasing production efficiency, lead to a reduction in employee numbers at the site, the need for less surface area and, for example, also to less refuse or less heavily contaminated waste water (fig. 1). The need for site services falls, for example, for those that are calculated on the basis of employees or area, but the fixed costs for ensuring the availability of these services cannot normally be eliminated in the short-term.

What solution remains? Neither a redistribution of costs to the companies still based at the site nor a scaling down of the facilities can be considered a practical solution. A more elegant solution would appear to be a dilution of the fixed costs and a better utilisation of resources by extending the range of services offered that are not site-related. Even if expansion outside the site is not considered to be a strategic goal, it does bring numerous advantages with it. For only those who are able to offer good quality service products at fair prices will be able to hold their own both in the marketplace and against the competition. This is exactly where in-house customers, associated companies and owners benefit, with whom a large part of the sales revenues are generated today. On the one hand, the fixed costs remain stable or may even be reduced and, on the other, it is only from the external market share held that customers can see that the services they are paying for correspond both in quality and price to what is available on the open market. Therefore, whoever does not take up a market-oriented position in time, runs the risk of not being able to defend themselves against the growing competitive pressure from outside and therefore of losing important business.

Industrial or Infrastructure Service Provider?

The service portfolio of an operating company is extensive and complex. Should you look for companies that are fully able to operate and manage complex infrastructures, your search would very quickly be narrowed down to alleged competitors, the operating companies of other chemical and industrial parts. Thus, you always know on whom you should concentrate in competition. Even the number of self-contained chemical and industrial parks in Germany is limited. If you were to speak about operating an entire infrastructure, you might have competition in this respect. But just how many chemical parks change owner every year in Germany? And which operating companies would be in a position today to take part in any such bidding? The necessary investment alone would be unaffordable due to the size or the ownership structure. If at all, these investments are made by external third parties – usually energy companies. Is there really any competition in today's operating market?

If you were to look at an operating company today outside the established chemical and industrial park market, it could be broken down into very many different industries. This would start with supply and disposal, through to security, IT, logistics, technical services, analytics and not forgetting the property management of the land and buildings. Each of these industries has its own market with its own, highly specialised players – the competition (fig. 2). Concentrating on the wrong "rival" here could have fatal consequences.

Summary

Marketable structures in the chemical and industrial parks are necessary in order to offer high-quality services and to provide support for Germany as an attractive location. At the same time, operating companies find themselves faced with increasingly stronger competition, regardless of whether it is their stated goal to grow through external sales or whether it is a matter of defending their own territory. Only site operators that have set themselves up to be marketable and competitive in the face of this competition will be able to offer services in the long run – even to their in-house customers – that are both high-quality and fair priced. For the benefit of "Germany as a location", operating companies must therefore close ranks and concentrate on the real competitors.

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Rhodia Polyamide Opens Technical Centre in China

Rhodia has opened a technical centre in Shanghai, consolidating Rhodia's global technical centre network. According to the company, the new facility brings the complete spectrum of engineering support to customers across the broad range of industries served by Rhodia Polyamide's engineering plastics materials in China and the wider Asian region.

From assistance with concept development through to final part optimisation, Rhodia's centre in Shanghai is equipped to provide a valuable extension to customers own technical teams and resources or undertake project assignments independently. Rhodia's engineers are able to conduct feasibility and performance studies on any applications in which its polyamide materials are used. Typically these include automotive, electrical and electronic, consumer and industrial components.

▶ www.rhodia.com

On Track for the Intelligent Factory

Pictures of the Future in Automation and Control

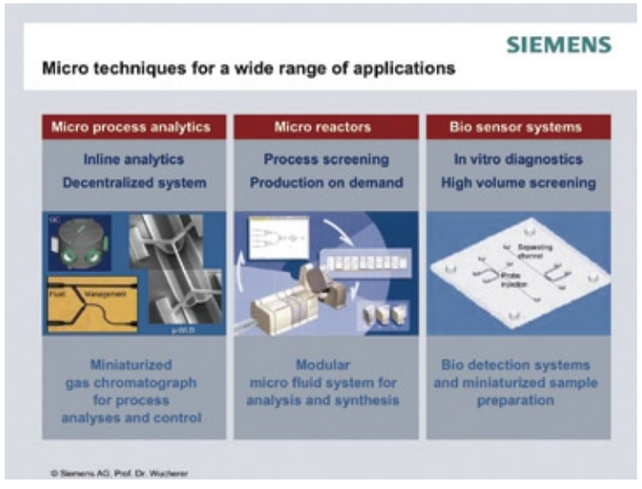
Continued Page 17

its components is designed, displayed, and simulated as a digital and virtual CAD model, complete factories are also supposed to be designed and simulated by computer. The automotive industry is paving the way here. In the future, new car models will only be produced after their digital counterparts have been successfully run through production simulation and all possibilities of optimising product design and production have been fully exhausted. The engineering system automatically reviews both the entire vehicle and the factory design whenever any detail is modified. Based on such a highly precise planning phase, the start-up time for a plant will be only a fraction of what it is today.

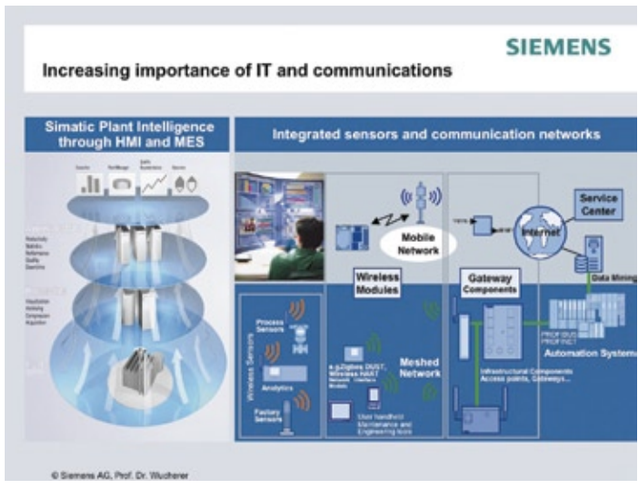
This ambitious vision was born in Germany in the mid-1980s under the name of CIM – Computer-Integrated Manufacturing. As early as 1986, at the newly created trade fair on 'Industrial Automation: Distributed process control systems and controlling systems as part of Hanover Industrial Fair, the terms CIM and Factory of the Future were all the rage. CIM was to be realized at company level on the basis of existing data pro¬cessing and automation solutions in a kind of interdisciplinary approach. Design, work planning and actual manufacturing were to be interlinked. This project was to comprise not only the digitisation of design, work planning, NC programming, manufacturing, maintenance and quality assurance, but also production planning and control. Even in those days there were visions of linking plant engineering with in-line production.

During this early phase there were many activities going on, including some of the projects initiated and supported by Siemens at a number of universities to study the flexibility of automated production systems. Over the years, this interdisciplinary work between the research, teaching and business communities has borne fruit and produced solid ties, even if the vision as such was not realised. In retrospect, we can see now what was lacking then: integrated communications, powerful processors and database systems.

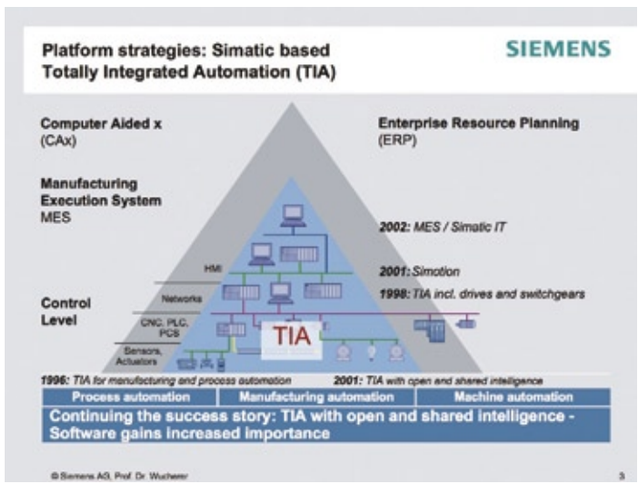
What has changed since then? Communications and processors have advanced to performance levels which were unimaginable 20 years ago.



Ethernet existed at Siemens in 1985 with a data rate of ten Mbit per second and the legendary



Sinec-H1-Yellow Cable. In 1990, the 10BaseT-Twisted Pair was added for communicating in a



star-shaped structure; in 1991 it was switches for isolating individual network segments, thus increasing throughput; in 1995 it was 100BaseT, and finally in 1999 it was 1000BaseT, which constituted another performance leap of an entirely different magnitude in communications.

What is more, the processing speed and in particular the memory capacities of PCs have grown exponentially. What is affordable today with PCs used to be unprofitable with CIM in mainframe computers in the past. Moreover, database technology for joint data management of individual programs has reached a much higher performance level, enabling today what we could only have dreamt of in the 1980s.

Convergence of Mechanical and Process Design

Although the advance of technology has made automation infrastructure much more powerful than 20 years ago, manufacturers today are still facing enormous challenges in the field of IT. Alongside integrated IT systems for asset management, HMI (Human Machine Interface) and MES (Manufacturing Execution Systems), it is mainly new developments in digital engineering which are now generating productivity gains. When all is said and done, it is not just the production, but also the design, dimensioning, construction, commissioning and conversion of production plants that are coming under growing time and cost pressure.

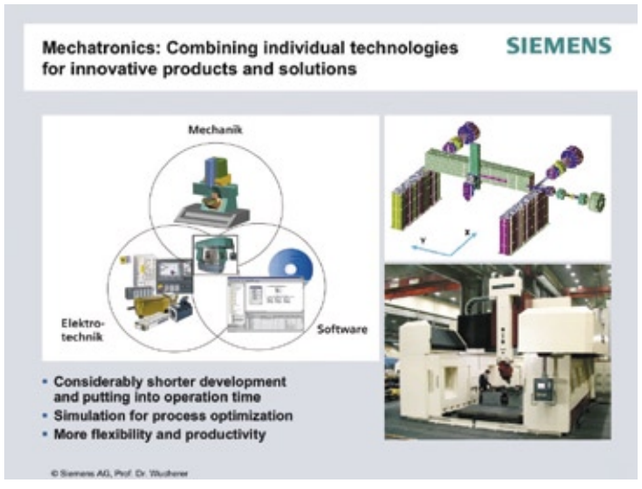
In the long term, mechanical design and automation will converge. We believe that this convergence will lead towards the integration of mechanical design, automation and control, with PLC codes being automatically generated via code converter.

By acquiring UGS and integrating PLM software technology into the Siemens portfolio, we have addressed this new technological trend. Whether CAx, PDM, or Digital Factory – it is the combination of the PLM portfolio with hardware and software at A&D which provides our customers with the decisive benefit of making both the design and production of their products more efficient. This is the step where we reduce the number of system interfaces and interlink data from product planning, plant design and physical production in very much the same way as was thought out in the CIM vision of the 1980s. Isolated stand-alone solutions that used to be commonplace in product design, pro¬duction and service software will increasingly change and turn into an integrated system business.

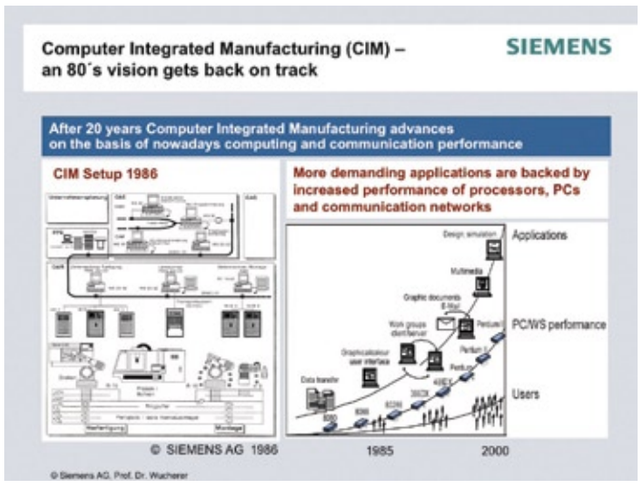
Software-based Innovation Networks

Let's take a look even further ahead into the future. What kind of support will we get from PLM software in realizing our vision?

In product and plant design in 2020, all processes along the production life cycle will be virtually supported, ranging from planning via mechanical and electrical design, programming and commissioning of the plant all the way to its operation. Irrespective of the software in use, all data will be read and merged into the digital engineering environment.



The creation of a product will be holistically mapped in the digital engineering process.



Once virtual commissioning has been completed, the data is directly applicable to the real plant, and the automation solution is generated automatically. This covers PLC programming, visualisation – including diagnostic information – and the creation of the relevant plant documentation. The automation of automation will become reality.

The Intelligent Factory

The globalisation of economies has already led to an internationalization of industry. To be competitive in a global market, producers are operating geographically distrib¬uted production facilities which form a globally linked production network. This trend is set to continue: Network environments are being created that work beyond corporate boundaries, bringing users closer to on-demand production. For those included in the value chain – product designers, machine makers and engineering companies, as well as suppliers, service providers and distributors – readily available information is the key to business success.

In this connection, PLM software in our Picture of the Future plays a pre-eminent role at various points in the value chain because it further strengthens our portfolio, increasing our customers productivity across the entire product and production life cycle.

CAD software tools, digital product data management and the simulation of manufacturing processes help to create both the product design and the product data and to simulate the products' physical properties. This package also includes the simulation of the products' actual making. Storage, administration and availability of product and production data allow the user to access any information throughout the entire product life cycle.

Since products are being designed, planned and simulated with the aid of computers, the existing data serves as a basis for searching for suitable automation suppliers and machine tool suppliers in the various markets. The production facilities identified can then demonstrate and prove the required quality levels by means of virtual commissioning and plant simulation. The advantages are obvious: Time-to-market will be dramatically reduced and prototyping will eliminate almost all machining needs. Moreover, the process is not only forward looking; it can also be traced back at any point or relaunched.

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The Direct Way is the Better Way

Simple Solutions from Pepperl+Fuchs

PRODUCT **Simplicity leads to faster, better and safer solutions. That's why simplicity is the core idea behind the innovative solutions for Foundation Fieldbus H1 and Profibus PA from Pepperl+Fuchs. One typical example is the new series R2 Segment Protector. It allows fast connection of field devices with all safety characteristics, such as short-circuit protection and the High-Power Trunk for explosion hazardous applications. It is a smart idea, designed for fast installation, easy wiring and guaranteed reliability.**

The new series R2 Segment Protector by Pepperl+Fuchs is an intelligent wiring block designed to add simplicity, speed and safety to the installation of any fieldbus infrastructure. Up to twelve field devices can be connected to the fieldbus via its own spur connection with built-in short-circuit protection. Using the High-Power Trunk concept guarantees Zone 2/Div. 2 explosion protection. In this configuration, the main line is fed with up to 500 mA, while the energy supplied to each individual spur is limited. Built-in short-circuit protection takes care of the needed reliability during operation. Live working on the field instrument does not require any hot work permit, since the trunk is free from feedback and remains fully in operation.

The new Segment Protector combines compact dimensions with easy operation and is designed for quick installation into any cabinet. A variety of pre-configured housing models offers a suitable solution for just about any situation. Easy-to-use clamp fasteners securely attach the unit to the DIN rail. All plugs feature retaining screws for reliable connection.

Connection to the trunk is done via a T-connector. This allows easy trouble shooting or replacement of the Segment Protector without disturbing the operation of the overall system. The fieldbus terminator finds its well-defined and easily visible position at the T-connector where it can be easily verified. In this way, faulty termination is avoided during the installation process. Specific test points are included to efficiently hook up diagnostic tools. Measurements during installation and trouble shooting can be performed without having to interfere with the wiring.

The new Segment Protector features innovative and well thought-out solutions which result in reduced wiring and considerably lower hardware and operating costs of the fieldbus infrastructure. The Segment Protector is a vital component to add reliability to the fieldbus. It leads to a continuously superior signal quality, thereby improving the overall availability of the system. Only the fieldbus guarantees unlimited flow of information from the process control system all the way to the field device. This allows comprehensive remote configuration and offers the technical basis for effective asset management.

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Implementing Single-use Technologies

Strategies for Optimising Today's Increasingly Disposable Processing Environments Part 1

Biopharmaceutical companies are no longer asking why they should adopt disposable processing methods, but rather what new processes can be made disposable. Disposable technologies are not only available for an increasing range of applications, but they are also expanding from stand-alone devices to multi-component systems. With this growing trend comes a greater number of benefits and implementation considerations.

Contract manufacturing organisations (CMOs) and biotech start-ups were among the earliest adopters of disposables technologies. CMOs saw disposables as a way of minimizing the risks of cross-contamination, while biotechs enjoyed a considerable reduction in the need for capital investment. Both recognized the significant time and cost benefits of eliminating steam sterilisation validation, cleaning and cleaning validation, as well as the reduced potential for operator error. Today, the disposable model is attracting new converts, particularly in the area of patient-specific therapies. Given the small batches in which these therapies are processed, it is now practical to move towards a totally disposable manufacturing paradigm.

The availability of disposable technologies for increasingly larger scale processes both upstream and downstream is reshaping the way traditional drugs are made, while providing an efficient path to manufacturability for emerging therapies. The availability of 0.1 micron-rated sterilizing grade filters for mycoplasma removal, used for filtration of media into bioreactors in disposable formats, has created new opportunities for significant time and cost savings on the upstream side. An expansive and growing array of disposable technologies exists for downstream processing applications, including Direct Flow Filtration (DFF) filters, Tangential Flow Filtration (TFF) cassettes, membrane chromatography capsules, lenticular depth filters, filling equipment, aseptic connections devices, tubing, adaptors, clamps, and bags.

Closing the Loop for More Efficient Facility Design

More than just the sum of its benefits, disposable processing represents a fundamental change in processing approach and facility design. As a closed loop system, disposable processing avoids the need to disassemble, transport, clean, validate, and reassemble components in classified cleanroom environment. In many cases, disposable products are supplied pre-sterilized to eliminate the need for Steam-In-Place (SIP) or autoclave. Opening a package and plugging a single-use device or multi-component disposable system into a product train is a welcome simplification to process development staff who otherwise must develop extensive cleaning protocols. The result is not only labor-savings, but also a shift in facility design towards fewer cleanrooms and reduced environmental monitoring.

Fig. 1: Mustang XT5000 capsules are uniquely designed to deliver high flow and high capacity with good resolution.

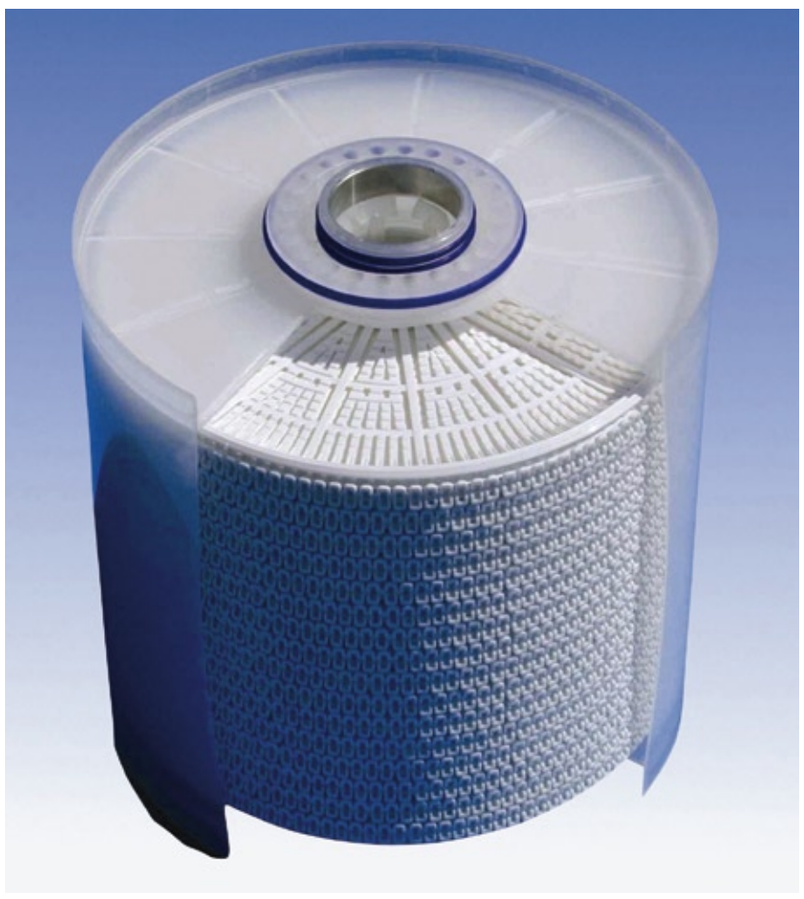

Fig. 2: Supracap 200 with the Supradisc II module inside.

With disposable operations, applications no longer need to be physically segregated. Instead, they can be performed side-by-side as closed loop systems. This makes more efficient use of facility space, especially for CMOs and biotech start-ups. At the same time that disposable systems seal off processes from contamination, the translucency of these components provides operators with convenient visibility into manufacturing operations. Users can observe fluid levels and flow, as well as spot fluid discoloration and air pockets immediately.

Disposable processes also allow for a high degree of modularity so that capacity can be built out gradually in phases as demand increases. Within conventional facilities, it is not only the hard-piped systems themselves that need to be factored into the initial facility design, but also the over-sized large utility systems in anticipation of future needs.

Retrofitting is significantly easier with disposables than with fixed equipment, because disposable components are inherently modular. For many of the same reasons, disposables simplify transfer of the drug production processes to other manufacturing sites, such as CMOs, or other facilities within a company.

Without the need for significant capital investment in hard-piped systems, disposable technologies have empowered biotech start-ups to manufacture in-house. This gives them more control over the development process, and enables production to be accelerated as needed. Previously, outsourcing production was the only economical option. The new flexibility affords companies to better manage their manufacturing expenses and investments during the development stages, when the requirement for greater drug supply in advanced clinical trials can still carry considerable risk of product failure.

Perhaps the most compelling reason to adopt disposable processing methods is the reality that all possibility of cleaning errors or potential carry-over residues from batch to batch are eliminated. Not surprisingly, the FDA has always been a major proponent of disposable processing. Considering that validation accounts for 10 to 20% of the cost of a new plant, disposables suppliers share the FDA's sentiment to provide practical solutions to the industry to alleviate the challenges and costs associated with cleaning operations.

Measuring Cost Savings

Because there is a wide range of both hard and soft economic benefits associated with disposables, assessing the complete cost savings picture can be subjective. For example, the elimination of cleaning and cleaning validation is seen as a significant source of time and labor savings, but the absence of these procedures also minimizes or removes the need to buy and maintain costly utilities, such as Water for Injection (WFI) systems. In the case of pre-sterilized disposable technologies, the need for boilers, clean steam generators and SIP systems is also eliminated. The reduction or elimination of stainless steel processing equipment and utilities translates into further savings by minimising space requirements.

New Innovations in Disposable Processing

Chromatography: The availability of ion exchange membranes in disposable capsule formats for chromatography is significant because this technology offers an efficient single-use alternative to traditional columns. In some applications, ion exchange membrane chromatography may complement column chromatography, and in others it may replace it.

Membrane chromatography is particularly effective in large molecule applications, because the membranes' large convective pores permit rapid mass transfer. The result is much higher volumetric throughput (up to 100x faster) and high dynamic binding capacity regardless of molecular weight. Generally satisfactory for purifying small molecules, packed columns are often inefficient for large molecule applications, due to the slow macromolecular diffusion through the resin porosity that is at least an order of magnitude smaller than membranes.

Ion exchange membranes are uniquely suited to bind DNA or viral particles in a single pass for the production of plasmid vaccines, gene therapy vectors, and antisense drugs. In such cases, where quality, safety and the ability to ramp up production quickly are of the utmost importance, the benefits of disposable processing contribute greatly to the economical development of these innovative treatments.

Depth Filtration: The safety and efficiency of depth filtration has been enhanced by single-use technologies. Traditionally, production-scale depth filtration has been a messy process because operators were exposed to soiled filter cartridges while removing them from the housing. Today, high performance depth filters are self-contained within plastic modules that are thrown away after use, making change-out a cleaner and safer operation. The housing for these disposable modules functions primarily as secondary containment and is readily cleanable.

Bioreactors: While there are fewer opportunities to introduce disposables to upstream processes, the availability of disposable 0.1 and 0.2 µ sterile filters and bioreactors are helping production processes get off to an efficient start. Single-use filters can be connected via plastic tubing clamps and aseptic connection devices to disposable bioreactors, which can be cell culture bags placed on a rocking platform. While disposable filters are offered in sizes as large as 30 in. in length and can be manifolded together in a variety of configurations to efficiently meet the process requirements of the largest production volumes, disposable bioreactors are limited to 500 to 1,000l batch sizes. The capacity limitation of disposable bioreactors is due to the material strength of the cell bag and supplying adequate mixing. While larger volume disposable bioreactors are probably a few years away, current offerings are commonly found in smaller cell culture applications, as well as for growing up seed inoculums while the large stainless tanks are being prepared.

Following in part 2 in our next issue, you can expect these highlights:

- Biocompatibility issues,
- Capacity limitations,
- Disposal,
- Managing supply and recurring costs,
- Answering a universe of application needs.

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Hamilton Visiferm DO Sensors

Optical Oxygen Measurement with Built-in Electronics in a 12mm Format

ADVERTORIAL **With Visiferm DO, Hamilton is the first company to offer a self-contained oxygen measurement in the typical 12 mm format similar to standard process pH electrodes and classical sterilizable oxygen sensors. Combined in the sensor shaft are high-temperature-resistant optical electronics, a microprocessor, a 4–20 mA analog output, a digital RS 485 interface with ModBus-protocol, and an ECS interface. The Electro-Chemical Sensor (ECS) interface allows Visiferm DO to be connected to existing classical measurement amplifiers (i.e. Yokogawa, Emerson, Knick or Mettler) designed for sterilizable oxygen sensors such as the Hamilton Oxyferm. Use the 4–20 mA analog output or the digital RS 485 interface integrated into the 12 mm shaft and an external measurement amplifier is unnecessary allowing measurement signals to be fed directly into a process control system.**

Every beginning is difficult, as the proverb says. But for Hamilton Bonaduz, the decision to invest in the development of its own optical oxygen measurement for the demanding biotechnology and pharmaceutical industries was easy. After all, it is clear from other market segments how quickly and thoroughly optical oxygen measurement has established itself when compared to classical electrochemical, membrane-covered electrolyte containing sensors. The most impressive example is that of O_2 measurement in wastewater. Now, roughly every second new measurement point in this area is equipped with an LDO, or light dissolved oxygen sensor.

Hamilton has successfully manufactured steam-sterilizable, autoclavable, CIP compatible sensors for pH, oxidation/reduction, conductivity and oxygen measurement for more than 10 years. These classical oxygen sensors are based, as is common for the industry on clark cell technology, in which oxygen that diffuses through a membrane is reduced on a precious metal. The involved electrons generate a very small current (nAs) which is converted to an oxygen measurement signal by a measurement amplifier. Such sensors have served well for decades, but the Visiferm optical DO sensors demonstrate a number of considerable advantages (see table).

"Sustained customer satisfaction" are among the first words Hamilton includes in its 50 year old family owned business philosophy. So it goes without saying that oxygen measurement offers, as always, the best possible measurement technology. The user of the Visiferm DO receives more than a sensor based on another measurement principle. Visiferm DO


Dirk Tillich, Director Marketing & Sales, Business Unit Analytics
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is a symbiosis of sensor and measurement amplifier, yielding an intelligent sensor.

Technology That Sets New Standards

The designation "intelligent sensor" gains new meaning when considering the integrated functions of Visiferm:

- Ingenious measurement optics, stable to 130 °C, with a symmetrically oriented diagnostic and measurement design;
- Temperature-resistant electronics built into the 12mm shaft;

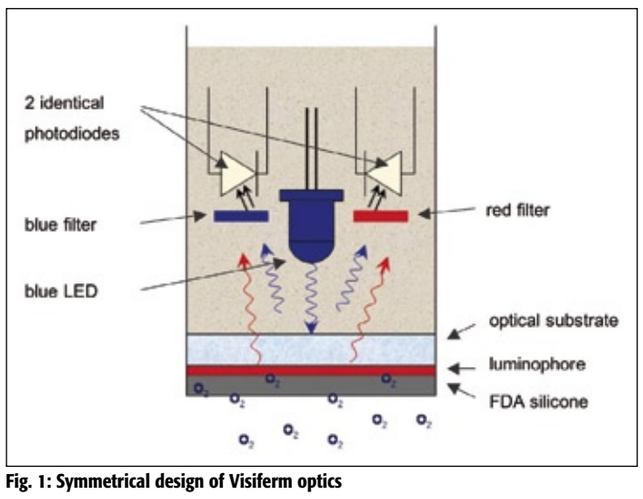

Fig. 1: Symmetrical design of Visiferm optics

- Replaceable sensor cap contains the sensing element
- Digital or analog communication via a proven VP 8.0 connector head with PG 13.5 process thread connection;
- Configurable through the RS 485 interface with a notebook, PC or via the ModBus connection from the process control system, or with Hamilton Visical or Visivisi modules.

Hamilton's Lightning Bright Optics

While other suppliers of optical oxygen sensors utilise sensitive light conductors, a single light channel or two different LEDs, Hamilton prefers a symmetrical design that is mechanically and thermally stable (fig. 1).

The Visiferm DO Measurement Principles

This unique design allows Hamilton to monitor the status of the blue LED with one of the photodiodes. The other photodiode with the red filter measures the oxygen dependent red light. The red light is generated on the luminophore through luminescence (fluorescence) after stimulation by the blue light. Electrons are excited to a higher energy level, and return to their original level after emission of red light.

When the luminophore comes into contact with elemental oxygen, the O_2 molecules absorb the energy, resulting in reduced intensity of red light emission. This difference in intensity is analysed within the instrument's self-monitoring to pinpoint photobleaching (bleaching of the luminophore).

For the measurement of oxygen concentration, the optical phase shift between blue and red light pulses is measured with high precision. The luminophore's excited electrons will remain in this state for some time. In the presence of oxygen they return to their ground state more quickly. Between the pulsing excitation of the luminophore with blue light and the emission of red light there is an oxygen-dependent time shift, which can be measured as an angle of phase. The entire measurement, calculation and output of the measured value occur inside the sensor.

It should be noted that Visiferm sensors measure the partial pressure of oxygen pO_2 just as classical sensors do; this can for be displayed as percent air saturation, concentration in mg/l, ppm or even as ppb.

The measurement range is currently limited to 0.1 % to 300 % air saturation, which corresponds to a range of 8 ppb to 25 ppm. For most applications this measurement range is more than adequate. Intensive tests are being conducted for an expansion of the measurement range to 1 ppb.

Operational Reliability Paramount

Whether a purification plant manager is upset over higher energy consumption, because the oxygen measurement in the aeration tanks indicates values that are too low, or the fermentation in a pharmaceutical operation fails because the oxygen sensor, newly sterilized at 130 °C, suddenly stops reporting useful values, every such problem is one too many.

The most common malfunction with classical Clark Cells is damage to the mechanically sensitive oxygen membrane. If the membrane is seriously damaged, chances are good that a visual check will catch the problem before use. But if only a small, unrecognisable defect arises on the membrane, this becomes apparent only as the electrolyte leaks out and the sensor stops working.

The very small electric currents (nAs) represent another typical problem area, since these are transmitted to a measurement amplifier via cable in a rough operational environment, even slightly moist or dirty contacts from sweaty fingers, can result in chaotic or irreproducible signals. In addition, small fluctuations in temperature or vibrations can alter cable resistances noticeably. Over time, cables that have become damp, and especially damp cable connections are often the cause of problems in oxygen measurement, and the measurement of other parameters such as pH.

Comparison between the classic and optical oxygen sensor (Visiferm next to the Oxyferm FDA).

- Monitoring of all sensor functions, including status diagnosis of the replaceable sensor cap, with corresponding signals via the 4–20 mA and digital interface. A history of the self-monitoring is recorded in the sensor; and

Table: Technology and Costs for Classical and Optical Oxygen Measurement

Characteristic	OXYFERM FDA Classical O_2-Sensor		VISIFERM DO Optical O_2-Sensor	
Mechanically sensitive membrane	Yes	–	No	+
Caustic electrolyte in sensor	Yes, will leak in case of membrane failure.	–	No	+
Pressure stability	6 bar	–	12 bar	+
Sensor interfaces	Typical 60 nA – analog signal and NTC 22kOhm, must be processed in a measurement amplifier	–	4–20 mA standard signal for direct analog analysis in a process control system or PLC; Alternatively conventional 60 nA – analog signal and NTC 22kOhm to existing amplifier; RS 485 ModBus-protocol for direct digital analysis in PCs or process control system; Supply: 7–30 VDC	+
Operational wait time following connection	Polarisation time (stabilisation): typical 15 min, max. 120 min.	–	Within 1 min.	+
Possible Sample Interferance	Alkaline electrolyte of Clark cells can be altered by acidic gases such as CO_2 oder H_2S in the sample, causing an erroneous measurement	–	Acidic gases such as CO_2 and H_2S cause no disturbance	+
Flow sensitivity	Max. 3 % deviation between stirred and unstirred sample	0	No flow sensitivity. No oxygen consumption.	+
Handling	Membrane and electrolyte must be changed regularly. Up side down mounting only with special electrolytes	–	Only the sensor cap needs to be changed. Can be installed in any orientation.	+
Cable length	Max. 10 m recommended	–	Max. 1000 m	+
Safety	Membrane rupture or malfunction in trace measurement is difficult to recognize.	–	Sensor detects developing or existing disturbances independently. Age of the sensor cap is continuously monitored. Trace measurement also yields a reliable signal.	+
Measurement amplifier	Must be externally available.	–	Integrated into the shaft.	+
Costs for a 4–20 mA oxygen standard signal	Measurement amplifier, cable and sensor: from €2,000.–	–	Sensor and cable. approx. €1,200.–	+

Measurement results from Visiferm can be exported from the sensor as 4–20 mA or digitally. Both types of signal are clearly more tolerant of difficult process conditions than the sensitive (nA) signals of a classical dissolved oxygen sensor.

Signal Availability

A measuring point that delivers no signal can cause great damage. The signal for process control depends on all the components necessary for that signal. For the classical oxygen measurement these are: the sensor, sensor cable, measurement amplifier, its power source, the cable from the measurement amplifier to process control, and usually a separate amplifier for galvanic separation and/or voltage surge protection. The weakest link contributes the most to system failure. In classical systems this is clearly the membrane-covered sensor first and secondly the cable to the measurement amplifier. With Visiferm, the especially vulnerable small currents are dispensed with and a considerably insensitive analog mA or digital signal is supplied as the measurement amplifier is built right into the sensor. Instead of a disturbance-vulnerable membrane, Visiferm has a robust sensor cap as a sensitive and selective element. Visiferm even tolerates low to medium damage to the sensor cover. The sensor is specified for operating pressures up to 12 bar and temperatures up to 130 °C.

Accurate Trace Measurements

Trace measurements with classical sensors are not considered particularly accurate, since in the absence of oxygen no O_2 molecules can be reduced, as a result no current flows. The same happens when a cable break occurs. This is different with Visiferm: at low oxygen concentrations the greatest amount of red light is emitted. Thus the function of the sensor is easily monitored during trace measurement.

Operational Reliability Through Simple Maintenance

User friendliness is a critical concern for sensors. In particular simple maintenance, since for example in the case of a nightshift problem the personnel on hand must be able to carry out the necessary maintenance and calibration. Every procedure saved signifies an increase in operational reliability. Visiferm obliges here: if the sensor cover should need to be exchanged, this can be done as simply and easily as opening and closing a bottle of soda. The sensor cover twists off and a new one twists on. To achieve high measurement accuracy, calibration need only be done in air, or if necessary in nitrogen or carbon dioxide.

Areas of Application for Visiferm DO

Visiferm DO sensors have been evaluated in a variety of applications. The sensors were developed to be steam-sterilized and autoclaved without any troubles. Typical CIP cleaning is also tolerated very well. These properties along with the standard design form of a classical 12 mm sensor with a PG 13.5 thread make Visiferm DO superior for use in fermenters and other similar demanding applications.

Hamilton manufactures pH, redox/ORP, oxygen, conductivity sensors, certified calibration solutions, sensor armatures, chromatography syringes and valves, pipettes, dosing appliances and pipetting systems for the biotechnology and pharmaceutical industries.

Applications in addition to biotechnology include wastewater processing. In breweries Visiferm is already being used to monitor carbon dioxide recovery. Tests in the area of bottle filling are currently being conducted. Visiferm Do is already available in various shaft lengths: 120, 160, 225, 325 and 425 mm.

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Tightening The Belt

An Optimal Model for Controlling Lab Maintenance Costs

Thermo Fisher Scientific has recently launched its Asset Management Services operations in Europe. As part of this launch, a new range of Lifecycle Enterprise Solutions is being introduced to help pharmaceutical, chemical and biotechnology organizations optimise the management of their laboratory assets from acquisition to disposition, thus improving productivity, reducing total cost of ownership and ensuring regulatory compliance.

The optimal model for reducing total cost of laboratory ownership while maintaining quality of service must be determined through a robust decision-making process. A detailed needs assessment is essential to specify the customer service configuration as success is dependent upon the solution's ability to meet these needs and evolve as these change over time.

Form a Team

For a successful implementation of an integrated services solution, a cross-functional team of individuals empowered to make decisions on behalf of their respective departments should be formed. The team should consist of an executive level sponsor and team leader, individuals from procurement, lab managers, quality assurance/quality control (QA/QC), facilities and end-user scientific and research communities.

Gather Data

An organisation must understand its current asset management situation. Data gathering can be very time-consuming depending on whether the information exists and in what form. Establishing a baseline for where you are today will help determine performance metrics for measuring success tomorrow.

An organization should also understand the environmental impact of an instrument's service needs. In R&D drug labs, various types of instruments are used; oftentimes similar instruments from a variety of manufacturers. The complexity, use and environment of this equipment mix impacts productivity and regulatory compliance. Managers should identify which instruments require high-availability and have a greater operational and/or financial impact when they are in need of repair and which instruments have redundancy or back-up capabilities.

Share Information

In case the organisation is unable to establish the baseline for their current asset management situation, they should determine a reasonable estimate of the approximate maintenance costs. Some challenges are due to the traditional nature of departmental roles and how maintenance has been managed over time.

Scientists and researchers may rely upon multiple service delivery resources, i.e. in-house, original equipment manufacturer (OEM) service providers, and independent service organizations (ISO), and service processes to maximise equipment uptime. Hence, they may be unable to track entitlements, capture and collect maintenance activity, analyse service information or verify that services are performed in a timely manner.

Finally, quality assurance and control may need improvement in the systems or procedures currently in place to review and approve documentation as well as simplify training, maintaining compliance with the U.S. Food and Drug Administration (FDA), Current Good Manufacturing Practices (cGMP) and Current Good Laboratory Practices (cGLP).

The inability to manage these processes efficiently results in higher maintenance costs, unnecessary administrative burden, lower end-user productivity, decreased asset performance and compliance issues. Without an accurate inventory, service agreements may be paid on items that do not exist. Without a systematic approach to assess end-user satisfaction, the organization is unable to address on-going performance and productivity improvements. Without management reports of maintenance activity or asset performance metrics, procurement and lab management are unable to identify problematic equipment to justify new purchases.


Photo: Pixelio

Identify Requirements

The cross-functional team should assemble and discuss the challenges and their impacts as well as their goals and objectives. Scientists and researchers may focus on quality of service, ease of use, asset performance and uptime. Quality Assurance and Quality Control (QA/QC) needs to be compliant with the FDA, cGMP and/or cGLP. Requirements of individual team members may vary and contradict one another.

A detailed needs assessment is critical to engage the necessary resources at the appropriate time and define the service delivery configuration. The team must prioritise and balance the desire to reduce and control costs with the desire to improve end-user productivity and equipment uptime.

Analyse Models and Methods

There are several maintenance models and methods utilised in whole or in part to support scientific instrumentation.

- Service Contracts or Support Plans – Contracts allow OEMs to deliver services based upon an individual instrument's entitlements. Comprehensive contract coverage usually includes technical telephone support, travel, on-site labor, parts, preventive maintenance, software updates and guaranteed response times. Advantages are high quality service, improved end-user productivity through guaranteed response times and fixed maintenance costs. Disadvantages are inability to manage maintenance on an enterprise-wide basis, leading to increased administrative burdens, lack of accurate inventory and useful management reports for informed decision making.
- Multi-Vendor/Direct Services (MVS) – This method may be sold by OEMs or ISOs. An MVS contract provides vendors with the responsibility to deliver support services for a variety of instrument types manufactured by numerous vendors. Advantages are increased instrument uptime and improved end-user productivity. Disadvantages are one fixed service provider, quality of service and additional costs. To effectively deliver MVS, companies need to make a long-term financial commitment to hire, train and maintain the appropriate resources and build the infrastructure to support them.
- In-house Engineers – This model requires a significant investment in engineering resources. Organisations must define their own staff requirements, hire service engineers, ensure they are trained on many instrument types, purchase tools and technology needed to maintain an accurate inventory and track services rendered. Advantages of in-house engineers are the potential for increased instrument uptime and improved end-user productivity through faster response times and higher PM completion rates. Disadvantages include increased administrative burden for time and materials purchase orders, finding and hiring qualified service engineers and on-going training costs associated with maintaining up-to-date instrument service knowledge. Other disadvantages include lack of a readily available parts and accurate inventory, lack of outside information to properly analyse and compare charges of individual repair events for technical accuracy and billing errors, lack of objectivity, lack of accurate cost data and lack of a maintenance activity database to generate reports.
- Managed Maintenance – A systematic approach to reducing and controlling maintenance cost by managing an organisation's services on a time and materials basis. One agreement includes the maintenance of all instruments to be covered by the model. Value-added services provided include an on-site personnel, business review meetings, quality review services for the reconciliation and review of field service reports and invoices, program updates, PM tracking, scheduling reminders and completion reporting, warranty tracking, on-going inventory management and easy access to maintenance activity and management reports. Advantages include cost savings, fixed maintenance budget, reduced administrative burden, flexibility to choose preferred service providers and inventory accuracy.

The Optimal Model

The 3D Model capitalises on the strengths of the available service models and methods and the proper blend of service providers to create an integrated services solution based upon a detailed needs assessment that focuses on three dimensions: business goals and objectives, operating environment and the instrument/equipment mix across the enterprise. The model leverages the managed maintenance infrastructure to create a solution that best meets the needs of the organization. Advantages are reduced and controlled costs, streamlined processes, reduced administrative burden, end-user flexibility to maintain quality of service and on-going inventory maintenance and control. Resources, tools and technology are used to track services and generate useful, uniform management reports. Information is provided for budgeting, benchmarking and measuring success.

Evaluate Vendors

The team should agree on the criteria used to evaluate potential vendors of enterprise-wide asset management models. The vendor should be an experienced change agent with a significant number of successful implementations. They should be able to demonstrate their ability to achieve results by improving financial and operational outcomes proven through case studies, references or site visits. The vendor should have a strong OEM relationship strategy whether it is for the actual delivery of services, back-up support or parts. Finally, a wealth of data and knowledge, such as a comprehensive database of instrument service information and trends, can be leveraged and used in a variety of ways to benefit customers.

Measure Success

Results achieved from the implementation of the new integrated services solution should be compared against the baseline established at the beginning of the process. If the organization was unable to establish a baseline, one measure of success is now having the ability to do so. Measurements of success include cost reduction, avoidance and control, inventory accuracy, end-user satisfaction and management reports that provide intelligence for informed decision making.

By following this process, an organisation should be able to determine their optimal model for controlling lab maintenance costs and maintaining quality of service. The optimal model's ability to evolve as the organization's requirements change over time will determine its success. Opportunities for improvements to the model should be identified through regular meetings with the team and new partner as well as through the deployment of on-going end-user and vendor satisfaction surveys.

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Sandoz to Invest US-$80 Million in Boucherville Facilities

Sandoz Canada announced that it will invest US-$80 million in its Boucherville facilities as demand for its generic sterile injectable pharmaceuticals continues to grow in Canada and around the world. In addition to more than 100 new positions created in 2006, 100 additional jobs will be created in Canada over the next two years.

The US-$80 million investment includes the construction of a second manufacturing site; the expansion of the drug development laboratory, purchase of state-of-the-art laboratory equipment and expansion of the quality control laboratory; new manufacturing equipment for the existing manufacturing plant; and the acquisition of additional land and building adjacent to the head office.

The investment will translate into the addition of 3,716 m^2 of manufacturing space, 975 m^2 of warehousing space and 1,579 m^2 for administrative support. In addition, the current manufacturing site will undergo improvements to ensure that it maintains its position as a top-performing production facility. By completion of this project, the production capacity will have been increased by 66 %.

According to the company, the Boucherville site is the largest small-volume injectable drug production facility in Canada and within the Novartis Group of companies. Its product portfolio includes over 100 molecules such as narcotics, sedatives, antibiotics, ophthalmics, hormone treatments, corticosteroids and cardiology drugs. In addition, Boucherville is a worldwide center of excellence for the development of sterile injectable pharmaceuticals within Sandoz.

▶ www.sandoz.com

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The German Drug Market

Reforms Could Endanger Pharmaceutical Innovation – Part 2

In Part 1 we explained, how the drug market is in the focus of increasing regulations for innovations. Despite those regulations pharmaceutical companies, who invested and delivered in highly specialized biotech innovations, nevertheless experienced a significant growth. Obviously, either true innovations are still a wild card for success, or, some areas of the markets are controlled tighter than others. If the classification of a true innovations is so important for the market success, this needs further clarification. In the second part of the article we address the question, what defines a true innovation.

Numerous countries and health care systems evaluate the therapeutic value of an active ingredient. In Germany, this evaluation is undertaken under the term "benefit evaluation," which has been carried out by the Institute for Quality and Efficiency in Health Care (IQWiG) since 2004. In addition, a pre-evaluation of medications has existed in Germany since 1978 through the pharmacologists Fricke and Klaus. Regrettably, the widely accepted view in Germany is that half of all drugs to be introduced onto the German market – those that were graded C by Fricke and Klaus – are not really innovative and therefore have no additional therapeutic value. These C-grade medications were recently placed onto a "me-too-list," which was accompanied by an urgent recommendation to avoid prescribing these drugs. This was in spite of the fact that a closer examination clearly illustrates that the predicative value of a pre-evaluation, in the fashion carried out by Fricke and Klaus, must be strongly questioned – since the pre-evaluation corresponded with the final therapeutic value in less than 20 % of all cases reviewed.

From the industry's point of view, it is important for me to emphasise that research-driven pharmaceutical companies are not just searching to imitate successful brand products, as the political discussion around me-too implies. Quite to the contrary, it is a means creating well-functioning innovative competition between numerous research businesses to achieve the goal of being the first in its substance-class. If a company can only bring its product to market after the originator, i.e. a competitor with a different substance in the same substance class made it onto the market earlier, the new (follower) substance in most cases is still marketed, despite harsher competition as to quality and price. This usually requires a cut in price, as the pharmaceutical industry experiences the phenomenon of a "first mover advantage." The industry consequently already tries to develop unique selling propositions during research, so that a medication can provide patients with the advantage of improved therapeutic benefit, better safety, and/or improved ease-of-use by its deliberately delayed introduction to the market.

Yet even when a true medical innovation is introduced, as an improvement society has been waiting for, a pharmaceutical corporation still faces the challenge of the already highly strained drug budgets. In many cases, it can be proven that more expenditure on drugs saves money in other sectors – in other words, that investments into drug therapy are budget-neutral. Nevertheless, the relatively rigid planning and budgeting systems often prevent possible gains in efficiency, as money does not follow the patients, and cross-sectoral saving opportunities remain untapped. In addition, the real innovation with a new treatment option of so-far untreatable conditions will no doubt result in increased costs, even when these costs are connected to a marked improvement in patients' health.

There are numerous examples for the reduction of adverse health consequences through new health technologies. For instance vaccinations have proven to be the most effective means in preventing infectious disease worldwide over the past several decades. They can prevent illness as well as help avoid the onset of complications. By avoiding illness-related costs and missed workdays, vaccinations are by large very cost-effective or can even lead to savings.

The Expanded Programme on Immunization (EPI) was launched by the World Health Assembly in 1974, aimed at increasing coverage of vaccines against six diseases (tuberculosis, diphtheria, neonatal tetanus, whooping cough, poliomyelitis and measles). As a result of these vaccinations, an estimated 3 million lives are saved each year, and an additional 750,000 children are saved from permanent disability.

The latest initiative of the G8 Finance Ministers Advanced Market Commitments to Vaccines Pneumococcal diseases targets another major public health problem all over the world. Streptococcus pneumoniae is responsible for an entire line of illnesses in children and in adults. A wide variety of international and German analyses can all testify the cost-effectiveness of vaccination with the heptavalent pneumococcal conjugate vaccine (PnC-7) against pneumococcal disease. With that in mind, the cost of vaccination covers not only a significantly reduced number of health consequences, but also constitutes savings that exceed the investment cost.

Even the burden of severe illnesses such as infections with the human immunodeficiency virus (HI-Virus, HIV) was successfully modified by drug interventions. For instance the death rate amongst patients with AIDS in Europe has decreased by approximately one fifth between 1995 and 1998; this is largely attributed to the use of antiretroviral therapy.

Outlook

A forward looking health care policy is a fine balance between patients' justified demands for optimal treatment, adequate access to new types of treatment, and societal responsibility for the fair financing of the public health care insurance system. Due to the cost-benefit evaluations mandated by law, in Germany the debate has intensified as to which innovations should be reimbursed in the future. These evaluations finally force decision-makers to be explicit and transparent, which is very encouraging.

The justified fear of patients, however, is that access to certain new medications will be explicitly denied due to economic motives. For this reason, the introduction of cost-benefit evaluations must be accompanied by well-grounded medical outcome research – to spot potentially negative consequences of these provisions early.

More intensive outcome research would enable:

- that health benefits, which extend far beyond the borders of an illness' sector group, be taken into account;
- that patients are informed to an extent that they can make their own decisions about individual quality of treatment and make their own financial contributions accordingly, instead of patients having to accept second-best therapeutic methods without a chance of being informed of alternatives;
- that health care politics can develop clear communication guidelines again, instead of repeating the incantation "everybody can get everything" and then making excuses for the necessary exceptions and disguising them as health concerns.

The competitive model of the research industry will be drastically changed. The continuous obligation to supply outcome data will increase the investments into complementary competencies such as health economics, biometry and clinical epidemiology. At the same time the knowledge of, and dealings with, the institutional decision-makers on the health care system are paramount to today's success. These decision-makers should give top priority to forming an overall, integrated observation of medication and medical care that takes all sectors into consideration. Striving for quality without thinking about costs is without a doubt prohibitively expensive. Yet the benefit of medicinal therapy to the health care system and to individual patients can only be realized when expenditure for medication is not seen as a cost, but rather as an investment in health. Quality pays off; the goal, therefore, must be: "giving all patients the right medication at the right time".

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An Overview of Reach Testing Requirements

The New EU Chemical Control Scheme

The information on hazardous properties required for registration under Reach is linked to the manufacture or import level, on the grounds that there is a potential for more exposure as more substance is in the EU. The annexes of the regulation specify the standard data requirements and give rules on the circumstances in which data may be omitted and when extra data are triggered. New animal studies are required only if surrogate data or in vitro alternative tests cannot provide the necessary information. The registrant can adapt the required standard information and provide the data using other information, such as non-standard or non-GLP tests, historical human data, a weight of evidence, structure activity relationships (SAR) or read-across to tested analogues. There is also the provision for data waivers on the grounds of low exposure, ie. substance-tailored exposure-driven testing.

Substances manufactured or imported, either neat, in a formulated preparation or present in a finished article if released, at 1 t/y have to be registered, unless exempted. There is the option for a non-EU manufacturer to appoint an EU-only representative registrant to register the substance on behalf of the EU importer(s). Substances notified under the new substance notification scheme are considered as having been registered, and there are other exemptions, in particular for products regulated by equivalent EU legislation, polymers, but not their consistent monomers, and non-dangerous natural substances. There are special arrangements for registration of some chemical intermediates and for substances used in product and process-orientated research and development (PPORD).

New substances have to be registered before manufacture or import. There is a review programme for phase-in substances, with the submission deadline based on the tonnage and whether they are classified as carcinogenic, mutagenic or toxic for reproduction (referred to as CMRs) of Category 1 or 2 under the EU scheme (ie. proven in humans or with such strong evidence that they can be regarded as proven) or very toxic to aquatic organisms and that may cause long term adverse effects in the aquatic environment (ie. labelled with R50/53), as summarised in Table 1. Companies enter their substances into the review programme by pre-registering them with the ECA between 1 June 2008 and 1 December 2008. The ECA perform a completeness check using an automated process and check at least 5 % of registration dossiers in detail.

Higher-tier testing is required at 100 and 1,000 t/y, and the registrant includes a testing programme proposal in the registration. For phase-in substances, the ECA evaluates these proposals and reaches agreement with the registrant within the deadlines specified in table 1, then the registrant is given reasonable time to complete the new studies.

Table 1: Timings for Registration

Register new substances at ≥ 1 t.p.a. before manufacture or import.
Pre-registration of phase-in substances between 1 June 2008 and 1 December 2008.

Registration for phase-in substances:	
Category 1 or 2 CMR's (> 1 t.p.a.):	by 1 December 2010
> 100 t.p.a (R50/53).:	by 1 December 2010
> 1,000 t.p.a :	by 1 December 2010
> 100 t.p.a.:	by 1 June 2013
> 1 t.p.a.:	by 1 June 2018

Draft decisions for phase-in substances for further testing:	
Category 1 or 2 CMR's (> 1 t.p.a):	by 1 December 2012
> 100 t.p.a (R50/53).:	by 1 December 2012
> 1,000 t.p.a.:	by 1 December 2012
> 100 t.p.a.:	by 1 June 2016
> 1 t.p.a. (if any):	by 1 June 2022

Table 2: General Annex VI Information Needed for Registration

Technical dossier (in a specified electronic format):
Technical data on the registrant, identification of the substance, manufacture and use and guidance on safe use
Robust summaries of safety data
Proposed classification and labelling
Statement whether animal testing was conducted
Proposal for any further testing
Chemical Safety Report, for substances at > 10 tonne per annum. This is a risk assessment including PBT and vPvB assessment.

Authorisation And Restrictions

Specific uses of substances of very high concern will have to be authorised. These substances are to be listed in Annex XIV of the regulation, and it is anticipated there will be around 1,500 such substances, with the first recommendations for inclusion in Annex XIV scheduled to be made by 1 July 2009. Very high concern substances are substances classified as Category 1 or 2 CM's or persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB). As additional very high concern substances are identified, largely from testing for registration and evaluation, they will be fed into the authorisation system.

Particular uses of very high concern substances have to be authorised taking into account the risk assessment. The authorisation application has to be submitted to the ECA 18 months before the sunset date given in Annex XIV. The ECA can take into account socio-economic factors in deciding if the use of the substance can be authorised. The applicant has to consider possible safer substitutes, or develop a research plan to investigate possible substitutes. Authorisations are subject to time-limited review of duration decided on a case-by-case basis, to allow further consideration of alternatives.

Table 3: Registration Safety Data

Annexes VII to X give standard data requirements (in column 1) and rules for omitting tests or additional studies (in column 2)
Annex XI covers adapting the standard data requirements:
existing non-standard and/or non-GLP data
historical human data
weight of evidence
SAR
grouping and "read across"
suitable in vitro tests, but confirmation of negative results may be needed from non-validated in vitro methods
data waivers, ie. a study is technically impossible
substance-tailored exposure driven testing

Table 4: Cost of Registration Safety Data

Typical approximate costs for substances with no surrogate data or data waivers:
Annex VII (if reduced data applies) at > 1 t.p.a. but < 10 t.p.a.: £20,000
Annex VII (if full data applies) at > 1 t.p.a. but < 10 t.p.a.: £40,000 to £50,000
Annex VII plus VIII at > 1 t.p.a. but < 100 t.p.a.: £140,000 to £190,000
Annex IX at > 100 t.p.a. but < 1,000 t.p.a.: £500,000 to £1,000,000 (highly variable)
Annex X at > 1,000 t.p.a.: £1,000,000 to £3,000,000 (extremely variable)
Average cost for phase-in substances taking into account available studies, surrogate data and data waivers, adapted from the KPMG study:
Annex VII (if reduced data applies) at > 1 t.p.a. but < 10 t.p.a: ca. 10,000 Euro
Annex VII (if full data applies) at > 1 t.p.a. but < 10 t.p.a.: ca. 20,000 Euro
Annex VII plus VIII at > 1 t.p.a. but < 100 t.p.a.: ca. 100,000 Euro
Annex VII to IX at > 1 t.p.a. but < 1,000 t.p.a. : 282,000 Euro
Annex VII to X at > 1 t.p.a. and up to > 1,000 t.p.a. : 323,000 Euro
Note t.p.a. means tonnes per annum.

The Registration Dossier, Chemical Safety Report and Data Requirements

The general technical, commercial and administrative information needed for all registrations for the technical dossier is specified in Annex VI of the Regulation (table 2). The dossier, including robust summaries of the study reports, has to be submitted to the ECA using the new Version 5.0 of the well-established International Chemical Information Database (IUCLID) format.

A Chemical Safety Report (CSR) is required for substances registered at 10 tonnes per annum unless the substance is present only on a preparation at below 0.1 %. The major part of a CSR is a risk assessment, following the general provisions of Annex I of the Reach regulation. These general risk assessment principles correspond with the current EU practice. In particular, environmental risk assessment is based on a comparison of the Predicted Environmental Concentration (PEC) with the Predicted No Effect Concentration (PNEC) for each compartment of the environment as a PEC/PNEC ratio, which is also referred to as the Risk Characterisation Ratio (RCR).

A key concept used in the CSR for human health risk assessment is the Derived No Effect Level (DNEL) for each exposed human population. In order to evaluate the human and environmental exposure for the risk assessment, exposure scenarios and relevant use and exposure categories must be available, so it is essential to have input from downstream users. The CSR also includes an assessment of whether the substance is classed as PBT or vPvB. The CSR is a key element in communicating important safety information to downstream users, and a summary of the CSR is to be included as an annex to the Safety Data Sheet. Any uses not registered and covered in the supplier's CSR have to be assessed by the downstream user or the registrant as a supplement to the CSR.

The information on hazardous properties needed for registration is specified in Annexes VII to X of the Regulation. It is linked to the annual tonnage, on the grounds that there is a potential for more exposure as more substance is in the EU. The Annexes specify the standard data requirements and give rules on the circumstances in which data may be omitted and when extra data are triggered. Any studies that are technically impossible clearly can be omitted. The registrant can adapt the required standard data requirements of the Annexes and instead use equivalent information that is adequate to assess the hazardous properties and conduct a risk assessment, such as existing studies that may be to non-standard methods or not conducted in compliance with Good Laboratory Practice (GLP) tests, effects on humans, structure activity relationships (SAR) or 'read-across' to tested analogue substances, possibly forming a category of related substances. Guidance on this intelligent approach to safety evaluation using such surrogate data and possibly taking a weight of evidence approach is given in Annex XI of the Regulation (table 3). This includes a provision for substance-tailored exposure-driven testing, i.e. data waivers on the grounds of low exposure. Only after collecting the existing information and considering use of surrogate data and data waivers can the data gaps be identified in the tonnage-driven information requirements. All new studies to fill the data gaps have to be conducted to standard EU (or Organisation for Economic Co-operation and Development) methods, and the toxicology and environmental studies have to be GLP compliant.

The cost of new testing will vary considerably between substances. For new substances or for the minority of phase-in substances where full testing is needed typical costs are given in table 4 for the various tonnages. Estimates have been used by the consultancy KPMG of the average cost of additional testing for phase-in substances, and these figures have been adapted in table 4 to take account of the revised testing requirements in the final Regulation.

Preparing For Reach

In general, the first step is to develop inventories of chemical substances supplied and purchased, including components of formulated preparations. For purchased chemicals, it may be possible to find out if the supplier is planning to support the substance in particular for the purchaser's uses. There are almost certain to be some unsupported substances in each company's inventory of purchased chemicals. A supplier of chemicals will have to decide which to support, and make plans to withdraw any that will no longer be profitable. To do this an evaluation of what existing safety data are available is an essential first step, taking into account in-house studies and literature data, to produce a preliminary data gap analysis, which can be refined after evaluating the reliability of the literature data to judge whether it can be used for registration and investigating the use of surrogate data or data waivers.

Many substances will be supported by more than one registrant, so after pre-registration, a SIEF will be formed, with the opportunity to reach agreement to use their existing data and co-operate in the development of new studies. Most registration dossiers for substances at below 100 t/y will not be evaluated in detail, so it is up to the registrant to make the case for using non-standard data and surrogate data, but for higher volume substances it may turn out that some new studies are needed to complete the basic data package when the higher-tier testing programme is being negotiated. Finally, there will be some very high concern chemicals for which uses have to be authorised. Many of these will already be known, because the CMR classifications are already established, but others will be identified as the registration data are generated.

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Product Development Worries

Significant Investment in Lifecycle Management Technology En Vogue

Streamlining product lifecycle processes is now a major priority for manufacturers looking to improve their market share. According to the latest report by independent market analyst Datamonitor (DTM.L), manufacturing companies are looking to enhance both internal and external collaboration, manage product data better and streamline workflows, as time to market becomes ever more important. Whilst by no means a new phenomenon, the report "Supporting product development with cutting edge IT" says this indicates it is now taking a higher priority. In turn, these strategies are leading to additional investment in technology such as product lifecycle management (PLM), creating one of the fastest growing enterprise application segments.

"As competition increases within various manufacturing industries, the time taken to develop a product and bring it to market has become a key metric for progressive manufacturers. Minimising this time, while maintaining quality and fostering innovation is the latest challenge in today's manufacturing industry," said Adam Jura, manufacturing technology analyst and author of the study. "In 2007, we can expect a lot of product-driven investment in IT – this is making an interesting balance act for manufacturing businesses."

US-$4.1 Billion to be Spent Product Lifecycle Management Software

PLM is the process of managing the entire lifecycle of a product from its conception, through design and manufacture, to service and disposal. Product Lifecycle Management software tools are used, primarily by industrial manufacturing companies to document and support the complete life cycle of their products and to devise and manage ancillary services, such as product maintenance. Datamonitor estimates that by 2012, the worldwide market for PLM software (excluding maintenance) will reach US-$4.1 billion in the manufacturing industry. This represents strong growth on 2006 revenues of US-$1.9 billion. Growth will be driven primarily by large enterprises however the mid-market sector is beginning to demonstrate stronger growth in uptake.

Datamonitor's PLM software forecast model also assesses the investment in PLM within sixteen individual manufacturing industries. Currently, the automotive, high-tech and electronic, and aerospace & defense markets are leading the way.

"Many manufacturers will turn to PLM technology to help alleviate their product-oriented dilemmas as the range of functionality and supported workflows and processes increases. Integration with other key enterprise applications such as enterprise resource planning (ERP) will be an essential component of PLM technology moving forward. Linking with supplier relationship management (SRM) and manufacturing execution systems (MES) applications is also growing in popularity," said Jura.

Changes Afoot

According to Datamonitor, vendors such as Dassault Systemes, UGS (now a part of Siemens Automation & Drives), PTC, Agile and SAP all stand to gain from a rapidly growing market. Industry expertise and regional distribution are still key elements of investment decisions within manufacturing companies, as is the use of xCAD systems which a PLM investment will seek to manage. Datamonitor believes that services vendors such as IBM and HP are also well placed to drive revenues in the PLM market as manufacturers look for a variety of services to assist in business process management and cross-border implementation.

2007 looks set to be a blockbuster year for industry observers with consolidation already underway. Recent M&A activity has seen MatrixOne fall into the hands of Dassault Systemes (March 2006) and UGS acquired by Siemens Automation and Drives (Jan 2007). Datamonitor predicts that 2007 is likely to see more of the same activity as the larger enterprise applications vendors such as Oracle, Infor and Lawson look to solidify their own PLM solutions, and established players divert more attention to the mid-market.

Jura concludes: "While product development has always been the mainstay of manufacturing companies, there's a real transformation occurring in the market that's seeing a lot more importance given to the area. What it all adds up to is that manufacturing companies are poised to both cut product development-related costs and introduce more innovative, successful products. Functionality, core integration capabilities, process and workflow support, and thought-leadership will determine which of the myriad of vendors will be the most successful in helping manufacturers reach their product lifecycle goals."

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Univar Expands in Central and Eastern Europe

Univar announced the establishment of two new subsidiaries in Eastern European. The new businesses, Univar Czech, located in Prague, and Univar Hungary situated in Budapest are the latest developments in Univar's planned growth in Europe. The company said this is their next step in extending its presence in Central and Eastern Europe, and follows an earlier move which saw the establishment of distribution operations through Univar Poland and its Mapol. business.

▶ www.univareurope.com

Bayer Schering Pharma Prevails in Litigation

Bayer Schering Pharma prevailed in both court proceedings concerning the domination and profit-and-loss transfer agreement concluded with Bayer subsidiary Bayer Schering. The District Court of Berlin dismissed as unfounded the action contesting the decision of the stockholders' meeting of Bayer Schering Pharma on 13 September 2006 to approve the agreement.

Bayer considers that the District Court's ruling fully confirms its legal view of the matter. The domination and profit-and-loss transfer agreement entered in the commercial register on October 27, 2006 has since served as the basis for the comprehensive and successful integration of the former Schering Group into the Bayer Group.

▶ www.bayer.com

Mylan Buys Merck KGaA Generics Unit

Mylan, the second largest generic maker in the US, has bought Merck KGaA's generic drugs unit. Mylan is set to significantly expand its generic drugs portfolio having beaten rival Teva to the acquisition of Merck Generics, in a US-$6.7 billion deal. On consolidation, the generics company will boast annual sales of US-$4.2 billion, making it the third largest generics business across the global healthcare market, behind Teva and Novartis' generics unit, Sandoz.

The acquisition is the second major piece of merger and acquisition activity conducted by Mylan, increasing its portfolio to 500 marketed generics products and expanding its staff to 10,000. Its first came in 2006, when it bought control of India-based API manufacturer, Matrix Laboratories, a move which gave it its first foothold outside of the U.S. generic market and access to less costly manufacturing.

The deal is not without its risk, however. At more than five times Mylan's annual revenues of US-$1.3 billion, the associated debt will have short-term implications on Mylan's financial position. Successful identification of synergies during integration could dampen an anticipated reduction in the new company's earnings potential. In the long-term, Mylan's enhanced competitive position – underlined by improved R&D capabilities (diverse dosing formulations) and increased manufacturing volume – should manifest as growth and profitability.

Merck will itself benefit from the divestment, despite the near-third of total revenues attributed to its generic arm that it will lose. The capital raised by the transaction is sizeable and, alongside its tightened corporate focus, should create opportunity for the hybrid company to expand its presence in ethical and OTC pharmaceuticals, or its chemicals unit with M&A of its own.

▶ www.merck.de
▶ www.myland.com
▶ www.datamonitor.com

Pall Opens New Centre of Excellence in India

Pall Corporation said it has opened its newest Life Sciences Centre of Excellence in Bangalore, India. The Centre will drive process optimisation innovations for the global life sciences market to meet the evolving opportunities and challenges of this fast-growing industry throughout Asia. The new Centre includes a state-of-the-art proteomics laboratory to help customers speed the drug discovery process. It also houses a validation laboratory and a training facility with specialty experts to support Indian and regional customers as they increasingly enter the stringently regulated drug export market. The company said it chose as the location for the Centre because of the country's highly regarded reputation in life sciences spanning biopharmaceutical research, development and production. Additionally, India's diverse market opportunities coupled with a large pool of qualified scientists and engineers provide an ideal climate for fuelling innovation and growth.

According to Pall, the biopharmaceutical industry throughout Asia is experiencing a major surge in activity. The Indian pharmaceutical industry is one of the world's largest, ranking fourth in terms of volume. According to Opportunities in Indian Pharma Sector (July 2006), India holds US-$6 billion of the US-$550 billion global pharmaceutical industry, an annual increase of 10% compared with the 7% annual growth of the overall world market. The biotechnology market is also booming in India and is expected to continue on a fast pace with the support of the government through its comprehensive national biotechnology policy. Indian Biotechnology Market Outlook (February 2007) reports that the Indian biotechnology industry has grown 28.09% from 2005, and is likely to touch the US-$5 billion mark by the end of 2010.

▶ www.pall.com


David K. Jones

Ashland Names Jones Director of Bioproducts David K. Jones has been named to a newly created position as director of bioproducts for Ashland. Jones joined Ashland in 1984 as a product development chemist in Specialty Polymers & Adhesives. He then progressed through roles in technical service, sales, marketing and global business management. His last role in Specialty Polymers & Adhesives was global director of sales. In August 2005, he was appointed to the initial growth office team and he has served as a director in Ashland's growth office since then.

▶ www.ashland.com


Dr. Gunther Kegel

Fieldbus Foundation Names New Board Member The Fieldbus Foundation announced that Dr. Gunther Kegel, chief executive officer of Pepperl+Fuchs, Mannheim, Germany, has been named to its board of directors. In 2005, Kegel was named chairman of the Fieldbus Foundation's Europe, Middle East & Africa (EMEA) Executive Advisory Council. He also serves on the board of directors for the FDT Group AISBL and on the supervisory board of the Mannheim University of Applied Sciences.

▶ www.fieldbus.org

CBA appoints New President, Vice-chairman The Chemical Business Association (CBA) has appointed Mike Smith, Norkem, as its president and Francis Osborn, Industrial Suppliers (Wimborne) as its vice chairman. Smith is chairman of Norkem Holdings and a former chairman of the association (2002–2004). Osborn is managing director, Industrial Suppliers (Wimborne) Limited, and has been a member of CBA Council since 1999. He is a member of the executive committee of the association and serves on its membership and communications committee.

▶ www.chemical.org.uk

Hikma Announces CEO The Board of Hikma Pharmaceuticals announced changes to its senior management team. Said Darwazah is appointed as CEO with effect from 1 July. Samih Darwazah, Hikma's current chairman and chief executive officer will continue in both positions until July, when he will assume the role of Non-Executive Chairman. Said was most recently Minister of Health in the Hashemite Kingdom of Jordan, a post which he held from 2003 until 2006. Said is currently on the Board of Directors of the Central Bank of Jordan and the King Hussein Cancer Institute. He has a degree in industrial engineering from Purdue University in the U.S. and an MBA from INSEAD.

▶ www.hikma.com

Nova, Ineos Name Senior Officers Nova Chemicals Corporation and Ineos announced the nomination of three senior officers for the companies' proposed, expanded joint venture. Nova Chemicals and Ineos have signed a letter of intent to expand the companies' existing joint venture in Europe, Nova Innovene, to include North American styrene and polystyrene assets. The expanded joint venture is expected to have initial revenues of approximately US-$3.5 billion per year. The following senior officers have been named to lead the organisation:

- Kevin McQuade – Chief Executive Officer. Currently, McQuade is chief executive officer of Ineos Styrenics.
- Martin Pugh – Managing Director, Europe. Pugh is managing director of Nova Innovene.
- Chris de la Camp – Chief Financial Officer. de la Camp is currently finance director of NOVA Innovene.

▶ www.novachem.com
▶ www.ineos.com

Shimadzu Corporation Names President Shimadzu Corporation has named Takeshi Kawami president of Shimadzu Scientific Instruments (SSI). Replacing Osamu Ando, who served as president for seven years, Kawami will oversee overall sales and management functions for SSI, the American subsidiary of Shimadzu Corporation (Kyoto, Japan). Kawami has spent 24 years with Shimadzu Corporation gaining focused knowledge of the company's sales, sales management, and corporate management. He conducted analytical instrument sales in Tokyo, Yokohama, Shizuoka, and Hiroshima, where he was promoted to sales manager. He returned to Tokyo in 2001. He was appointed president of a Shimadzu sales subsidiary in 2002. Kawami later became vice president of two merged sales subsidiaries.

▶ www.shimadzu.com


Dr. Manfred Jagiella

Endress+Hauser Conducta: New Managing Director Endress+Hauser Conducta has announced that Dr. Manfred Jagiella will be taking over as managing director of product centre in Gerlingen, Germany. He will take over from Dr. Wolfgang Babel. Before joining Conducta, Jagiella worked as head of the Sensors business division of Balluff in Germany.

▶ www.conducta.endress.com

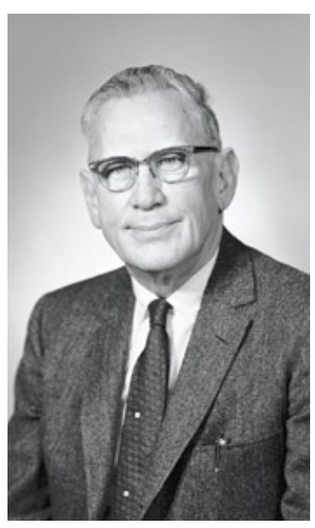
Rockwell Automation Announces CFO Transition Rockwell Automation has announced that James V. Gelly has resigned from his position as the company's senior vice president and chief financial officer. Gelly is expected to remain with the company's finance function over the next several months in an advisory capacity, in order to ensure a seamless transition. Replacing Gelly as chief financial officer on an interim basis is Theodore D. Crandall, senior vice president and head of the Control Products & Solutions segment.

▶ www.rockwellautomation.com

Scotch-brand Tape Inventor Honoured

Richard Drew, 3M's inventor of masking and clear cellophane tapes, was posthumously inducted into the National Inventors Hall of Fame in Akron, Ohio (U.S.) in May. Drew, hired by 3M as a lab technician in 1921, when the company was mainly a sandpaper manufacturer, overcame myriad problems by doggedly experimenting with a huge variety of substances until he succeeded, in 1925, creating a masking tape adhesive for automobile painting that could be safely removed without damaging the surface it covered. In 1928, he invented the first transparent tape, the precursor to an entire family of Scotch brand tapes.

In its 20-year lifetime, Drew's lab created technologies that account for as much as 20% of 3M's sales today, with products that span all six of 3M's businesses: Consumer and Office; Display and Graphics; Electro and Communications; Health Care; Industrial and Transportation; and Safety, Security and Protection Services. Since the inception of Drew's lab in 1943, 3M sales have grown from US-$47 million to more than US-$22 billion today.



▶ www.3m.com

ChemCon Americas 2007


Photo: Pixelio

From 18–21 September in Montreal, Canada, more than 200 experts from authorities and industry from all over the world are expected to take part in ChemCon Americas 2007. This international conference on chemical control legislation and trade aspects will address key issues of chemical control legislation, such as Reach, GHS and WEEE. An exhibition will accompany the conference and will provide detailed insight in various services (like IT or CRO) offered to the chemical industry.

▶ www.chemcon.net/asia_pac/chemcon2007ca.html

Bio-Europe 2007 in Hamburg


Photo: Pixelio

Close to 2,000 decision makers from biotech, pharma and finance will convene at the CCH-Congress Center in Hamburg, Germany, 12–14 November for the 13th annual Bio-Europe, the world's largest standalone biotechnology partnering conference. Delegates from all parts of the biotechnology value-chain will come to Bio-Europe to efficiently identify, engage and enter into the strategic relationships that drive their business successfully forward. Bio-Europe is co-organised by EBD Group and the Biotechnology Industry Organisation, in partnership with European Biopharmaceutical Enterprises. Early-bird registration with a discount of €200 is available until 31 August.

▶ www.ebdgroup.com/bioeurope/registration.htm

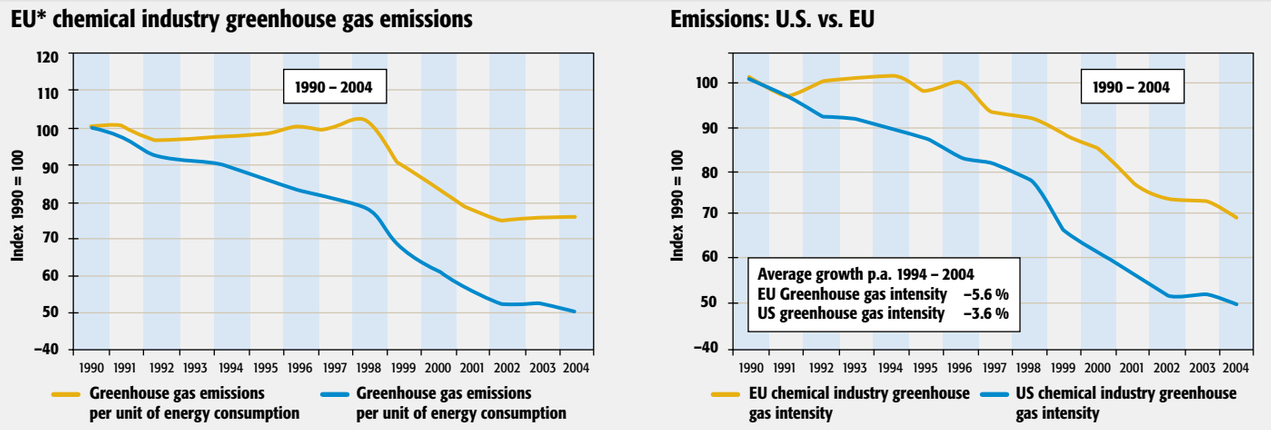
Special Presentation at K 2007


Photo: Pixelio

The special presentation "Plastics pack the punch!" will spotlight plastics' contribution to the basic functions of packaging – protection, information and distribution – during K 2007, to be staged in Düsseldorf from 24 to 31 October. The exposé covers far more than just product packaging and presents solutions from an all-encompassing perspective. Factors ranging from high-tech materials, transport, production and energy efficiency to environmental protection and sustainability will be addressed along with design and current trends. K 2007 exhibitors and trade visitors as well as the public at large should find plenty to pique their interest. The showcase is being organised by the German plastics industry, spearheaded by the trade association PlasticsEurope Deutschland and Messe Düsseldorf.

▶ www.k-online.com

Chemical Industry: Greenhouse Gas Emissions



* EU 15

Source: Cefic

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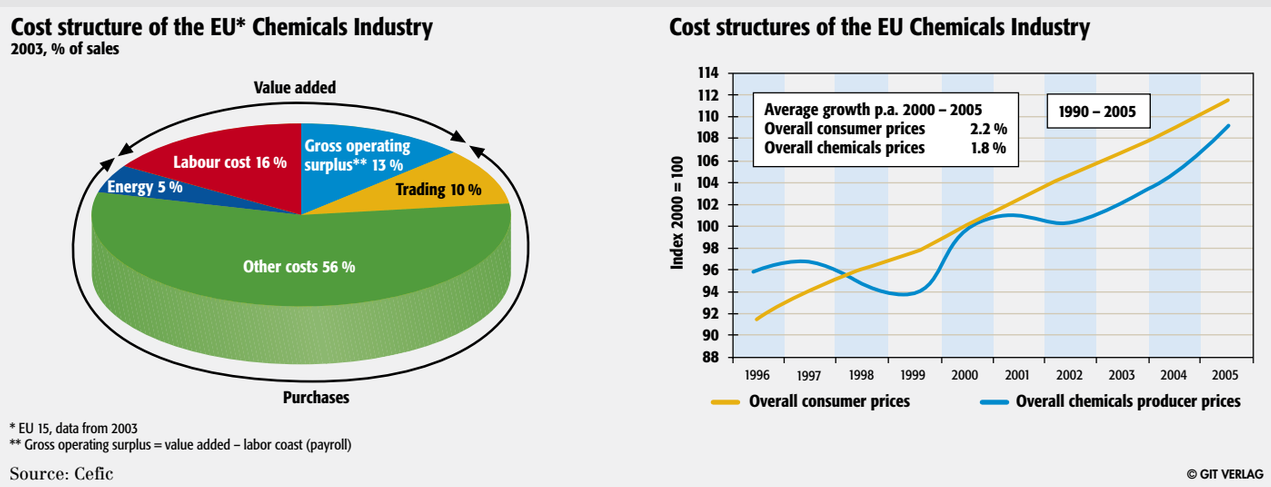
Between 1990 and 2004, production in the EU chemical industry rose by 56%, while total energy consumption was stable and greenhouse gas (GHG) emissions fell by more than 20%. Hence, GHG emissions per unit of energy consumption have been reduced by almost 25% and GHG and emissions per unit of production have basically been halved since 1990. This shows the enormous effort that the chemical industry is doing to minimize the environmental impact of its production. In comparison to the US, the EU has reduced its GHG emission intensity (emissions per unit of production) much more and today is more GHG emission efficient. The U.S. chemical industry has decreased its emission intensity by 30% since 1990, the EU by 50%.

Costs & Prices in the EU Chemicals Industry



* EU 15, data from 2003
** Gross operating surplus = value added – labor coast (payroll)

Source: Cefic

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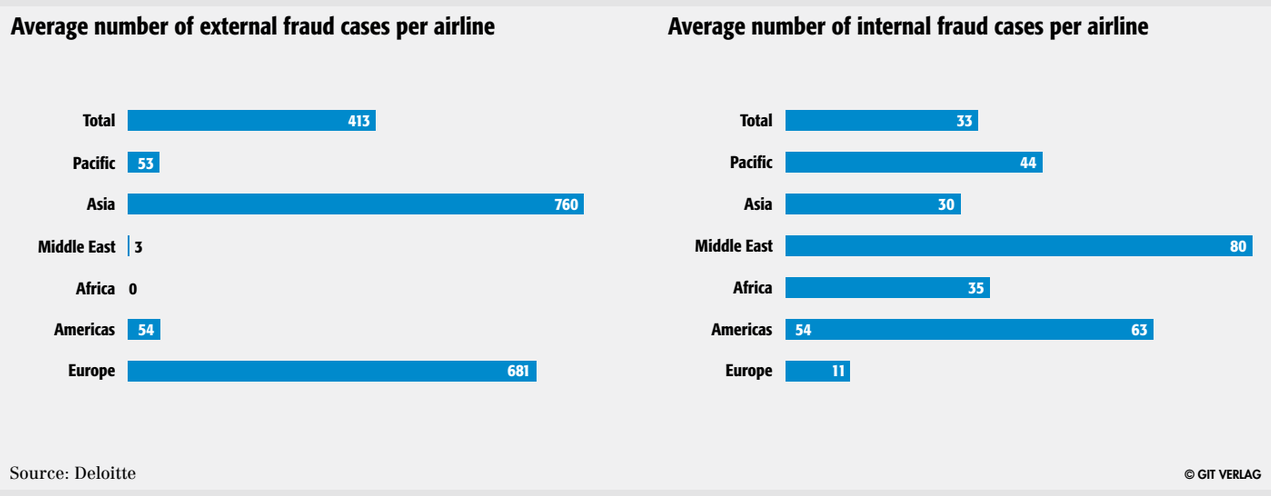
Purchases by the EU chemical industry account for 71% of the sales value. The remaining 29% constitutes the gross value added of the sector, which comprises gross operating surplus and payroll. Among purchases, it is possible to single out the costs of trading and energy. Trading represents the cost of chemicals purchased from third parties and resold in their original condition, and amounts to 10% of the sales value. Direct energy costs currently account for 5% of the sales value.

In 2003, the payroll accounted for some 16% of the chemicals sales value. The gross operating surplus is defined as profits before taxes, financial charges and depreciation and amounts to 13%. Consumer prices have risen more on an average than chemical prices over the last five years (2000–2005), 2.2% the former and 1.8% the latter. One can conclude that EU chemical industry is not boosting prices and inflation in the EU.

Airline Fraud: Where is the Exposure Higher?



Source: Deloitte

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Does location matter when it comes to fraud? If we look at the average number of cases of external fraud, there are big differences if the home base of the airline is taken into consideration. The average number of external fraud cases in each airline surveyed by Deliotte was 413. However, airlines based in Asia suffered an average of 760 cases a year; European airlines were hit with about 681. There is less disparity when we look at internal fraud. The average worldwide figure is 33 cases a year, and airlines in Asia, Africa and the Pacific are broadly in line with this. The number of cases was higher in the Americas – with 63 – and 80 the Middle East, but there were several instances affecting just one Middle Eastern airline; the figure is probably not reflective of the region as a whole.

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The World's Longest Nanotubes

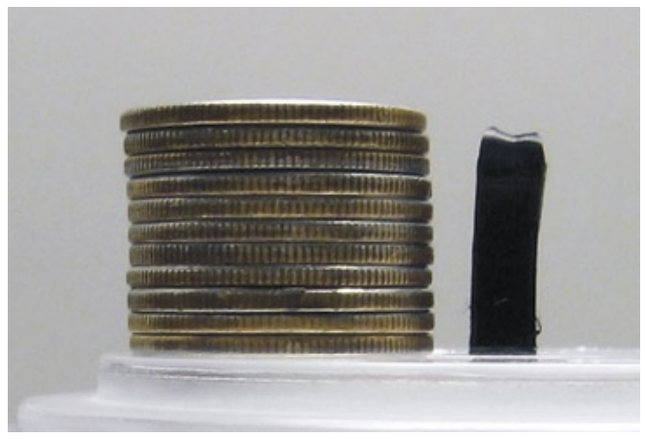
Using techniques that could revolutionise manufacturing for certain materials, researchers have grown carbon nanotubes that are the longest in the world. While still slightly less than 2 centimetres long, each nanotube is 900,000 times longer than its diameter.

The fibres – which have the potential to be longer, stronger and better conductors of electricity than copper and many other materials — could ultimately find use in smart fabrics, sensors and a host of other applications.

To grow the aligned bundles of tiny tubes, the researchers combined advantages of chemical vapour deposition (CVD), a technique for creating thin coatings that is especially common in the semiconductor industry, with a novel substrate and catalyst onto which the carbon attaches. Supported by the National Science Foundation (NSF) and the Office of Naval Research, University of Cincinnati (UC) professors Vesselin Shanov and Mark Schulz collaborated with post-doctoral researcher Yun Yeo Heung and students to develop the technique.

The researchers partnered with First Nano, a division of CVD Equipment Corp. of Ronkonkoma, New York (U.S.)., to use their laboratory and a specialized furnace. With the equipment, the researchers were able to break apart hydrocarbons to create a vapour of carbon-atom starting material. Within the vapor sat the new substrate – a catalyst made of alternating metal and ceramic layers atop an oxidized-silicon wafer base – which served as the foundation for growth.

"This process is revolutionary because it allows us to keep the catalyst 'alive' for a long period of time thus, providing fast and continuous transport of the carbon 'building blocks' to the carbon nanotube growth zone," said Shanov.



Researchers at the University of Cincinnati have grown the world's longest carbon nanotube arrays, long enough to be seen by the naked eye.
Photo: V. Shanov, M. Schulz, University of Cincinnati

The carbon nanotubes are extremely long compared to predecessors – the longest is 3 millimetres beyond the prior world record. More important for manufacturing, the research team grew a 12-millimeters-thick, uniform carpet of aligned carbon nanotubes on a roughly 10-centimeter silicon substrate, opening the door for scaling-up the process.

▶ www.nsf.gov
▶ www.uc.edu

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- A look at how Europe can remain a leading chemicals production platform.
- An interview with Boy Litjens, CEO of Sabic Europe
- Implementing single-Use technologies

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