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# Letter from the Editor

## Thunderstorms strike the economy

In the Letter from the Editor of last year's September issue, we noted that "dark clouds are gathering over global markets". In the aftermath, these clouds have formed into heavy thunderstorms hitting the world's economy. Economic growth has turned upside down, prices of raw materials have dropped and governments intervened in national economic systems in a way that had not been seen since World War II. A recent study by A. T. Kearney, the CHEManager Europe and the Institute of Business Administration at the Department of Chemistry and Pharmacy of the University of Münster showed that the chemical industry is hit extremely hard. Most companies' sales collapsed by 30 % or more. Nevertheless, the speed of the landslide decreased in recent weeks. It is to hope that the economy regains confidence in itself and that it can break the downward trend. Therefore, the current issue of the Journal of Business Chemistry deals with various aspects, which may be important for preparing for post-crisis-time, like optimizing regulation processes and patent negotiations:

This issue starts with a special historical section. Arthur Dehon Little, founder of the world's oldest management consulting firm, once wondered about the role of chemistry. This was in 1921. Being a chemist himself, he highlights the merits of chemistry in the past and gives an outlook on the importance of chemistry in the future. Even in these times, chemistry and business were interwoven with each other. Therefore, this article fits perfectly the scope of the Journal of Business Chemistry. 88 years later, Klaus Müllen, Director of the Max-Planck-Institute for Polymer Research and President of the German Chemical Society (GDCh), takes a look into the crystal ball of the chemist's future again. In his commentary "Chemists of the future" he gives kind of an update on Little's remarks. He paints a picture of future fields of operation and changes in the education of young chemists.

The contribution to the Research Section "REACH and the role of stakeholders in its Socio-Economic-Analysis" by Jan Boris Ingerowski, Daniel Kölsch and Heinrich Tschochohei deals with the requirements of REACH. In their paper, the three authors analyze the obligatory tool of Socio-Economic-Analysis (SEA) with a special focus on the relevant stakeholders. They evaluate these different groups in reference to their importance for the regulation process and provide a tool for SEA.

Jennifer Giordano-Coltart and Charles W. Calkins present a manual for license negotiations. In their article "Patent License Negotiation: Best practices", they provide a kind of check list referring to the field of Biotechnology. They regard licensing activities as especially important when it comes to regulation processes. Smaller companies often do not have the resources to complete such a process; in particular not during economic crisis, where funds are generally rare.

The contribution of Bernd Schneider, Stanislav Plakun and Tim-Frederik Slooth focuses more on a pre-crisis time-frame. Their article "M&A since Y2K – An overview of chemicals deals involving BRIC countries in the new millennium" evaluates the M&A activities in Brazil, Russia, India and China. The paper sheds light on various characteristics of M&As like deals' volume, investor type or specific subsector industry.

Finally, we want to thank all authors and reviewers for their contribution to this issue. Now enjoy reading the second issue of the Journal of Business Chemistry in 2009. If you have any comments or suggestions, please send us an e-mail at [contact@businesschemistry.org](mailto:contact@businesschemistry.org).

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## The Place of Chemistry in Business



Arthur D. Little\*

\* Born in 1863, he graduated from MIT as a chemist. In 1886, he and a co-worker, Roger B. Griffin, founded the world's first consulting company. They assisted private industry with analytical chemistry and technical product improvement services. Arthur D. Little died in 1935.

In the mind of the average business man chemistry is something quite apart from business, an abstruse science that deals with things of evil smell and unpronounceable names, something for the laboratory or the underpaid professor, but with which the hard-headed man of affairs has little need to concern himself. Yet you business men, who deal in dollars, think it well worth your while to learn all you can about them. You want to know where they are plentiful and where they are scarce. You follow their purchasing power and the interest rate they carry. You sit up nights trying to devise new ways to put salt on the eagle's tail. You employ bookkeepers and accountants and income tax specialists in order that you may trail these dollars through every portion of your establishment and persuade the Government that a few of them really belong to you. You study balance sheets and audits and inventories, and base your decision upon what they tell you about dollars.

But the dollar is merely a symbol, a generic symbol of the value of things. The values are in the things the dollars represent, not in the dollars themselves. The things behind the dollar are materials and labor, and labor creates values only as it works upon material. Obviously, therefore, the ways and properties of material or matter are of greater fundamental importance to you as business men than even the properties and ways of dollars.

Now chemistry is the science which deals with the properties of matter and the changes which they undergo. Whether you know it or not, chemistry is, therefore, a partner in your business in a far more real

and vital sense than the Federal Trade Commission, the Interstate Commerce Commission, the Tariff Board, the labor unions, the Federal Reserve Bank, or any other of the man-made agencies with which you admittedly have to reckon. As wise business men you take carefully into account freight schedules, city ordinances, insurance regulations you observe the man-made laws of legislatures and of Congress. But chemistry has some laws of its own that are not man-made: laws beyond the power of any legislature or Congress to repeal. What do you know about them, or how far do you take them into account in the conduct of your business? The science of chemistry is simply a codification of these laws and an orderly arrangement of the innumerable facts upon which they are based. The chemist is the counsellor-at-chemical-law, and as such you need him in your business. I suggest that you make an early reservation, as there is only one chemist to each 70,000,000 of our population. An ounce of whiskey in 55 gallons of water is a pretty thin mixture.

Now what have these relatively few chemists with their gradecessors and associates throughout the world been able to accomplish for business and the nations? What contribution have they made that bears upon your own affairs?

### THE SERVICE OF CHEMISTRY IN AGRICULTURE

We are still essentially an agricultural country. Our prosperity comes from the soil. Just now, in fact, it seems to be underground. Two Boston men were talking the

other day when their conversation took a theological turn- Boston is the home of Unitarianism, you know. Finally one of them said: "I'm a Unitarian. I don't believe in Hell and all that nonsense." "You don't believe in Hell?" the other replied, "Where has your business gone to?" With the same friendly interest I would inquire of you, "Where would agriculture go without chemical fertilizers?" But the great potash deposits of Stassfurt were not available to the farmer until van't Hoff applied the principles of physical chemistry to the separation of the salts. Two hundred and fifty great plants in this country are engaged in converting phosphate rock to acid phosphate by chemical methods. Nitrogen is another essential plant food. The world has derived its chief supply from the Chilean nitrate beds, but the exhaustion of these deposits is perilously near. It is bad enough to be tied in this way to a single far-away deposit, but the situation became alarming to those who realized that unless a new source of supply were found the world must make up its mind to starve. Fortunately, the chemists recognized that on every acre of the earth's surface the nitrogen of the atmosphere is pressing down with a weight of 33,800 tons. They have boldly attacked the problem of rendering available such portion of this inexhaustible supply as the world may need. The methods employed have been brilliant and daring in the extreme and so successful that our supplies of nitrogen for agriculture or for war are now assured, provided only our Government stands behind the chemists.

If you were a farmer, what would you think of the business if you had to pick potatoes by hand? Who would get the potatoes? My money is on the bugs. Meantime, what is the farmer to do with the other devouring hosts-the gypsy and brown tail moths, the inch worms, the boll weevil, the codling moth, the cabbage worm, and all the innumerable multitude of insects, molds and fungi that would feed at his expense? Were it not for chemical sprays and insecticides, he would be as helpless before them as were the Egyptians before the plague of locusts.

Chemistry puts new values on farm products by greatly extending their range of use. Kirchhoff discovered the inversion of starch to glucose by dilute acids, and as a result of that simple observation a single

corn products plant treats 50,000 bushels of corn a day. Not many years ago cottonseed was a nuisance. Laws were passed forbidding the throwing of it into streams. The chemist converted it into a perennial source of Southern wealth and the raw material on which are based such great enterprises as the Southern Cotton Oil Co., and the American and Buckeye Companies. From it he derived edible oils, soap stock, and cattle feeds. Then Sabatier supplied more chemistry, and by his process of hydrogenation converted vegetable oils to solid fats, which provide an adequate and satisfactory substitute for lard and butter. Again the price of cottonseed oil went up. A single company in England treats by this process 2000 tons of coconut oil a week, and in more than one county in the South peanuts are worth more than the cotton crop. Few discoveries have been more far-reaching in their influence than the observation by Schonbein in 1845 that cotton on exposure to nitric acid was converted into a new and highly explosive product. For seventy years research has been focused on that observation. It led von Lenk and Abel to guncotton; Viele, Nobel, Abel, and Dewar to various forms of smokeless powder. It revolutionized warfare. It led Hyatt to celluloid, Goodwin to photographic films, du Chardonnet to artificial silk, and is the underlying fact on which is based the manufacture of patent leather, artificial leather, lacquers, and a bewildering variety of other products which are everywhere in daily use. Hundreds of millions of feet of nitrocellulose film, most of which comes from Rochester, carry their message of instruction or amusement to hundreds of millions of people in the tens of thousands of moving picture theatres throughout the world each year. Before we leave the farmer you will perhaps permit me to quote from an advertisement of the laboratory with which I am associated. It is headed, "Chemistry and the Astonished Cow," and proceeds: "The cow made the milk for use in the family, her own family. She was indignant and surprised when the farmer ran it through a separator and extracted the cream, but she was astonished when the chemist took the skimmed milk, which the farmer threw away, and converted it into billiard balls and back combs, fountain pens, and a size for coated papers. Her astonishment was shared by the farmer." Years ago a manufacturer was making a water paint

from glue and gypsum. He had found a German product which was better than glue for his purpose. It made the paint insoluble when it was dry. Its analysis showed a mixture of casein and lime for which the Germans wanted 30 cents a pound. That was more than his product would stand. It was pointed out to him that casein was easily prepared from skimmed milk. His factory was in a dairy country. He was shown how to make casein. A few months later he moved to New York, organized a large corporation, pulled down a salary of \$50,000 a year, and took a house on Fifth Avenue.

### THE WORK OF LOUIS PASTEUR

There are few men to whom the world stands in greater debt than the French chemist, Pasteur. There is probably not a man in this room who is not under heavy obligation to him, and except for his discoveries some of you would not be here at all. His demonstration of the germ theory of disease and the development of the serum and antitoxin treatments have saved more lives than the recent awful war has cost all the belligerents combined. Such service is beyond estimate in monetary terms, but the direct financial value of Pasteur's discoveries was years ago appraised by Huxley as sufficient to cover the whole cost of the war indemnity paid by France to Germany in 1870. In 1865 a fatal epidemic among the silk worms had ruined the silk growers of France. In June of that year Pasteur was called to the south of France to study the disease. In September he announced the method which proved successful for its control. Other studies saved the French wine industry from the destructive ravages of phylloxera, stamped out chicken cholera and anthrax, and for the first time put brewing and wine making on a scientific basis. More recently they have reverted to the status of cottage industries, and the scientific control is less in evidence. Sufferers from gastritis who consult their physician are commonly greeted with the observation, "I see you make your own."

### RELATION OF THE CHEMIST TO THE TRANSPORTATION PROBLEM

Perhaps the greatest domestic problem before the country today is that of transportation. I still guard, not as carefully as formerly, a few

shares of the New York, New Haven & Hartford Railroad which I bought at 188. It was going to 200. I doubled up at 70. It is now about 16. And yet a New York banker had the nerve to tell the AMERICAN CHEMICAL SOCIETY at a dinner at the Waldorf that what he required of chemical investments was absolute security. We have lots of things at 30 Charles River Road, Cambridge, that are lead-pipe cinches in comparison with any bank-managed railroad that slides from 188 to 16. I know of one poor little chemical company which started with \$20,000 capital and in a few years wrote off \$750,000 in real estate and equipment.

However deeply your sympathies may be aroused, you must not let my ownership of a hand car or a water tank on the New Haven blind you to the fact that your business cannot go on without the railroads. You will admit that without argument, but what I want you to realize is that the railroads cannot go on without chemistry. They operate on steel rails, and those rails are cheap because of the Bessemer process of making steel. Few even among railroad men realize how greatly the whole community is in the debt of Dr. Dudley, whose laboratory work went far to standardize the railroad practice of the country. His specifications covered rails, soaps, disinfectants, oils for signals and for lubricating, paints, steel in special forms for every use, car wheels, cement, signal cord, and every detail of equipment. He made the transportation of life and property cheaper, safer, and more expeditious by reason of his application of chemistry to the problems of railroad management.

I would ask you to consider what chance you would have of securing cheap transportation without the Bessemer process, or that of Thomas and Gilchrist which followed for phosphatic ores. What without them would be the value of iron ore lands in this country or that of coking coal? What inducement would Germany have had to go to war if she could not smelt the phosphatic minette ores of Lorraine? Picture, if you will, the opportunities for labor which these processes have created in the mining of coal and iron ore, in the coking of coal, in the making of rails and structural steel and plates for ships. Shopkeepers who never heard his name owe their prosperity to Bessemer, and cheap Bessemer steel is the foundation of countless industries.



But modern civilization makes demands which cannot be satisfied by Bessemer steel. So the chemist has developed nickel steel for armor and for guns, and tungsten steel for army helmets and for tools whose cutting power is four times that of ordinary good tool steel. You regard the automobile and the motor truck as among the highest expressions of mechanical engineering. They are revolutionizing transportation. Because of them the road before your door which formerly seemed to lead only to the village or the town is now the opening to the highway upon which you may travel north or south or east or west upon the continent, as you choose. But the automobile is as truly a chemical creation as it is a mechanical product. Chemistry enters into its every part. It supplies the alloy steel, the aluminium, the artificial leather, plates the nickel, vulcanizes the rubber, provides lacquers and pigments and paints. It furnishes the gasoline and promises to develop new types of motor fuel. Good roads of cement or bonded with asphaltic compounds are replacing the stretches of dust on which we used to travel.

## ARTIFICIAL ABRASIVES

A chance remark of Dr. George F. Kunz in 1880 on the industrial value of abrasives turned the thoughts of Acheson to the problem of their artificial production, and led to the discovery in 1891 of carborundum and its subsequent manufacture on a small scale at Monongahela City, Pennsylvania. In 1894 Acheson laid before his directors a scheme for moving to Niagara Falls—to quote his own words:

To build a plant for one thousand horse power, in view of the fact that we were selling only one-half of the output from a one hundred and thirty-four horse-power plant, was a trifle too much for my conservative directors, and they one and all resigned. Fortunately, I was in control of the destiny of the Carborundum Company. I organized a new board, proceeded with my plans, and in the year 1904, the thirteenth from the date of the discovery, had a plant equipped with five-thousand electrical horse power, and produced over 7,000,000 pounds of those specks I had picked off the end of the electric light carbon in the spring of 1891.

## THE SULFUR INDUSTRY

Especially notable and picturesque among the triumphs of American industrial research is that by means of which Frasch gave to this country control of the sulfur industry of the world. There is in Calcasieu Parish, Louisiana, a great deposit of sulfur 1000 feet below the surface, under a layer of quicksand 500 feet in thickness. An Austrian company, a French company, and numerous American companies had tried in many ingenious ways to work this deposit, but had invariably failed. Misfortune and disaster to all connected with it had been the record of the deposit to the time when Frasch approached its problem in 1890. He conceived the idea of melting the sulfur in place by superheated water forced down a boring, and pumping the sulfur up through an inner tube. In his first trial he made use of twenty 150 h.-p. boilers grouped around the well, and the titanic experiment was successful. The pumps are now discarded, and the sulfur brought to the surface by compressed air. A single well produces about 450 tons a day, and their combined capacity exceeds the sulfur consumption of the world.

## OIL REFINING

An equally notable solution of a technical problem which had long baffled other investigators is the Frasch process for refining the crude, sulfur-bearing Canadian and Ohio oils. The essence of the invention consists in distilling the different products of the fractional distillation of the crude oil with metallic oxides, especially oxide of copper, by which the sulfur is completely removed, while the oils distil over as odorless and sweet as from the best Pennsylvania oil. The copper sulfide is roasted to regenerate the copper. The invention had immense pecuniary value. It sent the production of the Ohio fields to 90,000 barrels a day, and the price of crude Ohio oil from 14 cents a barrel to \$1.00.

## THE ELECTRIC DYNAMO

The dynamo supplies the current which lights our streets and homes and factories, drives our machinery, fires electric furnaces, creates new products in electrolytic cells, and is our ready and ever-willing servant responding in countless ways to our demands. It so serves us only because Faraday, by refined research, stimulated and directed by the scientific imagination at its best, developed the underlying principles on which its opera-



tion depends. Faraday was first of all a chemist. When he needed the science of electricity he created it as he went along.

## CHEMICAL INDUSTRIES AT NIAGARA FALLS

At no place in the world are the results of industrial research more strikingly evident than at Niagara Falls. The electrical energy derived from a small fraction of that stupendous flow produces, in its passage through electric furnaces and decomposing cells, aluminium, metallic sodium, carborundum, artificial graphite, chlorine and caustic soda, peroxides, carbide, cyanamide, chlorates, and alundum. The story of the electrochemical development behind these products is an epic of applied science. It starts with the wonderful story of aluminium. Discovered in Germany in 1828 by Wohler, it cost in 1855, \$90 a pound. In 1886 it had fallen to \$12. The American Castner process brought the price in 1889 to \$4. Even at this figure, it was obviously still a metal of luxury with few industrial applications. Simultaneously Hall in America and Heroult in Europe discovered that cryolite, a double fluoride of sodium and aluminium, fused readily at a moderate temperature, and, when so fused, dissolved alumina as boiling water dissolves sugar or salt, and to the extent of more than 25 per cent. By electrolyzing the fused solution, aluminium is obtained.

On August 26, 1895, the Niagara works of the Pittsburgh Reduction Company started at Niagara Falls the manufacture of aluminium under the Hall patents. In 1911 the market price of the metal was 22 cents, and the total annual production 40,000,000 pounds.

## EXTRACTION OF GOLD FROM ORES

As business men you are directly interested in gold as the standard of values. It is not a fixed standard, and any increase in the available supply reacts at once upon other values. Two chemical processes, cyanide and chlorination, have had a profound effect upon the volume of the world's supply of gold, and so influence the price of everything you buy and sell. They permit the profitable extraction of gold from low-grade ores like those so abundant in the gold fields of South Africa.

## EXPLOSIVES

Mining, the building of railroads, the great construction projects for which America is famous, like the Panama Canal and the vast works of the Reclamation Service, are possible only through the agency of explosives which make instantly and locally available enormous stores of chemical energy. To supply this energy chemistry has developed various types of black powder, nitroglycerin, dynamite, gun-cotton, and other compounds and mixtures so numerous as to require a "Dictionary of Explosives." Nowhere has their manufacture been so highly developed or conducted upon so vast a scale as in this country. The war, from which we are now slowly recovering, was in a very real sense a chemists' war, and if we have another, which God forbid, chemistry will make it inconceivably more terrible than the last. Fortunately for our country, the Chemical Warfare Service, which functioned with such magnificent resource, energy, and effect throughout the war, has had its continued existence assured as an independent though skeletonized branch of the military service.

## THE PLACE OF CHEMISTRY IN RECONSTRUCTION

The war, which has changed everything, has given a new aspect to chemistry and a fresh impetus to research. Hereafter the nation which would live must know. Through the wreck and peril of other peoples, Americans have learned with them that research has something more to offer than intellectual satisfactions or material prosperity. It has become a destructive, as well as a creative agency, and in its sinister phase the only weapon with which it may be fought is more research. The organization and intensive prosecution of research has thus become a fundamental and patriotic duty which can neither be ignored nor set aside without imperiling our national existence. Now we are carrying as cheerfully and hopefully as we may the stupendous burden of the war. Chemistry, with the sympathetic and understanding cooperation of business and financial men like yourselves, can do more to lighten that burden by the creation of new wealth in vast amounts than all the law makers in Congress and state legislatures. And the first step is to stop the stupid, wicked, childish waste of our basic natural resources. The time has passed for quoting figures. They are of astronomical proportions anyhow and make no more impression on the mind than the distances of

the fixed stars in light years. The time has come to demand action, to the end that we may pay our bills with what we waste. Let us develop our estate. It has potentialities vastly beyond anything we have accomplished. A very large proportion of industrial problems are problems in applied chemistry. Many of these so-called problems have already been solved somewhere. The present need of industry is not so urgent for new research and for new facts as for the immediate and proper utilization of facts already known and demonstrated.

A few of you may remember that in pre-prohibition days beer commonly became cloudy when placed on the ice. It was an objectionable tendency which the best skill of the brewers was unable to overcome. A little research by a clever chemist proved that the cloudiness resulted from the deposition of albuminoids previously in solution. He remembered that pepsin digested albumin, added a trace of pepsin to the beer, and the thing was done. The beer remained bright at any temperature.

Not long ago a Jewish manufacturer was using a leather stain for which he was paying eighty-five cents a gallon. It proved to be water containing a little gum tragacanth and still less aniline dye. He was shown how to make it at a cost of less than ten cents a gallon. He said he began to realize where the Gentiles get the money the Jews get from the Gentiles.

In a plant near Boston using two tons a week of special steel, rolled very thin, their chemist was able in about two years to reduce the cost of this material from eighty to forty cents a pound, at the same time standardizing and greatly improving the quality of the steel. Broken rails are more expensive than analyses, and there are no dividends in broken trolley wires, defective castings, spotted or tendered piece goods, or rejections in any line of manufacture. Competition is difficult when your wastes are your competitor's profit.

## WAYS IN WHICH CHEMISTRY CAN AID THE MANUFACTURER

By way of suggestion, let me point out a few of the more obvious ways in which chemistry can serve the manufacturer. There is, first, the control of quality of raw materials, as in case of steel, alloys, bearing metals, lubricants, coal, paints, paper, cement, and

practically everything else you buy. Second, perhaps, is the problem of finding suitable substitutes for such supplies as are unobtainable or unduly high in price. For example, there is the use of selenium in place of gold in the production of ruby glass, the substitution of tungsten points for platinum in spark plugs, of silica ware for platinum dishes for the concentration of sulfuric acid, of casein for glue, of chlorate of soda for chlorate of potash in dyeing, of zein (derived from corn) for the prohibited shellac for varnishing confectionery, of specification oils for oils whose value is largely in brand names, and of the specifically indicated chemicals in place of high-priced boiler compounds.

Of even greater importance is the scientific control of processes of production, control of formulas, temperatures, pressures, time and spacing, fineness of material, moisture content, and all the other factors which influence the quality and amount of your daily output. Correlative with such control are the studies having for their object the standardization of your product and the elimination of seconds and rejections.

Wastes can be minimized and often turned into profit by well-directed research. The waste liquor of the sulfite mills is now a source of alcohol and of adhesives. Barker waste is an excellent raw material for certain low-grade papers. The Cottrell process of electrical precipitation effects the recovery of values of smelter fumes, cement dust, and many other chimney products. In some industries, as lumbering, the potential values in the wastes are greater than the realized values in the product.

The wholly abnormal conditions under which business everywhere is now conducted lend particular interest to another function of industrial research, namely, that of finding new outlets for present products and new products for existing plants. Bankers and capitalists should realize, as they doubtless do, that the basis of credit for industrial enterprises has shifted. Past earnings have lost their significance. Audits and inventories and balance sheets tell the story of past performance. What is now required is the assurance of future earning power. That assurance can be safely based only on technical studies covering raw material supply, the adequacy of equipment, the relation of processes and methods to the best modern practice, the efficiency with which energy and material are utilized, and the status of the product in the



## Commentary

### Chemists of the Future



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The chemical industry is one of the most important economic sectors in Europe and particularly in Germany. This will presumably remain so in the future. In the aftermath of the recent commercial crisis, now more than ever there will be a greater demand on the chemical industry to be increasingly efficient and innovative. Many of the global challenges can only be addressed successfully by applying chemistry. Some of the most important areas in which chemistry will play an integral part in the future include better medicine, food for a growing population, provision of sustainable energy, mobility, and clothing. Accordingly, chemical production will remain at high levels as will chemical research. This follows as innovative chemistry is a prerequisite for creating the necessary chemical products and chemical answers to these challenges.

Hence, chemists working in research play a key role for future life on earth and will continue to do so. We have learned from several environmental problems during the last few decades that chemistry is often considered by the broader public as a problem maker. However, it undoubtedly has the potential to change this misconception and can be seen in a much more positive light as a problem solver. One example of this is in the field of chemical sustainability. Here, the focus is not solely directed at solving problems associated with chemical production and the related products (e.g. waste water treatment, dioxine-free production, or coatings free of organic solvents, all of which could be considered under the umbrella of Green Chemistry), but also at supporting other branches, social fields, and groups, or other research disciplines with the necessary chemical know-how to achieve more sustainability (e.g. in energy supply).

Let us now focus on the energy issue. This is truly an interdisciplinary issue as we need to address the potential dramatic shortfall in the global energy supply in the not too distant future. Engineers, physicists, biologists as well as chemists (of course) are involved. All of these scientists will have to intensify their cooperation, in academia as well as in industry. The contribution of chemistry to future energy supplies is manifold: The provision of fuels from crude oil, natural gas, coal, and biomass, the production and storage of hydrogen as a contribution to the hydrogen economy, the generation of energy from sunlight, the development of fuel cell technology, of new types of batteries, and supercaps, the provision of thermoelectric devices, of materials for collectors, and for superconductors, of luminescent materials, for example, for light-emitting diodes, of lightweight materials, and nanoporous foams. All of these diverse fields reflect innovations from chemistry at their core. Chemists and engineers will also continue to enhance the energy efficiency of chemical production processes and the development of power plant technologies.

To meet these challenges, we need traditionally educated chemists with a fundamental background in inorganic, organic, and physical chemistry whether they ultimately work as electrochemists, photochemists, chemical engineers, polymer chemists, solid-state chemists, or in other areas of chemistry. Modern Master Programs at our universities are increasingly becoming specialized and offer many options for an interdisciplinary education. This leads us to the question whether a chemist (with a Bachelor degree) is still a chemist after he or she has received a Master degree in a major such as "Hydrogen Technology" or "Renewable Energies", which a first sight might seem

relatively distant from “chemistry”. Admittedly, we have to anticipate new job titles for scientists and engineers now and in the future (such as material scientist, nanostructure scientist, or environmental scientist). Nevertheless, a chemist remains a chemist, when he has received the degree of a Bachelor of Science in Chemistry or when he is working on chemical issues.

For example, the Nobel Laureate in Chemistry in 2007, Gerhard Ertl, studied physics. He needed more than merely a foundation in physics for his chemical research on surface processes that are important for understanding the mode of operation of catalysts. Ertl, the physicist, worked as a chemist; thus he is both. This combined approach to physics and chemistry is certainly not new. After all, physical chemistry (as the chemists call it) or chemical physics (as the physicists call it) is one of the classical pillars of chemistry. Accordingly, many other similar interdisciplinary developments can also be expected in related fields.

Chemists need to learn more than just the fundamentals of biochemistry, biotechnology, and biology, not only for converting biomass into fuels and platform chemicals but also for promoting progress in medicine, pharmacy, and agriculture. Extensive knowledge in biochemistry and white, red, and green biotechnology are currently revolutionizing anthropogenic conversion processes of matter with great potential for the future. Nonetheless, it is essential to simultaneously preserve the classical core competences in chemistry.

The future belongs to the chemical and molecular sciences! This is one of the reasons why the Federation of European Chemical Societies in 2004 changed its name to the European Association for Chemical and Molecular Sciences (EuCheMS). Similarly, at the national level, the Gesellschaft Deutscher Chemiker (GDCh, German Chemical Society) regularly points out that it represents the entire field of the molecular sciences. I highly recommend that chemistry adopts a healthy self-confidence in the future, in which it does not abandon its classical areas, but resets its boundaries and welcomes interdisciplinary exchanges at all levels. In former times the natural scientist was a all-rounder, knowing nearly everything about chemistry, physics, biology, and

medicine. Today this is impossible, and even a all-rounder in chemistry will hardly survive in the future.

To be engaged in research and development is not the only business of a chemist. Many chemists follow a career path in which they seek to climb the job ladder within the management of a company. In the past that could only be realized through learning-by-doing, through enrolling in continuing education courses, or through additional MBA studies. Now, from the outset of their employment, chemists can signalize to their particular company that they wish to pursue a career in management simply by the fact that they have studied business chemistry (economics and chemistry). In Germany, several universities and higher education establishments offer this opportunity. Beyond this, the Gesellschaft Deutscher Chemiker (German Chemical Society) offers courses for younger chemists that culminate in the award of a certificate entitled “project manager of business administration in chemistry”. It is important that in the chemical and related industries, the top positions are filled with business-minded chemists, who have expertise in both areas.

At present, as far as I can see, we urgently need chemists with expertise in science management and communication. We need them to foster the interaction and cooperation between chemists, other scientists, and engineers in university research, in industrial research and development, and between this more or less scientific-technical community and the decision makers as well as the general public. To get national or European subsidies for research and development with the aim to advance innovation in molecular sciences in Germany or Europe, academic and industrial researchers and developers are frequently overwhelmed by the necessary bureaucracy. For the organization and handling of research projects of different types, scientists and engineers are required who have a broad knowledge in their fields, for example chemistry, and other organizational, administrative, and communicational skills. They have to effectively communicate their ideas to the general public, as spokesmen for scientific development and progress, so as to allay any unwarranted fears.

Importantly, the chemistry programs at universities need to provide the ideal environment to develop and hone the problem-solving skills in chemistry. That's what the public is expecting from chemists and why chemists are needed urgently. For these reasons we need to encourage the brightest students to study chemistry.

What else is there to say about the chemist of the future? Even more than today he or she will need to be a global citizen, and this should be developed already during university studies. Today, in the field of higher education, we talk about the European Education Area as created by the Bologna Process, in which the focus is the mobility of students and the comparability of degrees within Europe. These are important ingredients for both industrial and academic careers, and are also of importance to companies that want to expand and develop new markets abroad.

We should also discuss how we will promote a better use of the term "chemistry" in the future. At present, when the term chemistry is applied in newspapers, television, radio and other media, it has negative connotations in most cases. Sadly, even for highly educated people, chemistry is often associated with something to be afraid of, which probably accounts for why scientists – yes, chemists, too – when they have to write proposals for grants that will be reviewed by non-chemists (that means other scientists or politicians, for instance) avoid the term "chemistry" wherever possible. Even the chemical industry has developed a tendency to avoid the word chemistry (although fortunately not all of them, "BASF – The Chemical Company" being the most prominent counter example) preferring rather to be considered as the life science industry.

Chemistry as a subject at school, in contrast, is not under threat today. Far from it! The question remains, however, why chemistry is offered so late in German schools, and why pupils or students then normally have to learn complicated chemical equations with a complicated stoichiometry at the beginning of their chemistry education? If we could succeed in introducing children at a much younger age more passionately to chemistry, if teachers would start with the achievements chemistry has made possible,

if they could discuss new materials and their applications, if they would show chemistry in everyday use and life, before they start with complicated stoichiometries that discourage almost everybody – would that not be a better way to make chemistry more appealing?

Allow me to close on a personal note. In Germany there is consensus that we need better education in science and technology, because we can only improve our world if we understand scientific and technological relationships. We must attract children to the world of science and technology. This can be done in part through campaigns like the Year of Chemistry (which we had in Germany in 2003 and which is planned to be international for 2011), open days in the chemical industry or academic research laboratories, or chemistry shows. All this is nice, but more importantly we need a continuous, exciting, and fascinating education of the sciences from kindergarten nurseries up to high school. Glimmers of hope come in the form of television programs that describe scientific and technical phenomena in an entertaining manner. Depending on the level and depth of explanations, the various programs are targeted at audiences ranging from primary school children to adults. In addition, for those interested, there must be challenges to further improve their scientific training. I therefore consider contests like "Jugend forscht" (Young People's Research) in Germany or the International Chemistry Olympiad as very important tools in this regard.

To sum up, we should earnestly continue the discussions regarding what knowledge and content should form the integral part of the chemistry education from elementary school to Master degrees at universities and what content we should place less emphasis on or simply set aside. It is impossible to produce something like supermen in chemistry – the superchemists. Since the time of Georg Christoph Lichtenberg we know "Who only knows all about chemistry, cannot understand chemistry correctly." But on the other hand: Isn't it better to be an expert idiot than a real idiot?








## Research Section

# REACH and the Role of Stakeholders in its Socio-Economic Analysis

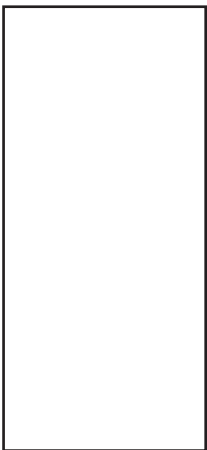


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In June 2007, the so-called REACH regulation (short for Registration, Evaluation and Authorization of Chemicals) came into effect in the European Community. Against the background of REACH, this article investigates who is directly addressed by this regulation (i.e. by means of the legal text) and which social groups are only indirectly affected. The socio-economic analysis (SEA), conducted as an obligatory step prior to substance authorization, demonstrates a general dilemma of chemical regulation: Chemicals and secondary products are inputs to a variety of goods and processes which, on the one hand, make daily life more comfortable, but on the other hand may have a negative impact on human health and the environment. The essence of this train of thought is that in order to make a regulation effective, the various segments of society must be considered in the process of regulation, inasmuch as these groups may either be affected by chemical safety or may have safety management obligations of their own.

## 1 Introduction

In June, 2007 the REACH Regulation, a new chemical regulatory scheme, went into effect in the European Community (EC). This project has been hailed as a major landmark in European environmental policy and has been the subject of controversial discussions both in the legislature as well as in the media (Bundesministerium für Umwelt, 2003; Lahl, 2006). The Acronym REACH describes the main elements of the new regulatory system: Registration, Evaluation, and Authorization of Chemicals. Whereas the process of authorization of diverse chemical substances with varying danger potentials underlies strict legal sanctions, the procedure of substance regis-

tration, in contrast, runs along more co-operative lines between government and industry.

This convergence of diverse elements of public and private regulation is known as "governance hybrid" (Hey et al., 2006; Hansen and Blainey, 2006; Führ and Bizer, 2007), and REACH exemplifies the increasing tendency taken by industry to play a more active role in regulatory matters (Siebenhüner, 2007).

The changing legal regulatory framework has also led to alterations in the attitudes and motivations of the directly and indirectly involved particular actors. In the context of REACH this article poses the question as to which social groups are directly addressed to (i.e. by the legal text) and which are (merely) indirectly affected by REACH. By means of a



structured approach, we analyze how the individual groups' vary with respect to the amount of influence they exert, and show that the differences are especially relevant against the background of the hybrid character of REACH. A conclusion which puts an emphasis on the governance structure of REACH: What societal groups shall be addressed when outweighing risks and benefits?

As an exemplary case we cite the corporate socio-economic analysis (SEA), which is carried out as an optional step in the authorization procedure. The SEA, as will later be seen, makes evident the basic dilemma inherent in chemical regulatory measures: Chemical substances cannot only serve as the basis of a myriad of useful products and essential processes in modern society but they also may have negative effects on humans and the environment. For the appropriate regulation of chemical production and application it is essential to carefully balance out the costs and dangers imposed on society against the desired advantages. In order to facilitate a comprehensive social assessment of these questions, we must inquire how the diverging social interests can be taken into consideration and concretely resolved. This consensus finding must also include legitimate commercial interests so as to insure the long-term viability of free enterprise.

When dealing with chemical regulation one must strive for a social optimum. This tenet is derived from Art. 1 (1) REACH, which states: "The purpose of this regulation is to guarantee a high level of protection for human health and for the environment [...], as well as to further free trade of chemical substances within the EC Market while simultaneously improving competitiveness and innovation."

## 1.1 Definition and Structuring

Under the premises of Policy Analysis (Jänicke et al., 2000) this study focuses on the identification of active participant groups, each with its own individual concept of the extent and significance of chemical management. This approach appears justified by the aforementioned shift in the relationships among the groups involved. Against this background, it appears acceptable to adopt the concept of corporate stakeholder claims (Freeman, 1984; Janisch, 1993; Schaltegger,

1999). This method has several advantages. The concept of corporate stakeholders, originating from the American corporate literature of the sixties (Teulings and Hartog, 1998; Patsch, 2001) recurs frequently when dealing with social groups with diversely structured interests. The information and facts thus collected are used to coordinate the asymmetric power structures and conflicting interests into a social contract of maximum benefit to all parties.

Consequently, diverse vested interests are to be considered and analyzed within the political arena surrounding REACH and not including industrial aspects. Hereby, we must differentiate between directly and indirectly affected stakeholders (e.g. either directly affected by chemical safety or not), as opposed to internal vs. external participants (e.g. those directly addressed to, or not, by the legal text). In the first case we define as to what degree a certain group is affected by product and occupational safety, whereas the latter case defines whether a collective is entitled to privileges or underlies obligations deriving from the legal text.

As in the case of the corporate "stakeholder analysis" it is the central aim of this article to identify the relevant participating groups and to define the extent of their influence in order to derive conclusions as to what extent a SEA shall consider different groups' claims. Based on the tenets of recent developments in public environmental management (Schaltegger et al., 1996), a number of questions can be formulated as follows:

- 1) How strong is the organizational capacity of a particular interest group and what is its assertiveness for a given social conflict?
- 2) What is the contribution of each group to the realization of a functional chemical safety management scheme?
- 3) To what degree does a certain group exert influence on the execution of existing chemical safety management programs?

With reference to Schaltegger et al. (2003), organizational capacity is considered to be a cost factor, which, in turn, is dependent on the organization size and the heterogeneity of individual interests within the organization. The effectiveness, thus, increases in inverse proportion to the higher costs of imple-

1) The concept of "actor" or "party" is not used here in the strict sense of political scientists since it would otherwise be necessary to differentiate between so-called "micro" and "macro" actors which derive from the REACH legal text.

menting REACH; for example, in cases of co-operation denial by individual groups. Cost also depends on whether the corresponding resource can be replaced or substituted.

In the subsequent sections we make no attempt to analyze the Power-Politics-Networks (Jänicke et al., 2000) using the criteria of political scientists, in as much as the structures of mutually interacting participant groups are not taken into account. Besides, we do not postulate constellations of prosperity optimization among the different social groupings, as discussed in the literature on corporatism. Our goal is to define and characterize the individual stakeholders. The information thus won can be utilized in the assessment of stakeholder-management for industrial scenarios.

In order to better comprehend the following analysis, we first present some of the major features of the new regulatory scheme, while citing weaknesses inherent in the previous regime. Moreover, the principle of “regulated self-regulation” in the chemical industry, which has been significantly strengthened by REACH, will be described and analyzed. Part 2 deals with rights and responsibilities of the various parties affected by REACH. In Part 3 the concept of “stakeholder analysis” is discussed in more detail, putting special emphasis on incentives and their role in the differen-

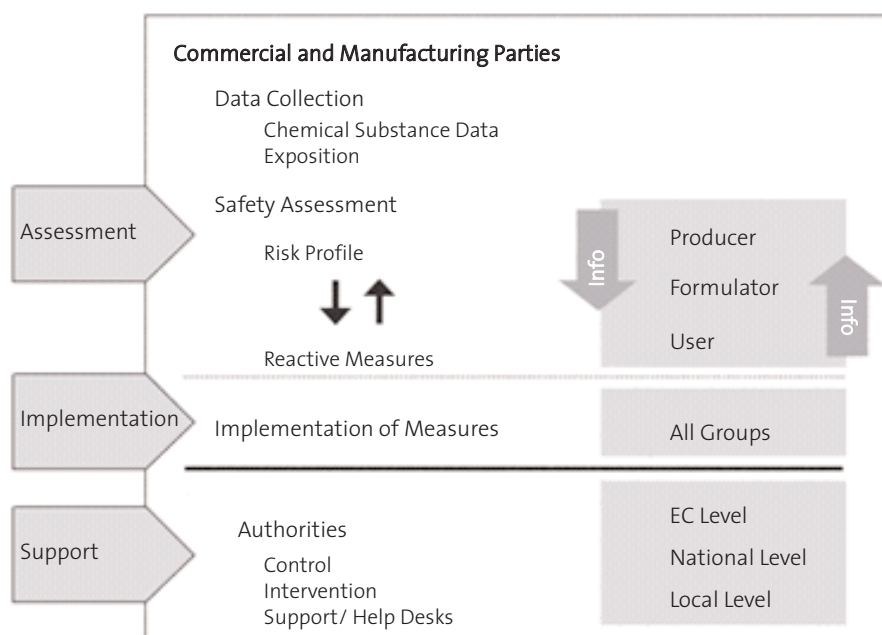
tiation of the various groups. Finally, the diversity of participant groups will be used in carrying out the socio-economic analysis as part of the Authorization procedure (Part 4). In the conclusion, we go into the significance of the SEA with respect to corporate REACH management.

## 1.2 Characteristic features of REACH and background development

A critical analysis of European chemical policy in 1998, culminating in the publication of the White Paper “Strategy for a Future Chemicals Policy” in 2001, initiated a process of re-assessment of chemical regulatory policy, which finally led to the abandonment of the prior existing system of EC chemical regulation, consisting of approximately 40 separate legal statutes.

**REACH revolutionizes the European chemicals regulation.** Under the new system of chemical regulation (REACH), which includes a uniform system of registration and data evaluation for all chemical substances, a fundamental shift of responsibilities for all interacting players in industry and government has taken place. Formerly, it was the obligation of government agencies to point out the risks and dangers due to chemical substances before sanctions or limits to usage could be

Figure 1 Benefit-Responsibility- Structure of REACH



Source: Heitmann and Tschochoei, 2007

made. The new regime introduces a “reversal of the burden of proof”; meaning that in the future the responsibility for assessment and evaluation of chemical substances rests in the hands of the manufactures and importers, who now must guarantee that their products can be safely handled, and therefore will not endanger human health or pose damage to the environment. If the producer, by means of the available data at his disposal, fails to demonstrate the safe usage of the questionable chemical substance in all its application forms, then further usage of it is interdicted. The guiding thought behind this new regulation system is the precautionary principle, with the positive side effect of a reduction in workload for overtaxed government agencies. The implementation of REACH has led to a paradigm change in as much as under the former chemical regulatory scheme the producer had been free to employ all chemical substances in any application form desired as long as no restrictions from government agencies were in effect.

**Shared Responsibility of Participants in the Supply Chain.** The over-riding guiding principle of REACH is to document the data pertaining to the “life cycle” of chemical substances over the entire course of their development and use and thus to guarantee their overall safe handling. This principle is formulated in REACH as a commonly shared responsibility between the primary chemical producing industry and the secondary manufacturers, which employ chemical products in finished goods. Whereas until now only the primary producers and importers of chemicals were obliged to provide extensive information concerning their products, the new regulation now also enlists all secondary users of chemical products into the extensive control, registration and authorization process. The mutual information exchange shall eliminate or at least reduce imbalances of information among producers and secondary users.

**Government Control Agencies: A Sweeping Pull-Back to a Flanking Position.** The governmental monitoring system of the chemical producing industry is reduced to a minimum. Its main function now is to check for the completeness and plausibility of the delivered data rather than to carry out individual tests on the substances in question. In cases of non-compliance, sanctions and related measures may be implemented. The tendency of the governmental agency to take action against a commercial enterprise is dependent

on how probable it is that the substance in question may have to undergo an extensive authorization procedure, which, in the last analysis, determines whether or not the product may have to be excluded from the market for certain specified usages. In such a case, the agency “mutates” from its role as an advisory and control institution to that of a classical regulatory authority.

The novel regulatory concept derives from difficulties experienced by government agencies in the delayed evaluation and regulation of EINECS substances (i.e. substances, which already had been on the EC chemicals market before 1981 and were listed in the EINECS, the European Inventory of Existing Commercial Chemical Substances) within the framework of the former regulatory regime. Because of the complex and costly registration procedures for the EINECS substances, the control agencies soon found themselves over-burdened with the workload and shifted more and more responsibility for executing regulatory procedures onto private enterprise. This freeing up of previously blocked work capacity now allows the agencies to turn their efforts to newly defined functions of control, sanctioning and advisory service.

## 2 Interest Groups from the Legal Standpoint

The degree to which individual interest groups may contribute toward the success of goals set by REACH is determined largely by the legal text. Using the analogy of the corporate stakeholder concept mentioned earlier (Part 1.1) we now attempt to define internal stakeholders elicited by the new European chemical regulation. In our analysis we restrict our attention to the identification of those actors which are explicitly intended to play a role in the chemical regulatory process and analyze their interactions with one another. One of the new aspects of REACH is that the entire “life cycle” of a particular substance is scrutinized as opposed to the more limited evaluation scheme under the former regulations. This means that responsibility for chemical safety rests not only with the primary producer but also extends along the entire production and utilization chain to include all secondary or down-stream users employing the substance in any way in their production lines. Thus, a certain industrial concern may, depending on the nature of its utilization of a specific substance, be responsibly involved on

more than one level at the same time.

**Manufacturers and Importers.** For evident reasons, the primary chemical manufacturers and importing firms carry the main burden of responsibility for chemical safety and as such are subject to an extensive package of duties and regulations, including data and information collection, proof deliverance as well as duties concerning co-operation and information exchange. A novel aspect of REACH is that the producers and importers of chemical substances must now consider whether their products can conform to chemical safety along the entire production and processing chain and are obliged to communicate this knowledge to all down-stream users. It is important to note that the primary producers and importers of the chemical substances in question must define how their product may be used at all processing levels, and only under these premises they can be expected to guarantee its overall safety.

**Secondary or Down-Stream Users.** Secondary users – i.e. those involved in the industrial processing of chemicals, as opposed to traders or consumers of such products (Art. 3 (13) REACH) – also underlie an extensive regulatory regime comparable to that of the primary producers and importers of chemical substances. Down-stream users can therefore be considered to have a parallel, secondary accountability for the chemical safety of their processed goods. In practice, this means that the secondary users must comprehend and implement the risk management concept already provided by their commercial sources. Thus the domain of responsibility for each individual commercial player in the production chain is clearly defined (Führ, 2007). The secondary user also takes on a control function in the case that, for example, the relevant data for a specified usage may be incomplete or not properly registered. Here, the responsibility for a completion of registration goes over to the secondary user and his supplier.

**Commercial Traders.** The term “traders” defines that group of persons which is not involved in the processing of chemical substances but only in the storage, transfer and marketing to third parties (Art. 3 (14) REACH). The concept of down-stream users does not include “traders” so that the latter do not underlie the duties stipulated by Art. 3 (17) REACH (so-called “players” in the production chain). Thus, traders are excepted from the formal registration duties, but must, on the other hand, support the general registration

process by supplying data already available to them (Art. 37 (1) REACH). In addition, traders are also obligated to co-operate in the transfer of relevant data within the production and processing chain (Art. 34; Art. 37 (3) REACH).

**Suppliers.** REACH defines the duties of the suppliers in several ways. A supplier is defined by REACH in Art. 3 (32) as a person who markets a raw or processed substance (“transfer to third parties or preparation for transfer to same”, Art. 3 (12) REACH). In practice, however, the term “supplier” does not conform to a separate category of REACH “actors”. Under the term “supplier”, REACH addresses primarily the category of traders, but also included in a wider sense are producers who market their products directly, and – according to the legal definition – secondary users and importers. Suppliers are required to serve as a data source and must regularly update their information (Art. 31 (9); Art. 32 (3)). The category to which the supplier is assigned to – i.e. whether he is considered as an importer/producer or as a trader – determines the degree of responsibility to which he will be subjected to by REACH.

**Summary and Lessons Learned.** In summary, shared responsibility instead of separate liability is the basic message sent to all parties and the key to success of REACH.

The brief outline of the distribution of responsibilities among the individual REACH-participants attempts to make it clear that the objectives can be achieved only if the various groups involved enter a closely knit communication process with free and bi-directional exchange of information from producer/importer to secondary down-stream users and to commercial traders. Although the main burden of guaranteeing chemical safety rests on the shoulders of the producers and importers of these substances, a truly effective risk management concept relies on the bundling of all information and its dispersion among the participants in chemical industry. In this sense, REACH focuses to a lesser extent on the individual active participant but rather attempts to create a framework for a “chain of responsibility” for all parties (Recital No. 58 REACH). To this purpose, REACH defines a number of measures to facilitate the exchange of information and to ensure the co-operation among the individual participants.

It is evident that the legal text of REACH addresses a significant number of internal interest groups, whereby it is essential that

these groups must be directly or indirectly affected by the realization and results of chemical safety management. In the next chapter, we look more closely on to how the internal interest groups elicited by REACH compare to the corresponding external interest groups with respect to their organizational and competitive capability.

### **3 Interest Groups from an Economic Perspective**

Having discussed the legal and regulatory aspects of REACH, we now turn our attention to some of the economic effects arising from incentives built into REACH regulation.

#### **3.1 Incentives for the Chemical Industry as an Internal Stakeholder of REACH**

The paradigm reversal in chemical safety management ensued, after REACH went into effect, that now commercial enterprises would play the major role as internal stakeholders of REACH. Assuming that the industrial firms affected by REACH will quickly and fully accept their responsibility for implementing REACH, it can be expected that the information exchange and communication along the chemical supply chain increases. Thus, the achievement of conformity to the REACH concept would derive lesser from strict adherence to the letter of the law but rather from the property of REACH as a strategic tool for structuring co-operation and information exchange along the production chain.

Especially two factors will be essential to the success of REACH: the guaranteeing of secure and stable strategic private commercial resources and the factor "public pressure".

As an example stemming from the first case it is possible that the supplier of a substance ceases with its production because of cost increases associated with implementing REACH. The down-stream user would then have to agree to cover the costs of the supplier in order to secure future deliveries. For small and medium-sized businesses there is the danger that their man-power capacity will be insufficient to guarantee legal conformity (Tschöchohei, 2007). In this case, the secondary users might have to initiate an adequate risk management policy or relocate responsibility to other areas.

In the second case, it might be advisable for a company with high public profile to

publicize its efforts to achieve the REACH goals as part of a general advertising campaign. If damage to the company's image is immanent, for example, because its products fail to achieve the goals set by REACH, it could then be rational for the firm to participate more actively in the overall REACH production chain management. The relative importance in achieving REACH conformity for individual companies also depends on the extent to which the information gathered by the European Chemical Agency (ECHA) is made available to non-governmental organisations (NGOs) and consumers. For the case of good data availability and assuming that consumers exercise their preferences, effectively communicated REACH conformity within a certain company may well generate a competitive advantage. For the extreme case of a commercial enterprise whose public image is sorely damaged, it is clear that urgent action must be taken. Finally, intrinsic personal motivation by company management to improve product and work safety is an ideal incentive of itself, but the question still remains whether REACH, as an extrinsic incentive, might possibly exert a so-called "crowding-out effect" on the former.

#### **3.2 External Stakeholders in the Context of Economic Incentives for Commercial Enterprises**

As described in the case of commercial manufacturers, external stakeholders may also play a significant role in REACH. Since consumers are not specifically addressed by the REACH legal text, they are considered to be external stakeholders. Even under the hypothetical assumption that all consumers could someday be united in a common claim towards chemical safety, this fictive group would still remain an external one because the procedures relating to chemical safety do not admit to participation by the public.

With respect to the viability of a chemical market, it can be said that consumers form a direct (but external) stakeholder group since they react out of personal motivation and are therefore essential for the further existence of the market, as in the case of consumer boycotts, which can cause serious damage to marketers.

"Producers" and "traders" are explicitly addressed by REACH and therefore are internal stakeholders and also are directly affected by chemical safety, whereby the external



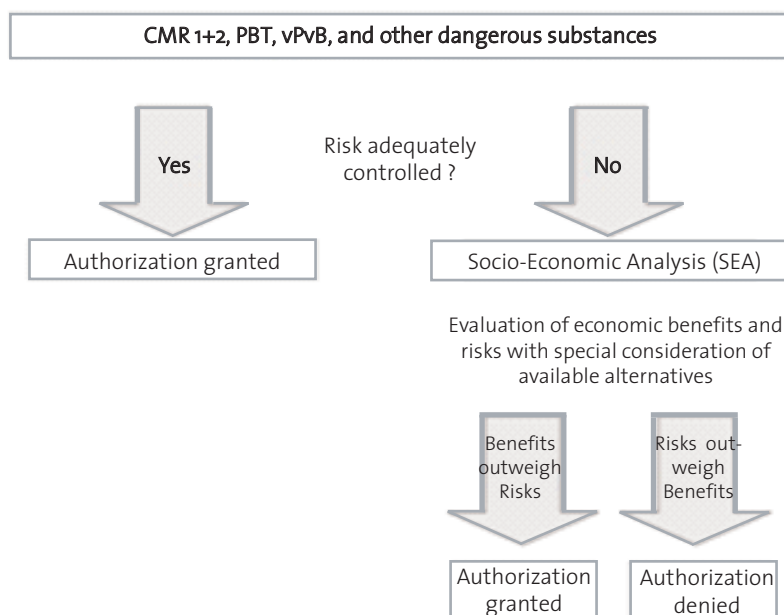
groups mobilize the topic and arouse public attention. In general, one must assume that a homogenously structured consumer group does not exist and that therefore it is impossible to summarize the numerous individual consumer preferences. For this reason, it is legitimate to refer to the general consumer population as an indirect stakeholder. However, the NGOs are increasingly taking on a representative function for consumers and can in special cases activate segments of the population to alter their consumer behavior. The NGOs themselves form a heterogeneous group (Løkke, 2006) where the theme of chemical regulation is concerned, the more relevant, chemical safety-related areas being industrial safety, environmental and consumer protection, and animal protection, with special emphasis on the theme of animal experimentation.

Despite the wide spectrum and lack of homogeneity among the NGOs, one can reasonably expect that through the existence of these organisations the chemical industry will become the subject of negative public discussion about specific substances or products, which may lead to general criticism of whole product areas (Heitmann and Tschochohei, 2007). Because of the potential that NGOs have for activating public opinion, it is plausible that REACH may become a platform for

NGOs. In order to convince the public of their standpoint, e.g., environmental protection, these organizations must first reduce present imbalances of information distribution. The consumer must be informed about the chemicals or substances which pose a threat to health or the environment, e.g., as in the case endocrine-disruptive properties and other detrimental effects of ubiquitous chemical substances (for hazardous effects of chemicals on humans see EEA 2003, 264/Tab. 12.4; WBGU 1998, 132 f.; WHO 2002, 2 f.; for effects on animals see EEA 2003, 251/263; WHO 2002, 2).

NGOs that have access to the relevant information at the ECHA might, with adequate communication, be able to exert pressure on the chemical industry, for example, to more actively engage in the substitution of toxic substances by less dangerous ones. Furthermore, when the REACH data bank is finally opened to public access, various NGOs might well use the newly won information to influence public opinion and win more adherents to their cause. An active competition among the NGOs can be expected to ensue from this. If governmental agencies can introduce effective measures to curb informational imbalance and asymmetry, the "market" for NGOs will tend to grow.

Figure 2 Scheme of the Authorization Process under REACH



Source: according to BASF SE, 2007

#### 4 Stakeholders in the Context of the Socio-Economic Analysis under REACH

The socio-economic analysis (SEA) is an elective but decisive step carried out during the authorization phase of REACH, which is intended to resolve conflicts arising from cases of authorization denial or other procedural hindrances. The SEA highlights the dilemma inherent in all questions relating to chemical regulation in the EC and elsewhere: How can evident benefits of chemistry for society be effectively balanced out against the risks posed by chemical substances to human health and the environment? To answer this question, the various social groups and actors must be considered in order to accurately describe community preferences. By applying the stakeholder concept an insight into the ways and means of the various groups of exerting influence in the practical decision-making process can be obtained.

The introduction of SEA into chemical regulation grew out of an initiative, beginning in 1998, of the Organization for Economic Cooperation and Development (OECD), which established the socio-economic approach as a tool for effective chemical safety management (OECD, 1999a, 1999b, 2000, 2002). Thereafter, an intensive debate took place within the EC concerning the integration of similar economic instruments into existing chemical legislation.

##### 4.1 Role and Function of the Socio-Economic Analysis under REACH

Under REACH the former differentiation between old and new substances has been abandoned (BAuA, 2007), so as to give priority to data collection on the older, previously introduced substances already on the market, which had been insufficiently regulated under the prior regime (Allanou et al., 2003). If the ECHA decides after registration and evaluation of a substance that an authorization procedure should be carried out, it will forward all relevant information to the corresponding national and European agencies (COM, 2006). An explicit authorization procedure is compulsory for all substances of very high concern. REACH categorized these as follows:

- carcinogenic, mutagenic or repro-toxic substances (CMR)
- persistent, bio-accumulative and toxic sub-

stances (PBT)

- very persistent and very bio-accumulative substances (vPvB)
- substances of an equivalent level of concern as those above e.g. endocrine disruptors)

Authorization for a defined use can only be given when the "risk to human health or the environment can be adequately controlled" (Art. 60 (2) REACH). For especially dangerous substances, for which no limiting values exist, the authorization on the basis of "adequate control" must be denied (COM, 2006). If the risk cannot be adequately controlled or the substance proves to be otherwise non-authorizable, then a final authorization can only then be granted by demonstrating that the socio-economic benefits outweigh the potential risks and adequate alternative substances or technologies are unavailable (Art. 60 (4) REACH). The formal evaluation of the risk-benefit situation of a substance in question is carried out in the SEA process (see Fig. 2).

A prerequisite for any comprehensive socio-economic analysis is that all participants of society be included in the analytic process, including the internal and external stakeholders as well as those directly and indirectly affected. The relative influence of a certain group within the framework of the SEA then depends on the central question of organizational size and homogeneity of interests (as variables of organizational competency) as well as on the availability of particular resources (as variables of assertive power and effectiveness) (Schaltegger, 1999). These groups will now be identified and analyzed with respect to their organizational competence and assertive power.

##### 4.2 Identification of Stakeholders

The authorization of especially problematic substances without suitable alternatives is only possible if socio-economic benefits outweigh potential risks. This decision is made by the EC Commission in the proceedings laid out in Art 60 (4) of REACH by evaluating the recommendations of the committees for risk assessment and socio-economic analysis, located at the ECHA. Further, socio-economic aspects disclosed by the applicant or other interested parties are also taken into account in the decision-making process. "Interested parties", as in annex 16 of REACH, may include, for example, EC Member States, third



Table 1 Summary of identified interest groups within the framework of the authorization process.

	Direct	Indirect
<u>Internal</u>	Applicant <sup>1</sup> Down-stream Users <sup>2</sup>	EC Comission ECHA <sup>3</sup> Member States National Authorities Help Desks
<u>External</u>	Interested Parties (as in annex 16) <sup>4</sup> Other affected Parties <sup>5</sup> Society at large <sup>6</sup>	Interested Parties (as in annex 16) <sup>4</sup> Other affected Parties <sup>5</sup> Research and Development Non-EC States
		Inter-governmental Organisations <sup>6</sup>

1) Manufacturer or importer.

2) Including all other members of the production pathway.

3) E.g. committees for risk assessment and socio-economic analysis.

4) E.g. NGOs for environmental, consumer or animal protection, commercial and industrial associations, and the media.

5) E.g. labor unions, trade organisations, health insurance, and patient interest groups.

6) E.g. EECD, UNEP, or OSPAR.

<sup>7</sup>) The lack of precision inherent in the term "society" is apparent. However, society at large is directly involved in several of the interest groups pointed out above. Since the interest group "society" is explicitly mentioned in REACH, we have included it in the above list.

party states, inter-governmental organisations, NGOs with special interest in environmental and consumer protection, labor unions and many others. Accordingly, a significant number of different stakeholders may be involved in the authorization process (for a description of the concept and background of stakeholder management see Part 1 of this report). The goal is now to distinguish the aforementioned addressees of REACH and other stakeholders in terms of direct and indirect concernment (e.g. either directly affected by chemical safety or not), and in terms of being internal or external addressee of REACH (e.g. those directly addressed to, or not, by the legal text)

Table 1 gives a summary of the major stakeholders identified as being relevant to the analytic and decision-making process according to Appendix 16 of REACH.

As it can be seen in the case of a single natural person, the assignment to a certain stakeholder group is not necessarily exclusive (Janisch, 1993; Patsch, 2001); on the contrary,

any individual or group of persons may simultaneously belong to several classes of vested stakeholder groups. For example, a chemical engineer involved in occupational safety would be a member of a direct and internal interest group; as a labor unionist he would also be a member of an indirect and external group; and finally as a consumer he would again be part of an external group, but, because of product safety he would be directly affected. For this reason, the broadly defined classes "interested parties" and "other affected parties" are listed in the above scheme both as directly and indirectly affected groups.

Doubtlessly, the internal stakeholders will be able to exert the strongest influence on the process of chemical management under REACH. These groups are bound by concrete obligations and regulations. The degree of actual involvement within this category, however, varies considerably, much as it does in the case of the external groups. At the same time, "interested parties" maintain

fewer contacts to internal stakeholders, such as commercial trade associations, which, by means of the active role played by their members, tend more effectively to participate in the process of chemical regulation than, for example, it is the case for consumer protection groups.

The main point here is that it is essential for external stakeholders to maintain direct interactions with internal stakeholders in order to exert influence on the chemical safety management process. It is also necessary for the externally and directly affected participants to have formal representation. The power of external groups to exert influence on the socio-economic analytic process increases as long as their representatives continue to act in the arena of internal (and not external) stakeholders. In the course of the formalized SEA procedure it is then possible for external groups to withdraw decisive resources (e.g., by denial of consensus or endorsement) from the decision-making process and thus increase their power to exert influence.

#### 4.3 Analysis of the Influence of Individual Stakeholders within the SEA Framework

In the following, two randomly chosen examples of different stakeholders, small and medium-sized enterprises (SME) and society at large, will be examined with respect to their levels of influence on the outcome of a SEA, using the three basic questions formulated in Part 1.1.

The organizational competence is determined by two factors. Firstly, the size of an organization<sup>2</sup> limits the flexibility of an individual group, the number of members in a particular group being an inverse indicator of its flexibility. Secondly, the homogeneity of the group is important because identical interests allow group objectives to be more easily defined, since increasing group size brings more divergence of opinion with it and thus a weakening of organizational competence.

At the same time the assertiveness must be taken into account. Using the analogy of the resource-based approach to institutional analysis (e.g. Duschek, 2004), one can postulate an organization which, by means of resource deprivation, is capable of undermining

**Table 2 Number of commercial enterprises, employees, and gross economic output for 2004 in the German chemical industry, arranged according to firm size classes**

	Firm Representation in Percent		
	According to Total Number	According to No. of Employees	According to Turnover
Very Small Commercial Enterprises ( $< 10$ employees, i.e. SME)	39.2	1.1	0.4
Small Commercial Enterprises ( $< 50$ employees, i.e. SME)	31.3	4.9	3.1
Intermediate Sized (50-249 employees, i.e. SME)	20.5	16.5	13.9
Intermediate to Large Commercial Enterprises (250 - 499 employees)	4.5	11.6	11.3
Large Commercial Enterprises ( $> 500$ employees)	4.6	65.9	71.3

Source : VCI, 2006

2) The term "organization" is not necessarily used in the strict formal sense but can be understood as the personalized form of any form of any institution (Schmoller, 1900).

support for a certain project. For example, if a numerically small group gains a membership majority in a shareholder commercial enterprise, then it might be able to use this resource to further its own group interests.

This having been said, we now look at the possibilities that small and intermediate commercial enterprises might have in the course of exerting influence on the outcome chemical safety management. We then analyze the role played by society at large (society as a whole), represented by consumer groups and environmental organisations, in this process. Emphasis is placed on the description of the exact roles played by these exemplary groups in chemical management as well as to what degree organizational competence and assertiveness are developed.

### Small and Medium Commercial Enterprises (SME)

#### *Relevance and Characterization of the Interest Group*

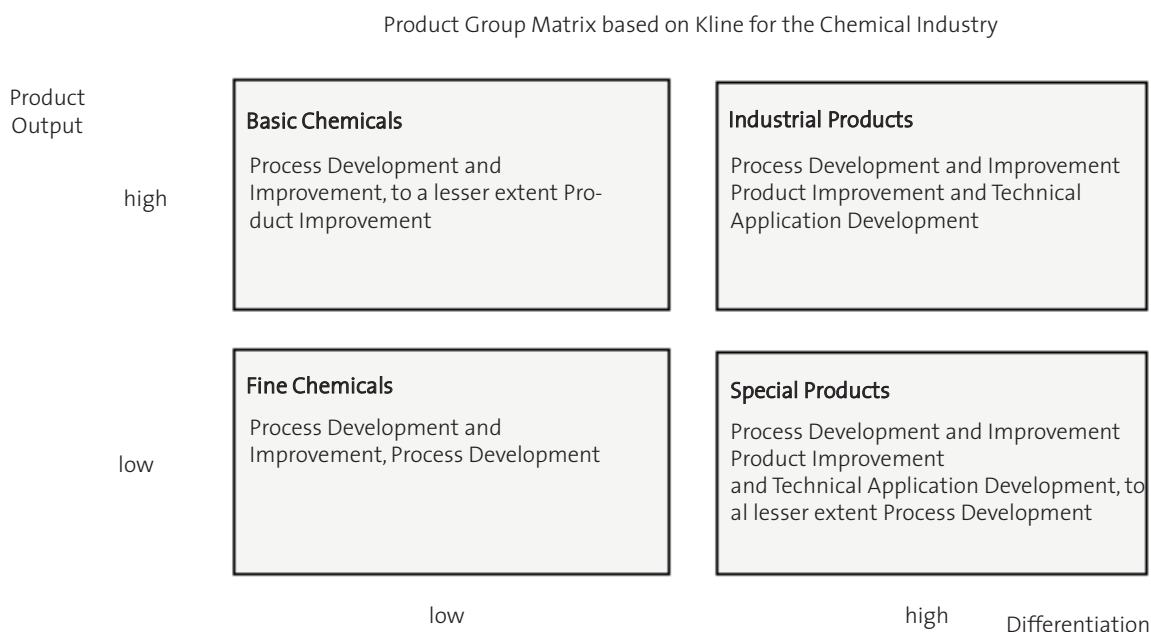
SME are explicitly mentioned and commented on in the Appendix 16 of the REACH legal text in connection with the process of the SEA. In the original text we can read that “wider implications on trade, competition and economic development (in particular for SMEs

[...]) of a granted or refused authorization, or a proposed restriction” should be considered. The special consideration granted by REACH to SME in the chemical industry (more than 1,800 in Germany alone) is due to the fact that this groups comprises over 90 % of all chemical manufacturing plants, employs nearly one third of the total manpower and accounts for one fourth of the total economic turnover in the chemical industry in Germany (VCI, 2007).

The following table summarizes the numerical distribution of chemical plants, employees and total economic output for various sized commercial chemical enterprises in percentage as given by the SME definition of the EC Commission (COM, 2003).

Despite the importance of the major chemical manufacturers with respect to gross output and number of employees (Schindel, 2003), the chemical industry as a whole is not considered as a highly concentrated industry in comparison to other areas (Löbke, 2001). There are, however, some notable exceptions, such as in the area of pesticide and fertilizer production, where only six large companies account for 90 % of the total economic output. These same six companies, on the other hand, manufacture only one fourth of the total paint and lacquer production in Germany (VDI/VDE Technik + Innovation GmbH,

**Figure 3 Product Group Matrix (based on Kline) for the Chemical Industry**



Source: Frohwein, 2003 and Kline, 1976

2004).

The product differentiation and variation in size classes within the chemical industry can be described by a number of criteria (VDI/VDE Technik + Innovation 2004). In addition to official statistical classification, a four-fold matrix can be employed (Kline, 1976) in which product quantity is set into relation to the degree of product differentiation (VDI/VDE Technik + Innovation GmbH, 2004; Frohwein and Hansjürgens, 2005), as it is shown in Fig. 3.

It can be assumed that the nature of product processes and the type of products will have an influence on the relative distribution of the firms in the various company size classes among the product groups. Large production volumes can only be achieved with the high capital intensity available to large and very large companies. Accordingly, a third of all large chemical enterprises is involved in the production of substances with a total quantity of 1,000 tons and more annually. In contrast, operational flexibility as well as high research and development costs are required for the production of highly specialized chemical products, so as to quickly respond to

changing customer needs (COM, 1998). This is the domain of SME (Frohwein, 2003).

The following data scheme depicts the distribution of manufacturing firms according to size and total tonnage output in relation to the various registration requirements.

For the sake of accurateness, it should be stated that in the above scheme SMEs are defined as those generating a gross annual product of less than € 40 million, in contrast to the definition by the EC Commission (COM, 2003). The Commission's SME definition was applied to Fig. 5 with regards to the number of employees; usage of different SME indicators is due to different data availability. Despite this minor discrepancy, it can be seen from the above data that the production of primary and intermediate substances in the lower tonnage range is mainly dominated by small and small to intermediate sized enterprises, which is in agreement with the aforesaid conclusions and implies a correspondingly high level of involvement by REACH. Nearly one fourth of the total output of chemical substances produced by SMEs (23 %) lies within the range of 1,000 t/a or more and as such underlies the more stringent test require-

**Table 3** Number of commercial enterprises, employees, and gross economic output for 2004 in the German chemical industry, arranged according to firm size classes

Test Requirements in Relation to Production Volume			Percentage of Total Substance Output by Large and Small to Intermediate Sized Companies			
<u>Chemicals to Market</u>	<u>Test Requirements for Registration</u>	<u>No. of Substances</u>	<u>Existing Substances</u>		<u>Intermediate Products</u>	
			Large	SME	Large	SME
< 1 t/y	None	n.a.	6	18	14	14
1-10 t/y	physico-chemical, toxicologic and eco-toxicologic data. In vitro test methods	19,700	19	21	17	25
10-100 t/y	Tests according to App.VII a, Directive 67/548/EEC	4,700	26	20	23	23
100-1.000 t/y	Basis Tests, Level 1 Tests	3,000	18	15	10	12
> 1.000 t/y	Basis Tests, Level 2 Tests	2,600	32	23	36	26

Source: Frohwein and Hansjürgens, 2005

ments of REACH.

#### *Analytic Appraisal of the Influence of SME on Chemical Management*

The degree of influence and control exercised in the process of chemical safety by the SME is dependent on the organizational capability and assertiveness of commercial interests. On a closer view, however, we find out that the question of organizational competence of SME is beset with a number of problems.

Approximately 1,600 chemical manufacturers in and outside Germany are organized in the Verband der Chemischen Industrie (VCI, German Chemical Industry Association), which supports their interests toward the media, the government and controlling agencies, as well as other areas of commerce and technology (VCI, 2007). A significant portion of chemical producers (including the SME sector) is also organized in one or more of 39 specialized trade organizations, which serve to better articulate the sub-specialty interests of their clients. In the concrete case of REACH those organizations can take over an informational function, organizing a data exchange from the industrial association to the ECHA concerning the far reaching consequences arising from a hypothetical substance restriction.

The VCI itself represents a large number of individual members with heterogeneous interests and as a result of this the degree of organization is relatively low. The enforcement ability, on the other hand, is very high due to the large member subscription and aggregation. For the specialized chemical organizations the opposite is the case: homogeneous interests and lower member populations lead to a higher degree of organization than that of the VCI.

As pointed out above, the effectiveness depends not only on the degree of organization but also on the availability of strategic resources to the group of small and intermediate corporations. It is questionable whether and to what extent these SME might be able to hinder or deny resources essential to the success of chemical regulation defined by REACH, but such restriction of strategic resources could be used as a means of political pressure to achieve corporate aims. Thus, resource denial itself would define goal effectiveness. The organizational capacity, in contrast, would depend on how well these

interests could be canalized and articulated. Examples of important resources are the choice of corporation location and public support for planned or ongoing industrial enterprises and legislation. Whereas the second aspect played a major role during the ongoing legislative process pertaining to REACH, the question of whether the present production location of the small and intermediate chemical industry in Europe will, in the future, still remain unchanged can only be answered after full REACH implementation. The resource "industrial location" only then transforms into an effective source of political pressure in relation to REACH when the denial of this resource becomes a fact. A further, less important resource is the process of notification and information exchange in accordance with REACH regulations. Compliance with this procedure ensures a successful outcome for REACH goals. Although direct refusal to comply may be sanctioned, it will be difficult for the over-seeing agencies to differentiate between lesser motivated enterprises (which might exploit deadlines to the utmost) and those which respond promptly and completely.

#### **Societal Actors**

##### *Relevance and Characterization of the Interest Group*

Special emphasis has been placed on "society at large" and to consumers in Appendix 16 of REACH, which deals with the process of carrying out the SEA. There it is explicitly stated that consequences which might ensue for the consumer by the granting or denial of substance authorization must be thoroughly examined. This includes changes in product price, quality, content, availability, and the effects of the product on human health and the environment. Furthermore, the social impact of the authorization outcome, for example the effect on job security and employment, must be scrutinized.

The legal text points out the various interests and claims of society in general with special reference to those of consumers. Such interests are concentrated and represented by diverse groups, e.g. NGOs, in the form of consumer, labor or environmental protection organisations. They may also function in the role of an "interested party" of REACH to address the interests that relevant social groups may have for a functional chemical

safety management.

*Analytical Assessment of the Socio-Political Effects on Chemical Management*

Here, the question of organizational competence and assertiveness of the relevant social groups is again confronted. In order to gain more insight into what existing influences and which role they play in complex social themes such as SEA, it is useful to examine the concept of "surrogate representation" as evidenced by NGOs.

NGOs function at various levels. On the one hand, they work along local channels as, for example, in the case of the Netzwerk Verbraucherschutz, a network for consumer protection in Berlin, with about 40 separate institutions and associations. Others are active on a wider, multi-regional basis, such as, for example, the Verbraucher-zentrale Bundesverband e.V. (VZBV; the German Federal Union of Consumer Protection), which is the central co-ordinating organization of 16 country-wide subdivisions and 25 other consumer-oriented associations and represents consumer interests in the political, economic and social arenas. Further examples of multi-regional, non-governmental organizations are Foodwatch and Greenpeace-Einkaufsnetz, a consumer network organized by the global environmental NGO Greenpeace. All over Europe there are a large number of similar active groups as evidenced, for example, by the European Environmental Bureau (EEB), which oversees 143 environmental groups from 31 countries.

The interests of consumers and of society in general are predominantly covered by the NGOs and other organisations, although these interests may be very heterogeneous. Especially with the NGOs we often see various strategic alignments, where some try to steer consumer opinion while others put their emphasis on political lobbying or conduct specialized image-campaigns focused on industry. Thus the high degree of organization present within one particular group must not necessarily be found in another. The enforcement ability of such groups, however, can be very great as can be seen by the various campaigns set into motion by NGOs, for example, the public scandals concerning contaminated meat products, pesticides in fruit and vegetables, phthalates in children's toys, etc., all of which demonstrate the power that such organizations exert on markets. Through effective public profiling, NGOs will probably

be able to set their influence to use against other interest groups in matters dealing with REACH. The problem of the inherent heterogeneity of interests remains, however.

One especially effective method of securing social interests against those of government and business – besides the sheer demonstration of political willpower – relies on consensus denial. The strategic resources of NGOs are voter opinion and consumer behavior, both of which are strongly influenced by consumer orientated information supplied by the NGOs. At the same time, this influence spills over to also affect general public opinion and the behavior of political parties and candidates.

Only if REACH is able to provide the necessary information transparency within the framework of chemical regulation for all involved parties the NGOs can continue to take part in the influence process now going on. It is of utmost importance that access to accurate and generally understandable data is guaranteed and that the various elements of society and their representatives be allowed to actively take part in the process of chemical regulation. This has already occurred in cases where NGOs have participated in the REACH Implementation Projects. On the other hand, care must be taken to protect industrial trade secrets and other legitimate interests of industry by carefully balancing out all interests when implementing REACH.

## Summary

The results of this analysis can be applied to the industrial-commercial level in exercising "stakeholder management". For the execution of a SEA under REACH the identification of stakeholders helps to decide which groups should ingeniously be included in the analysis, as REACH does not supply any definite provision and leaves the decision to the individual applicant. This method can be of use in the decision making process of granting or denying the authorization of a substance because such an identification step leads to the involvement of all the important interest groups including those which, alone, do not possess the necessary power and assertiveness to exert influence on the analysis process. SEA must, therefore, reflect the needs of all directly affected groups as well as those of external REACH groups. At the same time care must be taken to consider the interests of the indirect stakeholders who are allied



with internal actors.

## 5 Necessity for Involvement of Individual parties in the Stakeholder Oriented Chemical Management

The fact that, on the one hand, discrepancies exist between the relative organizational competence and efficiency of goal achievement amongst the individual stakeholder groups and, on the other hand, that these groups are seen to be involved in strongly varying degrees in the overall analysis process, gives rise to the question as to how the instruments of chemical management can cope with these differences. In general, choice of including a stakeholder's claim in a SEA is up to the entity which mandates a SEA (e.g. the applicant) and in particular up to the method employed. We now investigate the problem of how individual stakeholders' claims are considered using methods and concepts on the corporate level. Here, we find a broad set of instruments for use in the safety management of chemical substances. In a REACH implementation project jointly undertaken by representatives of governmental agencies and industrial associations, various methods for carrying out SEA in the authorization process were presented, e.g. the cost-benefit analysis, the compliance-cost-assessment, and other multi-criteria procedures. One such example of the latter is the method developed by the BASF Chemical Company in Ludwigshafen, Germany, which is known under the name of "SEEBALANCE"<sup>3</sup>. SEEBALANCE can be employed as an instrument in the execution of the socio-economic analysis at the corporate level. In the following it will first be described how SEEBALANCE functions and then it will be examined whether the major stakeholders in the chemical management process are adequately identified by it.

### 5.1 How SEEBALANCE Works<sup>3</sup>

SEEBALANCE<sup>4</sup> was developed by BASF as a method for quantifying sustainability of products and processes. The goal of SEEBALANCE is to unify all three aspects of sustainable development into an integrated instrument of product assessment in order to precisely

quantify and control sustainable industrial production at all levels. SEEBALANCE can also be used as an evaluation instrument for carrying out SEA under REACH. The purpose of the SEA, as we have seen, is to quantify the total costs, as well as the environmental and social effects that a product generates during the entire course of its "product life", starting from raw materials and ending with recycling or disposal. Furthermore, the analysis includes a detailed evaluation of the relative advantages and disadvantages of different alternatives regarding a defined functional unit, for example a so-called customer benefit.

The basic ecological data are obtained by performing a so called life-cycle analysis after ISO 14.040 and 14.044. The following ecological impacts are considered:

- 1) raw materials usage,
- 2) energy consumption,
- 3) emissions (air, water and soil),
- 4) eco-toxicity and
- 5) land usage.

By means of a weighting procedure, a total estimate of the environmental burden can be made (for further information for weighting procedure see Saling et al, 2002). Hidden risks and weaknesses in any phase of the production chain that could lead to negative environmental effects can thus be more easily detected at an earlier stage (Saling et al., 2002). The economic consequences of introducing alternative products are evaluated by SEEBALANCE on the background of total cost generation. As defined by Piepenbrink et al. (2004), costs are understood to be exclusively real costs, that is, ones which factually arise (including all secondary or follow-up costs). SEEBALANCE ignores so-called avoidance costs as well as other theoretical cases, such as the internalization of external costs, and thus guarantees a separation of ecological and economic factors. Real costs due to ecological considerations, such as those for water treatment plants, are, however, also included. All ensuing costs are then summed up (without weighting) to yield a total cost estimate. This procedure makes it possible to identify cost-intensive areas and to make the necessa-

3) The following description is partly taken from Kicherer and Kölsch (2007).

4) SEEBALANCE is based on the "eco-efficiency concept" of BASF. Based on the original work by Schaltegger and Sturm (1990), this concept was adapted to the needs of BASF in 1997 by the advisory bureau of Roland Berger and Partners by broadening the eco-efficiency concept to include social aspects. Hereby, a co-operation was initiated between BASF and the Institute for Geography and Geo-Ecology at the University of Karlsruhe, the Öko-Institut and the University of Jena, Germany. The project was carried out as part of the research program "Sustainable Aromatic Organic Chemistry" sponsored by the German Bundesministerium für Bildung und Forschung (Federal Ministry of Education and Research) from 2001 to 2004. As a result of the revised version of SEEBALANCE it is now possible not only to survey and quantify the effects and costs of industry on the environment but also to provide an estimation of the consequences of these activities on society as well.



ry corrections to optimize procedures. The use of alternative methods of cost calculation is also possible, which is of importance when investment capital is projected or different amortization and depreciation models come into play.

The social impacts of a product or industrial process can be determined by a critical evaluation of the roles played by 5 stakeholder groups (Saling et al., 2007). In analogy to the case of environmental balancing, various indicators are considered and compared to the entire developmental and processing chain of the alternative in question. A product then qualifies as being more advantageous than its alternative with respect to the social dimension of sustainability if it contributes more to the achievement of the social goals defined in the international debate on sustainable product development (or, in the converse, when its negative effects are less) (Schmidt, 2007).

In the course of the above research project on SEEBALANCE, the following groups have been identified as major stakeholders, who are affected by the social effects of production, usage and disposal of chemical substances (Schmidt, 2007).

Employees,

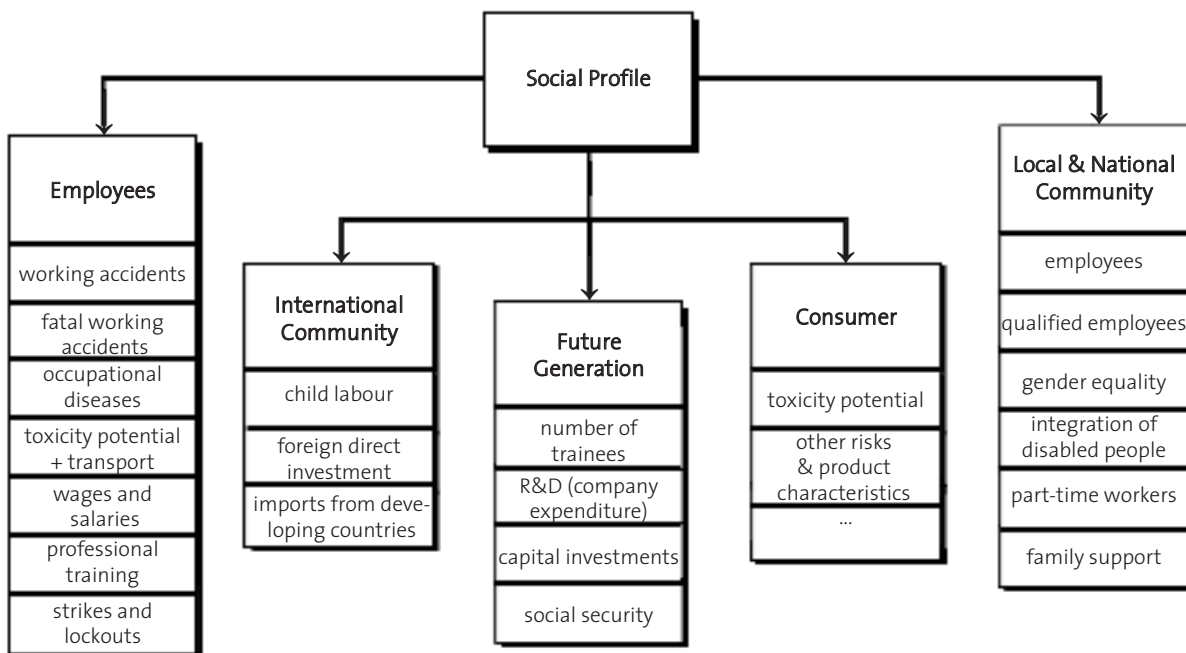
Future generations,  
Local and national community,  
International community,  
Consumers.

Figure 4 summarizes the relevant individual social indicators which are included under the overall concept of "social profile", and which serve to define major stakeholders.

In addition to factors of substance safety (e.g. toxicity, occupational disease and accidents), other socially relevant aspects are addressed by SEEBALANCE. The indicators can be classified as positive or negative. Positive indicators follow the rule of "the more, the better", i.e., the higher the wages, the more benefit for the employee. Negative indicators function in the opposite manner, as with the case, for example, of an increasing frequency of industrial accidents, which would tend to work to the detriment of worker well-being (see "increasing scale" and "decreasing scale" in Ott, 1987). The data elicited on economic, ecological and social factors are combined to yield a complete appraisal of the impact of a product or industrial process on society as a whole.

The results of the SEEBALANCE evaluation

Figure 4 Stakeholders and Identified Indicators



modified Saling et al., 2007

allow the identification of risks and weaknesses in finished products and industrial processes over the entire life cycle with respect to all three supporting branches of sustainable industry and to evaluate these by means of the various economic, ecological and social indicators. It should thus be possible to recognize those factors which, when optimized, will lead to a vast improvement in socio-economic efficiency.

### 5.2 Appraisal of SEEBALANCE with Respect to Stakeholder Related Chemical Management.

As it has been described, SEEBALANCE can be used in the assessment of various industrial processes and has been considered for use in the process of the socio-economic analysis under REACH. The question remains, however, whether or not SEEBALANCE addresses all the relevant stakeholders who might be a REACH-related stakeholder. As it can be seen in Fig. 3, a number of interest groups exist, which, in the case of substances of very high concern would become active under REACH and should thus be recognized and integrated (see Part 4.2, where the directly and indirectly affected stakeholders as well as the internal and external groups are described).

SEEBALANCE refers to only two groups as being direct and external players (compare Fig. 3 with stakeholders of Fig. 7): the local and national community as society at large as well as the product consumer as an interested party. The remaining interest groups of Fig. 3 are not explicitly included in any of the three dimensions of SEEBALANCE. The applicant for substance authorization as well as the downstream user, both of whom belong to the category "direct" and "internal", are not explicitly mentioned in SEEBALANCE. However, the applicant defines the functional unit (customer benefit) for SEEBALANCE. Without the definition of the functional unit the comparative evaluation of chemical substances would be impossible. From there it has a prominent position in a SEEBALANCE. The costs from an operational point of view for the manufacturer (who is also almost always the applicant) and the follow-up costs for downstream users are clearly given by the economic dimension of SEEBALANCE. Thus, these two stakeholder groups are not explicitly localized to the sociologic axis but rather more implicitly into the economic domain.

The stakeholders "interested parties",

"other affected parties", "consumers" and the "social community at large" all belong to the category of directly and externally involved stakeholders. These groups are subject to special attention and protection by REACH as evidenced by the following quotation from the REACH text: "The purpose of this regulation is to guarantee a high level of protection for human health and the environment [...]". In SEEBALANCE both the consumers and the social community are explicitly mentioned. "Other affected groups" and "interested parties", although not explicitly cited, can be included into and subsumed under the two indicators "local & national community" or "consumers". Furthermore, a number of the goals of the "interested parties" and "other affected groups" are equivalent to those of the category "future generations" and "international community" or can be found within the framework of the ecological dimension of SEEBALANCE. Finally, SEEBALANCE offers within the category "consumer" the possibility of widening the analysis to include further indicators. For all practical purposes, the groups "interested parties" and "other affected groups" appear to be adequately addressed by SEEBALANCE, so that chemical safety management can function properly. None of the initially identified indirectly affected groups under REACH are explicitly described by SEEBALANCE. And this appears to be not necessary for the externally, indirectly affected groups, such as the NGOs, compared to the case of directly and externally affected groups (e.g. consumers), as long as they are explicitly and sufficiently addressed, too. Also, a number of the goals of the various groups share a common basis with those of SEEBALANCE, namely, the protection of the environment and human society with maximum economic efficiency from there the interests seems to be appropriately represented in this approach.

## 6 Final Conclusion

In this paper we have shown how the corporate stakeholder concept is applicable to REACH. The main thesis is that – from a governance point of view – for a regulatory system to be effective, all social groups must be involved in the decision-making processes regardless of whether they are affected by any aspect of chemical safety or have direct obligations stemming from by the legal statutes. As can be shown, REACH affects the various parties involved in several ways. Thereby,

the essential conclusion concerning the socio-economic analysis is as follows: As the organizational competence and goal achievement effectiveness of all participants increase, so also does the necessity for single stakeholders to better organize themselves in representative groups so as to gain more influence in the process of the SEA. For example, final consumers are directly affected by product safety, but under REACH they are merely external stakeholders. Because consumers are only weakly organized, they must coalesce under competent representation if the process of SEA is actually to yield a true picture of the overall social situation. Effective chemical management as a primary environmental goal depends on the balanced evaluation of the benefits deriving from the use of chemical products and the potential (and real) risks they pose to human health and the environment (Wätzold, 2000). The process of risk balancing takes place in the form of the socio-economic analysis according to REACH. This formalized process ends with a socially legitimized decision on the authorization (or denial thereof) of a chemical substance for commercial use. By structuring the participating parties according to interest groups, we have seen that it is of the utmost importance to guarantee the adequate involvement of NGOs, the media as well as employees and public assistance personal (as direct and external stakeholders) into the evaluation process. It is essential that these groups have full access to information and participation rights during all phases of the socio-economic analysis.

From an authorization applicant's point of view the implication from this study is the following: if the applicant wishes to claim that its SEA depicts a true and in-depth evaluation of all societal risks and benefits it should demonstrate how external REACH stakeholders were included in his assessment. That translates into a method which firstly undertakes a REACH stakeholder analysis, also considering the characteristics of the substance in question. Secondly, the method applied in the SEA should integrate the interests not only of internal stakeholders but also of external ones to demonstrate the applicant's willingness to undertake a comprehensive evaluation.

The SEA committee at ECHA in turn, should integrate a stakeholder perspective when the EC Commission grants authorizations.

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## Practitioner's Section

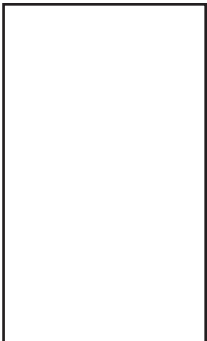
### Patent License Negotiation: Best Practices



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In all areas of the biotechnology and pharmaceutical industries, the licensing of intellectual property is in most cases an essential step in the translation of basic research into a commercial product. Negotiating IP licensing agreements and developing the terms of the business transaction involve evaluating numerous factors pertaining to the specific circumstances of the parties and the technology at issue. As the quality of the business relationship after licensing of the intellectual property is heavily influenced by the nature of the transaction, the negotiation process should be approached with great consideration. This article presents an overview of the negotiation process and makes suggestions for each stage.

Licensing of intellectual property is an inherent part of the biotechnology/pharmaceutical business. Very few technologies are commercialized without the licensing of intellectual property rights. Universities and emerging biotechnology companies often require the assistance of larger companies (so-called "big pharma") to fund and help navigate the regulatory approval process. Big pharma may look to emerging biotechnology companies for research and new marketable small and large molecules. Even products completely developed at in-house research facilities may require in-licensing of technology for the production of commercial quantities. The emergence of genetic testing to assist in the diagnosis and treatment of disease has resulted in analytical laboratories engaging in new rounds of patent licensing with the holders of intellectual property rights to the isolated genes.

In licensing, the negotiation process is a key determinant of the future business relationship between the stakeholders. In other words, "the quality of the final deal and the quality of the overall business relationship is governed by

the quality of the negotiation." But what approach should a party take to negotiating patent licenses? And how are the interests of the licensor and licensee balanced to arrive at a deal? Our experience, and a review of relevant business and legal background, suggests the following as a possible "best practices" approach to patent or technology licensing negotiations.

#### Preparing to Negotiate

A key to any deal is for each party to have an understanding of what they want from the deal. Thus, effective negotiation begins with effective preparation. Effective preparation includes assembling the right team, preparing a heads of agreement, defining guidelines for the process, negotiating honestly, and drafting the contract.

**The Team.** In many negotiations both parties will have a deal team. The deal team will conduct due diligence and negotiate the license. A deal team will generally include a

Business Development Executive; a Scientific/Technical Expert; a Decision Maker; and a Licensing Attorney. The scientific and legal roles may be filled by multiple team members; for example, if the licensing attorney is not a patent attorney, a patent attorney will be needed on the deal team to understand the scope and nature of the patent rights and/or potential patent rights. The Business Development Executive is the person responsible for finding the deal and bringing the parties to the table. The Business Development Executive is often the leader of the deal team and responsible for keeping the negotiation process moving and ensuring the other team members fulfill their assigned tasks. In smaller biotechnology companies, the Business Development Executive role may be played by the company's CEO. Technology Transfer Professionals often play the Business Development role for Universities. The Scientific/Technical Expert(s) provide scientific and technological expertise to the deal team and conduct due diligence research relating to the technology at issue. The Decision Maker may or may not be the ultimate decision maker for a company, but should be someone who has authority to commit a party to particular deal terms. In an emerging biotechnology company, the Decision Maker is often the CEO. In a larger company, the Decision Maker may be a Business Executive with authority to bind the company within certain parameters. The Licensing Attorney, who is often an experienced patent attorney, is responsible for committing the terms of the agreement, and the desires of the parties, to writing. An experienced Licensing Attorney may also assist during negotiations by providing suggestions on alternative deal structures or terms when the parties reach an impasse. One or more members of the deal team are likely to be individuals that will be responsible for maintaining the relationship during the term of the license.

**Initial Team Meeting.** It is important that the deal team meet and reach an understanding of the business motivation for the deal and the responsibilities and role of each team member during the process (e.g., spokesperson, technology review, business evaluation, record keeping).

In preparing for the negotiation, the deal team should identify, assess and prioritize the interests of their client. The "client" may be, for example, a business unit in the case

of a large corporation, the company in the case of an emerging biotechnology company, or the University in the case of a Technology Transfer Office. Client interests will be both tangible (e.g., longer terms, higher royalty rates, greater minimum guarantees) and intangible (e.g., building a trusting relationship, maximizing licensor's reputation, high quality product or service, creative commitment). While the tangible terms will structure the working relationship, they should not be achieved at the expense of intangible interests; otherwise the relationship itself may be compromised in the future.

The deal team should assess its own and the other party's position. To do so, steps could include 1) reviewing the strength and breadth of patent protection to determine the proprietary position offered by the patents, 2) conducting a right-to-use study on potential commercial products to determine the value of the patents and whether a license to any third party patent(s) are required, and 3) reviewing the developmental stage of the patented technology. For example, a small molecule pharmaceutical composition may be covered by species claims in a licensor's patent portfolio, but fall within the scope of a generic composition claim of a patent held by a third party. Thus, the value of the licensor's patents may be reduced by the need to license or otherwise deal with the third party patent. For the same small molecule pharmaceutical composition, the developmental stage will affect the amount of money a licensee will need to spend to bring the composition to market and the risk that the composition may fail to obtain FDA approval. Compositions that have shown efficacy through phase II clinical trials are generally worth more as the probability they will be approved is higher.

In addition, the team should evaluate and determine the marketing, technical, sales and services strengths of itself and the other party in the field of the patented technology. All of these factors are relevant to the amount of the licensing fee and royalty to be paid to the patent holder, in addition to other contract provisions, and help the parties to define the scope of the licensed technology and their competitiveness as potential licensing partners. Further, the team should carefully evaluate potential best alternatives to a negotiated agreement



(BATNAs) by determining, for example, the possibilities for alternative licenses, modifications or additions to existing contracts, delaying licensing, or bringing in additional partners or interests to raise capital and diffuse risk.

Before beginning talks with the other party, the deal team should determine what terms and conditions should be omitted from preliminary talks until formal negotiations begin. This is important because, until detailed negotiations begin, it is difficult to perceive the true value of any license and, thus, talks may unnecessarily breakdown due to discouragement over early positions that seem highly objectionable.

**The Term Sheet.** It is often helpful for parties to exchange a term sheet prior to the initial negotiation meeting. The term sheet typically covers the major issues in a potential deal in outline form, including: the licensed product or process; licensed territory; license fee and royalty; technical information and training required to develop and manufacture, sell and service the licensed product, and who will be responsible for same; sales and service support; degree of exclusivity, and duration of the license. The process of creating this document will help team members understand and focus on the overall objectives of the agreement and avoid unfavorable terms. Additionally, the document enables each party to understand their team's basic position from the start, avoiding potential misunderstandings as the negotiation proceeds.

**Deadlines.** Establishing preset deadlines for each of the major steps in the negotiation process is important because it forces the other party to reveal its true intentions and interests in the licensing agreement. Parties not committed to reaching an agreement will not meet deadline requirements, enabling the other party to cut its losses and look elsewhere for a potential licensing partner. Major steps in the negotiation process for which preset deadlines may be set include: the initial meeting, drafting the letter of understanding, executing the letter of understanding, meeting to review the draft agreement, revisions to the draft agreement, finalizing the licensing agreement and executing the licensing agreement.

The relative size of the parties will affect the ability of one party to hold the other to a deadline. In a situation where an emerging biotechnology or University is negotiating

with a larger pharmaceutical/biotechnology company, the relative importance of the deal may make it the highest priority for the emerging biotechnology company or University, but only one among other priority items for the larger company. Thus, while the emerging biotechnology company may want and be able to meet aggressive deadlines, the larger pharmaceutical company may not be able to do so. Nevertheless, setting deadlines will allow an emerging biotechnology company or University to judge the other side's actual interest in a deal.

**The groundwork for open dialog.** In any negotiation, a nondisclosure agreement can provide security for both parties to maximize information transfer. Some key terms include license and scope, enforcement rights, the financial arrangement, additional patent prosecution and maintenance costs, ownership of improvements, liability, indemnification, and warranties and representations. A Joint Privilege Agreement will also be necessary if the parties intend to discuss legal opinions and avoid waiving the attorney-client privilege. Free sharing of information will also avoid costly diversions and evasive maneuvers.

Once a preliminary agreement is reached, the team should draft a letter of understanding and deliver it as soon as possible to the other party. The letter of understanding is a nonbinding document that outlines the general understanding and agreement between the parties. Its primary purpose is to aid in the drafting of the final agreement by fine tuning the broad terms and conditions elucidated during the negotiation and serve as a reminder to each party of their previously stipulated understandings. The document will typically include the following provisions: definition of licensed product; license grants; licensed territory; exclusivity; license fee and royalty; technical information and assistance; duration of license; and a provision expressly indicating that the letter of understanding is a nonbinding legal instrument.

**Drafting the contract.** Commentators have suggested that the party drafting the contract is always in the more favorable position because that party will be in a position to ensure inclusion of desirable provisions and places the other party in the position of defending every request to modify the drafted agreement. In the experience of the authors, however, the non-drafting party

has not felt constrained to raise objections to an initial draft. Further, the non-drafting party may gain valuable insights into the other party's positions by making the other party "go first". Thus, there can be advantages to each position.

For the drafting party, including many minor provisions that can easily be given up is a good strategy, as this will permit the drafter to take a stronger position against objections to the more major provisions. By drafting the contract, a party is better able to evaluate any subsequent modifications or changes to the original draft and how such changes affect its primary goals. Drafting parties and non-drafting parties should approach negotiation over changes to the drafted contract differently: while the drafting party should relinquish minor claims early in order to take a stronger position on major provisions later on, the non-drafting party should attempt to review and revise major provisions first to avoid this.

The drafting party may be the licensor or the licensee. Universities often have "standard" license agreements that are used as first drafts. Emerging biotechnology companies with technology of interest to multiple suitors may be in a position to prepare initial drafts. When a deal is initiated by a licensee, they will often produce the first draft.

## The Negotiation

The terms of a licensing contract reflect the allocation of risk between the parties of the potential future development and marketability of the patented technology. A licensor that has taken a molecule through one or more phases of a clinical trial, or has the financial resources to do so, will likely be in position to negotiate narrow licensing agreements that incentivize development and marketing of the technology and that enable additional licensing agreements with other licensees of different strengths that can compete in other markets. A licensor without these resources, financial or otherwise, will often be in a weaker bargaining position. Thus, emerging biotechnology companies generally try to generate at least phase I, and often phase IIA, prior to seeking to license technology.

Conversely, a licensee wants an exclusive license with the broadest license rights for the least amount of money with the requirement that it is paying for the rights and

license scope that are required for its current and future possible business plans. Additionally, product liability and patent infringement indemnification are important to the licensee's security. To strongly support its negotiation position, a licensee should have a fully developed, detailed business plan that justifies the provisions it seeks by reasonably estimating profits and costs.

Ultimately, the market value of a patent is a measure of the potential sale of products or services that use the patented technology. To properly appraise the value of the patent it is thus necessary to determine the proprietary position (i.e., validity and enforceability) and competitiveness of the patent (e.g., minor improvement or pioneer breakthrough, market size and dynamism); and the existence, or lack of existence, of third party patent rights related to the technology. In addition, the developmental stage of the technology and the scope of the license are risk factors that affect the amount of investment required to develop and market the technology and the competitiveness of the subsequent products or services. Lastly, the potential profitability of the licensing arrangement and the contributions of each party should be assessed. Therefore, all these elements must be considered by the parties when determining the terms of the agreement.

**Valuation approaches.** A business school/MBA approach to valuation often uses one of three methods: the cost method, the market method, and the income method. The value of the technology using the cost method is the cost of developing or purchasing the technology, though this does not reflect changes in the market or new information about the technology. Usually these "sunk costs" are irrelevant to the licensee, but they can factor in where the licensor can afford to develop the technology on its own and has no need to enter into a licensing agreement. Using the market method, the value is determined by evaluating the value assigned to comparable technology licensed recently, which requires determining what transactions are comparable and obtaining current, reliable data. The income method values technology by the total estimated annual returns (compare the estimated revenue or savings that the technology is likely to produce to the estimated cost or savings of using another source), which

reflects the bottom line of what the licensee can pay. Each of these methods, or a combination of these methods are often utilized by larger licensees. Emerging technology companies seeking to in-license patents will often employ only the market method or the income method as developing technology in-house is not an option. Licensees should discount the estimated value of the technology by any risk factors specific to the licensing deal (e.g., the proprietary position of the licensor, the market share of the licensee, the length of time before revenue can be generated, the competitiveness of the product or service).

**Proprietary position.** A weak proprietary interest may exist where a patent is questionable in nature; one that covers only a very narrow technology, is very similar to other patented technology or was granted despite potentially not meeting the requirements for patentability. Such a patent does not offer significant market strength because it is either incapable of keeping products or services using similar technology off the market or potentially could be invalidated. Thus, a weaker proprietary interest is a risk factor for the future market success of products or services developed using the licensor's technology. As such, a weaker proprietary position is a factor that licensees can use to negotiate for smaller fees and royalties because large payment obligations would decrease the competitiveness of licensees in a market where the licensed patent does not afford them significant exclusivity, thus harming future market success.

Another significant factor in a licensee's potential proprietary position is the existence, or lack of existence, of third party patents that cover all or part of the technology of interest. In this situation, the license royalty may be significantly discounted in consideration for the need to negotiate additional licenses with third parties. Such a situation also strengthens a licensee's position in favor of stronger indemnification and breach of contract provisions.

**Developmental stage of invention.** Patented inventions that are in the early stage of development often require substantial investment and development before a commercially viable product is produced. But high fees and royalties can compromise the future market success of the licensed technology by siphoning licensee funds

away from development and marketing, particularly for an emerging biotechnology company licensee. Licensors are also often less invested, so licensees of early-stage technology should use such effects to negotiate for lower licensing fees and royalties.

**Exclusivity and field of use.** License exclusivity refers to whether the licensor has licensed the invention/technology to multiple licensees, whereas the field of use is the circumstances for which the licensor has granted the licensee permission to make, use and sell the patented technology. It is more advantageous for licensors to grant multiple non-exclusive licenses to further the goal of fully developing the patented technology. The ability of licensors to do so will depend on the strength of their proprietary position. However, such non-exclusive licenses can be limited by the field of use to specific applications, geographical areas, and patent right (manufacture, use, sale). A fairly typical field of use limitation in biotechnology/pharmaceutical licensing is limiting the field of use to a particular disease or group of related diseases. Often the licensee will request and negotiate an option or options for additional fields of use.

Typically, the licensor should aim to grant the narrowest field of use required by the licensee so that the licensor can retain the opportunity to exploit other potential licenses (e.g., where new uses for the technology are discovered or where a single licensee may not have the resources to fully develop the technology). Conversely, the licensee should aim to obtain the broadest field of use because this will provide the opportunity to develop the technology more fully and avoid competition in the market, particularly when the technology is in the early stages of development and the licensee bears the risk of first trying to develop and commercialize a new product or service.

Potential compromise positions include the following: 1) the licensor can grant a broad field of use with the right to retract fields if the licensor presents a use to the licensee and the licensee elects not to pursue it; and 2) the licensor can grant a narrow field of use, with the licensee having the right of first refusal for other uses that the licensor would like to propose to third parties. Alternatively, for generous consideration, a licensee could convince the licensor to restrict any future licensees from particular uses that fall within the licensee's specialty

or area of expertise. Even so, where the licensee provided research funds to the licensor to develop the technology, the licensee will typically negotiate for a worldwide, exclusive license for all patents arising out of the research. Such a broad license would give it more control and benefit from the process through sublicensing, even if the licensee lacks the resources to concurrently develop all possible uses or markets for the technology.

Granting a geographically large territory initially is unfavorable to the licensor because it would be incapable of controlling the speed with which the licensee enters the market and may forfeit potential licensing opportunities in those markets. Typically, the licensee will only have sales and marketing capabilities in its domiciled country and may not have the desire or capability to expand adequately into additional markets. Additionally, the licensee will typically only be will to pay an upfront payment for their domiciled country.

**Payment terms.** There are several forms of payment that licensing parties can negotiate to compensate the licensor for the patented technology. For example, when a University is the licensor, a typical license will include a signing fee, reimbursement and ongoing payment of patent prosecution costs, milestone payments, minimum annual royalties and a percentage royalty on sales. A University may also request that the licensee participate in Sponsored Research at the University. One or more of these provisions may be waived if the licensee is a start-up or emerging biotechnology company. In a situation where an emerging biotechnology company is licensing technology to a larger pharmaceutical or biotechnology company, the license agreement may include all of the above but, in addition, require that the licensee fund employee positions (FTE's) at the licensor to work on further development of the licensed technology.

The license or signing fee-essentially the "cost of admission" for the licensee-helps the licensor recoup some of its investment to date. As such, it is always beneficial for the licensor "to seek substantial upfront payments rather than higher royalties, especially for untried products and/or markets." Also, because this fee "must be recouped before the licensee can begin to realize profit, these payments are strong evidence of licensee commitment. However, a high initi-

al fee does not necessarily mean that the royalty rate must be lower. Licensees, on the other hand, benefit more from low upfront payments, leaving the licensor to be compensated by royalties. Having low upfront payments leaves the licensee with more funds for marketing and sales of the product and decreases the monetary risk of the licensee where the product is untried in the market. The size of the fee largely depends on the developmental stage of the invention or the exclusivity of the license as discussed above.

The purpose of annual or other periodic fees, which typically terminate when royalty payments begin, is to incentivize the licensee to aggressively develop and market the technology. Because licensors face the risk that licensees may be willing to pay such fees to "shelve" the technology, the fees should be sufficient to discourage a licensee from "sitting on the technology" or adequately reward the licensor even if the technology is not exploited. Towards this end, increasing annual fees can be effective. Alternatively, lump sum payments may be more practical than royalty payments where the technology is a part of a complicated piece of equipment or system.

Milestone payments are triggered by typical product or service developmental benchmarks, and serve to compensate the licensor commensurate with the increased value of the licensed technology. Most, if not all, license agreements in the biotechnology/pharmaceutical arts will require a licensee to use "best efforts" to meet such benchmarks (or milestones) in specified time periods, to take the patented technology to market. Typical milestones include designation of a "lead compound", filing of an IND (Investigational new drug application) or NDA (New drug application), completion of a phase of clinical trials, and first commercial sale. If a licensee is unable to meet the milestones, the license may provide for the reversion of all of the license rights back to the licensor, may provide for loss of exclusivity in one or more fields of use, or combinations thereof. In later stages of development, milestone payments are commonly in the tens of millions of dollars.

Percentage royalty payments are a percentage of the net sales of the product or service. A common method for calculating royalties is the 25 % rule. This rule starts with the premise that, under model cir-



cumstances, the licensor is owed 25 % of the licensee's net invoiced sales. This percentage is the starting point that should be adjusted by comparing the circumstances at hand to the ideal model. The percentage can be negotiated below 25 % based on the specific risks the licensee is bearing, including the fact that this rule would regularly generate royalties for the licensor regardless of the actual future profit performance of the licensee or substantial market fluctuations. Typical or standard royalties in the biotech/pharmaceutical area cover a fairly broad range. For example, a small-molecule composition-of-matter patent can bring a royalty of 10–20%, a large-molecule composition-of-matter patent 8–18% and method claims can bring 5–15%. In the pharmaceutical industry, the current range for royalty rates is from ~ 2% for a just discovered or engineered compound or material to ~ 20% for a fully developed product approved for sale.

Licensors should require a minimum annual royalty payment, particularly after the early years of the license agreement, to ensure that the licensee is aggressively marketing and selling the licensed technology or else to trigger possible termination of the agreement due to insufficient monetary returns, thus allowing the licensor to find a more appropriate licensee. Licensees, however, typically wish to avoid high minimum royalty payments, especially during the early years of the agreement, because it usually takes longer than expected to bring a product to market and because failing to meet the minimum could forfeit the license. But, if a licensee desires exclusivity, licensors often require a minimum royalty payment.

Acceptable minimum royalty payments should reflect [...] results which are at the low end of the licensor's acceptable range for returns. At a minimum, to avoid unnecessary contract termination, licensees should negotiate for a provision enabling them to pay a minimum royalty from either surplus royalty payments or general corporate funds. The licensor may also require the discretionary option of reducing of the rights of license if the minimum is not met. Where a licensee has conducted royalty stacking (i.e., licensed multiple different technologies from different licensors to combine into the final product or service), it should negotiate with its licensors to deduct some

or all of the royalties paid to third parties from the amounts payable to each licensor, though this is undesirable from a licensor's perspective.

Where a licensor is financially weaker than the licensee, it may desire to negotiate for prepaid royalties, the excess of which can be applied against future royalty obligations. This arrangement helps the licensor to recoup its monetary investment into developing the licensed technology, while not impairing the marketing ability of the licensee.

Also, where the licensor has confidence in the success of the licensee, it can try to negotiate for a higher royalty rate by "offering to share in the licensee's fortunes, good or bad" and risking no royalties if the technology fails to achieve its predictions. This is often useful for licenses for processes to improve efficiency or lower costs, where even marginal increases in efficiency can produce increased profits.

Another expense that can be factored into a license is fees for the patent prosecution program. Subsequent filing of patent applications and correspondence with the U.S. Patent and Trademark Office (Washington, D.C.), for example, in addition to international patent application filings for expansion into foreign markets, can be costly. Thus, licensors can negotiate to have licensees take on the costs of maintaining the patent prosecution program, while retaining the associated rights.

Finally, licensors may seek supplemental remuneration or other types of income. Royalty payments may be reduced or obviated under a variety of circumstances where the licensee can compensate the licensor for the use of the technology in other ways. The licensor may be able to secure the sufficient sale and price of key ingredients, components or special items for the manufacture or use of the licensed technology to the licensee. Alternatively, the licensee may be able to barter or make payments in kind by selling the products or services made under the license back to the licensor at attractive prices. Another potential arrangement is for the licensee to form a new corporate entity for the purpose of executing the license agreement in which the licensor receives a percentage of the voting stock and a veto right for decisions that are considered important to the continued viability of the venture. This arrangement can compensate

the licensor by providing equity in the new corporation in exchange for the licensing rights, and places the licensor in a position to influence the conduct of a future market competitor. In addition, the licensor can increase earning potential by requiring a percentage of the income from any sublicenses granted by the licensee.

The profitability of a license can also be increased if the licensor can negotiate to provide special additional services for the licensee (e.g., access to premises, consulting, troubleshooting, sales and service support). Licensees can pay for service fees via annual retainers or per diem charges, though often a certain amount of services could be provided free of charge. Because the licensor has a vested interest in seeing the licensed technology successfully commercialized, if these services are not expressly provided for in the agreement, the licensor can end up giving vast amounts of assistance and support with little or no consideration. Even so, limited or unlimited services and support is critical to any successful license, particularly where the licensee is unfamiliar with the technology or the technology is still in the early phases of development. Thus, to speed entrance of the technology into the market, limiting services and support and requiring compensation for them, will incentivize licensees to avoid delay that could jeopardize the amount of assistance and support they are entitled to under the license agreement or cost them significantly.

**Rights to improvements.** Parties should negotiate provisions to address the ownership of any current or future improvements of the technology. A licensee will want the right to use any variation of the technology claimed in the patent and developed by it or the licensor after the license agreement is entered into so that it does not need to renegotiate a license if the uses become desirable to it. Where improvements are developed by the licensee after the signing of the agreement, the parties will need to negotiate who will own the rights to the improvements. This will largely depend on circumstances before the contract: the relative bargaining strength of the parties, the developmental stage the technology, the potential market for new technologies.

## Conclusion

Licensing can be, and is often, essential

for the maximum development of biological and pharmaceutical inventions. Licensing arrangements can be specifically tailored to meet the legal and regulatory requirements of different jurisdictions, as well as the specific needs and capabilities of the parties, and characteristically includes provisions dealing with improvements to the licensed technology and to the granting of patent rights for that technology. By approaching licensing transactions for biotechnological/pharmaceutical technology in a well-planned, forward-thinking manner, both licensees and licensors, particularly those with different types of expertise, can maximize mutual benefits and establish a framework for a solid working relationship in the future. The best practices outlined here provide perspective on the negotiation process as a whole and should aid parties contemplating licensing arrangements for biotechnological and pharmaceutical inventions in establishing the proper approach for the transaction.

## Practitioner's Section

### M&A since Y2K - An Overview of Chemicals Deals Involving BRIC Countries in the New Millennium

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Brazil, Russia, India and China, also known as BRIC countries or the BRICs, are among the fastest growing economies in the world and have excellent raw material deposits for the chemicals and related industries. By 2007 the BRICs' combined weight in the global economy exceeded 15 % of GDP (O'Neill, 2007). Along with their fast integration into the international trading scheme, many companies within the BRICs emerged as global players, thereby becoming competitive on a global scale. International investors have thus been attracted and driven up the number of takeovers of BRIC-enterprises. More recently, BRIC companies are themselves started acquiring enterprises abroad, e.g. in order to gain access to new markets, know-how, feedstock and/or to increase the economies of scale (Schmiele/Sofka, 2008). Chemicals are among the key industries within the BRIC economies and have been impacted both by the generally observable M&A momentum and by the chemicals specific global reorganization process. The aim of this paper is to provide an overview of M&A deals and trends in the chemicals subsectors involving BRIC countries since the year 2000 ("Y2K").

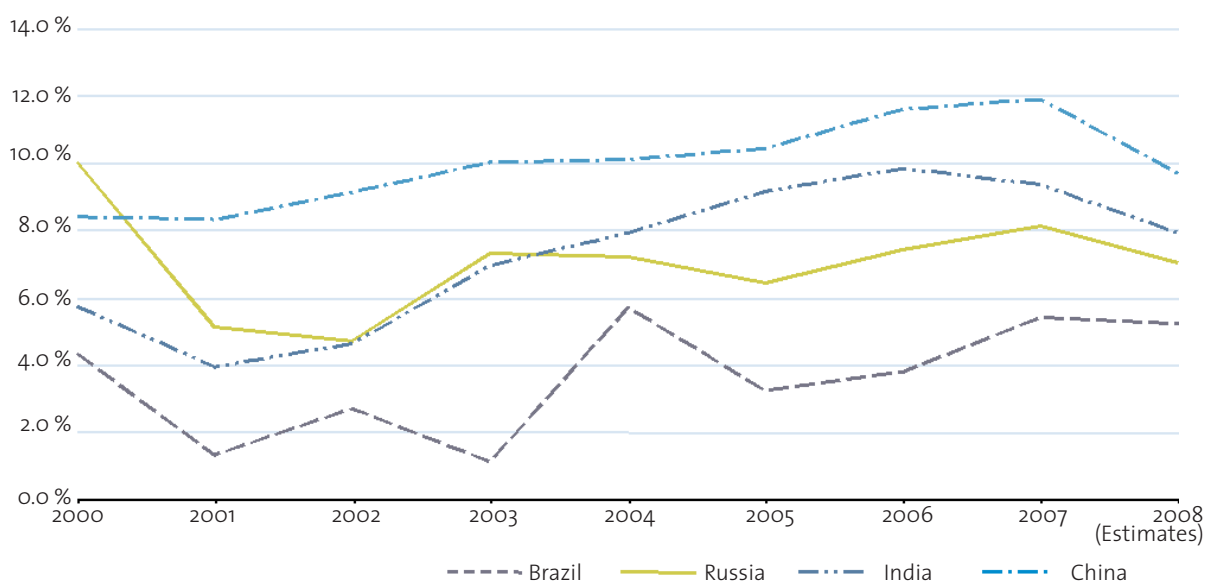
#### Introduction

China, for some industries known as the "world's workbench", can apply 800 million potential consumers to cause a strong and rapidly growing demand for a vast variety of goods. Brazil is regarded to be rich of mineral resources like iron ore and has a competitive edge on the agricultural side. India is the world's largest producer of Active Pharmaceutical Ingredients ("API") for generics. Like China, India bears a huge market potential due to the attractive potential customer base. Due to the large natural gas and crude oil reserves Russian chemical companies are equipped with comfortable

access to (petro)chemical feedstock. In all countries the GDP growth rates exceed clearly those of the developed countries and as well those of most of the emerging economies (see figure 1). The rapidly developing economies drive up the country's industrial output along with internal chemical consumption. The increasing economic wealth and the high GDP growth rates of the BRIC countries have been calling growing attention of many Western chemical companies as well as rendering the financial power to domestic chemical companies for the purpose of acquiring foreign companies. (O'Neill, 2007)



Figure 1 GDP growth rate in BRIC countries in 2000-2008



Source: IMF World Economic Outlook, October 2008

Table 1 Key indicators of chemical industries of BRIC countries in 2006

	Brazil	Russia	India	China	BRIC Total	World's Share
Output, EUR billion	64.99	25.36	54.63	204.56	349.53	16.1 %
Consumption, EUR billion	70.62	28.67	54.27	243.80	397.36	18.0 %
Export, EUR billion	7.90	8.76	12.42	32.98	62.06	6.5 %
Import, EUR billion	13.53	12.07	12.06	72.21	109.87	11.2 %

Source: CEFIC, Global Insight, VCI

## Chemical Industry of the BRIC Countries

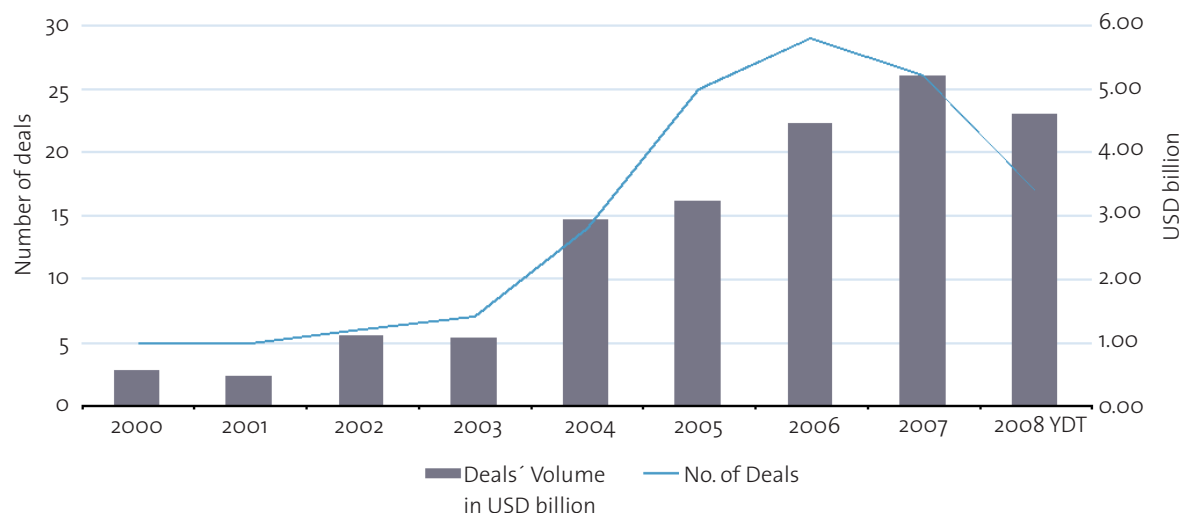
The Chinese chemical industry is the largest of the BRIC countries and the second largest worldwide. It accounts for about 9.5 % of global chemicals revenues in 2006. Due to the rapidly developing Chinese economy (GDP growth rate 2007: 11.9 %, figure 1), China is also one of largest importers of chemical products in the world and experiences significant chemicals trade deficit (VCI, 2008, table 1). The core segments of the Chinese chemical industry are basic chemicals, fertilizers & agrochemicals and commodity polymers. Those products primarily serve the strong demand of the domestic agriculture, automotive and construction industries. There are more than ten thousand che-

micals enterprises on the Chinese territory, most of them manufacturing only one or two products.

Looking beyond China, the core chemical segments of the BRICs are principally similar, though notably smaller compared to China. In Russia the majority of the industrial assets are distributed among the large oil companies and further raw material players. Despite having access to chemical feedstocks, the chemicals output is rather low, caused by a fairly old and technological outdated asset base. Furthermore the impact of political risks in Russia might deter potential investors.

The chemical production base in Brazil can be characterized by a strong focus on petrochemicals, since Brazil owns crude oil

Figure 2 GDP growth rate in BRIC countries in 2000-2008



Source: Bloomberg, Mergermarket, Factiva, PwC Analysis

resources. Furthermore, Brazil is the world biggest producer of Ethanol from renewable resources like sugar cane. Brazil exhibits a large trade deficit, e.g. due to a low capacity of the domestic market for production of fine chemicals and their high internal demand.

One of the reasons why India is the only country among the BRICs without chemicals trade deficit, lies in the capability of the Indian enterprises to balance between serving internal demand and export activities. With India being the world's largest generics manufacturer there's a strong fine and partially specialty chemicals industry. Cost disadvantages caused predominantly by relatively high energy costs and import duties continue to be the main challenges of the Indian chemical industry.

## Analysis and key findings

### Research approach

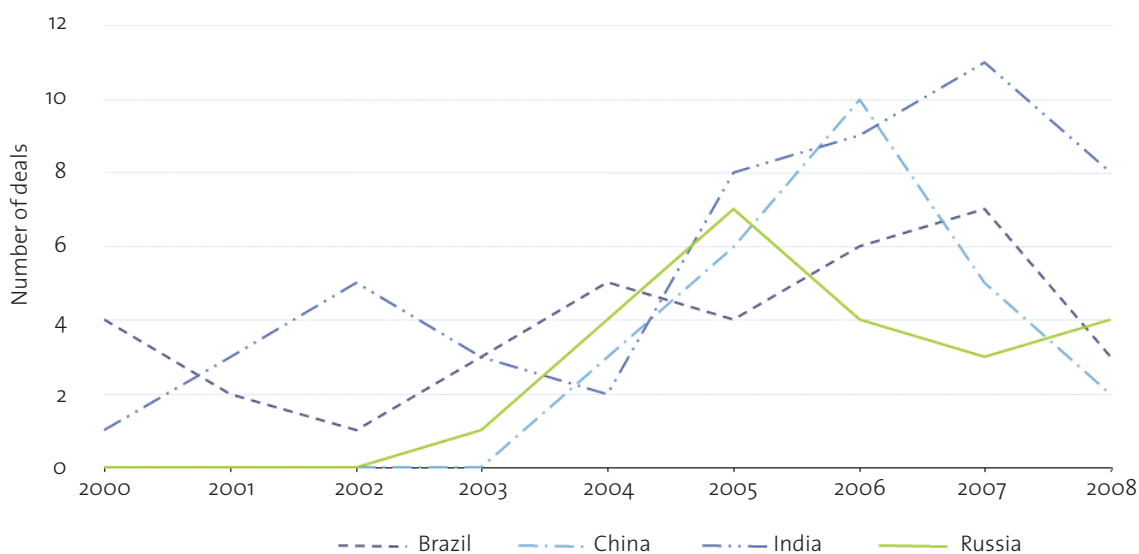
The data for our analysis were collated using following databases: Mergermarket, Bloomberg and Factiva, as well as websites of relevant enterprises. We analysed all available information about M&A transactions within the chemical industry with a deal value over USD 20 million involving at least

one of the participating parties (buyer and/or seller) being headquartered in a BRIC-country. Transactions in the oil and gas exploration and oil refining business were excluded as well as biotechnology and pharmaceutical deals. The analysis time frame covers deals that had been completed between January 1st 2000 and October 31st 2008.

### Number and value of completed deals

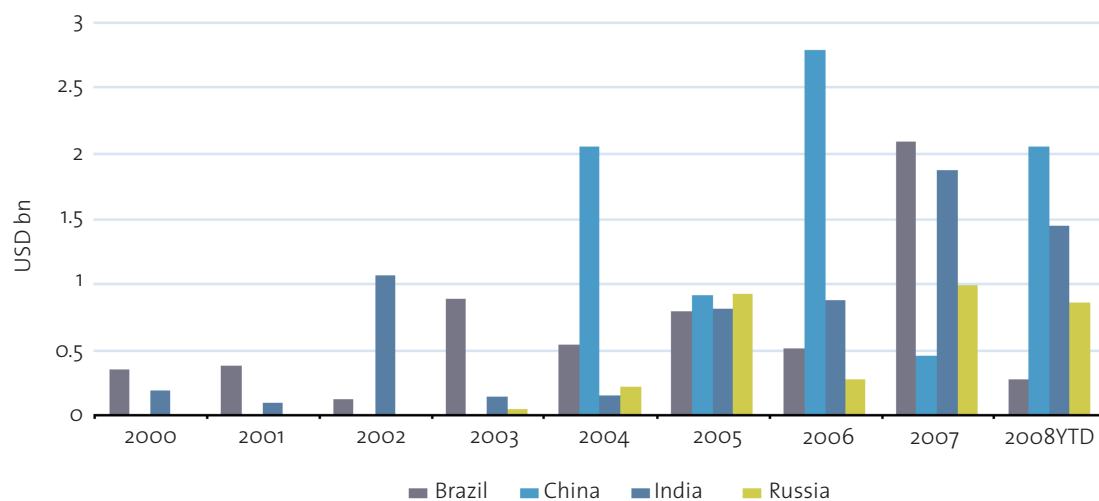
134 deals worth USD 20 million or more were recorded in the chemical industry of the BRIC countries since the year 2000 (see figure 2). At large, both the volume and the total deal value grew considerably until 2007. In contrast to the industrial economies of Europe and the USA, characterized by a large number of deals and a high deal volume (PwC, 2008), only few deals - mainly domestic or inbound - could be observed in BRIC Countries. This grounds on the relatively weak economic development level of the BRIC's in 2000. From 2001 to 2003 the number of deals and the transaction values continued to be low, caused mainly by the global economic downturn as consequence of the "dot-com bubble" crash and the Asian financial crisis from 1997 to 1999 (O'Neill, 2007). Beginning with the global picking up

Figure 3 Number of M&amp;A deals of the chemical industry in each BRIC country in 2000-2008YTD



Source: Bloomberg, Mergermarket, Factiva, PwC Analysis

Figure 4 Volume of M&amp;A deals of the chemical industry in each BRIC country in 2000-2008YTD

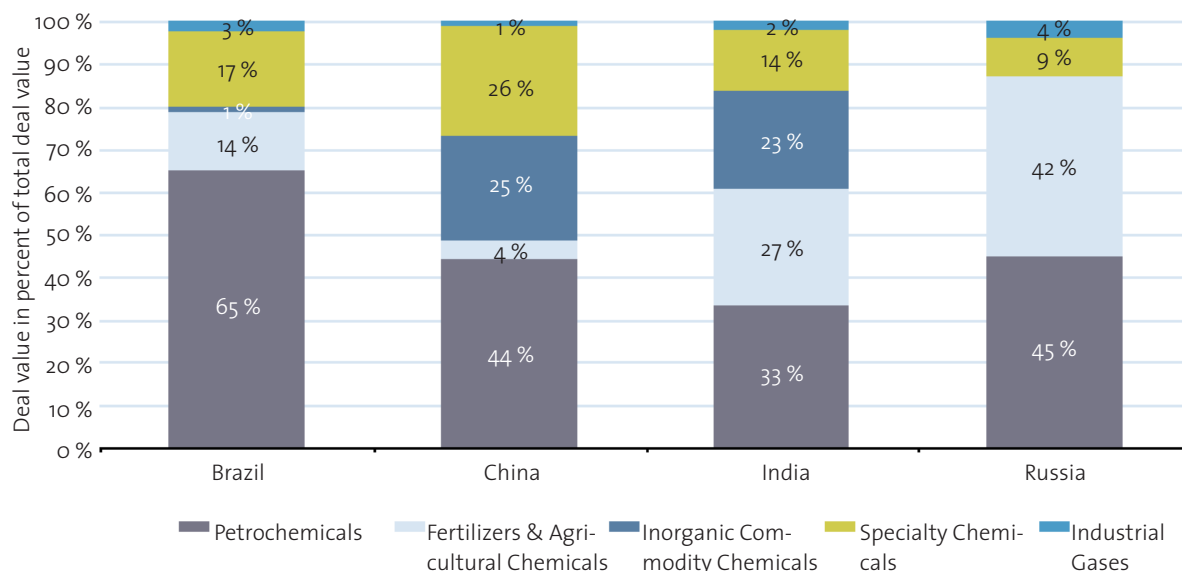


Source: Bloomberg, Mergermarket, Factiva, PwC Analysis

of momentum in world economy including chemicals at the end of 2003, M&A activities increased in the following years with respect to volumes and numbers of deals. Continuously low interest rates, readily available investment opportunities and available private equity funds together with relatively low enterprise values have contributed to that increase. In 2007, the deal volume (exceeding USD 5 billion) peaked,

dominated by several mega deals with transaction volumes higher than USD 1 billion (e.g. the acquisition of Indian Petrochemicals by Reliance). Compared to the worldwide M&A activity in the chemical industry with an overall deal value of more than USD 100 billion (PwC, 2008), M&A in BRIC countries represent only a minority. In 2008YTD there was still high activity with 16 reported deals, thereof two large deals with a value

Figure 5 GDP growth rate in BRIC countries in 2000-2008



above USD 1 billion. Looking at the second half year until now, only two relatively small deals were reported. One key reason for this trend might be the continuing impact of the financial crisis, making higher risk investments more expensive.

Figure 3 shows the number of deals in the chemical industry in each of the BRIC countries. In Brazil, the deals numbers grew relative steadily between 2000 and 2007, whereas the situation in India is more volatile. Especially from 2004 to 2005 there's a strong increase of deal numbers. As to Russia, the first deal is reported in 2003 and growing up to eight deals in 2005, while afterwards remaining rather constant (about 4 deals p.a.). Transactions in China occurred in 2004 and significantly increased until 2006. When looking at 2008, the deal number majorily turns down (except Russia).

A closer look at the transaction values for each BRIC country proofs, that the values vary from year to year in the observed period due to several acquisitions of petrochemical companies with disproportionately large deal sizes. The high aggregate transaction values for China in 2004 and 2006 are mainly driven by acquisitions of Sinopec, China's largest oil and petrochemical

corporation, which reinforced its downstream operations into higher margin value chain steps. The value in 2008 is caused by principally one large deal (conducted by Qinghai Digital Net Invest). The main driver for the fairly high values in 2002 and 2007 in India is Reliance Industries. Reliance acquired Indian Petrochemicals and became the leading chemical company in India. As to Brazil, Braskem, a financial investor consortium and Lanxess were determining the large deal volume in 2007 (with Braskem also in 2003).

#### Chemical subsectors of M&A transactions

Figure 5 shows a percentage-breakdown of the deal values according to the chemical subsectors for each of the BRIC countries, clearly pointing out the dominance of the petrochemicals sector. Especially in Brazil, 65 % of the aggregate deal values have to be allocated to that sector. Petrochemicals also account for the largest percentage of the total sum in the rest of the BRIC countries, though being not as dominant as in Brazil. For the fertilizers and agrochemicals the situation is different. Particularly in Russia (44 %), but also in India (27 %) the deal value contribution of that subsector proves to be

Table 2 Summary of large deals (&gt; USD 500 million) in the BRIC countries in 2000-2008YTD

Date Announced	Target Name	Target Nation	Acquirer	Acquirer Nation	Value of transaction in US\$ billion	Category
Jan-08	Qinghai Salt Lake Ind. (Grp) Co	China	Qinghai Digital Net Invest	China	1.98	Inorganic Commodity Chemicals
Dec-04	Sinopec Group Chemical Assets	China	Sinopec Group	China	1.49	Petrochemicals
Mar-07	Indian Petrochemicals Corp	India	Reliance Industries Ltd	India	1.13	Petrochemicals
Jan-08	General Chemical Industrial	United States	Tata Chemicals Ltd	India	1.01	Inorganic Commodity Chemicals
Oct-07	CIA Petroquimica	Brazil	Braskem SA	Brazil	0.76	Petrochemicals
May-07	JSC Salavatnefteorgsintez	Russia	Gazprombank JSB	Russia	0.74	Petrochemicals
Jul-02	OPP Quimica SA	Brazil	Braskem SA	Brazil	0.63	Petrochemicals
Feb-06	Sinopec Yangzi Petrochemical Co. Ltd.	China	Sinopec Group	China	0.61	Petrochemicals
Oct-06	Rhodia (Silicone division)	France	China National Bluestar Corp.	China	0.50	Specialty Chemicals

significantly high. Especially the deals in Russia have been supported by a strong, export orientated, but still fragmented fertilizer industry and large mineral resources, e.g. potash. Deals involving manufacturers of inorganic commodity chemicals like soda ash were mainly reported in China and India. Regarding the deal values for specialty chemicals, China is the country with the highest aggregate transaction value, which is caused by a government's programme to strengthen the country's specialty chemicals sector. The investigation towards industrial gases deals revealed only a few small deals in all BRIC countries.

#### Large deal summary (> USD 500 million)

About ten deals with a value larger than USD 500 million could be tracked. These deals reflect once more the domination of the inorganic commodity chemicals and petrochemicals sectors in the BRIC countries. It is interesting to note that the only large deal in the specialty chemicals sub-sector is outbound with the target in Europe.

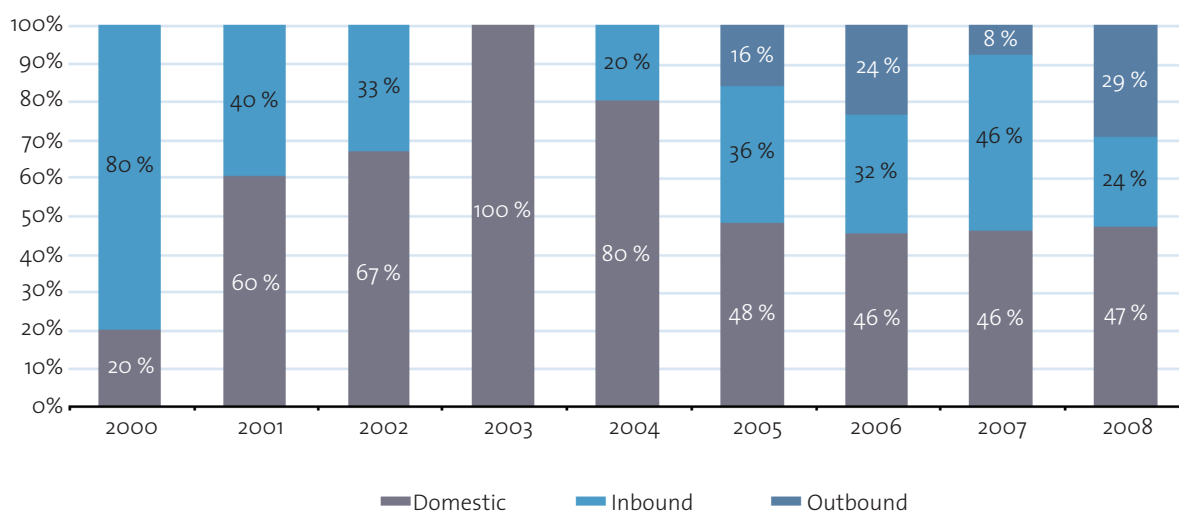
Qinghai Digital Net Investment Share Holding Group Co. Ltd. (QD) merged with Qinghai Salt Lake Industry (Group) Co. Ltd., a soda ash manufacturer, in exchange for slightly less than three billion new QD ordinary shares, valued at 14.28 billion Chinese Yuan (USD 1.98 billion), in a reverse takeover transaction. The shares were valued based on QD's closing stock price of 4.8 Yuan (USD 0.666) on January 24, the last complete trading day prior to the announcement. Upon completion, QD was to become the going-forward entity.

China National Petrochemical Corporation (Sinopec Corporation), China's largest oil & petrochemicals corporation, built on its downstream operations with the acquisition of various petrochemical assets from its parent, Sinopec Group, in an asset swap valued at USD 1.5 billion.

Reliance Industries, Indian's largest private company, acquired Indian Petrochemicals Corp (ICPL) and became the dominating oil & gas, refining and petrochemical company in India. ICPL was India's second largest petrochemical firm.

In October 2007, Braskem - the largest Brazi-

Figure 6 Domestic vs. cross-border deals in the chemical industry of the BRIC countries 2000-2008YTD



Source: Bloomberg, Mergermarket, Factiva, PwC Analysis

lian petrochemicals company - gained access to the petrochemicals producer CIA Quimica via the conjoint acquisition of the oil and chemical conglomerate Ipiranga. The acquirers' consortium comprised Braskem, Petrobras and Ultrapar.

Some years earlier, in July 2002, Braskem incorporated polyethylene producer OPP Quimica in order to strengthen its downstream business in the context of the total reorganisation of the whole company.

Sinopec Group purchased back its listed subsidiary Sinopec Yangzi Petrochemical Co. in order to deliver its promises to restructure its assets, thereby strengthening the competency of its core business.

Gazprombank, a subsidiary of the Russian Gas Company Gazprom OAO, has acquired 54 % stake in Salavatnefteorgsintez OAO, a Russia based petrochemical and refining facility, from the government of the Republic of Bashkortostan for a consideration of RUB 19 billion (USD 736 million).

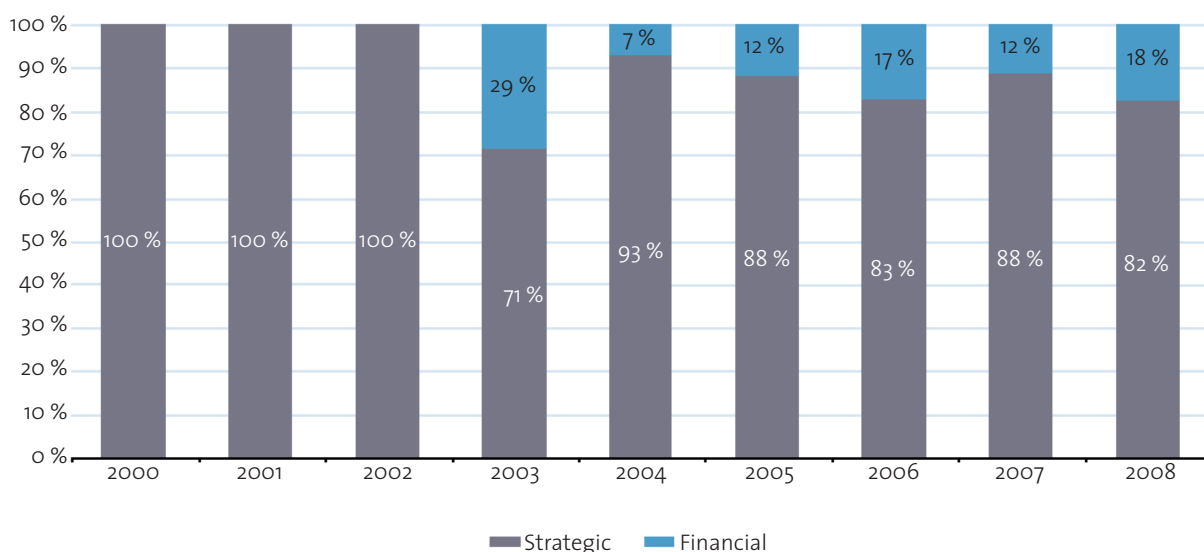
China National BlueStar (Group) Corporation, a subsidiary of ChemChina, took over the Silicone division of Rhodia, a listed France based specialty chemicals company, for a consideration of USD 504 million. The acquisition is supposed to enable BlueStar to expand the domestic silicon production scale, its industrial network and to gain competitive advantage on a global scale.

#### Ownership classification: domestic vs. cross-border deals

The observation of consolidated data for the BRIC countries shows that in 2000 80 % of the deal numbers were inbound (figure 6). In the following years the importance of domestic deals gained more importance with its climax in 2003 where all deals were domestic. Since 2004 the number had fallen down and has been remaining constant at 46-48 % from 2005 YTD while those of cross-border transactions kept taking their place. With reference to inbound deals, there is an increasing activity balancing between about 20 % and over 40 % from 2004 to 2008YTD. From 45 inbound deals the majority of the target companies was situated in India and Brazil. Looking at 2005, the first outbound deals were reported and grew up to 29 % of total deal number in 2008YTD. The dominating country for outbound deals is India since 15 of the 18 reported outbound deals were operated by Indian companies. The overall proportion between inbound and outbound deals is about 3 to 1. This reflects the strong dependence of the BRIC countries on foreign capital investments as engine for the strong economic growth in the BRICs. The main reason for outbound deals is the gain of know how, e.g. the acquisition of Rhodia's silicone division by China National BlueStar, or the access to new mar-



Figure 7 Strategic vs. financial investors of M&amp;A deals in the BRIC countries 2000-2008YTD



kets and resources (e.g. the acquisition of General Chemical Industrial by Tata Chemicals).

### Investor Types

Strategic investors dominate the consolidated M&A landscape throughout the observed period. The share of financial investors increased just slightly during the last several years (see figure 7). As to the chemical subsectors, a dominating subsector for financial investor could not be observed. Looking at the countries, the majority of the deals including financial investors took place in India with 7 of 17 reported deals.

### Outlook and Summary

This study examined M&A activities in the chemical industries of the BRICs from January 2000 to October 2008. We found that the number and value of deals increased significantly throughout the observed period in every BRIC country. The petro- and agrochemicals segments resulted to be most affected by M&A activities in all BRIC countries. Further affected subsectors strongly differ from country to country. While analysing the investor types, we found that strategic investors clearly prevailed in the observed M&A transactions. The number of

financial investments, however, has been playing a minor role.

Domestic transactions dominated the landscape in terms of the ownership nationality classification as a result of consolidation which took place within the industries. Despite that fact, shares of cross-border transactions have been growing over the last seven years. International companies (primarily investors from the US and Europe) participated more actively in acquisitions of chemical enterprises in the respective emerging economies. However, it can be seen that an increasing number of enterprises from the BRICs also took the opportunity to acquire chemical companies abroad.

The recent economic downturn indicates a slowdown of the consolidation commenced in the recent years. In the long term, the trend towards internationalisation of the globally still fragmented chemical activities can be expected to continue and BRICs might play a key role.

Additionally, we would like to note that the statistical coverage of M&A deals in Emerging Markets is still developing. Therefore it can be assumed that the data basis for M&A deals might be comparatively poor, and the real number and value of completed deals can be expected to be higher.

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