

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 cooperation 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-

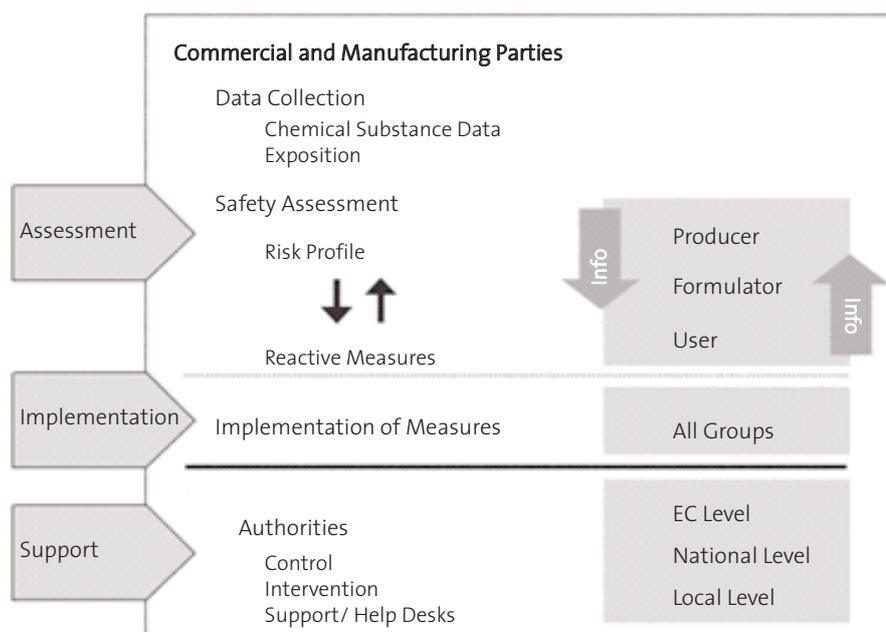
tiation of the various groups. Finally, the diversity of participant groups will be used in carrying out the socio-economic analysis as part of the Authorization procedure (Part 4). In the conclusion, we go into the significance of the SEA with respect to corporate REACH management.

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

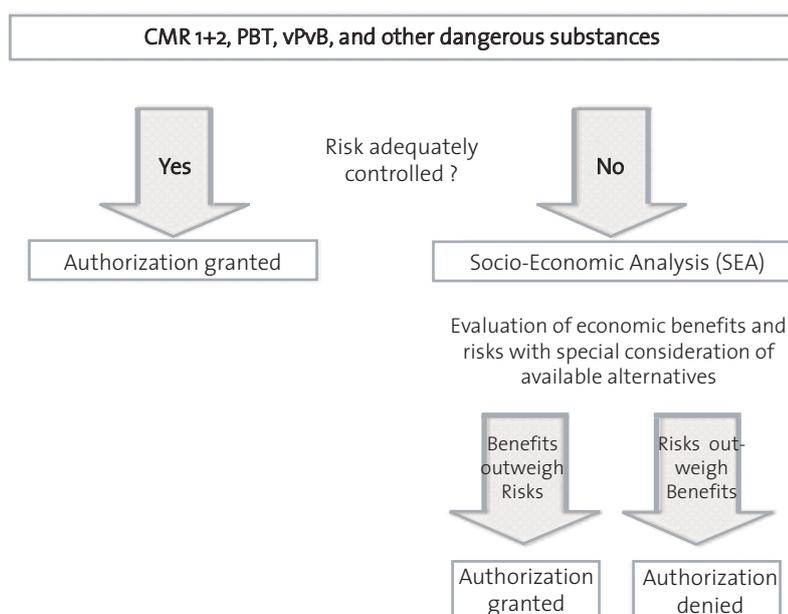
groups mobilize the topic and arouse public attention. In general, one must assume that a homogeneously structured consumer group does not exist and that therefore it is impossible to summarize the numerous individual consumer preferences. For this reason, it is legitimate to refer to the general consumer 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 Tschocher, 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 ¹ Down-stream Users ²	EC Comission ECHA ³ Member States National Authorities Help Desks
<u>External</u>	Interested Parties (as in annex 16) ⁴ Other affected Parties ⁵ Society at large ⁶	Interested Parties (as in annex 16) ⁴ Other affected Parties ⁵ Research and Development Non-EC States
		Inter-governmental Organisations ⁶

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.

⁷) 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 organization² 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

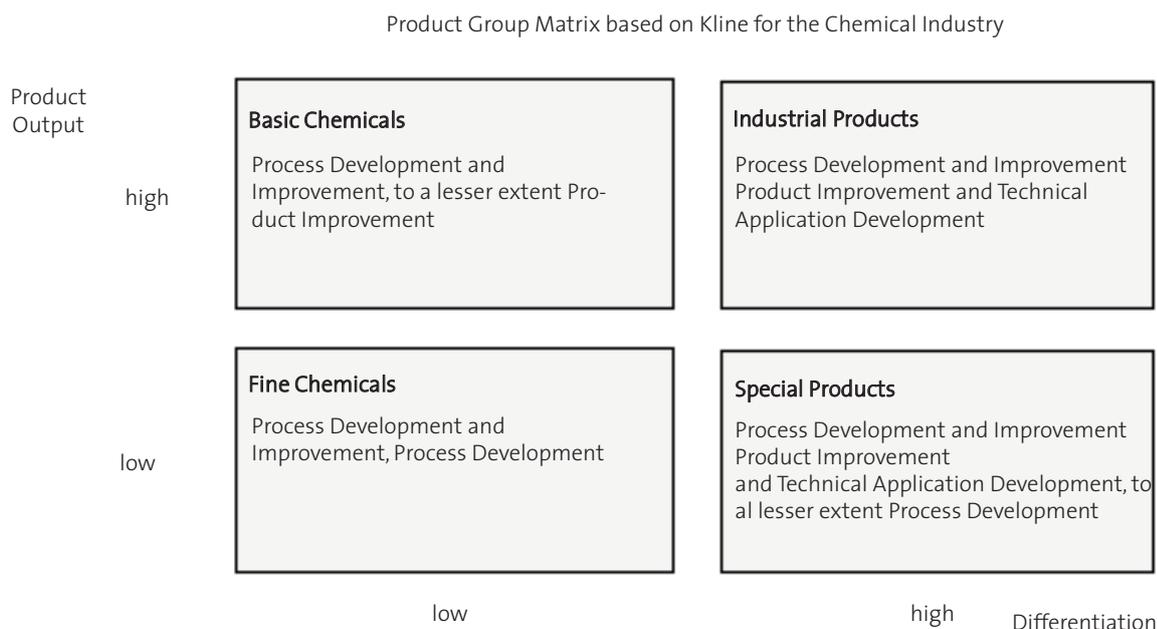
SME are explicitly mentioned and commented on in the Appendix 16 of the REACH legal text in connection with the process of the SEA. In the original text we can read that "wider implications on trade, competition and economic development (in particular for SMEs

[...]) 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 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			
Chemicals to Market	Test Requirements for Registration	No. of Substances	Existing Substances		Intermediate Products	
			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"³. 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 Works³

SEEBALANCE⁴ 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,

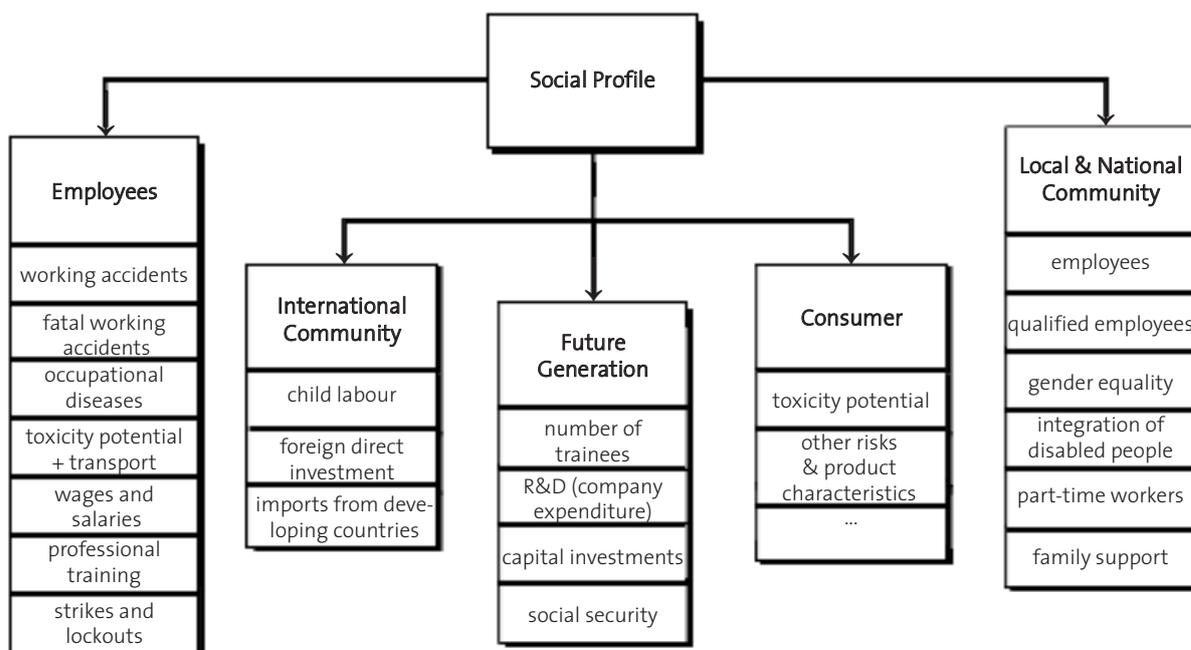
Future generations,
Local and national community,
International community,
Consumers.

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 authorization.

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