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Risk management under REACH Requirements upon technical and organisational guidance for producers, importers and downstream users

**Summary of a study performed for the
German Federal Environmental Agency (UBA), Dessau
FKZ 204 67 462/04**

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Darmstadt/Frankfurt/Köln/Hamburg/Göttingen, im November 2005

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The complete text of the study (in german) is available at:
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Summary

The success of REACH will depend on whether or not the actors are willing and able to adopt the roles allocated to them under the new regime. Yet it would be naive to assume that the simple fact of enacting the Regulation will be sufficient to effect the necessary changes in the behaviour of the responsible parties.

REACH aims to fill the gaps in the current chemicals safety assessment system for (existing) substances and to improve risk management where necessary. Responsibility for risk assessment and for developing the adequate risk management measures will shift from the authorities to economic actors. Furthermore, the current distinction between the risk assessment process on *existing substances*¹ and, based on this, the process of determining appropriate risk management measures will also be removed. This new scheme presupposes that the rights and responsibilities of all parties in the value chain are clearly defined. All parties' legal positions must be distinct and defined in relation to one another. Only then will a suitable framework exist to help companies, acting on their own responsibility, work together and create an efficient product safety system for the entire value chain.

The initial hypothesis in this preparatory study is that support, in the form of (technical and organizational) guidance specific to each type of economic actor, can help to push forward the necessary innovation and cooperation processes to implement REACH in the intended way. Thus transaction costs for each actor can be kept to a minimum and obstacles overcome. This also supports the central, structural objective of REACH to establish a "learning system", particularly with regard to the interaction occurring between the producers and users of industrial chemicals. To this end, sufficient regulatory (dis)incentives are essential. The question of possible amendments to the current draft of the Regulation will therefore also be addressed.

1

The starting point – *motivation matters*

The paradigm shift in chemicals regulation caused by REACH brings with it a clear requirement for more self-responsibility on the part of economic actors. The authorities' monitoring and inspection strategies will need adjustments to this development – indeed, it is this which makes the new regulatory regime such a paradigm shift.

The chemicals authorities have limited options for action as they are moved to the 'second line' as regards chemicals safety assessment. They must put aside the notion that all existing substances will be processed individually, under their supervision. In this respect, their range of 'imperative remote control' is curtailed. However, other control mechanisms increase. Improved availability of information enables more precise monitoring. And there are improved options for action on particularly problematic substances, as intervention procedures (such as authorization) become more efficient. In fact, REACH focuses 'imperative remote control' and thus makes it more effective.

Against this background, the central issue which emerges is the extent to which the various actors are willing to work together. Here, more than with any other regulatory scheme, the starting point for all efforts to bring about change is ensuring that the responsible parties addressed by the regulation are motivated – *motivation matters*. Another question must therefore also be asked:

¹ Substances marketed within the EC before 1981, the date when new requirements for pre-marketing notification of substances entered into force. The *existing* substances presently make up more than 90% of all substances in the chemicals market.

what incentives are there for the actors, and what obstacles lie in their way?

REACH addresses primarily companies. Therefore the motivations of economic actors need to be analysed. Experience gained with REACH simulation exercises so far shows that information relevant for risk management is held in different places within companies, for example in the sales department, the product development department or in the HSE (health, safety and environment) department. Communication and cooperation processes therefore need to be organized *within* as well as *between* companies covered by REACH. The decisive factor in this is the individual perspective of the managers within each business area. Therefore, where motivation is concerned, it is that of the people within the company in their individual roles and not just the motivation of the company as a whole which needs to be addressed when drawing up requirements for technical guidance – *personal motivation matters*.

The behaviour of a company and its employees is determined by a variety of factors. These can generally be divided into three distinct categories:

– *Willingness or motivation*

The company's motivation is to sell goods and services and thus make a profit.

– *Opportunity*

From the company's point of view, opportunities exist externally, for example in the form of market conditions or aspects of competition. They are also created by regulations and other institutional frameworks.

– *Capacity*

Capacity can be equated with those human and material resources available within a company that enable it to recognize and grasp opportunities which are in line with its motivation.

Factors from these three categories may be combined to predict the behaviour of the responsible parties in a regulatory context.

Traditional, normative legislative approaches have aimed at restricting the options available by means of requirements imposed by the authorities. They have also attempted to motivate addressees by threatening to impose penalties. In contrast, approaches based on self-responsibility must be centred on actors' own motivation, while also ensuring that they expand actors' capacity to achieve the objectives of the relevant legislation. However, such approaches must of course also keep in view the legal framework which enables regulators to limit the options available to companies to act in an undesirable way (regulatory (dis)incentives).

2

The basic question

This preparatory study addresses the basic question 'What is required of technical guidance which aims to support industry in its practical implementation of the REACH mechanisms?' Building on the behavioural approach outlined above, we can break this question down into two key areas:

1. Are the conditions (which in turn affect the opportunities open to companies) such that actors in the value chain are willing to adopt the new roles and responsibilities?
2. What conditions must be in place to allow actors within companies to fulfil these responsibilities (capacity)?

In the course of answering these questions, reference points will emerge which are relevant to

producing technical guidance in support of implementing REACh. At the same time, the roles to be played during the risk reduction process will be characterized in more detail.

3

The analytical approach

The methodology this study applies is a 'delta analysis' based on the institutional behaviour model (using *homo oeconomicus institutionalis*). The delta analysis aims to identify the deficits and barriers facing the various actors – issues which the technical guidance must address.

The responsible parties of REACh are primarily manufacturers and importers of substances, i.e. those who 'place these substances on the market' and hence bear 'primary responsibility' for the substances. These actors are at the top of the supply chain and bear the main weight of responsibility for assessing the safety of substances. The users of substances bear 'secondary responsibility', whether they use substances as such or substances in preparations. The draft REACh Regulation refers to such actors as 'downstream users'. Risks may also arise during the service life or disposal of articles. Although neither consumers, retailers nor waste management companies are addressed directly by REACh, substance manufacturers and importers must nevertheless consider in their safety assessments the risks which apply to these life cycle stages.

According to the REACh mechanisms, each actor must make specific contributions at particular times in order to spur the 'learning system' into action. It would not therefore be helpful to lump all actors together and consider 'the' incentives for companies. Instead, the aim must be to ask practical questions about which motivating factors will prevail when actors are in a given situation. The individual 'stages of risk reduction' required for REACh to work can be defined as follows:

S0	Introductory phase (Preparation for REACh)
S1	Identify the uses of chemicals and the operational conditions of use, as well as the existing and potential risk management measures (Preparation for registration)
S2	Ascertain conditions and measures for safe application by users in an exposure scenario; conduct and document safety assessment (Registration and chemical safety report in accordance with Article 34(4) of REACh)
S3	Apply management measures (to area(s) for which the respective actor is responsible)
S4	Communicate risk management measures to downstream users (DU/F)
S5	Communicate risk management measures to traders/consumers/those responsible for disposal

Figure 1: Stages of risk reduction under REACh

Delta analysis involves investigating the incentives and barriers at each of the above stages.

- a) What behaviour does REACh expect of the various actors in the value chain at each stage of the process?
What form of cooperation is required?

- b) What incentives are there for actors to behave in the desired way?
(What are the limitations or obstacles? Which business benefits? Available capacity?)
- c) Is there a discrepancy (or 'delta') between a) and b)?
- d) How can technical guidance contribute to reducing this motivational deficit?
- e) What motivational deficit persists even if technical guidance is used?

The answers to these questions were partly obtained from interviews with representatives of companies and associations. The findings from initiatives to prepare for REACH implementation (e.g. RIPs, SPORT) were also used.

In order to identify starting points for technical guidance, the principal possibilities for and limitations of technical guidance must first be established. Technical guidance on risk reduction should enable companies to identify and implement adequate risk management measures. However, technical guidance can neither increase the resources available for companies nor compensate significantly for a lack of motivation within a company. Another limitation is that technical guidance always goes hand in hand with standardization and therefore fails to take into account the unique context within each individual company. Nevertheless, technical guidance can be used to deploy available resources effectively and efficiently, using the motivation existing within a company, to achieve the required behaviour.

The role of technical guidance can lie purely in the realm of disseminating information to support the evaluation, planning and monitoring involved in risk management. However, it should also improve communications within and between companies by standardizing terms, concepts and procedures. This last point will be particularly important for the implementation of REACH. Technical guidance in support of communication processes has so far been very thin on the ground, so this is an area where considerable advances are needed. Furthermore, other forms of communication should be investigated besides the conventional type of written guidance documents.

4 Results of the analysis of incentives and barriers

In summarizing the results of this analysis, an initial distinction needs to be made between incentives arising from the market (market incentives) and those arising from the legal framework (regulatory and administrative incentives).

In respect of the factors motivating companies to apply the REACH mechanisms, the analysis shows that:

- In many cases, given the current setting, the market incentives for actors to actively identify substance-related risks and take preventative risk reduction measures exert little influence. Where such incentives exist (in consumer-near markets), even motivated actors fall at the hurdles of patchy information availability and high transaction costs. This is precisely why the EC legislator decided to take action.
- The determining motivating factor is therefore a regulatory one. The strength of this factor in terms of motivation depends on actors' perceived likelihood of being inspected by the authorities and on the penalties they would have to face in case of non-compliance.
- The improvements REACH will bring to the availability of information will allow the authorities to intervene in a more targeted way where actors fail to sufficiently control the risk. This will in turn

impact on the incentives for those responsible for production and use of substances, who will then attempt to prevent this type of intervention.

- Readiness to engage in the risk identification and reduction process will increase when actors recognize that the REACH mechanisms benefit them – such as through increased legal certainty and information-based measures – not just with regard to chemicals legislation but also in other areas where actors have to meet legal requirements. Such benefits, which stem from regulation but result in an improved competitive position on the market, can be expected in the following areas of law:
 - Product safety law and product liability law,
 - Occupational health and safety law, and
 - The various areas of sectoral environmental law (notably water, pollution prevention and control in industrial facilities and waste management).

The key benefit which actors on the market can derive from the REACH mechanisms in this context flows from their investment in information procurement. Such investment will yield clearly defined risk reduction measures, using standardized data on the hazards of substances and exposure assessments gathered and conducted in a structured process. Thus it will become possible to document the company's handling of the unwanted side-effects of substances in a way which is commensurate with risk and appropriate in view of the company's legal and societal responsibilities. This applies to communication within a company and in its dealings with customers, the authorities and other stakeholder groups (such as employees, local residents, shareholders and the general public). This documentation can be expected to contribute to an increased acceptance of the measures taken. The same could apply to legal disputes, for example in the context of (both civil and criminal) product liability cases or the authorization of industrial facilities.

- It should also be possible to counteract scandals being caused by certain substances contained in consumer products (such as textiles, nappies and vehicle upholstery) and thus prevent the drop in sales and negative publicity which often result.
- The REACH mechanisms may also contribute to a tangible increase in demand for products which are inherently safe to use, by reducing chemicals users' transaction costs of obtaining information on substance risks. This may be the case for production of construction materials, furniture or textiles (including vehicle upholstery), but could equally apply to manufacture of all types of household chemicals. A reduction in transaction costs can also be predicted for supply-side actors in the chemicals market (e.g. in the course of standardized evaluation and communication procedures). The supply of products with inherently safe product design is likely to increase.
- The clear identification and evaluation of risks will also provide a new basis for setting limits on emissions, which have to date mainly been based on available techniques, e.g. in issuing permits for industrial facilities. By adopting a more risk-based perspective it will be possible to move towards determining emission limits from the predicted environmental impacts, while retaining a precautionary approach. Thus the regulatory burden on companies can be more targeted.
- Another, similar advantage is that companies will have, in the results of the REACH mechanisms, a solid basis from which to defend their products from (excessive) legislative proposals aimed at restricting substance use or regulating products.

Where companies recognize the above advantages, they will be motivated to comply with the processes laid down in REACH and to translate these into risk reduction measures. These processes

require staff to implement them. If a company does not yet possess the required information on the substance' inherent properties, costs will be incurred in obtaining these. Reduction measures can of course also incur costs, certainly where adaptation of processes or product design is involved. The extent to which these cost factors may be influenced by technical guidance is discussed in chapter 6 below.

But first, here is a summary of the barriers identified during our analysis. At company level, the following barriers were identified:

- Ignorance of and uncertainty about the actual requirements and roles under REACH;
- A fundamentally negative attitude towards the Commission's draft Regulation;
- A lack of awareness that proactive behaviour brings advantages;
- Problems are also expected
 - with communication between departments in the same company in terms of data collection as well as
 - with the drafting of the chemical safety report and the expanded safety data sheet (due to a lack of tools).

Communication within and between companies is a key prerequisite for fulfilling REACH responsibilities throughout the value chain (vertical communication). Motivational issues with and barriers to this type of communication have been identified in the following areas:

- High start-up costs for communication structures;
- The lack of a common 'language' for discussing application of substances, operational conditions of use and risk management measures throughout the value chain;
- Concerns about the potential for breaking commercial confidentiality;
- A lack of incentives for downstream users to be proactive in approaching manufacturers;
- The first downstream user in the chain, normally a formulator, occupies a key position in the risk reduction process: As the first downstream user he receives the information from the manufacturer and also has a considerable knowledge of the conditions under which the substances are applied further downstream. In contrast, the manufacturer and the user of a preparation do not normally do business or communicate directly with one another. However, it is not clear to what extent the formulator will (want to) perform this bridging function in the REACH system;
- A lack of incentives for the manufacturer to identify and communicate adequate risk reduction measures for downstream users;
- Small companies may be overburdened by the requirements for communication and evaluation.

5

Managing self-responsibility:

Recognizing opportunity and building capacity

The results of the research project underline once again that, from the company's perspective, regulation concepts based on self-responsibility necessitate complex, challenging management strategies. Viewed through the lens of *regulatory choice*, this is therefore an approach which needs

many pre-requisites to be fulfilled if successful control is to be achieved.

For economic actors (actors in the market), REACH provides a greater degree of flexibility. Thus the orientation provided by behavioural requirements or threshold values set by the authorities will become less significant. The gain in flexibility, however, is also associated with the burden of communication and cooperation described above.

Since a thorough investigation of the factors that determine risk is neither possible nor realistic, REACH asks companies to perform a difficult balancing act. In each case, they must choose between a wide-ranging, broad-brush risk screening (scoping) approach and the requirement to undertake detailed risk analysis periodically. In business implementation, as in regulation, companies are required to *walk a tightrope* between standardized processes and case-by-case flexibility. REACH must both be user-friendly and elicit convincing results if it is to truly achieve the desired benefits for companies (and society). Technical guidance should therefore make both aspects clearly visible, so that actors are able to find the right balance for their own situations.

Self-responsibility does not mean regulating every last detail. Companies do not need detailed instructions. What they need is simple tools and the freedom to make *reasonable decisions* about how best to walk the tightrope.

The technical guidance should therefore contain a 'run-through' of the system, in the form of a straightforward (but fictitious) worked example which demonstrates the basic mechanisms, and allows simulation exercises such as gaming experiments. This run-through should be offered to selected customers and suppliers, a variety of departments in the relevant companies, associations/chambers of commerce and representatives from the authorities. This will give all these actors the opportunity to try out their new roles. Under the new requirement for 'self-responsibility', it will no longer be sufficient to organize compliance within a company. The challenge will be to (pro-)actively shape the processes.

6

Starting points for technical guidance

With regard to factors affecting companies' motivation (including the opportunity, willingness and capacity of both the company and its employees), the following starting points can be identified:

A. There is a need to support companies when it comes to their *capacity* (technical and procedural knowledge and skills).

1. In this context, the technical guidance would act as an aid, helping actors within companies to understand:

- Their roles and responsibilities within the REACH framework (implementing legal requirements correctly in their individual circumstances and gaining an overview of the REACH system);
- The specific nature of corporate behaviour in the context of self-responsibility;
- The need for action in the various stages of risk reduction;
- The necessary internal and external communication and cooperation processes (workflows relating to the internal flow of information and comprehensive planning processes for risk reduction measures).

For example, information-based tools such as 'conventional' guidelines based on knowledge transfer, but also training provision and online help can all contribute to building this capacity.

2. The importance of *communication processes* for the success of REACH cannot be overstated. The technical guidance should therefore focus on these processes in particular. It should aim to plot a course towards setting up and structuring internal and external processes. Again, this will not only be a question of merely disseminating information, but also of kick-starting (shared) learning processes in which actors can harness their *creative potential*.

Approaches which reduce actors' transaction costs provide the main starting points for technical guidance in this realm:

- Methods for gaining openness to seeing things from the perspective of other economic and administrative actors;
- Opportunities to identify and overcome barriers to communication;
- Approaches to identifying common interests;
- Methods for finding a common 'language' (to communicate uses, conditions of use and risk management measures by using standard phrases), and
- The development of suitable organizational frameworks for the cooperation processes required.

Targeted, guided learning experiences in 'protected environments' should play a particularly important part in the process. These could include experimental gaming exercises, which would not only allow actors to apply their factual, orientative and methodological knowledge in a practical scenario, but could also bring about changes to habitual behaviours and restrictive perceptual patterns. It would therefore be possible for actors to gain a new perception and open up to new ways of thinking.

The technical guidance should also describe models of communication processes, and should in particular make provision for training activities which provide personal learning experiences.

Due to resource requirements, it would be a good idea to employ the 'snowball effect', beginning a multi-stage process by offering initial, intensive training to skilled and knowledgeable multipliers.

This would also provide a good opportunity to establish standard phrases, concepts and methods, using existing chemicals industry standards as a basis in the first instance.

3. Actors need practical aids to draw up a chemical safety report (CSR), create a registration dossier and develop a safety data sheet (SDS).

Standardized formats (pick-lists containing standard wording, for example for types of application, conditions of application, risk management measures), technical guidance and other tools, including tools for evaluation, are all required. These could range from printed or electronic guidance documents to interactive tools.

The development of this technical guidance is already extensively covered by the REACH Implementation Projects (RIPs).

4. In view of the fact that the various actors each have their own interests, and that even the contributions required by REACH can vary greatly, it is recommended that all the tools outlined above be tailored to a particular target audience. It follows that, besides a 'general section', such tools should also contain 'specific components', designed to help individual actors identify their own information requirements and options. Such components could relate to

- the relevance of the REACH mechanisms to the actor's own portfolio of substances;
- the relevance of an actor's own products (substances, preparations and articles) to consumers and the environment;

- the question of which other actors to communicate with, on which issues;
- ways to analyse where customers' interests lie, and
- ways to assess the market value of REACH measures.

Guidance for analysing substance portfolios should therefore be included in the technical guidance, as well as communication aids for 'questioning' downstream users and customers. Illustrating best practice and worst-case scenarios by means of examples is particularly important.

B. There is also a requirement to support actors in companies in respect of their **willingness** and readiness to play an active part in REACH. This type of support could include help to understand the following points:

- The significance of having to obtain information on the properties and effects of substances;
- The market potential REACH will generate (improved customer relations, potential new applications, and an understanding of actors' own weight through their own demand on the market);
- The relevance of REACH mechanisms for the civil and criminal liability borne by company representatives;
- How to avoid negative publicity for actors' own companies and products;
- The relevance of the REACH mechanisms in terms of building a more robust foundation for action in other fields of law beyond chemicals legislation (such as product safety law, occupational safety or site related environmental law), and
- The development and furtherance of companies' strategies for safe product design.

These various facets of the draft Regulation may all be of benefit. This clearly illustrates the advantages actors in companies can gain from proactive engagement with REACH, even if their work does not hinge on the implementation of chemicals regulations.

The approaches listed under A.1 and A.2 come into play in addressing these motivational factors which have scarcely been part of the RIPs yet.

C. This study only examined the authorities' role insofar as it affects the willingness of REACH addressees to participate. The authorities' role mostly comprises:

- Helping companies to provide adequate documentation and to implement risk assessment and management (for example by providing implementation tools harmonized at European level, or providing help desks);
- Uncovering and penalizing any 'free riders' by means of compliance checks and enforcing sector-specific environmental legislation using the additional information obtained under REACH;
- Managing and evaluating information and, where appropriate, making this available to selected actors or the public (for example through the Substance Information Exchange Forum SIEF, or substance classification databases); and
- Making decisions about regulatory measures in relation to substances or uses for which market actors are unable to sufficiently limit the risks (authorization, restriction).

D. Sector associations and chambers of commerce have a particular role to play in the implementation of REACH. The main aspects of this role are:

- To support the formation of networks;
- To provide information to registrants on the usual conditions in which a substance is used. Based on existing risk management measures in the sector, good standard practice may be characterized;
- To paint a good image of a particular sector (in terms of REACH);
- To motivate and advise its member companies.

Sector associations and chambers of commerce need to rethink their roles. From now on, they may see more responsibility for initiating and moderating cooperation processes. Finally, they will be in a position to provide (highly qualified) advice, provided their employees are suitably trained. This will provide an opportunity to remind members of the added value they gain by belonging to an association/chamber of commerce.

In addition to the points made above (particularly those under A.1 and A.2), reports on the experiences of chemicals industry initiatives in forming networks would be useful.

7

Remaining regulatory deficits

Even assuming that the above proposals for actor-specific technical guidance are adopted, the motivational deficit will not be fully rectified. The following regulatory and administrative deficits can be seen as possible causes of this motivational deficit. These deficits have their roots in the division of responsibility between competent authorities at EC level, national chemicals authorities and regional enforcement agencies for occupational safety and environmental protection.

- With the legal framework currently foreseen in REACH, it is possible to submit registration documents containing insufficient information without being directly penalized. This means the registrant gains a cost advantage over any competitors who comply in full with the legislation (a clear case of ‘free riding’). The question of how to ensure that the safety documentation is of consistent quality across the board has yet to be resolved.
- One reason for this is that the text of the draft Regulation is not clear on the procedure and legal consequences to be applied in cases where registration dossiers remain insufficient in terms of safety documentation. It would therefore be appropriate to add the following clarification to Article 41(1) of the Regulation:

“If a registrant fails to submit the information required under Article 40(2) on time, or if it cannot be established with sufficient certainty on the basis of the information submitted which risks are associated with the manufacturing and use of the substance and how these are to be adequately controlled, the competent authority shall [may] draft a proposal for a decision which makes provision for the withdrawal [reversal] of registration; that decision shall be taken in accordance with the procedure laid down in Articles 48 and 49.”

A recital could be worded as follows:

This Regulation requires actors to practise self-responsibility. The obligation to submit meaningful registration documents is a key pre-requisite in order to nevertheless ensure a level playing field. Registration dossiers shall be subject to an initial, formal completeness check but not quality check. Registrants are responsible for the appropriateness of the information submitted. Irrespective of this, the authorities shall inspect random samples of dossiers submitted, including their content. Should the authorities establish as a result that a dossier fails to comply with the requirements of this Regulation, they shall demand that any missing information be supplied. If the registrant fails to supply this information on

circumstances he is responsible for within a reasonable timescale, the authorities shall be authorised to withdraw the registration. The authority to do so is not dependent on the existence of an unacceptable risk. Instead, this power to withdraw the registration shall apply as soon as significant deficits in the documentation are established. This is the case where documents contain no comprehensible risk management measures or where the proposed measures are not based on sufficiently firm evidence from the hazard and exposure assessments. The authorities' power to withdraw registration is intended to ensure that there is sufficient incentive for all registrants to submit meaningful registration documents. It will guarantee the consistent application of registration obligations and thus help achieve the objectives of this Regulation.

- Nor is it clear how to ensure that the recommendations producers make in relation to risk management are actually adopted by the other actors. Finally, there is the related question of how the substance-specific evidence generated within the REACH framework will be used to enforce other legislative regimes.

All of the deficits described above can lead to inequalities in the treatment of companies in different sectors or regions of the EC. The idea that competing companies would not be required to comply to the same extent with the REACH requirements is likely to have a negative effect on the willingness of every actor in the market. This could be expected to cause a deficit in the attainment of the REACH targets on risk reduction. At the same time, the issue arises of *unequal treatment*, which can be traced back to the regulatory level (a 'first-order implementation deficit' or 'instrument gap'), and responsibility for this therefore lies with the legislative bodies. It is possible that this constitutes an infringement of the principle of equal treatment, which would in turn mean that the Regulation was unlawful.

8

Conclusion: how technical guidance can help REACH succeed

Key factors for the success of REACH can be defined on the basis of an analysis of settings and incentives.

Chief among these factors is the **internalization of the paradigm shift** which REACH aims to achieve. This goes one step beyond mere 'compliance', to encompass a readiness among actors to adopt new attitudes and roles. In this regard, experience to date of the preparatory projects under REACH shows that it is essential to make available sufficient scope for and staff to support the preparation and learning processes.

The other key factors can be allocated to the behavioural categories outlined at the beginning of this summary, namely:

1. Possibilities (**normative boundaries, restrictions**):

Clarity on legal requirements themselves (responsibilities, laws, objectives and timescales), plus the likelihood of being caught and type of penalty for both infringement and free riding.

2. **Capacity**:

Resources available in companies (staff numbers, experience, skills, expertise and capital).

3. **Willingness**

Ability of economic actors to recognize benefits and opportunities; thus (un)certainly about financial cost and risks for their own company.

These are fundamental considerations for the design of the technical guidance. They can be

expanded as follows:

- Information has traditionally been part of all technical guidance ('the first component'). However, simply *being given* information and descriptions of processes is not enough. What actors need is *first-hand experience* (e.g. during a simulation) of the situations with which they will be faced. This means adding components to the traditional technical guidance model.
- Actors must also be *open* to the wishes and needs of other actors so they can each *see others' points of view*.

Whereas 'traditional' guidelines are aimed at a 'prototypical' actor within a particular organization (such as a company) and provide him or her with specific information and instructions, the 'second element' of guidance addresses the actor as a 'person'. It aims to enable actors to embrace the learning processes which are required if the normative objectives are to be achieved.

One particular point should be emphasized with regard to the effectiveness of technical guidance: a toolkit can help clarify normative requirements. It can build capacity and help provide an understanding of the motivational context. However, technical guidance cannot compensate for deficits in regulation. Nor can technical guidance in itself affect market forces. What technical guidance can do – and this is the main way in which it can provide support – is improve actors' awareness of the opportunities available and help them exploit those opportunities.

Finally, the processes supported by the technical guidance can also contribute to building trust between actors. Thus technical guidance fosters a vital resource for successful cooperation within society and the economy, and therefore for innovation.

9

Recommendations for producing technical guidance

The recommendations for action supplied in this study relate primarily to steps to develop and test technical guidance for REACH actors in industry. Yet aids should also be developed for actors within the authorities, especially with regard to the necessary regulatory incentives.

Finally, producing a cross-sectoral guide to the sets of technical guidance and guidelines for implementing environmental legislation that already exist in the various industry sectors would be a worthwhile endeavour.