

Self-responsibility as a regulatory concept – as illustrated by the REACH decision-making process

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1. Introduction

The term “*toxic ignorance*” plays a prominent role in the debate surrounding chemicals policy, not only within the EU, but also in countries such as the USA.¹ It refers to a lack of knowledge about the health-relevant and environment-related properties and effect mechanisms of the chemicals used,² and as such encapsulates one central problem which REACH is hoping to resolve. REACH aims to minimise existing knowledge gaps by calling on those responsible for substances to supply the relevant data. However, this alone is insufficient: The information thereby derived provides the basis for an assessment of substance-related risks and associated risk minimisation measures, which is ultimately the crux of the matter.³

Experience of existing substance regulations in the past has shown that this is impossible

¹ Environmental Defense Fund 1997 (Roe/Pease/Florini/Silbergeld): Toxic Ignorance: The Continuing Absence of Basic Health Testing for Top-Selling Chemicals in the United States, 06/01/1997 (<http://www.environmental-defense.org/pdf.cfm?ContentID=243&FileName=toxicignorance.pdf>); Massachusetts Precautionary Principle Project 2000 (Estabrook, Tom/Tickner, Joel): Facing Our Toxic Ignorance, <http://sustainableproduction.org/precaution/back.brief.html>; Winter (Ed.) 2000: Risk Assessment and Risk Management of Toxic Chemicals in the European Community, Baden-Baden.; v. Holleben/Schmidt 2002: Beweislastumkehr im Chemikalienrecht – Das Leitmotiv der Reformdiskussion auf dem Prüfstand, NVwZ 21, 532 – 538; Reh binder 2003: Allgemeine Regelungen - Chemikalienrecht, in: Rengeling, Handbuch zum europäischen und deutschen Umweltrecht (EUDUR), 2nd edition, Cologne, § 61, nos. 29 ff. and 214 ff.

² Lahl, Uwe; Tickner Joel: 2005: Chemicals Legislation – A Cross-Atlantic Comparison Zeitschrift für Stoffrecht, 3, 2004. <http://www.bmu.de/chemikalien/doc/6073.php>

³ Lahl, Uwe: REACH – Pro und Contra. Nachrichten aus Chemie und Technik. 1. 2003. Führ, Martin/Meremy, Stefanie: Interface Problems between EC Chemicals Law and sector specific Environmental Legislation (IPPC/WFD), German Environmental Protection Agency, Dessau 2005 (download: www.sofia-research.com). See also Gebers, Betty/Jendroska, Jerzy (Eds.) Environmental Control of Products and Substances with contributions (among others) by Eckard Reh binder, Jerzy Sommer, Luc Lavrysen, Halina Ward and Sanford J. Lewis and Pallem aerts, Marc: EC Chemicals Legislation: A Horizontal Perspektive, in: Macrory, Richard (Ed.): Reflections on 30 Years of EU Environmental Law - A High Level of Protection (liber amicorum for Ludwig Krämer), Europa Law Publishing, Groningen (NL), 2006, p. 199 – 234.

to achieve if every substance is required to pass through the various stages of evaluation and regulation by the public authorities. A substantial part of the burden must rest with the industry players if this is to succeed. To this end, the framework conditions need to be modified in such a way that the players are encouraged to make their own contributions to the correct functioning of the REACH mechanisms by means of adequate incentives. For this reason, the new system is designed to encourage those responsible for substances to obtain the necessary information, forward it to the competent authorities, and then initiate the necessary steps in order to limit the risks of their own accord, without the need for further government stipulations. REACH should be viewed as a “learning system” which is dependent upon proactive interaction between those responsible for substances throughout every stage of the value-added chain.

The paradigm shift in chemicals regulation brought about by REACH serves to significantly strengthen the responsibilities of industrial players, without being offset by an equivalent level of government control – this is the characteristic feature of the paradigm shift. The chemicals authorities need to move away from the idea that all existing chemicals are evaluated under government control; as such, their range of intervention is diminished. On the other hand, there are a number of specific control gains: As the information situation improves, government action will become more accurate. In the case of particularly problematic substances, opportunities will improve as a result of more efficient intervention procedures (e.g. authorization procedure) compared with the range of mechanisms previously available. Hence, under REACH, administrative control powers will become more focussed, whilst in a wider sense the emphasis will be on autonomous action by the players.

This central approach (self-responsibility) is currently the subject of a controversial debate between various different interest groups and within the decision-making bodies of the EC. For example, some of the more recent proposals favour the rejection of self-responsibility and a return to regulatory law and bureaucracy. We argue in favour of retaining the concept of self-responsibility and developing the associated mechanisms. Essentially, this is a vote in favour of the Commission’s original proposal and the British presidency’s mediation proposal (October 2005), as detailed below. First, however, we will examine self-responsibility as a regulatory concept within the general context of regulatory mechanisms, and will then explain how REACH utilises this approach.

2. Self-responsibility as a regulatory concept

Section (a) contains a brief description of “self responsibility”, while section (b) examines how this control mechanism is able to influence the opportunities available to individual players. Finally, an interim conclusion is drawn in section (c).

a) Obligations incumbent upon companies

Companies involved in environmentally relevant activities face a raft of “obligations”. These may be divided into three categories (see Fig. 1).

1. Firstly, companies are subject to “stringent” obligations which are punishable directly by law if violated, e.g. “Do not contaminate any waterbodies unless authorised to do so” (§ 324 of the German Penal Code - StGB -) or “Avoid damaging the legal assets of third parties (§ 823 of the German Civil Code - BGB -, § 1 of the *UmwelthaftungsG* <Environmental Liability Act>).
2. Secondly, there are also “incomplete obligations”, whereby the law demands a certain form of conduct – generally described in a positive way – but without stipulating the precise contribution expected from individuals. This type of obligation category may be characterised as “self-responsibility”, and is a legal requirement, despite its *ex ante* openness.
3. Finally, there are areas where no concrete conduct expectations have been formulated in law and which could be considered areas of “free will” (“voluntariness”), which does not mean to say that there are no conduct expectations whatsoever. Instead, such areas are still subject to informal rules in the form of social demands which could be described as ethical “virtue”. This could be characterised as “moral responsibility”.⁴

⁴ Of course, ethical conduct requirements also form the basis for legally formalised conduct expectations, but are not legally effective as such (and for this reason are shown beneath the dotted line) but need to be adopted in law, either explicitly by means of suitable standardisation, or by meeting “non-specific legal concepts” (such as “in good faith”, “significant impairment”) with recourse to social virtues; in this respect, cf. Führ 2003, *Eigen-Verantwortung im Rechtsstaat*, Berlin, 53 ff.

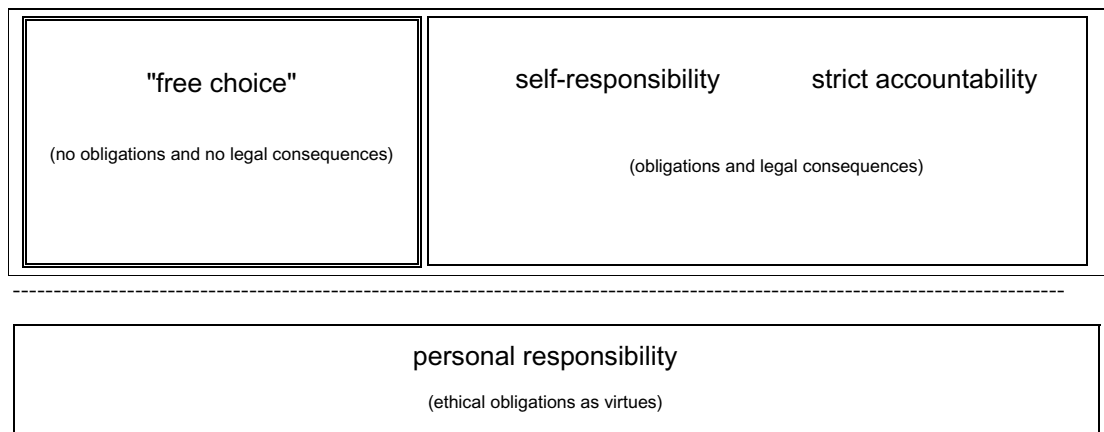


Figure 1: Overview of responsibility categories

Hence, it can be asserted that obligations based on self-responsibility are legal obligations which formulate certain conduct requirements but without drawing any clear lines. If a player fails to meet these requirements, the consequences ("sanctions") may be indirect to begin with (such as the loss of benefits or negative publicity), but may assume a more direct form later on following official or judicial concretisation.

b) Control through self-responsibility?

The purpose of legal standards is to influence human conduct. It is therefore necessary to examine the controlling effect of legal mechanisms based on self-responsibility against the backdrop of the incentive situation faced by the various players.

In general, it can be said that the more official enforcement is targeted at a specific individual case, the more resource-intensive and susceptible to counter-pressure it becomes. The enforcing authorities (or the parliaments which set the statutory and budgetary framework) therefore need to establish whether there are adequate enforcement mechanisms and resources available for the tasks allocated to them.

Environmental regulations should protect the general public as well as specific individuals from the undesirable consequences of economic (or planning-related) activities. Given the imprecise nature of statutory requirements based on self-responsibility, the key question centres on the level of protection demanded by the law in any given case. As such, it is a matter of concretising the basic obligations in relation to a specific situation. If this is successful, affected third parties may consider whether or not this is thought to provide an adequate level of protection.

Ultimately – and also with regard to the incentive situation of the companies and the authorities – the key question is whether third parties can effectively incorporate compliance with basic obligations into the decision-making process, and whether this can be enforced by the courts if necessary.⁵ Beyond the existing legal opportunities, any consideration of effectiveness must also examine the question of whether affected third parties have access to adequate resources as well as participatory and legal protection mechanisms.

From the general public's point of view, interest will focus on how the players make use of the responsibility conferred upon them. To this end, suitable mechanisms are needed in order to ensure transparency of the outcome and procedures, ideally in a user-specific form wherever possible. In this respect, regular enforcement reporting⁶ should ideally be anchored in law.

Additionally, a platform should be created via which the level of successful control achieved may be discussed. This may take the form of public or semi-public forums, supported by online facilities.⁷

c) Interim conclusion on control mechanisms

If environmental controls are to be successful, the mechanisms of imperative control are no longer sufficient; in addition, a full range of supplementary mechanisms is also needed. These should identify the respective incentive situation and steer it in the direction of the

⁵ According to the prevailing doctrine in Germany, this presupposes that the basic obligations are seen as "protecting third parties", either wholly or in part. This may vary in other EU States; but the jurisdiction of the ECJ is also more generous in this respect (cf. Wegener 1998: Rechte des Einzelnen). Thanks to the Aarhus Convention and the EC Aarhus Directive (2003/35/EC), environmental organisations now have access to improved opportunities; cf. in this respect Sadeleer/Roller/Dross 2005: Access to Justice in Environmental Matters and the Role of NGOs and Führ/Betty/Ormond/Roller, 1995: Access to Justice: Legal Standing for Environmental Associations in the European Union.

⁶ One such mechanism is the "Federal Government Immission Protection Report" pursuant to Article 61 of the Federal Immission Control Act (BImSchG). Since 2001, in accordance with Article 11 of the Environmental Information Act, there has been an obligation to report on the "state of the environment" as a whole. On the mechanism of enforcement reporting, which is now an established feature of the Trade and Industry Code (annual reports by the Trade Supervisory Office pursuant to Article 139b of the GewO), cf. also Lübke-Wolff 1996: Modernisierung des Umweltordnungsrechts, page 196 ff., which calls for a systematic comparison of the need for enforcement versus actual enforcement.

⁷ Cf. in this respect Becker/Dopfer et al 2005: Electronic Public Participation (ePP), www.sofia-darmstadt.de.

social control target (responsive regulation⁸). Self-responsibility addresses the core problem of modern environmental legislation in the dichotomy between stringent/general government regulation on the one hand, and dynamic (i.e. flexible) consideration of the individual case on the other.

From a politico-scientific viewpoint, if the legislator decides to rely upon elements of self-responsibility, the regulatory bodies may indicate the approximate direction, but not prescribe specific conduct contributions. As such, the problem of definition will shift into the hands of industry, and any intervention by the authorities is at best supplementary; figuratively speaking, the regulatory authorities take a back seat.

In this way, the legislator can avoid resolving the conflict directly. Often, however – as seen in the case of substance-related risk minimization – the requirements for successful imperative control do not exist in the first place. As such, the only remaining question is which form of self-responsibility the legislator will opt for.

This should also be viewed in connection with symbolic regulation: The legislator faces the risk of giving a mixed message, by on the one hand dictating that the problem must be seriously addressed, yet on the other hand, whether consciously or unconsciously, structuring the institutional framework in such a way that successful control becomes highly unlikely.⁹

Any serious attempt at a regulatory system based on self-responsibility needs to strike an effective balance between self-responsibility and stringent guidelines: The institutional context thereby created must offer adequate incentives for the players to make the required conduct contributions in order to fulfil the legislator's regulatory concept.

3. Self-responsibility under REACH

If one takes the view that the main objective of chemicals legislation is not to compile data but to minimise substance-related risks, suitable framework conditions need to be considered by the legislator. Additionally, if one accepts that successful risk minimization is dependent upon the involvement of the social players, the next logical question is to

⁸ Cf. in this respect Bizer/Führ/Hüttig (editors) 2002: Responsive Regulierung – Beiträge zur interdisziplinären Institutionenanalyse und Gesetzesfolgenabschätzung, Tübingen (Mohr Siebeck).

⁹ Cf. in this respect Hansjürgens /Lübbe-Wolff (editors) 2000: Symbolische Umweltpolitik., Frankfurt (Suhrkamp).

determine what form of motivational “assistance” is needed in order to support substance registrants and commercial users, and help them meet their obligations under REACH. This constitutes a very ambitious control problem, because various different players need to work together under REACH.

In the light of this, the key issue is the willingness of the players to become involved. To a greater extent than with other regulatory projects, this means that the motivational situation of those targeted by regulation must constitute the starting point for any attempt at change.

For this reason, with a view to successful risk management under REACH, we need to ask:

- a) which **conduct contributions** are needed from the individual players, and
- b) given the **incentive situation** created under REACH, whether these conduct contributions are likely to be forthcoming, or whether a “motivation gap” still persists?

In a third stage one would also need to consider which additional “assistance” and standards could be provided in order to facilitate self-responsibility.¹⁰

a) Conduct contributions of the players

With regard to risk minimisation abilities – and hence the conduct contributions achievable via REACH – there may be substantial differences between companies within the value-added chain (producers, formulators and users). This applies to the interest situation of the individual players (in part characterised by a competitive situation, where applicable), as well as to the opportunities for action at their disposal and the combination thereof throughout the various stages of the substance use chain.

A central factor in this respect is access to information and the (cooperative) processing of that information in relation to substance-based risk management. Whilst the holder of “primary” responsibility for a given substance (manufacturer or importer) is well-informed about the processes occurring within his own organisation’s sphere of influence and – if the substance is formulated by a third party – comparatively familiar with the latter’s

¹⁰ For a differentiated analysis of the incentive situation of the REACH players and associated proposals for supplementing the framework conditions, cf. Führ/Heitmann/Koch/Krieger/Ahrens et al. 2005: Risikominderung für Industriechemikalien nach REACH Anforderungen an eine Arbeitshilfe für Hersteller, Importeure und Stoffanwender, im Auftrag des Umweltbundesamtes (FKZ 204 67 462/04); further details are available at www.sofia-research.com.

requirements and manufacturing conditions, his knowledge of downstream processes and/or applications and the related emissions and exposures tends to be imprecise or inadequate, particularly with regard to processes at the end of the value-added chain. Conversely, the downstream user has in-depth knowledge of the respective substances in their specific application area, but tends to have major knowledge gaps vis-à-vis the effects and risks of the substances.

When controlling social risks, several players usually need to cooperate; this is true of many fields, not just chemical safety. It is impossible to predict in advance which specific contributions the individual players should make. As such, the law creates an institutional framework which is designed to initiate a process and accompany it in a controlling way. In the case of REACH, the key aims are as follows:

1. to identify and evaluate the substance-related risks throughout the entire value-added chain (risk assessment);
2. to identify and evaluate strategies for risk management, and
3. to ascertain which contributions to risk management are to be made by the various players.

As such, the question as to which *concrete* risk control measures should be performed by each of the individual players cannot be answered until the *learning process* institutionalised by REACH, which is based on cooperative interaction between the players, has been accomplished. At this stage we can only postulate the likely contributions to this learning process from the individual players. To begin with, conduct expectations will focus primarily on information and procedures, and only in a subsequent stage will these be supplemented by material risk limitation actions.

b) Incentive situation

Turning our attention to manufacturers and importers as the holders of “primary substance responsibility”, in simplified terms, the incentive situation may be outlined as follows: The supplier of an existing substance is wary of any potential threats to the established marketing of the substance. Any attempt to rectify “toxic ignorance” is viewed as an attack on his market position. For this reason, any such attempts may well be vehemently rejected. Admittedly, “toxic ignorance” also entails a liability and marketing risk for the supplier. However, the onus of proof lies with the damaged party, which is generally not in

a position to raise the “veil of ignorance”, not to mention the problem of establishing toxicological proof. Despite the associated uncertainties, from the point of view of the supplier there are several factors in favour of leaving the current state of play unaltered. As such, this group of players is often reluctant to get involved.

REACH's response to this has been to require the holders of primary substance responsibility to register their existing substances (with additional licensing in the case of particularly hazardous substances). Failure to register will mean that they are no longer entitled to market the product once the relevant transitional period of three, six or eleven years respectively has expired. With around 30,000 substances expected to be registered, the materials testing requirements are significantly lower than with new substances (according to existing law); on the other hand, the authority can only give the registration documents a cursory check for completeness and has few opportunities to verify the validity of the data. Now, however, manufacturers have a formalised, timetabled obligation to make a basic data record available containing toxicological information. Manufacturers who currently take their responsibilities under existing legislation seriously should not need to make any major additional efforts in order to pass the first hurdle of REACH.¹¹

Hence, basic information on substance properties is now available; however, the truly decisive stage – namely, of minimising substance-related risks – is still outstanding. On the other hand, manufacturers are required to give information on this aspect as well.¹² In the reasoning for Article 13 this provision is intended to ensure that “those creating or importing substances cannot shift *responsibility* for assessing the safe management of a substance onto downstream users¹³ who may be ill-equipped to deal with it. It also

¹¹ Lahl 2004: REACH und der Mittelstand. Mitteilungen der Fachgruppe Umweltchemie und Ökotoxikologie. 10, 3: http://www.bmu.de/files/reach_mittelstand.pdf.

¹² General obligations for the manufacturers and importers of substances liable to registration may be found under the title “Chemical safety report and duty to apply and recommend risk reduction measures” in Article 13 of REACH. A general risk management obligation – within the context of the application range of Article 13 – is contained in paragraph 6 of this provision: “Any manufacturer and importer shall identify and apply appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets which he supplies in accordance with Article 29”.

¹³ The definitions of terms in Article 3, no. 11 of REACH are as follows (on the term “use” cf. footnote 16): Downstream user: Any natural or legal person established within the Community, other than the manufacturer or the importer, who

facilitates the work of the authorities”.

Regarding the *scope of substance responsibility*, this comprises

- the manufacture of the substance, where this occurs in the EC,
- the use of the substance by the manufacturer or importer himself and
- all the registrant’s identified uses.¹⁴

The scope of substance responsibility is therefore comprehensively defined.¹⁵ It not only includes the manufacture, reprocessing and formulation by the manufacturer (or importer), but also includes other uses where listed in the registrant’s technical dossier. “Use” also includes the incorporation of the substance into a product (“production of an article”)¹⁶ and the risks associated with that product.

REACH does not give precise instructions on how this substance responsibility should be met by the manufacturer, stating only that the manufacturer must select certain applications and make corresponding recommendations in the safety data sheet.

On this basis, the manufacturer must consider which uses are to be included in his substance safety report. On the one hand, manufacturers have a vested interest in including many uses as possible, because this will broaden the sales potential for their substance. On the other, by including a given use in the substance safety report, the manufacturer is also assuming responsibility for its use.¹⁷ The less familiar he is with the

uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 4(2)(c) shall be regarded as a downstream user”.

¹⁴ The definition of this term in Art. 3 No. 25 of REACH is as follows: “Identified use: Use of a substance on its own or in a preparation, or use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user and that is covered in the safety data sheet communicated to the downstream user concerned”.

¹⁵ In this respect – with regard to the information to be submitted as part of registration – cf. Article 9 a iii) in conjunction with Annex IV, section 3 (which states that the manufacturer may also advise against certain uses in the form of a non-statutory recommendation, no. 3.7); on the scope of the exposure scenario, cf. No. 5.1.1, Annex I.

¹⁶ Cf. the definition of the term in Article 3, no. 12 of REACH: “Use: Any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation”.

¹⁷ The extent of this responsibility is in a civil and criminal law context depends on the circumstances of the individual case. For illustrative purposes cf. for example the leather spray judgment by the German Federal Court of 6 July

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concrete conditions of use, the more a manufacturer is dependent on the willingness of other players to get involved. From the viewpoint of manufacturers and importers, this poses the question of how to gain other players' support (and if unsuccessful, how the manufacturer will deal with the resultant uncertainty).

Considering the incentive situation from a substance user's perspective (downstream user), it is clear that the substance fulfils a certain function in the manufacturing process or in the product. Disregarding the costs and risks of conversion, it is irrelevant how this function is met. A lower-risk variant is undoubtedly preferable, in terms of both production and product design. Apart from the relevant provisions in installation and product legislation, both are favoured from a liability aspect. This affects both production risks (Environmental Liability Act) as well as risks resulting from the product itself. In this respect, the user represents the "interface" between production and the consumer market. If damage occurs, the user is the front line as far as the general public is concerned. He is also the main focus for liability under civil and criminal law.¹⁸ As such, his image and sales are also the first to be affected by the adverse consequences. He therefore has a vested interest in avoiding such consequences.

However, this does not necessarily imply that the user is willing to disclose his conditions of use to the holder of primary substance responsibility, as he may be concerned that such information could fall into the hands of competitors by a variety of means, including the information contained in the substance safety report. If there is a chance that operational and business secrets could be disclosed via such means (although the extent of the problem is debatable, since much of the information is likely to be known already to industry insiders or can be ascertained fairly easily), the security attainable from giving manufacturer recommendations must outweigh the competitive disadvantage if the user's support is to be gained.

1990 (BGHSt 37, 106 = NJW 1990, 2560). Even prior to this judgment, Schmidt-Salzer (NJW 1988, 1942) concluded that: "Just as within companies, responsibilities complement one another but can also overlap and intersect in some cases, so too can the duty of care of individual employees under criminal law overlap, intersect and complement one another in some cases. For this reason, the actual division of labour implies a multiplication of responsibility in criminal law terms." The same should be true of the division of responsibility along the value-added chain. For a very instructive account in this respect, cf. Schmidt-Salzer, in: Schering AG (editors) 1992.

¹⁸ This is illustrated, for example, by the aforementioned *leather spray* judgment by the German Federal Court of Justice; cf. footnote 17.

The formulators assume a key role when resolving these information problems: Compared with substance manufacturers or importers, they have access to broader and more accurate information about the value-added chain. Additionally, they are in any case in contact with their customers, and must be able of combining this information (and associated risk minimization measures) for several individual substances in a comprehensible format for users.

Like manufacturers, however, formulators are wary of losing “tried and trusted” marketing channels as a result of substance safety information. Provided material alternatives are available which are capable of fulfilling the user’s desired functions, and provided the formulator is capable of mastering the necessary procedures, he will be open to substitution. However, whether or not these requirements are met can often only be determined on the basis of practical trials and experience.

Disregarding transaction costs, the formulator will always opt for the lower-risk material alternative, provided the achievable benefit outweighs the cost involved.

Taking transaction costs into account, the formulator will seek institutional arrangements enabling him to guarantee the required exchange of information with his respective cooperation partners on both sides of the value-added chain. This will entail a number of new tasks. Above the individual level, the potential advantages will benefit other players as well as himself, particularly users, who will therefore be willing to cooperate without divulging any production secrets. For the manufacturer, there is a risk of losing individual marketing channels; but this may be offset by an opportunity to acquire more in-depth knowledge of the requirements throughout the value-added chain, which may prove useful for future entrepreneurial strategies.

c) Interim conclusion on self-responsibility under REACH

At the level of a legislative instruments, REACH combines a mixture of control tools with a significant departure from conventional “hierarchic” regulatory legislation. The current existing substances legislation, with its sovereign testing techniques and derived measures (primarily substance restrictions via EC-Regulations), has failed to achieve the desired results, due to the complex technical issues involved in chemical safety. The reform of substance law under REACH retains a core area of regulatory law for high-risk substances, but introduces “modern” control mechanisms for the bulk of chemicals based on independent risk identification and risk assessment, leading to a risk minimisation

process that incorporates all players.

Registration occurs by forwarding a data and assessment dossier to a central chemicals authority. This priority of communication between company and authority is the most visible aspect of the new substance law, but from a control viewpoint its importance is actually secondary. More important is the fact that companies are required to draft their findings according to a predefined procedure (self-responsibility). The true risk minimisation potential can only be exploited by means of communication and cooperation processes throughout the value-added chain. REACH expects the derived findings to be processed within the corporate structures and to culminate in responsible action. The procedural regulations will inevitably lead to the creation of documentation, which is significant from a liability viewpoint. First and foremost, however, this is about the introduction of a regulatory framework designed to strengthen the self-responsibility of players within the chemical industry and its customers (downstream users).

One problem with the Commission's draft of REACH is its lack of clarity regarding the consequences for a producer who submits a registration dossier which, although formally complete, is found to be inadequate in terms of content, thereby failing in his duty to self-responsibility. In order to create adequate incentives for this key motivational issue and prevent "freeloaders", REACH needs to be accompanied by liability provisions.¹⁹

4. VCI and the European Parliament: A return to regulatory legislation and bureaucracy

It is interesting to analyse how the various stakeholders assess the provisions of the REACH draft on the complex issue of self-responsibility.

Traditionally, environmental and consumer protection organisations, particularly NGOs, have been sceptical or opposed to the concept of control via self-responsibility. In the current REACH debate, however, this is not the case - on the contrary: These stakeholders are supportive of self-responsibility and consider it a correct and expedient control mechanism. However, they point out that the framework conditions should incorporate adequate incentives to ensure that self-responsibility is followed up by actions, and

¹⁹ In such a case, it would be necessary to waive the effect of registration and hence the right to market the substance. For a formulation proposal in this respect cf. Führ/Heitann/Koch/Krieger/Ahrens et al. 2005 (footnote10).

random sampling by the authorities must lead to sanctions if misconduct is ascertained.²⁰

The affected industry is particularly critical and unaccepting of the self-responsibility-activating elements of REACH, which are criticized as being too bureaucratic and impracticable.²¹ This viewpoint is expressed, for example, in the VCI proposal for a revision of the REACH draft.²² In this proposal, provisions aimed at self-responsibility are scaled down and replaced with a greater emphasis on etatistic, regulatory control mechanisms (whereby the envisaged central Agency in Helsinki would be responsible for examining individual cases, formulating requirements and specifications, and decision-making).²³

This rejection of self-responsibility as a regulatory concept is also repeated in some of the individual submissions from Member States.²⁴ For example, the Commission proposal envisages that manufacturers should perform risk analyses at their own responsibility, based on the data obtained. Apart from this, they need not schematically submit tests and conduct risk analyses according to a specific tonnage. They may at their own responsibility decide to deviate from the regulation according to clearly defined criteria, but must give a good justification for doing so and are responsible for any deviation from the rules.

The alternative proposals put forward by industry, which have now gained the majority support of the parliamentary committees on industry and internal markets as well as in the EP legislative resolution of November 17, 2005,²⁵ focus predominantly on the new

²⁰ Cf. for example the Common Position of the Federal Government, Greenpeace, Verbraucher Initiative and Women in Europe for a Common Future (WECF) of 4 July 2005; under http://www.greenpeace.de/themen/chemie/nachrichten/artikel/grossangriff_auf_eu_chemikalienreform/.

²¹ Handelsblatt of 25 November 2004 and lecture by G. Fink (VCI) at the conference "REACH? Ja – aber praktikabel! Studien und Vorschläge zur Umsetzung": Workshop VIII in the series "Gesprächsstoffe – Dialog zu Chemikalien, Mensch und Umwelt" <http://www.vci.de/default.asp?cmd=shd&docnr=103251&rub=738&tma=879&nd={4>>, <http://www.vci.de/default.asp?cmd=shd&docnr=92067&lastDokNr=90708&nd={4>#>.

²² In this respect cf. <http://www.vci.de/default.asp?cmd=shd&docnr=102353&lastDokNr=90708&nd={4>#> and also the legal text, which was due for submission at the end of January 2005.

²³ Cf. also the proposal of cefic: http://www.cefic.org/files/Publications/proposals_to_improve_workability.doc.

²⁴ As per the application by Malta and Slovenia for the minimum data record in the annual tonnage range of 1 to 10 tonnes in the EU Council, March 2005.

²⁵ European Parliament, Committee Internal Market and Consumer Protection: Amendment by Hartmut Nasauer and Committee on Industry, Research and Energy: Compromise Amendments C81-190 and Opinion of 16.9.2005. See

chemicals authority in Helsinki. Under this proposal, manufacturers would only be required (in the lower tonnage range) to submit available data. The authority would then decide whether to request additional data and would be responsible for enforcing such requests (within the context of a time-consuming comitology procedure). In simplistic terms, if the specialists at the chemicals authority in Helsinki were to conclude that a skin sensitization test were necessary for a given substance, a committee procedure would first need to be carried out, during the course of which the various Commission departments would compile draft implementation measures and opinions and submit these to the so-called comitology commissions, comprised of representatives of Member States, before a decision could be reached. This bureaucratic procedure means that the burden of work, justification and liability would shift from the manufacturer to the central authority, and this would apply to around 20,000 substances (or 25,000 substances, according to the internal market committee).

There are similar differences over the so-called waiving of long-term testing. The impacts of substances with long-term exposure are particularly significant from the viewpoint of health and environmental protection. The industry is fearful of the cost of testing, not to mention the possible outcome of the tests. The Commission proposal contains an option stating that the manufacturer may waive testing if he has reason to do so. Hence, a substance need not be subjected to time-consuming testing, for example, if it is permanently linked into a chemical matrix and is not released. Testing is waived on an autonomous basis and is only controlled by the authorities via random sampling. Waiving occurs at the responsibility of the manufacturer.

The proposals and decisions of the aforementioned parliamentary committees and the proposals of the chemical industry envisage that as a general rule, the chemicals manufacturers need not perform long-term testing and the authorities must justify and enforce exposure arguments if long-term testing is considered necessary for the purpose of risk analysis. As a result, responsibility for risk analysis in this field is transferred from the manufacturer to the authority.

also the EP legislative resolution of November 17, 2005, C5-0531/2003 – 2003/0257(COD) showing a differentiated picture of the EP position on REACH strengthening on the other hand the health protection emphasis and the role of the consumers in the REACH context.

5. Summary

For industry players, REACH offers a high degree of flexibility appropriate to the situation; the state is prepared to forego the security (which closer examination reveals is in any case limited) of government-prescribed conduct regulations at its own responsibility (e.g. in the form of limits or technical standards). However, this acquired flexibility is linked to the burden of communication and cooperation devised by the REACH mechanisms. The realisation that freedom and responsibility are “intimately intertwined”²⁶ in a state founded on the rule of law is obviously a deterrent for some. However, rather than reverting to regulatory patterns that in the past have already proved both inadequate (in relation to environmental and health concerns) and (from an economic viewpoint) innovation-hampering, it would be preferable to consider ways of assisting the players in order to enable them to utilize the freedom acquired.²⁷

The debate surrounding the Commission’s draft of REACH has shifted in recent months, and has moved away from a fundamental questioning of the reform of EC substance law to focus instead on the issue of how REACH may be structured as effectively and practicably as possible. This debate is currently taking place within the context of decision-making in the Council and in the European Parliament. It is noticeable that industry specifically opposes that part of REACH which formulates self-responsibility. Paradoxically, its central argument is that REACH is too bureaucratic. As an alternative, industry offers proposals whereby responsibility for risk evaluation and risk management is placed more firmly (or exclusively) on the future central chemicals authority in Helsinki. Whilst these proposals may appear “clearer” and “more manageable” at first glance, they are regulatory in nature. This was the very reason why current substance law has failed, because it is impossible to regulate the complexities of around 30,000 substances with millions of different application areas using a control mechanism whereby the onus is on the authorities to take action and decisions take the form of lengthy administrative procedures. The authorities are likely to be overburdened, leading to considerable time delays in processing the substance analyses. In essence, these proposals are actually far more bureaucratic than the Commission’s REACH proposal based on the principle of self-

²⁶ Raz, Joseph 1986: *Morality of Freedom*, Oxford, p. 19.

²⁷ Where this form of assistance can be applied and how it should be developed is the subject of a study by Führ/Heitmann/Koch/Krieger/Ahrens et al. 2005 (footnote 10).

responsibility. Presumably, the desire to relieve manufacturers from liability risks is an additional motivating factor.

The aforementioned proposals not only put the onus on the authorities to take action, but also – assuming use is made of them – require corresponding bureaucratic structures and procedures, the very thing which the EC is keen to minimise as part of its regulatory agenda.

Against this background, the REACH proposal is the correct response, by defining the procedures for industry to conduct risk analyses and risk management at its own responsibility and move in favour of liability legislation. The liability risk for self-responsibility should remain with the industry players in whose sphere of influence the substance use occurs and who are therefore in a position to develop and market innovative solutions. REACH's intention of encouraging innovations and facilitating their market success would be at risk, were the onus for action to shift onto the authorities. What is more, this would also restrict the economic opportunities of innovative companies who would otherwise have greater market opportunities, not only in the internal market but also in terms of export.

In order to elucidate this, any technical discussion of selected details in REACH must also consider the fundamental regulatory approach. The task of this debate will be to convince industry and the political decision-makers of the benefits of controlling risk minimization through self-responsibility. Consequently, in the decision-making process we should support the original Commission proposal and/or the mediation proposal by the British presidency, which does not contain the shift in responsibilities outlined above.

As such, the direction of thrust of this debate is twofold: On the one hand, the basic concept of self-responsibility is to be retained; on the other, the legal context must be developed in such a way that the REACH mechanisms give adequate motivation for risk identification and minimisation. Supplementary to this, work aids, user forums and other organizational arrangements should strengthen the companies' ability to minimise risks and communicate the liability consequences for "black sheep".

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