

ECRN Workshop

REACH-Regulation - the burden of proof and the work for experts and expert communities

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1. Introduction

The reform of European Chemicals legislation and the establishing of the REACH system is one of the most far-reaching legislative initiatives in the history of the European Union. The new system will not only make the European Union a global forerunner in the regulation of chemicals. It furthermore opens up a new dimension in regulatory standard setting in the EU. The shifting of responsibilities to industry, the combination of hierarchical rules with self-regulatory approaches in the supply chain as well as the proceduralisation of certain regulatory features have not been combined in such a comprehensive way before. REACH has therefore also been coined a “paradigm change” (cf. Führ/Bizer 2007) in terms of governance modes and the integration of different steering philosophies.

The ECRN workshop in Aachen was held to shed further light on the question of changing responsibilities under REACH and to discuss the following questions in detail:

- What new responsibilities does REACH constitute for the different actors affected by the regulation (industry, agencies, consultants etc.)?
- What new roles do the different actors have to play under REACH, and how are they accepting this challenge?
- What problems, further challenges or shortcomings of the regulation are emerging in the light of new responsibilities?

The outline of this report follows the three broad sections the workshop was divided into. The first section summarises the main lines from the workshop’s keynote address, giving an overview about the regulatory characteristics of REACH from a political science perspective. The second section concentrates on perspectives and insights from helpdesks at national and regional level, industry experiences as well as experiences of consultants with REACH. The final section includes a critical

reflection of the lessons learnt so far from the RIP process followed by the summary of a roundtable discussion with all workshop participants.

2. The paradigm change under the REACH Regulation and new responsibilities

In order to introduce into the question of changing governance modes under REACH, a general overview about different steering modes shall be given in brief. The overview distinguishes between three types of governance: (a) regulatory standard setting, (b) so-called “new instruments” and (c) self-regulatory modes of governance. Hey et al. (2007) distinguish these types of governance on two dimensions: the level of obligation and the level of discretion in implementing the rules. The results are depicted in *Figure 1*. In the case of regulatory standard setting (this includes “traditional” instruments like emission limit values, quality values, permitting requirements etc.) the level of obligation is high, but the level of discretion for Member States and target groups low. For the so-called “new instruments” (framework legislation, market-based instruments etc.) the level of obligation remains high, however leaving open concrete measures to achieve the given targets. The third mode of governance mentioned here – self-regulation (voluntary agreements or cooperative arrangements between the state and private actors) – shows a low level of obligation with a lot of freedom for Member States and regulated target groups.

Figure 1: Different modes of governance and their characteristics

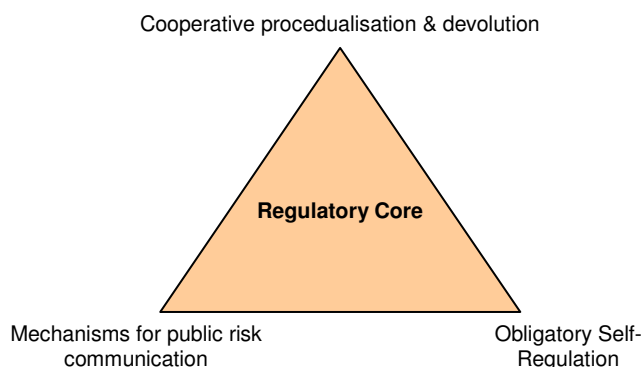
	Level of obligation	Level of discretion
Regulatory standard setting	High	Low
„New“ instruments	High	High
Self-regulation	Low	High

At a first glance it seems that REACH fulfils the main characteristics of regulatory standard setting. It is, however, not as easy to subsume REACH under this context of different modes of governance. In reality, REACH constitutes a major change in the regulatory aspects of European chemicals legislation. Looking at the different regulatory approaches of the Regulation, four different governance modes applied under REACH can be highlighted (Hey et al. 2007) (*Figure 2*):

- **traditional regulatory core**, especially concerning the obligatory submission of data and the possibility for substance restrictions
- **cooperative proceduralisation and devolution**: REACH only establishes a framework of basic rules and procedures. This framework is in need of further standards, operational criteria, procedural guidance, etc. Thus REACH launches a cooperative process to fill the overall framework with life
- **obligatory self-regulation** of producers as regards chemical safety and appropriate risk management along the value chain
- **mechanisms for public risk communication**, potentially enabling markets, consumers or the wider public to react to substances of concern, with a special focus in the authorisation phase

These additional regulatory aspects of REACH going beyond traditional hierarchical modes of governance bear a number of important implications for the role of stakeholders within the general regulatory framework of chemicals legislation and shall be analysed in closer detail in the following sections.

Figure 2: Modes of governance in REACH



Source: following Hey et al. (2007)

2.1 Cooperative proceduralisation and devolution

REACH can actually be regarded as a framework regulation leaving many political questions to the discretion of the bodies created for implementation. Key issues for further specification are for instance (cf. Hey et al. 2007):

- the exact information requirements for the information chain between producers and downstream users, especially as regards the level of detail of substance uses and exposure categories;
- the exact criteria under which producers may be exempt from delivering data (e.g. acknowledgment of available tests and other information sources, reading across substances, irrelevant exposure);
- the requirements for data sharing between producers of the same substance;
- an operational definition of “adequate control”, which is the essential precondition for authorisation;
- methodology and level of detail of the risk assessment and the socio-economic analysis, which is part of the authorisation system.

2.2 Obligatory self regulation and new responsibilities under REACH

REACH is an example of intensified self-regulation between different actors in the supply chain (Führ/Bizer 2007). The hierarchical regulatory model is limited to situations where it is indispensable, thus making self-regulation within given standards the general rule. Producers in cooperation with substance users identify the level of “adequate control” and the appropriate quality of risk management. They are responsible for classifying the substances into different categories of danger. Similar to an environmental management system (EMS), harmonised procedures and obligatory aspects interact. It can thus be stated that the core of REACH is an obligatory EMS related to chemicals safety. REACH is a form of regulated self-regulation, a policy mix that takes into account the specific incentives of different actors (Hey et al. 2007). It has therefore also been coined a “responsive regulation” in contrast to rather mandatory, traditional regulation (Führ/Bizer 2007).

Implications for self regulation in the supply chain

Given their rational predisposition in the light of potentially high transaction costs, producers naturally will be careful to change to substances with lower risks. They will instead look for institutional arrangements up and down the supply chain to exchange information. This constitutes new tasks for producers, allocating them a new and proactive role in the supply chain.

The primary responsibility about substance registration under REACH rests with the producer or importer who is usually well-informed about his production processes and those of his closer partners. Knowledge about downstream processes, however, decreases along the production chain. REACH sets incentives for producers to actively share information, while downstream users might in turn be interested to provide information to formulators and producers. Since they are closer to the final

consumer and thus face higher liability risks, it might eventually be producers and formulators that play a key role in the product chain and initiate substitution processes (Führ/Bizer 2007).

The case of the Substance Information Exchange Fora (SIEF) exemplarily demonstrates this form of self-regulation: Art. 30 (3) of the Regulation foresees that a registrant may not register if he does not provide other members of the SIEF with his study on vertebrate animals, while the costs have to be shared. A second example concerns the import of phase-in substances after the original phase-in period has ended. The importer will be obliged to contact the original registrant and to agree with him on information exchange and the sharing of costs. These examples constitute only a fraction of those aspects of REACH which provide for “regulated self-regulation” between industry actors.

2.3 Mechanisms for public risk communication

In the context of new modes in governance REACH combines the hierarchical model (regulatory core) not only with proceduralisation and self-regulatory elements, but also features an information-based approach to governance. One element of this governance can be found in the case of public risk communication under REACH. Against this background Article 64 (2) provides for the internet publication of information on uses, including a deadline until which information about alternative substances and technologies has to be submitted. The candidate list containing hazardous substances subject to authorisation bears additional potential for scandalisation and might in certain cases already serve as a “death list” for the substances that are listed. In this regard, the publication of substance characteristics and their potential to cause harm will eliminate information asymmetries both between companies and between companies and consumers. It will provide for an increased transparency along the supply chain and thus potentially create market incentives, i.e. for an active substitution behaviour of affected companies. However, it remains open to investigation and close observation how relevant actors like, e.g. customers, will react to the publication of substance characteristics and the prioritisation.

3. Experiences with REACH from different perspectives

Given the above considerations about REACH and changing modes of governance, the workshop invited a number of experts to discuss the practical implications of this “paradigm change”.

The following experts and expert groups provided insights into their work in section 2 of the workshop:

- a) National Helpdesks
- b) Supporting activities of Industry
- c) Regional support
- d) Consultants

3.1 National Helpdesks

Art. 124 of the REACH Regulation provides for the establishing of national helpdesks in order to give industry specific support for their implementation of REACH. In Germany the National helpdesk has been established in September 2006 under the auspices of the Federal Institute for Occupational Safety and Health (BAuA). The number of questions has since then been steadily increasing (*presentation Wiandt, BAuA*). Two information brochures for industry have been published so far (with currently three more to follow). The helpdesk’s activities in answering the questions is flanked by presentations of BAuA representatives at expert meetings and larger events. The cooperation with other initiatives is to be intensified in future.

In the Netherlands, REACH activities are coordinated by a central bureau and additional regional offices, the national REACH helpdesk being coordinated by SenterNovem (*presentation Korenromp, VROM*). An experts network with ca. 20 members meets every four months. In contrast to the German National helpdesk answers to REACH are mostly given by branch associations. A survey among branch organisations concluded that especially among small and medium-sized enterprises knowledge about REACH is still limited. The survey also showed that knowledge in companies has declined compared to former questionnaires. The helpdesks and its partners are currently reflecting on the extent of this problem and how to deal with it effectively.

The Belgian National helpdesk, which was established at ministerial level, consists of a team of six experts, but gets further support from the Federal Public Service (FPS). One major problem can be

detected with regard to the helpdesk's capability to maintain contact to smaller companies (*presentation Feyaerts, Federal Public Service, FPS*). These contacts are at the moment rather weak, making cooperation with other actors necessary (e.g. chambers of commerce, federations or research centres)

3.2 Support organised by industry

The industry helpdesk offered by the German VCI provides detailed information about REACH on its homepage (*presentation Hanschmidt, VCI*). The access to information, however, is restricted to member companies. The internet platform also offers summaries of single RIPs, guidelines and other REACH related official documents. The information is shared with other institutions but not publicly available. In terms of cooperation the VCI works closely together with the Federation of German Industries (BDI).

From an industry perspective it was made clear that there is strong need for consultancy in the companies (*presentation Hardt, Bozzetto*). Not all activities in the registration process can be performed inside a company. The experience from the implementation of European law in different national jurisdictions also shows that the different mechanisms of control and sanctioning in the Member States have to be closely evaluated. The downstream user perspective of RENOLIT underlined the benefits of as well as the need for communication in the supply chain (*presentation Eisner, RENOLIT*). The company already manages an extensive internal and external information exchange. More extensive communication to suppliers are either already based on or will eventually lead to more transparency on used raw materials. A broader knowledge on risks of used raw materials is under development as well as mutual support and recommendations in environment and employment protection measures.

3.3 Supporting activities at regional level

The Leitat technology centre in Catalonia, Spain, – an information platform, not a helpdesk – is focused on textiles and clothing (*presentation de la Varga, Leitat*). Today Leitat offers services to different kinds of industry branches like automotive, chemical and textile industries. It is being estimated that around 4500 SMEs in Catalonia will be affected by REACH, with automotive and textile industries being the most affected branches. Leitat cooperates with companies from the region by offering professional assistance on REACH interpretation, e.g. the interpretation of technical guidance documents (RIPs). Leitat has participated in a regional study on the capacities of laboratories for different testing procedures, and it has furthermore engaged in a study regarding the actual awareness of SMEs about REACH. In general it can be said, also with reference to the results from the Netherlands, that the companies' awareness of their role in REACH once again proves to be a crucial point for the successful implementation of the new Regulation in the entire supply chain.

The REACH-Net helpdesk, organised by the Land North Rhine-Westphalia, Germany, has been established with special emphasis on the support of SMEs (*presentation Deilmann, REACH-Net*). It is set up following the "bank principle" which aims at an integration of a common understanding between industry and authority experts. The pool of experts is especially diverse with members of different scientific backgrounds and different companies, allowing for high flexibility in terms of what specific questions can be answered. REACH-Net assigns great importance to the question of quality control, by submitting the answers to a double check by experts from authority and industry. Additionally, the enquirer is automatically asked for his opinion about the service quality, the timeframe and the quality of answers, and the degree of satisfaction with the answer. The dialogues can be checked via internet.

3.4 Consultants

The complexity and organisational challenges of REACH will not only demand new alliances between companies in the supply chain, but also intensify the collaboration of companies with consultants.

The REACH competence centre Bavaria strongly engages in direct training of REACH experts by organising a 10 day seminar in cooperation with the Austrian Federal Economic Chamber (WKÖ) (*presentation Schön, REACH competence centre Bavaria*). It also cooperates directly with manufacturers by offering an on-site consultation service, including assistance with the setup of internal substance inventories, inventory analysis and strategies for downstream users. Special SME support is given via the regional federations network. Additionally, the competence centre also assumes the role of a helpdesk by answering directly to questions posed via a hotline service. The

centre also assists companies in defining their specific role under REACH, i.e. whether they are a manufacturer, downstream user or importer. The competence centre is only accessible for members of the relevant industry organisations.

A similar strategy is pursued by the German association TÜV Rheinland Group (*presentation Langenohl, TÜV Rheinland Group*). The TÜV also offers awareness raising workshops for companies, including simple questions like informing about the general obligations under the new Regulation or the training of “REACH compliance managers”. The organisation furthermore offers an inventory of substances and a check of a company’s IT infrastructure. An important tool for a company’s preparation for REACH is the TÜV’s software simREACH® simulating the Regulation by translating it into individual cost calculations at company level. The TÜV also has experiences with a rather late REACH adaptation in SMEs and has furthermore observed insecurity among downstream users about the actual decisions of importers to register substances.

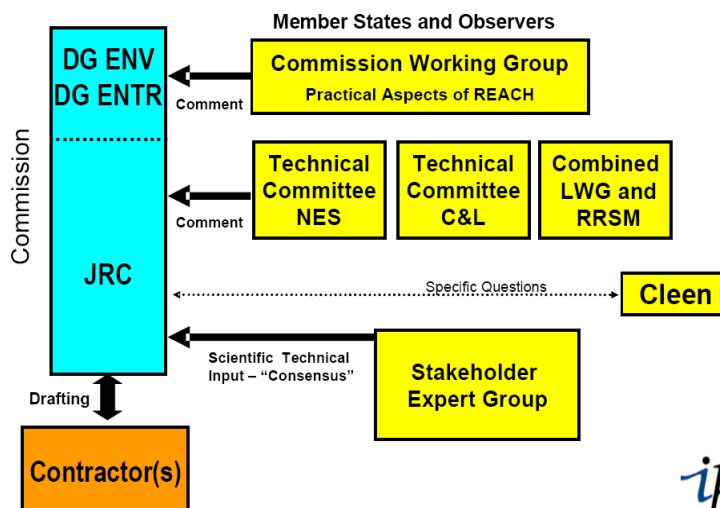
ExperChem Ltd., a consultant for chemicals marketing, notes that the paradigm change under REACH, concerning responsibility and accountability, has not yet been internalised by many company officials (*presentation Blumenthal, ExperChem Ltd*). This concerns additional burdens under REACH as well as the benefits REACH offers (e.g. longer time frames for registration, better access to market information on substances). Due to the complexity of REACH, ExperChem stresses – and responds to this challenge by its internal set up – that no single experts will be able to cover all areas of the new Regulation, but in fact a network of experts (consultants, testing facilities, toxicologists, lawyers) is necessary.

4. Experts and expert communities at EU level – The RIP process and Roundtable discussion

4.1 The RIPs process

The RIP process with its structural interaction of stakeholders under REACH is one of the most remarkable features of the new governance paradigm applied under REACH (Heitmann and Tschochohei 2007). Communication, standardisation and specification of the REACH requirements are organised within the several RIPs in close interaction between experts from industry, from Member States and from the European Chemicals Bureau (ECB). The overall process is being co-ordinated by the ECB, set up in the Joint Research Center (JRC) (*see Figure 3*). Working papers and draft final reports are being discussed in the Stakeholder Expert Group (SEG) meetings. Industry, Member States, NGOs and the Commission take part in the SEG meetings and provide input and written comments. The composition of the RIPs process institutionalises a communication process between stakeholders affected by the Regulation, allowing for self-regulatory practices. However, by allowing the new European Chemical Agency (ECHA) to assume a safeguarding role and intervene at critical points, this process is not set completely apart from hierarchical intervention.

Figure 3: The structure of the RIP process



Nevertheless, the RIP process is also subject to criticism. From the perspective of DuPont Performance Coatings (*presentation Werner Lenhardt, Du Pont Performance Coatings*) especially the content of the RIPs seems to be too complicated and difficult to understand even for a high number of specialists. As a downstream user, DuPont Performance Coatings sees itself in a kind of “sandwich” position between producers and customers. Particularly from the position of a downstream user, the discussion process at European level and in the RIPs (in this case RIP 3.2 and 3.5) must be regarded as a disappointing experience. Although branch organisations like CEFIC participate in the process this does not automatically include a representation of the downstream users’ positions. The overall organisation of the RIPs including the preparation of the respective meetings furthermore followed too short time schedules and did not allow for intensive discussions about separate issues. In the case of RIP 3.2 and 3.5 this might even constitute a need to redefine and discuss again several items, with a special focus on the need for downstream users.

A similar, rather disappointing image was sketched for the stakeholder discussions in RIP 3.10 (*presentation Michael Herzhoff, Lanxess*). Here it was stated that REACH and the RIPs do not sufficiently clarify the situation for substances and preparations definition. Furthermore, the application of the 80/20 rule bears risk to actually dilute the substance definition, eventually leading to a much higher number of substances to be registered than the number of phase-in substances. In this regard, the RIPs should only be seen as the beginning of a discussion, which will be held apart from the RIP process in the future.

4.2 Roundtable Discussion

Surveys from the Netherlands have shown that the awareness as well as the knowledge about REACH within small and medium sized enterprises (SME) is still limited. However, it has yet to be shown how grave this problem is in reality, and furthermore how it can effectively be dealt with. In the Netherlands, interviews with targeted companies will be performed to evaluate first of all the extent of this awareness problem among SMEs. Since it is generally a problem to get in contact with the right companies from the group, the respective branch organisations will have to play a key role in this process. In Germany, the inspectorates especially at Länder level already maintain close contacts with SMEs and should therefore be considered a key player in this regard. One figurative example from Germany shows that at least in certain companies there is a substantial lack of knowledge: The German National Helpdesk (BAuA) received a letter from one company in June 2007 asking for pre-registration of a substance.

In the case of regional support in Catalonia it was stated that there is urgent need for all support given to SMEs to distinguish between the technical language provided by several REACH experts and the rather technical, practically oriented language SMEs are in need of. From a general consultancy perspective it can be said that for a large number of SMEs REACH still remains an “illusion”. Judging from their experience from the actual implementation of past European policies like the RoHS directive, companies tend to adopt an attendant position, believing that REACH will finally be delayed and not be resolutely enforced. There sometimes appears to be an awareness problem at top level within the companies. CEOs still have to learn about what REACH is and what it means. In Belgium the problem of REACH and SMEs will be partly tackled by a press campaign to be started in the near future. This, however, also raises the question of the quality of consultancy and the actual help of industry associations in the light of REACH. There is at present no quality control of the consultants’ work for REACH. As regards the industry associations, their commitment to consult members is in certain cases also weak. The European Council of the Paint, Printing Ink and Artists’ Colours Industry (CEPE), e.g., does not offer any consultancy to its members. The chambers of commerce are more active in this regard.

Regarding the role of national helpdesks, their cooperation with industry is not very well established. This directly results from the fact that industry requests to be provided with authoritative information in order to prepare for REACH. Cooperation between the authorities and industry is rather a case for the RIP process. According to impressions from Estonian industry, it can be shown that national helpdesks are sometimes not trained well enough to support industry, thus allocating the Chemical Industry Associations a greater role in the process.

Concerning the RIP process it can be said that there are still large controversies about the respective roles of authorities and industry in the overall process. Industry reports that the authorities play too strong a role in the different RIPs, which makes adequate representation difficult especially for SMEs lacking resources to send more representatives into the RIP process. According to industry representatives, several RIP results are almost completely consistent with the authorities’ position.

However, it should not be neglected that the European Chemical Industry Council (CEFIC) is member of the SEGs and the CWGs in the RIP process, having sufficient resources at its disposal. It should be noted that the RIP process is organised as a new process. The documents are not “carved in stone” but living documents to be adjusted in the future. Concerning the use of the RIP results it will be important from the position of SMEs to translate the documents into languages other than English.

5. Conclusions from the workshop

The discussion of the national helpdesks’ work raises the question what role the ECHA and a European helpdesk could play in the provision of legally binding answers. At the moment information about REACH is available on national and regional level only, but not on European level. However, ECHA is not supposed to provide direct helpdesk information to industry, but rather to serve as a helpdesk for the respective national helpdesks. The question remains therefore how companies can get reliable and legally binding answers to REACH questions. This point has to be underlined since – despite the large extent of self-responsible aspects within REACH – the industry’s demand for authoritative answers remains high.

Another question concerns the question of quality standards for helpdesks. Such quality standards will have to be discussed and solved at broader level, preferably at Commission level. It might be a task for the ECRN to intervene at Commission level in order to set up such standards.

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