# REACH: A New Paradigm for the Management of Chemical Risks

Olivier Fuchs

December 2009

Health and Environment Reports n° 4

les rapports ifri

The Institut français des relations internationales (Ifri) is a research center and a forum for debate on major international political and economic issues. Headed by Thierry de Montbrial since its founding in 1979, Ifri is a non-governmental and a non-profit organization.
As an independent think tank, Ifri sets its own research agenda, publishing its findings regularly for a global audience.
Using an interdisciplinary approach, Ifri brings together political and economic decision-makers, researchers and internationally renowned experts to animate its debate and research activities.
With offices in Paris and Brussels, Ifri stands out as one of the rare French think tanks to have positioned itself at the very heart of European debate.

*The opinions expressed in this text are the responsibility of the author alone*.

ISBN : 978-2-86592-644-2


IFRI
27 RUE DE LA PROCESSION
75740 PARIS CEDEX 15 - FRANCE
TÉL. : 33 (0)1 40 61 60 00
FAX: 33 (0)1 40 61 60 60
Email: ifri@ifri.org

IFRI-BRUXELLES
RUE MARIE-THÉRÈSE, 21
1000 - BRUXELLES, BELGIQUE
TÉL. : 00 + (32) 2 238 51 10
Email: bruxelles@ifri.org

SITE INTERNET: *Ifri.org*

# THE HEALTH & ENVIRONMENT REPORTS

The “Health and Environment: from Safety and Security Issues to New Governance Options?” programme of Ifri seeks to elucidate the linkages that can exist between health and environmental issues and security considerations, and to analyse the impacts of such linkages in terms of efficiency and of the governance options available to international actors. The programme also wishes to stimulate a wider debate within the global civil society and bring to the fore innovative perspectives on these issues, through the linking together of practitioners within a dedicated network.

As part of the Health and Environment programme of Ifri, a minimum of three case-studies on global health and environmental issues are published each year: the *Health & Environment Reports*. All reports have an empirical, comparative and policy-oriented approach, and comprise:

- An empirical analysis of the health and/ or environmental issue under study;
- A prospective analysis of the future developments of the issue under study;
- Policy-oriented recommendations.

*The Health and Environment programme of Ifri is supported by the Taipei Representative Office in France.*

# TABLE OF CONTENTS

# ABBREVIATIONS

AFSSET: Agence Française de Sécurité Sanitaire de l'Environnement et du Travail

AISE: International Association for Soaps, Detergents and Maintenance Products

BERPC: Bureau d'évaluation des risques et des produits chimiques

Cefic: European Chemical Industry Council

CONCAWE: Conservation of Clean Air and Water in Europe, Oil companies' European association

CMR: Carcinogenic, Mutagenic or Reprotoxic (toxic to reproduction)

CSA: Chemical Safety Assessment

CSR: Chemical Safety Report

DRIRE: French regional directorate of the industry and the environment

DUCC: Downstream Users of Chemicals Co-ordination group

ECHA: European Chemicals Agency

ECJ: European Court of Justice

EEB: European Environmental Bureau

EFTA: European Free Trade Association

EINECS: European Inventory of Existing Commercial Chemical Substances

EU Commission: European Commission

EU Council: European Council

EU Parliament: European Parliament

ETUC: European Trade Union Confederation

FECC: European Association of Chemical Distributors

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

HPV: High Production Volume

ICCA: International Council of Chemical Associations

IFCS: International Forum for Chemical Safety

IFTH: Institut français du textile et de l'habillement

INERIS: Institut National de l'Environnement et des Risques

INRS: Institut National de Recherche et de Sécurité

IUCLID: International Uniform Chemical Information Database

JLDE: Journal de l'environnement

NGO: Non-Governmental Organisation

OECD: Organisation for Economic Cooperation and Development

PBT: Persistent, Bioaccumulative and Toxic

R&D: Research and Development

REACH: Registration, Evaluation and Authorization of Chemicals

SAICM: Strategic Approach for International Chemicals Management

SDS: Safety data sheets

SFF: SIEF Formation Facilitator

SIEF: Substance Information Exchange Forums

SMEs: Small and Medium Enterprises

SVHC: Substance of Very High Concern

UIC: Union des industries chimiques

UNCED: United Nations Conference on Environment and Development

UVCB: Unknown or Variable Composition Complex Reaction Products, or Biological Materials.

VPvB: very Persistent and very Bioaccumulative

WECF: Women in Europe for a Common Future

WTO: World Trade Organisation

WWF: Worldwide Fund for Nature

# INTRODUCTION

*In the last century, our society quietly underwent a chemicals revolution. This is reflected in global production rising from one million tonnes in 1930 to 400 million tonnes today. That revolution brought man-made substances into all strands of life and into most consumer articles. In fact chemicals are now everywhere! But the "success" of chemicals could also be the Achilles heel of our society. We have developed a very high dependence on chemicals. Yet this is not matched by sufficient knowledge about their potential risks and long-term effects, for which we are paying a high price. This is not just an issue for European countries. Chemical safety is a global concern. Countries all over the world are paying a high price for failures to address chemical safety.*

*M. Wallström, speech, 2nd US-EU Chemicals Conference*[1]

*The purest idea in REACH, really the original seed, was that REACH should create a very strict and clear framework for industry decisions. And if industry decided according to that framework, there would hardly ever need to be an intervention from outside. That is the core of the whole REACH. Everything is built around that idea.*

*B. Hansen, interview*[2]

Today, a life devoid of chemicals would be impossible. According to the European Chemical Industry Council (Cefic), world chemical sales were estimated at €1820

---

[1] Charlottesville, USA, 26 April 2004, <http://www.europaworld.org/week175/speechwalstrom30404.htm>.
[2] *ECHA Newsletter*, n° 1, <http://echa.europa.eu/publications_en.asp>, p. 5.

billion in 2007, the European Union (EU) accounting for 29.5% of the total.[3] The chemical industry's contribution to the EU's gross domestic product amounts to 1.2% of total GDP, and 1.9% when pharmaceuticals are added.[4]

Chemicals are everywhere: in the mechanical and electrical industries, in textile and clothing, in the car industry, in paper and printing products, in construction products etc. Some substances are even where they should *not* be. In 2007, Mattel had to recall various Barbie accessory toys due to violation of lead paint standards.[5]

But while chemicals can indeed be found everywhere, they were long used without their producers being required to know or to inform consumers or partners on their intrinsic properties. Such a situation could not persist in today's "risk society".[6] Risks became too important, their effects too deep, to be ignored. U. Beck, H. Jonas or P. Ricoeur are some of the thinkers that showed that if the consequences of human actions were once limited, both geographically and temporally, they are now far-reaching, and potentially devastating.[7] Health security has become a key concern in our society, along with the principles of prevention, anticipation and precaution.

It is in this context that the European Union (EU) adopted Regulation (EC) n° 1907/2006 of the European Parliament and of the Council of 18 December 2006, concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).[8] The regulation regime that was set up intends to change the paradigm within which chemicals management was until then implemented.

The idea of risk regulation is at the basis of this study. It can be defined as governmental interference through market or social processes, with the objective of controlling potentially adverse consequences of human activity on public health or on the environment.[9] A risk regulation regime, or system, encompasses the ways and means through which a risk is regulated in a particular policy domain.[10]

---

[3] Cefic, *Facts and Figures*: *January 2009*, <http://www.cefic.org/factsandfigures/level02/profile_index.html>.
[4] *Ibid*.
[5] See the press release of the U.S. Consumer Product Safety Commission, available at <http://www.cpsc.gov/cpscpub/prerel/prhtml07/07301.html>.
[6] U. Beck, *La société du risque. Sur la voie d'une autre modernité*, Paris, Aubier, 2001.
[7] *Ibid.*; H. Jonas, *Le Principe Responsabilité. Une éthique pour la civilisation technologique*, Paris, Flammarion, 1998 ; P. Ricoeur, *Lectures 1. Autour du politique*, Paris, Seuil, 1991.
[8] *Official Journal of the European Union*, 29 May 2007, n° L136/3; also available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:EN:PDF>.
[9] C. Hood, H. Rodstein, R. Baldwin, *The government of risk. Understanding risk regulation regimes*, Oxford University Press, 2001, p. 3.
[10] *Ibid.*, p. 8.

As far as the notion of risk is concerned, two different meanings will be used along this study. The first general meaning is that risk is the probability for an event, which can be avoided or mitigated, to happen. This definition presents risk as a macro social issue, which underpins for example the idea of a risk society. A second and more precise definition of risk presents it as being a function both a hazard, and of the exposure to it. For example, a very toxic chemical is hazardous but poses no risk whilst it is securely locked in a cupboard. However, if disposed on a waste tip, it may represent a considerable risk.

The questions we will try to answer in this study are the following: is the new regulation regime efficient and effective? In other words, does it meet the ambitious objectives that are expressed in article one of the Regulation, namely to ensure a high level of protection of human health and the environment while enhancing innovation and competitiveness, and how does it do so? In the negative, why is it so, and what recommendations can be made to improve the regime?

The analysis presented in this report is based on more than twenty interviews that were carried out from June to October 2008 with stakeholders. The issues dealt with within this report are still passionately debated. Some of the people that we contacted refused to publicly express their opinion on the on-going process. For this reason, and for the time they were kind enough to give us, we would like to thank all of the people that we met. This study also builds on an extensive review of the existing literature on the subject, as well as on official documents.

Chapter one of the study will provide an overview of the regulation, both the context for its emergence and its main provisions. In chapter two, the way the new regime was shaped will be analyzed, with a focus on the study of the opposition between the green coalition and the business coalition. Such a historical perspective is important to understand the current challenges faced by the regulation system. In chapter three, analysis will focus on the main regulation principles of the new system, and explain why it can be qualified as “modern”. Chapter four will present the organizational set-up of the regime and describe the ownership process taking place amongst its actors. A fifth and final chapter will assess the (potential) success of REACH, based on four criteria.

# I. UNDERSTANDING REACH: AN OVERVIEW

*Over the past 10 years we have forged a truly revolutionary chemicals policy. With the adoption of REACH at the end of 2006, the EU completed a fundamental reform of its chemicals legislation. It is certainly one of the most important pieces of law passed during the current Commission's mandate.*

*S. Dimas, Commissioner for the Environment*[11]

The Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals, which came into force on June 1st, 2007, is a crucial contribution of the European Union to a high level of protection of human health and the environment. Although it is too early to draw definite conclusions on this innovative strategy of the EU, REACH undoubtedly represents a turn in chemical policy. This chapter provides some keys to understanding it.

## BACKGROUND: WHY REACH?

Our everyday life is entirely dependent on chemicals. More than 100.000 different substances can be found on the EU market, 10,000 of which are marketed in volumes of more than 10 tonnes.[12] Chemicals may however also cause damages to health and the environment. Brominated flame retardant like hexabromocyclododecane, used

[11] Speech at the Helsinki Chemicals Forum, 28 May 2009, <http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/09/275&format=HTML>.
[12] EC Commission, 2001(a), *White Paper. Strategy for a future Chemicals Policy,* COM(2001) 88, Brussels, 2001, <http://eur-lex.europa.eu/LexUriServ/site/en/com/2001/com2001_0088en01.pdf>, p. 4.

mainly in the construction industry, may for example affect the liver or the thyroid and is very toxic to aquatic organisms. Scientific studies show that due to accumulation of this substance in fish, fish feeding mammals and birds are also exposed.[13] Phthalates are another example. Widely used as plasticisers, they are known to be endocrine disrupters.[14] More than a few of the 100.000 substances identified may indeed cause damage, sometimes in the course of the production or use of a product, more often after the release of the substance into the environment.

Against this background, ***toxic ignorance*** emerged as a major issue during the 1990s.[15] A review of the chemicals policy led by the EC Commission in 1998 however showed that ***the existing legislation at the time was unable to meet this challenge***.[16] The existing system, which was a patchwork of many Directives and Regulations, distinguished between chemicals declared as being on the market in September 1981 ("existing substances") and those placed on the market since that date ("new substances"). The testing and assessment of the risks posed by the 2.700 substance was required only for the latter. In contrast, existing substances, which represented 99% of the market, were not subject to such requirements. It was up to the Member States to carry out risk assessments on chemicals that were identified as priority substances. In 2001, about 150 substances only, out of more than 100.000, were concerned. This led the Commission to judge the existing system quite harshly in its White Paper, and to emphasize the need for a new instrument:

> *There is a general lack of knowledge about the properties and the uses of existing substances. The risk assessment process is slow and resource-intensive and does not allow the system to work efficiently and*

[13] See ECHA, *Member State Document for Identification of Hexabromocyclododecane and all Major Diastereoisomers as a Substance of Very High Concern*, 2008, <http://echa.europa.eu/doc/candidate_list/svhc_supdoc_hbccd_publication.pdf>.

[14] ECHA, *Member State Document for Identification of Bis(2-Ethylhexyl)phthalate as a Substance of Very High Concern*, 2008, <http://echa.europa.eu/doc/candidate_list/svhc_supdoc_dehp_publication.pdf>. "Endocrine Disruption is a mechanism whose effects relate to the functioning of the Endocrine system, that is, development, growth, reproduction and behaviour of human beings and wildlife. There is growing concern about a range of substances, which are suspected of interfering with the endocrine system - so-called "endocrine disrupters". These substances may cause adverse health effects such as cancer, behavioural changes and reproductive abnormalities" (EU Commission, *Community Strategy for Endocrine Disrupters*, COM(1999) 706, <http://www.europarl.europa.eu/meetdocs/committees/envi/20000418/123706_en.pdf>, (*Ibid.*, p. 4).

[15] This term is used in the literature to refer to a lack of knowledge about the properties and uses of chemicals as well as about the management of the risks resulting from these uses.

[16] EU Commission, *Working document*, SEC(1998) 1986 final. See also R. Allanou, B. Hansen, Y. van der Bilt, *Public Availability of Data on EU High Production Volume Chemicals*, European Chemical Bureau, 1999, <http://ecb.jrc.ec.europa.eu/documents/Existing-Chemicals/PUBLIC_AVAILABILITY_OF_DATA/datavail.pdf>.

> *effectively. The allocation of responsibilities is inappropriate because authorities are responsible for the assessment instead of enterprises, which produce, import or use the substances. […] Information on uses of substances is difficult to obtain and information about the exposure arising from downstream uses is generally scarce. Decisions on further testing of substances can only be taken via a lengthy committee procedure and can only be requested from industry after authorities have proven that a substance may present a serious risk. Without test results, however, it is almost impossible to provide such proof. Final risk assessments have therefore only been completed for a small number of substances.*[17]

The overall aims of a new legislation logically derived from these shortcomings. However, the combat against toxic ignorance was from the beginning said to be possible only if it did not hinder the competitiveness of EU industries. These two objectives, which needed to be balanced in the general framework of sustainable development, are expressed in article one of Regulation n° 1907/2006:

> *The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.*

More generally, ***seven objectives are pursued by the new regulation***:

- Protection of human health and the environment
- Maintenance and enhancement of the competitiveness of the EU chemical industry
- Prevention of fragmentation of the internal market
- Increased transparency
- Integration with international efforts
- Promotion of non-animal testing
- Conformity with EU international obligations under the WTO.[18]

---

[17] EC Commission, 2001(a), *op. cit.*, p. 6.
[18] EC Commission, *REACH in brief*, <http://ec.europa.eu/environment/chemicals/reach/pdf/2007_02_reach_in_brief.pdf>, 2007, p. 4.

# GETTING THERE: THE MAJOR STEPS TOWARDS THE REGULATION

The need for a better management of chemical risks emerged before the EU began reforming its legislation. The OECD for example established a program on the investigation of high production volumes chemicals (HPV program) in 1990. The issue was also discussed at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro in 1992, where a hundred nations decided to form the Intergovernmental Forum for Chemical Safety (IFCS), which is still active today.[19] Yet, ***it is the year 1998 which marks, at the EU level, the beginning of a new era.*** The major impetus for a new chemical policy came from Sweden and four other so-called "green States", which we will study in more detail in the next chapter. In early 1998, Sweden called for better knowledge on chemicals and for rules and procedures enabling the phasing-out of dangerous substances. This call was supported by Austria, Denmark, Finland and The Netherlands in a joint position issued in March 1998.

From then on, only a wide reform of the system was regarded as an adequate response. A review of existing legislative instruments dealing with chemicals underlined the need to adopt a more coherent approach in the legislation on chemical products.[20] Endocrine disruptors had also become a burning issue in 1999.[21] Last but not least, the Commission published in 2000 its communication on the precautionary principle, which expressed its desire

> *to be in the future even more determined to be guided by the precautionary principle in preparing proposals for legislation and in its other consumer-related activities and develop as priority clear and effective guidelines for the application of this principle.*[22]

The ***White Paper on a Strategy for a Future Chemicals Policy*** was published on 13 February 2001.[23] It aimed at promoting a non-toxic world while ensuring the

[19] The sixth session of the IFCS was held in 2008 on the theme "Global partnership for Chemical Safety, Contributing to the 2020 Goal".
[20] EU Commission, 1998 (a), *op. cit.* See also draft minutes of the 2153rd Council meeting (Environment) held in Brussels on 20 and 21 December 1998.
[21] EU Commission, 1999 (a), *op. cit.*
[22] EU Commission, *Communication on the Precautionary Principle*, COM(2000) 1, <http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf>, p. 8.
[23] EU Commission, 2001(a), *op. cit.*

efficient functioning of the internal market. The main principles underlying the REACH Regulation are already expressed in this document. Registration, evaluation and authorization are put at the heart of the regulatory system, and the Commission proposed to establish an agency responsible for its administration. *Inter alia*, the White Paper also emphasized the need for:

- Public access to information
- Making possible the substitution of dangerous chemicals
- Maximizing the use of non-animal test methods.

The publication of the White Paper ***opened the way for a lobbying battle***. Stakeholders wanted to influence the Commission's legislative proposal which was expected to follow the White Paper. An ***internet consultation*** on the content of a draft regulation was also held from May to July 2003, which allowed stakeholders to have their say. As we will see in the next chapter, REACH is the result of an opposition between a green coalition and a business coalition, arbitrated by EU institutions. While the first argued in favor of a strengthening of the system,[24] the latter expressed concerns about competitiveness and the workability of the system.[25]

The Commission adopted its ***proposal for a REACH Regulation*** on October 29, 2003.[26] This text has been judged by many to be a watered-down version of the White Paper,[27] and indeed some provisions had been dropped. The chemical safety report, for example, was not required in the final document for substances produced in volumes of less than 10 tonnes a year. The so-called "duty of care" provision, which states that actors bear responsibility for the safe management of the chemicals that they produce also disappeared from the Proposal. Yet these changes, as well as others, seem ***to have been necessary in order to come to a political agreement***.

---

[24] See for example NGOs' statements during the Internet consultation, especially the joint document submitted by four of the largest, <http://ec.europa.eu/enterprise/sectors/chemicals/files/ngo/ngo_349_4ngos_eu_en.pdf>.
[25] See associations and individual firms' comments on the draft consultation, <http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/consultation/contributions/firms/index_en.htm>.
[26] EU Commission, *Proposal for a Regulation of the European Parliament and the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)*, COM(2003) 644, <http://europa.eu/eur-lex/en/com/pdf/2003/com2003_0644en.html>. For a background documentation on this proposal, see <http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/proposal/index_en.htm>.
[27] See, for example, Greenpeace, *Toxic lobby. How the chemical industry is trying to kill REACH*, 2006, <http://www.greenpeace.org/international/press/reports/toxic-lobby-how-the-chemical>.

Almost ***three years of negotiations in the Council and the Parliament*** followed the proposal. After two readings and many informal discussions between the two institutions and the Commission, a final deal was approved on the 18th of December 2006.[28]

## A PARADIGMATIC SHIFT IN CHEMICALS POLICY

REACH is often referred to in the literature as a "paradigmatic shift" in chemicals policy.[29] M. Wallström calls REACH "a truly revolutionary chemicals policy", a "unique concept".[30] The new system indeed represents a major transformation, qualitative as well as quantitative, in the way chemical substances are regulated within the EU. The interviewees all agreed on the idea that REACH represented a turning point with regards to the previous system, leading to an upgrade in chemical policy standards.

### *REACH KEY PRINCIPLES AND PROVISIONS*

1. **REACH relies on a "no data, no market" principle to fight toxic ignorance: without proper information on a substance, manufacturing and placement on the EU market is forbidden.**

REACH requires enterprises to generate data on the substances they manufacture or import and to recommend appropriate risk management measures. To ensure the implementation of such requirements, the Regulation asks firms to register their substances. According to article 5 of the Regulation, "substances on their own, in preparations or in articles shall not be manufactured in the Community or placed on

[28] See the procedure file at <http://www.europarl.europa.eu/oeil/file.jsp?id=237952&noticeType=null&language=en>. See also M. Blainey, 2007, *op. cit.*, pp. 68-70.
[29] For example, M. Führ, K. Bizer, "REACH as a paradigmatic shift in chemical policy – responsive regulation and behavioural models", *Journal of Cleaner Production*, 2007, n° 4, pp. 327-334.
[30] M. Wallström, "We have the legislation – now it's time to make it work », *SIN Reporter*, 2009, n° 2, pp. 2-3. M. Wallström, now Vice President of the European Commission in charge of Institutional Relations and Communication, was Environment Comissioner in the Prodi Commission.

the market unless they have been registered". This is also referred to as the "no data, no market" principle.

2. **REACH reverses the burden of proof: the industry is responsible for the safety of its chemicals.**

REACH relies "on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use substances that do not adversely affect human health or the environment".[31] ***Safety of chemicals is thus the responsibility of firms***. This shift of responsibility towards producers and importers is a crucial element, as it places the burden of responsibility on firms rather than the State, a policy sometimes described as a self-responsibility approach.[32] That said, ***public authorities retain a central regulative and decision-making role.*** They also monitor and, whenever necessary, punish firms that do not comply with the Regulation. A key piece of the system, as we will see in the fourth chapter, is the new ***European Chemicals Agency*** (ECHA).

3. **REACH is mainly hazard-based, but includes risk approaches**

Hazard information constitutes REACH necessary background. The hazard a chemical poses is based on its intrinsic properties and its toxicity. REACH is primarily about identifying the possible hazards emanating from chemical substances. Yet, as we will see, such an approach does not exclude risk approaches, the risk being a function of the chemical's toxicity and exposure to it.

4. **REACH creates a single and wide-reaching system for all substances, whether existing or new.**

Unless explicitly exempted, all substances are covered by the regulation, whether manufactured, imported, used as intermediates or placed on the market, whether on their own or in preparations or articles. The main exemptions concern waste, radioactive substances, substances subject to customs supervision, carriage of dangerous substances and some intermediates, i.e. substances that are manufactured solely for the purpose of being transformed into another substance, and are used up within the chemical reaction. Besides, major provisions do not apply to substances used in medicinal products, food and cosmetics, which are regulated under other legislations.[33]

---

[31] Article 1 of the Regulation.
[32] M. Führ, K. Bizer, *op. cit.*, sp. pp. 329-333.
[33] Article 2 of the Regulation.

**5. Registration is the cornerstone of the new regime. No substance shall be manufactured or placed on the market unless previously registered.**

Firms have to submit a registration dossier to the ECHA for each substance manufactured or imported in quantities of one tonne or above per year, unless otherwise indicated. This dossier contains information on the properties, uses and classification of the substance, as well as guidance on safe use. A chemical safety report, compulsory for substances produced in quantities of 10 tonnes and more, specifically documents exposure scenarios, describing all identified uses of the substances during their life-cycle, and assessing the associated risks.

A ***special transitional regime*** is created for substances which, under certain circumstances, had already been manufactured or placed on the market before the entry into force of the Regulation on 1st of June 2007. Such substances are called ***"phase-in substances"***.[34] If they have been ***preregistered*** between June and December 2008, they are subject to the registration system but within different time frames. Different deadlines have been set for phase-in substances according to tonnage range: 1st December 2010 for substances over 1,000 tonnes/year, 1st June 2013 for substances over 100 tonnes/year and 1st June 2018 for substances over 1 tonne/year. Furthermore, some substances of high concern have been prioritized. These are mainly substances that are potentially carcinogenic, mutagenic or toxic to reproduction (CMR), persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).[35] All substances that do not meet the criteria for phase-in substances are considered as "non phase-in substances" and do not benefit from the transitional regime. They need to be registered before being manufactured or placed on the market.

The first step in the constitution of a registration dossier is the gathering of data on the substance and its intrinsic properties. The registrant also needs to provide a risk

---

[34] According to the Regulation (article 30.20), phase-in substances fall in at least one of the following criteria:
- it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). This list contains all substances on the Community market on December 1981;
- the substance has been manufactured after May 1992 without being placed on the market. If it was placed on the market, it would indeed have been notified and considered as registered;
- the substance is a so-called no longer polymer. It is a substance, placed on the market between September 1981 and October 1993, which was considered as notified under a previous directive but which does not meet the REACH definition of a polymer.
The transitional regime also apply to substances in articles as well as to some intermediates.

[35] Scientific criteria to assess whether a substance is PBT or vPvB are given in Annex XIII of the Regulation. They are substances that remain partly unaffected in the environment, travel up the food chain due to their tendency to be soluble in fat but not in water, and that are poisonous to the wildlife.

assessment and to recommend risk management measures. To do so, ***scientific tests***, which are run under the supervision of the registrant, are necessary. One of the objective of the Regulation is nonetheless to avoid unnecessary tests, especially on animals, and to reduce costs for the industry. ***Sharing and joint submission of data*** is encouraged and sometimes made compulsory.[36] Substance Information Exchange Forums (SIEFs), which are virtual platforms bringing together registrants of the same substance, are the main tool to achieve these goals. The role of such structures is described by article 29.3 as follows:

> *SIEF Participants shall provide other participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies (…) and arrange for such studies to be carried out.*

SIEFs are essential to fulfill REACH objectives of costs and tests reduction. They are however difficult to implement, as we will see in a later stage of this study.

6. **If registration is a major step, it does not mean that the dossier is complete or that all the properties and risks of the substance have been identified. Evaluation should ensure compliance with the legislation.**[37]

This process is divided into ***two phases: an evaluation of the dossier followed by an evaluation of the substance***. ECHA is the institution in charge of the evaluation of the dossier. First, the completeness of the dossier is checked. The Agency does not systematically check the compliance of registrants to their obligations, but carries out random checks. Moreover, proposals to carry out tests have to be checked by the Agency. Substances then need to be evaluated, according to a Community rolling action plan, decided by the ECHA in accordance with Member States. The evaluation is conducted by Member States.

7. **Authorization and restriction processes should ensure an efficient management of chemical risks.**

REACH is not only about gathering data and registering substances. Its effectiveness also depends on authorization and restrictions processes.[38] Substances of very high concern, mainly CMR, PBT, vPvB or substances with equivalent effects, are concerned. Once identified as being of high concern, such substances may not be

---

[36] Title III of the Regulation.
[37] Title VI of the Regulation. See also ECHA, *Guidance on Dossier and Substance Evaluation*, 2007, <http://guidance.echa.europa.eu/docs/guidance_document/evaluation_en.pdf>.
[38] Title VII and VIII of the Regulation. For a more detailed analysis, see chapter V.

placed on the market without an ***authorization*** from the Commission.[39] The aim is to ensure that the hazards deriving from these substances are properly controlled, and to encourage ***substitution*** by other chemicals. An authorization shall be granted only if the applicant can demonstrate that the risk from the use of the substance is adequately controlled, or, alternatively, if it is shown that "socioeconomic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies".[40] ***Restrictions*** shall also be applied where an unacceptable risk to human health and the environment is identified by the Agency or the Member States. In such a case, the identified substance will not be manufactured or placed on the market unless it complies with specific requirements for its use.[41] For example, a particular paint shall be prohibited, permanently and without any possible exemption, from use on cradles, but will be cleared for use on the fuselage of a plane. Restrictions and authorizations are thus different but complementary risk management measures.[42]

## CONCLUDING REMARKS

REACH is undoubtedly an innovative chemicals policy. It is a comprehensive system, which intends to place the legal burden of ensuring the safety of chemicals on the industry. This significant shift was necessary to launch a fight against toxic ignorance, which is no longer acceptable in our "risk societies".[43] REACH is designed to ensure an efficient management of chemical risks. Besides, the implementation of such a regulation placed the EU in the position of a worldwide norm-setter on the issue of chemical standards. However, whether this paradigmatic shift really results in practical success will depend on the conditions of its implementation. How REACH is implemented will indeed be the final criteria to assess the real political ambition behind the Regulation.

---

[39] Title VII of the Regulation.
[40] Article 60 of the Regulation.
[41] Title VIII of the Regulation.
[42] See chapter V.
[43] U. Beck, *op. cit*.

# II. SHAPING THE NEW REGIME

## BUSINESS VS. GREENS, AND THE ROLE OF EU INSTITUTIONS

*REACH saw "the heaviest industry lobbying known so far for any new EU legislation".*

*M. Wallström, former Commissioner for the Environment, Vice-President of the EU Commission*[44]

The REACH Regulation is the outcome of a highly controversial debate.[45] The new regulation was not introduced easily, but was concretized after years of intense negotiations and discussions. This complicated birthing process contributed to make the 2006 agreement a historical one.[46]

Timing also made the deal historical. It was important for the European Union, in 2006, to claim some successes. The EU was indeed in a bad shape after the rejection of the Draft Treaty establishing a Constitution for Europe by France and the Netherlands in May and June 2005 in their national referenda. For that matter, the adoption of the REACH Regulation has been a success, which asserted that the European Union was still on the move.

In our opinion, the main factor affecting the making and shaping of REACH was the existing opposition between a green and a business coalition.[47] Other factors had an impact on the elaboration of the regulation, but none had the structuring force of this political antagonism.[48] We think that such a cleavage is not reducible to a political or territorial dimension, but crosscuts them, as we will show.

---

[44] M. Wallström, 2009, *op. cit.*, p. 2.
[45] This point was debated during the peer-review seminar which preceded the publication of this report.
[46] For a detailed description of REACH policy making process, see G. Lind, *REACH – The Only Planet Guide to the Secrets of Chemicals Policy in the EU. What Happened and Why?*, The Greens and EFA, Brussels, 2004; D. Pesendorfer, "EU Environmental Policy under Pressure: Chemicals Policy Change between Antagonistic Goals?", *Environmental Politics*, 2006, n° 1, pp. 95-114; M. Blainey, "REACH – a Reality and the Future", *Journal of European Environmental and Planning Law*, 2007, n° 2, pp. 67-78.
[47] This position is mainly supported by D. Pesendorfer, *op. cit.*
[48] K.-O. Lindgren and T. Persson, in their study based on a survey of more than 600 individuals, show that the data they collected indicate that this opposition is much more important in explaining positions on

The making of REACH can thus be described as a battle between two main coalitions. In a polycentric game, since there are various decision loci (i.e. international, European, national, and within the EU the Commission, the Council and the Parliament) and many players,

> *actors can be aggregated into a number [...] of "advocacy coalitions", each composed of people from various governmental and private organizations that both (1) share a set of normative and causal beliefs and (2) engage in a non-trivial degree of coordinated activity over time.*[49]

These coalitions take part in a debate when they think it is in their interest to influence the outcome of the policy, by supporting or opposing policy proposals. The links between chemical policy and economic and competition policy made the debate over REACH all the more controversial.

## BUSINESS VS GREENS

### *THE COALITIONS*

The ***business coalition*** brings together mainly the industry, actors in charge of industrial and competition policy and actors close to the industry. Industry is the core actor and especially, but not only, the chemical industry. It is represented by professional organizations, amongst which Cefic and the European Association of Chemical Distributors (FECC) play a major role. National and sectoral organizations also have a significant role, as well as large firms, specialized in the production of chemicals. The involvement of such actors can be traced back, at the latest, to 2001. On the contrary, there was very little contribution of small and medium industries as

---

REACH than other factors ("The Structure of Conflict over EU Chemicals Policy", *European Union Politics*, n° 1, 2008, pp. 31-58).

[49] P. Sabatier, H. Jenkins-Smith, « The advocacy coalition framework : an assessment » in Sabatier (ed.), *Theories of the Policy Process*, Colorado, Westview, 1999, p. 120, quoted by D. Pesendorfer, *op. cit.*, p. 98.

well as of downstream users before the Commission's proposal in 2003.[50] Ministries responsible for economic affairs, business-friendly members of the European Parliament as well as some member states with a large chemical sector – especially the UK and Germany – were supportive of the business coalition.

Opposed to the business coalition is the ***green coalition***, led by environmental NGOs, especially Greenpeace, the Worldwide Fund for Nature (WWF), Friends of the Earth and the European Environmental Bureau (EEB). Such groups strongly advocate for a radical change in chemicals policy. Other NGOs also played a significant role within this coalition: animal rights and consumer organizations, women associations and trade unions. Trade unions, if they fight for better and safer working conditions, are also concerned about competitiveness and unemployment, and therefore adopted less radical positions than other organizations.[51] National environmental agencies, environment ministries and the so-called competent authorities, i.e. national bureaucracies in charge of the implementation of environmental regulations, could also be counted amongst the supporters of the green coalition.

## *RHETORIC: THE PROTECTION OF THE ENVIRONMENT AND HEALTH VS COMPETITIVENESS AND WORKABILITY*

As far as the REACH Regulation is concerned, the two coalitions relied on very specific rhetoric, articulated through a number of keywords.

The business coalition is above all concerned with economic growth. Accordingly, the recurrent themes that were put forward in the debate were competitiveness, which would be impaired by too strict regulations, and the "workability" of the new system.[52] The accent put on competitiveness followed the adoption of the Lisbon strategy in 2000. With this strategy, the EU sought to become the most competitive space of the world. This required an acceleration of market liberalization in a number of key sectors, an intensification of efforts to lower the costs of doing business, the removal

[50] Interview, E. Annys, Cefic, July 2009.
[51] D. Persendorfer, *op. cit.*, p. 102. This is confirmed by the findings of K.-O. Lindgren and T. Persson, *op. cit.*, p. 47.
[52] The word "workable" has become a key expression of actors from the business coalition (for example July 2009, interviews with E. Annys, Cefic; S. Lemoine, AISE; A. Affre, Businesseurope).

of unnecessary red tape and the shift to a knowledge-based and digital economy.[53] REACH was also criticized for its complexity, and for being too bureaucratic.

The green coalition, on the other hand, gives priority to environmental and health concerns, while supporting a conception of strict regulations as boosting innovation and benefiting the economy in the long-term.

The rhetoric used on both side was centered on these issues and the discussion became increasingly polarized. "The same arguments were put forward again and again, and many indications suggest […] that the actors tend not to listen to each other".[54]

## *STRATEGIES USED*

### The business coalition

In order to clear up sufficient hearing space for the competitiveness and workability rhetoric, the business coalition resorted to strong arguments. First of all, it pursued a strategy of ***underlining the costs of REACH and of its impact on the industry***. The multiplication of ***impact studies*** appeared to be a key instrument in this strategy. Indeed, more than 40 were carried out, mostly on health and environmental issues or economic effects, sometimes demonstrating partial analyses.[55] Some were commissioned directly by the industry. The study effectuated by Arthur D. Little for the German Industry Association and the Committee on Industry, Research and Energy of the European Parliament, and the one carried out by Mercer for the UIC,[56] are

[53] EU Council, *Presidency Conclusions*, Lisbon European Council, 23 and 24 March 2000, <www.europarl.europa.eu/summits/lis1_en.htm>.The Lisbon strategy, as amended in 2005, is detailed at <http://ec.europa.eu/growthandjobs/faqs/background/index_en.htm>.
[54] D. Friedrich, "Old Wines in New Bottles ? The Actual and Potential Contribution of Civil Society Organisations to Democratic Governance in Europe", RECON Online Working Papers, 2007, <http://www.reconproject.eu/main.php/RECON_wp_0708.pdf?fileitem=5456965>, p. 18.
[55] This classification is adopted by T. Lorenz, B. Lebreton, L. van Wassenhove, *The REACH Directive and its Impact on the European Chemical Industry: A Critical Review*, 2008, <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1259658>, pp. 8-9.
[56] Quoted by ECORYS, OpdenKamp Adviesgroep, *The impact of REACH. Overview of 36 studies on the impact of the new EU chemicals policy (REACH) on society and business*, Study for the Dutch Presidency of the EU, Workshop REACH Impact Assessment, 2004, <www.eu2004-reach.nl/downloads/Comprehensive_Overview-v2.pdf>.

particularly worth mentioning. Indeed, both studies were widely used,[57] even though they have been heavily criticized for their methodological flaws. According to the German Federal Environment Agency:

> *the method chosen by [Arthur D. Little] is not a suitable methodology for realizing absolute magnitudes via macroeconomic aggregates. The data contained in the ADL Study for losses in gross value added and for job losses resulting from the implementation of REACH cannot be validated and therefore cannot be a sound basis for the macroeconomic evaluation of EU chemicals policy.*[58]

On the approximately 40 studies published on REACH, estimations of future costs of the implementation of the regulation ranged between €500 million and €150 billion.[59] Such discrepancies show that studies could be used to convey very different pictures and messages.

The business coalition also opted to communicate on the subject using a ***rather catastrophic tone and vocabulary.*** E. Voscherau, then President of the Cefic, declared for example in 2003:

> *We are in effect going to de-industrialize Europe […]. There are likely to be significant GDP drops and correspondingly high job losses that are put at hundreds of thousands to up to two million […]. European industry, including the chemicals industry, must not be a test laboratory for a bureaucratic regulatory experiment.*[60]

The rhetoric of competitiveness and workability also gained in visibility through the intervention of the Heads of States of the UK, France and Germany (Tony Blair, Jacques Chirac and Gerhard Schröder). The latter sent a letter to then President of the Commission Romani Prodi, arguing that the draft regulation was too bureaucratic, that it may be impractical and, above all, that it may endanger competitiveness. The

---

[57] Interview, C. Lequime, UIC (July 2009); interview, N. Haiama, Greenpeace (July 2009).
[58] ECORYS, OpdenKamp Adviesgroep, *op. cit.*, p. 78 ; G. Lind, *op. cit.*, p. 95; *Greens / EFA Briefing on Study by Arthur D. Little*, <www.greens-efa.org/cms/topics/dokbin/102/102831.briefing_on_study_by_arthur_d_little@en.pdf>.
[59] T. Lorenz, B. Lebreton, L. van Wassenhove, *op. cit.*, p. 3.
[60] Quoted by A. Osborne, "Two million jobs "at risk" in chemical sector", *The Guardian*, 15 July 2003, <http://www.guardian.co.uk/business/2003/jul/15/environment.conservation>.

impact that this participation had on the evolution of the debate is hard to assess, but it represented in itself a very significant communication move.[61]

***Revolving doors strategies***,[62] i.e. staff transfer between official positions and the industry, was sometimes denounced. According to Greenpeace, some well-known lobbyists moved to the REACH Unit of DG Enterprise and Industry, while some officials took the same road the other way round.[63] One bewildering change concerned former Chancellor Gerhard Schröder, who was appointed chairman of the North European Gas Pipeline Company, partially owned by BASF.[64]

These lobbying positions have been judged harshly by some members of the green coalition:

> *Too many in the chemicals industry, and particularly its German lobbying arm, seem to believe that if you are going to tell a lie, then lie big; the costs of REACH have been grossly exaggerated from beginning to end […] If you think the lobbying over the past year or more has been intense, wait until the industry starts trying to stuff the (Chemicals) Agency with its own people. We will have to watch that process like hawks.*[65]

A few years after the struggle, business coalition lobbying persists, but in a less visible form. Views from the industry are indeed mostly expressed, as we will see, through a participative process. The fear expressed by some to see the Agency infiltrated by the industry was not concretized.

***A foreign policy guided by industrial interests: the US efforts to combat REACH***

At the urging of chemical industries, the Bush administration led a strong campaign, prior to the adoption of the REACH regulation, to influence the outcome of the on-going procedure. This strategy caused some political unrest.

---

[61] While French deputy and chemicals specialist D. Garrigue presents it as an important position (interview, July 2009), an official of the Commission said it had little consequence on the Proposal (interview, July 2009).
[62] T. Makkai, J. Braithwaite, "In and Out of the Revolving Door: Making sense of Regulatory Capture", *Journal of Public Policy*, 1995, n° 1, pp. 77-101.
[63] Greenpeace, 2006, *op. cit.*, p. 13.
[64] See <http://www.nord-stream.com/en/our-company.html>.
[65] Chris Davies, member of the EP (MEP) in UK Office of the European Parliament, *EP News 18th November 2005*, <http://www.europarl.org.uk/section/ep-news/november-18th-2005-no-236>.

Following a study from the Environmental Health Fund,[66] a small non-profit environmental organization, the Committee on government reform of the House of Representatives issued a report clearly demonstrating that the US foreign policy, as far as the REACH regulation was concerned, had been dictated by chemical industries.[67]

From the outset, US chemical industries strongly opposed REACH and advocated voluntary measures instead of the regulatory system adopted by the EU. The election of Bill Clinton changed this set-up, as the US government put to a halt anti-REACH lobbying. This transformation resulted in the intensification of funding by the chemical sector to the Republican party, and particularly to the Bush candidacy.[68]

When the Bush administration took office, a new position on REACH emerged. Following meetings between the Commerce Department, the US Trade Representative, the US Environmental Protection Agency (EPA), representatives of the industries, in particular the American Chemistry Council, and industrial leaders such as DuPont and Dow, a strategy was elaborated. Its objective was clearly to combat efforts for a new EU regulation. This position is revealed by the comments publicly made by W. Lash, Assistant Secretary to the Commerce Department, in which he described REACH as "a barrier based on unsound science or non-existent risk analysis that damages our exports".[69]

As described in the report from the Committee on government reform, the US strategy relied on two main channels to influence the EU policy-making process. First, ***the US sought***

[66] J. Digangi, *US intervention in EU chemical policy*, Environmental Health Fund, 2003, <www.noharm.org/details.cfm?type=document&ID=823>. This study is based on documents obtained through Freedom of Information Act requests. They include e-mails, cables, and memoranda from the State Department, the U.S. Trade Representative, the Commerce Department, and the Environmental Protection Agency.
[67] US House of Representatives, Committee on government reform, Minority staff special investigation division, *A special interest case study: the chemical industry, the Bush administration and European efforts to regulate chemicals*, 2004.
[68] *Ibid.*, pp. 2-3.
[69] J. Digangi, *2003, op. cit.,* p. 10.

***to build opposition within the EU***. It was agreed that six Member States needed to be specifically targeted because of their interests in the chemical industrial sector: Germany, UK, France, Italy, Netherlands and Ireland. US officials, frequently accompanied by representatives of the American Council on Chemicals, made trips to Europe to meet both Member States and stakeholders. An "outreach plan" was also developed by the Department of Commerce to influence European stakeholders, which included the involvement of US Congressmen. The American Chamber of Commerce to the European Union (AmCham EU), which describes itself as "the voice of companies of American parentage committed to Europe",[70] also played an important role within this strategy.

The reports also show that ***the US tried to build opposition outside the EU***. Actions were taken to involve the Asia-Pacific Economic Cooperation (APEC) Business Advisory Council, as well as the Asia-Pacific Chemical Industry Coalition (APCIC). Twenty-one countries were thus targeted. This approach was maintained until the final version of the text was passed. During a meeting at the AmCham EU in June 2006, just before the completion of the second reading of the text, ambassadors and senior representatives from thirteen countries outside the EU once again expressed their concerns about REACH.[71] US ambassador to the EU C. Boyden Gray insisted on the fact that "the chances of trade disruption are too high to risk imposing such an unwieldy process on trade partners".[72] This initiative triggered responses from NGOs. WWF qualified such a position as "out of date", for example, and as failing to take account the changes that had already been made to REACH.[73]

It is difficult to assess the success of the US strategy. The efforts made contributed to the weakening of the proposal issued by the EC Commission in 2003 and, broadly, to

[70] See <http://www.eucommittee.be/AboutUs/about.htm>.
[71] These States were: Australia, Brazil, Chile, India, Israel, Japan, Korea, Malaysia, Mexico, Singapore, South Africa, Thailand and the United States.
[72] See <useu.usmission.gov/About_The_Ambassador/Gray/Jun0806_Gray_REACH.asp>.
[73] See *WWF Response to "EU Trading Partners" statement*, 9 June 2006, Brussels.

changes that ensured a better workability of the Regulation. It also certainly helped to build opposition to REACH. That said, the will of the EU to pass stronger chemicals regulation could not be undermined.

## The green coalition

NGOs from the green coalition seem to have had above all an ***agenda-setting role.*** This was done in many different ways. For instance, Greenpeace launched a Vigitox campaign, published several studies, organized workshops, and even a toxic free catwalk with the participation of major companies.[74] NGOs also have had an impact on policy formulation, by participating in institutional workshops or lobbying in favor of some choices, like the substitution of dangerous chemicals.[75]

The green strategy was founded on the use of ***arguments based on scientific evidence***, which were publicly exposed. The WWF for example launched a blood-testing campaign in which more than 150 people, amongst which MEPs and the then Commissioner for the Environment M. Wallström, took part. The Commissioner announced that 28 chemicals were found in her blood, including substances that were banned under EU legislation.[76] The tactic of relying strongly on scientific arguments seems to be a good one, officials of the Commission and MEPs being particularly receptive to it. However, according to B. Kohler-Koch, environmental groups

> *regret that they have neither the financial nor the staff resources to ensure a continuous monitoring and to get their own information about the course of the debate within Parliament. Their reliance on their close contacts*

---

[74] See for example Greenpeace, *Chemical Footprints in Blood. The Evidence*, 2004, <www.greenpeace.org/raw/content/eu-unit/press-centre/reports/chemical-footprints-in-blood>; Greenpeace, *Fragile – Our reproductive health and chemical exposure*, 2006, <www.greenpeace.org/raw/content/eu-unit/press-centre/reports/reproductive-health.pdf>; Greenpeace, *Substitute with style*, 2005, <www.greenpeace.org/raw/content/eu-unit/press-centre/reports/substitute-with-style.pdf>.

[75] For example, in favour of substitution of dangerous chemicals: Greenpeace, *Safer Chemicals within REACH – Using the Substitution Principle to drive Green Chemistry*, 2005, <www.greenpeace.org/raw/content/eu-unit/press-centre/reports/safer-chemicals-within-reach.pdf>.

[76] <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/03/219&format=HTML&aged=0&language=EN&guiLanguage=en>.

> *to members of the "Greens" is born out of a lack of promising alternatives.*[77]

The green coalition also ***took part in negotiations, both officially and unofficially***.

## FACTORS INFLUENCING MEMBER STATE POSITION

The preferences of Members States are shaped in part by domestic interests and, within those, by the need to balance out commercial interests and the protection and provision of public goods at a national level. From this argument follow two hypothesis: first, countries with large chemical industries will work against REACH since it is a far-reaching regulation, which will transform the very nature of their day-to-day activities. Second, so called "green states", for whom protection of the environment and/or the consumer is a central element of domestic policy, will tend to side with supporters of a stricter chemicals regulation. ***Did countries with large chemical industries work against REACH?*** The answer is complex, since such countries did not act as a block. Each individual mix of domestic interests can produce more nuanced behaviours. ***Germany,*** for example, is traditionally viewed as a leader in the field of environmental policy,[78] while simultaneously being home to a large pool of chemical companies, the most important one being the gigantic BASF. Germany was, to begin with, supportive of a new chemicals policy. Yet, from 2001 onwards, lobbyists from the industry rolled out a campaign directed towards parliamentarians, and especially targeting German social-democrats. This did not seem to reap any particular results,[79] until the position of the German government began to change shortly after the publication of the *White Paper*. In 2002, a common position was adopted together with the heads of the German chemical firms.[80] In June 2003, soon after the letter was sent to R. Prodi, G. Schröder also gave a supportive speech at the Cefic general assembly in Hamburg. The head of the Cefic at that time was E.

---

[77] B. Kohler-Koch, "Organized Interests in the EC and the European Parliament", *European Integration online Papers*, 1997, n° 9, <http://www.eiop.or.at/eiop/texte/1997-009.htm>.
[78] See for example M. S. Andersen, D. Liefferink, *European Environmental Policy: The Pioneers*, Manchester, Manchester University Press, 1997.
[79] See G. Lind, *op. cit.*, pp. 109-111.
[80] D. Pesendörfer, *op. cit.*, p. 105.

Voscherau from BASF.[81] Territorial factors, mainly the weight of the chemical industry, clearly influenced the German position on REACH.

Another significant territorial determinant is that of the so-called ***"green States"***. Following this typology, "green States" are States for which environmental policy is an important part of domestic policy, and who act as a result as leaders in the environmental policy field, and as norm-breakers within the EU forum.[82] As we have already seen, the political impetus for REACH was given by Sweden and supported by four green States. The Swedish government could also count on a woman of influence from 1999 onwards, since Swedish politician M. Wallström became Environment Commissioner. The anti-REACH lobby was quick to point out that Sweden had no chemical industry and that it was thus easier for its industrial sector to absorb a more stringent chemicals policy.[83] Members of the European Free Trade Association (EFTA), especially Norway, also supported a green approach.[84]

## EU INSTITUTIONS

> *Institutions as organised entities discriminate among conflicts; they "channel conflict" and do not treat all conflicts impartially [...] The notion is not that institutions as a rule "invent" conflicts, however, institutions may systematically activate some latent cleavages while routinely ignoring others.*[85]

Institutions matter. Although interest groups have multiple channels through which they can influence EU institutions, at the end of the day, European institutions are the ones deciding on the course of action to be taken by the legislative process.

---

[81] *Ibid.*, p. 95.
[82] M. S. Andersen, D. Liefferink, *op. cit.*; L. Kramer, *Focus on European Environmental Law*, London, Sweet and Maxwell, 1997, p. 343.
[83] G. Lind, *op. cit.*, pp. 110-112.
[84] L. Varden and H. Riegels, EFTA (interview, July 2009).
[85] M. Egenberg, "EU Institutions and the Transformation of European Level Politics – How to understand profound change (if it occurs)", *Arena Working Papers*, 2004, WP 04/19, <http://www.arena.uio.no/publications/working-papers2004/papers/wp04_19.pdf>, p. 7.

The first important player in this regard is the European Commission. It can be considered as a transnational actor. Its structure, organised around sectoral and functional directorates general (DGs), rather than along national lines,

> *explains why patterns of cooperation and conflict at the Commission so often seem to follow sectoral rather than territorial lines.*[86]

Studies reveal for example that the attachment of DG officials to their DGs provided a reliable indication of what their political position would be.[87]

This sectoral segmentation of the Commission results in a stronger autonomy between DGs. Indeed, the Commission's Directorates

> *have become increasingly autonomous. They have their own functional profile and are closely locked up in well established policy communities.*[88]

Thus, it is no surprise that ***DG Enterprise and DG Environment*** do not share the same views on REACH. The decision making process under REACH saw significant disagreement emerge between the two, the latter being more receptive to arguments from the green coalition, and the former to those of the business coalition. For example, DG Environment and DG Enterprise had trouble finding an agreement on the Commission's proposal.[89] Scope of authorization and inclusion of PBT and vPvB was also a major issue.[90] As we will see in chapter V, such disagreements persist to this day. According to the literature, DG Enterprise can be categorized as a central actor within the business coalition, since it is responsible for competitiveness.[91] However, rather than being members of one or the other coalition, we think DGs are more akin to policy-brokers, sensitive to certain arguments and positions depending on their sectoral belonging. The ***Council*** is similarly segmented, along specialized councils serving as more specific discussion forums.

> *Although the institutional set-up of the Council is supposed to be primarily conducive to the "politics among nations" pattern, the Council's dual structure*

---

[86] *Ibid.*, p. 11.
[87] M. Egenberg, "An organisational approach to European integration - What organisations tells us about system transformation, committee governance and Commission decision making", *ARENA Working Papers*, WP 02/19, 2002, <http://www.arena.uio.no/publications/working-papers2002/papers/wp02_19.htm>.
[88] B. Kohler-Koch, *op. cit.*, p. 2.
[89] D. Pesendorfer, *op. cit.*, p. 109.
[90] G. Lind, *op. cit.*, p. 81.
[91] D. Persendorfer, *op. cit.*, p. 101.

> *also opens up for the activation of sectoral identities that cut across nationalities.*[92]

Significantly, the REACH policy making process saw the ***transfer of decision-making responsibilities from one arena to another,*** namely from the environment to the competition sector. By adopting the Lisbon strategy in 2000, the EU set itself the goal of becoming the most competitive and dynamic knowledge-based economy in the world. This didn't mean that competitiveness would subsume every other objective, such as the protection of the environment and of human health, but this context catalyzed the business coalition's lobbying battle, until a change of competency occurred in 2003. In the October meeting of the European Council, President Berlusconi, followed by the others heads of States, decided that competency for decision-making on REACH should shift from the Environment to the Competition council. According to the Council in 2003:

> *EU legislation should not be a handicap to EU competitiveness compared to that of other major economic areas.*[93]

Moreover, the Commission had set new goals in 2004 to implement the Lisbon strategy, stating that:

> *Synergies between enterprise and the environment need to be fully exploited to foster economic growth that brings broader benefits while minimizing environmental damage. To this end, it is necessary to strengthen the policy and regulatory framework that gives clear signals to all economic actors, and to include innovative instruments that may reconcile certain business sector preoccupations with environmental protection.*[94]

This change is significant, since it promotes a liberal interpretation of the Lisbon strategy, in which the environment is seen as a means to competitiveness. However, given the additional specialization of the Council, sectoral identities are evoked simultaneously.[95] This change of policy arena can thus be considered as a blow for the green coalition, since the ministries in charge of REACH were, from 2003 inwards, those responsible for competitiveness rather than environmental protection.[96]

---

[92] M. Egenberg, 2004, *op. cit.*, p. 9.
[93] Brussels European Council, *Presidency Conclusions*, October 2003, http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/ec/77679.pdf.
[94] Report from the Commission to the Spring European Council, *Delivering Lisbon, Reforms for the Enlarged Union*, COM(2004) 29, p. 24.
[95] M. Egenberg, 2002, *op. cit.*
[96] In France for example, the competency to negotiate on REACH went to the Ministry responsible for the industry.

However, this was counterbalanced by the fact that the Council also worked within an Ad Hoc working group with a cross-sectoral representation for the purpose of negotiating REACH.[97]

Having gained more power over time, the ***European Parliament*** is another decisive actor of the legislative process. Voting behavior in the EP mostly coincide with a left-right dimension.[98] However, the work of various commissions is also of importance and adds a sectoral dimension to the traditional determinants of support groups. The Committee on the Environment, Public Health and Food Safety, and its Rapporteur G. Sacconi, led the work on REACH in the EP and largely contributed to make the Parliament an important player in the REACH legislative process. Duty of care, substitution and animal welfare were some of the topics pushed by the EP on the negotiation stage.[99] For example, the so-called "duty of care" provision, which states that actors have responsibility for the safe management of chemicals they produced, was not included in the Commission's proposal, but the EP introduced it during its first reading, and took it up in the final regulation within two recitals.[100] The EP also pushed for a stricter authorization regime, which was, and remains, a controversial issue. In the final regulation, if the approach of the Commission on this topic remained roughly unchanged, the substitution provision was strengthened, as well as on the general transparency of the system.[101]

## CONCLUDING REMARKS

The REACH Regulation went through a painful birthing process. Lobbying was strong and negotiations were long and difficult. It seems, as a whole, that the business coalition won more battles than the green coalition, and succeeded in turning the tide to its advantage.[102] The REACH Regulation can indeed be seen as a watered down version of the White Paper. However, one must bear in mind that the EC's White Paper was only a sketch of a future legislation, which drew broad contours. To put

[97] M. Blainley, 2007, *op. cit.*, p. 68.
[98] S. Hix, "Legislative behaviour and party competition in the European Parliament: An application of nominate to the EU", *Journal of Common Market Studies*, 2001, n° 39, pp. 663-688.
[99] M. Blainley, 2007, *op. cit.*, pp. 68-75.
[100] See recitals 16 and 17.
[101] For a detailed analysis on that point, see M. Blainley, 2007, *op. cit.*, pp. 73-74.
[102] See in particular G. Lind, *op. cit.*

such lines into practice necessarily involved the making of compromises amongst factions with competing interests. Business lobbying was strong, but the stakes were high. The voice of business was, at some points, perhaps more audible or listened to than others. However, the mere existence of the REACH Regulation shows that EU institutions did not arbitrate in favor of the industries' interests only. As we will see in the next chapter, REACH is indeed a modern way, and a constraining way, for companies, to regulate chemical risks.

# III. A MODERN TOOL TO MANAGE CHEMICAL RISKS

Contemporary literature abounds with theories of risk regulation. Our purpose here is not to enter a theoretical debate, but to demonstrate that the REACH regulation system can be qualified as a "modern" tool. By modern, we mean that the regulatory pattern of REACH differs from traditional approaches, such as command-and-control, or self-regulation. Moreover, the system takes into account a number of contemporary expectations. Mostly, it is a preventive and inclusive approach, based on a risk defined scientifically as well as socially and economically.

REACH is indeed based:

- On a vast participation of stakeholders in the regulatory system
- On a far greater responsibility of the business sector
- On transparency
- On a combination of hard and soft norms
- On a definition of risk according to multiple criteria.

In other words:

- REACH rests on the contemporary principles of environmental law and of an efficient regulation
- REACH is polymorphic: compliance and efficiency are not dependent on a single tool, such as a panel of sanctions for example, but is designed to be the result of a variety of tools.

# REGULATION OF CHEMICAL RISKS IN THE EU BEFORE REACH

Before REACH, chemical risks were regulated in two ways in the EU. First, through a vast array of Directives and Regulations, reflecting ***a traditional command-and-control approach***.

> *Traditional command and control regulation is characterized by the use of rules reinforced by legal sanctions. Required behavior is stipulated, standards are fixed, unacceptable actions are defined and outlawed and penalties for non-compliance are set out. Command and control regulation's strength derives from the use of law to designate what is acceptable.*[103]

This traditional pattern of governance proved insufficient, for various reasons exposed in chapter one.

Second, risks posed by the production and use of chemicals were managed through a ***self-regulative*** approach. Self-regulation is a governance model in which enterprises adopt voluntary regulative measures, or in which members of a professional sector decide to build a system within which they will define rules and designate a regulator. Proponents of self-regulation insist on the strengths of this form of governance:

- It is marked by a high compliance rate on the part of those who are governed
- It involves low public costs.[104]

However, self-regulation can be also seen as secretive, unaccountable and poorly enforced.[105]

Industries will tend to prefer voluntary measures and self-regulation over other more constraining approaches. There are three main reasons why industries would want to control risks: bad chemicals management may lead to economic losses, through lawsuits or a drop in profits in cases of industrial accidents; they may harm firms' reputation and consumer confidence in the products; they may lower the quality of products.

---

[103] R. Baldwin, B. Hutter, H. Rodstein, *Risk Regulation, Management and Compliance. A Report to the BRI Inquiry*, LSE, 2000, <http://www.bristol-inquiry.org.uk/Documents/Risk%20regulation%20report.pdf>, p. 7.
[104] *Ibid.*
[105] *Ibid.*

Self-regulation has been a key issue for the chemical industry ever since, in 1985, the Canadian Chemical Producers' Association, soon followed by the International Council of Chemical Associations (ICCA), launched its Responsible Care program. According to its Global Charter, Responsible Care commits companies to:

> *continuously improve the environmental, health and safety knowledge and performance of our technologies, processes and products over their life cycles so as to avoid harm to people and the environment.*[106]

The ICCA supports other voluntary programs (the High Production Volume Chemicals Initiative, in cooperation with the OECD; the Long-Range Research Initiative; the Global Product Strategy).[107]

These programmes led to some improvements. For instance, many large firms now have a Responsible Care Unit. Yet, self-regulation did not appear to be an adequate approach, given the objectives pursued by the EU, and this for two main reasons. First, the EU elaborated with REACH an ambitious strategy, and it did not want to leave the definition of what constituted an acceptable level of risk to the chemicals sector. Second, self-regulation can only be effective if it is based on the confidence of governments that the targeted sector can be trusted to self-regulate. Such a confidence is hard to build in the face of the various scandals and accidents that have peppered the activities of the chemicals sector - (Bhopal, Seveso, AZF in France in 2001).

## REACH REGULATORY PRINCIPLES

The REACH regulatory regime goes further than these traditional approaches. The regulatory principles it is founded on are more modern.

---

[106] Responsible Care Global Charter, <http://www.icca-chem.org/ICCADocs/09_RCGC_EN_Feb2006.pdf>.
[107] For more information on these programs, see www.icca-chem.org.

## A PREVENTIVE APPROACH

***The REACH regulatory system is based on a preventive philosophy.*** This was seen as the only possible way to fight toxic ignorance. As we have seen, the manufacturing and placing of substances on the market will not be allowed unless they have previously been registered, i.e. unless information requirements issued by the ECHA, relative the intrinsic properties of substances and the risks arising from their use, have been fulfilled.

Besides, the REACH regulatory system applies the principle, expressed in article 174 of the EC Treaty, according to which ***preventive action should be taken***. Indeed, when a hazard is identified under REACH, for instance when a substance is classified as CMR or PBT, regulators can control it through the authorization process, and the risk it could cause trough the restriction process.

REACH is also seen by some as applying the ***precautionary principle,*** also outlined in article 174.[108] This assertion must be treated cautiously. According to Principle 15 of the Rio Declaration,

> *where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.*[109]

There are multiple interpretations of the precautionary principle,[110] the common denominator being the type of hazards concerned, i.e.:

> *hazards the very existence of which has not been either formally established or refuted by sound scientific approaches. Such hazards are just asserted as potential, with various degree of plausibility, under existing scientific knowledge.*[111]

Given this definition, ***the REACH regulatory system is not a straight application of the precautionary principle***. The method chosen within REACH, i.e. getting the necessary knowledge on the hazards of a substance and/or its uses, will tend to assess the risks before managing them on this basis. This is consistent with a

---

[108] *S*ee for example J. Applegate, "Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform", *Ecology Law Quaterly*, 2008, pp. 747-749.
[109] See <http://www.unep.org/Documents.Multilingual/Default.asp?documentID=78&articleID=1163>.
[110] See for example O. Godard, *The Precautionary Principle. Between social norms and economic constructs*, Cahiers du laboratoire d'économétrie de l'Ecole Polytechnique, 2005, n° 20, <http://ceco.polytechnique.fr/fichiers/ceco/publications/pdf/2005-06-27-996.pdf>.
[111] *Ibid.*, p. 1.

preventive approach rather than a precautionary one. However, ***under some circumstances, regulators could apply the precautionary principle under REACH***. For instance, confronted with a potential risk, regulators have the tools to address it through the authorization or restriction processes.

This preventive approach places a large part of the responsibility for chemical management on firms.

### *SELF-RESPONSIBILITY*

In the classical command-and-control approach to regulation, the intervening State prescribes a policy allowing certain actions and forbidding others. Such a system rests on a control of compliance to the rules, and/or sanctions. As a consequence, within such systems,

> *the responsibilities of businesses were often overlooked as it was assumed that it was the job of the regulator to ensure risk management standards.*[112]

This traditional system is however doomed to fail in the case of EU chemical regulation, for at least three reasons, identified by M. Führ and K. Bizer:

- Information is complex, costly and cannot be obtain without cooperation of the industry
- Impacts may change depending on production processes
- Some substances cannot be substituted.[113]

REACH thus adopts ***a less hierarchal approach by shifting responsibility from the States to importers and producers***. The latter have to identify the intrinsic properties of a substance, assess its risks and develop risk management strategies. Such an approach is consistent with current trends in regulation, since, as B. Hutter and T. Amodu underline:

---

[112] B. Hutter, T. Amodu, "Risk Regulation and Compliance: Food Safety in the UK", *LSE and LSE Enterprise Report*, 2008, <http://new.wales.gov.uk/ecolidocuments/NCP/NCP.04219.pdf>, p. 6.
[113] M. Führ, K. Bizer, 2007, *op. cit.*, p. 328.

> *in recent years there has been a move to emphasize the responsibility of business and simultaneously give more leeway to determine how to manage risks itself*[114]

To base its chemical policy on self-responsibility was quite a challenge for the European legislator, since

> *it must adopt an approach which takes into account the incentive situation of the relevant actors and design a regulatory framework which makes it reasonable to them to comply.*[115]

A sociological approach to law-making shows that even if they are theoretically legally binding, rules remain vulnerable to non-compliance. Inclination to comply may be affected by many factors, such as the relative costs of complying or breaking the rules, the reputation of a firm or a professional sector, or the seriousness of risks at stake. In order to ensure compliance, it was necessary for the legislator that the vast majority of firms comply without having to resort to sanctions. For this reason, ***self-responsibility thus had to be conceptualized within an inclusive and transparent system, based on a pragmatic approach to problem-solving.***

## *INCLUSIVENESS*

Inclusiveness refers to the ability of a regulatory system to associate various categories of actors to its elaboration and functioning. Traditional command-and-control regimes tend to be exclusive, built around the sole regulator.

However, regulatory regimes have tended to become increasingly inclusive, for a number of reasons. First, threats to health, safety and the environment tend to elicit high levels of public concerns. Second, European environmental law is expected to ensure satisfactory levels of public participation within decision-making processes, as expressed, *inter alia*, in the Aarhus Convention of 1998.[116] Thirdly, as V. Heyvaert puts it:

---

[114] B. Hutter, T. Amodu, 2008, *op. cit.*, p. 6.
[115] M. Führ, K. Bizer, 2007, *op. cit.*, p. 328.
[116] Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Affairs, Aarhus, 25 June 1998, <http://www.unece.org/env/pp/documents/cep43e.pdf>.

> *The greater legitimacy that inclusiveness aspires to convey is not only normatively attractive, but can crucially influence regulatory effectiveness.*[117]

Inclusion of various actors is indeed a way of encouraging voluntary compliance with the rules.

The REACH decision-making process has been marked by the Commission's will to ensure participation of the public. One can question, however, and as expressed in the literature, the actual effectiveness of civil society participation in ensuring the democratic quality of decisions.[118] Concerning REACH, the answer is unclear, according to D. Friedrich. Old forms of participation, such as lobbying, seem to have had more impact on the outcome of the process than new ones.[119] D. Friedrich indeed argues that

> *the participatory infrastructure has not kept up with the pace of the participatory discourse.*[120]

According to the author, the problem is mainly that the so-called aggregative forms of participation, such as lobbying, which are purely voluntaristic, entail democratic deficiencies.[121] D. Pesendorfer also underlined that although it was formally inclusive, the process favored certain interests over others.[122] During the REACH policy-making process, it could be argued that such forms of participation were indeed overrepresented.

However, we can argue that the Internet consultation has been an interesting development and is a good tool to foster an effective participation of the civil society. The Internet consultation on the REACH proposal went on from May to July 2003. Some 6400 contributions were received, as well as a number of specific questions.[123]

---

[117] V. Heyvaert, « The EU Chemicals Policy : Towards Inclusive Governance ? », *Society and Economy Working Papers*, LSE Law, 2008, n° 7, <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1111968>, p. 4.

[118] One of the main contributors to these issues has been J. Harbermas, *Droit et démocratie. Entre faits et normes*, Paris, Gallimard, 1997 (first published under the title *Faktizität und Geltung. Beiträge zur Diskurstheorie des Rechts und des demokratischen Rechtsstaates*, Frankfurt, Suhrkamp, 1992).

[119] D. Friedrich, "Old Wines in New Bottles ? The Actual and Potential Contribution of Civil Society Organisations to Democratic Governance in Europe", *RECON Online Working Papers*, 2007, <http://www.reconproject.eu/main.php/RECON_wp_0708.pdf?fileitem=5456965>, pp. 1-24.

[120] *Ibid.*, p. 19.

[121] *Ibid.*, pp. 10-11.

[122] D. Pesendorfer, *op. cit.*

[123] Contributions are available at <http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/consultation/contributions/index_en.htm>.

Given the complexity of the draft regulation and the short period of the consultation, such a result is indeed remarkable.

Another significant move has been to develop guidance and IT-tools in close collaboration with all stakeholders through a number of ***REACH implementation projects*** (RIPs).[124] The former European Chemicals Bureau in Ispra was given the responsibility to develop such tools and methodologies. RIPs also allowed stakeholders to prepare for the practical application of the new system.

But the inclusiveness of a regulatory regime is above all related to its functioning.[125] The institutional design of REACH puts two Community institutions, namely the ECHA and the Commission, at the heart of the regulatory system. However, ***a variety of stakeholders intervene at different stages of the process***. The industry is a key actor for the gathering of data on chemicals and the management of risks. It is also represented in various working groups through professional organizations. The same is true of NGOs from the green coalition.[126] Besides, the ECHA set up Internet consultations for stakeholders in a number of occasions.[127] Member States also participate to the ECHA's work through the Member States committee,[128] and through their responsibilities within the authorization and restriction processes.[129]

The REACH regulatory regime also ***includes experts***. This group is represented in two of ECHA's Committees, and have a central role in a number of other processes.[130] Experts from Member States also have a crucial responsibility as they control and sanction individual firms.

As a consequence, the REACH regulatory regime can also be qualified as modern because it is part of the contemporary trend which sees

[124] See <http://ec.europa.eu/environment/chemicals/reach/preparing/index_en.htm>.
[125] On this topic, see also V. Heyvaert's analysis (*op. cit.*).
[126] N. Haiama, Greenpeace (interview, July 2009).
[127] <http://echa.europa.eu/consultations_en.asp>.
[128] See chapter IV.
[129] See chapter V.
[130] See chapter IV.

> *a rapid expansion in the scope and intensity of civil society's role in decision-making processes. From the ad hoc to the highly institutionalized, 'civil dialogue' is now a pervasive and enduring feature of EU governance.*[131]

## *TRANSPARENCY*

An essential counterpart of inclusiveness is transparency. According to recital 97 of the Regulation,

> *The effective communication of information on chemical risks and how they can be managed is an essential part of the system established by this Regulation.*

Internet plays a central role in ensuring transparency. For instance, stakeholders and the public in general have ***access to a large amount of information*** on the ECHA's and the Commission's websites. The Regulation indeed states that

> *EU citizens should have access to information about chemicals to which they may be exposed, in order to allow them to make informed decisions about their use of chemicals. A transparent means of achieving this is to grant them free and easy access to basic data held in the Agency's database, including brief profiles of hazardous properties, labeling requirements and relevant Community legislation including authorized uses and risk management measures.*[132]

However, the REACH regulatory system does not only require transparency from the regulators. It also requires information gathered from producers and manufacturers to be subjected to ***democratic control.*** As such, information shall be provided, on demand, to consumers[133] or workers, if they risk being exposed to a chemical substance in the course of their work.[134] It is also crucial that information be made available all along the supply chain.[135]

---

[131] J. Scot, D. Trubek, « Mind the Gap : Law and New Approaches to Governance in the European Union", *European Law Journal*, 2002, n° 1, available at <http://eucenter.wisc.edu/OMC/Papers/EUC/scotttrubek.pdf>, p. 3.
[132] Point 117 of the Regulation. More generally on the transparency of the regulators, see title XII of the Regulation and article 109 of the Regulation.
[133] Article 34 of the Regulation.
[134] Article 35 of the Regulation.
[135] See chapter IV.

This right to know is also closely bound to a more general system of ***classification and labeling***.[136] A new EU regulation on classification, labeling and packaging of substances and mixtures, the so-called CLP Regulation, entered into force on January 20, 2009.[137] This Regulation contributes to international coordination by applying terminology, evaluation principles and criteria defined by the United Nations in its Globally Harmonized System of Classification and Labeling of Chemicals.[138] This Regulation also includes or modifies the provisions of several other legal instruments, including the REACH regulation. Classification and labeling is a crucial component of consumer information and the overall transparency of the REACH regulatory system more generally.

## *A PRAGMATIC APPROACH*

The final principle on which the REACH regulatory system is based is pragmatism. It was important, given the wide scope of REACH and its other founding principles, that the system remain flexible in order to ensure its workability.

At the present time, actors implementing REACH are learning-by-doing. A collective process of cognition thus takes place, mainly between downstream users, producers and the regulators.

Against this background, and from a legal point of view, pragmatism calls for the ***combination of hard and soft law***. This is no surprise since

[136] Article 115 of the Regulation.
[137] Regulation (EC) n° 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) n° 1907/2006, <http://eur-lex.europa.eu/JOHtml.do?uri=OJ%3AL%3A2008%3A353%3ASOM%3AEN%3AHTML>.
[138] See <http://www.unece.org/trans/danger/publi/ghs/presentation_e.html>.

> *many of the approaches emerging in the area of "new governance" […] rely less on formal rules and "hard law" than on open-ended standards, flexible and revisable guidelines, and other forms of "soft law". In this way, these mechanisms can adapt to diversity, tolerate alternative approaches to problem-solving, and make it easier to revise strategies and standards in light of evolving knowledge.*[139]

Guidance produced by the ECHA is an example of soft law under the REACH Regulation. It is widely used by stakeholders to understand and implement REACH.[140]

But ***pragmatism can also lie in other provisions***, such as the multiple deadlines for phase-in substances, the collective setting of priorities under the authorization and restriction processes, the various exemptions incorporated in the Regulation, or the limited risk assessment requirements for substances placed on the market in proportions of less than 10 tonnes.

The regulatory principles on which the REACH is founded make it a modern tool for the management of risks. This characteristic is strengthened by the way an acceptable level of risk is defined within REACH.

## DEFINING ACCEPTABLE RISKS UNDER REACH

### *FIRST STEP: IDENTIFYING THE (HAZARDOUS) PROPERTIES OF A SUBSTANCE*

The REACH Regulation strives to fight against toxic ignorance. The first step in the definition of what constitutes an "acceptable risk" under REACH is thus to identify the properties of a substance, especially if they are hazardous. The hazardous potential of a chemical substance is based on its toxicity.

REACH is mostly a hazard-based regulation system. The authorization process thus leads to the classification of substances according to the intrinsic properties of a

[139] J. Scott, D. Trubek, *op. cit.*, p. 6.
[140] See chapter IV.

substance. The latter may for instance be included in Annex XIV if it meets the criteria of:

- A carcinogenic, mutagenic and toxic for reproduction (CMR) substance
- A persistent, bioaccumulative and toxic (PBT) substance
- A very persistent and very bioaccumulative (vPvB) substance
- An "equivalent level of concern", i.e. substances for which there is scientific evidence of probable serious effects to human health or the environment, raising a level of concern equivalent to that of substances identified as CMR, PBT or vPvB.[141] Differential uses of the substances, varying with the level of dispersion in use and the volume of production for example, should also be taken into account.[142]

However, risks also have to be defined. The risk is a function of the chemical's toxicity, i.e. its hazardous properties, and the probability of exposure to it. To put it simply, one could say: the more hazardous a chemical and the higher the exposure, the higher the risk.

### *SECOND STEP: IDENTIFYING RISKS THROUGH A COMBINATION OF MULTIPLE CRITERIA*

In every risk regulation regime, a crucial step is the definition of the level of tolerability regarding the risks at stake. To a large extent, getting this step right depends on the criteria adopted.

The perception of what constitutes a risk, as well as its intensity, varies with the perspective taken:

- A technical perspective, i.e. actuarial or engineering approaches
- An economic perspective, integrating a cost-benefit analysis
- A psychological approach, defining risk on the basis of individual cognition
- A sociological approach, underlining the social construction of risks

---

[141] Article 57 of the Regulation. On Annex XIV and the authorisation and restriction processes, see chapter V.
[142] Article 58 of the Regulation.

- A cultural perspective, in which the definition of risk varies according to cultural biases, i.e. attitudes and beliefs shared by a group.[143]

The criteria chosen should, as much as possible, encompass such approaches. The tolerability of risk is indeed a contingent notion, dependent on standards and public expectations set in a particular society and time.

The Health and Safety Executive, Great-Britain's regulator on Health and Environmental issues, identified three pure criteria used by regulators on their own or in an aggregate form to define what constitutes a risk.[144] These criteria, which are not exclusive, rest on the various approaches described above.

These are:

- ***an equity-based criterion***, which

> *starts with the premise that all individuals have unconditional rights to certain levels of protection. This leads to standards, applicable to all, held to be usually acceptable in normal life, or which refer to some other premise held to establish an expectation of protection. In practice, this often converts into fixing a limit to represent the maximum level of risk above which no individual can be exposed.*[145]

The first step of the authorization and restriction processes is mainly guided by the equity-based criterion. In later stages, the danger posed by certain substances can, under certain circumstances, forbid the granting of an authorization even if the risk is said to be adequately controlled.[146] This clearly refers back to the idea that there exists a maximum level of risk above which no one should be expected to be exposed. This also shows that the hazard-based system includes risk-based elements.

- ***a utility-based criterion***, which

> *applies to the comparison between the incremental benefits of the measures to prevent the risk of injury or detriment, and the cost of the measures. In other words, the utility-based criterion compares in monetary terms the relevant benefits (eg statistical lives saved, life-years extended) obtained by the adoption of a particular*

---

[143] See R. Baldwin, B. Hutter, H. Rodstein, *op. cit.*, pp. 10-14.
[144] Health and Safety Executive, *Reducing risks, protecting people*, Norwich, HSE Books, 1999, <http://www.hse.gov.uk/risk/theory/r2p2.pdf>, pp. 40-43.
[145] *Ibid.*, p. 41.
[146] Article 60.2 and 60.3 of the Regulation.

> *risk prevention measure with the net cost of introducing it, and requires that a particular balance be struck between the two.*[147]

This criterion is tied back to an economic perspective on the perception of risk. Under REACH, an authorization may be granted if it is shown that socioeconomic benefits outweigh the risk posed to human health or the environment by the use of a substance, and if there are no suitable alternative substances or technologies.[148] More specifically, both the socioeconomic benefits arising from the use of a substance and the socioeconomic implications of a refusal to authorize it on the market are taken into account. Moreover, when assessing whether suitable alternatives are available, economic feasibility is of importance.[149]

It could also be said that the limitation of the scope of the Regulation to substances produced in volumes of one tonne per year or more relates to this utility-based criterion. The economic and social costs of an extension of the scope to all substances would have indeed been too substantial.

- ***a technology-based criterion***, which

> *essentially reflects the idea that a satisfactory level of risk prevention is attained when 'state of the art' control measures (technological, managerial, organizational) are employed to control risks whatever the circumstances.*[150]

This criterion is also present in the definition of what constitutes an acceptable risk during the authorization process. An authorization shall indeed be granted if the risk to human health or the environment from the use of a substance containing properties specified in Annex XIV is adequately controlled.[151] Adequate control of a risk entails ensuring:

- Exposure levels of human populations (such as workers or consumers) and the environment are not excessive
- The likelihood and severity of an incident occurring due to the physicochemical properties of the substance is negligible.[152]

---

[147] Health and Safety Executive, *op. cit.*, p. 41.
[148] Article 60.4 of the Regulation.
[149] Article 60.5 of the Regulation.
[150] Health and Safety Executive, *op. cit.*, p. 41.
[151] Article 60.2 of the Regulation.
[152] Annex I, Section 4 of the Regulation.

These three criteria are thus combined to determine what constitutes adequate levels of chemical risks inside the European Union. The REACH regulatory system can be seen as encompassing, within a singular framework, various philosophies of risk perception.

## CONCLUDING REMARKS

The REACH regulatory regime is definitely modern. It takes into account changes in the way risks are defined, changes in the preferences, values and expectations of the society, as well as changes in the regulatory environment. It is designed to be open, easily accessible to stakeholders as well as other voices, through democratic participatory channels. It is a preventive instrument, which places responsibility both on the regulators and on the "producers" of risks, i.e. firms producing or using chemicals. Finally, the regulation strikes a balance between different ways of taking decisions, and of compelling enterprises to comply with rules. In other words, REACH is a polymorphic instrument, tailored to answer multiple expectations.

That said, the modernity of the REACH instrument does not necessarily result in its effectiveness, or in other words its ability to protect public health and the health of the environment, whilst avoiding excessive social and economic costs. The question of REACH's effectiveness remains open at the time of writing, even if some elements were proposed in this chapter to answer it. Whether REACH is an efficient tool will depend on the way actors will absorb it (chapter IV), and on how, practically, it will be implemented (chapter V).

# IV. IMPLEMENTING REACH: ORGANIZATIONAL SETUP AND THE OWNERSHIP PROCESS

The REACH regulatory regime is a modern tool. The question of its efficiency will depend for a large part on the way it is implemented, through the organizations created, and the use that actors will make of them. In this chapter, we will first analyze the organizational set-up of the regulatory regime. We believe that institutions matter and that the way the REACH regulatory regime is structured will have a significant impact on its effectiveness.

Such an institutional perspective is compatible with an analysis of individual behavior. If institutionalism is attractive because it highlights the power of internalized rules and practices, it does not seem sufficient to account for the implementation of REACH. Such an approach indeed needs, in our opinion, to be combined with a perspective in which the interests of individual, rational actors seeking to maximize their expected utility of the mechanism, are taken into account. We will therefore turn in the second part of this chapter to the study of the ownership process that seems to be taking place amongst the actors of the regulation. Enterprises are getting to know and to integrate REACH rules; they are getting organised to ensure compliance, while simultaneously trying to take advantage of the regulation.

## GOVERNING REACH: APPROPRIATE INSTITUTIONAL CHOICES

After describing the three-layer organizational structure of the REACH institutional framework we will focus on the outcomes of such an institutional choice and question whether it is an efficient one.

## *REGULATORS: A THREE-LAYER SCHEME*

### The European chemicals agency (ECHA) as the main regulator

*a) The establishment of the ECHA: functional and institutional accounts*

The ECHA belongs to what the literature refers to as the "third generation of agencies", which saw the creation of no less than 22 agencies since 2001.[153] After the resignation of the Santer Commission in 1999 on accounts of fraud and nepotism, the creation of agencies was seen as a way for the Commission to promote better governance.[154] Indeed, according to the Commission:

> *They help the Commission to focus on core tasks, making it possible to devolve certain operational functions to outside bodies. They support the decision-making process by pooling the technical or specialist expertise available at European and national level. And the spread of agencies beyond Brussels and Luxembourg adds to the visibility of the Union.*[155]

This analysis is essentially functional. It is indeed

> *primarily based on the assumption that structure is determined by contextual factors: structures exist because they match functional needs.*[156]

However, if such an analysis is widely shared in the literature, it is also challenged.[157] M. Martens, taking the ECHA as a case study, accounts for its establishment through an institutional analysis. She demonstrates that the Commission initially attempted, in

---

[153] See for example J. Saurer, "The Accountability of Supranational Administration: The Case of European Union Agencies", *American University International Law Review*, 2009, p. 443; S. Andoura, P. Timmerman, "Governance of the EU: The Reform Debate on European Agencies Reignited", European Policy Institutes Network, Working Paper, October 2008, n° 19, p. 3-4.

[154] See EC Commission, *European Governance. A White Paper*, COM(2001) 428 final, <http://eur-lex.europa.eu/LexUriServ/site/en/com/2001/com2001_0428en01.pdf>, sp. pp. 23-24 and EC Commission, *European Governance: Better Lawmaking*, COM(2002)275 final, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0275:FIN:EN:PDF>, p. 5.

[155] EC Commission, *European agencies – The way forward*, COM(2008) 135 final, p. 2.

[156] M. Martens, "Executive Power in the Making. The establishment of the European Chemical Agency (ECHA)", *ARENA Working Paper*, 2009, n° 8, p. 2.

[157] For an account of the various theoretical approaches, see M. Egenberg, M. Martens, J. Trondal, "Building Executive Power at the European Level. On the role of EU-level Agencies", *ARENA Working Paper*, 2009, n° 10, pp. 12-15.

the White Paper, to preserve and expand its own regulatory capacities within existing structures, mainly the European Chemical Bureau (ECB), part of the Joint Research Center,[158] a general service of the Commission. It advocated strongly for the expansion of its tasks, in order to increase its resources and organizational capabilities.[159] Thus, it can be said that, at least at the beginning, the Commission demonstrated "institutional resilience to the Agency model."[160]

It seems however that the European Parliament and the Member States were not willing to grant the Commission the necessary resources. Moreover, it was perceived that an independent Agency could more easily collect fees than a service of the Commission. The latter concern was voiced in particular by DG Enterprise, which put forward the example of the European Medicines Agency (EMEA), funded trough fees from the pharmaceutical industry.[161]

This point is interesting, because it reveals, once again, that the Commission is not a unitary actor, but is subject to internal conflicts.

### *b) Establishing ECHA as the main regulator*

Officially set up in June 2008, the ECHA began its activities a year earlier, in order to prepare for the preregistration phase (June to December 2008). Until June 2008, its work was thus devoted to intensive preparations, including staff recruitment and the establishment of support structures and procedures. It also provided REACH guidance, and ran a helpdesk.

According to a common classification, the ECHA is a regulatory agency.[162] There is no general framework governing the creation and operation of regulatory agencies. The delegation of powers to the Agency is however subject to conditions, which were first expressed in the Meroni-case.[163] Within these limits, a regulatory agency may be entrusted with some form of legal power, but may also take measures

---

[158] See M. Martens, *op. cit.*, pp. 2-4 and 8-11.
[159] *Ibid.*
[160] *Ibid.*, p. 4.
[161] *Ibid.*, pp. 8-10.
[162] As opposed to executive agencies, which are responsible for the management of Community programmes (such as Europe for Citizens, Marco Polo or the Public Health Programme). Their statute is defined by Regulation (EC) No 58/2003 of 19 December 2002 laying down the statute for executive agencies to be entrusted with certain tasks in the management of Community programmes, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:011:0001:0008:EN:PDF>. This classification is adopted by the Commission itself: EC Commission, 2008, *op. cit.*, p. 2-3.
[163] CJCE, 13 June 1958, case 9/56, *Meroni & co.*

> *of more incentive nature, such as co-regulation, self-regulation, recommendations, referral to scientific authority, networking and pooling good practice, evaluating the application and implementation of rules, etc.*[164]

***The tasks delegated to ECHA make it a strong agency, and an essential component of the REACH system***. It must indeed manage and carry out most of the technical, scientific and administrative aspects of REACH. First of all, its role is to receive and administer the ***preregistrations and registrations***. ECHA's handling of preregistration (from June to December 2008) was the first test regarding this crucial role. Unfortunately, it did not go as smoothly as hoped for given information technologies (IT) problems,[165] and since neither the Agency nor the Commission foresaw the very important influx of preregistration applications. More than 2.7 millions dossiers were received and 150.000 substances preregistered by more than 65.000 companies, amongst which 82% of small and medium-sized enterprises.[166] This was far more than expected. Many firms, encouraged by professional organizations, preregistered just to "be on the safe side", since it was free to do so.[167] Moreover, some legal interpretation issues led to confusion over products that were exported and then re-imported, and for products that were recycled, leading to a duplication of applications.[168]

The agency is also responsible for the management of chemicals databases and publishes part of the information on substances and their properties submitted as part of the registration dossiers, thus contributing to the transparency of the REACH system. ECHA also runs IT based tools[169] and produces guidance documents on best

---

[164] EC Commission, *Draft Interinstitutional Agreement on the operating framework for the European regulatory agencies*, COM(2005)59 final, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2005:0059:FIN:EN:PDF>, p. 4.
[165] See for example "Reach chemicals regulation hit by computer problems", *Chemistry World*, 17 June 2008, <http://www.rsc.org/chemistryworld/News/2008/June/17060801.asp>.
[166] B., European Commission (interview, July 2009). The list of pre-registered substances is available at <http://apps.echa.europa.eu/preregistered/pre-registered-sub.aspx>.
[167] E. Annys, Cefic (interview, July 2009) ; A., inspecteur des installations classées (interview, July 2009).
[168] S. Lemoine, AISE (interview, July 2009); J.-L. Ponchon, Rhodia (interview, July 2009).
[169] Two software tools are used:
- REACH-IT, which allows companies to submit registration dossiers on chemicals and the Agency and Member States authorities to review the dossiers.
- IUCLID 5 (*In*ternational *U*niform *C*hemica*l* *I*nformation *D*atabase), that allows the user to enter, manage, store and exchange information on intrinsic and hazard properties of chemical substances. This software uses the Harmonised Templates developed by the OECD, which means that it is compatible with various chemical legislation and programme requirements, among them REACH, the EU Biocides Directive and the OECD HPV Programme.

practices to fulfill obligations under REACH, which facilitate its implementation.[170] The ECHA is consequently a ***key actor in day-to-day operations***.

However, the agency also plays an ***important role within the governance of the system, along with the European Commission***. It is indeed required by the Regulation to identify substances of very high concern (SVHC) that are proposed for prioritization, and to include them in a so-called "candidate list". This list of recommended substances is then submitted to the Commission, which decides by comitology procedure whether the featured substances have to be included in Annex XIV of the directive, i.e. if they will be subject to the authorization procedure.[171] This procedure is a burning issue, as including a substance in the candidate list is the first step to blacklisting it. The ECHA also issues proposals on substances coming under the restriction procedure, and on classification and labeling.

However, as far as ***risk management*** is concerned, the power of the ECHA is not undisputed. As we have seen, such power is often shared with the Commission, and the ECHA's decisions can be challenged before the European Court of Justice (ECJ),[172] in other words, they are ***judicially accountable***. The regulation is also ***politically and financially accountable***, since the governing body of the Agency, the Management Board, responsible *inter alia* for nominations and adoption of the financial planning and budget work programme, is composed of representatives originating from EU Member State, the European Commission, the EU Parliament, and of observers from NGOs and the industry.

But the ***credibility and the legitimacy of the ECHA mostly derive from its expertise capacities***. It is common for agencies to be assisted by scientific and technical committees.[173] The ECHA is no exception to this rule. A Risk Assessment Committee, composed of independent experts,[174] plays a major role in assessing the

[170] More than twenty technical guidance documents have been developed with the participation of many stakeholders. They deal with the different REACH procedures (guidances on pre-registration, on registration, on data sharing, on the preparation of an application for authorisation, etc.), with specific products or activities (guidances for intermediates, for monomers and polymers, on scientific research and development, etc.) or with specific actors (guidance for downstream users). They are available at <http://guidance.echa.europa.eu/guidance_en.htm>.

[171] The ECHA first recommendation was issued on 1 June 2009, seven substances being prioritised. See <http://echa.europa.eu/doc/authorisation/annex_xiv_rec/annex_xiv_subst_inclusion.pdf>.

[172] The ECHA is provided with an internal chamber for the review of legality of the adopted acts, the Board of Appeal. Decisions can then be challenged before the ECJ on the basis of article 230 of the Treaty.

[173] S. Andoura, P. Timmerman, *op. cit.*, p. 11.

[174] Experts are appointed by the Management Board, from candidates nominated by the Member States, for a renewable term of three years. Some experts are also co-opted, chosen on the basis of their competence. It is forbidden for members to be employed by private enterprises that could have any direct

risks posed by a substance and the appropriateness of the risk management measures taken, as well as in the formulation of restriction and classification proposals.[175] A Committee for Socio-Economic Analysis also plays a role in assessing the socioeconomic determinants and impacts of the authorization and restriction processes.[176] When an authorization is required, the availability, suitability and technical feasibility of alternatives associated with the use(s) of a substance are also assessed.[177]

Although ECHA is the main regulator, it has to work hand-in-hand with the European Commission and the Member States.

## The European Commission: Implementing and updating the legislation

The European Commission remains a strategic actor within the REACH system, through the involvement, mainly, of ***DG Enterprise and Industry***. G1 Unit is in charge of the ECHA and has a vital role in updating the REACH legislation. This is done mainly through the reviewing and amendment of the Annexes.[178] This unit is also responsible for the granting of authorizations. ***DG Environment*** is the other main DG concerned with REACH, the role of the two DGs being relatively equal. DG Environment is indeed co-responsible for the regulation, and especially its D1 Unit on Chemicals. According to some stakeholders and to members of the Commission themselves,[179] divergences exist between the two DGs. DG Environment has been described in our interviews as “more on safety” than DG Enterprise. This comes as no surprise, the Commission not being a unitary actor.

---

interest in matters dealt with by the Committee nor by an industry association or other body which can be considered as an interest group in the context of the field dealt with by the Committee. See *Rules of Procedure for the Committee for Risk Assessment*, availble at <http://echa.europa.eu/doc/about/organisation/rac/rac_rops.pdf>.

[175] Article 64.4.a of the Regulation.

[176] ECHA, *Rules of procedure for the Committee for Socio-Economic Analysis*, available at <http://echa.europa.eu/doc/about/organisation/seac/seac_procedures_rules.pdf>.

[177] Article 64.4.b of the Regulation.

[178] So far, reviews have been made or are currently ongoing of the following Annexes: Annex I, Annex II, Annex IV, Annex V, Annex XI, Annex XIII, Annex XVII. See <http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review-annexes/index_en.htm>. See also M. Blainley, “REACH, sill being developed!”, *Journal for European and Environmental Planning Law*, 2009, pp. 51-73.

[179] For example N. Haiama, Greenpeace (interview, July 2009); B., European Commission (interview, July 2009); C., European Commission (interview, July 2009).

## The Member States, in charge of enforcement

Member States are continually involved in REACH governance. They are invited, by the ECHA and the Commission, to issue comments on hot topics, and they take part in various Committees and working groups.[180] The main task of the Members States is however the ***enforcement of the Regulation***. They maintain a system of official controls and inspections, and set effective penalties within their respective national legislations.

In France, the institutional scheme has recently been simplified, following the incorporation of the Bureau d'évaluation des risques et des produits chimiques (BERPC)[181] within the Agence Française de Sécurité Sanitaire de l'Environnement et du Travail (AFSSET).[182] The objective was to group scientific expertise within a single organization. This new institutional framework could be expected to change again in the coming months, because of a possible merger between the AFSSET and the Agence française de sécurité sanitaire des aliments (AFSSA). This project has been criticized for it could endanger the expertise capacities developed by the AFSSET.[183] The helpdesk mission of the BERPC, i.e. technical and legal assistance, has been transferred to the Institut National de l'Environnement et des Risques (INERIS).[184]

## *THE OUTCOMES OF REACH INSTITUTIONAL CHOICES*

Is the three-layer scheme adopted by the EU to implement REACH a good one? We will focus in this section on the outcomes of such a choice.

The main characteristic of the regulatory regime is the significant place given to an agency. This organizational setting tends to weaken the space for political manoeuvring and to enhance bureaucratic autonomy. As M. Egenberg and J. Trondal have indeed shown, priority is given in such structural settings to ***professional considerations rather than to political concerns***. More weight also tends to be

[180] For instance, there is a Member State Committee of the ECHA. Its role is to allow Member States to come to an agreement on various issues, including the authorisation process. See <http://echa.europa.eu/doc/about/organisation/msc/msc_procedure_rules.pdf>.
[181] Bureau for the evaluation of risks and chemical products
[182] French public agency for health security, environment and work
[183] S. Casalonga, "Inquitétudes quant à la fusion Afsset-Afssa », *Journal de l'Environnement*, 6 October 2009, <http://www.journaldelenvironnement.net/fr/document/detail.asp?id=1932&idThema=5&idSousThema=27&type=JDE&ctx=9>.
[184] National institute of environment and risks.

given to stakeholder concern.[185] This conclusion is consistent with the idea that "agencification" places executive power out of its usual surroundings. The establishment of such an organizational pattern indeed implied a shift of the coordinating capacities usually held by the Commission to an external structure. What consequences can we draw from the reinforcement of institutional autonomy? First of all, the Agency is expected to commit itself to the goals set out in the Regulation. The allegiances of Agency officials will tend to be more sectoral than national or political.[186] The fact is that the agency helps ***consolidate a professional identity*** around the development of technical expertise, [187] which is essentially sectoral.

> *Representatives meet frequently with professional colleagues in a context where matters of common interest and shared problems are discussed that transcend national preoccupations.*[188]

As a consequence, it can be said that ***the choice to entrust the ECHA with the role of regulator of the chemicals policy is a good one***. One could argue, however, that the ECHA is a highly undemocratic organization, and that the scientific jargon that constitutes its working language makes it as inaccessible to the public as its remote location in Helsinki. It could also be said that the system is too technocratic. However, we have seen in previous chapters that REACH was based on principles of inclusiveness and transparency, and that such objectives had been attained, according to a number of interviewees.[189] The ECHA is indeed strongly committed to developing a dialogue with stakeholders. Public consultations are numerous and open on the Internet, stakeholders being invited to comment on various proposals.[190] Stakeholders have access to the meetings of the Committees, to the forum,[191] and stakeholders meetings are held regularly.[192]

---

[185] M. Egenberg, J. Trondal, "Political Leadership and Bureaucratic Autonomy. Effects of agencification", *ARENA Working Paper*, 2009, n° 9, <http://www.arena.uio.no/publications/working-papers2009/papers/WP09_09.pdf>.
[186] *Ibid*.
[187] M. Martens, *op. cit.*, p. 18.
[188] *Ibid.*, p. 18.
[189] E. Annys, Cefic (interview, July 2009); S. Lemoine, AISE (interview, July 2009); P. Van Der Zandt, DG Environment (interview, July 2009); N. Haiama, Greenpeace (interview, July 2009); E. Moreau, Ministère de l'écologie, de l'énergie, du développement durable et de la mer (interview, July 2009).
[190] See <http://echa.europa.eu/consultations_en.asp>.
[191] ECHA, *Proactive Engagement with all ECHA Stakeholders*, 2008, <http://echa.europa.eu/doc/ECHADocuments/echa_stkhol_policy_en_20080528.pdf>.
[192] See, for example, *ECHA Newsletter*, 2009, n° 4, <http://echa.europa.eu/doc/press/newsletter/echa_newsletter_2009_08_07.pdf>, p. 6.

The set up of the ECHA as the central body of the regime also enables the ***equal implementation*** of the REACH regulation within each Member State. One caveat concerns the ***sanctions policy***, which is under Member States competency and are therefore implemented rather disparately across the EU area.[193] This degree of slack granted to Member States is inevitable under the principle of subsidiarity, which underpins the EU governance system. The forum of the ECHA is also an important policy space. It enables a process of "soft harmonization" between Member States, by supporting the coordination of enforcement activities.[194]

One of the questions left to be answered is that of the articulation of the different roles and actions of the regulators. The quality of it will largely depend on the way the Agency, the Commission and Member States interact, and it seems too early, at the time of writing, to draw any firm conclusions on this point.

From an organizational point of view, the legislator seems to have made the appropriate choices. The structure of the regime will most probably enable its efficiency. We will now inquire into the way stakeholders, mainly firms, receive the rules of REACH, and how they incorporate them. This will enable us to determine whether the REACH regulation leads or not to an ownership process amongst actors.

## COPING WITH REACH: AN ACTOR'S PERSPECTIVE

Self-responsibility is one of REACH's key regulatory principles. The Regulation is indeed based on the principle that producers and importers are responsible for the safety of the chemicals that they put on the market, and demands that they carry out the necessary analyses to collect information on their chemicals and to assess the risks arising from their use.

For the industrial sector, REACH remains perceived as a constraint. However, the vast majority of actors interviewed position themselves favorably towards the objectives pursued by the Regulation.[195] A number even go as far as advocating to

[193] E. Annys, Cefic (interview, July 2009) ; S. Lemoine, AISE (interview, July 2009); E. Moreau, Ministère de l'écologie, de l'énergie, du développement durable et de la mer (interview, July 2009) ; C. Lequime, UIC (interview, July 2009). On the French approach, see articles 521-17 to 521-22, Environment Code.
[194] B., European Commission (interview, July 2009).
[195] For example, C. Lequime, UIC (interview, July 2009); E. Annys, Cefic (interview, July 2009); L. Gaillet, Dolfus & Muller (interview, June 2009); J.-L. Ponchon, Rhodia (interview, July 2009).

take advantage of REACH and "transform[ing] a legal restraint into a business project".[196]

The implementation of the different rules of REACH at the industry level can be expected to be successful, based on the strong commitment that can be observed amongst professional organizations, and on the organizational changes that were put in place in a number of firms. These organizational changes, which facilitate the emergence of an ownership process, also create, in the longer-term, a net of REACH-related institutions that will sediment REACH in its environment and promote its endurance in time.

### *A STRONG COMMITMENT OF PROFESSIONAL ORGANIZATIONS*

At the European level, two main organizations contribute to the implementation of REACH within the chemicals sector: Cefic and the European Association of Chemical Distributors (FECC). Other sectoral organizations also play an important role, as well as institutions at the national and international level. ***The Cefic is a particularly proactive actor***. Aside from its participation in the lawmaking and regulatory process, it provided a number of tools that assisted firms, mainly but not only from the chemical sector, to comply with REACH. Practical guidelines and tools have been developed with Cefic members, together with partners from the industrial sector.[197] These guidance notes are open to all actors. The Regulation was thus taken as an opportunity to strengthen the links between enterprises and the organization, with the objective of increasing the level of chemical risks management. REACH also allows the Cefic to develop profitable activities. Through its "REACH Centrum" initiative, the organization offers services such as consultancy, workshops, trainings and Substance Information Exchange Forum (SIEF) support.[198] The Cefic also built, in association with its German, Spanish, Italian and French national counterparts, a project called "REACH Link". An IT platform for SIEF collaboration has also been developed,[199] which is widely used.[200] It thus appears that the Cefic follows a three layer strategy:

---

[196] J.-L. Ponchon, Rhodia (interview, July 2009).
[197] See <http://cefic.org/templates/shwPublications.asp?HID=750>.
[198] See <http://www.reachcentrum.eu/EN/home.aspx>.
[199] See <http://www.reachlink-eu.com/>.
[200] C. Lequime, UIC (interview, July 2009). See <http://www.atoutreach.fr/>.

- Taking part in the lawmaking and regulatory process
- Providing free guidance for the implementation of REACH
- Seizing a share of the new markets opened by REACH in the service sector.

At a national level, the UIC, a French member of the Cefic federation, carried out from 2006 to 2008 a number of actions to raise public awareness on REACH, especially in the case of small and medium enterprises (SMEs), in partnership with the Economy and the Environment Ministries and with the support of the regional directorate for the industry and the environment (DRIRE). Meetings and workshops were organised.[201] The organization also developed a range of services, quite similar to "REACH Centrum", called ATOUT Reach.[202]

***The strong commitment of professional organizations reaches beyond the chemical sector.*** Most sectoral organizations, even when their members are only downstream users, will centralize the information and guidance on REACH that is directly related to their respective sectoral specificities.[203] A Downstream Users of Chemicals Co-ordination group (DUCC) was founded in 2001 by sectoral organizations in order to advise and help downstream users to implement REACH, and to offer a platform where associations and federations could exchange information and expertise.[204]

Professional associations are committed to the success of REACH. Their strategy aims at helping the industry implement the rules of REACH, but also at enhancing their lobbying capacity in order to weight on the regulatory process, and seizing their share of the new markets opened up by the regulation. REACH is thus an important instrument for these organizations both to reinforce their position with regards to their members, and to expand it by developing old and new activities.

## *COMPANIES' ORGANIZATIONAL RESPONSE TO REACH*

Firms, especially those from the chemicals sector, needed to evolve to be able to implement REACH. In large firms, the issue was dealt with most of the time as part of

[201] *Ibid*.
[202] See <http://www.atoutreach.fr/Default.aspx>.
[203] For instance, the AISE build a "REACH information and communication support", providing public access to information on exposure scenarios. See <http://www.aise.eu/reach/>.
[204] See <http://www.duccplatform.org/home.html>.

a "Responsible Care" programme. This was the case for firms such as BASF, Bayer or ExxonMobil.[205] These companies had the necessary financial means to anticipate the implementation of REACH. For instance, Rhodia closely monitored the legislative process from its inception and had experts working on its implementation even before it was adopted.[206] This should not come as a surprise, considering the costs and stakes involved for such chemical giants: ExxonMobil communicated almost 4.000 preregistrations,[207] and Rhodia 700.[208] Additionally, most of these chemical multinationals are simultaneously producers, importers and downstream users.

REACH thus induced structural changes in many companies. Rhodia provides a good example of such changes.[209] Indeed, a wide-ranging networking strategy was developed, within which a targeted REACH "task force" was created within each of the 17 legal entities composing the group. These teams are in close contact with the different horizontal departments of each entity, i.e. the IT, R&D, financial departments, as well as with a team of scientific and legal experts. Regular meetings take place between those actors, to which directors and CEOs sometimes attend. Similar structures have been developed in other large chemical companies.[210]

It is more difficult for small companies to engage in such a strategy, and as a matter of fact, most of the time it is not necessary that they do so. Small enterprises outside the chemical sector are indeed mainly downstream users, a position which limits their responsibilities under REACH. Small chemical firms deal with a limited number of substances and can therefore count on the support of professional associations.[211] That said, SMEs are obviously less able to mobilize resources for the implementation

---

[205] See <http://www.bayer.com/en/position-on-global-product-strategy.aspx>; <http://www.basf.com/group/corporate/en/sustainability/reach/index>; <http://www.exxonmobileurope.com/Europe-English/products_reach.aspx>.
[206] J.-L. Ponchon, Rhodia (interview, July 2009).
[207] <http://www.exxonmobileurope.com/Europe-English/products_reach_implementation.aspx>.
[208] J.-L. Ponchon, Rhodia (interview, July 2009).
[209] The following information has been given by Rhodia REACH network team project director J.-L. Ponchon (interview, July 2009).
[210] See ECHA, "Large chemical companies will pre-register about 800 substances", *op. cit*.
[211] Another example than those already quoted is given by the *Institut français du textile et de l'habillement* (IFTH), a technological research center working to develop new products and processes. A REACH programme has been set up, following progressive steps, in order to accompany the industries of the sector in the implementation of REACH. See <http://www.ifth.org/innovation-textile/IFTH-pagesHTML/reach-l-accompagnement-reach-de-l-ifth-reach-un-parcours-de-formation-progressif.htm>. See also ECHA, "REACH at a small enterprise", REACH Case Story, <http://echa.europa.eu/doc/press/reach_case2_en_20080603.pdf>.

of REACH, and the regulation is therefore a greater constraint for them than for large firms.[212]

***A particular case: the sector of petroleum products issued from refining activities***

Less than 40 companies make up the oil sector in Europe.[213] Activities can be divided as follows: exploration, refining and chemistry. Products resulting from refining activities are very specific, since they have a variable or unknown composition (the so-called UVCB).[214] Their intrinsic properties, and the risks that they pose are thus difficult to assess.

Concawe, the sectoral organization for such substances, had for some time developed methodologies enabling such assessments within its Risk Assessment Programme.[215] Actors from the sector, which were also members of Concawe, decided to make good use of this existing programme and to fully collaborate, through the organization, to the REACH registration process by submitting common elements whenever possible,.[216] Moreover, Concawe members decided to freely exchange the studies and information on a number of products that they already possessed.[217] In addition, for practically all petroleum products, Concawe has volunteered as the SIEF Formation Facilitator. In the case of this particular industrial sector, the implementation of REACH thus strongly rests on the actions of the concerned professional organization, and on the openness of each individual company.

---

[212] Many actors expressed their concerns on that point (D. Garrigue, member of the French Parliament, interview, July 2009; F. Loos, former Ministry for the Industry; L. Gaillet, Dolfus & Muller, interview, June 2009).
[213] Concawe has 37 members, which refining capacities represent practically 100% of the total refining capacity in Europe (see <http://www.concawe.be/Content/Default.asp?PageID=9>).
[214] UVCB stands for Unknown or Variable Composition complex reaction products, or Biological materials.
[215] See <http://www.concawe.be/Content/Default.asp?PageID=469>.
[216] *Ibid.*; C. Deconninck, Total (interview, August 2009).
[217] *Ibid.*

REACH also implies changes along the supply chain. When a number of conditions are fulfilled, registrants have to produce a chemical safety report (CSR). Elaborating this report requires carrying out an exposure assessment, which is built on exposure scenarios for all identified uses of the substance at hand. The registrant is expected to be able to demonstrate his control of the risks posed by a substance for all its uses, and for the whole length of its life cycle.[218] As a consequence, manufacturers / importers are required to have a knowledge the various uses that are made of the product that they sell.

This entails a deepening of the relationship between the producer and its clients, through the strengthening of an information chain disseminating information on exposure scenarios from the bottom (downstream users) to the top (producers / importers), as well as information on the risks posed by different uses of the substance from the top to the bottom.[219] The implementation of REACH thus appears to be generating new relationships between firms from one end to the other of the supply chain. Firms and professional organizations seem to have gradually tamed the REACH regulatory system and its rules. The reverse seems to be the case for NGOs.

## *NGOs: MISSING A CRUCIAL STEP?*

NGOs have been far less active since the adoption of the Regulation. The means employed for campaigning during the policy-making process have been re-allocated to other issues.

According to a 2007 article of the Environmental Data Service Report, the finalization of the EU's chemicals regime

> *marks the end of an era. WWF now wants to focus on climate and resources with its "one living planet" agenda [...] Chemicals is one of the areas which has fewest cross-overs with climate and benefits least from its high*

[218] According to the Regulation (article 3.37), an exposure scenario "means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment". See also ECHA, *Guidance on Information Requirement and Chemical Safety Assessment. Part D: Exposure Scenario Building*, 2008, <http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_d_en.pdf?vers=20_08_08>.

[219] J.-L. Ponchon, Rhodia (interview, July 2009) ; P. Van Der Zandt, European Commission (interview, July 2009); S. Lemoine, AISE (interview, July 2009); L. Gaillet, Dolfus & Muller (interview, June 2009).

> *profile. WWF is certainly not alone in dropping its chemicals campaigning – a relatively technical topic that can be difficult to explain to the public.*[220]

This analysis is consistent with what we observed. When trying to get appointments for interviews, many of our interlocutors informed us that there was no chemicals specialist in the organization any more. It appeared to us that if some experts are still working on REACH, it is mainly at the European level, where large NGOs are still active on the REACH front.

Two explanations can be summoned: first, NGOs function on limited resources, and the allocation of funds has to be determined by the relative importance of issues. Once the Regulation was passed, chemicals sunk down on the list of priorities. Second, the potential benefits of an action on REACH are limited.

It is important to mention, however, that a number of important initiatives are developed at an inter-NGO level.[221]

## CONCLUDING REMARKS

Whether the REACH regulatory system is efficient or not depends for a large part on the way it is implemented, through the organizations created and through the actions of its actors. One of REACH's primary consequences, as well as condition for its success, has been the triggering of organizational changes within the governance of chemicals policy at the European level, and at the industry level.

It appears to us that the organizational choices that were made, i.e. the choice of a three-layer format, are efficient. From an actor perspective, an ownership process is taking place as firms get to know the rules, re-organise themselves in accordance to them and take advantage of the regulatory changes introduced by the Regulation to develop new activities, or strengthen their position. It thus appears that the REACH regulatory regime, because of the efficiency and success of its implementation process, has the potential to be an effective tool. It is now time to examine the other variables conditioning REACH's success.

---

[220] *ENDS Report*, "Chemicals NGO Forms as Climate Takes Centre Stage", May 2007, n° 388.
[221] See the SIN List project, chapter V.

# V. REACH: ASSESSING THE POTENTIAL FOR SUCCESS

> *We must always bear in mind that the first aim of REACH is to ensure a high level of protection of human health and the environment. If we continue to stick to this aim, I believe that over the coming 10 years we will see a more healthy and transparent chemicals sector, a more green and clean chemicals industry, less pollution in the environment, safer workplaces and safer homes. But to make this vision of a sustainable development to come true, we need to continue to cooperate.*[222]
>
> *M. Wallström, Vice-President of the European Commission*

REACH is a modern regulatory tool. Its organizational set-up is efficient, and its implementation is accompanied by a process of ownership amongst its actors. Such conclusions, drawn and exposed in previous chapters, were necessary to assess the efficiency and effectiveness of the REACH regulatory regime. One question remains to be answered, however, and it is that of the actual potential for success of REACH, with regards to the objectives it had set itself to attain. Four interrogations can be summoned in order to answer this question:

- Does REACH meet the requirements of legal certainty?
- Does REACH raise significant operational difficulties in its day-to-day practice?
- Does REACH lead to an upgrade of the standards of chemical risks management?
- Does REACH achieve its fundamental objectives?

---

[222] M. Wallström, 2009, *op. cit.*, p. 4.

# DOES REACH MEET THE REQUIREMENTS OF LEGAL CERTAINTY?

Legal certainty is a principle of EC law, requiring that legal rules be clear and precise, and that situations and legal relationships remain foreseeable. In EC law, legal certainty relates mostly to the principle of non-retroactivity and the protection of legitimate expectations.[223] However, a wider conception of legal certainty encompasses concerns such as the quality of the law, i.e. its clarity, simplicity and consistency.[224]

The issue of legal certainty is of high importance, because actors cannot be expected to fulfill their obligations in a regulatory system where rules are unclear and/or uncertain. Legal uncertainties can thus lead to regulatory inefficiency.

## *INTERPRETATIONAL ISSUES*

Given the complexity of the Regulation, it is no surprise that a number of interpretational issues were raised. We will focus on two of them.

### Substances in articles

One of the main interpretational issues relates to articles 4 and 33 of the Regulation. According to article 4,

[223] J. Raitio, *The Principal of Legal Certainty in EC Law*, Kluwer Academic Publishers, 2003.
[224] A. Wagner, S. Cacciaguidy-Fahy (eds), *Obscurity and Clarity in the Law. Prospects and Challenges*, Ashgate Publishing, 2008.

> *Any producer or importer of articles shall notify the Agency […] if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1), if both the following conditions are met:*
>
> *(a) The substance is present in those articles in quantities totalling over one tonne per producer or importer per year*
>
> *(b) The substance is present in those articles above a concentration of 0,1% weight by weight (w/w).*

Article 33 of the Regulation states that any supplier of an article containing a substance meeting these criteria

> *shall provide the recipient of the article with sufficient information […] to allow safe use of the article.*

The supplier is also expected to do so upon the request of consumers. The criteria of article 57 referred to in these articles are the criteria according to which a substance is included in Annex XIV, i.e. substances of very high concern that are identified, according to the procedure described in article 59, as CMR, PBT, vPvB or endocrine disrupting substances.

The question open to debate is the following: ***is concentration assessed with reference to a complex article in its final produced or imported form, or to the individual articles, parts or materials that make up a complex article?*** In other word, does it relate, for example, to a car as a whole, or to its steering wheel? Depending on the answer, the scope of the registration requirement varies greatly.

According to the ECHA:

> *The substance concentration threshold of 0.1% (w/w) applies to the article as produced or imported. It does not relate to the homogeneous materials or parts of an article, as it may in some other legislation, but relates to the article as such (i.e. as produced or imported).*[225]

However, this part of the guidance was not endorsed by six Member States. According to them, such an interpretation would lead to the relevant REACH Regulation provisions, which are especially important for consumer protection, being inoperative.[226] Moreover, such an interpretation implies arbitrary differences in

[225] ECHA, *Guidance on requirements for substances in articles*, <http://guidance.echa.europa.eu/docs/guidance_document/articles_en.pdf>, p. 16.
[226] *Dissenting views on the Guidance on requirements for substances in articles*, <http://guidance.echa.europa.eu/docs/guidance_document/dissenting_en.pdf>. See the German statement.

application depending on whether the article is marketed as a separate part or integrated in a complex article.[227]

In other words, and in cases where risk from exposure is equivalent, some users will get information on the risks, while others will not. This issue is still on the table at the time of writing. Industrials remain divided on the topic.[228] On the impulsion of Sweden, a working group has been created, involving various stakeholders,[229] and the ECHA has agreed to reopen discussions on this part of the guidance for a possible future review.

## Monomers and polymers

Polymers play an essential role in everyday life, as they are the basic material for a wide range of applications. A polymer is a substance formed of sequences of monomer units. Conversely, a monomer is a substance which, via the polymerization reaction, is converted into a repeating unit of the polymer sequence.[230]

For example, propylene (C3H6) is used for the manufacturing of polypropylene (-$CH_2$-$CH(CH_3)$-), a polymer widely used in plastic items such as hinged lids or wastebaskets.

Polymers are regarded as being of low concern, because of their high molecular weight. They are thus exempted from registration under REACH. However, according to article 6 of the Regulation, a monomer contained in a polymer has to be registered if it has not already been registered by an actor higher up in the supply chain, and if both of the following conditions are met:

---

[227] *Ibid*. See the Danish and Swedish statements.
[228] E. Moreau, Ministère de l'écologie, de l'énergie, du développement durable et de la mer (interview, July 2009). The UIC expresses no position on the issue (C. Lequime, UIC, interview, July 2009).
[229] E. Moreau, Ministère de l'écologie, de l'énergie, du développement durable et de la mer (interview, July 2009).
[230] ECHA, *Guidance for monomers and polymers*, 2008, <http://guidance.echa.europa.eu/docs/guidance_document/polymers_en.pdf>, p. 7.

> *(a) The polymer consists of 2% weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s)*
>
> *(b) The total quantity of such monomer substance(s) or other substance(s) makes up one tonne or more per year.*[231]

Four chemical enterprises challenged the interpretation of the term "monomer substances" before the ECJ. Their main argument was that reacted monomers, that is, monomers which have reacted together and have thus become inseparable from the polymer they are a part of, should not be subject to registration since polymers are not. Such a request seemed to be doomed to failure from the start, but it enabled the ECJ to specify the contents of the challenged provision. The ECJ rejected the claim made by the plaintiffs, based on the spirit of the REACH legislation and on the principle of registration. Moreover, and according to the Court, in order to ensure genuine competition within the Community, importers of monomer substances should be subject to the same obligations as the ones faced by manufacturers, or to similar ones, to ensure an adjustment of costs.[232]

## Mind the gap: REACH and other legal instruments

Legal certainty also depends on the way REACH interacts with existing legislation. We will focus here on the interaction of REACH with waste legislation, and with competition law,[233] two hot topics at present.

### *a) REACH and waste legislation*

According to article 2.2 of the Regulation, waste, as defined in Directive 2006/12/EC, is not a substance, preparation or article covered by REACH. However, waste is not totally exempt from REACH, in particular because exposure scenarios are expected to account for the uses of a substance during the entirety of its life-cycle.[234] Moreover, as

[231] Article 6 of the Regulation.
[232] ECJ, 7 July 2009, aff. C-558/2007, *The Queen*, available at <curia.europa.eu>. See also D. Wagner, "The EU's ECJ Rejects First Legal Challenge to the Registration Requirements of the REACH Regulations", *Environmental Law Resource*, <http://www.environmentallawresource.com/2009/07/articles/chemicals/the-eus-ecj-rejects-first-legal-challenge-to-the-registration-requirements-of-the-reach-regulations/>.
[233] For other examples, see M. Führ, S. Merenyi, "Mind the Gap: Interface Problems between EC Chemicals Law and Sectoral Environmental Legislation", *RECIEL*, 2006, n° 3, pp. 281-292.
[234] Article 3.37 of the Regulation. See also Annex I, paragraphs 5.1.1 and 5.2.2.

soon as a material ceases to be considered as waste, after a recovery process, it enters the regulatory grounds of REACH.

However, as shown by the case of contaminated land examined by the European Court of Justice,[235] the legal qualifications of waste have never been easy to define under EC law.[236]

The question of the exact moment where waste ceases to be waste is, against this legal background, a difficult and tricky one. The Commission, the ECHA and the Member States held several meetings to try and answer similarly difficult questions, such as:

- Should recovery be considered as a manufacturing process under REACH?
- Are recovered materials substances, preparations or articles?
- Should all recovered substances be exempt from REACH?[237]

The ECHA is expected to issue guidance on the interface between REACH and waste legislation. This will be necessary to clarify the scope of application of REACH, and identify inter-legislative gaps. However, it is likely that such interface problems remain, considering the difficulties in agreeing on a definition of waste.

### *b) REACH and competition law*

One of the founding objectives of REACH is the reduction of the burden placed on registrants by requiring firms to collaborate, through the pooling of data on substances. This objective can be hampered by the "rules of the game" of a free market, within which coordination with competitors is viewed with a certain degree of skepticism. According to recital 48, the Regulation

> *shall be without prejudice to the full application of the Community competition rules.*

Compliance with competition law as part of REACH-related activities may at times be challenging. There is indeed an ***opposition between some of the requirements of REACH and certain obligations under competition law:*** REACH requires

[235] ECJ, 7 July 2004, case C-01/03, *Van de Walle*. See also O. Mc Intyre, "The All-Consuming Definition of "Waste" and the End of the "Contaminated Land" Debate?: *Van de Walle* and Others", *Journal of Environmental Law*, 2005, n° 1, pp. 109-127.
[236] See the special issue « Trente ans de droit des déchets », *Bulletin de droit de l'environnement industriel*, June 2006.
[237] See for example EU Commission, *Follow-up to the 5th Meeting of the Competent Authorities for the implementation of Regulation (EC) 1907/2006*, 2008, Doc. CA/24/2008 rev.3, <http://www.minambiente.it/moduli/output_immagine.php?id=2459>.

collaboration and data sharing between firms. Moreover, the significant resources – financial, organizational – needed to register a substance can create a barrier to competition.

Companies can as a consequence be exposed to sanctions under competition law in a number of cases, as identified by S. Megregian.[238] Mostly, companies that develop data under REACH will want to protect their investments. As a consequence, they may try to limit access to their data, or provide access on unreasonable terms.

Collusion can also be expected:

> *In order to prepare a registration dossier, competitors must work directly with one another [...] Such co-operation requires competitors to speak and meet frequently. They must take decisions on the scope of work and financing their efforts. This creates an opportunity for them either intentionally or unintentionally to agree on matters that could restrict or distort competition.*[239]

As far as competition law is concerned, REACH could also be seen as a protectionist instrument. This risk is however weak, since REACH was submitted to WTO Committees.

Companies should be aware of these different risks in order to avoid them. REACH sets an ambitious regulatory system. It meets, for the most part, the criteria of legal certainty, and can be applied without doubts on the scope or the meaning of the Regulation. However, ***on some important points, a clarification of the rules is still needed***. This is problematic since actors are expected to implement rules that are not perfectly clear and can change over time.

[238] S. Megregian, "The risk of REACH. Finding the right balance between co-operation and competition is hard", *Competition Law Insight*, 28 July 2008, pp. 11-13.
[239] *Ibid.*, p. 13.

# DOES REACH RAISE SIGNIFICANT OPERATIONAL DIFFICULTIES IN ITS DAY-TO-DAY PRACTICE?

REACH places a burden on manufacturers and producers by setting legal obligations. But in day-to-day practice, operational issues are as important as legal ones. They indeed have palpable consequences on the effectiveness of the system. Moreover, they are at the heart of the rhetoric of the industrial sector, as it emerged from the interviews that we had with a number of representatives. We will focus on three major concerns in this section.

## Puzzling Substance Information Exchange Forums (SIEF):

The concept of the Substance Information Exchange Forums is crucial to the REACH system. According to the Regulation, the aim of each SIEF is to:

> *a) Facilitate, for the purposes of registration, the exchange of [information] between potential registrants, thereby avoiding the duplication of studies; and*
>
> *(b) Agree classification and labeling where there is a difference in the classification and labeling of the substance between potential registrants.*[240]

In practical terms, a SIEF is a virtual platform with no prescribed legal form, established for each substance required for registration. It is designed to act as a powerful information exchange tool, allowing to cut back on registration costs and to avoid unnecessary testing. In order to carry out obligations under REACH, some companies have also decided to organise themselves in so-called consortia. Members of a consortium will agree on an organizational structure, such as technical committees and a secretariat,[241] and on functioning rules, including the allocation of tasks and responsibilities such as costs and data valuation.

SIEFs and consortia are thus fundamental components of the success of the registration process. At the present time, however, the problems arising from the operation of such new forums are unanimously identified by industrials as ***the***

[240] Article 29 of the Regulation.
[241] The above mentionned REACH Centrum has for example been contracted to manage several consortia. See <http://www.reachcentrum.eu/EN/consortium-management/consortia-under-reach.aspx>.

***topmost difficulty in the implementation of REACH.***[242] First of all, ***a difficult discussion has to be held on the nature of the substance*** around which a SIEF will be created, and on the identification and invitation of all the industries using the exact same substance. This preliminary identification process takes place in a loose, pre-SIEF type forum. Once the substance has been identified, a SIEF can be formed. Pre-registrants with a different substance are asked to form or join another SIEF. In order to facilitate the transition between a pre-SIEF and a SIEF, a company can volunteer to be a SIEF Formation Facilitator (SFF). Tasks entailed by such a position are mainly to contact the other participants of the pre-SIEF in order to form a SIEF. It appears however that the ***answering rate in such cases is very poor*** – around ten to thirty percent only according to some actors.[243] Once a SIEF is formed, ***a Lead Registrant has to be selected***. With the agreement of the other assenting registrants, this actor is responsible for submitting the Joint Dossier to ECHA. It follows that all subsequent registrants only have to submit the information relative specifically to their company.

The issues of ***data and costs sharing*** also arise within this context. They are addressed within an ECHA guidance paper.[244] However, practice seems to show a ***significant difference in the price set for studies,*** depending on the forums or consortiums.

Even if REACH allows companies, under certain conditions, to opt-out of the obligation to participate in the joint submission if this creates disproportionate costs or would lead to the disclosure of confidential business information, some concerns have been voiced on confidentiality and competition law.[245]

Another problem is that the whole SIEF process is extremely ***time-consuming***,[246] as the first deadline for registration draws nearer (2010). In order to raise public

---

[242] The following issues have been or are still problematic according to C. Lequime, UIC (interview, July 2009); E. Annys, Cefic (interview, July 2009); S. Lemoine, AISE (interview, July 2009); C. Mordini, engineer (interview, July 2009); F. Litty, IFTH (interview, September 2009). See also presentations at the 2nd Stakeholders Day of the ECHA, at <http://echa.europa.eu/news/events/2nd_stakeholders_day_en.asp>.

[243] J.-L. Ponchon, Rhodia (interview, July 2009); C. Lequime, UIC (interview, July 2009).

[244] See ECHA, *Guidance on Data Sharing*, <http://guidance.echa.europa.eu/docs/guidance_document/data_sharing_en.pdf>.

[245] For example, S. Lemoine, AISE (interview, July 2009).

[246] J.-L. Ponchon, Rhodia (interview, July 2009); H. Abma, Director General of FECC, "From Pre-SIEFS to SIEFS – feedback from the Chemicals Distributors / SMEs", ECHA 2nd Stakeholders Day, presentation available at <http://echa.europa.eu/doc/press/events/stks_day_20090525/2nd_stk_day_feec_eu_voice_chem_distr.pdf>.

awareness on the issue, the ECHA launched, during its second Stakeholders Day in May 2009, a campaign entitled "The clock is ticking".[247] More than 2.000 SIEF had been created in December, which is well short of the 4,500 that were hoped for by the end of the summer.[248] The clock is definitely ticking. Since the deadlines are set in the Regulation, which can not be easily changed, ***pressure is put on the companies as well as on the ECHA*** to meet the challenge. One could question the choice of setting such deadlines in stone. The ***risks taken are also high: what will happen when the objectives for the first registration deadline are not met?*** Will the ECHA and the ECJ accept a gentleman's agreement, or will every substance that has not been recorded be banned from the market? This does not seem to be a hypothetical question at the time of writing. ***SIEF and registration deadlines could indeed become a pitfall for many companies, as well as for the general efficiency and workability of the regulatory system***.

## Checking the registration dossiers: Watch the hurdles

Registration dossiers undergo a complex review process, beginning with a completeness check. If the dossier passes this first test, the ECHA can proceed to performing a compliance check and examine testing proposals. If the dossier fails its completeness check, a second chance to complete it within a new deadline is given. If the dossier is rejected once more, the manufacturer will be forced to stop producing the substance until the submission of a new dossier and the payment of new registration fees.

The completeness check comprizes three steps:

- A business rules check, focusing mainly on the format of the dossier and administrative information
- A technical completeness check, which checks that all elements required are included
- A financial completeness check, monitoring the payment of fees.[249]

---

[247] See G. Dancet (executive director of the ECHA) closing remarks during this conference at <http://echa.europa.eu/doc/press/events/stks_day_20090525/2nd_stk_day_closing_remarks.pdf>.
[248] "ECHA offers help for REACH registration marathon", *Chemical Watch*, 14 September 2009, <http://chemicalwatch.com/index.cfm?go=2665>.
[249] See D. Hirman, "Completeness check, ECHA's approach", 2nd Stakeholders Day, May 2009, presentation available at <ttp://echa.europa.eu/doc/press/events/stks_day_20090525/2nd_stk_day_completeness_check.pdf>;

***Experience of the completeness check so far is problematic***. According to the ECHA, of the 94 dossiers submitted in 2008, only 10 passed the completeness check.[250] In March-April 2009, Cefic had submitted 12 registration dossiers, all of which failed the business rules and technical completeness tests.[251] Amongst other reasons, it appears that information had not been correctly entered in the IUCLID 5 fields,[252] that the dossiers were not complete, or that different substances had been registered within a single dossier. According to other sources, a major firm submitted about 100 dossiers, of which 25 passed the business rules check and only 10 the technical completeness check.[253]

This stage is followed by a compliance check, which also raises some issues. The director of assessment for ECHA, J. Malm, says that the main concerns during this check are substance identification, inadequate justifications when deviating from standard data requirements and poor quality of documentation.[254]

### *OTHER ISSUES*

Operational issues are numerous, and may vary according to the status of the company (manufacturer, downstream user, etc) and the sector of production.

One point that is often highlighted is that despite continuous work from the ECHA, the Commission and the other stakeholders, ***some important tools are still missing***. Some guidance is still unavailable, or available only in English, which makes it difficult to ensure that it is well used, especially when it comes to SMEs. For example, a draft guidance on Annex V on exemptions has been submitted in November 2009 for

---

J. Lebsanft, "ECHA's first experience with evaluation", 2nd Stakeholders Day, May 2009, presentation available at <http://echa.europa.eu/doc/press/events/stks_day_20090525/2nd_stk_day_first_exp_with_evaluation.pdf>. See also ECHA, *REACH-IT Data Submission Manual 8. Business Rules Validation*, <http://echa.europa.eu/doc/reachit/reachit_data_submission_manual_8_business_rules_validation_20090417.pdf>.ECHA, *REACH-IT Industry Manual. Part 8. Invoices*, <http://echa.europa.eu/doc/reachit/industry_user_manual/reachit_invoices_en.pdf>.

[250] ECHA, *Evaluation. Progress Report 2008*, <http://echa.europa.eu/doc/progress_report_2008.pdf>, p. 3.

[251] "ECHA builds up for REACH dossier evaluation challenge", *Chemical Watch Briefing*, June 2009, <http://chemicalwatch.com/2408>.

[252] The difficulty to complete some fields in IT tools is indeed an issue according to C. Deconninck, Total (interview, July 2009).

[253] Procter and Gamble internal note, transmitted to the author.

[254] "ECHA builds up for REACH dossier evaluation challenge", *op. cit*.

consultation by ECHA's Committees. The first draft of the guidance on the scope of exposure assessment is planned to be issued on the ECHA's forum in February 2010.[255]

In addition, the ECHA is still busy developing some tools, which are therefore not usable as yet. At present, the Chemical Safety Assessment Tool, an IT tool devised to support registrant's chemical safety assessment process, is still under development.[256] In terms of registration, the Technical Completeness Check IT Tool is also still unavailable. This is particularly problematic since a number of the dossiers that fail the checks do so at the stage of the completeness check.

This proves that ***if companies are under pressure to meet the requirements set by the Regulation, so is ECHA***. The development of the necessary instruments is a long process. Yet, without those, how can institutions expect registrants to correctly meet their requirements?

The problem of the lack and cost of scientific resources, i.e. of experts in toxicology and ecotoxicology is also sometimes raised.

These practical issues will be progressively solved. Some have already been solved (such as the ones related to preregistration), others will emerge. Such obstacles are logical and expectable, in a learning-by-doing process such as the establishment of REACH. Yet, ***registration appears to be a marathon in which the progress of participants is hindered by many obstacles***.

## DOES REACH LEAD TO AN UPGRADE OF THE STANDARDS OF CHEMICAL RISKS MANAGEMENT?

In terms of the long-term assessment of REACH efficiency, ***this question is fundamental***. As we have already seen, the REACH regulatory regime is definitely modern.[257] This conclusion does not presuppose, however, the success of REACH in

[255] See <http://guidance.echa.europa.eu/guidance4_en.htm>.
[256] On the difficulties raised by this project, see A. Ahrens, P. Deceuninck, H. Magaud, "CSA Tool Development", presentation at REACH IT Workshop, March 2009, available at <http://echa.europa.eu/doc/press/events/reachit_workshop_20090326/REACHIT_IUCLID5_stakeholder_workshop_csa_tool_20090326.pdf>.
[257] See chapter 3.

*practically* upgrading the standards of chemical risks management. Does REACH really raise the standards? To answer this question, we will look at the European and global levels.

## *AT THE EUROPEAN LEVEL*

REACH upgrades standards of chemical risks management in two ways: through improved self-management practices, and via the authorization and restriction processes.

### Structural factors leading to a better self-management of risks

Various structural factors lead to a better self-management of risks:

- REACH requires companies to assess the risks inherent to a substance as well as those following exposure. This is especially true for substances produced above the 10 tonnes threshold
- REACH compels companies to work together, and in particular along the supply chain. This process ensures that products are better known by its users
- REACH is based on transparency. It can be expected that chemicals-related information will be widely diffused and taken into account.

Against this background, better self-management occurs in two ways, which can be characterized as positive and negative. Self-management will be *positively* triggered by the fact that REACH will probably ***foster a higher level of awareness on health and environmental issues***, thus leading to a

> *stronger practice of self-selection within the chemicals industry, determined by more than the commercial viability of the contemplated product.*[258]

This point can be taken further. Since some substances risk being phased-out, it can be expected that the industry will carry out research on the various existing alternatives, and assess their technical and economic feasibility. Companies will probably choose, before the actual phasing-out process, to carry out a ***comparative risk assessment*** themselves. This could

[258] V. Heyvaert, *op. cit.*, p. 20.

> *weed[s] out the more obvious cases where substitutions should be made, thus obviating the need for a lengthy, vexatious and perhaps ultimately unsuccessful authorization procedure.*[259]

Such a process will more likely take place in the case of substances put on the market in volumes exceeding 10 tonnes a year.

Self-selection can also occur through a *negative* process. Information on a substance suspected to be dangerous for health or the environment – but which is not subject to the authorization or restriction processes – is likely to spread within the REACH community. This could have the effect of blacklisting certain substances even before they are addressed within REACH, consumers or downstream users choosing to buy/work with another substance. This mechanism could once again force companies to choose less risky options from an environmental and health point of view.

## An upgrade via the authorization and restriction processes

*c) Authorization and restriction processes as risk management instruments*

Authorization and restriction are the main processes under REACH to limit the use, and therefore the risks, arising from chemicals. It is important to bear in mind here that *risk,* as exposed in the introduction of this report, refers to the combination of:

- The *dangerosity* of a substance – the intrinsic danger that it represents, drawn from the dangerosity of its constitutive properties, and
- Its *exposure potential* – the possibility for humans and/or the environment to come into contact with such a substance.

Authorization: When included in ***Annex XIV***, a substance is subject to the authorization procedure. This means that such a substance ***cannot be placed on the market after a sunset date without an authorization***. Authorization is a process that concerns ***only SVHC*** (vPvB, PBT, CMR or a substance of equivalent concern). It is therefore a hazard-based approach. First, a Member State or the Commission has to constitute an Annex XV dossier. If such a dossier is endorsed by the Member State Committee of the ECHA, the substance will then be inscribed on the ***Candidate List***. Prioritization of a substance, according to its hazards, uses and volume, then leads to its inclusion in Annex XIV. The ***authorization process is mainly a hazard-based***

[259] *Ibid.*

***approach***: substances that prove to be hazardous given their intrinsic properties are subject to authorization. Yet, this approach is combined with a risk-based approach, since a substance, even if considered SVHC under to the authorization process, could be kept on the market if the producer can prove that the risks posed are adequately controlled.

Conclusion n°3 of the *Workshop on the Candidate List and Authorization as Risks Management Instruments*, where Member States, the EC Commission and the ECHA were represented, clearly states the goal of the process:

> *"the aim of including substances in the list of substances subject to authorization (Annex XIV) is the* **substitution / phase-out of SVHC by regulatory intervention.** *It is using market forces by (a) industry having to prove that use is safe or that the socioeconomic benefits outweigh the risks and that there are no alternatives and (b) making use of a the substance undesirable".*[260]

Restriction: Restriction of a substance can be used if there are ***community-wide unacceptable risks*** related to the manufacture, import, use or placing on the market of a substance. Restriction is thus made to ***limit the risks*** arising from the use of a substance. It is not based on its intrinsic properties, but on exposure to a substance and its result for health or the environment. The consequence of restriction is the ***ban*** of a substance, either for specific uses or totally. Triggered by Member States or by the Commission, the decision to impose a restriction is adopted by the Commission under a comitology procedure.

Authorization and restriction are clearly designed to manage the risks and dangers arising from the use of chemicals.

### *d) Choosing the best risk management options between authorization and restriction*

The respective advantages of the authorization or restriction processes are currently debated. Indeed, the choice between the two is not obvious.[261]

First of all, it should be underlined that if a substance is included in Annex XIV, i.e. subject to authorization, no new restriction may be imposed.[262] For example, if a

[260] ECHA, *Workshop proceedings on the Candidate List and on Authorisation as Risk Management Instruments*, Helsinki, 2009, <http://echa.europa.eu/doc/consultations/authorisation/authorisation_workshop_proceedings_20090121.pdf>, esp. p. 9.
[261] *Ibid.*

substance is included in Annex XIV because of its PBT properties, no restriction process shall be triggered to address the risk arising from these properties. On the other hand, using restriction process forbids going through authorization process for the same use of a substance.[263]

Secondly, the scope of the two processes are different. An authorization process can only be triggered if the substance meets the SVHC criteria listed in article 57 of the Regulation. Moreover, some uses, such as research and development or use in cosmetic products, cannot be targeted, and authorization does not apply to the manufacturing process of a substance but only to its placement on the market and its use.[264] On the contrary, the restriction process can be triggered in order to deal with almost any hazard.[265] According to the Regulation, a restriction process is launched to demonstrate an unacceptable risk for human health or the environment, and to show that the risk needs to be addressed at the Community level.[266]

Given the previous considerations, it seems that the restriction process is a better way to manage risks arising from manufacturing processes, and in cases of consumer exposure. Authorization could on the other hand be preferred if information on the risks posed by a substance is insufficient, or if there exists no substitution option, since it is always possible to allow uses on a case by case basis. Authorization, from a broader point of view, is a better way to take into account specific circumstances, and risks can be managed given the substances' intrinsic properties. Whenever a substance is used by many under similar use conditions, it is easier to ensure a good management of risks through the restriction process. Other factors can also be taken into account, such as the length of either processes, the restriction process being significantly shorter.[267]

These considerations underline the importance of the choice, which will be made by the Member States and the Agency, between the authorization or the restriction processes. Such a choice is not self-evident. What is certain is that it should be conducted ***as early as possible whenever a risk arises***. A general framework for

---

[262] Article 58 of the Regulation.
[263] *Ibid*.
[264] ECHA, 2009, *Workshop proceedings…*, pp. 33-35.
[265] There are indeed very few exemptions, see *Ibid*., p. 36.
[266] Article 68 of the Regulation.
[267] The above mentioned *Workshop proceedings on the Candidate List and on Authorisation as Risk Management Instruments* are very complete on these points.

the analysis of the best risk management option, which would identify and list all the factors needing to be taken into account, is also under development.[268]

Another major issue regarding risk management tools is the scope of Annex XIV.

*e) The authorization process: Candidate List, Annex XIV – a drop in the ocean?*

***Inclusion of substances in Annex XIV is a fundamental issue under REACH***, since it is the first step to determine whether such substances will be subjected or not to the authorization procedure.

The first candidate list has been published by ECHA in October 2008. It encompasses ***15 substances, most of which were already known to be highly dangerous***. For example, triethyl arsenate is known to be carcinogenic, toxic by inhalation and very toxic to aquatic organisms. Triethyl arsenate as such and triethyl arsenate in preparations containing 0,1% or more were already prohibited from sale to consumers and from use in cosmetics, and its use was very limited in biocide products.[269] Many other substances were already concerned by bans or limitations under other EC legislation, such as bis(tributyltin)oxide, which was already classified under an EC Directive as toxic for human health and likely to cause long-term adverse effects in the aquatic environment.[270] Still, this list is of importance since it includes a brominated flame retardant which, according to Greenpeace, is "commonly found in house dust, in wildlife and the wider environment, as well as being detectable in human blood".[271] It also contains three plastic softeners (the phthalates DEHP, DBP and BBP). Another list of 15 substances has been submitted on August 2009 for public consultation.[272] ECHA's Member States Committee agreed unanimously in December 2009 that these 15 new substances should be included on the candidate list.[273]

***The question raised here is simple: is the inclusion of 30 substances enough?*** More than 30 substances are indeed known to be hazardous. For actors of the industrial sector, REACH must be implemented progressively. Including a substance

[268] ECHA, 2009, *Workshop proceedings…*, pp. 8-9.
[269] See the Norwegian proposal for identification of this substance as SVHC, <http://echa.europa.eu/doc/candidate_list/svhc_axrep_norway_cmr_triethylas.pdf>.
[270] See ECHA, *Member State Committee Support Document for Identification of Bis(tributyltin)oxide as a SVHC*, <http://echa.europa.eu/doc/candidate_list/svhc_supdoc_tbto_publication.pdf>.
[271] Greenpeace, "First REACH hazardous chemicals identified", press release, 9 October 2009, <http://www.greenpeace.org/eu-unit/press-centre/press-releases2/First-REACH-hazardous-chemicals-identified>.
[272] See <http://echa.europa.eu/consultations/authorisation/svhc/svhc_cons_en.asp>.
[273] Press release, <http://echa.europa.eu/doc/press/pr_09_15_msc_svhc_20091207.pdf>.

on the candidate list indeed has tangible implications: first, including a substance on the list has an immediate blacklisting effect, which mechanically eliminates the given substance from the market. Clients will, as a consequence, tend to ask for products that are free from such a substance.[274] Second, it implies finding a replacement, in the short or long term. However, some substances do not have any substitutes, or do only in specific cases.[275] Authorities should therefore weigh their choice very carefully when including a substance in the candidate list.

A number of NGOs defend an alternative strategy through the "Substitute It Now List" (SIN List) project.[276] This list comprizes 267 chemicals identified as SVHC, and is used to weigh on the regulatory process.[277] It also serves companies wishing to develop a substitution strategy within their activities. The Carrefour group, for example, is said to have sent the SIN List to its suppliers in order to foster R&D on substitution.[278] Alternative lists have also been published.[279]

This situation illustrates the huge importance of the candidate list for the efficiency of REACH. Those in favor of an ambitious instrument thus call for the quick inclusion of other hazardous substances on the list. In a "welcome package" sent to newly elected members of the European Parliament in the Environment, Public Health and Food Safety Committee, it is underlined that:

---

[274] J.-L. Ponchon, Rhodia (interview, July 2009).
[275] This is the case for brominated flame retardant as well as for phthalates according to E. Annys, Cefic (interview, July 2009).
[276] The members of the SIN List Advisory Committee are the following: European Environmental Bureau, WWF European Policy Office, Friends of the Earth Europe, Greenpeace European Unit, Instituto Sindical de Trabajo, Ambiente y Salud, The European Consumers' Organisation, Women in Europe for a Common Future, Center for International Environmental Law, The Health and Environment Alliance.
[277] See <http://www.chemsec.org/images/stories/publications/Downloads/080917_reach_sin_list.pdf>.
[278] See "Retailers integrate REACH into chemicals management", *Chemical Watch Briefing*, February 2009, <http://chemicalwatch.com/index.cfm?go=1788&q=carrefour>.
[279] See for example the one published by the European Trade Union Confederation, including more than 300 substances, at <http://www.etuc.org/a/6023>.

> *The current candidate list only includes a small percentage of existing SVHC and thus undermines the substitution objective and prioritization process under REACH.*[280]

A. Schomaker, currently head of DG Environment's chemicals unit (D1), publicly voiced her discontent with the current list.[281]

The number of substances included in the candidate list and subsequently in Annex XIV is ***an indicator of the level of ambition of actors*** in setting up new standards in chemical risk management. Indeed, the quicker hazardous substances are included, the more efficient the system will be.

Moreover, the authorization process paves the way to substitution. But regarding this objective, the inclusion of fifteen substances was no more than a drop in the ocean. The inclusion of thirty substances is a step in the right direction. Significantly upgrading the standards of risk management will imply strengthening this trend, i.e. speeding up the process of identification of SVHC and inclusion on Annex XIV.

***The debate concerning a long versus a short candidate list would however be less relevant if a clearer distinction was made between the candidate list and the Annex XIV list***. If the candidate list is indeed generally a stepping stone to authorization, in practice a substance can be included in the candidate list for other reasons than a final inclusion in Annex XIV. For example, it can increase awareness on SVHC. Participants of the Workshop on the candidate list thus suggested to ***develop "de-prioritization arguments"***, in order to include substances on the candidate list, but not select them for the authorization procedure. This could be the case for substances solely used as intermediates, substances for which use is outside the scope of authorization (pesticides, biocides) or substances where all uses are known to be well controlled.[282]

---

[280] Directorate General for Internal Policies of the European Parliament, *Welcome Package on Environment*, 2009, <http://www.eurosfaire.prd.fr/7pc/doc/1251363164_environment_welcome_package_en.pdf>, p. 106.
[281] « REACH list could leap from 15 to 400 next year », *Pesticide and Toxic Chemical News*, 20 July 2009, <http://www.agra-net.com/portal2/home.jsp?template=pubarticle&artid=1248082781827&pubid=ag100&pubid=ag100>. P. Van der Zandt, from the same Unit, expressed the same discontent (interview, July 2009).
[282] On this point, see ECHA, 2009, *Workshop proceedings…*, pp. 8-11.

## *NON-EU STATES AND REACH*

Outside the EU, the elaboration and implementation of REACH has been monitored closely, as exemplified by the lobbying campaign launched in the United States that we mentioned earlier in this paper. REACH indeed "reaches" beyond EU borders, because:

- Non-EU companies have to meet REACH requirements in order to access the European market
- Increasingly precise data on chemicals – including the list of chemicals subject to authorization and restriction – is available worldwide, given the transparency of the REACH system.

REACH could thus trigger a worldwide upgrade of standards, which would place the EU in the position of the norm-breaker, or standard setter. Even if the regulatory system remains in its infancy, its influence can already be observed in some countries. This is due mainly to what D. Wirth calls an "upward harmonization". It occurs

> *when a jurisdiction with high standards and that commands a very large market makes a unilateral regulatory decision, even one that ostensibly applies only internally. If that jurisdiction's market share is sufficiently large, regulatory requirements can affect an even larger area, including those under the control of other sovereign authorities. Whether states or private entities, the trading partners of a jurisdiction adopting demanding regulatory standards may find it disadvantageous to produce products or services that do not meet the higher requirements, even if other markets have less rigorous regulatory standards. The net effect is an upward pressure on standards even outside the jurisdiction that established them.*[283]

Some countries are closing the legislative gap, while others do not seem to want or to be able to upgrade their standards.

[283] D. Wirth, "The EU's New Impact on US Environmental Legislation", *Legal Studies Working Paper Series*, Boston College Law School, 2007, n° 144, <http://ssrn.com/abstract=1028733>, p. 96.

## Closing the gap:
## Towards an upgrade of domestic chemical standards

We will focus on the United States of America before examining the situation of some Asian countries.

### *f) The United States of America*

At the beginning, the arrival of REACH in the United States did not occur at the federal level so much as at an individual State level. This illustrates that

> *in a system of polyphonic federalism, individual states can serve as policy entrepreneurs.*[284]

***California offers a very clear model of how REACH can prompt domestic reforms outside its European bounds***. J. Scott shows that several moves in California followed the adoption of REACH. Two major bills were passed in 2008 and a Green Chemistry Initiative was launched.[285] According to the author,

> *One of California's principal concerns in responding to REACH was economic. Another was the compliance burden it would impose upon small and medium sized businesses seeking to sell in Europe. Trade relations have thus emerged as a key factor in generating interest in REACH.*[286]

Other States chose to upgrade their legislation as well, such as the States of Massachusetts and Maine.[287]

At a federal level, if the US fought against the adoption of REACH, it changed its stance once the legislation was passed. A number of official reports at the time insisted on the necessity for a new approach to chemicals regulation.[288]

---

[284] J. Scott, "From Brussels with Love: The Transatlantic Travels of European Law and the Chemistry of Regulatory Attraction", *SSRN Working Paper*, 2009, <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1333685>, p. 4.
[285] *Ibid.*, pp. 29-36.
[286] *Ibid.*, p. 36.
[287] *Ibid.*, pp. 36-42.
[288] See for example, US Government Accountability Office, *Chemical Regulation. Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals*, August 2007, <http://www.gao.gov/new.items/d07825.pdf>; US Government Accountability Office, Environmental *Protection Agency: Major Management Challenges*, March 2009, <http://www.gao.gov/new.items/d09434.pdf>.

One important move was the nomination in 2009 of C. Dooley, former democratic Congressman of California, at the head of the American Chemistry Council. An op-ed that he wrote in *The Hill* clearly illustrated the turning of the tide. According to him:

> *The time has come to harness the scientific and technological advances that have been developed since 1976. Modernizing the law will help us safeguard our most valuable resources as we continue to bring to market the products that save lives, protect our children and strengthen our economy. […] Today, the EPA cannot make a formal determination on whether or not a chemical is safe for its intended use. That must change. […] Another important component is establishment of clear scientific principles and protocols to evaluate all chemical research and testing. The chemical industry certainly supports ongoing, rigorous testing of our products. But all chemical research should be held to high and consistent standards to support the decision-making process.*[289]

Even if REACH is not formally mentioned here, ***its influence in setting a new standard for the regulation of chemicals can be perceived.*** A sign of this influence can also be seen in the introduction in the Senate of the "Kid-Safe Chemicals Act of 2008". Its Preamble stated that

> *(10) There is significant global trade in the chemical sector and many of the companies that conduct business in the United States must also comply with chemical safety regulatory programs in other countries*
>
> *(11) The data that is generated to comply with these other regulatory programs would be useful in understanding hazards presented in the United States.*[290]

The willingness to reform the Toxic Substances Control Act (TSCA) and to upgrade US chemicals standards thus appears to be prompted, at least partially, by the international context and the implementation of REACH.

---

[289] C. Dooley, "The chemical-law formula", *The Hill*, 6 July 2009, <http://thehill.com/opinion/op-ed/49497-the-chemical-law-formula>.
[290] See <http://www.govtrack.us/congress/billtext.xpd?bill=s110-3040>.

### *g) Asian States: Japan, Korea and Taiwan*

According to recent studies,[291] ***Japan, Korea and Taiwan are currently filling the regulatory gap between REACH and their national regulatory systems***.

Japan has established an effective chemical control system.[292] A Working Group was formed in 2008 in order to discuss adaptation to the former legislation. This led in particular to the adoption of amendments in May 2009, which reinforce hazard communication requirements and introduce a new classification system for chemical substances.[293]

Korea is the Asian country that has been the most receptive to the upgrade in chemical standards launched by REACH, through various amendments made to its Toxic Chemicals Control Act[294] and the outline of the "Green SHIFT" action plan. The Ministry of Environment aims to introduce stringent chemical control measures on new and existing chemicals, and to improve the quality and access to information on chemicals within the supply chain, emergency response, and the competitiveness of chemical industries.[295] This is part of a larger program, launched in 2005, which aims to introduce a sustainable economic growth model for the future, based on Korea's experience in implementing environmental protection alongside economic growth.[296]

Taiwan also reacted to REACH by proposing two guidelines in 2009, one for the identification of existing chemical substances, and the other for the notification of new chemical substances.[297] If such an initiative will probably lead to an upgrade of chemical standards, it is closer in its approach to the American position than to the European one.[298]

Other countries are taking advantage of REACH to carry out a review of their legislation, thus feeding into a more general process of upgrade of chemical standards.

---

[291] See especially D. Park, M. Song, K. Lee, D. Yoon, X. Cong, "REACHing Asia: Recent Trends in Chemical Regulations of China, Japan and Korea", *SSRN Working Paper*, 2008, <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1121404>; D. Park, "REACHing Asia Contiuned", *SSRN Working Paper*, 2009, <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1474504>.
[292] For an overview, see D. Park, *op. cit.*, pp. 4-5.
[293] *Ibid.*, pp. 8-9 ; D. Park, M. Song, K. Lee, D. Yoon, X. Cong, *op. cit.*, pp. 5-6.
[294] See <http://eng.me.go.kr/docs/laws/laws.html?topmenu=D&cat=400>.
[295] See D. Park, op. cit., pp. 9-10; D. Park, M. Song, K. Lee, D. Yoon, X. Cong, *op. cit.*, p. 6.
[296] See <http://eng.me.go.kr/docs/greengrowth/concept.html?topmenu=G&cat=810>.
[297] See W. Feng, C. Hu, "Taiwan – Draft Proposal of Guidelines for Existing Chemical Substance Nomination (ECN) and New Chemical Substance Notification (NCN)", Keller and Heckman LLP, 2009, <http://www.khlaw.com/Files/5798_Memo_Taiwan%20New%20Chemical%20Registration%20System.pdf>.
[298] *Ibid.*

## Not good enough? The Russian and Chinese examples

Others countries are unwilling, or unable to close the gap with the European legislation. The Russian and Chinese cases are interesting in this respect. Both countries have been trying to upgrade their legislation on chemicals,[299] but have to face a number of obstacles. In the case of Russia, it has been observed that the adoption of

> *such a complex Regulation would be virtually impossible given the current Russian – economic and administrative – realities.*[300]

The successive drafts of a new Regulation are judged rather harshly by I. Danilov:

> *It lacks proper definitions and contains ambiguous concepts, procedures and inconsistencies. Importantly, it also grants discretionary powers to the competent authorities on procedural issues, such as the granting and amending of authorizations. It also duplicates control functions by different Russian authorities which, taking into account the current enforcement practices in Russia, is of particular concern. As the debate continues on the draft Regulation, it is possible – even likely – that future drafts will contain yet more departures from the original REACH Regulation.*[301]

China's situation is slightly different. Key measures have been taken in response to REACH.[302] However, the Chinese system suffers from structural weaknesses which can hamper the implementation of such measures. First, it is characterized by an overwhelming jurisdictional complexity, which

> *may be prohibitive for integrated chemical control at workplace and make difficult the introduction of a holistic chemical regulation like REACH.*[303]

Second, according to D. Park, scientific infrastructure is deficient. Despite China's efforts to establish internationally recognizable good laboratory practice,

---

[299] See "Russia harmonizes its chemical legislation with EU Reach", *Energy and Enviro Finland*, 17 June 2008, < http://www.energy-enviro.fi/index.php?PAGE=1832&NODE_ID=1832&LANG=1>; D. Park, *op. cit.*, pp. 2-4 and pp. 6-8.
[300] I. Danilov, "Legal Spotlight Special – Russia: a case study in responding to REACH", *Chemical Watch Briefing*, February 2009, <http://chemicalwatch.com/1794>.
[301] *Ibid*.
[302] D. Park, *op. cit.*, pp. 6-8.
[303] D. Park, M. Song, K. Lee, D. Yoon, X. Cong, *op. cit.*, p. 3.

> *there is no laboratory which can generate OECD-acceptable chemical test data.*[304]

***Whether for cultural or structural reasons, Russia and China do not seem to be closing the gap with the EU legislation***. On the other hand, a number of other countries are, demonstrating the upwards normative impact of the REACH beyond its European borders. These interrogations on the potential effectiveness of REACH culminate in a final question.

## DOES REACH ACHIEVE ITS FUNDAMENTAL OBJECTIVES?

According to article 1 of the Regulation,

> *The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.*

In other words, REACH will have achieved its objectives if the new regulatory system:

- Ensures a high level of protection of human health and the environment
- Enhances innovation and competitiveness.

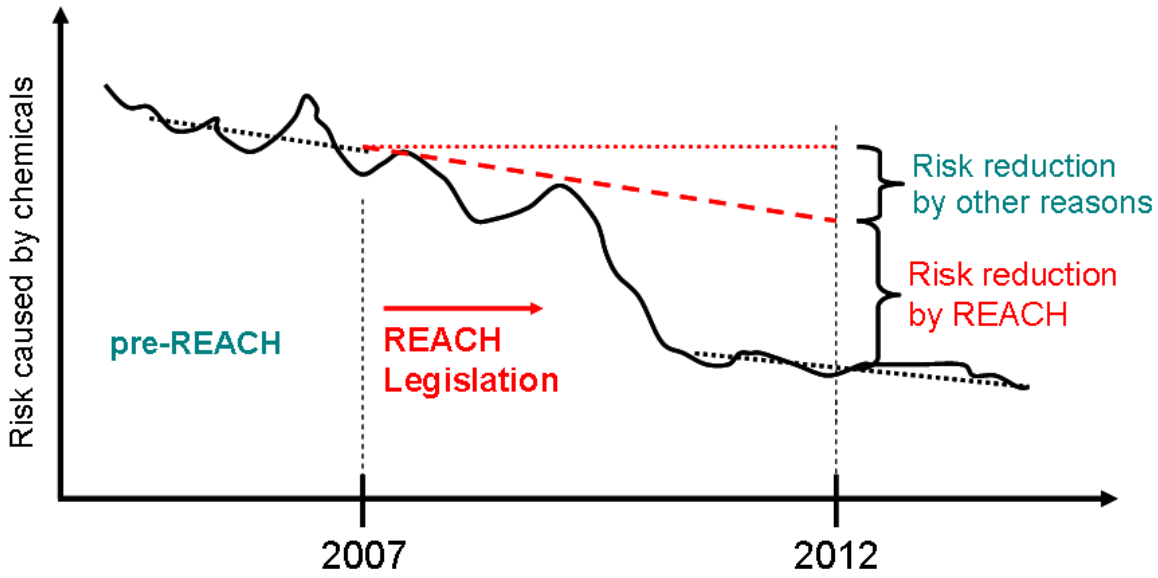
### *ENSURING A HIGH LEVEL OF PROTECTION OF HUMAN HEALTH AND ENVIRONMENT*

The question of REACH's effectiveness in protecting human health and the environment bears no simple answer for the time being, particularly as the first registration phase has not been closed yet.

The European Commission recently produced a study, undertaken by Eurostat, attempting to define indicators for REACH effectiveness from a public health and an

[304] D. Park, *op. cit.*, p. 9.

environmental point of view, and giving a first analysis of the data thus gathered.[305] The first conclusions are that REACH is expected to foster a decrease in chemical risks, as illustrated by the following diagram:




*proposed, but because of uncertainty about their implementation. However, REACH is clearly an opportunity to reduce the number of chemicals-related occupational diseases and the associated costs for both industry and society.*[306]

Nevertheless, some discordant views are also voiced, coming mostly from the industry. The main argument is that it is far from certain that REACH will allow identifying more hazardous substances than under previous legislation.

We believe however that by promoting substitution of SVHC and upgrading chemical safety standards in the EU as well as around the world, REACH is prone to ensure a higher level of protection of human health and the environment than the previous regime. Improved hazard detection and risk management in chemical use will also contribute to the protection of health problems caused by chemical exposure. It is

[305] Eurostat, *The REACH Baseline Study. A tool to monitor the new EU policy on chemicals*, Bruxelles, 2009, <http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-RA-09-003/EN/KS-RA-09-003-EN.PDF>.

[306] S. Pickvance, J. Karnon; J. Peters, K. El-Arifi, *The impact of REACH on occupational health with a focus on skin and respiratory diseases*, University of Sheffield, 2005, <http://hesa.etui-rehs.org/uk/newsevents/files/reach-sheffield-complet.pdf>.

however too soon to say how ambitious the regulation will be in achieving such objectives, and some points remain problematic.

For example, substances that are produced or imported in volumes of less than 10 tonnes a year will be subject to significantly less important data requirements than substances produced in volumes exceeding 10 tonnes: the chemical safety report, which contains the exposure scenario, is indeed necessary only above this threshold. Moreover, substances produced or imported in volumes of less than one tonne are excluded from the scope of REACH. Amongst those substances, some will be covered as SVHC, but the REACH system still seems to be creating pockets within which a number of substances can be put on the market without the proper accompanying data requirements, a situation which could jeopardize the objective of a higher level of protection of human health and the environment.

## *ECONOMIC ISSUES: COSTS AND COMPETITIVENESS*

The issue of the competitiveness of the European chemical industry is one of REACH's fundamental objectives. It is also recurrently used by the industrial sector to argue that REACH requirements are too costly to implement and/or that they hinder competitiveness.[307] BUSINESSEUROPE has been especially dynamic in developing such a discourse. It underlines that REACH is a resource – and time consuming process, and that many companies have had to hire consultants to fulfill all requirements, resulting in supplementary costs for firms.[308]

Two toxicologists also underlined in a recent study published by *Nature* that the costs of REACH could spiral and level up to six times more than originally estimated. According to them, under a best case scenario, complying with REACH is likely to cost €9.5 billion and require 54 million vertebrate animals over the next 10 years. One of the biggest problem comes with the two-generation tests used to evaluate reproductive toxicology, in which toxic effects are studied in the offspring of exposed rats, and then again in the following generation. These tests, according to the study,

[307] For example, L. Gaillet, Dolfus & Muller (interview, June 2009); A. Affre, BusinessEurope (interview, July 2009); C. Lequime, UIC (interview, July 2009).
[308] BusinessEurope, "Seven priorities for optimising implementation of REACH : lessons learned from the first two years", Position Paper, 2009, <http://www.businesseurope.eu/DocShareNoFrame/docs/2/GOPPNPPDHCAGNOBIACOMAFPIPDBG9DWY7D9LTE4Q/UNICE/docs/DLS/2009-01190-E.pdf>, pp. 2-3.

cost €600,000 per substance and last two years.[309] Moreover, other costs have to be added to the ones of the studies, such as fees or the costs involved by the management of the SIEF. ***Economic costs thus remain one of REACH's most crucial issue***.

The abovementioned study published by *Nature* has however been criticized as being biased, and ECHA issued a press release to reject its results. According to ECHA, the new study overestimates three things: the likely number of substances that will be registered, the likely number of tests that will be required and the likely costs for conducting the tests.[310]

The ***current financial and economic crisis*** has only strengthened the strength of such arguments.[311] According to Cefic, the production of chemicals dropped by 14.5% in the 4th quarter of 2008. Demand is weak, and prices and confidence have decreased.[312] The prices of a number of commodities have also significantly increased in the last few years.

REACH will thus impose significant economic costs, on firms most particularly, but also on the EU and the Member States. This is burden is particularly felt in times of economic crisis.

The industry also argues that REACH is going to hinder its competitiveness. This argument can nuanced however.[313] Regarding substances as such, no competitiveness issue can be raised, for a substance has to be registered whether it is manufactured or imported. Some argue that polymers or articles being exempt from this rule, a number of manufacturing processes could be delocalized to countries not covered by REACH.[314] According to BusinessEurope,

---

[309] T. Hartung, C. Rovida, "Regulators have overreached", *Nature*, 27 August 2009, 460, pp. 1080-1081.
[310] ECHA, « New study inaccurate on the number of test animals for REACH », Press release, 2009, <http://echa.europa.eu/doc/press/pr_09_11_animal_testing_20090828.pdf>.
[311] For example, D. Garrigue, member of the French Parliament (interview, July 2009); A. Affre, BusinessEurope (interview, July 2009).
[312] Cefic, *State of affairs in the European Chemical industry in the face of the global economic crisis*, 2009, <http://www.cefic.be/Files/Publications/2009-05-07-Final-Cefic-follow-up-crisis-pape.pdf>.
[313] One point will not be further discussed. Many actors told us it was of significance that in the recent REACH baseline study (*op. cit.*), competitiveness was not taken into account (S. Lemoine, AISE, interview, July 2009; A. Affre, BusinessEurope, interview, July 2009). However, it seems that this criticism shall not to be taken into account, since the goal of the study was to provide an indicator to monitor whether REACH as for consequence a decrease in risks or not (*Ibid.*, p. 6).
[314] F. Loos, former Minister for the Industry (interview, July 2009); E. Annys, Cefic (interview, July 2009).

> *European manufacturers of articles are therefore not on a level playing field with non-European companies.*[315]

Such reasoning is valid, but partial, as it does not take into account the fact that every major non-European company will have to level up with European standards to be able to continue selling its products there. Moreover, the implementation of REACH will, with time, ***make Europe the leader in the management of chemical risks***. This will entail cost reductions at the societal level as well as, in the long run, at the level of each firm.

One can also argue that an ambitious REACH will foster R&D on substitutes, thus contributing to ***strengthening a European economy based on knowledge and leading technologies***. For that matter, the objectives of the REACH can be seen as following the conclusions of the High Level Group on the Competitiveness of the European Chemicals Industry,[316] which recommend, *inter alia,* further enhancing competitiveness and innovation in the European market.

## CONCLUDING REMARKS

Four questions were raised in order to assess the success of the REACH regulatory regime.

- Does REACH meet the requirements of legal certainty?

Overall, the Regulation meets the criteria of legal certainty. However, on some important points, a clarification of the rules is still needed.

- Does REACH raise significant operational difficulties in day-to-day practice?

Yes, but such difficulties do not appear to be conclusive or insurmountable for the time being. Overcoming them is nevertheless crucial in order to make the first registration phase a success. Aware of the various problems posed, the French ministry for the environment, in partnership with the UIC, announced in December

[315] *Ibid.*, p. 7.
[316] High Level Group on the Competitiveness of the European Chemicals Industry, *European Chemical Industry Enabler of a Sustainable Future – Final Report*, Brussels, 2009, <http://bookshop.europa.eu/eubookshop/download.action?fileName=NB7809771ENC_002.pdf&eubphfUid=10275753&catalogNbr=NB-78-09-771-EN-C>. This group did not, however, treat directly with the impacts of REACH (*Ibid.*, p. 36).

2009 the launch of a programme to help firms, especially SMEs, comply with REACH requirements. Such an initiative goes in the right direction.

- Does REACH lead to an upgrade of the standards of chemical risk management?

The answer appears to be a positive one. This is true both at a European and at a global level. It does not appear that such an upgrade will be trivial. However, the level of ambition of the objectives set within the regulatory regime still remains to be defined, and will depend in a large part on the political choices of regulators.

- Does REACH fulfill its fundamental objectives?

The REACH regulatory system seems to provide a better protection of human health and the environment than the previous legislation, or at least to set the framework to do so.

In economic terms, REACH is undeniable costly. However, in the mid- to long-term, REACH is expected to boost innovation, which will in turn foster competitiveness and entail cost reductions. The costs of chemical risks to society will also decrease.

In sum, REACH has the potential to become a very effective tool, which would successfully achieve its objectives. That said, the dice have yet to be cast, and significant steps still need to be taken in order to secure such a evolution.

# CONCLUSION

One must be very careful when assessing a process that has just only begun. However, we can say that REACH has already been successful in the promotion of a paradigmatic shift, through the implementation of a "no data, no market" principle and of the principle of self-responsibility that both provide a basis for a new chemicals policy. This regulatory regime can be seen as a *modern* system, enabling a wide participation of stakeholders and upholding transparency as one of its founding principles. The organizational set-up of the system is, on the whole, satisfactory, seemingly enabling actors to fulfill their missions. The ownership process taking place between actors is a good sign of the robustness and good embedment of the regulation. Finally, REACH leads to an upgrade of the standards of chemical risk management.

However, as we have seen, REACH still raises crucial issues. If it meets the overall requirements of legal certainty, there is a need to clarify some crucial points. Moreover, the operational difficulties raised by its implementation, if they are not crippling, are deeply rooted. Such issues are the primary concern of actors at present, and rightly so. If they are not overcome by the end of the first registration phase, the implementation of REACH could go awry. What's more, the devil is in the details, and some issues raised by the implementation of the regulation still need to be addressed.

That said, REACH remains but the first step towards the achievement of a high level of protection of public health and the environment in the EU.[317] The level of ambition of the regulation will be unveiled by the next steps taken, and the political decisions underpinning them.

In order to improve the REACH regulatory regime, we put forward the following recommendations.

---

[317] C. Ruden, S. Hanson, « REACH is but the First Step – How Far Will it Take Us? Six Further Steps to Improve the European Chemicals Legislation", *Environmental Health Perspectives*, National Institute of Environmental Health and Science, 2009, <http://www.ehponline.org/members/2009/0901157/0901157.pdf>

# RECOMMENDATIONS

Such suggestions aim at ensuring a higher level of protection of human health and the environment, as well as the workability of the regime.

## *1. ENSURE A HIGHER LEVEL OF PROTECTION OF HUMAN HEALTH AND THE ENVIRONMENT*

### 1.1. Develop risks management instruments

- Identify new substances for the candidate list and Annex XIV. Achieving this objective is central to the effectiveness and credibility of REACH. Many substances that are still outside such lists are known to be SVHC. A wide-ranging strategy in favor of their inclusion on the candidate list, and subsequently on Annex XIV, has to be pursued.

- Clarify the aim of the candidate list and of Annex XIV. While the vast majority of the substances that are included in the candidate list tend to be, with time, included in Annex XIV, this is no formal obligation. In practice, the candidate list could help achieving other goals. De-prioritization arguments should be developed in order to exclude some SVHC from Annex XIV (for example when they are outside the scope of authorization, like biocides or pesticide products).

- Develop a framework of analysis to guide the choice between authorization and restriction: This is an important recommendation from the final report of the *Workshop proceedings on the Candidate List and on Authorization as Risk Management Instruments*.[318] There is indeed a need for better guidance and support of the decision making process for selecting the best risk management option.

[318] *Op. cit.*

## 1.2. Develop a REACH-related strategy to promote substitution of dangerous chemicals

A substitution strategy should be developed and implemented, with the objective of replacing high-risks substances by less risky alternatives. In this regard, the following points are of importance:

- Supporting research and development geared towards substitution. A fund could be created in order to promote and finance such projects. This has been set up in Italy for instance, where 120 million euros are awarded to companies and institutes promoting research into substitutes for SVHC.

- Supporting companies that have a clear substitution policy: This could be done via a communication operation, such as a "Substitution Award" for example. It could also be done via a financial incentive, such as a registration fee discharge.

## 1.3. Extend, in the long run, the scope of data requirements

For many substances, produced or imported in volumes under 10 tonnes a year, data requirements are less demanding than for substances produced or imported above that threshold. Under the threshold of one tonne a year, substances are entirely excluded from REACH. This is done in order to ensure the workability of the system, but it takes the regime away from its objective of a high level of protection of human health and the environment.

REACH should be reviewed in order to harmonize data requirements for substances produced in volumes above 10 tonnes a year and substances produced in volumes of one to 10 tonnes a year. This cannot be done in the short term, however, for the priority must be given to ensuring the workability of the system.

## 1.4. Acknowledge uncertainty

REACH is based on the principle that preventive action is needed in the realm of chemicals policy. However, uncertainty should be better acknowledged.

C. Ruden and S. Hanson rightly underline that REACH does not make any distinctions between a substance that has not been tested at all and a substance that has been

tested with a negative outcome. We support their proposal to introduce a new label, giving out the basic information on the toxicity of a substance when it is lacking.[319]

## 1.5. Promote higher standards worldwide

REACH will be a complete success if it leads to a worldwide upgrade of chemical safety standards. Such a phenomenon would have the additional benefit of closing the gap between Europe and the rest of the world, thus minimizing a number of issues such as competitiveness. Some countries have already begun to change their legislation. International actions, such as the update of the Stockholm Convention on Persistent Organic Pollutants, have to be supported and emulated whenever possible. Participation in international forums (OECD, International Conference on Chemicals Management etc.) is necessary. Technical help should also be provided to countries in need of it.

# *2. ENSURE THE WORKABILITY OF THE REGULATORY REGIME*

## 2.1. Clarify and inform on legal issues

Some issues need to be clarified, such as the crucial issue of interpretation of substances in articles. For example, we are exposed to brominated flame retardants, which are classified as SHVC, through building materials or furniture rather than through chemicals. Such gaps need to be identified and their legal situation clarified through the set-up of clear rules. Such rules should make it possible to keep track of product content.

Besides, information on the gaps existing between REACH and other legislative regimes should be provided and made accessible to actors in the industrial sector.

[319] C. Ruden, S. Hanson, *op. cit.*, p. 20.

## 2.2 Increase efforts to solve operational issues

Operational issues are the day-to-day challenges hindering the implementation of REACH. In this regard, it is necessary to increase efforts in order to bring practical solutions to registrants. An emphasis should be put on:

- IT issues: Preregistration has shown that the IT system is unable to meet the needs of the regulation. A further development of REACH-IT is required to deal with the up-coming registrations. As for the technical completeness check test as well as the chemical safety assessment test, the deadlines set for their development should be respected. More generally, REACH demonstrates the central importance of IT systems in the good implementation of regulatory regimes, especially when data collection is involved.

- SIEFs: Given the current situation, it is of the utmost importance that the ECHA and professional organizations intensify and improve their communication strategies towards registrants, in order for the latter to form the required SIEFs. Exchange of experiences and provision of information on this topic should be a priority in the coming months.

- Registration dossiers: Although guidance is published on the required contents for registration dossiers, it seems necessary that the ECHA provide experience feedback on the first round of registration dossiers received. Setting a new deadline for registration would hamper the effectiveness of REACH as well as its credibility, and would open up difficult discussions on the form given to such a process, which is not provided for within the existing regulation. Rather, a strategy of flexibility regarding the second deadline could be adopted whenever a given registration dossier is judged to be incomplete.

## 2.3. Develop a comprehensive policy to assist actors

Some actors play a special role in the implementation of REACH, which should be recognized. A comprehensive policy to assist such actors needs to be developed:

- In favor of the industry, and especially SMEs. Some industries are hit by the economic crisis just as they are required to fulfill their obligations under REACH. This should not impair the implementation of the regulation. Financial and technical help is needed for those companies. National helpdesks should, for example, communicate more extensively towards SMEs.

- In favor of the ECHA. The workload the ECHA has to deal with is ever increasing. The first registration deadline will be a true test for REACH, which needs to go as

smoothly as possible. Additional financial means should be given to the ECHA as long as registration fees remain insufficient to secure good working conditions. In particular, the ECHA should be able to recruit all the technical staff needed to carry out its future missions. Efforts have already been made towards this aim, they should be strengthened.

- Financial and fiscal measures could also be taken, such as phased payment of REACH fees to help solve cash management issues; accelerated depreciation of REACH related costs from a fiscal point of view; or granting of REACH loans, especially to SMEs.

## 2.4. Preserve good coordination between actors

The REACH regulatory regime is remarkable in that it rests on a wide participation of stakeholders. This trend has to be preserved. REACH can only be a success if actors in the industrial sector are willing to play the game, and if public authorities have trust in the industrial sector's experiences and feedbacks.

Dialogue and cooperation between actors should be preserved.

- This is the case also for national authorities. The implementation of REACH should be homogeneous across the EU territory. A better understanding of the various national practices regarding control and sanctioning is thus necessary. Common enforcement projects could be developed, taking further the soft harmonization operated via the ECHA's forum.

- Dialogue between Member States and the European authorities is necessary in order to find an answer to interpretational issues, especially regarding the substance in articles.

- Dialogue between European authorities and companies that are taking advantage of REACH to develop new activities (consulting activities, SIEFs or consortia management) should be developed. In particular, European authorities should check that such actors have the adequate expertise and means to complete their business objectives.

- Dialogue with the World Trade Organization should be fostered, in order to ensure, at every step, that the implementation of REACH does not lead to the creation of barriers to free trade.

# INTERVIEWS

*Not all of the persons interviewed appear in this list.*

Alexandre Affre, Business Europe, Brussels, July 2009.

Erwin Annys, Cefic, Brussels, July 2009.

C. Deconninck, Total, Paris, August 2009.

Luc Gaillet, Dolfus & Muller, Paris, June 2009

Daniel Garrigue, Paris, July 2009.

Nadia Haiama, Greenpeace, Brussels, July 2009.

Sylvie Lemoine, AISE, Brussels, July 2009.

François Litty, IFTH, Mulhouse, September 2009.

Catherine Lequime, UIC, Paris, July 2009.

François Loos, Former Minister for the Industry, Paris, July 2009.

Claude Mordini, Engineer, Paris, July 2009.

Emmanuel Moreau, Ministère de l'écologie, de l'énergie, du développement durable et de la mer, Paris, July 2009.

Jean-Luc Ponchon, Rhodia, Paris, July 2009.

Peter Van der Zandt, DG Environnment, Brussels, July 2009.

A., Inspecteur des installations classées, Paris, July 2009.

B., European Commission, Brussels, July 2009.

C., European Commission, Brussels, July 2009.

# BIBLIOGRAPHY

*Official documents, reports and newsletters*

*European Chemicals Agency*

ECHA, *ECHA Newsletter*, <http://echa.europa.eu/publications_en.asp>.

ECHA, *Guidance on Dossier and Substance Evaluation*, 2007, <http://guidance.echa.europa.eu/docs/guidance_document/evaluation_en.pdf>.

ECHA, *Guidance on Data Sharing*, 2007, <http://guidance.echa.europa.eu/docs/guidance_document/data_sharing_en.pdf>.

ECHA, *Member State Document for Identification of Hexabromocyclododecane and all Major Diastereoisomers as a Substance of Very High Concern*, 2008, <http://echa.europa.eu/doc/candidate_list/svhc_supdoc_hbccd_publication.pdf>.

ECHA, *Member State Document for Identification of Bis(2-Ethylhexyl)phthalate as a Substance of Very High Concern*, 2008, <http://echa.europa.eu/doc/candidate_list/svhc_supdoc_dehp_publication.pdf>.

ECHA, *Proactive Engagement with all ECHA Stakeholders*, 2008, <http://echa.europa.eu/doc/ECHADocuments/echa_stkhol_policy_en_20080528.pdf>.

ECHA, *Guidance on Information Requirement and Chemical Safety Assessment. Part D: Exposure Scenario Building*, 2008, <http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_d_en.pdf?vers=20_08_08>.

ECHA, *Guidance for monomers and polymers*, 2008, <http://guidance.echa.europa.eu/docs/guidance_document/polymers_en.pdf>.

ECHA, *Guidance on requirements for substances in articles*, 2008, <http://guidance.echa.europa.eu/docs/guidance_document/articles_en.pdf>.

ECHA, *REACH-IT Industry Manual. Part 8. Invoices*, 2008, <http://echa.europa.eu/doc/reachit/industry_user_manual/reachit_invoices_en.pdf>.

ECHA, *Evaluation. Progress Report 2008*, 2008, <http://echa.europa.eu/doc/progress_report_2008.pdf>

ECHA, *Recommendation for the inclusion of substances in Annex XIV (the list of substances subject to authorization) of Regulation (EC) n° 1907/2006*, 1st June 2009, <http://echa.europa.eu/doc/authorisation/annex_xiv_rec/annex_xiv_subst_inclusion.pdf>.

ECHA, *Rules of Procedure for the Committee for Risk Assessment*, 2009, <http://echa.europa.eu/doc/about/organisation/rac/rac_rops.pdf>.

ECHA, *Rules of procedure for the Committee for Socio-Economic Analysis*, 2009, <http://echa.europa.eu/doc/about/organisation/seac/seac_procedures_rules.pdf>.

ECHA, *REACH-IT Data Submission Manual 8. Business Rules Validation*, 2009, <http://echa.europa.eu/doc/reachit/reachit_data_submission_manual_8_business_rules_validation_20090417.pdf>

ECHA, *Workshop proceedings on the Candidate List and on Authorisation as Risk Management Instruments*, Helsinki, 2009, <http://echa.europa.eu/doc/consultations/authorisation/authorisation_workshop_proceedings_20090121.pdf>.

ECHA, "Large chemical companies will pre-register about 800 substances", *REACH Case Story*, <http://echa.europa.eu/doc/press/reach_case1_en_20080603.pdf>.

ECHA, "REACH at a small enterprise", *REACH Case Story*, <http://echa.europa.eu/doc/press/reach_case2_en_20080603.pdf>.

ECHA, « New study inaccurate on the number of test animals for REACH », Press release, 2009, <http://echa.europa.eu/doc/press/pr_09_11_animal_testing_20090828.pdf>.

*Commission of the European Communities (EC Commission)*

EC Commission (1998a), *Working document*, SEC(1998) 1986 final

EC Commission (1999a), *Community Strategy for Endocrine Disrupters*, COM(1999) 706, <http://www.europarl.europa.eu/meetdocs/committees/envi/20000418/123706_en.pdf>.

EU Commission (2000a), *Communication on the Precautionary Principle*, COM(2000) 1, <http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf>.

EC Commission (2001a), *White Paper. Strategy for a future Chemicals Policy*, COM(2001) 88, Brussels, 2001, <http://eur-lex.europa.eu/LexUriServ/site/en/com/2001/com2001_0088en01.pdf>.

EC Commission (2001b), *European Governance. A White Paper*, COM(2001) 428 final, <http://eur-lex.europa.eu/LexUriServ/site/en/com/2001/com2001_0428en01.pdf>.

EC Commission, *European Governance: Better Lawmaking*, COM(2002)275 final, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0275:FIN:EN:PDF>.

EC Commission, Proposal for a Regulation of the European Parliament and the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), COM(2003) 644, <http://europa.eu/eur-lex/en/com/pdf/2003/com2003_0644en.html>.

EC Commission, *Draft Interinstitutional Agreement on the operating framework for the European regulatory agencies*, COM(2005)59 final, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2005:0059:FIN:EN:PDF>.

EC Commission, *Follow-up to the 5th Meeting of the Competent Authorities for the implementation of Regulation (EC) 1907/2006*, 2008, Doc. CA/24/2008 rev.3, <http://www.minambiente.it/moduli/output_immagine.php?id=2459>.

EC Commission, *REACH in brief*, 2007, <http://ec.europa.eu/environment/chemicals/reach/pdf/2007_02_reach_in_brief.pdf>.

EC Commission, *European agencies – The way forward*, COM(2008) 135 final, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0135:FIN:EN:PDF>.

Health and Safety Executive, *Reducing risks, protecting people*, Norwich, HSE Books, 1999, <http://www.hse.gov.uk/risk/theory/r2p2.pdf>, 88 p.

*Others*

Austria, Belgium, France, Germany, Sweden, *Dissenting views on the Guidance on requirements for substances in articles*, <http://guidance.echa.europa.eu/docs/guidance_document/dissenting_en.pdf>.

Directorate General for Internal Policies of the European Parliament, *Welcome Package on Environment*, 2009, <http://www.eurosfaire.prd.fr/7pc/doc/1251363164_environment_welcome_package_en.pdf>.

Eurostat, *The REACH Baseline Study. A tool to monitor the new EU policy on chemicals*, Bruxelles, 2009,

<http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-RA-09-003/EN/KS-RA-09-003-EN.PDF>.

High Level Group on the Competitiveness of the European Chemicals Industry, *European Chemical Industry Enabler of a Sustainable Future – Final Report*, Brussels, 2009, <http://bookshop.europa.eu/eubookshop/download.action?fileName=NB7809771ENC_002.pdf&eubphfUid=10275753&catalogNbr=NB-78-09-771-EN-C>.

US Government Accountability Office, *Chemical Regulation. Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals*, August 2007, <http://www.gao.gov/new.items/d07825.pdf>.

US Government Accountability Office, Environmental *Protection Agency: Major Management Challenges*, March 2009, <http://www.gao.gov/new.items/d09434.pdf>.

*Books, articles, working papers and speeches*

Abma H., "From Pre-SIEFS to SIEFS – feedback from the Chemicals Distributors / SMEs", ECHA 2nd Stakeholders Day, presentation available at <http://echa.europa.eu/doc/press/events/stks_day_20090525/2nd_stk_day_feec_eu_voice_chem_distr.pdf>.

Ahrens A., Deceuninck P., Magaud H., "CSA Tool Development", presentation at REACH IT Workshop, March 2009, available at <http://echa.europa.eu/doc/press/events/reachit_workshop_20090326/REACHIT_IUCLID5_stakeholder_workshop_csa_tool_20090326.pdf>.

Allanou R., Hansen B., Van der Bilt Y., *Public Availability of Data on EU High Production Volume Chemicals*, European Chemical Bureau, 1999, <http://ecb.jrc.ec.europa.eu/documents/Existing-Chemicals/PUBLIC_AVAILABILITY_OF_DATA/datavail.pdf>.

Andersen M. S., Liefferink D., *European Environmental Policy: The Pioneers*, Manchester, Manchester University Press, 1997.

Andoura S., Timmerman P., "Governance of the EU: The Reform Debate on European Agencies Reignited", European Policy Institutes Network, *Working Paper*, October 2008, n° 19.

Applegate J., "Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform", *Ecology Law Quaterly*, 2008, pp. 721-769.

Baldwin R., Hutter B., Rodstein H., *Risk Regulation, Management and Compliance. A Report to the BRI Inquiry*, LSE, 2000, <http://www.bristol-inquiry.org.uk/Documents/Risk%20regulation%20report.pdf>.

Béal S., Deschamps M., Ravix J., Sautel O., "La mise en place de la législation européenne REACH : Une analyse des effets anticoncurrentiels", *Working Paper*, 2009.

Beck U., La société du risque. Sur la voie d'une autre modernité, Paris, Aubier, 2001 (Risk society : Towards a New Modernity, London, Sage, 1992).

Bergeson L., "Chemical Regulation: Preparing to Address the Challenges Ahead", *Environmental Law Reporter News & Analysis*, 2009, pp. 10029-10033.

Berny N., « Le lobbying des ONG internationales d'environnement à Bruxelles », *Revue française de science politique*, 2008, n°1, pp. 97-121.

Blainley M., "REACH, still being developed!", *Journal for European and Environmental Planning Law*, 2009, pp. 51-73.

*Bulletin de droit de l'environnement industriel,* « Trente ans de droit des déchets », special issue, June 2006.

Dancet G., *Closing remarks*, 2nd Stakeholders Day, 2009, <http://echa.europa.eu/doc/press/events/stks_day_20090525/2nd_stk_day_closing_remarks.pdf>.

Danilov I., "Legal Spotlight Special – Russia: a case study in responding to REACH", *Chemical Watch Briefing*, February 2009, <http://chemicalwatch.com/1794>.

Digangi J., *US intervention in EU chemical policy*, Environmental Health Fund, 2003, <www.noharm.org/details.cfm?type=document&ID=823>.

Egenberg M., Trondal J., "Political Leadership and Bureaucratic Autonomy. Effects of agencification", *ARENA Working Paper*, 2009, n° 9, <http://www.arena.uio.no/publications/working-papers2009/papers/WP09_09.pdf>.

Egenberg M., Martens M., Trondal J., "Building Executive Power at the European Level. On the role of EU-level Agencies", *ARENA Working Paper*, 2009, n° 10, <http://www.arena.uio.no/publications/working-papers2009/papers/WP10_09.pdf>, 25 p.

Feng W., Hu C., "Taiwan – Draft Proposal of Guidelines for Existing Chemical Substance Nomination (ECN) and New Chemical Substance Notification (NCN)", Keller and Heckman LLP, 2009,

<http://www.khlaw.com/Files/5798_Memo_Taiwan%20New%20Chemical%20Registration%20System.pdf>.

Friedrich D., "Old Wines in New Bottles ? The Actual and Potential Contribution of Civil Society Organisations to Democratic Governance in Europe", *RECON Online Working Papers*, 2007, <http://www.reconproject.eu/main.php/RECON_wp_0708.pdf?fileitem=5456965>.

Führ M., Merenyi S., "Mind the Gap: Interface Problems between EC Chemicals Law and Sectoral Environmental Legislation", *RECIEL*, 2006, n° 3, pp. 281-292.

Führ M., Bizer K., "REACH as a paradigmatic shift in chemical policy – responsive regulation and behavioural models", *Journal of Cleaner Production*, 2007, n° 4, pp. 327-334.

Godard O., *The Precautionary Principle. Between social norms and economic constructs*, Cahiers du laboratoire d'économétrie de l'Ecole Polytechnique, 2005, n° 20, <http://ceco.polytechnique.fr/fichiers/ceco/publications/pdf/2005-06-27-996.pdf>.

Goldstein B., "Toxic Torts: The Devil is in the Dose", *Journal of Law and Policy*, 2008, pp. 551-587.

Griller S., Orator A., "Meroni-revisited – Empowering European Agencies between Efficiency and Legitimacy", New Mode of Governance Project, Europainstitut, Vienna, 2007, <http://www.eu-newgov.org/database/DELIV/D04D40_WP_Meroni_Revisited.pdf>, 21 p.

Hansen B., Blainey M., "Registration: The Cornerstone of REACH", *RECIEL*, 2008, n° 1, pp. 107-125.

Harbermas J., *Droit et démocratie. Entre faits et normes*, Paris, Gallimard, 1997.

Hartung T., Rovida C., "Regulators have overreached", *Nature*, 27 August 2009, 460, pp. 1080-1081.

Heyvaert V., « The EU Chemicals Policy : Towards Inclusive Governance ? », *Society and Economy Working Papers*, LSE Law, 2008, n° 7, <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1111968>, 23 p.

Hirman D., "Completeness check, ECHA's approach", 2nd Stakeholders Day, May 2009, presentation available at <ttp://echa.europa.eu/doc/press/events/stks_day_20090525/2nd_stk_day_completeness_check.pdf>.

Hood C., Rodstein H., Baldwin R., *The government of risk. Understanding risk regulation regimes*, Oxford University Press, 2001.

Hutter B., Amodu T., "Risk Regulation and Compliance: Food Safety in the UK", *LSE and LSE Enterprise Report*, 2008, <http://new.wales.gov.uk/ecolidocuments/NCP/NCP.04219.pdf>, 25 p.

Jonas H., Le Principe Responsabilité. Une éthique pour la civilisation technologique, Paris, Flammarion, 1998.

Lebsanft J., "ECHA's first experience with evaluation", 2nd Stakeholders Day, May 2009, presentation available at <http://echa.europa.eu/doc/press/events/stks_day_20090525/2nd_stk_day_first_exp_with_evaluation.pdf>.

Lind G., *REACH – The Only Planet Guide to the Secrets of Chemicals Policy in the EU. What Happened and Why?*, The Greens and EFA, Brussels, 2004.

Lindgren K.-O., Persson T., "The Structure of Conflict over EU Chemicals Policy", *European Union Politics*, n° 1, 2008, pp. 31-58.

Martens M., "Executive Power in the Making. The establishment of the European Chemical Agency (ECHA)", *ARENA Working Paper*, 2009, n° 8, <http://www.arena.uio.no/publications/working-papers2009/papers/WP_08_09.pdf>, 25 p.

Marks G., McAdam D., « Social Movements and the Changing Structure of Political Opportunity in the European Union », *Western European Politics*, 19 (2), 1996, pp. 249-278.

Mc Intyre O., "The All-Consuming Definition of "Waste" and the End of the "Contaminated Land" Debate?: *Van de Walle* and Others", *Journal of Environmental Law*, 2005, n° 1, pp. 109-127.

Megregian S., "The risk of REACH. Finding the right balance between co-operation and competition is hard", *Competition Law Insight*, 28 July 2008, pp. 11-13.

Narbonne J.-F., « L'expertise française en toxicologie : un cas désespéré ? », *La Revue pour l'histoire du CNRS*, 2007, n°16, <http://histoire-cnrs.revues.org/document1557.html>.

Park D., "REACHing Asia Continued", *SSRN Working Paper*, 2009, <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1474504>.

Park D., Song M., Lee K., Yoon D., Cong X., "REACHing Asia: Recent Trends in Chemical Regulations of China, Japan and Korea", *SSRN Working Paper*, 2008, <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1121404>.

Pesendorfer D., "EU Environmental Policy under Pressure: Chemicals Policy Change between Antagonistic Goals?", *Environmental Politics*, 2006, n° 1, pp. 95-114.

Pickvance S., Karnon J., Peters J., El-Arifi K., *The impact of REACH on occupational health with a focus on skin and respiratory diseases*, University of Sheffield, 2005, <http://hesa.etui-rehs.org/uk/newsevents/files/reach-sheffield-complet.pdf>.

Raitio J., *The Principal of Legal Certainty in EC Law*, Kluwer Academic Publishers, 2003.

Richardson J., « Interest Groups and EU Policy-Making.Organisational Logic and Venue Shopping », *in* Jeremy J. Richardson (ed.), *European Union. Power and Policy-Making*, Londres, Routledge, 2006, pp. 247-268.

Ricoeur P., *Lectures 1. Autour du politique*, Paris, Seuil, 1991.

Ruden C., Hanson S., « REACH is but the First Step – How Far Will it Take Us? Six Further Steps to Improve the European Chemicals Legislation", *Environmental Health Perspectives*, National Institute of Environmental Health and Science, 2009, <http://www.ehponline.org/members/2009/0901157/0901157.pdf>.

Saurer J., "The Accountability of Supranational Administration: The Case of European Union Agencies", *American University International Law Review*, 2009, pp. 429-487.

Scott J., "From Brussels with Love: The Transatlantic Travels of European Law and the Chemistry of Regulatory Attraction", *SSRN Working Paper*, 2009, <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1333685>.

Scot J., Trubek D., « Mind the Gap : Law and New Approaches to Governance in the European Union", *European Law Journal*, 2002, n° 1, available at <http://eucenter.wisc.edu/OMC/Papers/EUC/scotttrubek.pdf>, 20 p.

Thieffry P., "REACH : l'enregistrement, l'évaluation et l'autorisation des substances chimiques en Europe", *Environnement*, 2007, n° 3, étude n° 4.

Wagner A., Cacciaguidy-Fahy S. (eds), *Obscurity and Clarity in the Law. Prospects and Challenges*, Ashgate Publishing, 2008.

Wagner D., "The EU's ECJ Rejects First Legal Challenge to the Registration Requirements of the REACH Regulations", *Environmental Law Resource*, 2009, <http://www.environmentallawresource.com/2009/07/articles/chemicals/the-eus-ecj-

rejects-first-legal-challenge-to-the-registration-requirements-of-the-reach-regulations/>.

Wirth D., "The EU's New Impact on US Environmental Legislation", *Legal Studies Working Paper Series*, Boston College Law School, 2007, n° 144, <http://ssrn.com/abstract=1028733>.

*Stakeholders' literature*

BUSINESSEUROPE, "Seven priorities for optimising implementation of REACH : lessons learned from the first two years", Position Paper, 2009, <http://www.businesseurope.eu/DocShareNoFrame/docs/2/GOPPNPPDHCAGNOBIACOMAFPIPDBG9DWY7D9LTE4Q/UNICE/docs/DLS/2009-01190-E.pdf>.

Cefic, *Facts and Figures*: *January 2009*, <http://www.cefic.org/factsandfigures/level02/profile_index.html>.

Cefic, *State of affairs in the European Chemical industry in the face of the global economic crisis*, 2009, <http://www.cefic.be/Files/Publications/2009-05-07-Final-Cefic-follow-up-crisis-pape.pdf>.

ICCA, *Responsible Care Global Charter*, 2006, <http://www.icca-chem.org/ICCADocs/09_RCGC_EN_Feb2006.pdf>.

Greenpeace, *Chemical Footprints in Blood. The Evidence*, 2004, <www.greenpeace.org/raw/content/eu-unit/press-centre/reports/chemical-footprints-in-blood>.

Greenpeace, *Safer Chemicals within REACH – Using the Substitution Principle to drive Green Chemistry*, 2005, <www.greenpeace.org/raw/content/eu-unit/press-centre/reports/safer-chemicals-within-reach.pdf>.

Greenpeace, *Toxic lobby. How the chemical industry is trying to kill REACH*, 2006, <http://www.greenpeace.org/international/press/reports/toxic-lobby-how-the-chemical>.

Greenpeace, *Fragile – Our reproductive health and chemical exposure*, 2006, <www.greenpeace.org/raw/content/eu-unit/press-centre/reports/reproductive-health.pdf>. Greenpeace, *Substitute with style*, 2005, <www.greenpeace.org/raw/content/eu-unit/press-centre/reports/substitute-with-style.pdf>.

Greenpeace, "First REACH hazardous chemicals identified", press release, 9 October 2009, <http://www.greenpeace.org/eu-unit/press-centre/press-releases2/First-REACH-hazardous-chemicals-identified>.

*WWF Response to "EU Trading Partners" statement*, 9 June 2006, Brussels.

*Press articles and press interviews*

Casalonga S., "Inquiétudes quant à la fusion Afsset-Afssa », *Journal de l'Environnement*, 6 October 2009, <http://www.journaldelenvironnement.net/fr/document/detail.asp?id=1932&idThema=5&idSousThema=27&type=JDE&ctx=9>.

Dooley C., "The chemical-law formula", *The Hill*, 6 July 2009.

Hansen B., "REACH in Perspective. Interview", *ECHA Newsletter*, July 2008, n° 1, <http://echa.europa.eu/doc/press/newsletter/echa_newsletter_2008_07_08.pdf>, pp. 5-6.

Loubière P., "REACH fait trembler les PME", *Challenges*, 4 Juin 2007.

Wallström M., "We have the legislation – now it's time to make it work », *SIN Reporter*, 2009, n° 2, <http://www.chemsec.org/images/stories/publications/ChemSec_publications/SIN_Reporter_2.pdf>, pp. 2-3.

"Chemicals NGO Forms as Climate Takes Centre Stage", *ENDS Report,* May 2007, n° 388, <http://www.endsreport.com/index.cfm?action=report.article&articleID=17256>.

"Reach chemicals regulation hit by computer problems", *Chemistry World*, 17 June 2008, <http://www.rsc.org/chemistryworld/News/2008/June/17060801.asp>.

"Russia harmonizes its chemical legislation with EU Reach", *Energy and Enviro Finland*, 17 June 2008, < http://www.energy-enviro.fi/index.php?PAGE=1832&NODE_ID=1832&LANG=1>

"Retailers integrate REACH into chemicals management", *Chemical Watch Briefing*, February 2009, <http://chemicalwatch.com/index.cfm?go=1788&q=carrefour>.

"ECHA builds up for REACH dossier evaluation challenge", *Chemical Watch Briefing*, June 2009, <http://chemicalwatch.com/2408>.

"REACH list could leap from 15 to 400 next year", *Pesticide and Toxic Chemical News*, 20 July 2009, <http://www.agra-net.com/portal2/home.jsp?template=pubarticle&artid=1248082781827&pubid=ag100&pubid=ag100>.

"ECHA offers help for REACH registration marathon", *Chemical Watch*, 14 September 2009, <http://chemicalwatch.com/index.cfm?go=2665>.