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PRECAUTIONARY REGULATION OF CHEMICAL RISK: HOW REACH CONFRONTS THE REGULATORY CHALLENGES OF SCALE, UNCERTAINTY, COMPLEXITY AND INNOVATION

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1. Introduction

It is widely agreed that past EU chemicals legislation was lacking in effectiveness with regard to both addressing chemical risk and stimulating innovation.[1] An important reason for this regulatory failure was the underlying principle that EU institutions first had to prove risks to human health or the environment posed by tens of thousands of existing chemicals before they could impose standards that burdened industry. Because of the scientific uncertainties and complexities that surround chemicals, this onus on the EU legislator in practice meant that dangerous chemicals were often marketed without prior authorization. At the same time, innovation in new chemicals was discouraged by a time-consuming and costly notification procedure, so that industry preferred the continued use or re-development of existing substances, notified to the European Inventory of Existing Chemical Substances, in order to avoid the more stringent regulatory regime that applied to new substances.

In the abstract, we can therefore say that EU chemicals legislation did not effectively engage with:

1. the large numbers and volumes of chemicals (which we refer to as "the problem of scale");
2. toxic risks posed by chemicals, and in particular scientific uncertainty about those risks ("the problem of uncertainty");

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1. See e.g. Winter (Ed.), *Risk Assessment and Risk Management of Toxic Chemicals in the European Community: Experiences and Reform* (Nomos, 2000); Heyvaert, *Coping with Uncertainty: The Regulation of Chemicals in the European Union* (PhD Dissertation, European University Institute, Florence, Italy, 1999). See Molyneux for annual reports on Substantive European Community Law – Chemicals, in Somsen (Ed.), *Yearbook of European Environmental Law* (OUP, 2005–2008).

3. complex interactions between various elements of (ecological) systems that require permanent monitoring, surveillance and regulatory adaptation ("the problem of complexity");
4. the goal of stimulating innovation by finding alternatives for dangerous chemicals ("the challenge of innovation").[2]

In essence, these four challenges do not only pertain to the regulation of chemicals, but go to the heart of the regulatory puzzle to which technological modernity more generally gives rise. Biotechnology, nanotechnology and synthetic biology, for example, generate regulatory quandaries that similarly translate as problems of scale, uncertainty, and complexity. To be sure, these technologies are regarded as at least as crucial for the EU's competitiveness and future prosperity as the chemicals industry.[3]

The importance of the regulatory reorientation that the Commission proposed in 2001,[4] which led to the Regulation on the Registration, Evaluation and Authorization of Chemicals (REACH),[5] must therefore not only be assessed in the isolated context of EU chemicals policy, but should more generally be appreciated in light of the Lisbon goals for the EU to become "the most competitive and dynamic knowledge-based economy in the world capable of sustainable economic growth with more and better jobs and greater social cohesion".[6]

Article 1 of REACH clarifies that the Regulation represents an exponent of so-called precautionary regulation. Precautionary elements (explored extensively elsewhere)[7] that indeed underpin REACH include provisions on the continuous supply of data, risk assessments for substances used in certain

2. Our understanding of "innovation" follows the classic notion developed by Schumpeter, i.e. that innovation denotes novel combinations of knowledge, resources etc. subject to attempts at commercialization (or carried out in practice). See Schumpeter, *The Theory of Economic Development* (Harvard University Press, 1934). See also the report *Innovation in the Chemicals Sector and the New European Chemicals Regulation*, WWF Chemicals and Health Campaign Report (2003).

3. See Lisbon EC of 23 and 24 March 2000, Presidency Conclusions available at: <www.consilium.europa.eu/uedocs/csm_data/docs/pressdata/en/ec/00100-r1.en0.htm>.

4. European Commission, "White paper laying down a strategy for a future chemicals policy", COM(2001)88, 27 Feb. 2001.

5. Reg. (EC) No. 1907/2006 of the European Parliament and of the Council of 18 Dec. 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (hereafter: REACH), O.J. 2006, L 396.

6. Presidency Conclusions, Lisbon European Council, 23 and 24 March 2000.

7. For an analysis of the constitutive elements of precautionary regulation see Fleurke, "Innovation through precaution: The case of the Dutch Wadden Sea" in Somsen and Etty (Eds.), 8 *Yearbook for European Environmental Law* (2008), pp. 80–132.

volumes, shifts in the burden of proof, the requirement to search for safer alternatives, and provisions concerning review and monitoring. As we will see, the combined effect of these provisions is the allocation to the industry of a range of responsibilities that had previously resided with public regulatory authorities. Simultaneously, regulatory and market pressures on the most hazardous chemicals are increased, stimulating the continuous development and use of safer and greener alternatives.

In this role, precautionary regulation amounts to significantly more than a tool to direct risk regulation under circumstances of scientific uncertainty, but also becomes instrumental in organizing a regulatory response to the challenges of scale, complexity and innovation. Our primary aim in this article is to investigate whether the precautionary principle can plausibly be said to fulfil that ambitious role in REACH. However, for the reasons alluded to above, we believe that our conclusions will be of more general significance for future EU regulatory initiatives targeting high risk/high reward new technologies.

In the next section, we first provide a brief characterization of the chemicals industry as a regulatory target. Section 3 then gives a synopsis of REACH, with particular attention to the institutional and procedural frameworks it establishes. Section 4 represents the heart of this article, and uncovers how the precautionary approach adopted in REACH attempts to overcome the four challenges that previous legislation so clearly failed to address. A concluding section 5 brings together suggestions for further improvements to the REACH regime, and suggests priorities for future research.

2. The regulatory landscape: the worlds of chemicals and risk

2.1. *The chemicals industry*

The chemicals industry is Europe's third largest industry, and has been at the forefront of European industrial development for decades.[8] Any EU regulatory regime pertaining to chemicals must have the maintenance of its global competitiveness as one of its core objectives, alongside protecting health and the environment. This amounts to a much more ambitious and proactive goal

8. Fourteen of the world's biggest thirty chemicals companies are headquartered in the EU, and the EU's annual chemicals sales amounts to €476 billion. More than half of global exports of chemicals originate in the EU, compared to 14.3% in NAFTA. EU exports of chemicals to the NAFTA region amount to €36.5 billion, while NAFTA chemicals sales in Europe are valued at €22.9 billion. The approximately 29 000 chemical and pharmaceutical companies currently employ a total staff of about 1.84 million, which amounts to 6% of the overall workforce in the manufacturing industry. Another 3 million employees are in jobs that are directly dependent on the chemicals sector. CEFIC, available at: <www.cefic.org/factsandfigures/level02/employment_index.html>. These figures relate to Jan. 2009 (last visited on 2 Oct. 2010).

than those traditionally associated with EU environmental law, i.e. that of securing an internal market in chemicals, or even the mere regulation of risk.

An effective EU regulator will seek to respond to the regulatory landscape of which the chemicals industry forms part.[9] A first striking feature of the industry is that, although it includes a small number of large companies (almost all transnational), it also consists of many smaller companies. These smaller firms are likely to respond very differently to the plethora of regulatory instruments that may be considered than their bigger counterparts.[10] For example, where "naming and shaming" has proved to be a potentially effective regulatory strategy to regulate large companies that are sensitive to public image loss, this is much less so for smaller companies.[11] Similarly, smaller companies often lack strong R&D departments necessary for the development of new and safer chemicals. Small companies therefore represent a particularly difficult challenge to regulate effectively.

Irrespective of size, the industrial processes within the industry are extremely heterogeneous and complex, making sector-wide standards a difficult proposition.[12] On the positive side: regulators can attempt to mobilize an industry association that is hugely influential, and has real impact on the behaviour of its members and policy makers.[13] EU institutions also should make the best use of the fact that the environmental performance of the chemicals industry is relatively transparent, and thereby open to public scrutiny.[14] This is reflected in significant environmental investments and high levels of preparedness to comply with environmental regulation.[15]

2.2. *Environmental and human health risks*

The chemicals industry is a prime contributor to environmental point source toxic chemical pollution, has the largest total emission of hazardous waste,

9. See Baldwin and Black, "Really responsive regulation", 71 MLR (2008), 59–94. The authors argue that "real" responsiveness implies awareness of attitudinal settings of regulatees, institutional environments, the logics of different regulatory tools and strategies, the regime's own performance and effects, and a responsiveness to change.

10. Gunningham, Gabrosky and Sinclair, *Smart Regulation: Designing Environmental Policy* (OUP, 2004), p. 143.

11. Gunningham, "Regulating small and medium sized enterprises", 14 *Journal of Environmental Law* (2002), 3–32.

12. Gambel, "US Environment Protection Agency, The Dutch Model: Lessons for the US" (1995) UD EPA, Washington DC, at 2.

13. See the European Chemical Industry Council, published at: <www.cefic.org/>.

14. According to CEFIC, the Brussels-based organization representing the European chemicals industry, between 1990 and 2006, production of the EU chemicals industry (including pharmaceuticals) rose by 67%, while total energy consumption was rather stable and greenhouse gas (GHG) emissions fell by almost 32%. CEFIC, figures available at: <www.cefic.org/factsand figures/level02/sustainable_index.html>.

15. Gunningham, Gabrosky and Sinclair, op. cit. *supra* note 10, p. 143.

and is a significant cause of ozone depletion and the greenhouse effect.[16] In addition, chemicals industries themselves are high-risk installations and calamities often result in serious and sometimes irreversible harm to the local and wider environment.[17] As observed above, sources of chemical pollution are often relatively easy to identify. Some problems, however, are invisible yet pose irreversible global risks.[18] For example, various hazardous persistent organic pollutants (POPs) have been found in the Arctic regions, although these chemicals have obviously never been produced there.[19]

Without a doubt the most tenacious regulatory challenge is to find a safe and pragmatic response to the scale, complexity and uncertainty of chemicals and the risks they pose. At present, some 30,000 chemicals are used in significant volumes, even though their use may be surrounded by toxic uncertainty or even toxic ignorance.[20] Unlike toxic ignorance, in cases of toxic uncertainty possible outcomes are clear (such as specific degrees of harm or benefit) but it is impossible to quantify the probability of such outcomes actually materializing. An exacerbating factor is that the totality of information that could go some way towards filling knowledge gaps is dispersed over a wide range of producers and users of substances. Moreover, what *is* known often is too tenuous to serve as a basis for a proper assessment of the environmental and public health risks.

Traditional EU command-and-control approaches have proved ill-suited to respond to these challenges, resulting in chemicals legislation that was inefficient, difficult to enforce, costly and that failed to encourage industry to move beyond compliance with existing and out-dated standards.[21] In good part,

16. Ibid., p. 139.

17. A well-known example is the Seveso disaster, an industrial accident that took place on 10 July 1976 in a small chemical manufacturing plant approximately 15 km north of Milan. It resulted in the highest known exposure to 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) in residential populations. In response, EU legislation was adopted; Dir. 82/501/EEC ("Seveso I") of 24 June 1982 on the Major-Accident Hazards of Certain Industrial Activities, followed by Seveso II Dir. 96/82/EC.

18. Foss Hansen, Carlsen and Tickner, "Chemicals regulation and precaution: Does REACH really incorporate the precautionary principle", 10 *Environmental Science and Policy* (2007), 395.

19. Fromberg, Cleeman and Carlsen, "Review on persistent organic pollutants in the environment of Greenland and Faroe Islands", 38 *Chemosphere* (1999), 3075–3093.

20. Winter, *Risk Assessment and Risk Management of Toxic Chemicals in the European Community* (2000), Estabrook and Tickner, *Massachusetts Precautionary Principle Project: Facing our Toxic Ignorance* (2000), available at: <sustainableproduction.org/precaution/back.brie.faci.html>. Toxic ignorance refers to a situation in which regulators cannot pronounce on either probabilities or outcomes ("regulators don't know what we they don't know"). See also Functowicz and Ravetz, "Science for the post-normal age", 25 *Futures* (1993), 739–756.

21. Gunningham, Gabrosky and Sinclair, op. cit. *supra* note 10, p. 151. See also Case, "Corporate environmental reporting as informational regulation: A law and economics perspective", 7 (2005), 379. 6 *University of Colorado Law Review*

this is because centralization is prone to give rise to information and capacity overload or, as a result of insufficiently reliable information, over-inclusive or under-inclusive risk management requirements.[22] By way of illustration: under the former regime, it took 14 years to assess the risks of 141 out of a total of about 2700 chemicals that are produced in volumes of more than 100 tonnes per year.[23] Of these 141, only two dozen were subject to a Commission Recommendation.[24] This amounts to a rate of about 10 chemicals per year and implies that it would have taken another 250 years for the remaining chemicals to be evaluated, never mind the chemicals at lower production levels.

The approach that is now enshrined in REACH was foreshadowed by the Seveso Directives, which marked a shift towards a process based philosophy.[25] The Seveso regime puts the onus of continuously collecting and updating safety information on operators of dangerous industrial plants, leaving national public authorities with the role of assessing the performance of those private assessors. In the parlance of regulatory theorists, Seveso established a precedent for the use of "responsive regulation" at EU level.[26] Quite how this has been worked out in REACH is what we will explore next.

3. A brief synopsis of REACH

Compared to the previous EU regime, the most important regulatory innovation at the heart of REACH undoubtedly is the "no data, no market" principle.[27] Simply put, the principle means that it is the responsibility of private actors

22. Foss Hansen, Carlsen and Tickner, op. cit. *supra* note 18, 396.

23. Schaafsma, Kroese, Tielemans, Van de Sandt and Van Leeuwen, "REACH, non-testing approaches and the urgent need for a change in mind set", 1 *Regulatory Toxicology and Pharmacology* (2009), 70.

24. Available at: <ecb.jrc.ec.europa.eu/documents/Existing-Chemicals/RISK_ASSESSMENT/REPORT/dinpreport046.pdf>.

25. Dir. 96/82/EC, cited *supra* note 17.

26. We ignore theoretical debates on the relative virtues of "reflexive", "responsive", "meta" and "smart" modes of regulation. Instead, we use the term "responsive regulation" in a very broad fashion to embrace notions of deliberative democracy, and the intelligent employment of actors and tools to enhance or substitute public regulatory capacities. See in similar vein Braithwaite, "Responsive regulation and developing economies", 34 *World Development* (2006), 884. See also Black and Baldwin, "Really responsive risk-based regulation", 32 *Law & policy* (2010), 181–213, Gunningham, "Regulating biotechnology: Lessons from environmental policy" in Somsen (Ed.), *The Regulatory Challenge of Biotechnology* (Edward Elgar, 2007), Teubner, "Substantive and reflexive elements in modern law", 2 *Law and Society Review* (1983), 239–285, Luhmann, *Soziale Systeme: Grundriß einer allgemeinen Theorie* (Suhrkamp, 1984) (English translation: *Social Systems*, Stanford University Press, 1995).

27. REACH, Art. 5.

manufacturing or importing chemicals to demonstrate safety by collecting and providing pertinent data. A second central plank of REACH is the principle of substitution: if safer alternatives exist, certain dangerous substances – the "Substances of Very High Concern" (SVHC) – must be phased out.[28] Third, *all* private actors in the supply chain are obliged to ensure the safety of substances they handle.[29] This means that both producers and downstream users are caught by the system. Indeed, REACH contains requirements pertaining to the sharing of data up and down the supply chain of substances. Fourth, REACH is meant to be transparent. This is reflected in the establishment of a publicly accessible internet database on chemicals.[30] For SVHC, this database includes information directed at consumers.

REACH contains a number of different procedures relating to the registration of chemicals, their evaluation, authorization (in the case of SVHC), and the possibility to impose restrictions on the manufacture and marketing of substances, which are briefly explained in sections 3.2 to 3.4. Chemicals undergo one or more of these pathways depending on two variables, one based on volume and one based on the properties of certain very dangerous substances.

The newly established European Chemicals Agency (ECHA) performs an important role in the administration of these schemes. Although REACH is a regulation, which normally implies a high level of detail, it actually leaves important questions to the discretion of a range of public and private actors within the regime, including the control and approval of registration dossiers, the evaluation of decisions, and the authorization and restriction of substances. At this point, we should turn to the role of ECHA in the regulatory scheme established by REACH, and the different regulatory pathways that apply to different classes of chemicals: registration, evaluation, authorization and the adoption of restrictions.

3.1. *The role of ECHA*

At the centre of the institutional design of REACH is ECHA, whose role it is to furnish Member States, the institutions and firms with the best possible scientific and technical advice on questions related to REACH and chemicals more generally.[31] To this end, ECHA has established a central online resource

28. Ibid., Recital 12 and Art. 55.
29. Ibid., Title III and IV
30. Ibid., Arts. 118–1 19. Commercial confidentiality clauses are only allowed under strict conditions.
31. Ibid., Art. 75(1). ECHA is based in Helsinki and with some 400 employees is the largest EU agency.

with news and information for industry, policy makers, and the general public.[32] Crucially, ECHA is also responsible for managing all registration dossiers, and undertakes "dossier evaluations", procedures that will be explained hereafter. In addition, it assigns certain Member States with the responsibility to undertake "substance evaluations".

As for the institutional design of ECHA more specifically, the Agency is managed by an Executive Director, and constitutes of a Management Board, a Committee for Risk Assessment (CRA), a Committee for Socio-Economic Analyses (CSEA), a Member State Committee (MSC), a Forum, and a Board of Appeal.[33] The CRA is involved in ECHA opinions on evaluations, applications for authorization, proposals for restrictions and proposals for classification and labelling, and other questions relating to risks to human health or the environment. The CSEA participates in ECHA opinions on applications for authorization, proposals for restrictions and any other questions that relate to the socio-economic impact of possible legislative action on substances. The MSC resolves potential divergences of opinions on draft decisions proposed by ECHA or the Member States on evaluation and proposals for identification of SVHC that are subject to the authorization procedure. The committees work independently from national authorities. In formulating opinions, the committees aspire to reach consensus, but if this is not possible the grounds for the majority opinion as well as the minority position(s) are published.[34]

Decisions taken by ECHA or its committees can be brought before the Board of Appeal,[35] but may simultaneously be the subject of a complaint to the European Commission pursuant to Article 263 TFEU.[36] The EC Regulation regarding public access to documents also applies to ECHA.[37]

Manufacturers and importers of SVHC must submit applications to ECHA for authorization of the continued use of these substances. ECHA, through its specialized committees, issues an opinion on the safety of the substance and the Commission subsequently formulates a proposal on the basis of the opinion by ECHA. The importance of ECHA is thus paramount in relation to authorization. This is notwithstanding the fact that Member States have an

32. Published at: <echa.europa.eu/>.

33. REACH, Art. 76.

34. Ibid., Art. 85(9).

35. Ibid., Arts. 89–93. Members of the Board of Appeal are appointed by the Commission in accordance with the procedure of regulatory committees under comitology.

36. Ibid., Art. 118(4). See on legal remedies under REACH Bronkers and Van Gerven, "Legal remedies under EC's new chemicals legislation REACH: A new model of European governance", 46 CML Rev. (2009), 1823–1871.

37. Reg. (EC) No. 1049/2001/EC of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, O.J. 2001, L 145.

opportunity to be involved in the identification of substances for evaluation, as well as in the task of substance evaluation through the different bodies within ECHA, in particular through the MSC.

Another important aspect of ECHA's work is to ensure consistency among Member States with regard to the implementation of REACH. To this end, ECHA issues numerous Guidance Documents concerning, *inter alia*, registration, data sharing, classification of chemicals, and preparation of chemical safety reports.[38] Because REACH essentially is a framework, ECHA wields real power and influence in this coordinating role. In effect, ECHA not only is the main administrator of REACH, it also represents a new central regulatory authority with real executive and implementation powers.[39]

Finally, "the Forum" is a platform for Member States to exchange information and to coordinate activities related to the implementation and enforcement of chemicals legislation.[40] The role of the Forum remains advisory, because in formal terms implementation of the Regulation proceeds in accordance with the regulatory procedure with scrutiny under comitology.[41] The rationale behind the establishment of the Forum was that "the currently informal cooperation between Member States .... would benefit from a more formal framework".[42] It is thought that active participation of competent national authorities is useful since "because of their closeness to stakeholders in the Member States, [they can] play a role in the exchange of information on the risk of substances and on the obligations of natural or legal persons under chemicals legislation".[43]

The Forum thereby plays an important role in realizing the shift REACH seeks to bring about away from substantive EU control of all chemicals towards a more responsive, procedural and information-based decentralized approach that will come to apply to the vast majority of substances, with a much more confined focus on the substantive and centralized control of a much smaller class of very dangerous substances. The gist of this new approach will be

38. The Guidance Documents are voluminous (approx. 7000 pages) and complex. Full understanding of the contents of all Guidance Documents is almost impossible.

39. See on the role of regulatory agencies in the EU: Vos, "Independence, accountability and transparency of European regulatory agencies", in Geradin, Munoz and Petit (Eds.), *Regulation through agencies: A new Paradigm of European Governance* (Edward Elgar, 2005), pp. 120–137; Kraphol, "Credible commitment in non-independent regulatory agencies: A comparative analysis of the European agencies for pharmaceuticals and foodstuffs" 10 *European Law Journal* (2004), 518–538; Majone, *Regulating Europe* (Routledge, 2005).

40. REACH, Preamble, Recital 105.

41. Ibid., Preamble, Recital 123 and 124. The Forum is thereby likely to gain the same function within REACH as the Advisory Forum has within the European Food Safety Authority (EFSA).

42. Ibid., Preamble, Recital 120.

43. Ibid., Preamble, Recital 119.

explained next, as we turn our attention to provisions concerning registration, evaluation, authorization and restrictions.

3.2. *Registration*

REACH imposes an obligation for industry to provide information on chemicals manufactured or imported at or above one tonne per year, through a procedure known as "registration".[44] Unless chemicals have been registered with ECHA, they are not allowed on the market (the "no data, no market" principle). Quantities below one tonne per year of any specific substance are exempted from the registration requirements,[45] as are substances used for research and development purposes only. In addition, chemicals used in biocides, agriculture, and cosmetics are excluded, as they are covered by existing specific legislation.[46]

The registration requirements apply to individual substances, groups of substances, and chemical products (i.e. substances included in "articles" where the substance is intended to be released under normal or reasonably foreseeable conditions of use).[47] This implies that registration duties apply to chemicals manufacturers and importers, but also to groups of traders selling a plethora of products that contain chemicals. There are a number of exemptions from registration, as well as groups to which less onerous information requirements apply, such as intermediates.[48]

The standard information that has to be submitted by each registrant consists of a technical dossier made up of information pertaining to the identity, classification, intended use(s), produced or imported quantities, physical properties and toxicological and ecotoxicological information of the substances.[49] This general standard is supplemented with specific rules that are triggered with reference to volume.[50]

44. Ibid., Art. 7.

45. The registration requirement for new chemicals has been increased from 10 kg/year to 1 tonne/year, the information requirements have been reduced.

46. See De Sadeleer, "The impact of the registration, evaluation and authorization of chemicals (REACH) regulation on the regulatory powers of the Nordic countries" in De Sadeleer (Ed.), *Implementing the Precautionary Principle. Approaches from the Nordic Countries, EU and USA* (Earthscan, 2007), 334.

47. REACH, Art. 3, which gives a definition of an article: "an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition." ECHA has issued a guidance document to clarify this definition, available at: <reach.jrc.it/docs/guidance_document/Art.s_en.pdf>.

48. Ibid., Recital 75, Annex IV and V.

49. Ibid., Art. 12(1).

50. Except for substances subject to authorization.

Substances that are produced or imported in volumes of 10 tonnes or more need a "safety assessment report", which is a central instrument for the control of chemicals in REACH. The registration requirement took effect on 1 June 2007, and the registration of existing substances is to be progressively phased in by 1 June 2018, with chemicals prioritized by production volume and with accelerated registration for known carcinogens, mutagens and reproductive toxins (CMR).[51] However, pre-registration by 1 December 2008 was required in all cases; ECHA received pre-registrations, relating to around 143,000 chemical substances by some 65,000 companies.[52]

For each registration, a completeness check is undertaken by ECHA, but this does not involve an assessment of the quality or adequacy of the submission.[53] In the absence of indications to the contrary from ECHA, registrants can proceed to manufacture (or import) within three weeks of registration.[54] Although this formalistic completeness check allows registrants considerable freedom in the selection and appreciation of data, ECHA may verify that the information submitted complies with the requirements of the Regulation, including its Annexes.[55]

3.3. *Evaluation*

Whereas registration requirements are satisfied as long as all the required fields of information have been covered, a substantive quality evaluation of that information is required for all testing proposals involving substances in volumes over 100 tonnes. In the course of such evaluations, testing proposals giving rise to additional safety data are examined. ECHA can accept or reject such test plans proposed by registrants.

In addition to the "dossier evaluations" that occur for all substances manufactured or imported in quantities over 100 tonnes, "substance evaluation" is carried out, irrespective of volume, when initial data raise suspicions concerning the health or environmental impact of chemicals.[56] It is for ECHA, in

51. REACH, Art. 23.

52. Ibid., Art. 28(2). A list of pre-registrations is available at: <apps.echa.europa.eu/preregistered/pre-registered-sub.aspx>.

53. Ibid., Art. 20(2), 41.

54. Ibid., Art. 21.

55. Ibid., Art. 41. The list of dossiers being checked for compliance by ECHA is made available to the competent authorities of the Member States. The Regulation also introduces random compliance checks. To ensure high quality registration, ECHA has to select a percentage of those dossiers, no less than 5% of the total received by ECHA for each tonnage band, for compliance checking. REACH, Art. 41(5). ECHA gives priority, although not exclusively, to dossiers meeting at least one of the criteria listed; e.g. when a dossier for a substance is listed in the Community rolling plan for evaluation of a substance.

56. Ibid., Art. 44(2).

cooperation with the Member States, to develop criteria for prioritizing substance evaluation, and to select substances for a three year rolling plan based on those criteria. Targeted substances are allocated to Member States, which evaluate them and act as rapporteurs.[57] Subsequent decisions require unanimous approval by the MSC within ECHA or, in case of disagreement, by the Commission (using the advisory procedure of comitology).[58] If initial concerns are confirmed, evaluation may trigger further risk management actions, such as the inclusion of the chemical on the list of substances subject to authorization, or the adoption of risk reduction measures.

The registrant(s) or downstream user(s) concerned can make comments on a draft decision concerning dossier evaluation, the compliance check, or a decision for further information.[59] The evaluation process thus offers the opportunity to assess certain suspected risks of dangerous properties, to add them to the rolling action plan, so that they will become subject to an evaluation in the near future, and can lead to restrictions and authorizations.

3.4. *Authorization*

SVHC (Substances of Very High Concern) require authorization before they can be marketed or used in the EU, irrespective of the volumes in which they occur.[60] This is probably the most striking feature of REACH, and certainly the most invasive. The obligation rests with firms to furnish proof that risks posed by SVHC are either "adequately controlled", or to show a "socio-economic need for their continued use, while no viable alternative currently exists".[61] The open and dynamic norm of "adequate control" is a key concept throughout the Regulation, and serves as a deliberative platform on the acceptability of risk. If conducted in a fashion that is in agreement with the principle of participation – engaging all interested parties – this is entirely consistent with precaution.

57. Ibid., Art. 45(1)(2). Member States may also notify the Agency at any time of a substance not on the Community rolling action plan, whenever they are in possession of information which suggests that the substance is a priority for evaluation. The Agency decides whether to add this substance to the Community rolling action plan on the basis of an opinion from the Member State Committee. Art. 45(5).

58. Ibid., Art. 45(3) refers to the procedure in Art. 133(3).

59. Ibid., Art. 50.

60. Ibid., Art. 56. Art. 57 lists certain categories of chemicals: vPvBs, PBTs and Carcinogens, mutagens and substances that exhibit reproductive damaging effects (CMRs). Substances exhibiting endocrine disrupting effects may also require authorization on a case by case basis. ECHA will publish a list containing such candidate substances. See on the contemporary debates on the risks of endocrine disruptions Durodié, "The true costs of precautionary chemicals regulation", 23 *Risk Analysis* (2003), 289–398.

61. Ibid., Title VII.

The criteria for authorization are laid down in the Regulation, and will be discussed elsewhere. However, it is the Commission that takes the decision, taking into account the opinion of the ECHA. If the risks are shown to be adequately controlled, the Commission must authorize. If, alternatively, it is impossible fully to contain the risks, the Commission may still grant authorization, depending on the severity of the risk and the viability of alternatives. In making its decision, the Commission has to follow the advisory comitology procedure under scrutiny.[62]

This latter procedure involves considerable influence from the European Parliament. Decisions are no longer the product of a simple agreement between the Commission and the Committee of national representatives, as was the case under the traditional comitology procedure.[63] Rather, after the Commission proposal has been approved by the Committee of national representatives, it is forwarded to the EP and the Council for "scrutiny". The Council can oppose the proposals by qualified majority, while the EP can oppose the proposal with a simple majority.

The introduction of the comitology procedure is intended to speed up the process. However, as Heyvaert observes, it is doubtful that this new form of comitology will be able to deliver results more efficiently than the decision-making process it replaces.[64] In part this is because such EP involvement renders risk decision making on the release of chemicals less technocratic and inevitably more political. This enhanced EP involvement will be welcomed by those advocating increased democratic control of scientific expertise,[65] but it is an innovation that quite possibly will come at the price of slow decision-making or paralysis, problems that REACH was of course precisely designed to address. Although the issue of democratic control over scientific experts for this and other reasons remains controversial, within the EU the case for such control in cases of toxic uncertainty in good part has been settled by virtue of the central position of the precautionary principle. In brief, if and to the extent that substances subject to authorization generate toxic uncertainty, the case for EP involvement is a compelling one.

62. Ibid., Art. 64(8) refers to Art. 133(3).

63. Council Decision 2006/512/EC amending Council Decision 1999/468/EC laying down the Procedures for the Exercise of Implementing Powers conferred on the Commission, O.J. 2006, l200/11. See on this procedure Pocklington, "Comitology under greater scrutiny", (2006) *European Environmental Law Review*, 306–311.

64. Heyvaert, "No data, no market: The future of EU chemicals control under the REACH Regulation", 9 *Environmental Law Review* (2007), 204.

65. See Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States*, (Princeton University Press, 1990).

3.5. *Restrictions*

According to the Commission, restrictions are the ultimate safety net to deal with "unacceptable risks to human health and the environment", and may come to apply to any substance risking human health or the environment, irrespective of quantitative thresholds or prior registration.[66] ECHA administers a list of restriction measures from EINIECS (European Inventory of Existing Chemical Substances), which may be amended. Whereas pursuant to the authorization procedure all uses of listed chemicals are banned unless applicants can defend a specific use, in the context of the restriction procedure it is the authorities that must provide justifications for banning specific uses (or in some cases production).

The procedure for the adoption of restrictions is as follows. If the Commission or a Member State considers that the placing on the market of a specific substance gives rise to risks that are not adequately controlled, thus presenting an unacceptable risk that needs to be addressed, it can require ECHA to prepare a dossier on the matter.[67] ECHA can also prepare a dossier on its own volition if it deems this necessary.

Risk reduction measures are adopted by the Commission in accordance with the regulatory procedure with scrutiny under comitology, acting on an ECHA opinion of the Committee for Risk Assessment and the Committee for Socio-Economic Analysis.[68] Our earlier observations about the merits of EP involvement also apply to the adoption of restrictions.

4. The challenges of scale, uncertainty, complexity and innovation

In section 1, we posited that the effectiveness of the precautionary regulatory scheme instituted by REACH will depend on the extent to which it manages to organize a response to the challenges of scale, uncertainty and complexity, as well as to stimulate innovation in new "green" chemicals.

The "problem of scale" quantitatively refers to a high number of substances, or high volumes of a single substance (e.g. a million tons). The regulation of a very high number of substances is obviously more likely to run into problems of toxic uncertainty and ignorance than regulation of a single substance, and in that sense the problem of scale is closely related to the challenge of toxic

66. Ibid., Art. 68. See also European Commission, Questions and answers on REACH Brussels, 2007, at 3, published at: <ec.europa.eu/environment/chemicals/pdf/qa.pdf>.

67. Ibid., Art. 69.

68. Ibid., Art. 73(2). Prior to REACH, the adoption of each new restrictive measure required Council and EP decision-making. Commission decision-making will make it more effective to take emergency measures in order to protect human health and environmental interests.

uncertainty. However, this does not necessarily need to be the case: it is perfectly conceivable that for a very large number of substances both probabilities and outcomes are known. In those latter cases, the regulatory challenge is not to deal with toxic uncertainty, but to cope with the sheer number of substances to be brought under control with limited resources. In addition, the problem of scale denotes the phenomenon whereby qualitative change occurs after a certain threshold (expressed in volume of a single substance or the total number of different substances), so that regulatory approaches tailored to lower volumes or numbers may no longer work for larger numbers or volumes of substances.

When we refer to "toxic uncertainty", we refer to a state of scientific uncertainty in which possible outcomes are clear (such as specific degrees of harm or benefit) but in which it is impossible to quantify the probability of such outcomes actually materializing.[69] It is this kind of uncertainty that triggers the precautionary principle and allows regulators to negotiate the threshold which, but for the precautionary principle, might have impeded regulatory action.

"The problem of complexity" we conceive as a qualitative problem that stems from intricate relationships between parts of a larger system. Interactions between those parts are complex, as changes in one part of the system impacts on the system as a whole, as well as on any or all of its other individual parts. More concretely, the complex system we are most concerned with here is ecological, although complexities evidently also concern political and legal systems.

In the remainder of this section, we turn our focus to the question whether REACH can indeed be said effectively to engage with these four challenges, which we do by critically analysing the most important features of the Regulation set out in section 3 above.

4.1. *The problem of scale*

On 7 September 2009, the Chemical Abstracts Service (CAS) recorded the 50 millionth substance in "CAS registry", the world's most comprehensive database of publicly disclosed chemical information. Incredibly, CAS registered the 40 millionth substance just nine months earlier. To put these numbers into proper perspective: it took as much as 33 years for CAS to register the 10 millionth compound in 1990.[70] All these substances invite some regulatory response, notwithstanding limited public resources and commitments to uphold

69. Functowicz and Ravetz, "Science for the post-normal age", 25 *Futures* (1993), 739–756.

70. Science Daily, 16 Sept. 2009. Available at: <www.sciencedaily.com/releases/2009/09/090910184310.htm> (last visited on 2 Oct. 2010).

the ideals of transparency and accountability of European environmental governance.

As we have seen, REACH alleviates this problem in two distinct ways which we will subject to closer examination in this section. First, it introduces a volume-based system with corresponding generic procedures and standards that come to apply depending on three categories based on volume; (1–10 t/y; 10–100 t/y; > 100 t/y). Second, REACH allocates the burden to prove safety with private actors (manufacturers, users, importers), thereby sharing the workload amongst a high number of private actors who as a rule are also in the best position to collect and interpret relevant risk related information concerning those substances.

4.1.1. *Scaling down: a volume-based system*

REACH presumes that the volumes in which substances are produced, used or imported correlate to exposure, which in turn correlates to dangers to humans and the environment. Protective standards therefore increase with volume (tonnes/year).

Although the quantitative threshold for registration starts at 1 t/y, the robustness of the registration procedure all depends on volume.[71] For the vast majority of approximately 30,000 substances (1–10 t/y), a simple system for the collection of data applies, without setting accompanying substantive standards. As we have seen, compliance with these informational requirements is essentially a formal affair, and does not imply compliance with substantive standards.[72] Only for substances that are produced and imported in quantities of 10 t/y or more does a "chemical safety assessment" need to be undertaken, culminating in a "chemicals safety report".[73] For that purpose, a hazard assessment for the substance must be made, as well as an assessment whether the substance is to be classified as PBT or vPvB.[74] In the latter case, an exposure

71. The minimum 1/t threshold for triggering the most basic information requirements forms a significant problem for the regulation of nano-scale chemicals. Toxicity of substances at this scale can also be caused by other characteristics, such as shape and quantum effects. E.g., concerns relating to the inhalation of carbon nanotubes fall outside the scope of REACH, since they are not related to quantity. Donaldson et al., "Carbon nanotubes: A review of their properties in relation to pulmonary toxicology and workplace safety", 92 *Journal of Toxicological Sciences* (2006), 5–22. The Commission has recognized this problem, but has – for the moment – pointed to the possibility of the authorization and restriction procedures. Commission (EC), "Nanomaterials in REACH" (Follow-Up to the Sixth Meeting of the REACH Competent Authorities, 16 Dec. 2008, CA/59/2008 rev.1: 5, published at: <ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf4>.

72. It also has to be noted that the Regulation occasionally offers special protection to consumers, see e.g., REACH, Art. 68(2).

73. REACH, Art. 14(1).

74. PBT= Persistent, Bioaccumulative and Toxic; vPvB= very Persistent, very Bioaccumulative.

assessment and risk characterization must be carried out.[75] What is striking about these chemical safety assessments is that they revolve around the open-ended and dynamic notion of "adequate control" of risk.[76] Higher risks will therefore simply invite more stringent exposure controls on the part of producers. Registrants must inform their downstream users as to how risks from the use of their substance can be "adequately controlled", giving rise to producer responsibility, which we will discuss further below.

In plain language, all this means that no genuine risk assessment needs to be carried out for substances produced or imported in quantities under 10 t/y. It is true that in those cases the "no data no market" rule offers some solace, but the protective effect of that rule may appear tenuous, given the absence of a routine substantive quality check of those data. Indeed, for substances produced under 100 t/y ECHA merely performs a basic, largely automated completeness test.

A substantive public assessment is triggered only for substances that are manufactured or imported in volumes of 100 tonnes or more. ECHA in that case examines testing proposals generated in the context of a registration or a downstream report (so-called "dossier evaluation").[77] As we saw, this should not be confused with substance evaluation, which may occur in respect of lower volumes of prioritized substances.[78]

4.1.2. *Sharing regulatory load: private actors as co-regulators*

Whereas under the old regime, it was the responsibility of public authorities to provide evidence of potential risks, the precautionary approach REACH aspires to implies that this responsibility now rests with manufacturers, importers and users.[79] All actors in the supply chain are obliged to ensure the safety of the substances they handle. As observed, the core provision is that substances on their own, in preparations or in goods falling under the scope of the Regulation must not be manufactured in the EU or placed on the market *unless* they have been registered.

Accordingly, it is for manufacturers, importers and users to undertake the registration process, and thereby to provide the necessary information on

75. Ibid., Art. 14(3)(4).

76. See Warhurst, "Assessing and managing the hazards and risks of chemicals in the real world – The role of the EU's REACH proposal in future regulation of chemicals", 32 *Environment International* (2006), 1033.

77. Ibid., Art. 40(1). Priority will be given to substances which have or may have PBT or vPvB sensitizing and/or carcinogenic, mutagenic or toxic for reproduction (CMR) properties, or substances classified as dangerous according to Dir. 67/548/EC above 100 tonnes per year with uses resulting in widespread and diffuse exposure.

78. Ibid., Art. 44.

79. Ibid. Recital 16, 18 and Art. 1.

chemical use and toxicity. If the required information is not readily available, manufacturers, importers and users must gather this information, and propose additional testing aimed at ensuring responsible and well-informed management of the risks that the substances may present.[80] If the outcomes of these additional tests provide insufficient grounds to presume satisfactory levels of protection, appropriate measures to adequately control the risks identified have to be taken.[81]

It is also the responsibility of manufacturers, importers and downstream users, in the context of registration, to identify the appropriate risk management measures needed to ensure a high level of protection for human health and the environment. Besides the Annexes of the Regulation, which spell out in detail the informational duties of registrants, ECHA has prepared guidance documents on the different processes under REACH, mainly for industry use.[82]

Following registration, an obligation remains with the registrant to provide ECHA with any relevant new information pertaining to the health and environmental risks of the substance.[83] The charge of a fee in such instances amounts to a curious disincentive for registrants to come forward with new information on their own volition.[84]

Suppliers of substances are required to carry out a safety chemical assessment for a substance, and are also responsible for information throughout the supply chain.[85] In fact, they are under such an obligation even when no safety data sheet is required.[86] All information passed on down the supply chain needs to be updated where new relevant information becomes available.[87] Registrants must identify and apply appropriate measures for adequate control so that safe use is assured throughout the life cycle,[88] and downstream users must therefore be informed how to "adequately control" risks.[89]

80. Ibid., Arts. 6 and 10. See also Art. 22 for further duties of registrants.

81. Ibid., Recital 86, Art. 14(6).

82. Published at: <guidance.echa.europa.eu/guidance_en.htm>.

83. REACH, Art. 22 (1). See also Art. 31 on the Safety Sheet that has to be passed down the supply chain.

84. Ibid., Art. 22(5), which refers to Title IX on Fees and Charges.

85. Ibid., Title IV. The supplier of a substance provides the recipient of the substance with a data sheet. The data sheet has to be consistent with the chemical safety assessment in accordance with Annex II.

86. Ibid., Art. 32.

87. Ibid., Title V sets out the obligations of the downstream users.

88. Ibid., Art. 14(6).

89. Warhurst, op. cit. *supra* note 76. REACH does not oblige downstream users to inform producers about their uses, but if they do not, and they are not covered by an existing exposure scenario, then the downstream user must do their own assessment. If they are using 1 t/y or more of the substance then downstream users must also send ECHA a short report, which includes the identity of the substance and a general description of the use.

The sum total of these changes pertaining to who must provide information about the properties and use of chemicals is substantial compared to the previous regime, and undoubtedly improves the chances of efficiently engaging with the challenge of scale. Some potentially troubling questions remain, however. One such question concerns the guidance notes which, although they may be necessary to curtail discretion and stimulate uniform implementation, basically amount to a type of detailed re-regulation, which was precisely what REACH was intended to replace. Second and perhaps most obviously, the onerous regulatory responsibilities that REACH allocates with industry do not sit easily with basic profit-making instincts that drive commerce. It therefore may be safely presumed that, all else being equal, companies will be reluctant to volunteer that their chemical products pose or could pose risks.

To be sure, whereas the volume-based system indirectly serves to alleviate regulatory burdens for smaller firms, it often appears to do so without simultaneously offering solid guarantees that this will not go at the expense of the precautionary regulatory approach REACH is intended to represent. If the enlistment of private actors in the regulatory process is to result not only in higher levels of efficiency (by allocating part of the workload to private actors with specific knowledge about chemicals) but also higher levels of effectiveness (realization of environmental and health goals), much will depend on the nature and credibility of background threats and incentives pushing industry towards compliance. We explore that question in section 4.3 below, devoted to the question how REACH deals with complexity.

4.2. *Dealing with toxic uncertainty*

The central assumption of REACH is that scientific and technical knowledge should underpin the regulation of chemicals. The notion of science-based environmental risk assessment becomes a tenuous one, however, when both probability and impact of potential damage are highly uncertain. Indeed Annex I, containing general provisions for assessing substances and preparing chemical safety reports, reflects the precautionary principle, by imploring that information gaps must be acknowledged. In addition to risks that are scientifically established, "*potential effects*" of substances must be taken into account.

In the latter respect, it is significant to note that REACH signifies a major shift in focus from hazard assessment to exposure assessment and risk management.[90] Thus, for SVHC an "exposure assessment" is conducted examining each relevant route of human exposure, leading to a broad range of exposure estimations. Different vulnerable population groups and environments are

90. Schaafsma et al., op. cit. *supra* note 23.

considered, and spatial and temporal variations of the exposure pattern taken into account.[91] In the chemical risk assessment, hazards (toxicity, flammability etc.) are analysed, and the quantitative relationship between different levels of exposure and occurrences of such hazards are determined.

In practice, scientific uncertainty makes the relationship between dose and response very difficult to determine, however, and long-term and chronic effects usually cannot be accurately ascertained, simply because predicting effects of low exposures over prolonged periods is shrouded in uncertainty. In brief, the collected and produced data on risks for human health and the environment are usually highly uncertain.[92] Uncertainties are further exacerbated by the impossibility adequately to account for combined effects of and interactions between different substances. More robust future science is thought unlikely to remove scientific uncertainty, and thereby create a more certain basis for risk management measures.[93]

Whereas it is therefore obvious that toxic uncertainties surround the regulation of chemicals, for our purpose at least as important is the question how these uncertainties are accommodated in REACH. In that respect, the informational burden is such that it is applicants seeking authorization of a substance that must show the safety of that chemical. This in turn implies that, consistent with precautionary regulation, measures can be taken even in the absence of conclusive scientific evidence establishing the existence of risk. Similarly, REACH requires registrants to draw up guidance notes and safety data sheets for downstream users and, for substances above 10 tonnes, risk assessments (chemicals safety assessments). The risk assessment is referred to as a "safety chemical report", implying that safety has to be established before the chemical can enter the market.[94]

Although risk assessments under REACH therefore may appear to acknowledge rather fully different kinds of uncertainties that hamper science-based regulation of chemicals, this leaves unaffected the fact that for the majority of chemicals (those produced or imported in quantities under 10 t/y) no genuine risk assessment is required at all. Also, the effectiveness of the authorization process ultimately depends on the number of substances that have been added to the list subject to authorization, and thus on the willingness of the Commission and Member States to put suspicious substances on that list. Moreover, risk assessments are in function of dynamic concepts such as "adequate con-

91. REACH, Recital 69 and Annex I.

92. Winter, op. cit. *supra* note 20.

93. Ashford, "Implementing the precautionary principle: Incorporating science, technology, fairness and accountability in environmental health and safety decisions", 5 *International Journal of Risk Assessment and Management* (2005), 112–124.

94. See for a description and explanation of a Chemical Safety Report REACH Annex I.

trol". Finally and crucially, as we will see in more detail, REACH entrusts the identification and acknowledgement of scientific uncertainty to industry, which goes considerably beyond expecting industry to identify and address known risks: "[u]ltimately, the importance of uncertainty analysis to each individual chemical safety report will depend on the specific circumstances and will be a matter of judgment for the report's author(s)".[95]

Irrespective of how one judges the appropriateness of affording the chemicals industry such a central role in regulating hazardous substances, it is obvious that this approach is only likely to work if there is some credible incentive pushing industry towards compliance. We turn our attention to such incentives next.

4.3. *Responding to complexity*

Overcoming the challenge of scale is predominantly an endeavour in pursuit of regulatory efficiency. REACH deals with this challenge essentially by operating a simple volume-based regime, and by resorting to a system of co-regulation, i.e. by sharing regulatory responsibilities with private actors. We have seen that this approach goes a long way towards addressing the problem of scale, but also that it gives rise to serious concerns about the effectiveness of REACH in realizing its environmental and health goals. Our reservations pertain to two concerns in particular. First, the simplification that the volume-based regime brings about may do insufficient justice to the risks and complexities that characterize the regulation of hazardous chemical substances. Second, the system of "co-regulation" which is at the heart of REACH implies that in the majority of cases companies evaluate their own substances and performance (on the basis of the assessment procedures of Annex I and the guidance document), notwithstanding the fact that those companies *prima facie* stand little to gain from identifying risks at their own volition.

After first examining how REACH deals with severe risks and complexities, in the second part of this section we turn our attention to mechanisms located within and outside the confines of the Regulation that may push reluctant co-regulators towards compliance.

95. ECHA, "Guidance on information requirements and chemical safety assessment", Guidance for the Implementation of REACH, May 2008, at 8. Available at: <guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1251717086>.

4.3.1. *Severe risk and complexities*

4.3.1.1. *Severe risk: REACH revisited*

REACH presumes that the toxic risk posed by chemicals relates to the volumes in which they are produced and imported. Public authority and EU involvement in the regulatory process therefore become more pronounced as volumes, and by implication toxic hazards, increase.

This bold over-simplification, which in good part is a response to the challenge of scale, is subject to three correctives. First, a special regime applies to SVHC. Second, substance evaluations may give rise to authorizations and restrictions, irrespective of volume. Third, REACH caters for the possibility of the adoption of restrictions in case of "an unacceptable risk to human health or the environment …. which needs to be addressed on a Community-wide basis".[96] It is precisely these in essence fairly traditional command-and-control type regulatory devices that ultimately form the backbone of the protective regime instituted by REACH. They are "safety nets" in the sense that they allow the imposition of conditions and restrictions to any substance irrespective of volume.

For prioritized substances,[97] a draft rolling action plan for evaluation is compiled every three years. Substances are included if there are reasons to believe (on the basis of a dossier evaluation carried out by ECHA, or on the basis of any other appropriate source, including information in the registration dossier) that a given substance constitutes a risk to human health or the environment.[98] After an opinion from the Member State Committee it is left to ECHA to decide whether to add the substance to the Community rolling action plan.[99]

Article 45(5) allows a Member State at any time to propose a substance to ECHA for inclusion in the Community rolling action plan whenever it is in possession of information which *suggests* that the substance is a priority for evaluation. It is the competent authority that carries out this risk assessment,

96. Ibid., Art. 68(1).

97. Substances which have or may have PBT, vPvB, sensitizing and/or/ carcinogenic, mutagenic or toxic for reproduction (CMR) properties, or substances classified as dangerous according to Dir. 67/548/EEC above one tonnes per year with uses resulting in widespread and diffuse exposure.

98. REACH, Art. 44(2). ECHA shall submit the first draft rolling action plan to the Member States by December 2011. ECHA adopts the final Community rolling action plan on the basis of an opinion of the MSC, and shall publish the plan on its website, identifying the Member State who will carry out the evaluation of the substances listed therein, determined according to REACH, Art. 45.

99. REACH, Art. 44(2).

and can request further information from the registrant.[100] Once the competent authority has completed the substance evaluation and the suspicions are confirmed, it can propose to authorize, to adopt restriction measures, or to classify and label the substance.[101]

We saw that in respect of authorizations REACH completely reversed the burden of proof compared to previous legislation. Thus, it is for manufacturers, importers or downstream users to prepare and submit applications for authorizations, and such authorizations will only be granted if the applicant has established that chemicals have been brought under "adequate control".[102] To this end, applicants submit a description of the risk management measures and operational conditions which the manufacturer or importer has implemented, or recommends to be implemented by downstream users.[103] This shift of the burden of proof equally pertains to the uses to which any given chemical may be put: it is for industry to convince the Commission that continued use is justified, rather than *vice versa*.

The type of information that may be taken into account in arriving at a decision about authorization includes socio-economic analyses, and information concerning the risks and technical feasibility of alternatives.[104] It is therefore for applicants either to show that the chemicals are adequately controlled or, if they cannot do this, that risks are outweighed by socio-economic benefits or that there are no suitable alternatives available.[105] It should not too easily be concluded that alternatives are not feasible, as this would undermine both the objectives of innovation and protection of health and the environment.

Next to dossier evaluations and authorizations, risk reduction measures similarly amount to a powerful corrective for the simplification that the volume-based system represents. However, risk reduction measures require proof of an unacceptable risk.[106] In light of the many uncertainties surrounding risks posed by chemicals, it would seem unlikely that risk-reducing measures will be a frequent occurrence.[107]

100. Ibid., Art. 46.This can include information not required in Annexes VII-X. See also Art. 47(1) and Art. 50(4).

101. Ibid., Art. 48. The competent authority shall inform ECHA of its conclusions as to whether or how the to use the information obtained. ECHA in turn informs the Commission, the registrant and the competent authorities of the other Member States.

102. Ibid., Art. 60(1).

103. Ibid., Arts. 37 and 60(4)(a).

104. Ibid., Arts. 62(5) and 62(4)(e).

105. Ibid., Arts. 60 and 62.

106. Ibid., Art.68(1).

107. Rudén and Hansson, "Improving REACH", 44 *Regulatory Toxicology and Pharmacology* (2005), 38.

4.3.1.2. *Regulating toxic complexity*

The notions of scale, uncertainty and complexity are intimately related. Indeed, many of the challenges that concern the complexity surrounding the use of (high numbers and volumes of) chemical substances in part are addressed by the precautionary principle and the explicit acknowledgement of uncertainty, as well as by the volume-based regime explored in the previous subsections. Earlier, we defined complexity as a qualitative problem that stems from intricate relationships between parts of a larger system (e.g. an ecological system). We posited that it is the interactions between those parts that are at the root of complexity, as changes in one part of the system impact on the system as a whole, as well as on any or all of its other individual parts.

In this section, we focus on the need for the EU to swiftly respond to constantly changing circumstances and insights, which is one of the most striking consequences of toxic complexity. This need for regulatory plasticity invites tensions with important fundamental principles, including legal certainty and transparency, and moreover further stretches an already overburdened EU legislature and executive. Yet, continuous critical reflection on dangers posed by chemicals and the effectiveness of existing authorizations and restrictions is a key component of precautionary regulation.[108] REACH oversees a discursive process, as standards are continuously adapted reflecting advances in scientific knowledge.[109] Such a reflexive and responsive regulatory approach translates, *inter alia*, in continuous data collection, monitoring and risk communication, with a view to reducing scientific uncertainties. REACH incorporates reflexive mechanisms in a number of different ways, which we will now briefly discuss.

(i) Review and temporary validity of authorizations. Authorizations are subject to periodic review, and normally subject to conditions, including monitoring.[110] No upper-limits of the duration of an authorization are specified, although authorizations must specify the duration.[111] Authorizations are valid until the Commission decides to amend or withdraw them, but withdrawal is only possible in the context of a review.[112] Holders of authorizations must submit a

108. Van Zwanenburg and Stirling, "Risk and precaution in the US and Europe: A response to Vogel", 3 YEEL (2003), 50.

109. Von Schomberg, "The precautionary principle and its normative challenges" in Fisher, Jones and Von Schomberg, *Implementing the Precautionary Principle* (Edward Elgar, 2006), 34; Fleurke, op. cit. *supra* note 7.

110. REACH, Recital 60(8) and 72. The authorization list is also provisional and can be amended over time, Art. 58(4).

111. Ibid., Art. 60(8)(9). The duration for any authorization shall be determined on a case-by-case basis taking into account all relevant information.

112. Ibid., Art. 61(1). In the EP version of REACH, all authorizations were to be subject to review periods and the manufacturers in this proposal had to present new plans for substitution,

review report at least 18 months before expiry of the authorization. For this review, an update of the analysis of alternatives has to be submitted, including information about any relevant research and development activities by the applicant, if appropriate, and any substitution plan. If this update shows that a suitable alternative exists, the holder of an authorization submits a substitution plan, including a timetable for proposed actions by the applicant. In addition, when circumstances of the original authorization have changed so as to affect the risk to human health or the environment, or the socio-economic impact, or when new information on possible substitutes becomes available, the authorization can be reviewed at any time.[113] In cases where there is a serious and immediate risk to human health or the environment, the Commission can suspend the authorization pending the review.[114]

The procedure hence encourages the development of safer alternatives, substitution and innovation. Strikingly and against the spirit of precaution, however, no opportunity is built in for interested or third parties to voice their comments in the context of the review procedure. Certainly in those cases in which toxic uncertainty prevails, and the authority of science therefore is tenuous, it is rational and desirable to involve interested and third parties with a view to filling knowledge gaps.

(ii) Review of core criteria for prioritizing and testing chemicals. The list of substances subject to authorization is crucial for the ultimate effectiveness of REACH, and it is therefore vital that the criteria for prioritizing chemicals can be subject to review periods for certain uses.[115] Likewise, the criteria in Annex XIII relating to PBTs and vPvBs (Criteria for the identification of persistent bio-accumulative and toxic substances, and very persistent and very bioaccumulative substances) have to be reviewed taking into account current and new experience with the identification of these substances and, if appropriate, must be amended with a view to ensuring a high level of protection for human health and the environment.[116] In similar vein, testing methods have to be regularly reviewed and improved with a view to reducing testing on vertebrate animals and the number of animals involved.[117]

see European Parliament Legislative Resolution on the Proposal for a Regulation of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC)…./… [on Persistent Organic Pollutants] 2005, (COM(2003)0644-C5-0530/2003–2003/0256(COD), Amendment 235.

113. Ibid., Art. 61(2).
114. Ibid., Art. 61(3).
115. Ibid., Art. 58(1)(d).
116. Ibid., Recital 76.
117. Ibid., Art. 13(2).

(iii) Monitoring. REACH contains numerous provisions on monitoring, applying to both private actors and national and EU public authorities. A general monitoring obligation on the part of registrants is implied in the duty to inform ECHA of changes pertaining to information previously furnished in the context of registration.[118] Safety data sheets also must be updated by suppliers in the light of new information that may affect risk management measures, or of new information on hazards.[119] As observed earlier, the Achilles Heel of these provisions is that it is ultimately for manufacturers, importers or users of chemicals to respond to new information they possess, even though the consequences of doing so may be detrimental to those same manufacturers, users or importers. The prospect of strict product liability and the possibility of reliance on a "state of the art defence" may offset this obvious asymmetry, an idea to which we will briefly return below.

Member States and ECHA must issue regular reports on the implementation of REACH, as well as on trends in the field.[120] Member States must put in place a system of effective monitoring and control, as well as an appropriate framework for penalties for non-compliance.[121] ECHA is to submit a report every five years to the Commission on the operation of the Regulation, again implying a duty to monitor.[122] Similarly, the Commission is required to carry out a variety of specific reviews of the provisions of REACH, in accordance with a timetable specified.[123]

(iv) Emergency measures. Consistent with numerous similar provisions in other environmental directives, Member States can take provisional measures if they have justifiable grounds for believing that urgent action is essential to protect human health or the environment in respect of a substance (on its own, in a preparation, or in an article), even if the requirements of the Regulation have been satisfied. The Member State has to substantiate its action by submitting scientific or technical information.[124]

118. Ibid., recital 46, Art. 14(7), Art. 22(1).

119. Ibid., Art. 31 (9). Also when an authorization has been granted or refused or a restriction has been imposed. See Arts. 37 (7) and 38 for monitoring obligations of downstream users.

120. Ibid., Art. 117(1). The first reports were due by 1 June 2010.

121. Ibid., Title XIV and Arts. 125 and 126.

122. Ibid., Art. 117(2). The first report shall be submitted by 1 June 2011. In addition, every three years ECHA has to submit a report to the Commission on the status of implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of the Regulation.

123. Ibid., Art. 138.

124. Ibid., Art. 129. The Commission then takes a decision in accordance with the procedure referred to in Art. 133(2) within 60 days, either authorizing that provisional measure or requiring the Member State to revoke it.

According to the Commission, this should ensure that the precautionary principle is honoured in cases where it would take too long to establish the data necessary for a scientific evaluation, or where data does not allow the risk to be determined with sufficient certainty.[125] It is questionable if this is true; Member States wishing to take emergency measures must advance scientific and technical justifications for taking precautionary action. Similarly, the Commission can only suspend authorization when there is a "serious and immediate risk".[126] Having to demonstrate that there is a risk before restrictions can be implemented, particularly after indications of severe but uncertain risks, is hardly in line with precaution.[127] Precaution, after all, is designed precisely to provide guidance in cases where societal stakes are high and claims are uncertain or complex.

4.3.2. *Pushing reluctant co-regulators towards compliance*

As to the prospect of involving firms as co-regulators Gunningham has observed: "Put crudely, while companies are allowed to grade their own exam papers, there is an obvious temptation to fudge the results of their own internal monitoring, and even in the unlikely event that they fail themselves, there are no credible sanctions".[128]

Of course, it may be hoped that the shifts in responsibilities REACH effectuates will foster a new culture of industrial responsibility. Yet, failing prospects of some form of sanction for non-compliance or reward for continuous improvement on existing standards, realists will justifiably wonder why a company should make all the efforts. Optimists will maintain that enterprises at the very least will strive to comply with the legally prescribed standards in REACH but, as we have seen, in respect of significant classes of chemicals, these are relatively open-ended and at times even non-committal.

Indeed, as has been repeatedly shown in regulatory theory and practice, the effectiveness of co-regulatory initiatives depends on many variables, not least some mechanism to push industry towards compliance or, ideally, beyond compliance. Such mechanisms are obviously often rooted in the law, for instance in the form of liability regimes or public sanctions, but may be equally or more effective if they (sometimes simultaneously) involve the mobilization of societal forces (NGOs, etc.) or the market (e.g. labelling). In this section, we will explore important devices that do or may perform that function.

125. European Commission, Questions and answers on REACH Brussels, 2007, at 3, available at: <ec.europa.eu/environment/chemicals/pdf/qa.pdf>.

126. REACH Art. 61(3).

127. Foss Hansen, Carlsen and Tickner, op. cit. *supra* note 18.

128. Gunningham, Gabrosky and Sinclair, op. cit. *supra* note 10, 168.

4.3.2.1. *Environmental and product liability*

The system of producer responsibility discussed in section 4.1 above raises important liability issues. To be sure, plausible prospects of incurring producer liability for damage to persons, or environmental liability for damage to the environment amount to forceful background incentives for suppliers to comply with the spirit of REACH.[129]

The Environmental Liability Directive creates strict liability for "operators" that engage in activities requiring a licence under the Directive on Integrated Pollution Prevention and Control,[130] activities which discharge heavy metals into water or the air, installations producing dangerous chemical substances, waste management activities (including landfills and incinerators), and activities concerning genetically modified organisms and micro-organisms.[131] Some of these activities undoubtedly involve chemical substances covered by REACH. Fault or negligence is required for liability to arise in respect of other activities, and only if and insofar as damage occurs to habitats and species protected by EU law.[132]

Considerable discretion is left to Member States, especially as to the question whether to provide for state-of-the-art and permit defences, implies that producers and suppliers of chemicals may be less or more inclined to comply with REACH, depending on the particulars of national environmental liability regimes.[133]

The prospect of product liability arising out of the defective use of chemicals, by contrast, serves as a potentially effective background threat, incentivizing compliance. Thus, the Product Liability Directive puts in place a harmonized strict liability regime pertaining to defective products.[134] A Supplier

129. A case study has been conducted on the "announcement effect" of substance lists. It was concluded that a candidate list of substances subject to authorization could have the effect on downstream users wishing the substance to be excluded from the product they purchase. Heitmann and Reihlen, "Case study on the 'announcement effect' in the market related to the candidate list of substances subject to authorisation: Final report", (Okopol, 2007). Available at: <ec.europa.eu/environment/chemicals/reach/background/docs/report_announcemnt_effect.pdf>.

130. Dir. 2008/1/EC of the European Parliament and of the Council concerning Integrated Pollution Prevention and Control, O.J. 2008, L 24.

131. Dir. 2004/35/EC of the European Parliament and of the Council on Environmental Liability with regard to the Prevention and Remedying of Environmental Damage, O.J. 2004, L 143, Art. 3 referring to Activities listed in Annex III.

132. Ibid, Art. 3(1)(b).

133. See for a discussion on discretion of Member States in European environmental law: Somsen, "Discretion in European Community environmental law", 40 CML Rev. (2003), 1413–1 453.

134. Council Dir. 85/374/EEC Concerning Liability for Defective Products, O.J. 1985, L 210.

can invoke the development risk defence of Article 7(e) of the Directive, if and to the extent that he can show that "the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered." Obviously, the chances of successful reliance on this defence will markedly increase when suppliers have gathered, monitored and passed on all potentially relevant information concerning the risks associated with the product. State of the art defences hence serve as a stimulus for suppliers to comply with the informational obligations of REACH. Without such a defence, strict liability implies that they will be liable even if they acted in accordance with the state-of-the-art. This observation would appear to apply equally to environmental liability: state-of-the-art provisions in national legislation might be expected to give rise to a proactive role on the part of the chemicals industry in respect of information gathering and monitoring.

Whereas producers or suppliers thus have an interest in addressing information deficits that are constitutive of toxic uncertainty, the phenomenon of toxic ignorance *ipso facto* means that information requirements can never be constructed in such a way so as to incentivize these actors to address the problem of toxic ignorance. In other words, the very notion of toxic ignorance signifies that suppliers will be oblivious of hazards, and hence not know what to look for. In practical terms, this means that suppliers will always be strictly liable for damage that arises out of toxic ignorance.

4.3.2.2. *Public enforcement*

Private liability schemes aside, traditionally EU environmental law has relied predominantly on public agencies for its enforcement. The public enforcement of EU environmental law remains first and foremost a responsibility residing with Member States, with a corrective role for the Commission under Article 258 TFEU. This is no different for REACH, which in Title XIV implores Member States to "maintain a system of control" and to provide for "effective, proportionate and dissuasive penalties".[135] It would appear that they are largely free to choose how to do this, in the sense that Directive 2008/99/EC on the Protection of the Environment through Criminal Law does not list REACH in Annex A of that Directive.[136] The newly established Forum has the coordination of activities related to the implementation and enforcement of chemicals legislation as one of its prime tasks. Cooperation in the field of enforcement will expedite knowledge transfer between the 27 and, to the extent that more uniform levels of enforcement result, counter forum shopping.

135. Ibid., Arts. 125 and 126.
136. O.J. 1998, L 328/28.

4.3.2.3. *Mobilizing society: transparency and access to information*

Stakeholders and the public are represented in decision-making pursuant to REACH,[137] for instance by submitting comments on a proposal to restrict the manufacture, marketing or use of a particular chemical.[138] ECHA has to consider this information when checking and selecting dossiers.[139] REACH facilitates stakeholder participation by the general rule that all information gathered is publicly available on an internet database hosted by ECHA,[140] and safety information submitted as part of the registration process may not be excluded, according to Article 118(2).[141]

Such examples of transparency are of course first and foremost vehicles allowing public involvement in chemical risk regulation, thus supporting the democratic legitimacy of REACH. The reason why we are dealing with transparency and public participation in this section devoted to pushing reluctant co-regulators towards compliance, however, is because they may help realize this.[142] A study by Konar and Cohen, for instance, shows that stock markets respond to high releases of chemical companies.[143]

In a similar vein, Scott perceives these possibilities to participate in the authorization process as a framework for "competition-based regulation", resulting in a race to the top, with distinct roles for third parties, the CSEA and the CRA, and ECHA.[144] Thus, third parties can demonstrate socio-economic benefits arising from the use of a substance and the socio-economic implications of a refusal to authorize.[145] The CSEA can ask either the applicant or third parties to give additional information on substitutes. ECHA has to make broad information on uses of substances for which applications have been received, and on reviews of authorizations, available on its website.[146] In response, third

137. See e.g. REACH, Arts 40(2), 64(3), 70, and 71(2).

138. Ibid., Art. 69(6).

139. Ibid., Art. 41(6).

140. Ibid., Arts 118–1 19.

141. Pursuant to Article 119(2) registrants may try to prevent public access to certain other types of information, including summary safety information, but it is not allowed to exclude the full reports. See on this issue Bronkers and Van Gerven, op. cit. *supra* note 36.

142. See Koch and Ashford, "Rethinking the role of information in chemicals policy: Implications for TSCA and REACH", 14 *Journal of Cleaner Production* (2006), 37.

143. Ibid., 43.

144. Scott, "From Brussels with love: The transatlantic travels of European Law and the chemistry of regulatory attraction", 57 AJCL (2009), 929.

145. REACH, Art. 60(4)(b).

146. Ibid., Art. 64(2). Heyvaert points out that it is pertinent that ECHA is allowed to select the body of information to be disclosed, Heyvaert, "The EU chemicals policy: Towards inclusive governance?" in Vos, *European Risk Governance- Science, Its Inclusiveness and Its Effectiveness* (CONNEX – Network of Excellence, Mannheim, Germany, 2008), 203.

parties may submit information on alternative substances or technologies to both the CSEA and the CRA, which then will have to be taken into account.[147]

4.3.2.4. *Mobilizing markets: labelling*

Increasingly, labelling is a device politicizing markets by empowering consumers to exercise the kind of political power that the forces of globalization and European integration have taken away from national electorates. In effect, European citizens exercise political choice in their capacity of consumer, in the case of REACH by discriminating on the basis of the (environmental) performance of goods and services, of which labels inform them. The primary reason why we draw attention to labelling in this section, however, is that labels also are market-based devices designed to set in motion a process in which companies compete for environmental performance and innovation. Hence, labelling may serve to expose differences between producers of the same substance, to which citizens participating in the market may respond.[148]

In respect of the realization of this potential, however, REACH clearly leaves much to be desired. Harmonization of classification and labelling is confined to carcinogenic, mutagenic or toxic for reproduction category 1, 2 or 3 properties and respiratory sensitizes.[149] For other effects, harmonized classification and labelling at Community level can also be added to Annex I of the Dangerous Substances Directive (67/548/EEC) if justification is provided demonstrating the need for action at EU level. Besides individual Member States, industry can also request harmonization of the classification and labelling of a substance when the substance is either a CMR or a respiratory sensitizer.

In addition the EU system has to comply with the UN Globally Harmonized System for Classification. It requires labelling of dangerous substances and preparation, as well as mixtures. Labelling of substances in articles is however not included, however. This system in now translated into the so called CLP Regulation which entered into force on 20 January 2009.[150] It is striking that REACH itself should not require consumer warnings to be made available for

147. Ibid., Art. 60(4)(c) and Art. 64 (2). ECHA has to set a deadline on its website by which the information on alternatives has to be submitted.

148. Ibid., Title III on Data Sharing and the Avoidance of Unnecessary Testing.

149. Ibid., Art. 115(1).

150. See UNECE, UNECE – Dangerous Goods and Special Cargoes Section – GHS, available at: <www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html> and Reg. (EC) No 1272/2008 on Classification, Labelling and Packaging of Chemical Substances and Mixtures, the so called CLP Regulation entered into force on 20 Jan. 2009. The CLP Regulation will gradually replace the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (1999/45/EC). Both Directives will be repealed on 1 June 2015.

substances in articles at points of sale, not even if SVHC are to be released.[151] And although a classification and labelling inventory is established and maintained by ECHA in the form of a publicly accessible database, that database does not cover all substances.[152]

The relatively weak labelling regime attached to REACH is regrettable, as it hampers competition-based races to the top. It would be more consistent with the precautionary approach that is said to underpin REACH to allocate the burden of proof with manufacturers to show that labelling is not justified. California's so-called Proposition 65 illustrates how this could work.[153] Chemicals that are carcinogenic or harmful to fertility may not be marketed without a clear warning. Manufacturers wishing to challenge this prohibition must prove that the exposure level of the product is below "a significant risk" level. Practice in California indicates that public information acts as a strong incentive for manufacturers and suppliers exclusively to use the safest chemicals.[154]

4.3.3. *Innovation*

Innovation, in the shape of the substitution of hazardous chemicals with safer alternatives, is a key element of precautionary thinking.[155] Incentivizing substitution has numerous payoffs, not only relative to environmental goals, but also in terms of energy use, workplace safety, industrial innovation and, ultimately, competitive advantage. Against a fraction of the resources devoted to the study of a single substance, a broader search for alternatives could generate invaluable knowledge about future technological options. Even if shifting to alternative technologies were to be more costly, their adoption may still be justified because of lower risks.

151. See on this point Scott, op. cit. *supra* note 141, 51.

152. REACH, Art. 114. Thus, if the thresholds for registration or notification of substances are not met, or if in relation to SVHC it has been demonstrated that exposure to humans or the environment will be excluded during normal or reasonable foreseeable conditions of use. In such cases, consumers must file a specific request that the supplier provide this information in accordance with Art. 33(2).

153. The Safe Drinking Water and Toxic Enforcement Act of 1986 of the State California USA, commonly known as Proposition 65.

154. Rechtschaffen and Williams, "The continued success of proposition 65 in reducing toxic exposures", 35 Environ. Lit. Rep. (2005), 10850.

155. Hanssen, Carlsen and Tickner, op. cit. *supra* note 18, Tickner and Geiser, "The Precautionary Principle stimulus for solutions-and alternatives-based environmental policy", 24 *Environmental Impact Assessment* (2004), 801–824, Koch and Ashford, op. cit. *supra* note 142. However, the element of safer alternatives is not included in EC Communication on the Precautionary Principle, COM(2000)1.

4.3.3.1. *Substitution of hazardous substances*

The search for alternatives, embodied in the substitution principle, is a declared objective of REACH: "The aim is … to encourage and in certain cases to ensure that substances of high concern are eventually replaced by less dangerous substances or technologies where suitable economically and technically viable alternatives are available".[156]

This signifies a shift away from a preoccupation to gather scientific information pertaining to risk, towards exploring technological options pertaining to innovation and increased environmental performance. Accordingly, a Technology Options Analysis (TOA) seeks to identify where and what superior technologies could be adopted to eliminate the possibility of pollution and accidental releases.[157] By requiring firms to undertake TOAs, regulators stimulate technological advance. As we saw earlier, in the context of the review of authorizations an update of the analysis of alternatives and a substitution plan must be submitted. If this update shows that a suitable alternative exists, the holder of an authorization submits a substitution plan, including a timetable for proposed actions by the applicant.

Even so, substitution is only required for substances that fall under the authorization procedure.[158] The Regulation states that the aim of authorization is to "ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled or that these substances are replaced by suitable alternative substances or technologies".[159] To this end, all manufacturers, importers and downstream users applying for authorization have to analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.[160]

The general principle is articulated in Article 60(4), which states that an authorization for SVHC can only be granted if it is shown that the socio-economic benefits of authorization outweigh the risk to human health and the environment, and if moreover there are no suitable alternative substances or technologies. When assessing alternatives, the Commission must take into account whether recourse to alternatives is likely to result in reduced overall risks to human health and the environment, as well as the technical and economic feasibility of alternatives for the applicant.[161] If suitable alternatives are

156. REACH, Recital 12, 72, 73. Some 1500 substances subject to substitution requirements are already identified in the Regulation, see European Environmental Law Website, available at: <www.asser.nl/default.aspx?textid=33404>.

157. Koch and Ashford, op. cit. *supra* note 142.

158. REACH, Art. 60(4).

159. Ibid., Art. 55.

160. Ibid.

161. Ibid., Art. 60(5).

available, a substitution plan including a timetable for proposed action has to be provided.[162]

In its draft opinion on authorization, The CRA likewise must include risks arising from possible alternatives.[163] The same applies to the CSEA.[164] In short: the Committees must not only opine on evaluations, applications for authorization and proposals for restrictions, but also on the availability of alternatives. This stimulates innovation in safer alternatives and reduces risks of regulatory lock-in.

Very interesting and positive is the way in which REACH intelligently mobilizes market forces in support of its objective to expose and introduce safer alternatives. Thus, after receipt of an application by ECHA, interested third parties can also submit options for alternatives within a deadline set by ECHA.[165] This creates an opportunity for competitors to promote superior alternatives.[166] There is a strong incentive to do so, as existence of a suitable alternative implies that future applications for authorization are automatically denied. Scott has typified this "an adversarial process of sorts", since applications set in motion an adversarial process about the availability of suitable alternatives overseen by ECHA.[167] In the restriction process alternatives also have to be considered, and the CRA must take into account the feasibility of alternatives in their opinions.[168]

Some NGOs have argued that application of the principle of substitution should be extended to *all* applications for authorization, not just to those which are not considered to be adequately controlled, or are subject to review.[169] The European Parliament, likewise, had proposed to focus much more discretely on substitution and the encouragement of safer alternatives than what ultimately has been agreed.[170]

162. Ibid., Art. 62(4)(e)(f).

163. Ibid., Art. 64(4)(a).

164. Ibid., Art. 64(4)(b).

165. Ibid., Art. 64(2).

166. Wagner, "Using competition-based regulation to bridge the toxic data gap", 83 *Indiana Law Journal* (2008), 629–659. Although, as Wagner rightfully points out the competitive advantage is not exclusive; all other manufacturers, users and importers using the safer substance will benefit from the decision to reject authorization.

167. Scott, op. cit. *supra* note 144, 67.

168. REACH, Art. 69(1). Annex XV also requires the authorities to document the available information on alternative substances and techniques in the restriction proposal.

169. European Trade Union Confederation Declaration on REACH, the proposed reform of EU policy on chemicals, 2004, available at: <tutb.etuc.org/uk/dossiers/files/ETUC-%20REACH-122004-en.pdf>. Warhurst, The REACH Files: A Policy Guide. (Brussels: 2005), available at: <www.panda.org/downloads/europe/reachfilespolicy guide.pdf>.

170. European Parliament, 2005, cited *supra* note 112, amendment 80

Although substitution indeed is only required for SVHC, it is nonetheless important to remember that the provisions relating to testing show much more flexibility than in the previous regime. Thus, applicants must prepare an assessment to show how toxic chemicals are used and how they could be reduced within the whole life cycle, which essentially boils down to a TOA,[171] and may therefore accommodate the testing of alternatives.

4.3.3.2. *Proportionality*

The most fundamental criticism levelled against the precautionary principle, which underpins REACH, is that benefits of technological developments are systematically disregarded and that precautionary regulation therefore often is disproportional.[172] A crucial question indeed is whether REACH adequately regulates the environmental performance of firms at acceptable costs, without ignoring possible benefits that arise from the development of new chemicals. As for taking account of possible benefits of innovation, we refer to the previous section regarding substitution.

REACH takes heed of the principle of proportionality in a number of different ways. First, it is focused on SVHC.[173] Decision-making is hence based on prioritization: ECHA needs to develop criteria for prioritizing substances with a view to their further evaluation. In particular, Article 57(3) states that priority is given to certain substances for inclusion in the list of Annex XIV (substances subject to authorization). Second, only chemicals produced or imported in volumes of at least 1 t/y are subject to registration. This means that about 60,000 substances listed in the European Inventory of Existing Chemical Substances (EINECS), even though many are produced or traded in non-negligible quantities, are not caught by REACH. Moreover, REACH excludes certain categories of chemicals, for example those used in agriculture, biocides and cosmetics. These categories will continue to be governed by separate legislation.[174] Third, the Regulation aims, in a Title on data-sharing and avoidance of unnecessary testing, to reduce costs.[175]

The proportionality principle is most manifestly present in the authorization process itself, however. If authorization is rejected because it has not been shown that the risk to human health or the environment from the use of the

171. See e.g. Title III, Arts. 25–30 on Data Sharing and Avoidance of Unnecessary testing. Art. 25 states that in order to avoid animal testing, testing on vertebrate animals for the purpose of this Regulation has to be undertaken only as a last resort. It is also necessary to take measures limiting duplication of tests.

172. Sunstein, *Laws of Fear: Beyond the Precautionary Principle* (Cambridge University Press, 2005).

173. REACH, Recital 115.

174. See on the different regimes, De Sadeleer, op. cit. supra note 46, 334.

175. REACH, Title III.

substance arising from the intrinsic properties is "adequately controlled", the Regulation explicitly provides that authorization may be granted if the socio-economic benefits of authorization outweigh the risk to human health or the environment.[176] The applicant or other interested parties then have to demonstrate the socio-economic benefits arising from the use of the substance and the socio-economic impacts of the refusal, thus in essence setting in motion a proportionality review.[177] This socio-economic analysis (SEA) must be conducted in accordance with Annex XVI on Socio-Economic Analysis,[178] and may address any issue that is considered to be relevant by the applicant.

5. Conclusions

REACH represents a milestone in EU environmental law and is of paramount importance in its own right. The central importance of the European chemicals industry, and the environmental and health risks to which it gives rise, place an immense responsibility on the EU effectively to address known and unknown toxic risks without unduly undermining competitiveness and innovation. The number of scholarly writings devoted to REACH not only underscores its pivotal importance, but also reflects the daunting complexity of the REACH regime.

Our attempt has not so much been to add to this solid body of literature elucidating on the proper interpretation of the individual provisions of REACH, however, but more generally was to investigate how REACH deals with challenges of scale, uncertainty, complexity and innovation that increasingly define our "post-normal age".[179] Although numerous scholars have questioned the precautionary pedigree of REACH, we conclude that the principle has defined the contours of a regulatory response to these challenges that holds great promise for the future. Importantly and perhaps somewhat counter-intuitively, precaution not only serves to address toxic uncertainty and complexity, but also is instrumental in finding appropriate responses to the challenges of scale, and not in the last place innovation.

The systematic allocation of responsibilities with manufacturers and users of chemicals to prove safety – a defining feature of precaution – considerably alleviates the problem of scale, and in effect has given rise to an EU system of co-regulation. Certainly, the volume-based logic of REACH is a crude response to the vast numbers of chemicals, and is open to criticism. Yet, the

176. Ibid., Art. 60(4).
177. Ibid., Art. 62(5)(a).
178. Ibid., Art. 62(5).
179. Functowicz and Ravetz, op. cit. *supra* note 20.

authorization of SVHC and the prioritization that finds further expression in substance evaluations do not necessarily compare unfavourably with previous practice. In addition, further safeguards exist in the form of restrictions and emergency measures that can be adopted by Member States.

The reflexiveness and responsiveness required to deal with complexities are similarly logical consequences of the discursive nature of precautionary regulation, and in REACH has found concrete expression in provisions concerning permanent review and monitoring.

Finally, in respect of the challenge to stimulate innovation and avoid regulatory lock-ins, obligations on the part of manufacturers and users of SVHC continuously to search for safer alternatives clearly support that aim. Whereas we have often identified room for improvement, the fact remains that this positive aspect of REACH again is consistent with, if not a consequence of, its precautionary nature.[180]

We therefore believe that REACH is taking the EU in the right direction, both specifically as regards the regulation of chemicals, as well as more generally when it comes to facing future products of our technological modernity. The direction chosen constitutes a conscious departure from past command-and-control traditions, however, and its ultimate success therefore is far from given as it requires a new responsiveness on the part of EU institutions. We have touched upon numerous of the aspects of responsiveness identified by Baldwin and Black, and without exception concluded that the EU appears to be lacking in what it takes to be, in the words of the same authors, "really responsive".[181]

Even our superficial analysis suggested that the EU would do well to invest in liability regimes, as these are likely to persuade potentially reluctant co-regulators to comply with registration, evaluation and authorization requirements. We arrived at similar conclusions in respect of the market based instrument of labelling, EU initiatives to orchestrate societal involvement in the implementation and enforcement or REACH, as well as informal enforcement networks. In other words, the EU regulatory environment within which REACH is embedded at present does not appear to be optimally suited to maximize its potential for success.

To conclude, REACH is more than merely an important environmental regulation. It marks a new era in EU environmental regulation, and constitutes *avant garde* EU law. It invites a reorientation of the EU institutions, as well as scholars of EU regulation and governance, in search of instruments, procedures and institutional arrangements under which responsive EU regulation can flourish.

180. Foss Hansen, Carlsen and Tickner, op. cit. *supra* note 18.
181. Baldwin and Black, op. cit. *supra* note 9.