



Essential Readings in Environmental Law
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THE REGULATION OF CHEMICALS: THE EU REGULATION ON REGISTRATION, EVALUATION, AUTHORIZATION AND RESTRICTION OF CHEMICALS (REACH REGULATION)
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Overview of Key Scholarships

The emergence of chemicals regulation as a policy issue in Europe

1. Pallemarts, M., *Toxics and Transnational Law: International and European Regulation of Toxic Substances as Legal Symbolism*, Hart Publishing, Oxford/Portland (2003)
2. Winter, G. (ed.), *Risk Assessment and Risk Management of Toxic Chemicals in the European Community*, Nomos, Baden-Baden (2000)

Design of the REACH Regulation

3. Herbatschek, N., L. Bergkamp and M. Mihova, 'The Reach Programmes and Procedures', in: Bergkamp, L. (ed.), *The European Union REACH Regulation for Chemicals. Law and Practice*, Oxford University Press, Oxford (2013), pp. 82 – 107 (nos. 4.01 – 4.298)
4. Führ, M. and U. Lahl, 'Self-responsibility as a regulatory concept – illustrated by the REACH decision-making process', in: Ormond, T., M. Führ, and R. Barth, *Environmental policy and law at the turn of the 21st century*, Lexxion, Berlin, (2006), pp. 209 – 220

Objectives and values

5. Bergkamp, L. and N. Herbatschek, N., 'Key Concepts and Scope', in: Bergkamp, L. (ed.), *The European Union REACH Regulation for Chemicals. Law and Practice*, Oxford University Press, Oxford (2013), pp. 52 – 57 (Nos. 3.42 – 3.56)
6. Fisher, E., 'Opening Pandora's box: Contextualising the precautionary principle in the European Union', in: Everson, M. and E. Vos, (eds.), *Uncertain Risk Regulated*, Routledge Cavendish, Abington, Oxon (2009), pp. 21 – 48
7. Heyvaert, V., 'Guidance without constraint: Assessing the impact of the precautionary principle in the European Community's Chemicals Policy', 6 *Yearbook of European Environmental Law* 27 (2006)
8. Streffer, C. et al., *Low Dose Exposures in the Environment. Dose-Effect Relations and Risk Evaluation*, Springer, Berlin, Heidelberg, New York (2004)

Relationship to sectoral environmental laws

9. Führ, M. and S. Merenyi, 'Mind the Gap – Interface problems between EC Chemicals Law and sectoral environmental legislation', 15 *Review of European and International Environmental Law* 381 (2006)

Challenges

10. Führ, M., 'Boxenstopp für die REACH-Verordnung', 25 *Zeitschrift für Umweltrecht* 270 and 381 (2014)

11. Azoulay, D. and V. Buonsante, 'Regulation of Nanomaterials in the EU: Proposed Measures to Fill in the Gap', 11 *Stoffrecht* 114 (2014)

12. Kortenkamp, A., T. Backhaus, T. and M. Faust, *State of the Art on Mixture Toxicity*, Report, (22 December 2009), http://ec.europa.eu/environment/chemicals/pdf/report_mixture_toxicity.pdf (last accessed 19 March 2015)

Background: The problem

The unintentional release of chemicals which are produced or gained for use in the manufacturing process (intermediaries) or use as components of a multitude of industrial and consumer products may be associated with significant risks to human health and the environment. Released chemicals are ubiquitously present in the environment. The relevant risks have long been neglected, if not ignored although they raise no less concerns than the risks presented by conventional pollution from production processes on which modern environmental has long focused. The most significant environmental problems of chemicals originate from high volume substances which have been on the market for decades, but as to which our knowledge has been very limited. New substances seldom reach higher volumes and are of less concern. **Rachel Carson** in her seminal book "*The Silent Spring*" (1962) had impressively addressed the environmental risks of pesticides. However, awareness that "toxic ignorance", that is, the lack of sufficient knowledge about the hazardous properties of chemicals and exposures of humans and the environment, needed to be tackled with respect to all chemicals has only very slowly gained ground.

The emergence of chemicals regulation as a policy issue in Europe

1. In Europe, a relatively early but rather weak response to chemical risks was the *Hazardous Substances Directive of 1967* which was limited to the classification, labelling and packaging of substances with known properties. **M. Pallemmaerts** dissertation on *Toxics and Transnational Law : International and European Regulation of Toxic Substances as Legal Symbolism* presents a very critical view of the early responses to the chemical challenge by the European Economic Community and later on the European Community, characterising them as merely symbolic legislation. He points out that even after the reform of the *Hazardous Substances Directive* in 1979 which introduced notification and testing obligations on producers of new substances and the following selective inclusion of existing substances in the system of information gathering in 1993, European law did not meet the chemical challenge. The simple reason in his view was that one continued to concentrate on known risks and new substances and no attempt was made to gather comprehensive information about the hazardous properties of the many high volume substances already on the market and the exposure of people and the environment to them. Hence, the existing powers of the authorities to ban or restrict chemicals could not be effectively used.
2. The collective book edited by **G. Winter** on *Risk Assessment and Risk Management of Toxic Chemicals in the European Community* presents an excellent overview of the various facets of the reform discussion about the European chemical policy which started at the end of the 1990s. It contributes to a better understanding of the later

REACH Regulation which was adopted in 2006 (*EU Regulation on the Registration, Evaluation, Authorization and Restriction of Chemical Substances – Regulation 1907/2006*).

Design of the REACH-Regulation

3. The REACH Regulation is the most ambitious regulation of chemicals that exists in the world. It has set in motion a process of modernising relevant regulation also outside Europe. Chapter 4 of **L. Bergkamp**'s book on the *EU REACH Regulation*, written by **N. Herbatschek, L. Bergkamp and M. Mihova** and titled *The Reach Programmes and Procedures*, contains a comprehensive analysis of the highly complex structure of the Regulation, the quality of its various regulatory building blocks, the relationships between the relevant actors and the foreseeable implementation problems. It is a very good introduction if the reader is able to devote some time to become acquainted with REACH.¹ According to the authors, REACH represents a mixed system of information gathering and regulation, responsibility of producers and authorities and *ex-ante*- and *ex-post*-regulation. The authors emphasize that a major element of REACH is the generation of information about the hazardous properties of substances through registration and testing obligations of producers which are gradually extended to all existing substances based on production volume and risk-related criteria ("phase-in substances"). This is coupled with the obligation of producers to undertake a risk assessment and devise risk reduction measures and communicate both in the supply chain. This is not to say that the position of the European and member state authorities involved in implementing the Regulation is weak. The authorities are empowered to: check the completeness and, selectively, the quality of the data submitted to them; to undertake, based on priorities, their own (supplementary) risk assessment; to require additional testing; to adopt restrictions for protection from significant risk; to subject substances of very high concern to the requirement of an authorisation and decide on applications for an authorisation.
4. A crucial structural decision in chemicals regulation concerns the choice of the regulatory model. **M. Führ and U. Lahl** in their article titled *Self-responsibility as a regulatory concept – illustrated by the REACH decision-making process* show that in contrast to traditional, state-based regulation of chemicals, the REACH-Regulation is innovative in that it lays the emphasis on the "regulated self-responsibility" of producers and, in this framework, on information, communication and cooperation. The authors in principle favour self-responsibility but emphasize the motivational factors necessary to justify reliance on producers in this respect. They also point out that the system of authorisation of substances of very high concern has intended motivational impacts because already the listing of such substances as candidates for future authorisation creates substitution incentives.

Objectives and values

According to its Article 1 paragraph 1 and 3, the REACH-Regulation aims for a high level of protection and explicitly refers to the precautionary principle. However, whilst the whole system of prior registration ("no data, no market") reflects the precautionary principle, there are relatively few provisions in the Regulation which mandate the application of the precautionary principle as a decision-making standard.

5. **L. Bergkamp and N. Herbatschek**, in the chapter titled *Key concepts and Scope*. in the book by **L. Bergkamp** on the *EU REACH Regulation* give a comprehensive account of the context in which the precautionary principle and the traditional

principle of prevention are employed in the REACH-Regulation, distinguishing between hazard-based and risk-based regulation. Hazard means potential (or uncertain) risk associated with the hazardous properties of substances (as well as potential exposure). Examples of hazard-based regulation are the classification and labelling of substances (which is regulated, on the basis of existing or new hazard information generated under REACH, by the supplementary *Regulation on the Classification, Labelling and Packaging of Chemical Substances – CLP Regulation*), the limited imposition of authorisation requirements and to a certain extent the application of the principle of substitution in authorisation procedures. By contrast, the notion of chemical risk denotes future harm to be caused by the coincidence of hazardous properties and the exposure of people or the environment. As the authors show, despite the existing precautionary features, a risk-based approach is the dominant type of regulation of chemicals under the REACH-Regulation.

6. The next two texts provide goods insights into the controversies which accompany the application of the precautionary principle. ²**E. Fisher**'s chapter, *Opening Pandora's box: Contextualising the precautionary principle in the European Union*, in the edited book by **M. Everson** and **M. Vos** titled *Uncertain Risk Regulated*, addresses the principle in the context of the whole body of EU health-related law, but her criticism of a monolithic understanding that ignores the different legal contexts and legal cultures in which the principle is applied is worth reading also in the context of chemicals regulation.
7. **V. Heyvaert**'s article, *Guidance without constraint: Assessing the impact of the precautionary principle in the European Community's Chemicals Policy*, contests that the frequent reference by the authorities and courts to the precautionary principle in European chemicals policy is reflected by actual practice. Based on a careful analysis of selected cases, she argues that most decisions are just precautionary rhetoric and could have been justified by conventional risk assessment.
8. **C. Streffer et al.**, *Low Dose Exposures*, give a comprehensive account of the role of risk assessment and risk management in the regulation of chemicals. The book is interesting because it informs the reader about the relationship between legal and scientific concepts in chemicals regulation. The authors emphasize that conventional risk assessment already contains certain precautionary ("prudential") elements such as "conservative" extrapolation factors (which are employed to transfer findings on animal testing to humans) and their multiplication, "proxy" criteria and scientific risk models. In their opinion, all these elements of risk assessment are liable to blur the distinction between prevention and precaution. As regards risk management, the criteria for determining tolerability of risk, including quantification concepts, the balancing of costs and risks and the role of distributional justice are discussed.³

Relationship to sectoral environmental laws

9. The information relating to adverse effects of chemicals on human health and the environment generated in the REACH process is of primary relevance in substances and product regulation even if one considers that the regulation of special use substances such as pesticides, biocides, food additives, pharmaceuticals and cosmetics is subject to special regulation and therefore to a major degree exempted. A seldom addressed and unresolved question is whether and to what extent risk information generated under REACH may also set a standard for conventional pollution control under media- and process-related laws. In a pioneering article titled *Mind the Gap – Interface problems between EC Chemicals Law and sectoral environmental*

legislation, **M. Führ** and **S. Merenyi** argue that information about risks to human health or the environment generated under REACH, e.g., regarding an exposure which exceeds the Derived no-effect level (DNEL) or the Predicted no-effect concentration (PNEC), is in principle relevant since the exposure of environmental media and control measures taken under sectoral environmental laws are considered in the risk assessment process. However, besides occupational health regulation, explicit “reception clauses” are missing in these laws. The authors also admit that often the risk assessment under REACH is not specific enough.

Challenges

There still is much unfinished business in the implementation of the REACH-Regulation, not the least because the gradual phase-in of existing substances is not yet concluded and the second phase of the authorisation programme for substances of very high concern, that is, the processing of applications for authorisation, has not yet started.

10. **M. Führ**, who as a member of the European Chemicals Agency’s (ECHA) Administrative Council has good insight into the REACH process, discusses problems that have as yet emerged in the implementation of REACH in *Boxenstopp für die REACH-Verordnung*. He emphasizes that industry has made major efforts to live up to the mandate of the Regulation, but he also denotes major deficiencies. These are in his view the reluctance of small and medium-sized users in the supply chain to comply, the often inadequate quality of the registration dossiers, the inability of ECHA to evaluate a sufficient number of dossiers (which points to the general problem of data overload) and the lack of common surveillance standards in the EU. He concludes that major efforts are still needed to make REACH a full success.

Besides the implementation of the REACH Regulation, there are two problems that have recently come into focus:

11. One problem is the regulation of nanomaterials. These are very small-scale fractions of substances (often well researched substances such as carbon) which due to their small scale are, or are suspected to be, associated with special adverse effects on human health or the environment. Whilst there is special regulation under food, consumer goods and cosmetics law, nanomaterials are by and large unregulated under the REACH Regulation because they do not reach the relevant volume thresholds for registration or the risk assessment procedures do not take account of the specific risks presented by them. Against this backdrop, **D. Azoulay and V. Buonsante** in *Regulation of Nanomaterials in the EU: Proposed Measures to Fill in the Gap* give the reader an insight into the reform discussion. The authors propose a series of amendments of the REACH Regulation to tackle the risks presented by nanomaterials. In particular, they propose that the definition of “substance” should be broadened, nanomaterials be treated as new substances, the production threshold that triggers the registration obligation be lowered and specific testing protocols be introduced.
12. The other “new” problem is the regulation of combined effects of chemicals. Besides the classification of intended chemical mixtures under the *CLP Regulation*, combined effects are neglected and therefore practically unregulated. Relying on a number of epidemiologic studies, **A. Kortenkamp, T. Backhaus and M. Faust** in a report titled *State of the Art on Mixture Toxicity* come to the conclusion that exposure to several hazardous chemicals which have the same mechanism may result in cumulative effects even if the thresholds of adversity are not exceeded, but where the mechanism are different the relevant effects on human health will normally be independent from one

another so that compliance with substance-specific standards is sufficiently protective. As regards effects on the environment, there may be even more extensive combined effects. The authors take the position that where cumulative effects are probable or at least possible, the risk model of dose/concentration addition would provide an adequate level of protection. This suggests that deliberations as to the development of a coherent policy towards mixture risk assessment are warranted.

Selected further readings

- Dana, D.A. (ed.), *The Nanotechnology Challenge. Creating Legal Institutions for Uncertain Risks*, Cambridge University Press, Cambridge, (2012)
- De Sadeleer, N., *Les Principes du Pollueur-payeur, de Prévention et de Précaution*, Bruylant, Brussels (1999)
- Drohmann, D. and M. Tounsend, (eds.), *REACH – Best Practice Guide to Regulation (EC) No 1907/2006*, C.H. Beck, Hart, Nomos, München, Oxford, Baden-Baden (2013)
- Everson, M. and E. Vos, (eds.), *Uncertain Risk Regulated*, Routledge Cavendish, Abington, Oxon (2009)
- Fisher, E., J. Jones, J. and R. von Schomburg, (eds.), *Implementing the Precautionary Principle – Perspectives and Prospects*, Eartscan, London, Sterling, (2007)
- Führ, M. (ed.), *Praxishandbuch REACH*, Carl Heymann Verlag, Köln (2011)
- Führ, M. and K. Bizer, ‘REACH as a paradigm shift in chemical policy – responsive regulation and behavioural models’, 15 *Journal of Cleaner Production* 327 (2007)
- Hansen, S., L. Carlsen, L. and J. Tickner, ‘Chemicals regulation and precaution: Does REACH really incorporate the precautionary principle?’, 10 *Environmental Science & Policy* 394 (2007)
- Rehbinder, E., ‘Stoffrecht’, in: Hansmann, K. and D. Sellner, (eds.), *Grundzüge des Umweltrechts*, E. Schmidt Verlag, Berlin, 4th edition (2012), chapter 11 (pp. 811 – 894)

¹ For shorter introductions see Bergkamp, L. and M. Penman, ‘Introduction’, in: Bergkamp, L. (ed.), *The European Union REACH Regulation for Chemicals. Law and Practice*, Oxford University Press, Oxford (2013), pp. 3 – 8; Jans J. and H. Vedder, *European Environmental Law*, 3rd. ed., Europa Law Publishers, Groningen (2008), pp. 396 – 400; V. Heyvaert, ‘No data, no market. The future of EU Chemicals Control under the REACH Regulation’, 9 *Environmental Law Review* 201 (2007).

² See also Hansen, S., L. Carlsen and J. Tickner, ‘Chemicals regulation and precaution: Does REACH really incorporate the precautionary principle?’, 10 *Environmental Science & Policy* 394 (2007) who assert that REACH is not precautionary enough to effectively protect human health and the environment.

³ Chapter 10 of this book, ‘Low Doses in Health-Related Environmental Law’, pp. 325-377 was written by Rehbinder, E.