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Editorial

In 2002 the European Commission published the “Communication on Impact Assessment (276 final)” and supplemented it in 2005 with the “Impact Assessment Guidelines (SEC(2005) 791)”. The latter defines the Regulatory Impact Assessment (RIA) as “a set of logical steps which structure the preparation of policy proposals” (p. 4). The aim of the RIA is paraphrased as “deepening the analysis and formalising the results in an autonomous report.” In bold letters the Guidelines add: “Remember: Impact assessment is an aid to political decision-making, not a substitute for it.” The aid offered by the RIA is nothing other than a more “rational” foundation of policy proposals, newly apostrophised as “good governance”. The underlying assumption therefore is that such an aid is helpful to achieve more rational results in the proposals presented by the Commission to the Council and the European Parliament.

Five years after the Communication, quite a number of Commission proposals have gone through the “logical steps” required by the RIA. But rather than supporting the search for the best solution to a “regulatory choice problem”, critical observers may view the results of the RIA as “deepening the analysis and formalising the results in an autonomous report.” In bold letters the Guidelines add: “Remember: Impact assessment is an aid to political decision-making, not a substitute for it.” The aid offered by the RIA is nothing other than a more “rational” foundation of policy proposals, newly apostrophised as “good governance”. The underlying assumption therefore is that such an aid is helpful to achieve more rational results in the proposals presented by the Commission to the Council and the European Parliament.

Beyond this background, two articles in this issue evaluate the results of the RIA approach: The question “A balanced appraisal? Impact Assessment of European Commission proposals” is raised by Susan Owen and “Theory and Practice” of the RIA are analyzed by Ekkehard Hofmann.

Two other articles deal with another form of Impact Assessment – the “classical” Environmental Impact Assessment (EIA). Pavel Čermý and Jerzy Jendroška examine the “Transposition and Implementation of EIA Directive in some EU Member States (with special emphasis on transport infrastructure cases)”. A methodological approach for an ex-post “Evaluation of the German Act on Environmental Impact Assessment” is presented by Nils Bedke, Jaqui Dopfer, Simone Kellert and Detlef Koher.

In an article by Florence Coroner, an overview is given on the legislative process on a national level. Herein, she observes that in the transposition of the Environmental Liability Directive the “Member States [are] missing the opportunity to implement ‘polluter pays’ principle”.

In the sixth article of this issue, Uwe Lahl addresses the REACH Regulation, one of the largest legislative projects on an EC level, which was published in the Official Journal of the EU right at the end of 2006. He presents an “Assessment of the political agreement” reached in the trilogue procedure.

In the final article in this issue, Gerhard Roller provides an analysis of the amended Comitology Decision which came into force in the summer of 2006. His message is clear: it “strengthens [the] position of European Parliament”.

Last but not least, the “New Books” column presents two recently published anthologies: “Implementing the Precautionary Principle” (edited by Nicolas de Sadeleer) and the liber amicorum for Eckard Rehinder (both founder members of elni).

The next issue of the elni review will focus on the implementation of the Aarhus Convention. Please send contributions on this topic as well as other interesting articles to the editors by the end of June 2007.

Martin Führ
March 2007

1 The topic “Rational Environmental Policy – Rational Environmental Law” was analyzed by a research group at the Bielefeld “Center for Interdisciplinary Research” in 1998/99, directed by Gertraude Lübbe-Wolff, see http://www.uni-bielefeld.de/ZIF/FG/1998Umweltrecht/.

1 Introduction

The purpose of the REACH Regulation is to comprehensively restructure European chemicals law,
- with a standardised testing and registration procedure for old and new substances that will cover a total of some 30,000 substances,
- improved regulations on communication of substance information throughout supply chains,
- the possibility of subjecting substances that are particularly hazardous – for example, carcinogenic substances – to a certification procedure, and
- the establishment of a European Chemicals Agency, in Helsinki, that will be responsible for carrying out the new procedures.

The relevant Proposal for a Regulation and the Common Position of the Council have been discussed elsewhere, and thus here we simply refer to those documents.

On 27 June 2006, the Council adopted its Common Position on the basis of the political agreement reached on 13 December 2005. Since September 2006, the European Parliament (EP) has been deliberating the proposed regulation, on the basis of the Council’s approved text. This process is now at the 2nd reading stage. This 2nd reading was accompanied by “trilogue” negotiations, between the Parliament, Council Presidency and the Commission, with the aim of achieving a so-called “agreement in the 2nd reading”, i.e. a resolution of the European Parliament that the Council could then accept without any changes. In difficult negotiations, this aim was finally achieved. The resulting agreement was then formally approved on 13 December 2006 by the European Parliament’s plenary assembly and on 18 December 2006 by the Council. The new Regulation is to be promulgated in the Official Journal in force on 1 June 2007.

2 An overview of the trilogue results

The following table presents the key results of the trilogue, broken down by the most important interest groups (note: the article and recital references in the table and throughout the present text are in keeping with the numeration used in the Common Position; in the final text, that numeration will change slightly, as a result of modifications made in the trilogue).

In sum, the results can be assessed as follows:
- The overall result is close to the Council’s Common Position of 2005, which has been changed only with regard to details.
- The agreed changes are thus balanced in that they give equal consideration to environmental and consumer-protection concerns, on the one hand, and to issues of improving implementation for the affected industry, on the other.
- Among the points responding mainly to environmental and consumer concerns, those worthy of special mention include the introduction of a right of information, for consumers, with regard to the presence of substances of high concern in products, and expanded possibilities for taking account of suitable substitutes in the certification procedure, especially in connection with regular reviews of certifications.
- Among those points that respond primarily to industry concerns, the highlights include a more practicable design of provisions for financial compensation for use of existing data – a key point for companies – and better protection for company and business secrets.
- Among the other points, those worthy of special mention include the many detailed changes aimed at intensifying promotion of use of alternatives to animal experiments; these changes have significantly enlarged this area of the regulation.

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### Overview table presenting the main features of the trilogue's compromise package on REACH

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<th>... primarily to environmental and consumer-protection concerns</th>
<th>Points that are neutral or that respond to specific EP interests</th>
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3 "Substitution", a central area of conflict

The issue of substitution was a central point of contention in the trilogue and, thus, in the overall agreement between the EP and the Council / Commission. With the support of a surprisingly large majority in the environmental committee of the EP, EP representatives sought to add to the regulation strong incentives, especially in the framework of the certification procedure, for substitutions for substances of high concern, i.e. substitutions consisting of less critical substances. Environmental and consumer-protection groups, and unions, deemed the achieved overall compromise to be inadequate because it did much too little for the area of substitution. This area thus deserves a closer look. The following section analyses it.

REACH will provide considerable incentives for substitution of hazardous substances and applications. And it will do this as a whole, because REACH will give all stakeholders considerably improved access to information. Information about effects and risks is the basis that makes it possible to substitute less-hazardous substances for hazardous ones. Potentially, the more hazardous a substance is, the greater the incentives for finding substitutes, since many detailed obligations, from data requirements to provision of information in supply chains and to obligations of downstream users, grow as substances become more hazardous.

Initially, those producers will make important contributions to substitution who, in collecting data, realize and accept that responsible action requires them to discontinue use of certain substances. Then, the registration procedure itself will promote substitution by prompting chemical producers to register only applications that have proven acceptable in light of risk analysis. In cases in which users in the supply chain develop different applications, it will be necessary to check whether such applications are acceptable. Where applications are unacceptable, a search for substitute substances will ensue. In the REACH controversy of the past few years, most of industry's concerns in the area of "excessive burdens for medium-sized companies" have revolved on just these sorts of substitution pressures.

Needless to say, the substitution pressures are greatest with regard to substances of high concern within the meaning of Art. 56 (carcinogenic, mutagenic and toxic for reproduction substances, and the so-called "PBT" and "vPvP" substances, which are of special concern because they are highly persistent and tend to accumulate in organisms). Such substances can be subjected to the certification procedure, and many other areas of the regulation impose special provisions for them. Companies thus have every reason to find less hazardous alternatives to these substances wherever possible. In general, it is expected that, of the some 30,000 chemicals that fall under REACH, about 1,500 substances will have pertinent characteristics within the meaning of Art. 57. On the other hand, since it is expected that, due to capacity limitations, only comparatively few substances per year (about 50) will actually be subjected to the certification procedure, in this area as well the decisive incentives for substitution will come not from concrete decisions on certification of substance uses, but from the entire system as a whole (with the certification procedure functioning as a "sword of Damocles"). In order to reinforce this effect, the Common Position, in Art. 58 (1), introduced the concept of a list of "candidate substances" for the certification procedure, substances that clearly fulfil the criteria of Art. 56 and are slated for later inclusion in the certification procedure.

In this light, it is clear that the issue of how the availability of potential substitutes should be treated in concrete certification decisions – an issue that was hotly debated in the trilogue – is of more conceptual than actual practical importance with regard to REACH's substitution incentives. The result that has been achieved must be judged accordingly.

Art. 61 (4) letter e of the Common Position mandates that all certification applications must include substitution analysis. In practice, this means that with his certification application, a producer or importer of a substance of high concern must include records of testing, for each planned use, showing whether a suitable, less hazardous substitute is available for the use. Pursuant to the Common Position, the importance of so-determined potential substitutions with regard to the rest of the procedure depends decisively on whether certification is being sought via the argument "the risk is adequately controlled" (claim to certification pursuant to Art. 59 (2) or via the argument "the benefits outweigh the risks" (possibility for certification pursuant to Art. 59 (4). In the case of certifications on the basis of benefits/risk considerations, the possibilities for substitution should apply – and, under the trilogue agree-


ment, should continue to apply – i.e., as a rule certification must be denied. For cases involving certification on the basis of adequate control, however, the Common Position's sole criterion is the existence of such adequate control, so that possibilities for substitution should not be a major factor in the decision on substitution. The "adequate control" avenue for certification has been tightly restricted from the outset, however. Pursuant to the relevant provisions in Art. 59 (3) and Annex I, it is available only for carcinogenic, mutagenic and toxic for reproduction substances for which an impacts threshold can be determined. To date, it has generally not been possible to determine such thresholds for such substances!

Under the trilogue agreement, in cases in which the applicant's own required substitution analysis points to a suitable, less hazardous substitute, the applicant must also submit a substitution plan. In case of adequate control, such a plan still does not affect the "yes or no" of a certification decision (a claim to certification still applies), but it can influence the elements of the decision (for example, it can help determine what review intervals are mandated). At the same time – and this is the actual conceptual change – Art. 61 (3) mandates that the Commission, in reviewing certification decisions, may take up the question of substitution for all certifications – i.e. also for those issued on the basis of adequate control. An important additional aspect of the agreement is the clarification in Article 60 (5) to the effect that the suitability of a possible substitution also depends on the technical and economic feasibility for the applicant in question. Art. 61 (3) also expressly cites the principle of proportionality.

The extent to which this change, which is certainly of conceptual importance, will be effective in practice remains to be seen. In mandating substitution, the competent authority assumes a great responsibility and must meet stringent requirements. Ultimately, it assumes full responsibility for the relevant applications, a responsibility that, in complex practical situations, the state can take on only with great difficulty. The expected difficulties become especially apparent when one considers the potential impacts of Art. 64 (2), which enables all persons to submit opinions in connection with certifications and reviews. For example, this possibility could enable market competitors to attack an applicant by claiming to know of a possible substitute (ideally, a competitor would do this by referring to a substance it has introduced to the market exclusively). Where such a substitute substance is actually non-critical or less critical, once might actually welcome such a tactic. But what about borderline cases, which would probably be the most common type of cases? Would it be possible and acceptable to make the competent authority a permanent arbiter of market competitors and their strategic and technical arguments? It does not require much imagination to predict that the option of mandating substitutions, an option that actually applies to all certifications, will ultimately be chosen only for just a few individual cases in which clearly more favourable substitutes are available.

In cases in which more favourable substitutes are available, the question then arises as to what would motivate an applicant, who identifies such a substitute in his own substitution analysis, to even apply for certification. In all likelihood, only one sort of motivation would arise, a motivation that is reasonable and justified, however: The applicant sees the need to discontinue use of the product, but he needs a few years' time to implement the available substitution option. The certification procedure, taking his substitution plan into account, then gives him the opportunity to establish an authority-approved safe basis for his transition. Consequently, the new provision ultimately is in keeping with interests of industry.

From the aforementioned considerations regarding the system-immanent effects of REACH's substitution incentives, and regarding the comparatively limited importance of provisions on authority-mandated substitution, it also follows that a completely different change made via the trilogue agreement will have greater impacts on substitution than will changes in the certification procedure: the consumer's right, as set forth in the new Art. 33 (2), to information from his supplier regarding whether a product contains more than 0.1 % by weight of substances found on the list of certification and certification-candidate substances pursuant to Art. 59 (1). In the case of products for the consumer market, the negative publicity linked to the certification system will issue stronger substitution incentives than will certifications themselves. Substances included on the list of certification candidates, and substances that have received certification will be substances of high concern – from the standpoint of risk, these substances will head up the group of hazardous substances. Via certification by authorities, one can obtain the right – a right subject to regular review – to use such a substance, but any stakeholders would prefer that their products not contain such substances. In what is known as "clean production", efforts are already being made – efforts that will increase on both national and international levels – to produce and sell products that contain no substances of high concern.
The consumer has the right to information about the presence of substances of high concern in products of particular importance – the trilogue accepted this right, which was introduced by the EP, without much ado, in a restricted form. In light of the above, this right is of central importance. One does not have to be a prophet to predict that in the coming years this right will be the right most often claimed by consumers and their organisations in the chemicals sector. When a consumer, with reference Article 33, asks his supermarket for information about whether a purchased toy or electronic device contains any critical chemicals, this right will have direct and indirect consequences. The consumer's question will be passed on, and new awareness about the need for "clean production" will arise throughout the entire relevant supply chain. All in all, the dictates of consumer communications will foster a general motivation to find substitutes. After all, ultimately, all sellers – at least those in the consumer sector – want to be able to tell their customers that their products are "clean" and contain no substances of high concern.

4 Outlook

The trilogue agreement represents the successful conclusion to a reform process lasting more than eight years. It will bring great progress in the areas of environmental, consumer and worker protection, while giving companies throughout industry new innovation opportunities via improved knowledge about substances.

REACH will bring about an "explosion" of knowledge about substances properties. It will thus provide an effective basis for achieving the aim of "clean production". REACH's most important practical impact will thus be to drive use of substitutions; it will help to phase out substances of high concern and risky applications.

REACH has been adopted following a controversy lasting years. The next step is for it to be implemented. At the EC level, this will especially involve setting up the European Chemicals Agency in Helsinki, in the very near term, and making this agency functional. At the same time, the application guidelines, which are to be applied to numerous REACH-related individual questions, and which have been under preparation for some time in the framework of the "REACH Implementation Project" (RIP), will have to be finalised. Furthermore, in a number of areas, including that of lists of exceptions pursuant to Annexes IV and V, which is relevant to pre-registration obligations, the regulation text gives the Commission review tasks that will have to be carried out in the short term and that in some cases may have to be implemented via relevant amending regulations from the Commission.

At the national level, existing German chemicals law will have to be adapted to REACH. Large parts of existing laws, such as existing provisions on the procedure for registration of new substances, will have to be stricken. New provisions will have to be developed – e.g. provisions on the Federal Government's administrative responsibilities in the area of evaluation, on penalties and fines for violations of the REACH regulation and on the establishment of a national information agency ("help desk"). Legal adaptations will thus be needed both in the area of the Chemicals Act (Chemikaliengesetz) and in the ordinances and administrative provisions issued on the basis of that Act.

Editorial remark:

Other aspects of REACH were discussed in the last issue of the elni-review (1+2/2006):

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Editors: Regine Barth, Miriam Dross, Martin Führ, Andreas Hermann, Gerhard Roller

Editor in charge of the current issue:
Martin Führ

Editor in charge of the forthcoming issue:
Gerhard Roller, GerhRoller@aol.com.

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Focus of the forthcoming issue:
Transposition of the Aarhus Convention

Manuscripts should be submitted as files by email to the Editors using an IBM-compatible word processing system.

Authors of this issue

Nils Bedke, Dipl.-Volksw., Dipl.-Hdl., University of Göttingen, Department of Economics, Chair in Economic Policy and SME Research, Platz der Göttinger Sieben 3, 37073 Göttingen, Germany, nbedke@gwdg.de.

Florence Coroner, Student of public affairs management and political science at the Institut Supérieur du Management Public et Politique, which is based in Paris and Brussels. She works as an intern at the European Environmental Bureau, mainly on the transposition process of the Environmental Liability Directive, florence.coroner@sky-net.be.

Pavel Černý, member and Staff Lawyer of the Environmental Law Service, Czech Republic, brno@eps.cz.

Jerzy Jendrośka, Director of the Environmental Law Center, Poland, jerzy.jendroska@eko.wroc.pl.

Jaqui Dopfer, Dipl.-Bau.-Ing., Society for institutional analysis (sofia), University of Applied Sciences Darmstadt, Haardtring 100, 64295 Darmstadt, Germany, dopfer@sofia-darmstadt.de.

Martin Führ, Professor of public law, legal theory and comparative law, Society for Institutional Analysis (sofia), University of Applied Sciences Darmstadt, Germany, fuehr@sofia-darmstadt.de.

Ekkehard Hofmann, Privatdozent (University of Hamburg) Dr. iur., Department of Environmental and Planning Law, Helmholtz Centre for Environmental Research, Leipzig, Germany, ekkehard.hofmann@ufz.de.

Simone Kellert, Dipl.-Ing.; University of Cassel, Faculty of Architecture, Urban Planning, Landscape Planning, Department Policy and law of spatial development in the European context, Henschelstraße 2, 34109 Cassel, Germany, kellert@asl.uni-kassel.de.

Detlef Kober, University of Cassel, Faculty of Architecture, Urban Planning, Landscape Planning, Department Policy and law of spatial development in the European context, Henschelstraße 2, 34109 Cassel, Germany, kober@asl.uni-kassel.de.

Uwe Lahl, MinDir Dr. habil., Department Director in the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU), Bonn, Germany, uwe.lahl@bmub Inn.de.

Susan Owens, University of Cambridge, Department of Geography, Downing Place, Cambridge CB2 3EN, UK; seo1000@cam.ac.uk.

Gerhard Roller, Professor of Environmental Law at the University of Applied Sciences in Bingen (Germany) and Chercheur associé à la Faculté universitaires St. Louis, Brussels, GerhRoller@aol.com.
If you want to join the Environmental Law Network International, please use the membership form on our website: [http://www.elni.org](http://www.elni.org) or send this form to the elni Coordinating Bureau, c/o IESAR, FH Bingen, Berlinstr. 109, 55411 Bingen, Germany, fax: +49-6721-409 110, mail: Roller@fh-bingen.de.

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The Environmental Law Division covers a broad spectrum of environmental law elaborating scientific studies for public and private clients, consulting governments and public authorities, participating in law drafting processes and mediating stakeholder dialogues. Lawyers of the Division work on international, EU and national environmental law, concentrating on waste management, emission control, energy and climate protection, nuclear, aviation and planning law.

Contact
Freiburg Head Office:
P.O. Box 50 02 40
D-79028 Freiburg
Phone +49 (0)761-42 59-0
Fax +49 (0)761-42 59 88

Darmstadt Office:
Rheinstrasse 95
D-64295 Darmstadt
Phone +49 (0)6151-81 91-0
Fax +49 (0)6151-81 91 33

Berlin Office:
Novalisstrasse 10
D-10115 Berlin
Phone +49(0)30-280 486 80
Fax +49(0)30-280 486 88
www.oeko.de

The University of Applied Sciences in Bingen was founded in 1897. It is a practice-oriented academic institution and runs courses in electrical engineering, computer science for engineering, mechanical engineering, business management for engineering, process engineering, biotechnology, agriculture, international agricultural trade and in environmental engineering.

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  - Effectiveness of legal and economic instruments
  - European governance
- Environmental advice in developing countries
  - Advice for legislation and institution development
  - Know-how-transfer
- Companies and environment
  - Environmental management
  - Risk management

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- Federal Ministry of Consumer Protection, Food and Agriculture

Contact
Darmstadt Office
Prof. Dr. Martin Führ – sofia
University of Applied Sciences
Haardtring 100
D-64295 Darmstadt/Germany
Phone +49(0)6151-16-8734/35/31
Fax +49(0)6151-16-8925
fuehr@sofia-darmstadt.de
www.h-da.de

Göttingen Office
Prof. Dr. Kilian Bizer – sofia
University of Göttingen
Platz der Göttinger Sieben 3
D-37073 Göttingen/Germany
Phone +49(0)551-39-4602
Fax +49(0)551-39-19558
bizer@sofia-darmstadt.de
www.sofia-research.com
elnı

In many countries lawyers are working on aspects of environmental law, often as part of environmental initiatives and organisations or as legislators. However, they generally have limited contact with other lawyers abroad, in spite of the fact that such contact and communication is vital for the successful and effective implementation of environmental law.

Therefore, a group of lawyers from various countries decided to initiate the Environmental Law Network International (elnı) in 1990 to promote international communication and cooperation worldwide. Since then, elni has grown to a network of about 350 individuals and organisations from all over the world.

Since 2005 elni is a registered non-profit association under German Law.

elnı coordinates a number of different activities in order to facilitate the communication and connections of those interested in environmental law around the world.

Coordinating Bureau

The Coordinating Bureau was originally set up at and financed by Öko-Institut in Darmstadt, Germany, a non-governmental, non-profit research institute.

Three organisations currently share the organisational work of the network: Öko-Institut, IESAR at the University of Applied Sciences in Bingen and sofia, the Society for Institutional Analysis, located at the University of Darmstadt. The person of contact is Prof. Dr. Roller at IESAR, Bingen.

elnı Review

The elni Review is a bi-annual, English language law review. It publishes articles on environmental law, focussing on European and international environmental law as well as recent developments in the EU Member States. It is published by Öko-Institut (the Institute for Applied Ecology), IESAR (the Institute for Environmental Studies and Applied Research, hosted by the University of Applied Sciences in Bingen) and sofia (the Society for Institutional Analysis, located at the University of Darmstadt). The Coordinating Bureau is currently hosted by the University of Bingen. elni encourages its members to submit articles to the Review in order to support and further the exchange and sharing of experiences with other members.

elnı Conferences and Fora

elnı conferences and fora are a core element of the network. They provide scientific input and the possibility for discussion on a relevant subject of environmental law and policy for international experts. The aim is to gather together scientists, policy makers and young researchers, providing them with the opportunity to exchange views and information as well as to develop new perspectives.

The aim of the elni fora initiative is to bring together, on a convivial basis and in a seminar-sized group, environmental lawyers living or working in the Brussels area, who are interested in sharing and discussing views on specific topics related to environmental law and policies.

Publications series


Elnı Website: elni.org

On the elni website www.elni.org one finds news of the network and an index of articles. It also indicates elni activities and informs about new publications. Internship possibilities are also published online.

elnı, c/o Institute for Environmental Studies and Applied Research
FH Bingen, Berliner Straße 109, 55411 Bingen/Germany

www.elni.org