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CONTENTS

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[1] 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[2] 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 receive the impression that the justification of political agreements that have already been made is the central function of the Impact Assessments undertaken by the Commission.

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 Černý* and *Jerzy Jendrośka* 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 Kober*.

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 Rehbinder* (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

elni forum on Nanotechnology

in memoriam of Betty Gebers
took place at Thursday, 7 December 2006, 6 p.m.,
at the Joint Representation of the States of Hamburg and Schleswig-Holstein,

The lecture given by Stefanie Merenyi, Martin Führ and Andreas Hermann led to a lively discussion. The programme and a few photos of the event can be found on the elni website.

The charts and the complete study (on behalf of the German Environmental Protection Agency - Umweltbundesamt) can be downloaded from the elni-website (www.elni.org).
The study is based on the final version of REACH.

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 *Gertrude Lübbe-Wolff*; see http://www.uni-bielefeld.de/ZIF/FG/1998Umweltrecht/.

2 See, for example, the study on behalf of the European Parliament: The Proposed Directive on Waste - An assessment of the Impact Assessment and the Implications of the Integration of the Hazardous Waste Directive into the existing Waste Framework Directive www.europarl.europa.eu/comparl/envi/pdf/externalexpertise/proposed_waste_directive_assessment_en.pdf.

The New European Regulatory Impact Assessment - In Theory and Practice

Ekkehard Hofmann

1 Introduction

With its communication on impact assessment of June 5, 2002, the European Commission has initiated a new era concerning the preparation and explanation of European legislative action.[1] Although the European Communities have a long history of employing formal analyses, mainly in the fields of environmental policy, the practice of the Commission could well be deemed as sporadic and ad-hoc. In most of the cases, legislative proposals were based on so-called "economic evaluations"[2] that considered only a segment of the expected outcomes of the proposed directive or regulation, for instance its expected effects on businesses, trade, health, gender mainstreaming or employment. Moreover, formal methods were rarely being employed in terms of *justifying* regulatory policy choices, while there is some indication that this is exactly what the European Commission is aiming at for the foreseeable future.[3] The Commission now strives for an integrated assessment of all major initiatives, taking into account each and every segment concerned. The Commission expressly thought of the introduction of the "Regulatory Impact Assessment" (RIA) as a means of justifying a chosen policy option.[4] The impact assessment process is part of the Commission's efforts to implement the subsidiarity principle (Art. 5 section 2 TEEC) in the area of governance and better lawmaking.[5] According to the Secretariat General, the process aims to improve the quality of Commission proposals as well as to improve and simplify the regulatory environment.[6]

Following this introduction, I will explicate the basic features of the Commission's approach, illustrated by three examples for impact assessments that have been carried out under the new regime: Section 2 will focus on the question as to how recent impact assessment practice fared compared to the standards set by the Commission itself. However, the (potential) role of assessment reports as a means to foster transparency even in the judicial context seems to be underdiscussed in the literature. Hence, I will examine the material legal requirements concerning the substance of governmental reasoning, and legal demands as to whether and how to present explanatory statements under Community law (3). Finally, I shall attempt to assess the pros and cons of using assessment reports as statements of basis and purpose pursuant Art. 253 TEEC (4).

2 New Concept of the European Commission

2.1 The Concept

Initially, the Commission had set up a two-step procedure by which each one of its regulatory projects underwent a preliminary impact assessment in order to determine whether a project should be subject to an extended impact assessment. Since 2005, all projects of the annual work programme are evaluated regardless of their complexity or their pre-evaluated need of an extensive impact assessment. With regard to the applicability of the impact assessment procedure, the crucial "switching" point is now whether a project becomes a part of the work programme. According to the Commission, 29 impact assessments had been completed in 2004, compared to 77 impact assessments in 2005.[7]

Pursuant to Annex 2 of the Communication on impact assessment, the following questions should be answered when carrying out an impact assessment:[8]

1. what issue is the policy/proposal expected to tackle; what would be the Community added value;

1 *European Commission*, Communication from the Commission on Impact Assessment. COM (2002) 276 final (2002), 2002.

2 For a survey on the studies that have been carried out for the European Commission, see http://ec.europa.eu/environment/pubs/studies.htm. Example: Economic Evaluation of Air Quality Targets for Tropospheric Ozone, Part C: Economic Benefit Assessment, http://ec.europa.eu/environment/enveco/air/tropozone-c.pdf.

3 *European Commission*, Communication from the Commission on Impact Assessment. COM (2002) 276 final (2002), 2002.

4 Id., at 10. It is noteworthy that the German version of the proposal does not use the literal translation of "justification" (Rechtfertigung), but the term "Begründung" (reasoning). Spanish: justificara, French: justifiera; Danish: begrunder; Italian: giustificherà; Swedish: motiveras.

5 The most important documents relating to „Governance" in Europe can be found at http://ec.europa.eu/governance/index_en.htm. See, for instance, *European Commission*, Action plan "Simplifying and improving the regulatory environment", COM (2002) 278 final, and the reports on better regulation, cf. European Commission, "Better Regulation 2005" COM (2006) 289 final.

6 http://ec.europa.eu/governance/impact/aims_en.htm.

7 *European Commission*, Report from the Commission "Better Lawmaking 2005" pursuant to Article 9 of the Protocol on the application of the principles of subsidiarity and proportionality (13th report), COM (2006) 289 final, 2006, p. 15.

8 *European Commission*, Communication from the Commission on Impact Assessment. COM (2002) 276 final (2002), 2002, Annex 2.

2. what is the main objective that the policy/proposal is supposed to achieve;
3. what are the main policy options available to achieve the objective;
4. what are the impacts – positive and negative – expected from the different options identified;
5. how can the results and impacts of the policy/proposal be monitored and evaluated.

Regarding the procedures that should be applied in the course of answering these questions, the Commission suggests that any method be used that allows for an integrative, comprehensive assessment of the effects incurred by the chosen option.[9] This approach rules out methods that examine only segments of the expected effects. Generally, the Commission holds that the choice of method and the level of detail will vary according to the nature of the problem and judgements about its feasibility.[10] The issue and the analysis of the options should "be expressed as concretely as possible in qualitative, quantitative and where possible monetary terms."[11]

The Commission mentions the following procedures as feasible in principle:

– cost-benefit analysis,
– cost-effectiveness analysis,
– compliance cost analysis,
– multi-criteria analysis and
– risk assessment.

Technical Guidelines explain these methods in detail, including information on how to valuate non-marketable goods,[12] discounting[13] and several approaches to risk assessment and sensitivity analyses.[14] Taken together, the concept of the Commission appears to have extinguished the previously sporadic character of impact assessments, although the new one-step procedure concerning the question as to whether to carry out an impact assessment or not is less transparent than the two-step-process that used to be applied initially. However, the level of scrutiny that has been applied in the last couple of years differs a lot, even in the fields of environmental policies. In the next section, I shall detail three examples, the amendment of the European chemicals policy, the thematic strategy on air pollution, and the thematic strategy on biodiversity.

2.2 Impact Assessments of Environmental Policies

2.2.1 European Chemicals Policy (REACH)

The chemicals industry is not only a key factor in the production of food, pharmaceuticals, textiles, and cars. At the same time it places a heavy burden on human health and the environment. Therefore, the Commission regarded it as unsatisfactory that existing chemicals are not subject to testing requirements pursuant to Council Directive 67/548/EEC. Existing chemicals amount to more than 99 % of the total volume of all substances on the market. Additionally, the Commission considered knowledge about the properties and the uses of existing substances to be insufficient. The new chemicals policy, referred to as *REACH* (registration, evaluation, and authorisation of chemicals), is meant to address both shortfalls. The recently adopted regulation 1907/2006[15] and the accompanying Directive 2006/121/EC[16] represent the outcome of a comprehensive lawmaking process, of which the Commission's White Paper of 2001,[17] its 2003 proposal for a regulation[18] and the Common Position of June 12, 2006[19] mark crucial points. In particular, the new scheme requires manufacturers and importers of a substance in quantities of 1 tonne or more per year to submit a registration to the newly established European Chemicals Agency.[20]

The implementation of *REACH* will entail considerable costs for both chemical industry and government agencies.[21] In its White Paper, the Commission assumed that testing procedures will cost approximately between 85,000 and 350,000 Euro per substance.[22] Taking the entirety of 30,000 existing substances into account, the Commission expected total testing costs of about 2.1 billion Euro up to 2012. In its impact assessment report, the Commission estimated combined testing *and* registration costs of between 2.8 and 5.2 billion Euro in

9 *European Commission*, Communication from the Commission on Impact Assessment. COM (2002) 276 final (2002), 2002, p. 3; cf. also *European Commission*, Ex ante evaluation. A practical guide for preparing proposals for expenditure programmes, December 10, 2001.

10 *European Commission*, Communication from the Commission on Impact Assessment. COM (2002) 276 final (2002), 2002, p. 15.

11 Ibid., pp. 13, 15.

12 *European Commission*, SEC (2005) 791, 2005, p. 37 *et seq.*

13 *European Commission*, SEC (2005) 791, 2005, p. 39 *et seq.*

14 *European Commission*, SEC (2005) 791, 2005, p. 44.

15 OJ L 396/1, December 30, 2006.

16 OJ L 396/850, December 30, 2006.

17 *European Commission*, Strategy for a Future Chemicals Policy. White Paper, COM (2001) 88 final.

18 *European Commission*, *REACH*-Proposal, COM 2003/644 final, 2003.

19 Interinstitutional Document No 2003/0256 (COD).

20 Regulation 1907/2006/EC, Art. 6 section 1.

21 Regarding the proportionality of the duty to register, cf. *W. Köck*, in: Rengeling (ed.), Umgestaltung des deutschen Chemikalienrechts durch europäische Chemikalienpolitik, 2003, p. 37 (56 ff.).

22 *European Commission*, Strategy for a Future Chemicals Policy. White Paper, COM (2001) 88 final, p. 15.

present value terms.[23] The report holds that health benefits could not be quantified because of considerable uncertainties due to – among others – cocktail effects, non linear dose-response-functions and poor aggregate data.[24]

However, the impact assessment report uses the following illustration to "give a feel" for the potential magnitude of the health impacts. Concerning the proportion due to agro-industrial chemicals and chemical pollution from diffuse sources, the Commission refers to a World Bank estimate of between 0.6% and 2.5% in developed market economies. The illustrated scenario takes 1.0 % as a conservative figure, and assumes further that a proportion of 10 % of this disease will be identified and tackled by *REACH*, "implying that 90% of the health impacts associated with chemicals are either related to historical exposures, will not be identified by *REACH* or cannot be tackled".[25]

As a measure of all diseases, the Commission uses DALYs (Disability Adjusted Life Years), concurring with studies carried out on behalf of the World Bank. Expressed in DALYs, the Commission expects 45,000 DALYs will be avoided every year due to *REACH*. 1 DALY being equivalent to 1 life saved, this amounts to 4500 statistical lives saved per year. Using these presumptions, the total benefits would accrue to approximately 50 billion Euro over the next 30 years, which lead the Commission to the conclusion that the legislative proposal represented a "balanced approach which

- will contribute to improved health for the citizens of the EU and greater protection of the environment; will bring added benefits to worker safety;
- will improve the conditions for innovation, by making it easier and cheaper to develop new and safer substances;
- and, also by limiting cost, will help to maintain the competitiveness of the chemicals industry."[26]

2.2.2 Thematic Strategy on Air Pollution

Curbing air pollution is another field of regulation focussing on health issues that has a long-standing European tradition. The Framework Directive 96/62/EC[27] and its daughter directives[28] set up a comprehensive scheme of air quality standards and their enforcement with regard to guiding pollutants including, among other substances, sulphur dioxide, nitrogen oxides, particulate matter including fine particles less than 10 µm in diameter, lead, ozone, carbon monoxide, polycyclical aromatic hydrocarbons, cadmium, arsenic, nickel, and mercury. Continuing this approach, the "Thematic Strategy on Air Pollution" underpins the importance of setting limit values and implementing them, complying with some of which has already turned out to be quite a challenge to a number of German communes. As a means of justification for the values chosen, the impact assessment report reasons that any option should be set against "the long-term objectives of achieving levels of air quality that do not give rise to significant negative impacts on and risks to human health and the environment", including no exceedance of critical loads and levels for natural ecosystems. In order to execute this approach, five different scenarios were analysed: (1) a base-line or "business-as-usual"-scenario, taking account of the effects of emissions control legislation, against the background of future economic development; (2) a "Maximum Technically Feasible Reduction" (MTFR) scenario whereby all possible emissions abatement measures are deployed irrespective of cost; (3) to (5) called Scenarios A, B, and C, representing further variants of measures.

Alternative environmental interim objectives up to 2020

		Human health		Natural environment					
Ambition level	Cost of reduction (€bn)	Life Years Lost due to $PM_{2.5}$ (million)	Premature deaths due to $PM_{2.5}$ and ozone (thousands)	Range in monetised health benefits[16] (€bn)	Ecosystem area exceeded acidification (000 km^2)			Ecosystem area exceeded eutrophication (000 km^2)	Forest area exceeded ozone (000 km^2)
					Forests	Semi-natural	Fresh-water		
2000		3.62	370	-	243	24	31	733	827
Baseline 2020		2.47	293	-	119	8	22	590	764
Scenario A	5.9	1.97	237	37 – 120	67	4	19	426	699
Scenario B	10.7	1.87	225	45 – 146	59	3	18	375	671
Scenario C	14.9	1.81	219	49 – 160	55	3	17	347	652
MTFR	39.7	1.72	208	56 – 181	36	1	11	193	381
Strategy	**7.1**	**1.91**	**230**	**42 – 135**	**63**	**3**	**19**	**416**	**699**

Source: *European Commission*, Thematic Strategy on air pollution, Impact Assessment, SEC (2005) 1133, p. 16.

As shown in the table above, the set of measures included in the „Strategy" achieves environmental effects between scenarios A and B, which strikes, according to the Commission, an "optimal balance

23 *European Commission*, Strategy for a Future Chemicals Policy. White Paper, COM (2001) 88 final, p. 19.

24 *European Commission*, SEC (2003) 1171/3, 2003, pp. 24 *et seq.* The Commission, however, refers to a study that has been conducted on behalf of the World Bank: *K. Lvovsky*, Health and Environment, 2001, p. 38, that uses monetarized assessments of which the Commission thinks that the World Bank has misinterpreted the data by 150 % (based on *K. R. Smith, et al.*, 10 Epidemiology 1999, p. 573 ff.).

25 *European Commission*, SEC (2003) 1171/3, 2003, p. 30.

26 *European Commission*, SEC (2003) 1171/3, 2003, pp. 32 *et seq.*

27 Council Directive 96/62/EC of 27 September 1996 on ambient air quality assessment and management, OJ L 296, p. 55.

28 Directive 1999/30/EC - OJ L 163, June 29, 1999, p. 41; Directive 2000/69/EC - OJ L 313, December 13, 2000, p. 12; Directive 2002/3/EC - OJ L 67, March 9, 2002, p. 14.

between economic and environmental goals, contributing to Lisbon and the Community's Sustainable Development Strategy objectives".[29] That seems to be a comprehensible conclusion at least in terms of the positive social net benefit of all scenarios with regard to the comparison of reductions costs and monetized health benefits. Moreover, the Commission is right to point out that the costs of moving from Scenario A to Scenario B are estimated to almost double and increase further when moving to Scenario C for relatively small benefits.[30]

However, the weightings of the effects on the natural environment remain opaque just like the measures comprised by the scenarios that are neither published within the Thematic Strategy nor in the corresponding impact assessment report. The measures are only detailed in the cost-benefit analysis that can be found elsewhere on the internet.[31] Furthermore, it must be remarked that the Commission does not provide an explanation for why only technical measures were considered, leaving out instruments such as increasing fuel taxes or other financial incentives. Nevertheless, taken as a whole, the "Thematic Strategy" can be viewed as an ambitious attempt to justify a chosen concept by heavily referring to quantitative procedures.

2.2.3 Biodiversity

The above examples, however, cannot be taken as prototypal for the general approach of the Commission. The communication from the Commission of May 22, 2006 on halting biodiversity loss may serve as an illustration of a very common natural-language approach.[32] The communication recognizes the intrinsic value of nature as well as biodiversity's usefulness for "ecosystem services", including production of food, fuel, fibre and medicines. Continuing the process of global efforts to halt biodiversity loss, the Commission proposes an EU Action Plan to 2010 and beyond that identifies four key policy areas, namely[33]

1. biodiversity in the EU,
2. the EU and global diversity,
3. biodiversity and global change, and
4. the knowledge base.

Ten different objectives are deployed to make these key areas more tangible. With regard to "2. The EU and global diversity", for instance, the Commission defines three goals:[34]

- to substantially strengthen effectiveness of international governance for biodiversity and ecosystem services;
- to substantially strengthen support for biodiversity and ecosystem services in EU external assistance; and
- to substantially reduce the impact of international trade on global biodiversity and ecosystem services.

However, for none of the objectives are quantified criteria set. In general, the Commission relies on the implementation of four key measures in the field of halting biodiversity loss:

1. Ensuring adequate financing,
2. strengthening EU decision-making,
3. building partnerships, and
4. building public education, awareness, and participation.

The communication includes particulars concerning the instruments that are linked to these key measures,[35] supplemented by the impact assessment of the Action Plan.

In contrast to the previous approach of the EU, the new biodiversity strategy aims not only at measures on European level, but embraces the Member States by applying an integrative concept that transcends the boundaries of different segments. For example, key policy area 1 ("Biodiversity in the EU") requires that the Natura-2000 network be established, safeguarded and designated in order to protect Europe's most important habitats and species by 2010 (2012 in marine). The Commission suggests using funds stemming from Rural Development funds, Cohesion and Structural Funds, Pre-Accession Instrument, Life-III, and Life+ on the one hand *and* Member State sources on the other.[36]

The impact assessment of the effects of the Action plan examines three different, clearly stated scenarios,

- "business as usual",
- EU Action Plan,
- EU Action Plan plus regulation.

The Commission argues that it was evident that continuing the path already chosen will not be compatible with the goal of halting biodiversity loss. The second option, the EU Action Plan, was preferable over the third alternative, which is mainly

29 *European Commission,* SEC (2005) 1133, p. 18.

30 European Commission, SEC (2005) 1133, p. 15 et seq.

31 *AEA Technology Environment*, Cost-Benefit Analysis of the Thematic Strategy on Air Pollution, 2005, cf. http://www.cafe-cba.org/.

32 *European Commission*, Communication from the Commission on Halting the Loss of Biodiversity by 2010 - and Beyond, COM (2006) 216 final.

33 Ibid., p. 11 *et seq.*

34 Ibid., p. 12.

35 Ibid., pp. 14 *et seq.*

36 Ibid., pp. 66 *et seq.*

based upon further legislative action. Putting further legislative instruments into force would require considerable loss of time, which would conflict with the objective to halt biodiversity loss until 2010. In order to test whether the Action Plan can be expected to yield the desired outcomes, the impact assessment report relates to a set of quantitative indicators that was apparently supposed to be published as annex 2 of the communication on biological diversity. However, the Document COM (2006) 216 final does not contain an annex.

The impact assessment in the narrower sense („analysis of impacts“)[37] describes the proposed actions and discusses potential pros and cons. However, with regard to five of the ten objectives, the Commission holds that no impact assessment of the new or accelerated actions is required at this stage.[38] When articulating the costs and benefits, the Commission relies mainly on natural language. For example, the impact analysis argues that the improved coherence, connectivity and resilience of the Natura-2000-network will result in “important benefits”, costs of applying a nature-directives type approach to the French outermost regions would depend largely on the area of important habitats needing protection and management, and might be proportional to the costs estimated for Natura 2000 in the European territories of the Member States.[39] With respect to objective 4 (“reinforcing compatibility of regional and territorial development with biodiversity in the EU”), the Commission holds that benefits of better treatment of biodiversity concerns in spatial and programmatic planning, and in tourism development, will be *considerable* with respect to protecting natural capital and ecological services.[40] Additional short-term costs may be incurred in terms of additional capacities and resources for planning, and certain developments foregone. The impact assessment argues further, “medium to long-term benefits are expected *to significantly outweigh* these short-term costs. Overall, an investment in better planning should pay off”.[41] Explanations such as these do not utilize the possibilities to communicate value judgments transparently vested in numerical procedures.

2.3 Preliminary Conclusions

The above presented legislative proposals have been evaluated by carrying out impact assessments that do not fully live up to the level of scrutiny that the Commission itself had stipulated. Although all of the assessment reports elaborate on the options that had been analysed and which alternative was deemed to be the best, the reasoning is almost always presented by using natural language. This contrasts especially with the guidance provided by the Technical Annexes to the Communication on Impact Assessment. While the assessment report about the then proposed amendment of chemicals policy (*REACH*) attempts to illustrate the justification of the project in quantitative (monetary) terms, the air pollution assessment report only quantifies the costs, but not the environment benefits, which are only expressed in tons in order to articulate the amount of emission reduction or by explaining the size of affected areas in square kilometres. Regarding the impact assessment on the strategy for halting biodiversity loss, there is almost no quantification of benefits or costs. On the contrary, the Commission explains the effects as being “important” or “significant”. Predictions are also communicated continuously by natural language expressions.[42]

The reliance on natural language is one of the reasons why the impact assessment practice of the Commission has been criticized for its new procedure.[43] In particular, the leading Directorates-General did not inform environmental agencies and other stakeholders early enough to allow for sufficient review of the projects.[44] It has also been pointed out the Directorate General in charge seems to work closely together with the impact assessment body, eventually compromising the preferably neutral perspective as to the review of proposals.[45] However, it would go beyond the scope of this paper to examine options to overcome those issues, given that they turn out to qualify as valid objections. The following considerations focus on the potential usefulness of impact assessment reports as statements of reasons and purpose pursuant to Art. 253 TEEC, comparing Preambles that fulfil this function at present with assessment reports that may make use of detailed numerical analyses.

37 Ibid., pp. 51 *et seq.*

38 Ibid., pp. 53, 54, 58, 59.

39 Ibid., p. 52.

40 Ibid., p. 55.

41 Ibid.

42 Ibid., pp. 25, 33, 40: “likely“.

43 Cf., for instance, *J. Gebauer*, Die neue Praxis der Folgenabschätzung auf EU-Ebene und die Auswirkungen auf das deutsche Umwelt- und Planungsrecht in: Ziekow (ed.), Aktuelle Fragen des Luftverkehrs-, Fachplanungs- und Naturschutzrechts, forthcoming, and *European Environment and Sustainable Development Advisory Councils*, Impact Assessment of European Commission Policies, 2006.

44 European Environment and Sustainable Development Advisory Councils, (Fn. 43), p. 16.

45 European Environment and Sustainable Development Advisory Councils, (Fn. 43), p. 18.

3 Legal Requirements

In order to evaluate the aptitude of impact assessment reports as statements of reasons pursuant to Art. 253 TEEC, it is necessary to consider the material standards which guide public decision-making, particularly the principle of proportionality (3.1), and the requirements pertaining to the explanation of reasons (3.2).

3.1 The Principle of Proportionality as a Guiding Standard ex ante

With regard to EU law, Article 2 TEEC provides a number of objectives of governmental activity, including a harmonious, balanced and sustainable development of economic activities, a high level of employment and of social protection, equality between men and women, sustainable and non-inflationary growth, a high degree of competitiveness and convergence of economic performance, a high level of protection and improvement of the quality of the environment, raising the standard of living and quality of life, and economic and social cohesion and solidarity among Member States. It is obvious that between some of these goals, trade-offs will occur. Therefore, a procedure is needed in order to give guidance on how to reconcile conflicting objectives. In this regard, Article 5 section 3 TEEC, in conjunction with Protocol No. 30 on the application of the principles of subsidiarity and proportionality,[46] expressly stipulates the principle of proportionality for any action of EU institutions.[47] Note that pursuant to the jurisdiction of the European Court of Justice, government bodies are required to balance public and private interests within the framework of an overall assessment.[48] Unless escape or exception clauses allow otherwise, national measures also have to comply with the (European) principle of proportionality.[49] In particular, state measures are required to be

- capable of achieving their desired objectives,[50]
- necessary in light of alternative options,[51] and lastly,
- proportionate to the goal in view.[52]

The approach of the ECJ does not only stipulate the principle of proportionality as such, but demands the consideration of all relevant aspects, of which there can be many. Generally, they include the interests of the European Community, of EU citizens, and of the Member States. For instance, the Court argued that the common organization of the banana market is not manifestly inappropriate with respect to the directive's aim to achieve the integration of markets, the interests of the plaintiff (i.e., the Federal Republic of Germany), and other Member States.[53] Specifically, the Court recognized that the Council "had to reconcile the conflicting interests of some Member States which produce bananas and were concerned that their agricultural population living in economically less-favoured regions should be able to dispose of produce of vital importance for them and thus avoid social problems and of other Member States which do not produce bananas and were primarily concerned to ensure that their consumers were supplied with bananas on the best price terms and had unlimited access to third-country production."[54]

All in all, the ECJ pursues an approach that is characterized by

- adopting the principle of proportionality as a standard of review that is mainly directed towards the final outcomes, not the justification of a public decision,[55]
- thereby granting European lawmaking bodies considerable leeway (judicial restraint), and
- considering all concerned matters, not just the matters that are relevant to the plaintiff.

Reconstructed as a standard for making decisions *ex ante*, the ECJ's understanding of the principle of proportionality requires the European Commission, Council and Parliament to employ integrative and comprehensive procedures that identify the policies that seem best on the basis of an overall assessment.

46 OJ C 340, 10/11/1997, 105.

47 For a survey of the different functions of the proportionality principle within European Community Law, see Takis Tridimas, The General Principles of EC Law 89 (1999). Also cf. Francis G. Jacobs, Recent Developments in the Principle of Proportionality in European Community Law, The Principle of Proportionality in the Laws of Europe 1 (Evelyn Ellis ed., 1999).

48 Case 15/57 *Chasse v. HA* [1958], ECR 211 at 228, Cases 17 and 20/61, *Klöckner v. HA* [1962] ECR 325 at 340; Case 5/73, *Balkan-Import-Export* [1973] ECR 1091 at 1110-12. The concept of balancing interests is also used by the U.S. Supreme Court (326 U.S. at 509); *Mathews v. Eldridge*, 424 U.S. 319 (1976); *Memphis Light, Gas and Water Division v. Craft*, 436 U.S. 1 (1978).

49 See, for instance, Case 41/76 *Donckerwolcke v. Procureur de la Republique* [1976] ECR 1921, para. 29; Case 62/70 *Bock v. Commission*, [1971] ECR 897, para. 14; cf. Tridimas, *supra* note 47, at 125-126; Jacobs, *supra* note 47, at 8-20.

50 Case C-317/92 *Commission v Federal Republic of Germany* [1994] ECR I-2039, para. 17 of the judgment.

51 Case C-315/92 *Clinique* [1994] ECR 1994, I-317 ff., para. 21 *et seq.* of the judgment.

52 Case 261/81 *Walter Rau Lebensmittelwerke v De Smedt PVBA* [1982] ECR, para. 12

53 Case C-280/93 *Germany v Council* [1994] *ECR* I-4973 par. 94.

54 Case C-280/93 *Germany v Council* [1994] *ECR* I-4973 par. 92.

55 See *infra* III.B(1).

3.2 The Adequate Statement of Reasons (Art. 253 TEEC)

3.2.1 Purposes and Scope

Moreover, government decisions often have to be explained in order for the public and the courts to determine whether parliaments and public agencies have complied with the standards outlined above. Thus, public decision-makers are frequently required to submit a written explanation of the reasons for their choice of action. Under European law, the European Parliament, the European Council and the European Commission must state the reasons for the development of regulations, directives, and other decisions.[56] The ECJ requires that the statement of reasons must be "appropriate to the act at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in question in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the competent Community court to exercise its power of review. The requirements to be satisfied by the statement of reasons depend on the circumstances of each case, in particular the content of the measure in question, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining explanations."[57]

However, "it is not necessary for the reasoning to go into all the relevant facts and points of law, since the question whether the statement of reasons meets the requirements of Article 253 TEEC must be assessed with regard not only to its wording but also to its context and to all the legal rules governing the matter in question".[58] More specifically, the Court has held that although regulations must clearly indicate the purpose pursued, the legislature is not required to specify the often very numerous and complex matters of fact and law dealt with, or to give a specific statement of reasons for each of the technical choices made. According to the ECR, the degree of precision of the statement of the reasons for a decision must be weighed against practical realities and the time and technical facilities available for making the decision."[59] Moreover, in the case of a measure of general application, the statement of reasons may be confined to indicating the general situation which led to its adoption on the one hand, and the general objectives which it intends to achieve, on the other. The ECR requires, nevertheless, that explanations must be consistent.[60]

In summary, European law stipulates a transparent communication of reasons that must be sufficiently informative with respect to the European courts whose mission is to exercise legal review. However, the ECR acknowledges a considerable degree of flexibility with regard to the level of scrutiny pertaining to the disclosure of the reasons on which the decision was based.

3.2.2 Statements of Reasons in practice – the Example of REACH

In practice, the Commission produces communications about legislative proposals for directives or regulations, and includes details particularly on the reasons and objectives. Taking *REACH* as an example, the Commission states that it wishes to foster

- protection of human health and the environment,
- maintenance and enhancement of the competitiveness of the EU chemical industry,
- prevention of the fragmentation of the internal market,
- increased transparency,
- integration with international efforts,
- promotion of non-animal testing,
- conformity with EU international obligations under the WTO.[61]

None of these objectives are quantified with the help of operable criteria.

Concerning the rationale for the chosen concept as outlined in the proposal, the Commission deals extensively with the prospective costs that would be incurred for the chemicals industry, because it was sensed that the costs, particularly those for the assessment of low volume chemicals, downstream users and small and medium sized enterprises were excessive. Unlike the impact assessment report, the proposal does not include a quantitative assessment of costs and benefits. For instance, the proposal explains that a "Safety Data Sheet" should be kept as an instrument that is already well known and understood, since requirement of a new tool would "increase costs for little benefit to human health and the environment".[62] In respect of the total net benefit of the *REACH*-proposal, the Commission does not attempt to monetarize or even quantify the ex-

56 Art. 253 TEEC.

57 Case C-367/95 *Commission* v *Sytraval and Brink's France* [1998] ECR I-1719, para. 63 of the judgment.

58 Ibid., para. 63 of the judgment.

59 Case C-350/88 *Delacre/Commission* [1990], ECR I-395, para. 16 of the judgment.

60 Case 158/80 *REWE* [1981] ECR 1805, para. 26 of the judgment (not in the English version, but cf. the French and the German versions of the judgment).

61 *European Commission*, *REACH*-Proposal, COM 2003/644 final, p. 5.

62 Ibid., p. 26

pected benefits. However, the proposal refers to the corresponding impact assessment that would take studies into account pertaining to the likely impact of the system.[63]

After a regulation or directive has been adopted, the Preamble functions as a statement of reasons pursuant to Art. 253 TEEC. The 40-page-Preamble of *REACH* points out that "the free movement of substances, on their own, in preparations and in articles, is an essential aspect of the internal market and contributes significantly to the health and well-being of consumers and workers, and to their social and economic interests, as well as to the competitiveness of the chemical industry."[64] Once again, additional objectives are also mentioned. According to the Preamble, the regulation aims at preserving the integrity of the internal market and at ensuring a high level of protection for human health and the environment.[65] In particular, an "important" objective of the new system to be established by the *REACH* regulation was to encourage the substitution of dangerous substances by less dangerous substances or technologies where suitable economically and technically viable alternatives are available.[66] The Preamble refers extensively to the documents that had been written in the course of developing the regulation, among others to the White Paper on Chemicals Policy of 1998, in which the Commission evaluated the then applicable law and found grounds enough to initiate an amendment process. The Preamble does not contain, however, monetarized or at least quantified information as to the costs and benefits that would probably result from the new system.

3.2.3 Appraisal with Respect to Art. 253 TEEC

If one evaluates the above mentioned documents by the standards set by Art. 253 TEEC, it must be noted that the Commission's proposal and its rationale does not represent the statement of reasons pursuant to Art. 253 TEEC. The provision pertains to the statement of reasons given by Community institutions such as the Council and the European Parliament, not to reasons presented by the Commission as the author of legislative proposals. As already mentioned, the statement of reasons is in practice the Preamble of regulations and directives in most of the cases. Hence, the ECJ's jurisdiction about the statement of reasons is directed towards the Preambles. The Preamble of the *REACH* Regulation meets the requirements set out by the ECJ. Since the regulation is a measure of general application, the statement of reasons "may be confined to indicating the general situation which led to its adoption…and the general objectives which it is intended to achieve". The Preamble to the *REACH* Regulation elaborates extensively the issues of chemicals policies including the shortfalls of the former legal situation. It also states the objectives of the regulation by mentioning a high level of protection of human health and the environment as well as the free movement of substances, and the efficient functioning of the internal market.[67] All in all, the Preamble complies with any standard the ECJ has formulated concerning the adequate statement of reasons pursuant to Art. 253 TEEC. Although statements of reasons have to be "clear and unequivocal"[68], the European Courts have never, as far as can be seen, taken offense at statements of reasons in which predictions or value judgments have been expressed in natural language.

4 Conclusions: Assessment Reports as Statements of Reasons?

However, since expressions such as "important" or "significant" are semantically vague, it can be doubted that they really convey the Council's or Parliament's justification in a "clear and unequivocal" manner. Given the necessity of considering all relevant matters when making a decision, it is perhaps most difficult to aggregate verbally the different outcomes of the options for action. Aside from lexicographic orderings and some other simple cases, there is a need to find an operable representation for degrees. Some approaches include terms like "likely", "more likely", and "highly likely" for predictions, or "insignificant", "significant", "massive" for value judgments.[69] The trouble begins when we try to solve problems by seeing the whole picture of factors involved. What do we get if we add a "likely" outcome to a "highly likely" result? How do we aggregate a "significant" and a "massive" change? As long as we do not define the meaning of these terms with sufficient precision, a verbal representation approach does not appear to be a very useful decision-making tool, and arguably, government agencies typically fail to provide such definitions when using verbal expressions.

63 Ibid., p. 10.

64 Regulation (EC) No 1907/2006, para. 1 of the Preamble.

65 Regulation (EC) No 1907/2006, para. 7 of the Preamble.

66 Regulation (EC) No 1907/2006, para. 12 of the Preamble.

67 Regulation (EC) No 1907/2006, para. 1 and 2 of the Preamble.

68 Case C-367/95 *Commission* v *Sytraval and Brink's France* [1998] ECR I-1719, para. 63 of the judgment.

69 Take for example a permit for enlarging a factory site that is detailed in Hofmann & von Wangenheim, Trade Secrets Vs. Cost Benefit Analysis, 22.4 Int'l Rev. L. Econ. 511, 514 (2003), at 514-517, and the German Federal Transport Infrastructure Plan 2003 (German Federal Ministry for Transport, Building, and Housing, German Federal Transport Infrastructure Plan, Berlin, draft 2003, at 14).

Nevertheless, even if they did, that would not necessarily lead to a logically consistent justification for the action chosen.

The ECJ could, drawing on considerations sketched above, require the statement of reasons to employ numerical analyses in certain cases. By doing so, the ECJ could secure higher minimum standards with respect to the level of care that the Commission applies in the process of making legislative proposals and communicating their rationales. Although the Commission has undoubtedly started a new era of regulatory impact assessment by committing itself to an integrative and comprehensive approach, some of the recent impact assessment reports seem to give reason for skepticism with regard to their transparent reasoning. For instance, the impact assessment report concerning the Thematic Strategy on Halting Biodiversity Loss argues that benefits of better treatment of biodiversity concerns in spatial and programmatic planning, and in tourism development, will be *considerable* in terms of protecting natural capital and ecological services.[70] Without revealing data on what kind of effects are exactly referred to, in particular what probability distributions are assumed by the Commission, or how the impacts are evaluated in proportion to other effects, the statement remains rather opaque to the public and the courts. It should be noted, however, that even assessment reports such as the one on the Biodiversity Strategy are much more informative than their typical German counterparts.[71]

Since the assessment report represents the rationale of the Commission, while the statement of reasons pursuant to Article 253 TEEC refers to the considerations of the legislature, the Commission, Council and European Parliament would have to adopt the assessment reports as their own by referring to them in the European directive or regulation, which could be done by mentioning the assessment report in the Preamble. This would not only align with the initial approach of the Commission to present the reasons that "justify the chosen option",[72] it would also render the principle of proportionality as a standard of review that requires an "overall assessment" of all available policy options more stringently.

With respect to the procedure by which the projects should be identified that are subject to an impact assessment, it seems plausible to assume that a judicial review of statements of reasons that relies on a formal impact assessment would generate a certain incentive to avoid undertaking an impact assessment. Hence, the Commission should consider returning to the two-step procedure that had been initially deployed for selecting the projects that seem worth the effort of carrying out an extensive impact assessment. US President Clinton's Executive Order No. 12,866, according to which any regulatory action that is likely to result in a rule that may have an annual effect on the economy of $100 million or more, or may adversely affect the economy in a material way, is subject to formal evaluation of costs and benefits, may serve as a model for guiding the selection process.[73] A criterion devised along the basic features of this model would allow for a transparent split between projects whose political relevance seems high enough to justify the costs incurred by an extensive impact assessment and those which are not sufficiently significant.

70 *European Commission*, Impact Assessment on Halting Biodiversity Loss, SEC (2006) 607/2, 2006, p. 55.

71 Frequently, regulatory impact assessments in Germany only state that there are no alternatives and no costs (to the legislator who is in charge of the act in question).

72 *European Commission*, Communication from the Commission on Impact Assessment. COM (2002) 276 final (2002), p. 10.

73 Exec Order No.12,866, 3 C.F.R. 638 (1994), section 3 f). A similar requirement is set up by the Safe Drinking Water Act (section 1412 (b)(3)(C), 42 U.S.C. § 300g-1). For application to EPA regulation on arsenic, see 40 CFR Parts 9, 141, and 142, 7010-7023.

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The Society for Institutional Analysis was established in 1998. It is located at the University of Applied Sciences in Darmstadt and the University of Göttingen, both Germany.
The sofia research group aims to support regulatory choice at every level of public legislative bodies (EC, national or regional). It also analyses and improves the strategy of public and private organizations.
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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 (elni) 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.

elni 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.

elni 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.

elni Conferences and Fora

elni 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 researches, 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

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