

Risks, Costs and Alternatives in EC Environmental Legislation: The Case of 'REACH'

Gerd Winter

European Community standards of environmental law are commonly framed in terms of the risks of activities to human health and the environment. Under this cover of uni-dimensional concern, considerations of an activity's benefits, regulatory costs and the availability of alternatives play a crucial role in the regulatory practice. The REACH proposal is a first and ambitious attempt to bring these other dimensions to the fore and give them shape. This article analyses this approach, identifies its merits and flaws, and develops a scheme that makes the complex calculus practicable. It is submitted that the scheme is applicable also in other areas of EC environmental law.

INTRODUCTION

Whenever dangerous products, which are to be placed on the market, are regulated, various consequences may emerge, including the following:

- a certain level of protection of human health and the environment will be reached;
- the consumer can no longer make use of the restricted product in order to meet his or her demand;
- alternative products or technologies possibly serving the same use will be developed or imported by the relevant industry;
- the profits thus far obtained from the production or importation of the restricted product collapses;
- the costs of developing or importing alternative products or technologies may be offset by the benefit drawn from sales of the same.

These consequences may come out as a mismatch. In practice, due to an overestimation of the involved costs and an underestimation of the benefit obtainable from substitute products, the authorities often abstain from a restriction, thus allowing environmental damage to persist. Conversely, it does happen that due to an overestimation of environmental risks, the authorities restrict a product, thus hindering an essential use and causing unnecessary costs to industry.

Environmental product regulation in Europe has traditionally been based on criteria focusing on concerns for human health and the environment but widely disregarding the use value of restricted products, the profit drawn from their manufacture and sale, and the costs of placing substitute products on the market. In practice, however, as analyses of restriction procedures prove,¹ cost considerations do play a role, and perhaps even a decisive one. This is legitimate where the legal criteria provide the regulator with a discretionary margin, but less so in cases where the regulator is bound to take action.

The question is whether cost and other trans-environmental considerations should be left to the discretion and hidden in the practice of regulators, or if they should become part of the official set of criteria, thus inviting more structured reasoning. Against this argument, it should be noted that the US cost-benefit analysis, which was introduced as a legal requirement during the Reagan era, has allegedly retarded environmental protection.² But it can be argued that this consequence is not unavoidable. A prudent conception of considering trans-environmental concerns can avoid obstructive effects and, at the same time, avoid the contradiction of declared environmentalism and clandestine economism.

This article will present a concept of which trans-environmental criteria should be used in the risk assessment and risk management of toxic chemicals. Criteria to be taken into consideration include, beside the risk to human health and the environment, the loss of use value and the possibility of substitution, and the economic cost of restrictions, as balanced against the return drawn from substitutes. It will be discussed if such criteria are based in EU constitutional principles, and how they are specified in the Proposal for a

¹ G. Winter, H. Ginzky and B. Hansjürgens, *Die Abwägung von Risiken und Kosten in der europäischen Chemikalienregulierung* (Erich Schmidt Verlag, 1999), at 237ff.

² N. Ashford, 'Implementing the Precautionary Principle: Incorporating Science, Technology, Fairness and Accountability in Environmental, Health, and Safety Decisions', 5:2-4 *Int. J. Risk Assessment and Management* (2005), at 112-123.

Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) that the European Commission submitted in 2003,³ taking into consideration also the draft European Parliament Opinion on the same proposal, adopted on 17 November 2005 and the draft Common Position of the Council, as politically agreed on 13 December 2005.⁴ The following questions will be posed:

- What basis do criteria for risk assessment and management have in EU primary (or 'constitutional') law?
- What logical framework is appropriate to structure the balancing of conflicting interests?
- What criteria will be established by the proposed REACH regulation?
- Should the criteria be the same for both authorization and restriction of chemicals being placed on the market?
- How can the risk assessment of chemicals be conducted in a precautionary way?
- How can considerations of substituting dangerous chemicals by less dangerous ones be entered into the assessment of regulatory options?
- How should regulatory costs be weighed against risk-reduction benefits?
- How can the concept be put in a practically manageable form?

THE CONSTITUTIONAL BACKGROUND

Constitutional law – EC or national, depending on what authority has acted – may be invoked if an economically overprotective abstention from regulation is challenged for violation of health and environmental protection duties, or, conversely, if an environmentally overprotective restriction is accused of violating basic economic freedoms. Therefore, although the focus of this article is on analysing secondary EC law, it also takes a brief look at the EC constitutional level.

The conventional checking of the constitutionality of EC secondary law proceeds along three questions:

1. Does the regulation constitute an encroachment on economic freedom?
2. If so, is there justification by public interests (such as human health and the environment)?

³ Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), COM (2003) 644 (hereinafter 'REACH Proposal').

⁴ Draft Common Position of Council of the European Union (Document No 15921/05, 13 December 2005) and see European Parliament legislative resolution on the proposal of the European Parliament and of the Council on REACH (Pe-TA-PROV (2005) 0434, 17 November 2005).

3. If so, is the regulation proportionate to the public interest?⁵

However, this construction does not adequately reflect that, not only economic freedom, but also human health and the environment are – by Article 174 of the EC Treaty – constitutionally protected. To protect these goods is not the legislator's political discretion but its obligation. Thus, the European Court of Justice has determined in the *Safety High Tech Case* that Article 130r of the EEC Treaty (now Article 174 of the EC Treaty) 'sets a series of objectives, principles and criteria which the Community legislature must respect in implementing environmental policy'.⁶ The doctrinal construction must indicate that environmental protection does not only legitimize governmental action should the legislator be politically willing to act but that, under certain conditions, action can be mandatory.⁷ The German Federal Administrative Court has pronounced itself on this matter as follows:

In those cases where an encroachment on basic rights collides with basic rights of third parties or other constitutional goods the solution of such tension is to find a proportional balance of the conflicting constitutionally protected interests with an aim of optimization. The conflict between the basic right and other constitutionally protected goods must be solved by case-related balancing.⁸

This means that the second and third questions must be modified. The following framework is suggested:

1. Does the regulation constitute an encroachment on economic freedom?
2. If so, is there justification by a public interest or even a legal mandate?
3. Is the regulation proportionate to the public interest? If the regulation is mandatory, is it optimal in view of both the economic freedom and the legal mandate?

The change from proportionality to optimality implies a slight readjustment of the weights of the balanced

⁵ See T. Kingreen, 'Artikel 6', in C. Callies and M. Ruffert (eds), *Kommentar zu EU-Vertrag und EG-Vertrag*, 2nd edn (Luchterhand Verlag, 2002), article 6, nos 64 et seq.

⁶ ECJ 14 July 1998, Case C-284/95, *Safety Hi-Tech Srl*, [1998] ECR I-4329, at para. 36.

⁷ G. Winter, 'The Legal Nature of Environmental Principles in International, EC and German Law', in R. Macrory (ed.), *Principles of European Environmental Law* (Europa Law Publishing, 2004), at 19 and 22ff.; W. Köck, 'Das System "Registration, Evaluation and Authorization of Chemicals" (REACH)', in H.-W. Rengeling (ed.), *Umgestaltung des deutschen Chemikalienrechts durch europäische Chemikalienpolitik* (C. Heymanns Verlag, 2003), at 47. In contrast, L. Krämer, *EC Environmental Law*, 5th edn (Sweet & Maxwell, 2003), at 13, argues that the environmental principles only provide political guidance.

⁸ Judgment of 18 October 1990, Case 3 C 2.88, 87 Federal Administrative Court Reports 37, at 45ff.

MATRIX OF BALANCING ALTERNATIVE MEASURES

	INTEREST A: E.G. ECONOMIC FREEDOM	INTEREST B: E.G. CONSUMPTION	INTEREST C: E.G. ENVIRONMENTAL PROTECTION
Option I	+	-	++
Option II	0	++	-
Option III	++	0	+

goods: the proportionality test starts from the perspective of basic freedoms and, thus, gives these priority. In contrast, the optimization test gives both goods – the basic freedom and the mandatory protection – equal weight.

In addition, cases are imaginable where, because of governmental inaction, a suit is filed in order to compel government to act. In that case, the questions to be posed are these:

1. Does the inaction encroach on a constitutional obligation to take a measure?
2. If so, would the envisaged measure encroach on an economic freedom?
3. If so, is the measure optimal in view of both the economic freedom and the legal mandate?

THE LOGIC OF WEIGHING CONFLICTING INTERESTS

The conventional concept of checking proportionality or optimality assumes a situation where two interests stand in conflict with each other. However, political and administrative decisions often affect third or even more interests, which must be taken into consideration. In the realm of environmental product regulation, the third interest besides industry and human health/environment is the consumers' welfare. In the case of dangerous products, those who benefit from the use of the product may be affected if the product is prohibited. For instance, heat-resistant asbestos may be missing in brakes and thus frustrate consumer needs if asbestos is prohibited.

The doctrinal concept of balancing two interests must therefore be opened for multilateral consideration. It is submitted that a matrix should be used as a rationalizing tool (see table above). In this matrix, one dimension represents the environmental and social goods positively or negatively affected by a measure, and the other represents the alternative measures to be considered. Single or accumulated positive, negative and neutral symbols indicate the relative value of the goods and the intensity of their impacts. Of course, the variables and loadings of the matrix must be adjusted

in accordance with the specific legislation and the individual case under consideration. An example is given at the end of this article.

MATERIAL STANDARDS IN THE PROPOSED REACH REGULATION

Unlike conventional legislation, the proposal for a Regulation of REACH will not confine itself to laying down one-sided environmental protection criteria. It rather displays a quite ambitious set of criteria. As they are scattered over many different provisions in the proposed regulation itself and in its annexes (showing also some inconsistencies between criteria of authorization and of restriction of the placing on the market of chemicals), they need some systematization and clarification. An attempt will be made to systematize and clarify these in the remainder of this article.

For the *authorization of substances* the material standard is laid down in Article 57 of the proposed REACH Regulation, which states (emphasis added):

2. An authorization shall be granted if the *risk* to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIII is *adequately controlled* in accordance with Annex I, section 6, and as documented in the applicant's chemical safety report . . .
3. If an authorization cannot be granted under paragraph 2, an authorization may be granted if it is shown that *socio-economic benefits outweigh the risk to human health or the environment* arising from the use of the substance and if there are no suitable alternative substances or technologies. This decision shall be taken after consideration of all of the following elements:
 - (a) the *risk* posed by the uses of the substance;
 - (b) the socio-economic *benefits* arising from its use and the socio-economic implications of a refusal to authorize as demonstrated by the applicant or other interested parties;
 - (c) the analysis of the *alternatives* submitted by the applicant under Article 59(5) and any third party contributions submitted under Article 61(2);
 - (d) available information on the health or environmental *risks of any alternative* substances or technologies.

For restrictions of the manufacture, placing on the market or use of substances in preparations or articles, the material standards are contained in Article 65(1) (emphasis added):

1. When there is an *unacceptable risk* to human health⁹ or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVI shall be amended in accordance with the procedure referred to in Article 130(3) by adopting new restrictions, or amending current restrictions in Annex XVI, for the manufacture, use or placing on the market of substances on their own, in preparations or in articles, pursuant to the procedure set out in Articles 66 to 70.¹⁰

Article 66 regulating the procedure of preparing restriction measures refers to Annex XIV, where the content of the dossier preparing the decision is specified. In doing so, Part C of Annex XIV implicitly expounds more material standards (emphasis added):

a) Evidence that *implemented risk management measures* (including those identified in registrations under Articles 9 to 13) are *not sufficient* . . .

c) Identification of the available options for addressing the concerns identified in Part B. For restrictions, this includes evidence that *alternative substances and/or processes* have been considered in the preparation of the proposal.

d) Identification of the administrative, legal or other tools by which the available options can be implemented.

e) Justification for the option and implementation method selected. The options shall be evaluated using the following criteria:

- i) *effectiveness*: the action must be targeted to the effects or exposures that cause the risks identified and must be capable of reducing these risks to a level where the risk is adequately controlled within a reasonable period of time;
- ii) *practicality*: the action must be implementable, enforceable and manageable. Priority should be given to those measures that can be implemented with the existing infrastructure;
- iii) *monitorability*: the ability to monitor the result of the implementation of the proposed action;
- iv) a *socio-economic assessment* may be made of the impact of the proposed action on the producers/importers and/or downstream users of the substance and on other parties. This assessment should follow Annex XV.

Annex XV contains guidance for the so-called socio-economic analysis (SEA), which applies both to authorizations and restrictions. The following elements may be included in a SEA (emphasis added):

- Impact of a granted or refused authorization on the applicant(s), or, in the case of a proposed restriction, the *impact on industry* (e.g. manufacturers and importers). The impact on all other actors in the supply chain, downstream users and associated businesses in terms of commercial consequences, such as impact on investment, one-off and operating costs (e.g. compliance; transitional arrangements; changes to existing processes, reporting and monitoring systems; installation of new technology, etc.).¹¹
- *Impacts* of a granted or refused authorization, or a proposed restriction, *on consumers*; for example, product prices, changes in composition or quality or performance of products, availability of products, consumer choice.¹²
- *Social implications* of a granted or refused authorization, or a proposed restriction; for example job security and employment.
- Availability, suitability, and technical feasibility of *alternatives*, and economic consequences thereof, and information on the rates of, and potential for, technological change in the sector(s) concerned. In the case of an application for authorization, this may include the social and/or economic impacts of using any available alternatives identified in Article 59(5)(b).
- *Wider implications on trade, competition and economic development* (in particular small- and medium-sized enterprises (SMEs)) of a granted or refused authorization, or a proposed restriction. This may include consideration of local, regional, national or international aspects.
- In the case of a proposed restriction, proposals for *other regulatory or non-regulatory measures* that could meet the aim of the proposed restriction (this shall take account of existing legislation). This should include an assessment of the costs linked to alternative risk management measures.
- In the case of a proposed restriction, the *social and economic benefits* of the proposed restriction; for example worker health, environmental performance and the distribution of these benefits, i.e. geographically or population groups.

⁹ In the European Parliament Opinion of 17 November 2005, n. 4 above, the following words are inserted after the word 'health': 'including that of vulnerable populations and citizens exposed early in life or continuously to mixtures of pollutants'. The insertion gives the precautionary approach more weight.

¹⁰ In the draft Council Common Position of 13 December 2005, n. 4 above, the following sentence is added to the paragraph: 'For such decision the socio-economic consequences of the restriction including the availability of alternatives shall be considered'.

¹¹ In the draft Council Common Position, *ibid.*, the following words are added to the paragraph: 'taking account of the general market and technology development'.

¹² In the draft Council Common Position, *ibid.*, the following words are added to the paragraph: 'as well as impacts on human health and the environment as far as they affect consumers'.

HARMONIZATION OF STANDARDS FOR AUTHORIZATIONS AND RESTRICTIONS WHEN CHEMICALS ARE PLACED ON THE MARKET

It appears at first sight that the standards for authorizations and restrictions differ because, for authorizations, a complex consideration of risks, socio-economic benefits, substitutability and costs is required; whereas, for restrictions, the standard is simply whether the risk is unacceptable. However the annexes to the proposed REACH Regulation add some of the criteria missing in the provision on restrictions. This is particularly true with regard to the socio-economic analysis. Both substitutability and socio-economic analysis will explicitly be added should the draft Common Position of the Council be adopted.¹³

Authorizations and restrictions differ in one respect: an authorization procedure presupposes that the activity under scrutiny may not be undertaken *until* the authorization is given, whereas the restriction procedure is concerned with ongoing activities. This difference in the regulatory situation does not, however, justify a difference in material standards: risks should, in both cases, be weighed against costs in relation to a number of feasible alternatives. However, it does justify a difference in distributing the burden of proof between operator and regulator: in order to obtain an authorization the operator bears the burden of proving that his or her activity meets the legal standards; while, in order to restrict an ongoing activity, the authorities must prove that the activity does not meet them. Authorization requirements presuppose that the activity is *prima facie* dangerous and should therefore not be admissible without the operator proving that it is safe. By contrast, powers of restriction presuppose that the activity is *prima facie* safe but may be regulated after closer scrutiny. Hence, Article 57(1) of the proposed REACH Regulation should be read to mean that the operator must prove that the risk is 'adequately controlled', while Article 65 should be understood to lay on the regulator the burden of proving that there is 'unacceptable risk'.

With the advent of socio-economic analysis the question arises whether the allocation of the burden of proof known in relation to health and environmental risks should also apply to facts about socio-economic impact. The REACH proposal appears to follow this line with regard to restrictions, because the consideration of socio-economic impact is contained in the

formula for 'unacceptable risk' used in Article 65. The burden of proof therefore lies with the regulator. Strangely enough, the same appears to be true in cases of authorizations: Article 57, paragraph 3 of the proposed regulation, which allows for authorizations based on balancing costs and risks, is framed as an exception to paragraph 1, which strictly excludes an authorization if the risk is not adequately controlled. Exceptions to rules normally imply the shifting of the burden of proof. This would mean that, while the operator must prove the adequacy of the control of the risks, the regulator must prove the exceptional situation that the costs outweigh the risks.

This solution disregards the rationale of submitting activities to authorizations. For this reason, the burden of proving costs should therefore be shifted to the operator. However, beyond this, there is another reason of such shifting, which also covers restrictions: facts about regulatory costs are known to operators but they are a black box for the regulator in most instances. Therefore, it must be the burden of the operator to submit and prove such facts should he or she claim that a restriction or refusal of an authorization causes excessive costs.

Legislation both on the European Community and the Member State level often provides the authorities with discretion to decide on authorizations and restrictions. It is noteworthy that the REACH proposal does not follow this line. Both authorizations and restrictions are obligatory if the conditions set out in the relevant provisions are met. The reason for this is that the balancing of interests, which is typical for discretionary powers, is structured in some detail by legislative decision, thus leaving little room for further administrative discretion.

PRECAUTION

The precautionary principle, as commonly understood at Community level, means that measures can and sometimes must be taken even if there is not yet proof, but rather a suspicion, of dangerous effects. The measures should be provisional until better knowledge has been accumulated.¹⁴ In addition, some Member States such as Germany understand precaution to mean that measures should also be taken if the probability of an adverse effect is low, or if the adverse effect is not grave, or if the effect materializes in the distant future only, or if it occurs at a distant location. The term in German law that embraces these situations of uncertainty, low probability, low severity, long-term and

¹³ See draft Council Common Position, n. 4 above.

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¹⁴ Communication of the Commission of 2 February 2000 on the Application of the Precautionary Principle, COM (2000) 1.

long-range effect is low risk.¹⁵ Low risk is to be distinguished from cases of high risk or danger, i.e. the scientifically based high probability of serious, imminent and nearby damage. The implication of this broader conception of precaution is that in situations of high risk (danger) measures of danger avoidance must be taken more or less irrespective of costs and availability of substitutes; while in situations of low risk, measures of precaution can be taken upon balancing these with other concerns, including regulatory costs.

The REACH proposal does not mention the precautionary principle, at least not explicitly. It does however use the term 'risk' to describe the situation that may trigger management measures.¹⁶ Risk is commonly defined as the likelihood of a certain adverse effect, taking into account the level of certainty.¹⁷ The term as commonly understood also covers situations of uncertainty and low probability of effect. Therefore, the use of the term 'risk' means that the regulator shall be empowered to take precautionary measures.

The quest for precaution in the REACH concept is reinforced by the fact that precaution was given EC constitutional status. According to Article 174(2) of the EC Treaty 'Community policy . . . shall be based on the precautionary principle'. This was supported by the European Court of First Instance in the *Pfizer* judgment.¹⁸ In that case, the court examined Article 6(2) of Directive 70/524 on additives in feeding stuffs, which states that a substance may only be included in the list of food additives 'if . . . at the level permitted in feeding-stuffs [the substance] does not endanger animal or human health . . .'.¹⁹ The Council had deleted a *Pfizer* substance from the list, claiming that this condition was no longer satisfied. Upon *Pfizer*'s complaint, the court ruled that Article 6(2) could be read in terms of the precautionary principle and accepted that the scientific basis of the Council decision was not secure.

In spite of this conclusion, it would be preferable for the sake of clarity if the proposed REACH Regulation would explicitly make reference to the precautionary principle. This would be in line with more modern secondary law like the IPPC Directive²⁰ and the directive

on the release of genetically modified organisms.²¹ It would then be clear that risk management measures of dangerous substances (such as the refusal of authorization, a conditioned authorization and a marketing restriction) do not presuppose full scientific knowledge. It could even be framed to include the elements of the German definition, i.e. non-severe or long-term or long-range effects.²²

In the practice of risk assessment, it can occur that the state of knowledge is so undeveloped that no meaningful conclusion can be drawn whether the substances pose a risk or not. In terms of evidence rules, this is the situation of *non liquet*. The decision must, in such situations, be taken following the legislator's allocation of the burden of proof. Authorizations and restrictions differ in this respect. As noted earlier, an authorization could not be granted in such a situation because the operator bears the burden of proof. Conversely, the authorities could not issue a restriction if the substance is already placed on the market because it is they who bear the burden of proof in this case.²³

The total risk of a substance depends on both the substance's properties and the exposure to it of organisms and other end-points. Such twofold assessment is typical for product-related legislation, the idea being that a toxic substance *per se* may nevertheless be kept in containment, thus neutralizing the toxicity. The REACH proposal mirrors both aspects by making the authorization dependent on whether the risk is 'adequately controlled'.²⁴ With this reference to exposure control, a more radical approach is rejected, which would suppress the marketing of a substance based on a cluster of mere innate properties such as toxicity, persistence, mobility and bio-accumulation, alleging that, even if a substance may be controlled during its lifetime, it will finally nevertheless enter the environment in the form of waste.

However, the term 'adequately controlled' is somewhat unclear. In particular, the baseline of expectable caution on the side of the user is not defined, other than in the biocides legislation, where reference is made to a user who observes the pertinent conditions of the authorization taking into account the normal

¹⁵ M. Klopfer, *Umweltrecht*, 3rd edn (Verlag C.H. Beck, 2004), at 176ff.

¹⁶ See REACH Proposal, n. 3 above, Articles 57(2) and 65(1).

¹⁷ G. Banse, 'Herkunft und Anspruch der Risikoforschung', in G. Banse (ed.), *Risikoforschung zwischen Disziplinarität und Interdisziplinarität* (Edition Sigma, 1996), at 8.

¹⁸ ECJ 11 September 2002, Case T-13/99, *Pfizer Animal Health Council*, [2002] ECR II-3305.

¹⁹ See Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs, [1970] OJ L270/1, Article 6(2).

²⁰ Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control, [1996] OJ L257/26; Article 3 states 'any appropriate precautionary measures'.

²¹ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, [2001] OJ L106/1; Article 4 states 'in accordance with the precautionary principle'.

²² See M. Klopfer, n. 15 above.

²³ I. Appel, 'Besonders gefährliche Stoffe im europäischen Chemikalienrecht – Neuorientierung im Weißbuch zur Chemikalienpolitik', in *Das Europäische Weißbuch zur Chemikalienpolitik, Umwelt- und Technikrecht (UTR)*, Vol. 68 (Erich Schmidt Verlag, 2003), at 95ff. and 118.

²⁴ See REACH Proposal, n. 3 above, Article 57(2). For restrictions, exposure is – somewhat less systematically – mentioned in Annex XIV, Part C, (e)(i).

practice of use.²⁵ This means that an imperfect user of biocides is assumed, i.e. one who has negligent habits in normal daily life. Such a realistic standard should also apply in the chemicals area, at least when chemicals are used by end consumers.

In any case, even if a substance is not adequately controlled, Article 57 of the proposed regulation provides that it may, nevertheless, be placed on the market under certain circumstances. These are the already noted substitutability of the substance, in view of the use value of the substance and the relative costs of different regulatory options, which shall now be discussed in turn.

USE VALUE AND ALTERNATIVES

GENERAL MERITS OF THE TESTING OF ALTERNATIVES

The fact that Article 57 and Annex XIV of the REACH proposal request actors to consider the substitutability of a dangerous substance fits with a more general trend to open up environmental protection instruments for the testing of alternatives. Thinking in alternatives increases the likelihood of finding better solutions and may reduce the need for information because, if an obviously less dangerous alternative can be found, the further investigation of the primary option can be disrupted and the intricate weighing of incommensurate risk and costs can largely be avoided.²⁶ The testing of alternatives originates from the US National Environmental Policy Act (NEPA)²⁷ and plays a major role in practical decision making. The requirement was also introduced in the EC Directive on Environmental Impact Assessment²⁸ as well as in the Directives on Occupational Health,²⁹ on Cars³⁰

and on Electronic Devices.³¹ It could play a major role also in the area of chemicals control. For instance, the Ministerial Conference to the Commission of the Oslo and Paris Convention in June 2003 asked the EC 'to promote the substitution of hazardous substances with safer alternatives, including promoting and facilitating the development of such alternatives where they do not currently exist'.³²

ALTERNATIVES TESTING AND RISK-COST ANALYSIS

There is some need for clarifying the relationship between the analysis of the substitutability of a substance and the costs of its restriction. The alternatives testing enquires whether a use benefit of a substance can be satisfied with a means that involves less environmental risks than the means under scrutiny. The risk-cost analysis enquires whether an environmental risk can be reduced with a means that involves less economic costs than the option under scrutiny. Both tests have a similar structure because they look for less intrusive means to reach a certain goal. But the direction of enquiry is different: the alternatives testing asks how much environmental resources shall be sacrificed for societal welfare goals; whereas the risk-cost test asks how much societal welfare shall be sacrificed for the preservation of environmental resources.

One might argue that the difference of direction can be made to disappear by a more neutral framing of the questions. But there is in fact a difference if one either hinders society to reach certain welfare goals, or if one hinders the State to take regulatory measures in view of the involved economic costs. In the first case, political and legal practice are less willing to conduct enquiries and take action because they have to put societal welfare goals into question, a matter widely left for individuals to decide in liberal States. In the second case, political and legal practice is more at ease because it is widely accepted that State action should be kept to a minimum, and that it is a governmental task to collect information and take action in this regard.

As the REACH proposal demands both of the tests, it is, for the sake of clarity, submitted that the two operations should be kept separate. This means, if the risk assessment of a substance concludes that a risk is

²⁵ Directive 98/8 of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, [1998] OJ L128/1, Article 5.

²⁶ See, for an elaboration of this argument, G. Winter, *Alternativen in der administrativen Entscheidungsbildung* (Nomos Verlag, 1997) at 12ff.

²⁷ National Environmental Policy Act (1969) 42 USC §§ 4332, section 102(1)(C).

²⁸ Council Directive of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, [1985] OJ L175/40.

²⁹ Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, [1989] OJ L183/1 and Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), [1990] OJ L196/1.

³⁰ Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of-life vehicles, [2000] OJ L269/34.

³¹ Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, [2003] OJ L37/19.

³² See Bremen Statement of the Ministerial Meeting of the OSPAR Commission (Bremen, 25 June 2003), para. 23(c), available at <http://www.ospar.org/eng/html/md/Bremen_statement_2003.htm>.

given and the denial of an authorization or a marketing restriction should be considered, two more tests apply: whether there are alternatives to serve the same goal; and whether the measure can be replaced by a less costly one. In more abstract terms, the alternatives and the risk-costs test require that the regulation is checked in terms, first, of the loss of use value and, second, in terms of the induction of costs to industry.

ALTERNATIVES TESTING

As noted earlier, the REACH proposal prescribes alternatives testing both for authorizations and for restrictions. For authorizations this is explicitly mentioned in Article 57, while for restrictions it must be extrapolated from the term 'unacceptable risk'. 'Unacceptable' is a risk if there are alternatives serving the same use but involving less environmental risks. That this is a correct interpretation is grounded by the already mentioned guidance in Annex XV of the proposal.

With all its requirements put together, the alternatives testing proceeds as follows:

1. identification of the use(s) of the substance under scrutiny;
2. determination of the socio-economic benefit (or use value) of this substance;
3. identification of alternative substances or technologies serving the same use(s);
4. (rough) assessment of the risks of the alternatives;
5. balance of benefits and risks of the primary substance and the alternatives.

Requiring alternatives testing helps to gain rationality in decision making because it structures the discretionary margin of government and thus makes the outcome more predictable. It is also to be welcomed that the alternatives to be considered not only look at other substances but also at other technologies. This broadens the possibility of reducing the use of dangerous substances. For instance, the authority when considering suppressing a chemical cleanser which has environmentally harmful side-effects may take into account that the cleaning can be done just as well by hot water and a cleaning cloth.³³

When identifying the use of an incriminated substance one difficulty emerges. One substance often serves many different uses. For instance, a solvent may be

used for paints, machines, cooling, cleaning and other uses at the same time. If alternatives testing is taken seriously, alternatives for all of the uses must be identified. However, there are probably only very rare cases where a use cannot also be served by other means. The analysis may also be simplified through concentration on the core uses that the incriminated substance stands for.

Another concern is the mode in which, in the case of authorizations, the risk and the alternatives tests are linked in the REACH proposal: the link is such that the availability of substitutes shall only be considered if the risk is not adequately controlled.³⁴ If the risk is not adequately controlled but the socio-economic benefit outweighs the environmental risk and no viable alternative is available the authorization may nevertheless be given. In other words, if the result of the alternatives test is a negative one, an authorization may nevertheless result (provided the socio-economic benefit is preponderant).³⁵

This strips alternatives testing of some of its potential to rationalize the decision. Before it is conducted, the socio-economic benefit must be weighed against the environmental risk. This is very difficult to do because no common denominator exists. In particular, neither the benefits nor the risks can be expressed largely in monetary terms. Against this, if alternatives testing was applied as a first step it could be said that if an alternative exists the authorization shall not be granted, notwithstanding whether the socio-economic benefit of the incriminated substance outweighs the risk or not. Only if no alternative is available would the difficult weighing of risk and benefit have to be made.

Moreover, the potential of alternatives testing could also be used in relation to those risks that appear to be adequately controllable.³⁶ Assessing a risk as 'adequately controlled' often involves uncertainties. If alternatives are available, why should a risk not be prevented, even if there is still uncertainty about whether the risk is significant or controllable? Therefore, both with regard to authorizations and to restrictions, alternatives should be taken into account (1) if the significance of the risk or its adequate controllability is uncertain; and (2) if

³⁴ See REACH Proposal, n. 3 above, Article 57, paras 2 and 3.

³⁵ No such stepwise order is foreseen for decisions on restrictions; see Annex XIV. The availability of substitutes is one of several points to consider.

³⁶ Requiring that an analysis of alternatives must be submitted with the application for authorization, the European Parliament has made a first step in this direction. However, this procedural requirement is not mirrored in the formulation of the substantive criterion for authorization. See European Parliament Opinion of 17 November 2005, Article 59, para. 4 lit. db. The same requirement is also contained in the Political Agreement of the Council of 13 December 2005, Article 59, para. 4 lit. da. (Thanks to Axel Singhofen for alerting the author to this flaw.)

³³ A similar test, including alternative technologies, applies to the authorization of pesticides. See as an example the Administrative Court of Braunschweig judgment of 29 April 1992 (6 A 6001/90) (unreported) where the court found the risk of a pesticide unacceptable because, instead of using the pesticide, the farmer could also have removed the weeds by mechanical means. For a more theoretical view, see G. Winter, *Brauchen wir das? Von der Risikominderung zur Bedarfsprüfung* (Kritische Justiz, 1992), at 395.

the risk is not adequately controllable. Substitution would, in this way, become a proactive tool to prevent uncertain risks rather than only functioning as a 'negative' barrier against allowing uncontrollable but avoidable risks.

Be this as it may, one possible misunderstanding of the alternatives test must in any case be overcome. The availability of a substitute is, at least in practice, sometimes taken as a precondition of any regulatory action. For instance, the prohibition of fluorochlorocarbons was only adopted when industry had developed a substitute. The same is true with asbestos, polychlorinated biphenyl (PCBs), and other bans or restrictions of the recent past. In legal terms, however, substitutability is not a precondition of regulation. The testing of alternatives is, but not the actual availability of an alternative. If the adverse effect on human health or the environment is serious, the regulator is empowered and possibly also obliged to prohibit the substance even if no substitute is available. An understanding that disregards this would conflict with the constitutional protection of human health and the environment. It would be intolerable to sustain a serious risk for the only reason that no substitute is available to satisfy the relevant societal need. Article 57 of the proposal must be understood to mean precisely this: an uncontrolled risk that outweighs the socio-economic benefit must be prohibited even if no substitute is available. Of course this does not exclude that a phasing-out scheme is built into the ban allowing for time to develop alternatives.

RISK-COST ANALYSIS

Besides an analysis of the regulatory impact on the consumer, Annex XV of the REACH proposal also asks for a study of impacts on industry. The Annex specifies what the proposed regulation says concerning authorizations in Article 57(3)(b) ('the socio-economic implications of a refusal to authorize') and concerning restrictions in Article 65, in particular regarding the notion of the unacceptability of the risk.

This requirement would be misunderstood if it were read to mean that regulatory costs to industry could lead to admitting uncontrolled risks. If from the previous tests it is concluded that a risk is significant and not adequately controlled, and that either substitutes are available or the use value outweighs the risk, then there is no way that the substance would be authorized (or non-restricted) due to reasons of impact on industry. For instance, high-risk substances used for modest use values like decoration cannot be authorized on the ground that the relevant producers make good profits and provide jobs. To make profits and create job opportunities is perfectly legitimate even if the product

is totally useless. Things are different, however, if the product poses a risk to human health and the environment. To endure such risks from a useless product for the only reason that the product provides profits and jobs would not only be politically unwise but also a misbalance of constitutionally protected goods.

Risk-cost analysis is, however, not irrelevant in the regulatory calculus. Its proper role is not to contribute to the 'if at all' of the taking of measures, but rather to provide guidance for what kind of measure should be selected. It is concerned with what the risk methodologists call option assessment as opposed to risk assessment and evaluation.³⁷ If a risk is significant and not adequately controlled, measures must be taken. In most cases, however, several measures can be considered, ranging from a complete ban (or non-authorization) to conditioned restrictions and market information strategies, such as safety data sheets and public warnings. In order to evaluate the regulatory options, in addition to effectiveness, in view of the goal of protection, cost implications are a major criterion in identifying the best solution.

This kind of cost consideration envisaged here is a cost-effectiveness analysis rather than a full blown cost-benefit (or cost-risk) study. The regulatory goal, i.e. the control of the risk, should in the normal case be taken as authoritative for the selection of appropriate measures, rather than being transposed into economic terms in order to balance it against economic costs, as a full benefit-cost analysis would require. This does not exclude the fact that small cuts in the level of protection are acceptable because not every regulatory option has exactly the same effectiveness. Only in the unrealistic event that even the cheapest measure still involves exorbitant costs, may it be reasonable to assess the economic benefit of reducing the risk and balance it with the regulatory costs.³⁸

When calculating the regulatory costs it is important to note that the prohibition of a substance often releases creativity and effort to develop alternative substances, thereby opening competitive advantages for innovative producers. Sometimes a radical prohibition can have a much more productive effect than softer measures, which at first sight appear to spare industry. Such opportunities must be deducted from the immediate costs caused by the prohibition of the incriminated substance.

It may nevertheless occur that the new advantage accrues to the competitors, rather than the initial

³⁷ See Risk Commission, *Revision of Risk Analysis Procedures and Structures of Standard Setting in the Field of Environmental Health in the FRG* (Bundesamt für Strahlenschutz, June 2003), available at <<http://www.bfs.de>>.

³⁸ See *ibid.*; see also the proposals made by G. Winter, H. Ginzky and B. Hansjürgens, n. 1 above, at 418.

MATRIX OF OPTION ASSESSMENT FOR THE REGULATION OF DANGEROUS SUBSTANCES

	BENEFIT FOR HUMAN HEALTH AND THE ENVIRONMENT	BENEFIT FOR CONSUMERS	BENEFIT FOR PRODUCERS
Option 1 (status quo)	--	+	++
Option 2 (e.g. public warning) ⇒ substance X remains	-	+	+
Option 3 (e.g. contamination limits in products) ⇒ R&D of substitutes A, B	+	+	+
Option 4 (phasing out – ban of substance X) ⇒ R&D of substitutes D, C	++	+	+

producer. This is not, however, a viable objection because nobody has a right to, or can legitimately demand, protection for a certain market share. It is true that a State and even the European Community sometimes takes a nationalistic approach and hesitates to prohibit substances that can be substituted by products from external producers. Politically understandable as this is, such practice however touches upon limits set by the World Trade Organization's free trade requirements. Should, for instance, a Contracting State prohibit the importation of less dangerous products for the simple reason that the domestic producers are not yet able to bring a like product on the market, this would be a clear violation of Article XI of the General Agreements on Tariffs and Trade and Article 2, paragraph 2 of the Agreement on Technical Barriers to Trade.

SYNTHESIS

In conclusion, a matrix outlining how to elaborate on the regulation of dangerous substances is suggested. In the matrix, the protected goods are listed horizontally (the regulatory costs being considered as part of the yield – or loss – of the producer), while the instrumental options are placed vertically, which also covers alternatives, as a qualification of those options. The symbols in the cells represent two measurements combined: (1) the intensity of the positive or negative impact of an option on the protected good; and (2) the relative weight of the protected good, (++) meaning effective service of a highly worthy good, (+) modest service of a modest good or modest satisfaction of a highly worthy good, (--) effective disservice for a highly worthy good, and (-) modest disservice to a highly worthy good.

In this case, the example is given of the possible restriction of a persistent and toxic varnish (= substance X) used for ship hulls. The options include the

status quo ante (no action), a measure such as a public warning, which will not effectively remove the substance from the market, the gradual phasing out of the substance, and a strict ban of the substance. The protected goods to be considered include benefits for human health and the environment, for consumers and for producers.

Option 1 causes damage to human health and the environment, which is slightly offset by consumers' and producers' gains. Option 2 does not effectively abate health and environmental risks, and reduces, at the same time, the benefits for producers. Option 3, the fixing of contamination limit values, will lead to the development of substitutes, thus serving the needs of consumers and of human health and the environment, while the costs to producers will be offset by profits from the substitutes in the long run. Option 4 comes out best (in this scenario) because the gains for human health and the environment are more immediate and thus higher than in the other options, which will, under normal conditions, also serve the benefit of consumers and producers. This would reflect the so-called Porter hypothesis, which claims that clear and strict regulation is often a better incentive for innovation than over-zealous respect for cost effects.³⁹

Gerd Winter is Professor of Public Law and the Sociology of Law at the University of Bremen. He is director of the Research Unit for European Environmental Law (FEU). His current focus of research is the institutional dimensions of global environmental change. His recent publications include *Multilevel Governance of Global Environmental Change* (Cambridge University Press, 2006) and *Die Umweltverantwortung multinationaler Unternehmen* (Nomos Verlag, 2005).

³⁹ M.E. Porter and C. van der Linde, 'The Competitive Advantage of Nations', *Harvard Business Review* (March/April 1990), at 73–93.