The Precautionary Principle: Its Use Within Hard and Soft Law

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The precautionary principle in public decision making concerns situations where following an assessment of the available scientific information, there are reasonable grounds for concern for the possibility of adverse effects on the environment or human health, but scientific uncertainty persists. In such cases provisional risk management measures may be adopted, without having to wait until the reality and seriousness of those adverse effects become fully apparent. This is the definition of the precautionary principle as operationalized under EU law. The precautionary principle is a deliberative principle. Its application involves deliberation on a range of normative dimensions which need to be taken into account while making the principle operational in the public policy context. Under EU law, any risk management measures to be adopted while implementing the precautionary principle, have to be proportionate to ensure the chosen high level of protection in the European Community.

This article will illustrate the established practice concerning the release of genetically modified organisms into the environment and how the principle is implemented under hard law. The article also provides an outlook on what this may imply for the relative new case of nanotechnology and the use of precautionary principle within the context of soft law (use of codes of conduct).

I. The normative political dimension of decision making

At the initial level of considering the invocation of the precautionary principle, one has to distinguish between applying the precautionary principle in the context of a particular regulation, such as EU regulations concerning Genetically Modified Organisms (GMOs) and existing national laws, and the *political* decision to invoke the precautionary principle for a particular subject matter, (such as agricultural biotechnology, climate change, and the protection of the ozone layer), before any regulation or law is available. At this initial level, the decision is purely a political one. Even if there is no existing regulation regime existing in relation to the issue, such a political decision, is, and should be guided by a *definition or general understanding* of the precautionary principle which provides a *rationale for action.* Over recent years such a rationale and understanding have emerged from political discussions at the international level, and are reflected in several descriptions of the principle in international agreements and, in the EU in (apart from the formal inclusion of the precautionary principle in the EU treaty) in court rulings of the European Court of Justice, Communications from the European Commission and in the general principles and requirements of EU food law.

In any specific case, the rationale specifies *particular circumstances,* for which the possible invocation of the precautionary principle is specifically reserved and consists of two crucial elements:

1. The principle is to be applied in cases of potential adverse impacts on the environment or human

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health with serious consequences (thus implying that these consequences are unacceptable if realised, see for the normative dimension concerning the "seriousness of these consequences," further below).
2. Governmental action should be taken even though "complete" scientific evidence is not available, there is on-going scientific controversy, and/or there are disagreements about the lack of scientific knowledge. These circumstances are referred to as instances of scientific uncertainty. Scientific uncertainties arise because of controversies over the possibility of adverse effects to the environment or human health, their scope or their degree of seriousness.

The precautionary principle *establishes a rationale for action*: it substantially lowers the threshold level for action by governments (and possibly, depending on its national implementation, makes it easier for governments, when citizens or interest groups appeal to the precautionary principle in socio-political or judicial controversies). It represents a departure from the previous state of affairs where political actors could use or abuse a persistent dissent among scientists as a reason or excuse, for not taking action at all.

A similar rationale for action based on the precautionary principle has often been applied in the human health area. For example, the Judgements of 5 May 1998, in cases C-157/96 and C-180/96, rulings of the European Court of Justice concerning its Judgement on the validity of the European Commission's decision banning the exportation of beef from the United Kingdom to reduce the transmission risk of bovine spongiform encephalopathy (BSE or "mad-cow disease"): "Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent." As the European Union treaty[1] states, "Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community."

In the European Union, the discussion at the political level has led to firmly embed the principle in European policy, as it is enshrined in the 1992 Maastricht Treaty as one of the three principles upon which all environmental policy is based. It has been progressively applied to other fields of policy, including food safety, trade and research.

1. Chosen level of protection

Every nation state has under international agreements the sovereign right to determine its own level of protection. For a particular nation, this level can either be higher or lower than the level applied by other nations depending on its economic situation and socio-political priorities. With or without the precautionary principle, nations can thus determine such a general level of protection as they deem to be appropriate. Having the precautionary principle in place does not imply any new standard setting and therefore does not, for instance, imply the application of strict (or stricter) environmental or health standards: it only changes the procedure on how nations can act when they want to implement their chosen levels of protection in the light of scientific uncertainty.

When it comes to protecting the environment or human health, the essential normative political choice is thus the determination of the chosen level of protection. However, the level of protection is not always very clearly determined or defined. The EU treaty states only that the level of protection should be "high" (e.g. for environment, consumer protection, human, animal and plant health). It has been clarified that this does not necessarily have to be the highest level that is technically possible, and depending on the regulations involved, Community institutions do enjoy a broad discretion, in relation to the determination of the level of risk deemed unacceptable for society. Therefore, "consistency" and "non-discrimination" become relevant guidelines while invoking the precautionary principle and determining the chosen level of protection in a particular field and over a particular time-frame[2].The precautionary principle can only legitimately be invoked, according to the above rationale, if there is a threat that this chosen level of protection could be violated by particular products or activities. The proper application of the precautionary principle has to be seen in the light of this chosen level of protection. The choice of the level of protection determines the actual standards for health and the environment which should be

1 Consolidated versions of the treaty on European Union and of the treaty establishing the European community, *Official Journal of the European Union, C325,* 24 December 2002, Title XIX, article 174, paragraph 2 and 3.

2 Communication from the European Commission on the Precautionary Principle, (COM 2000/001), Brussels.

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employed. This normative/political choice will have to be applied under all policies and is independent from the invocation of the precautionary principle.

In most cases, the level of protection is hardly ever defined in quantitative terms. Indeed in cases of significant scientific uncertainty, such quantification is not feasible. Moreover, one is possibly not even sure whether the anticipated adverse effects actually pose a problem for our chosen level of protection (and therefore, possibly, should not be seen as an adverse effect after all) or that one is not aware of effects which may indeed pose such problems. Some asked the "so, what?" question when the spread of transgenes into the environment as a possible consequence of the massive use of GMOs was defined as a possible unacceptable environmental effect[3]. In the context of climate change, for instance, there was a long period without clearly defined standards for temperature rise which were to be seen as unacceptable: the uncertainty of the science is related to the uncertainty of what still could count as acceptable in terms of health and environmental effects. Invoking the precautionary principle, therefore, implies a delicate interplay between the choice of possible normative standards of acceptability and scientific assessments whether such standards would be violated without regulatory measures. While invoking the precautionary principle, one may in the light of acquisition of new knowledge, need to redefine the level of protection as well.

It is important to recollect at this point that the combination of an operational rationale of the precautionary principle and the obligation of maintaining a high level of protection (accompanied with possible non-quantified standards) *sets the terms of the debate*. At this stage of our deliberation, the question on the use of normative qualifiers which are connected to the effects which trigger the precautionary principle can already be clarified: the terms "negative," "serious" or "significant" cannot be operationalized in a public policy context, since their use would start a new discussion on their degree of seriousness, significance etc. The only possible proper qualifier is therefore the "chosen level of protection," so that any possible infringement of that level can count as "negative," "serious," etc. The general term "adverse" effect implies an infringement of that level of protection.

2. The choice and design of a particular framework

The political dimension of the initial invocation is not fully exhausted by the mere existence of a constitutional or European Treaty-based rationale for the precautionary principle. It is important to note that the precautionary principle is, at the level of the EU treaty, a formal principle which implies that, depending on the area to which it will be applied, will result in quite different types of environmental policies/regulations with a range of possible measures, which in themselves are in need of a proper justification. Although the basic rationale justifies proactive action, the range of possible actions might vary considerably and it also raises the issue of applying the precautionary principle in a consistent, non-discriminatory and proportional way, for all areas concerned. The European Commission had to set up guidelines for the precautionary principle's application, among others, in order to tackle this issue, thereby ensuring that the precautionary principle can and will not be abused as a disguised protectionist trade measure and is compatible with the EU's international obligations such as those under the WTO and the UN (see footnote 3). Two of these guidelines stand out in relation to decisions with a normative political nature, namely the requirement of a proportional application of the precautionary principle and the requirement to examine the benefits and costs of action or lack of action The latter requirement has also been mentioned as a requirement for environmental policy in the Treaty on the European Union (Article 172 of the Environment Title in footnote 2).

As far as the examination of the benefits and costs of action or inaction is concerned, it has to be taken into account that human health issues in the EU take precedence over economic concerns. For example, the Order of 30 June 1999, in Case T 70/99, *Alpharma vs Council* states: "requirements linked to the protection of public health should undoubtedly be given greater weight than economic considerations." The Commission's guidelines clearly state that this examination should not be reduced to a pure economic weighing of costs and benefits[4].

3 Gerard De Vries (ed.), *Proceedings second international work CCRO workshop – Commission Genetic Modification* (Bilthoven: 1999), pp. 125136.

4 Communication from the Commission on the Precautionary Principle, (COM 2000/001), Brussels (previously cited) and the European Council Resolution on the Precautionary Principle, 2000, Brussels.

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Christoforou[5] rightly points out that this type of consideration does not play a decisive role in *whether* to adopt a precautionary principle based regulation or policy, but only in the *actual choice or design* of the framework. The choice and the design of the framework are part of political deliberations before they conclude in actual regulations and policies, and this is why this aspect of the implementation of the precautionary principle must be seen at the normative political level.

The EU regulation on Genetically Modified Organisms, for example, shows a particular design of a precautionary regulatory framework. It established a *case by case* and *step by step* procedure[6]. The framework does not prejudge the *acceptability* of individual GMO releases. This framework thereby takes a normative stand on GMOs as such, since it defines GMOs as a priori *potentially* hazardous, and shifts the burden of proof to the proponents of the activity, e.g. the applier for a GMO release has to demonstrate safety rather than that regulatory agencies or third parties have to demonstrate a risk. EU regulation concerning chemicals (under protest from EU industry) has moved in a similar direction with a mandatory risk assessment to be produced by the applicant. The European Court has also confirmed that the legislation "already makes provision, as *one* (italics by the author) of the possible ways of giving effect to the precautionary principle, for a procedure for prior authorisation of the products concerned"[7].

3. The choice of potential measures and the requirement of proportionality

Although the requirement of proportionality has its roots in the basic principles of Community Law, it won't and cannot be considered a trump card that could override the invocation of the precautionary principle. Whereas the cost/benefit analysis requirement constrains and guides the setup of the general regulatory framework for policy actions, the proportionality requirement relates in particular to the *normative choice* of possible alternative measures under such regulations or policy actions but does not eliminate the precautionary principle based justification of taking measures as such. According to Community law the principle of proportionality requires that measures adopted by Community institutions should not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question, and where there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued.

Thus the proportionate implementation of the precautionary principle is not aimed at categorical bans of products or processes (which might jeopardise the learning process) but certainly does not exclude such measures in individual cases. For instance, the EU recently withdrew particular antibiotics in feeding stuffs from the market while invoking the precautionary principle. A subsequent very revealing European Court of Justice ruling, concerning this antibiotics case (Judgment Case T-70/99, *Alpharma vs Council* [2002] ECR II-3495) included a judgement relating to both a contested interpretation of the precautionary principle and the principle of proportionality. The Court judged this ban to be justified[8].

The principle of proportionality has an impact on the choice of possible measures, and in the trade context, this could mean that one adopts measures that would be the least trade-restrictive. In general terms, the *normative* line of thinking here is that a proportionate application of the precautionary principle involves the least onerous measure while still attaining the legitimate objective. However, the European Court of Justice has clarified, in the context of the above judgement *(Alpharma vs Council)*, that a cost/benefit analysis should be seen as a particular expression of the principle of proportionality in cases involving risk management. In the case of the invocation of the precautionary principle, risk management is by definition involved (the invocation of the precautionary principle is a risk management decision in the EU context) and the proportionality principle is integrated in the context of a broadly defined cost-benefit analysis. The outcome of such an analysis can, therefore, favour an option other than the least onerous one in terms of restrictions to trade, de-

5 Theofanis Christoforou, "The Precautionary Principle and Democratising Expertise: A European Legal Perspective", 30 *Science and Public Policy* (2003), pp. 205–213.

6 René Von Schomberg, René, "An Appraisal of the Working in Practice of Directive 90/220 Concerning the Deliberate Release of Genetically Modified Organisms in the Environment", *STOA report of the European Parliament* (1998).

7 European Court of Justice, *Greenpeace France and Others*, Judgement C 6/99, 21 March 2000

8 Ellen Vos, "Antibiotics, the Precautionary Principle and the Court of First Instance", 11 *Maastricht Journal of European and Comparative Law* (2004), pp. 187–200.

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pending on the normative decision rules (including priority setting) employed while exercising such an analysis. The costs of particular measures can vary considerably in relation to the economic and social importance of the issue at stake as well as whether the invocation of the precautionary principle would lead to interference in planned activities or would involve various degrees of remediation. In the latter case, it also matters whether alternatives are available. For example in relation to banning substances that depleted the ozone layer there were alternative products, while in contrast managing climate change requires changing entrenched current practices.

II. The normative dimension of assessing scientific uncertainty

The precautionary principle is applied in the context of scientific controversy and the acquisition of new knowledge. In order to apply the precautionary principle properly, a clarification is needed as to what is precisely understood by "scientific uncertainty" and what types of uncertainties are relevant for the invocation of the precautionary principle. This section is particularly concerned with the issue of how the normative qualifier *"reasonable grounds for concern"* can be used for triggering the precautionary principle. Any scientific advice is surrounded by some degree of uncertainty and this in itself is not a reason for, nor usually leads to, the invocation of the precautionary principle. We can distinguish four circumstances. The first type of circumstances relate to "hypothetical effects and imaginary risk." A conjectural approach which involves the identification of a purely hypothetical risk cannot be considered for the invocation of the precautionary principle. Both the EC guidelines on the precautionary principle and the ruling of the European Court of Justice (T70/99 for example) exclude such situations and confirm that *any* invocation of the precautionary principle should start with a scientific examination of the issue. It involves a mapping or identification of the possible adverse effects and is subsequently followed by a risk assessment. It is acknowledged that such an assessment is not necessarily either complete or conclusive in all its details. This scientific examination can also include or build upon minority views within the scientific field. Minority views, however, do not need to be seen in isolation. Scientific evaluations work best in the context of independent scientific peer review. It speaks for itself that those scientific evaluations need to be done in a transparent way and that the results should be publicly accessible. Thus, the invocation of the precautionary principle is always scientifically informed and, procedurally, it is mandatory to have such an examination available before invoking the precautionary principle.

A second type of circumstance which can be distinguished relates to the normal situation of a defined risk, whereby the level of protection is defined, and the risk (e.g. the probability of the occurrence of the adverse effects multiplied by their impact) can be quantified. In such situations, the policy makers can respond with a normal risk management approach whereby, for example, thresholds can be set, risks can be either minimised or kept below a certain level, and precautionary measures can be taken to keep particular effects well below particular thresholds by employing the ALARA (as low as reasonably achievable) principle. The invocation of the precautionary principle is neither necessary nor relevant. Note that one can take "precautionary measures" without invoking the precautionary principle. Because there is scientific consolidated basis concerning the adverse effects in question, one can act with preventive (in contrast to precautionary) interventions.

The situation becomes completely different when one encounters a third type of situation in which one cannot fully rely on the scientific information system as such when it comes to the estimation of possible adverse effects. This is notably the case when an epistemic debate is going on in science: e.g. disciplines use competing models or analogies or basic assumptions to disclose the subject matter under investigation in order to acquire new knowledge[9]. In the case of long-term effects from the introduction of GMOs, for instance, biotechnologists usually refer, by analogy, to the practice of conventional plant breeding as a basis for making "predictions" concerning their risks. Ecologists, on the contrary refer, also by analogy, to experience based on the introduction of particular species into new environments (thereby causing "problem" plants and pests). This debate even went so far that representatives of the different disciplines dismissed the relevance of each other's knowledge base for the actual assessment of risks.

9 See for example: René Von Schomberg, (ed.), *Science, Politics and Morality: Scientific Uncertainty and Decision Making* (Dordrecht: Kluwer, 1993); René Von Schomberg, *Der Rationale Umgang mit Unsicherheit* (Frankfurt am Main: Peter Lang, 1995).

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The epistemic debate concerning the long-term effects in terms of their predictability will need decades to be completely resolved: Both the analogies of the ecologists and biotechnologists are plausible, but refer to a completely different potential scientific information base that still needs to be disclosed by on-going research. The possible effects of individual releases (although one needs to take into account the accumulation of many releases over time) may not be either fully identifiable, nor be known in their scope (in terms of possible negative indirect-effects, long term or delayed effects). However these effects might be monitored for and practical management and monitoring practices could enable an early identification of unexpected events. Also their degree of seriousness can be identified to some extent. Particular effects may be irreversible, since if transgenes are in the environment, then they cannot be easily retrieved. The situation is different from a classical risk management situation: a precautionary approach can be justified.

Less dramatic in terms of scientific debate, but with similar relevance for the invocation of the precautionary principle, are cases relating to a fourth type of circumstance when particular cause-effect relationships cannot be scientifically established while at the same time the adverse effects are known. The withdrawal of the use of particular antibiotics in feeding stuffs as well as the protection of the North Sea from dumping of waste provides us with such examples.

The overview of these four types of circumstances establishes the need to have an assessment of the state of affairs in science and type of uncertainties involved. Drawing the border line, between classical risk management practice and the situation of a purely conjectural risk involves making normative choices which need to be made explicit. But even more importantly, in the case of epistemic uncertainty, a normative relationship between the nature of the uncertainties and the possible adverse effects needs to established in order to justify policy and regulatory intervention. In assessing the uncertainties involved, *normative* qualifiers come into play while invoking the precautionary principle. It does make a difference if the invocation of the precautionary principle needs to be established in relation to the anticipated adverse effects: "reasonable grounds for concern" (EC communication on the precautionary principle, op cit.), the identification of possible harmful effects on health following an assessment of available information (Regulation EC 178/2002, general principles and requirements of food law) or the "balance of evidence"(Intergovernmental Panel for Climate Change 2001) or "sufficient evidence for safety."

However it is difficult to outline precisely the normative constraints of the type of scientific information needed which is "sufficient" to trigger it off. Some argue that there is a "degree of likelihood" associated with those qualifiers[10]. However, it seems misleading that one would be able to assess the "risk" of false positives, for example cases where unnecessary action will be taken on what later will turn out to be fears rather than facts. The uncertainties which are usually involved are precisely related to the impossibility of assigning a degree of likelihood to the anticipated adverse effects. Some of the qualifiers belong, to the vocabulary of risk regulation (such as "sufficient evidence" or "identified" risk) rather than to precautionary practice.

It may be better to relate the normative qualifiers to the *quality* of the available information. This is not determined by the amount or degree of uncertainty but relates especially to what type of information is known or should be known and of which one is ignorant: For example the knowledge concerning established cause-effect relationships and the degree of necessity to know those relationships in order to make a judgement. The qualifier "reasonable grounds for concern" as employed by the EC guidelines makes no prejudice about the degree of likelihood, but this qualifier relates in fact to a judgement on the quality of the available information. Therefore, it may be misleading to situate this qualifier in a scale of possible levels, or degrees of proof. It becomes even more complicated to take the linguistic connotations of suggested "degrees" or "levels" into account. Some may feel that this degree needs to be balanced against the degree of seriousness of anticipated effects. It suggests that a very serious violation of our chosen level of protection would lower our requirements concerning the quality of available scientific information and arguments. This is obviously a particular normative choice which needs to be justified in relation to other possible choices.

10 Poul Harremoës, David Gee, Malcolm MacGarvin, et al. (eds.), *The Precautionary Principle in the Twentieth Century: Late Lessons From Early Warnings* (London: Earthscan Publications, 2002).

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III. The choice of transformable normative standards

Precautionary regulation always implies the regulation of a subject matter on the basis of standards that remain open for discussion, concerning the societal acceptability of particular emissions or products. The regulation itself cannot define these standards. This is a completely new dimension in international environmental policy and not always appreciated, but it can be illustrated by the case of GMOs.

The European directive on GMOs states: "Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs."[11] The directive leaves open what precisely can be considered as an "adverse effect on human health and the environment." The directive also leaves open what could be "a sufficient demonstration of safety," let alone that it requires substantializing the degree of uncertainty which could justify restricted use or a ban of a particular GMO. The combination of a case by case evaluation and the absence of fixed standards for evaluating these cases provide the background for on-going deliberations at national level and in scientific advisory committees.

Without a normative standard, however, it is impossible to draw a valid conclusion on the acceptability of a product or a release. Therefore, risk managers have to make normative assumptions about which products are acceptable or not acceptable. In the case of GMOs, the implicit strategy has been to make an appeal to a conventional norm, that is to say a standard which would be acceptable because one can be certain it is widely accepted and uncontroversial (and would fit to our chosen "high level of protection"). What kind of standard would that be? The Dutch advisory committee on genetic modification (COGEM) made the following statements in the evaluation of the application concerning an herbicide resistant rapeseed: "outcrossing transgenic characteristics will not cause a persistently negative impact on the environment [and] outcrossing the gene and its property male sterility ... will not lead to a persistently unacceptable impact of these relatives on the composition of varieties in natural vegetation"[12].

To draw a conclusion on the acceptability of an impact, one has to use phrases with normative implications such as "negative impact" or "unacceptable impact." In this case, the advisory committee assumed that a conventional standard, and therefore a non-controversial reference point, would be the "natural situation" itself. It is assumed that so long as any impact would be an impact which could be counter-balanced by nature, which would allow nature to return to its original situation, it would be an "acceptable impact". Generally, this conclusion, which at first glance seems quite uncontroversial, implies that any process or impact caused by releases or new agricultural practices would be acceptable if one finds that such a process or impact would be an instance occurring in nature itself. Indeed, advisory committees came to the conclusion that herbicide-resistant genes, for instance, are widespread in the natural environment and that, therefore, a possible spread of these genes caused by man-made varieties would be an acceptable phenomenon, comparable with existing natural processes.

However unproblematic this appeal to a conventional norm seems to be, it soon runs into difficulties when one tries to apply this normative reference point, in diverse cases over time. Our knowledge of nature is far from complete and our perception of nature changes over time while our scientific knowledge grows and our cultural values change. Until several years ago, for example, the general belief was that gene flow is not a natural phenomenon (and therefore unacceptable), but now it has been discovered that it occurs under particular circumstance in nature as well, which would turn it again into an acceptable impact, provided one agrees that what happens in nature is always acceptable. So, further analysis turns our "convention" into a transformable normative standard, which depends on (and evolves synchronically with) the historical change in our perception of nature.

If one analyses the case of GMOs in more detail (see footnote 7), one will find that "reduction of biodiversity" is not the only transformable standard which can be employed while assessing the acceptability of releases. Alternative standards are:

11 Article 4 of European Communities, 2001, 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-Commission Declaration, *Official Journal of the European Communities*, L 106, 17 April 2001.

12 COGEM (Dutch Committee on Genetic Modification) (2004), The Hague: reference nr C/UK/94/M1/1 public register in the library of the Dutch Ministry for the Environment (VROM)

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"Comparison with conventional agricultural practices," that is to say, anything that does not yield an impact substantially different from the impact of existing agricultural practices would account for an "acceptable" release.
"Compatibility with sustainable agricultural practice," that is to say only those releases which could be integrated in a sustainable agricultural practice would account for an "acceptable release."

There seems to be a sort of institutional preference to compare alternatives with current practice. However, before taking current practice as the default norm or benchmark, one needs to evaluate whether future developments do not allow us to get to policies which retrospectively define current practices as insufficient. The "sustainability" requirement inherently links to such discussions.

In the European context, conflicting scientific assessments among scientific advisory bodies can be traced to the normative choice of one those standards and the way in which these standard were applied, whereas they hardly relate to the probability of major environmental impacts. Consensus on such an issue seems a matter of agreeing on the standards to be used. Up until now, precautionary regulation has probably relied too much on an implicit use of such standards. The obvious solution for the problem is to embark on an open discussion on such standards. An undefined high level of protection in combination with a precautionary regulatory framework forces risk managers to look out for standards which are "transformable" by nature in order to make the necessary normative conclusions concerning adverse effects. Analysis of other complex scientific issues, such as climate change, the management of large ecosystems etc. involve always the use of such transformable standards. This is a crucial difference from the context of classical risk management issues under which standards can be pre-defined. In the following section I will have a closer look to the relatively new field of nanotechnologies

IV. Applying the precautionary principle to nanotechnology

Policy development treads a fine line: governments should not make the mistake of responding too early to a technology, and failing to adequately address its nature, or of acting too late, and thereby missing the opportunity to intervene. A good governance approach, then, might be one which allows flexibility in responding to new developments. After a regulatory review in 2008, the European Commission came to the conclusion that there is no immediate need for new legislation on nanotechnology, and that adequate responses can be developed – especially with regard to risk assessment – by adapting existing legislation.

While, in the absence of a clear consensus on definitions, the preparation of new nano-specific measures will be difficult and although there continues to be significant scientific uncertainty on the nature of the risks involved, good governance will have to go beyond policy-making focused on legislative action. The power of governments is arguably limited by their dependence on the insights and cooperation of societal actors when it comes to the governance of new technologies: the development of a code of conduct, then, is one of their few options for intervening in a timely and responsible manner. In the second implementation report on the action plan for Nanotechnologies, the Commission states that "its effective implementation requires an efficient structure and coordination, and regular consultation with the Member States and all stakeholders"[13]. Similarly, legislators are dependent on scientists' proactive involvement in communicating the possible risks of nanomaterials, and must steer clear of any legislative actions which might restrict scientific communication and reporting on risk.

The ideal is a situation in which all the actors involved communicate and collaborate. The philosophy behind the European Commission's code of conduct, then, is precisely to support and promote active and inclusive governance and communication. It assigns responsibilities to actors beyond governments, and promotes these actors' active involvement against the backdrop of a set of basic and widely shared principles of governance and ethics. Through codes of conduct, governments can allocate tasks and roles to all actors involved in technological development, thereby organising collective responsibility for the field[14]. The EC Code of Conduct also views Member States of the

13 European Commission, Communication from the Commission to the Council, the European Parliament and the European Economic Committee: "Nanosciences and Nanotechnologies: An action plan for Europe 2005–2009: Second implementation report 2007–2009", Brussels, 29.10.2009, COM (2009) 607 final.

14 European Commission, "Recommendation of 7 February 2008 on a code of conduct for responsible nanosciences and nanotechnologies research", C(2008) 424.

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European Union as responsible actors, and invites them to use the Code as an instrument to encourage dialogue amongst "policy makers, researchers, industry, ethics committees, civil society organisations and society at large" (recommendation number 8 cited on page 6 of the Commission's recommendation in footnote 15), as well as to share experiences and to review the Code at the European level on a biannual basis.

The responsible development of new technologies must be viewed in its historical context. Some governance principles have been inherited from previous cases: this is particularly notable for the application of the precautionary principle to the field of nanosciences and nanotechnologies which inherits the experience with GMOs.

The principle runs through legislation that is applied to nanotechnologies, for example in the "no data, no market" principle of the REACH directive for chemical substances, or in the pre-market reviews required by the Novel Foods regulation. More generally, within the context of the general principles and requirements of the European food law it is acknowledges that "scientific risk assessment alone cannot provide the full basis for risk management decisions" – leaving open the possibility of risk management decision-making partly based on ethical principles or particular consumer interests. Regulation (EC) no 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety states "it is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls." Therefore it is also important for policy makers to have a good understanding of an ever evolving public debate on nanotechnologies in order to consider options for public policy[15].

In the Code of Conduct, the principle appears in the call for risk assessment before any public funding of research (a strategy currently applied in the 7th Framework Programme for research). Rather than stifling research and innovation, the precautionary principle acts within the Code of Conduct as a focus for action, in that it calls for funding for the development of risk methodologies, the execution of risk research, and the active identification of knowledge gaps. Under the Framework Programme an observatory has been funded to create a network for the communication and monitoring of risk. The European Commission funded the consortium "Nanocap" – featuring deliberation among European NGO's, trade unions and academic researchers which made a number of suggestions regarding further building blocks for a precautionary approach[16]. They argued consistently with the spirit of EU legislation that the "no data, no market" principle should mean in practice: no data, no exposure. Although it may prove to be difficult to establish such a practice, it certainly implies the reduction of the exposure to a minimum and requires mandatory registration of exposure procedures at the workplace as long as serious uncertainties persist. As with the case of GMOs, the principle can only be implemented meaningfully if we have sufficient information from the producers. Therefore the authors call for, among other, mandatory notification of nano-product composition by manufactures and suppliers.

An early example of a precautionary and responsible practice in the field of nanotechnology is provided by the Swiss Federal Office of Public Health and the Swiss Federal Office for the Environment with the introduction of the use of a precautionary matrix for synthetic nanomaterials. This precautionary matrix provides a structured method to assess the "nanospecific precautionary need" of workers, consumers and the environment arising from the production and use of synthetic nanomaterials. The matrix is a tool to help trade and industry meet their obligations of care and self-monitoring. It helps them to recognise applications which may entail risk and to take precautionary measures to protect human health and the environment on the basis of a limited number of evaluation parameters, including size of the particles, their reactivity and stability, their release potential and the amount of particles. The matrix is intended to enable users to conduct an initial analysis on the basis of currently available knowledge and indicates when further investigations are necessary. The ma-

15 René Von Schomberg and Sarah Davies (eds.), *Understanding Public Debate on Nanotechnologies – Options for Framing Public Policy* (Luxembourg: Publication Office of the European Union, 2010).

16 Peter Van Broekhuizen and Astrid Schwarz, "European Trade Union and Environmental NGO Positions in the Debate on Nanotechnologies", in René Von Schomberg and Sarah Davies (eds.), Understanding Public Debate on Nanotechnologies, *supra* note 15, pp. 81–108.

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trix will be continuously adapted and further developed in close cooperation with trade, industry and science as well as with consumer and environmental organisations.

V. Conclusion

Precautionary measures are provisional measures by nature, and need to be regularly reviewed when scientific information either calls for relaxation or strengthening of those measures. Within the EU context, these provisional measures do not have a prefixed expiry date: one can only lift precautionary measures if scientific knowledge has progressed to a point that one would be able to translate former uncertainties in terms of risk and adverse effects to terms of defined, consensual levels of harm and damage.

Precautionary frameworks facilitate in particular deliberation at the science/policy/society interfaces to which risk management is fully connected. Applying the precautionary principle is to be seen as a normative risk management exercise which builds upon scientific risk assessments. It is therefore not imaginable that a proper invocation, implementation and application of the precautionary principle would be based solely on a "perceived" risk. Since the application of the precautionary principle starts with a (yet incomplete) scientific risk assessment, any perceptional element is already initiated with a scientific content. An on-going scientific and normative deliberation at the science/policy interface involves a shift in science-centred debates on the probability of risks towards a science-informed debate on uncertainties and plausible adverse effects: this means that decisions should not only be based on available data but on a broad scientific knowledge base including a variety of scientific disciplines.

The application of transformable standards is an inherently discursive process. On each single case such standards need to be applied over and over again, with possible different outcomes over time. These normative standards reflect and should reflect the chosen aim of a "high level of protection" as enshrined in the EU treaty. In a certain sense, this is also a transformable standard in itself, since what is considered as "high" changes over time and relates to socio-economic circumstances. The impossibility of defining fixed standards and operating with necessary open standards is a positive feature of a regulatory framework in democratic societies. It invites citizens to discuss those standards as they cannot be solely defined by risk managers and scientific advisers. The challenge is to interconnect those standards with the discussions within scientific committees, the risk management level and society at large. Technology assessment and technology foresight exercises can thereby be helpful to feed such a deliberative process. Expertise needs also to be extended with forms of knowledge assessments, to assess the normative quality of the information, in order to identify the meaning of particular uncertainties, the quality of the available knowledge (which includes knowledge beyond the area of science), and their relevance for policy[17].

17 René von Schomberg, Angela Guimarães Pereira and Silvio Funtowicz, "Deliberating Foresight-Knowledge for Policy and Foresight-Knowledge Assessment", European Commission, Directorate General for Research (2005).

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