

# Nanomaterials and the Precautionary Principle in the EU

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**Abstract** This article focuses on the risks of nanomaterials and nanotechnologies, and the challenges they pose to European consumer law. These risks are exemplary for the sociological phenomenon of modern risk society, living under the condition of uncertainty with regard to the likelihood and the extent of possible negative effects. Generally, in law important functions in risk societies are fulfilled by the precautionary principle. It serves both, as a justification for state measures vis-à-vis other legal interests, especially economic human rights, and as a request for state action in response to possible risks. This paper will argue that the precautionary principle applies at least to health protection as a core part of consumer protection and basically EU law is well equipped to deal with uncertainties. This is established in case law and practice. However, although there is pressure to apply the precautionary principle to nanomaterials and nanotechnologies, the European Commission has adopted a rather modest approach. That has been criticized especially by the European Parliament. For dealing with the gap in basic research and methodology, this article suggests a burden sharing in financing taking into account both, the precautionary principle and the principle of proportionality.

**Keywords** Nanomaterials · Consumer protection · European Union · Precautionary principle—Proportionality

## Functions of a Legal Principle of Precaution in Risk Societies

The possible hazards of nanomaterials might serve as a paradigm for the notion of risk society as established in sociology (Beck 1992; Giddens 1999). The term refers to modern industrialized societies being increasingly occupied with manmade risks and hazards, with the new key objective being safety. That seems to be jeopardized less by a lack of wealth

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than by the pervasive effects of risks (Beck 1992). Pre-modern societies have been exposed to risks as well, but these have primarily originated from the forces of nature. In contrast, risk society is faced with mega-dangers or -hazards, created by society itself. Exemplary, in the case of nanomaterials the focus is on the possible hazards of synthetic, i.e. anthropogenic nanomaterials (Merenyi et al. 2007, p. 51). Accordingly, the new differentiation is between producers of risks, e.g., nanotechnology, and people being exposed to these risks, working with or consuming nanomaterials. The latter group does not follow the traditional wealth- and strata-lines in society. That becomes apparent in the wide-spread field of application for nanomaterials which turns all people into possible consumers exposed to any probable inherent risk (Allianz and OECD 2005, p. 14; SCENIHR 2005, p. 12).

Modern risk society is characterized by uncertainty: risks are contested; experts are struggling over their evaluation and assessment (Beck 1992). So, knowledge becomes a major concern. Furthermore, not only due to this lack of certainty responsibilities become obscured. The hazards can be neither attributable nor accountable or even manageable within society, e.g., nuclear or genetic risks leading to an “organized irresponsibility” (Strydom 2002, p. 59). In response to these challenges, societies turn to concepts of reflection, debating the management of risks on the institutional and personal level. There is a shift in the tasks of societies from producing (more) goods to minimizing “bads.” In law, this task is translated into the principle of precaution, requesting the state to avoid hazards or at least minimize possible risks. In this course, it calls and allows for state action even in times of considerable uncertainty. In a condensed form, the precautionary principle serves two main functions in risk society: the first is a programmatic mandate to protect, not only the environment, but the consumer as well, before risks materialize, as in the case of nanomaterials. The second function is to allow the state to strike a balance between the tasks of helping to produce wealth and to prevent hazards even under conditions of uncertainty. Since in Western societies the pursuit of wealth in a legal sense is backed up especially by economic human rights, the state has to justify any interference with these in the course of preventing hazards. The process of balancing the conflicting interests is governed by the principle of proportionality and in the case of uncertainty, the economic human rights affected might outweigh safety interests. In this situation, the precautionary principle backs up the call for state action in the absence of scientific certainty.

## Potential Risks of Nanomaterials

### Size Matters

The usage of the notion of nanomaterials spreads, not only in scientific literature, but also in policy statements and not least in advertising products with new and sometimes amazing properties. However, for ages nanomaterials have appeared in nature with hardly anyone bothering about their possible risks and without taking up a stance on precautionary measures (the focus clearly is on manmade nanomaterials (nanomaterials, see RCEP 2008, p. 77; SCENIHR 2005, p. 9; SCENIHR 2008, pp. 16–20). It is rather the success of modern nanotechnology that has triggered concerns about it. Often, the new properties of nanomaterials are due to their bigger surfaces, created by surface sciences and engineering. Thus, they offer promising applications in a broad range of consumer products, including foodstuffs, dyes, fillers, paints, colloids and emulsions, cosmetics and sunscreens, as well as fibres, textiles, and not least medicinal products (Allianz and OECD 2005, pp. 14–15; SCENIHR 2005, p. 12).

However, these properties are only to appear on a certain scale. That is reflected in the debate on the definition of nanomaterials. According to the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR 2005, p. 5) a nanomaterial is a “material with one or more external dimensions, or an internal structure, which could exhibit novel characteristics compared to the same material without nanoscale features.” In this definition, the focus is on new characteristics as it is in the application of nanotechnology. However, from that viewpoint not all materials on the nanodimension come into sight. This becomes even more apparent if the definition is restricted to synthetic, i.e. anthropogenic nanomaterials (Merenyi et al. 2007, p. 51).

Similarly, nanoscale as part of the definition is not restricted to nanometers only but defined by “having one or more dimensions of the order of 100 nm or less” (see Merenyi et al. 2007, p. 51; SCENIHR 2005, p. 9). Under this broad approach—as opposed to limitations of 1–30 nm for instance—all materials which are likely to exhibit new characteristics are covered (compare the approaches to particles that talk about “ultrafine particles,” SCENIHR 2005, p. 5f.). It is true that even on the nanoscale, new properties of substances differ according to their size (Umweltbundesamt 2009, pp. 9–10), but not least due to the specific ratio of surface area to volume the characteristics of properties change significantly in the range of 100 nm or less. For a legal definition, which does not circumvent potential problems of discriminations by eliminating aspects due to a narrow definition, all materials with dimensions on that broad definition of nanoscale should be included.

### Different Levels of Uncertainty

Exploiting nanomaterials is interesting not only from an economic point of view, but because it may open new possibilities in the common interest, such as environmental protection (RCEP 2008, pp. 31–32; Umweltbundesamt 2009, pp. 15–16) or health care (Allianz and OECD 2005, pp. 15–17), which might outweigh potential risks in particular cases. At the same time, the new properties might be dangerous and especially more dangerous than the characteristics of the substances concerned on the conventional scale. While knowledge of the possible advantages is promoted due to industry’s efforts in applied research, the gap in fundamental research on potential risks grows in significance (EP 2009, recitals A, D, F, and L; Umweltbundesamt 2009, pp. 14–24). So uncertainty, some even say ignorance (RCEP 2008), pp. 76–77) about the risks remains.

Uncertainty is to be found in every phase of the life cycle of nanomaterials: their production, supply, manufacturing, wholesale and retail, commercial and industrial use, consumer use, and finally their disposal. Although consumers might be excessively exposed to nanomaterials in terms of time, they seem by and large to be unaware of potential risks, while workers’ unions call for precautionary measures in the working environment (ETUC 2008, see also Allianz and OECD 2005, p. 43, Swiss Re 2004, pp. 33–35).

In many ways, the risks linked to nanomaterials are paradigmatic for risk societies. This especially holds true for their ability to pass the blood-brain barrier as well as the blood-lungs barrier (Führ et al. 2006, p. 45; RCEP 2008, pp. 32–53; SCENIHR 2009, pp. 23–44; Umweltbundesamt 2006, pp. 14–15; Umweltbundesamt 2009, pp. 9–19; references to further studies by Kingdollar 2005, p. 12). Hence, the question of accumulative effects gathers a new dimension. Under certain circumstances, evidence of nanomaterials affecting the DNS structure has been reported (Umweltbundesamt 2009, p. 9). The possible risks are not limited in time and space. Evidence has been presented for nanomaterials passing the blood-lung- as well as the blood-brain-barriers in animals (Umweltbundesamt 2009, p. 9).

Therefore, uncertainty is not only to be found with regard to long-term effects, but to short-term effects as well. Ubiquitous risks—esp. from emissions of nanomaterials or their discharge into the water (Umweltbundesamt 2009, pp. 10–11)—cannot easily be matched by analyzing only the exposure of limited items to them. After all, nowadays it is common knowledge that a specific methodology has to be developed in order to assess and evaluate risks of nanomaterials in an appropriate manner (EP 2009, no. 19; European Commission 2008d, p. 12; Umweltbundesamt 2009, p. 13). The quest for a specific nanotoxicology has started.

Furthermore, the risks of nanomaterials escape immediate perception. They might be catastrophic due to their specific properties. And their effects will be global, not only following the international flow of merchandise streams. Since they are not visible, and therefore neither localized nor easily containable, they pose specific challenges to risk assessment, evaluation, and management in a society at risk.

Often, the possible risks are compared to the situation of asbestos in the 1980s. While some point to similarities (Umweltbundesamt 2009, p. 9), others point to differences in the characteristics of the materials (Swiss Re 2004 no. 7.1, p. 42). Up to now, some negative short-term effects have been scientifically established in certain cases. Still, as with asbestos, long-term effects seem to be possible. One is especially concerned about free engineered nanomaterials not bound in another structure. The ability to cross borders formerly regarded as impenetrable makes nanomaterials even more capable of possible detrimental effects than asbestos.

While for the time being, the word “nano” offers a connotation of positive effects, this might well change as it has been the case for genetically modified organisms in several EU-countries. This could lead to a situation in which societies become increasingly reluctant to accept even a minor residual risk.

### Challenges to Law

While risks of nanomaterials are hardly attributable to particular producers, traditional methods of legal accountability, especially for consumer protection, are likely to fail. For instance, an aftercare by liability seems not to be sufficient (see Tomasco 2006, p. 244). Thus, notwithstanding different legal traditions for risk prevention in the Anglo-American system on the one hand and the continental European regulatory systems on the other hand, the focus is on precaution (see for the US, US EPA 2007, pp. 63–69, and Lin 2007, pp. 361–374; for the UK, RCEP 2008, pp. 56–75) and adequate risk management. In the past, regulators have had the chance to learn some lessons in cases such as asbestos, acid rain, and GMOs. Although they do have some similarities, nanomaterials show specific new properties. So the challenge to law is not a completely new one, but a rather specific one.

The legal instruments traditionally applied for risk assessment, evaluation, and management are, i.e. information requirements, procedural provisions and rules of labelling, authorization, or even restriction. They are employed especially in the EU laws on chemical substances, pesticides, and biocides (Umweltbundesamt 2009, p. 11–12). But since the regulatory frame in these areas is set with reference to substances without differentiating between nano- and non-nano-scale, severe lacunae might be found in risk management. In order to close those gaps, it is necessary to turn to the precautionary principle and argue for an interpretation of the relevant provisions in the light thereof. Therefore, it is necessary to analyse the contents of the precautionary principle and its application in the case of nanomaterials.

## Basic Legal Elements of the Precautionary Principle

### Different Concepts in EU-Member States

At least in environmental law one might well say that the precautionary principle is recognized in all EU Member States. However, differences can be detected if one asks not only for its binding nature but for its function and significance. These reflect cultural diversity in risk societies at the European level. Legal cultures vary not only across Europe in their understanding of risks (Groves et al. 2008, p. 7; for an anthropologists view see Douglas and Wildavsky 1982; see also Mythen 2004). Some people are not only more sceptic about potential risks, but are more scrupulous about the positive effects in ethical terms. The different approaches in EU Member states to the release of GMOs (Heselhaus 2009, p. 210) are notorious. In respect of nanomaterials, it raises the question of a specific “nano-ethic.” For instance, these differences in legal culture have led to different interpretations of the notions of “prevention” and “precaution” in EU environmental law (see Epiney 2005, p. 101), i.e. whether they are identical or refer to different grades of risk.

In Germany with its well elaborated legal system of protecting human rights, especially under the freedoms of property and profession, a broad interpretation of the precautionary principle serves as a tool to allow for the justification of state action aimed at preventing any risks while interfering with the professed human rights of the individual. Not unexpectedly, the EU jurisprudence has turned to the precautionary principle in justifying interferences of Member States’ actions with the EC fundamental freedoms or national provisions departing from harmonization through safeguard clauses, such as enshrined in Art. 95 para. 4–9 and Art. 176 ECT (Alemanno 2007, pp. 11–24).

Basically, the principle of precaution can be narrowed down by differentiating three categories of hazards. In the first, just short of damages, traditional police laws deal with threats to common goods or individual rights. These lead to an obligation of the state to react, to prevent harm or damages (Calliess 2001, pp. 154–158; Reh binder 2007, para. 25–27).

In the second category, below that threshold, an area can be identified in which the possibility of harm or damages is not unlikely. However, it does not yet amount to a threat. This could be due, i.e. to time or to a lack of certainty. But if the possible occurrence of harm and damages is unlikely to be prevented at a later stage, the state might be obliged or at least allowed to take preventive action already in advance. In Germany, this area is described as “risk” and the actions applied may be based on the precautionary principle (Calliess 2001, pp. 162–169; Reh binder 2007, para. 28). In comparison, EU law rather uses “risk” as the overall generic term (Reh binder 2007, para. 20) and would deal with the German understanding of “risk” under the heading of “hazard.” Because harm is not imminent in that area and is uncertain, the interference by respective state measures with economic human rights affected might outweigh the objective of protecting health and the environment, thus failing the traditional test of proportionality. But backed up by a constitutional principle of precaution (for this interpretation see Heselhaus 2007, para. 48), the common interest might outweigh individual economic interests even if lacking overwhelming scientific certainty.

Some legal commentators suggest a third category, a threshold below which the so-called residual risk is placed (Calliess 2001, p. 164). It describes the grade of risk accepted by society and thus not calling for any preventive action. The notion gained great significance in nuclear energy law, showing that the accepted nuclear risk might well go beyond the general risks of life. In life sciences it is doubtful whether a “zero risk” really

exists. In law, an area not calling for preventive action could be due to different reasons: There might be a lack of a “risk” in legal terms, but it could well be that an existing risk would have to be accepted as the result of applying the test of proportionality.

Under the precautionary principle there is a broad range of instruments to be applied. According to German laws it may even lead to a shift in the burden of proof, so that it would not be the interfering state that would have to produce enough evidence for a risk to be prevented, but the person causing that risk (Calliess 2001, pp. 232–235; Rehbinder 2007, para. 69). That is of specific interest in the case of nanomaterials, since a major question is who has to finance the necessary fundamental toxicological research. Here, the precautionary principle shows links to the polluter pays-principle in environmental law.

### Binding Character and Elements of the Precautionary Principle in EU Law

Art. 174 para. 1 Treaty on the European Community (ECT) enshrines the environmental objectives of the EC including not only the preservation of nature, but also the protection of human health. Para. 2 of that provision adds the principles governing EC environmental policy, especially the precautionary principle (Epiney 2005, p. 101). Their legally binding nature has been established by the European Court of Justice.<sup>1</sup> Hence, any disregard of these principles can be challenged before the European Courts in the frame of an admissible action. Clearly, the principles are rather abstract and need to be implemented by the legislator. However, they are important governance tools as they put a legal pressure on the legislator not to stay inactive in the face of environmental problems. At the same time, they legitimize environmental actions which might interfere with other principles or rights (Calliess 2007, para. 46). So with regard to risks by nanomaterials the principles require the EC to react and not to be satisfied with monitoring the development. Moreover, the environmental principles influence the interpretation not only of secondary legislation, i.e. preparing existing legal acts to deal with the challenges of nanomaterials, but also of EC primary law, thus providing a leeway for Member States to react to these challenges in the absence of EC measures (esp. under the fundamental freedoms).

When introducing the chapter on environmental policy to the EC-Treaty in 1985, in a literal sense it was not the principle of precaution that was included, but the principle of prevention. As the wording suggests, both focus on combating environmental problems at an early stage and not waiting for damages to occur. Legal commentators struggled over whether or not the principle of prevention should be interpreted in the wide sense as in German environmental law, which was already coming into use in cases of uncertainty about possible damages (Rehbinder 2007, para. 66–69). This question was solved in a pragmatic way in the Maastricht-Treaty by adding the principle of precaution to the EU-Treaty (Art. 174 para. 2 ECT). Now, one might differentiate between both principles in referring to different grades of risks. However, in practice both principles are invoked together with the clear ambition of administering early upstream actions.<sup>2</sup> So basically, even in times of uncertainty about the real risks of nanomaterials, the precautionary principle requires the EC organs to act in order to avoid or minimize possible risks.

The principles of prevention and precaution are accompanied by the polluter pays principle and the principle that environmental damages should be rectified at source (Art.

<sup>1</sup> ECJ, case C-284/95 Safety Hi-Tech [1998] ECR I-4301 (para. 36); ECJ, case C-9/00 Palin Granit Oy [2002] ECR I-3533 (para. 23).

<sup>2</sup> See ECJ, cases C-175, 177/98 Lirussi [1999] ECR I-6881 (para. 51); ECJ, case C-504/04 Agrarproduktion Staebelow [2006] ECR I-679 (para. 39).

174 para. 2 ECT). Obviously, the latter adds some more precise elements in relation to possible environmental damages and costs. However, since implementing them will always have some preventive effect as well, in some areas the principles might overlap with each other. Some regard the precautionary principle as the leading environmental principle (Rehbinder 2007, para. 17), as it is the only one that could introduce the necessary elements into EC policies in respect of the objective of sustainable development, as enshrined in Art. 6 ECT, that calls for the integration of environmental protection requirements in the definition and implementation of Community policies and activities. However, it is uncontested, that in cases of conflicts between the different environmental principles there is no legal hierarchy giving precedence to the precautionary principle (Epiney 2005, pp. 114–118). So, with regard to financing basic research in nanotoxicology, it is unclear, whether the polluter pays-principle could be applied in placing the burden on industry unless it is established that using and/or producing nanomaterials leads to pollution. So the question arises, whether the precautionary principle could fill in that gap.

Since there is no legal definition of the precautionary principle in EC law despite a basic common understanding in some respects, certain aspects of its content remain unclear. It does not give precise information about the level of precaution to be established and it offers a wide margin of discretion to the legislator. Notwithstanding this discretion, it undoubtedly calls for procedural requirements in order to ensure that there is no inaction in the face of environmental risks. Thus, typical for the standards of risk societies as sketched out in sociological sciences, it calls for taking into account the possible effects of nanotechnology already in the definition of EC policies (see Art. 6 ECT). This procedural requirement is designed to back up environmental aspects of the process of policy formulation as opposed to (and often suppressed by) economic interests. However, Art. 174 ECT does not call for a one-sided formulation of EC environmental policy, but requires taking the possible economic effects into account at an early stage (Art. 174 para. 3 ECT). This could be regarded as part of the quest for sustainable development, making the balancing of interests more transparent. Since the principle of proportionality requires estimating the effects on individuals, Art. 174 ECT adds the effects on the regional level and on the Community as a whole to that process. So clearly, the promising market for nanomaterials and its possible contribution to wealth should not be precluded completely by setting up EC environmental policies.<sup>3</sup>

With regard to nanomaterials, the question arises whether in EC law the precautionary principle is limited to the area of environmental policy, i.e. effects on the environment, or might it call for an assessment of effects on the consumer as well.

### Serving Consumer Protection?

In the EC-Treaty the precautionary principle is mentioned explicitly only in the EC environmental policy (Art. 174-176 ECT). Albeit some are prepared to accept it as a general legal principle of EC law (see Alemanno 2007, pp. 5-6; de Sadeleer 2006, p. 139). This would correspond to the pleading of the EU before the panel and appellate body of the WTO referring to the precautionary principle as part of customary international law.<sup>4</sup>

<sup>3</sup> For such an approach EC (2004, p. 3) and EC (2008a, b, c, d, Code of Conduct, p. 2, 3. Recital), for the opposite view see EP (2009, resolution 2008/2208, AA).

<sup>4</sup> See Appellate Body of the WTO, EC Measures Concerning Met and meat products (Hormones), 16 January 2008, WT/DS26/AB/R.

Usually reference is made to the European Courts invoking the precautionary principle in various cases.

In the so-called BSE cases concerning the Common Agricultural Policy, the ECJ has established a formula, which has been recognized as the general definition of the precautionary principle although the Court did not explicitly name it.<sup>5</sup> The Court relied on Art. 174 para. 1 TEC, which includes “human health” as part of the description of the notion “environment.” And indeed, one might say that harm to the environment is of a very high concern if it results in harm to human health. The Court went on to spread the objective of health protection to other EC policies by referring to the clause of integrating the aspects of environmental protection into the definition and implementation of all other Community policies (Art. 6 ECT). So the focus in the field of consumer protection cases has been on “human health,” which although it is a major concern, is not the only concern of consumer protection.

It was the Court of First Instance that explicitly referred to the precautionary principle as a general principle of EC law.<sup>6</sup> It did so in a case on medicinal products connecting the principle to a high level of protection of health, safety of consumers and of the environment.<sup>7</sup> Furthermore, it relied on the provisions for the protection of consumers (Art. 153 ECT) and the environment (Art. 174 ECT), adding the so-called integration clauses in both respects (Art. 153 and Art. 6 ECT). In conformity with the ECJ, it reached the conclusion, that the treaty gives these objectives precedence over economic interests.<sup>8</sup> However, that does not foreclose balancing the colliding interests according to the principle of proportionality.<sup>9</sup>

Commenting on this development, one has to establish, that in jurisprudence the precautionary principle is not linked to any common interest, but to the objectives of health and environmental protection. So when talking about its “general” application, that does not mean linking it to the protection of any common good, but making sure that—in this rather narrow understanding—it is “generally” respected in all EC policies.

However, one might well detect traces of precaution in other policy areas as well. With regard to the fundamental freedoms of the EC-Treaty, the so-called *Dassonville* formula pays attention to mere “potential” detrimental transboundary effects on the internal market.<sup>10</sup> That could be interpreted as a policy of precaution regarding interferences with the internal market. But the deeper sense of the aforementioned case-law on the precautionary principle is to secure an efficient protection for otherwise more vulnerable common goods. These are listed in the Charter of Fundamental Rights: protection of health (Art. 35 CFR), of the environment (Art. 37 CFR) as well as of the consumer (Art. 38 CFR). Obviously, all three—although not human rights in the traditional sense—have been regarded as deserving specific protection. One of their similarities is that they are protecting diffuse interests which individuals might not always be ready to present before the courts. This seems to have influenced the European Courts in granting them basically “precedence” over economic interests. In balancing these conflicting interests in specific cases, consumer interests are likely to outweigh economic interests when negative effects on human health are at stake. That does not exclude precautionary measures for consumer protection in other

<sup>5</sup> ECJ, case C-180/96 United Kingdom/Commission [1996] ECR I-3903 (para. 99).

<sup>6</sup> CFT, cases T-74, 76 and 141/00 *Artegoda*n [2002] ECR II-4945 (para. 184).

<sup>7</sup> CFT, cases T-74, 76 and 141/00 *Artegoda*n [2002] ECR II-4945 ( para. 183).

<sup>8</sup> CFT, joint cases T-74, 76 and 141/00 *Artegoda*n [2002] ECR II-4945 (para. 184).

<sup>9</sup> ECJ, case C-236/01, *Monsanto Agricoltura Italia/ Presidenza del Consiglio dei Ministri* [2003] ECR I-8105 (para.128).

<sup>10</sup> ECJ, case 8/74 *Procureur du Roi v Benoît and Gustave Dassonville* [1974] ECR 837 (para. 5).



situations if the effects on industry are to be regarded as proportionate. So, the call for appropriate labelling, informing the consumer about the use of nanomaterials in a certain product (compare European Parliament 2009, no. 17), could well be supported by the principle of precaution. Although under the economic fundamental freedoms the EC-Courts rely on a concept of the circumspect consumer, placing the responsibility for precaution to a large extent on the consumer himself,<sup>11</sup> they would in all likelihood back up calls for labelling products (Umweltbundesamt 2009, p. 20) with regard to the content of nanomaterials.

## Unfolding the Concept of Precaution in EU Law

### Differentiations in Secondary Legislation?

Notwithstanding the precautionary principle covering environmental policy as well as (parts of) consumer protection, especially in food safety cases, some believe there are differences in the application of the precautionary principle in each area. They try to draw evidence to show that these areas are “far from [...] similar” from “the fact” that the EC lawmaker has cited the principle more often in the area of health protection in EC-food law than in EC environmental law (de Sadeleer 2006, p. 172). Furthermore, the Courts are said to apply different approaches to the precautionary principle when safeguarding public health as compared to “genuine environmental cases” (de Sadeleer 2006, p. 172). As a reason for this, a different role of scientific knowledge in both areas is claimed (de Sadeleer 2006, p. 140). So it is argued that the relevance of the case law relating to health safety for the legal management of environmental issues is rather doubtful (de Sadeleer 2006, p. 172).

This view has to be challenged. First, it is simply not true that the precautionary principle is not cited in EC secondary legislation on environmental law. For instance, the REACH-regulation not only refers to the principle in its recitals<sup>12</sup> but also states, that “its provisions are underpinned by the precautionary principle.”<sup>13</sup> However, even if in numbers the references in food law were more than in environmental law the reason would be quite clear. Since the precautionary principle in primary law is explicitly found only in the environmental policy and the jurisprudence expanding that principle to the area of health protection is rather young, in the latter area the EC legislator has much more reason to ensure the application of the precautionary principle by explicit references.

Furthermore, that the significance of scientific knowledge is basically different in both policy areas is questionable. A counter-example proving that scientific knowledge in health and food safety cases is not “far more advanced” (for the opposite view see de Sadeleer 2006, p. 140) than in the field of environmental protection is just a case of nanomaterials which can be released to the environment as well as used in food. And uncertainties about their impact on human health resulting from consumption are no less important than those resulting from environmental pollution (for the opposite view, see de Sadeleer 2006, p. 140). It is simply, that in the case of food laws it is mostly hazards to human health are at stake and not other consumer interests.

<sup>11</sup> See the quality of informed consumers referred to in ECJ, case 178/84, Commission/Germany (German purity law for beer) [1987] ECR 1227 (para. 35).

<sup>12</sup> Recital 9 and 69 Regulation EC No. 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ 2006 L 396, p. 1.

<sup>13</sup> Art. 1 para. 3 REACH regulation (see FN 12). That is disregarded by de Sadeleer (2006, p. 172) when explicitly alleging that REACH would not “encapsulate the principle.”

These similarities are obscured when comparing consumer health protection and so-called genuine environmental laws. On the one hand, health protection is only a part of consumer protection policy, but it is a very important one that is likely to prevail over economic interests in the necessary test of proportionality. On the other hand, a restriction of environmental policy to “genuine” laws (a contestable notion) disregards the fact that environmental policy not only deals with indirect effects on human health, but in severe cases with imminent dangers to human health as well. So, a comprehensive analysis suggests that there are not different types of the precautionary principle but different results when the measures required by precaution have to meet the test of proportionality.

Further, the similarities of applying the precautionary principle are reflected in EC secondary law concerning novel foods and the deliberate release of GMOs. In both cases, the procedure for risk assessment and evaluation, implementing the precautionary principle, refers to the comitology-procedure. Generally speaking, risk assessment starts with a scientific assessment by the competent EC authority. Then, the matter is referred to the competent committee, trying to get a unanimous decision by experts from Member States and the Commission. This is a classic example of shifting risk decisions from the political authorities to the presumed technical staff of the administration. And it is applied in both policy areas, consumer and environmental protection.

Moreover the growing concern in Member States about GMOs has shown the shortcomings of this approach. As a growing number of Member States wants to prohibit the use of GMOs, the competent committees are blocked from reaching consensus. Thus according to the procedural rules, the GMO-matter is referred to the Council only to be blocked by the same coalitions. In the end, the decision falls back to the Commission, either to take the political blame or to permit a de-facto moratorium, thus giving rise to possible WTO disputes. Lately, the Commission has sent a sensitive matter back to the scientific agency to do further research.<sup>14</sup> If the level of protection and of risk acceptable to society in a certain area becomes a contested political question, the comitology procedure seems to be more and more inadequate.

So with significant basic similarities, differences in the approaches by the European Courts may be due to the specific procedural situation. Many food safety cases have arisen in areas not yet harmonized, leading to a strict scrutiny by the Courts under the fundamental freedoms in primary EC law, while some environmental cases deal with secondary legislation, i.e. interpreting their provisions in the light of the precautionary principle. Only the first situation, eliminating possible protectionist measures, is of major concern, because in the second situation the Courts deal with actions of EC organs, which are less likely to turn to protectionism than a single Member State (compare de Sadeleer 2006, p. 140).<sup>15</sup> Additionally, in areas already harmonized, prerogative should be given to the approach chosen by the democratic EC legislator in applying the precautionary principle. Consequently, in this situation, the ECJ does not apply a very strict test of scrutiny but refers to the complexity of a policy area and the discretion offered to the legislator.<sup>16</sup>

<sup>14</sup> For the conflict between the European Commission and some Member States see Heselhaus (2009, pp. 210–211).

<sup>15</sup> However, there are environmental cases dealing with the fundamental freedoms in the non-harmonized areas as well. This is evidenced by the rulings in ECJ, case C-67/97 *Bluhme* [1998] ECR I-8033 (para.15–38), however, just cited by de Sadeleer (2006 p. 145), as an example for a judgement departing from “obligations laid down in secondary law.”

<sup>16</sup> ECJ, case C-280/93 *Germany/Council* [1994], ECR I-4973 (para. 89).

## Establishing a Test of Precaution in Jurisprudence

In the 1980s, the ECJ was called to decide upon the justification of Member States' measures under the (economic) fundamental freedoms in a situation of scientific uncertainty. Without explicit reference to the precautionary principle, the Court declared, that it is "for the Member States in the absence of full harmonization, to decide what degree of protection of the health and life of humans they intend to assure..."<sup>17</sup> In the BSE-judgements in the 1990s the Court had the opportunity to further elaborate on the underlying question of precautionary measures and developed a formula that can be considered as the general definition of the precautionary principle: "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."<sup>18</sup> This definition clarifies that the uncertainty might include the extent as well as the existence of an alleged risk. Furthermore, the ECJ was satisfied with the finding, that the Commission's measure was not "manifestly inappropriate" and referred to "the seriousness of the risk and the urgency of the situation." In later cases the CFI and the ECJ expressly referred to the precautionary principle or the "principle of preventive action."<sup>19</sup>

It was for the EFTA-Court to further elaborate the principle in the famous Kellogg case. This case concerned a provision of the EEA-Agreement, similar to Art. 28, 30 TEC on the free movement of goods. In line with the case law, the Court granted the Member States a wide margin of discretion. However, this is delimited by the principle of proportionality as a prerequisite for justifying an interference with a fundamental freedom. With reference to uncertainty, the Court held, that "measures taken... must be based on scientific evidence."<sup>20</sup> Furthermore, a comprehensive risk assessment has to be carried out. In order to exclude any protectionism, the Court stated that the measures must be "non-discriminatory, transparent, and consistent with similar measures already taken."<sup>21</sup> The Member State, Norway, lost that case because of lack of risk assessment and of inconsistency, since it allowed the contested ingredients in other foodstuffs.

In the well-known Pfizer-case, the CFI clarified that: "[...] a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified [...]. Rather, it follows from the community Court's interpretation of the precautionary principle that a preventive action may be taken only if the risk, despite the reality and extent not having been "fully" demonstrated by conclusive scientific evidence, nevertheless appears to be adequately backed up by scientific data available at the time when the measure was taken."<sup>22</sup>

The ECJ built on this when describing the whole process required by the precautionary principle: "a proper application of the precautionary principle presupposes, in the first place, the identification of the potentially negative consequences for health [...] and, secondly, a comprehensive assessment of the risk to health based on most reliable scientific

<sup>17</sup> ECJ, case 174/82 Sandoz BV [1983] ECR 2445 (para. 16).

<sup>18</sup> ECJ, case C-180/96 UK/Commission [1998] ECR I-3903 (para. 99).

<sup>19</sup> ECJ, joined cases C-175 and 177/98 Lirussi and Bizzaro [1999] ECR I-5291 (para. 51-52); CFI, case T-199/96 Bergadern and Goupil/Commission [1998], ECR II-2805 (para.66).

<sup>20</sup> EFTA Court of 5 April 2001, case E-3/00 EFTA Surveillance Authority/Norway [2001] EFTA Court Report 2000/20001, p. 73 (para. 26).

<sup>21</sup> EFTA Court (FN 20) p. 73 (para. 26).

<sup>22</sup> CFI, case T-13/99 Pfizer/Council [2002] ECR II-3305 (para. 143-144).

data available and the most recent results of international research.”<sup>23</sup> This has to be followed by the risk management phase wherein the appropriate measures to be taken must be decided upon. After such an assessment, “when it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures.”<sup>24</sup>

To sum it up, the jurisprudence has established a two-step-approach starting with a risk assessment as the basis for further risk management. In the first phase, the focus is on the risks for human health, etc. Firstly, possible risks have to be identified. Secondly, they have to be assessed, i.e. there must be a detailed analysis of possible detrimental effects in the case at hand. Previously, this phase was regarded as being apolitical, i.e. governed by objective scientific evidence. However, with experts differing in their analysis, this has become a contested area where majority views are confronted by minority views and even the methodology to be applied might be debatable. This is especially the case for the relationship between the possible risk and the possible harm of nanomaterials. So with uncertainty infecting even the first phase, authors convincingly plead for applying the precautionary principle there as well (de Sadeleer 2006, p. 148). This is objected to by the Commission. In its view this first phase should be governed by a prudential approach to be differentiated from precaution. Both aspects are regarded to be complementary but are claimed to be different (European Commission 2000, p. 13). Surely, the Commission has a point in not giving up the quest for certainty at an early stage. However, with gaps in the methodology, as in “nanotoxicology,” any approach has to be based on some kind of uncertainty unless reliable data is established. This is proven by prudential aspects listed by the Commission (European Commission 2000, p. 15): i.e. “adopting a safety factor in evaluating an acceptable daily intake to account for intra- and inter-species variability; the magnitude of this factor depends on the degree of uncertainty of the available data,” “adopting the “ALARA” (as low as reasonable achievable) level as a basis for certain toxic containments.” Here prudence equals precaution. In this spirit, the line of the ECJ could be read as stating that the precautionary principle is an integral part of the decision-making process (for a different reading, see de Sadeleer 2006 p. 148).<sup>25</sup> This is backed up by the European Courts giving a considerable leeway to Member States’ authorities if the three preconditions of insufficiency, inconclusiveness, or imprecision are fulfilled.<sup>26</sup>

Although the details of these three elements are not yet clarified by the Courts one can give a vast outline of their meanings. Results are insufficient when scientific disciplines involved are not sufficiently well-elaborated enough to explain the cause-and-effect relationship (de Sadeleer 2006, p. 156). For instance, the novel characteristics of nanomaterials call for a specific nanotoxicology, a specific methodology. Conclusiveness asks for a broad approach, taking into account whatever might affect the quality of investigations and not setting unpredictable variables aside (de Sadeleer 2006, p. 156). Often, this is not fulfilled with respect to long term effects. Finally, imprecision could be due to data being unavailable, being out of date, or having information gaps, as—again—is the case with nanomaterials. However, establishment of these criteria in itself is open to

<sup>23</sup> ECJ, case C-192/01 Commission/Denmark [2003] ECR I-9693 (para. 51).

<sup>24</sup> ECJ, case C-192/01 Commission/Denmark [2003] ECR I-9693 (para. 52).

<sup>25</sup> ECJ, case C-236/01 (FN 9) (para. 133).

<sup>26</sup> ECJ, case C-192/01 (FN 24) (para. 52).

interpretation, i.e. an assessment. So, the first step of the risk evaluation shows some aspects of a political task as well.

In contrast, the second phase, the risk management, obviously requires political decisions to determine the measures to be taken. This phase starts off with the precautionary principle with a view to avoiding possible risks. But it is accompanied by the principle of proportionality, taking into account the effects on other areas, e.g. economic rights and interests. This can be illustrated by referring to the established three steps of the test of proportionality. First, when defining a measure appropriate for reaching the proposed safety objectives, one does not look at other effects. But already the second step, choosing the measures with the least interference with the rights of others or public interests, requires one to open up that area of focus. Even more so in the third step, when comparing the positive effects on safety to the negative effects on others and attempting to strike a balance.

In literature, some questions are raised concerning the limits of the frame of risk management. Is there a minimum threshold, below which no action is required, i.e. the risk accepted by society? Is zero tolerance a possible political option, eliminating any possible risk? And could a duty to react arise? It is short-sighted to connect these questions only to the precautionary principle (de Sadeleer 2006, p. 160–165), because the answer includes reference to the principle of proportionality as well. Of course, a duty to react cannot arise in the absence of any possible risk. However, only an overwhelming threat or an overwhelming possible damage could narrow the margin of appreciation normally offered to the democratic legislator. Likewise, a policy of zero-tolerance requires that any possible risk would be precluded. However, these risks would have to be important enough to justify respective restriction on others. When asking for the threshold of risks accepted by society, i.e. risks not calling for any preventive action, in theory we deal with a very political question which should be answered at the beginning of the risk evaluation and is governed by the precautionary principle as well. In the terms of the Commission, the question is “the political decision to act or not to act as such” (European Commission 2000, p. 13). But in practice, the political organs as well as the administration, when called upon to decide on action, refrain from such an overall approach and prefer decision making in a pragmatic way on a case by case basis. Hence, they can avoid unnecessary political debates if there is a large agreement in the specific case at hand.

### The General Approach of the Commission to the Precautionary Principle

In 2000, the Commission issued a communication on the precautionary principle (European Commission 2000), relying mostly on the case law so far, but adding some new elements. The objective of the communication included an internal and an external aspect. On the one hand, in focussing on proportionality and non-discrimination it aimed at giving guidelines to Member States when restricting the flow of goods in the internal market. On the other hand, it sought to establish a consistent approach of the EU when invoking the principle of precaution before WTO-panels (European Commission 2000, pp. 11–13, 18–22).

Basically the Commission accepts the approach developed in jurisprudence, but adds as a third element a specific executive tool: the risk communication, which should include all stakeholders (European Commission 2000, p. 3). In sociological terms, this is an instrument to draw legitimacy to the “eminently political” decisions (European Commission 2000, p. 4) to be taken by the Commission or other administrative authorities in the process of risk evaluation.

Surprisingly, it is stated that the first “general principle of application” should be “proportionality” (European Commission 2000, p. 18). The Commission wants to refer to it

as an integral part of the precautionary principle, but clearly fails to do so, when stating that “the desired level of protection [...] must not aim at zero risk” (European Commission 2000, p. 18). Explicitly, it is looking for “less restrictive alternatives” (European Commission 2000, p. 18), thus taking into account opposing interests which are to be balanced under the test of proportionality. The risk management may lead to a total ban of products, processes, etc., or to a mechanism of prior approval. In the latter case, the Commission points out, that a change in the burden of proof is triggered by the precautionary principle urging industry to produce the scientific evidence necessary for a comprehensive risk evaluation (European Commission 2000, pp. 21–22). It is worth while analyzing how this general approach to precaution has been applied by the Commission to nanomaterials.

### **The Strategy of the European Commission Concerning Nanomaterials**

The Commission has followed the development of nanotechnology from its early stages. Besides the communication on the precautionary principle of 2000 (European Commission 2000), the strategy on nanotechnology communicated in 2004 (European Commission 2004), followed by several expert opinions of the SCENIHR starting in 2005 (SCENIHR 2005, 2007, 2008, 2009) were the cornerstones. These led to an action plan for 2005–2007, which has been reported on in 2007 (European Commission 2005). In 2008, the Commission issued a communication on regulatory aspects of nanomaterials (European Commission 2008a, b) and introduced a specific code of conduct (European Commission 2008c). In general, the Commission identifies the risks of nanomaterials but follows an approach which may be described as precautionary with regard to the public reception of the risks, reducing the agenda to strengthening implementation of existing EU laws (European Commission 2008a, no. 3.2., p. 9). On the contrary, in 2009 the European Parliament beat the drum, challenging the Commission’s approach as being insufficient and calling for major changes in EU legislation with regard to the risks of nanomaterials. Basically, the Parliament wants to fully apply the principle “no data, no market” to nanomaterials (EP 2009, resolution 2008/2208, AA.).

The core elements of the Commission’s approach are set out in its strategy for nanotechnology, the communication on regulatory aspects, and in the code of conduct for responsible nanosciences and nanotechnologies (N&N) research. Although the Commission clearly admits that there are broad gaps in knowledge about nanomaterials and their characteristics and effects, it is of the opinion that existing EC-regulations are well equipped to deal with the possible risks thereof (European Commission 2008a, p. 8–11). It does not bother itself with too much scientific analysis, not providing for a definition of nanomaterials, but relying on a rather broad and vague description (European Commission 2004, no. 1.1., p. 4). Even though the Commission downplays the need for new regulatory approaches (European Commission 2008a, p. 11), when promising more technical guidance it is well aware that this will touch on severe questions of balancing economic, environmental, as well as consumer interests in practice. However, in the Code of Conduct “prohibitions, restrictions or limitations” are not excluded. It states, i.e. that “as long as risk assessment studies on long-term safety are not available, research involving deliberate intrusion of nano-objects into the human body, their inclusion in food (especially in food for babies), feed, toys, cosmetics and other products that may lead to exposure to humans and the environment, should be avoided” (European Commission 2008c, p. 9, no. 4.1.17). Considering the possibility of nanomaterials crossing the blood-lung- and the blood-brain-barrier, “avoidance” seems to be a rather reluctant approach.

Further, in comparison with the Commission's communication on the precautionary principle it is striking that there is no attempt to use a shift in the burden of proof as an instrument of risk management. Obviously, when talking about a new industry with promising surpluses but a need for basic research in methodology and specific toxicology, it is not far-fetched to think about involving industry in the necessary funding. Instead, the Commission's strategy places the burden of financing primarily on the public sector. Parts of the five "dynamics" demanded by the Commission are public investments in R & D, setting up European research programmes, establishing an infrastructure of "poles of excellence" responding to the "needs" of industry (European Commission 2004, p. 13, no. 3.2.1.).

After all, the Commission includes the aspects of risk communication. It calls for an open, proactive dialogue including the discussion of ethical principles (European Commission 2004, pp.19–20). But the perspective is clear, when fearing that "nanotechnology innovations could face an unjust negative public reception" (European Commission 2004, p. 20): It is for the possible benefits for society. For a different evaluation of openness, see Lin-Easton (2001, pp. 132–133).

Following this line one can easily detect how much the aspect of competition has been a main driver for the Commission's measures. Large parts of the Commission's strategy address the funding in third states, competitors to the EU. In the executive summary, the link to the Lisbon process on enhancing competitiveness is explicitly established (European Commission 2004, p. 3) as well as in the recitals of the code of conduct (European Commission 2008c, p.2, 3. recital). Consequently, the Commission refers to the Council (competitiveness), when stressing the need to foster synergies between nanosciences and nanotechnologies (European Commission 2008c, p. 3, 9. recital). On the basis of "sustainable economic, social and environmental development", one of the objectives is that the "governance of N&N research should encourage maximum creativity, flexibility, and planning ability for innovation and growth" (European Commission 2008c, p. 7, no. 3.6). In political terms, there might be several arguments in favour of this approach. However, from the perspective of the precautionary principle it seems to be only a minimal attempt. And it is not primarily the principle of proportionality in the frame of individual economic rights calling for this reluctance, but the general interest in economic development and growth that plays a major role. So, in the case of nanomaterials one can see the strong opponents of environmental and consumer protection.

Obviously, the solution for striking a balance by the Commission has been an invitation for critics, and the European Parliament has taken on that role in its resolution of April 24, 2009 mentioned above. Taken together, both instruments reflect the range of possible measures of risk management and highlight the political character of that task. The Parliament rather briefly pays tribute to the aspect of competition, but then goes on to point out all areas where regulatory modifications seem to be necessary. By making nanomaterials subject to the principle "no data, no market", the EP seems to be ready to place a rather heavy burden on industry (EP 2009, resolution 2008/2208, AA). Although coming in the form of an invitation, its proposals on investigating far reaching modifications of existing EC laws suggest that the appropriate response has to be in the affirmative. Other proposals by the Parliament are more balanced, e.g. the demands for a definition of nanomaterials, for establishing a code of precaution for producers, and the call for a list of nanomaterials used in the EU to be introduced as well as insisting on the labelling of the use of nanomaterials in consumer goods (EP 2009, resolution 2008/2208, No. 10, 16, 17; see also Umweltbundesamt 2009, p. 20). It is these sensible points that make the Commission's strategy look less than comprehensive.

## Conclusion

The case of nanomaterials shows that the precautionary principle is an important legal tool to deal with the specific tasks of risk societies. It is well established in EC environmental law and has been applied in other sectors for the protection of human health. So, at last, it covers the most important part of consumer protection policies.

The principle should be followed in every stage of the process of risk evaluation. Giving the scientific uncertainties, it is convincing to apply it to the first stage of risk assessment with its rather scientific character. There is common acceptance that it clearly governs the second stage, the risk management. This is regarded as a very political task. However, in governing the process leading to the decision on the measures to be applied to a certain case of nanomaterials the principle of proportionality plays a decisive role. Especially in a highly competitive area such as nanomaterials it is the main driver when choosing from the broad range of instruments offered by the precautionary principle.

In the case of nanomaterials the Commission's strategy puts an emphasis on the aspects of competition, thus following a rather reluctant approach of (non-)regulation, relying on a voluntary code of conduct addressing primarily the public sector. Although the Commission adds a strong line of risk communication to its approach, its implementation is rather biased by the positive, optimistic reception of the possible effects of nanomaterials in health care, etc. Although this view is not far-fetched, it is doubtful whether that perspective really leads to an "open" dialogue.

A major task in N & N is to fill the existing gap in knowledge. Inevitably, this raises the question of financing and who is to bear the burden. Although such issues are dealt with under the polluter pays-principle in EC environmental law, it is a case for the precautionary principle as well. Any requirement of registration or authorisation—as governed by the precautionary principle—has effects on the burden of financing. So it seems to be consistent to rely on that principle in cases of uncertainty, when deciding on the burden of financing basic scientific research, e.g. for a nanomethodology. Here, the Commission calls upon the public sector to help in the area of research. But one could think of more balanced views that still pay due respect to the competition faced by the European nano-industry. The setting up of hybrid funds financed by both, industry and the public sector would be a more convincing application of both the principles of precaution and proportionality.

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