

3 The precautionary principle

In this chapter, the Committee considers what the precautionary principle actually involves and what common elements have been identified in the various national and international descriptions of that principle.

General

The Minister has asked “What precautionary measures does the Social and Economic Council consider should be taken with regard to working with nanoparticles?” In order to answer that question, the Committee has considered what the precautionary principle actually involves. In order to do so, it has surveyed the common elements that have been identified in the various national and international descriptions and process definitions of that principle. The Committee has also taken account of the views of the Health Council of the Netherlands regarding the precautionary principle, as set out in the Council’s recommendations *Prudent Precaution*.¹

When one considers what the precautionary principle actually involves, it becomes apparent that no real definition exists. It appears, for example, from the legal literature that there is virtual unanimity to the effect that “the” precautionary principle as such does not exist. The description/definition, scope, and interpretation of the precautionary principle depend to a large extent on how it is formulated (in the various treaties and legislation) and how it is interpreted.² The precautionary principle is often explained as a process definition, with a description of the process steps to which conditions and rules are attached, frequently tailored to specific topics. All of this is then directed at those who are required to take the relevant policy decisions, generally the authorities.

The common elements that can be found in virtually all descriptions of the precautionary principle are:

- uncertainty;
- damage;
- consideration of the pros and cons (cost-benefit analysis);
- a transparent decision-making process and stakeholder involvement;
- an active stance.

Although application of the precautionary principle is basically not exactly the same as preventing or prohibiting activities, it should be noted that in some cases that may be the most appropriate approach. Such a prohibition, for example on the introduction of a new technology or the use of certain materials or processes, can be formulated in terms of a

1 Health Council recommendations *Voorzorg met rede*, Health Council of the Netherlands, The Hague, 26 September 2008, publication number 2008/18.

2 Health Council R (2003) *Juridische afbakening van het voorzorgbeginsel: mogelijkheden en grenzen*, publication number A03/03, The Hague.

ban – for a limited period of time – associated with the requirement that further studies be carried out. A ban may also mean a general prohibition, with exceptions being made subject to the issuing of permits.³

Uncertainty

One thing that is clear is that where the precautionary principle is concerned we are in any case dealing with uncertainty. That uncertainty may, for example, involve the dangers and risks posed by substances;⁴ uncertainty about environmental dangers and risks;⁵ or the major uncertainty regarding whether the special properties of free, persistent synthetic nanoparticles will affect their behaviour in the environment, their uptake and distribution within the body, and their ability to cause or exacerbate medical conditions.⁶ There may also be uncertainty regarding the likelihood and/or extent of potential damage.⁷

In a number of documents, this is referred to as situations of scientific uncertainty,^{8,9} more specifically the lack of sufficient scientific certainty.¹⁰ One is dealing here with scientific uncertainty resulting from the lack of relevant scientific information and knowledge regarding the extent of the possible harmful effects.¹¹ One may also be dealing with specific situations in which the scientific evidence is insufficient, inconclusive or uncertain.¹²

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- 3 See the recommendations by the Health Council of the Netherlands in *Voorzorg met rede* (2008) and by the Scientific Council for Government Policy in its report *Onzekere veiligheid* (2008).
 - 4 House of Representatives, Session Year 2000–2001, 27 646, Strategic Memorandum *Dealing with Substances [Omgaan met Stoffen]* (SOMS), no. 2.e.
 - 5 Memorandum *Nuchter omgaan met risico's, beslissen met gevoel voor onzekerheden* by the Ministry of VROM, January 2004, and RIVM report *Nuchter omgaan met risico's*, report 251701047/2003.
 - 6 Health Council of the Netherlands *Betekenis van nanotechnologieën voor de gezondheid*, The Hague 2006, no. 2006/06.
 - 7 Scientific Council for Government Policy *Onzekere veiligheid. Verantwoordelijkheden rond fysieke veiligheid*, The Hague 2008, report 82.
 - 8 In addition to scientific complexity and ignorance. Health Council of the Netherlands *Voorzorg met rede*, The Hague 2008, Nr 2008/18.
 - 9 See in this connection, for example, the *Opinion on the appropriateness of the risk assessment methodology in accordance with the technical guidance documents for new and existing substances for assessing the risks of Nano-materials* published by SCENIHR (Scientific Committee on Emerging and Newly-Identified Health Risks), which advises the European Commission, March 2007, and the Rathenau Institute's *Tien lessen voor een nanodialoog. Stand van zaken rondom nanotechnologie*, The Hague 2008.
 - 10 This must not be taken as an argument for delaying measures to prevent and/or restrict damage to the environment, the threat of the decline or loss of biological diversity, or climate change. See in this connection the 1992 Rio Declaration, the 1992 Treaty on Biological Diversity, and the 1992 Agreement regarding Climate Change.
 - 11 Protocol on Biosafety concerning the safe transfer, handling and use of living modified organisms resulting from modern biotechnology (28 January 2000).
 - 12 *Communication from the European Commission on the precautionary principle*, COM (2000), 1 final, 2 February 2000. The Social and Economic Council also applies the Commission's description in its advisory report *Nieuwe risico's* (2002).

Damage

Another common element in the various descriptions of the precautionary principle is that there must be the risk of *adverse effects on the environment, human, animal or plant health* that require protective measures.¹³ “Dangers” and “risks” (and management of those risks) are also terms that are frequently used in this connection.¹⁴ This element basically reappears in all the descriptions and definitions surveyed, if in different phrasing; that phrasing can be of a general nature,¹⁵ but in some cases it may have a more specific character and be tailored to a particular environment that is to be protected.¹⁶

Possible pointers for the extent of the damage can be found in descriptions and definitions which state that there must be “serious risks” (i.e. sufficient likelihood of “serious and irreversible damage”), “non-negligible damage”, “a threat of serious or irreversible damage”, “significant damage or harm”, or “serious or irreversible threats to health or the environment”.¹⁷

Consideration of the pros and cons (cost-benefit analysis)

When applying the precautionary principle, the dangers and risks of an activity must also be emphatically and as far as possible weighed up against the societal pros and cons of that activity.¹⁸ This consideration too is a common element and is found frequently, although sometimes worded rather differently.¹⁹

A transparent decision-making process and stakeholder involvement;

Other common features of the precautionary principle that were noted during the survey were *transparency of the decision-making process, with a clear division of responsibilities between*

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- 13 *Communication from the European Commission on the precautionary principle* COM (2000), 1 final, 2 February 2000.
- 14 See, for example, the Government vision papers *Nuchter omgaan met risico's* and *Nanotechnologiën* and the *Actieplan nanotechnologie*, but also the VNO-NCW's *rondje Europa* 1 July 2005 – 1 January 2006, the recommendations by the Health Council of the Netherlands regarding *Juridische afbakening van het voorzorgbeginsel* (2003), and *Voorzorg met rede* (2008).
- 15 In its report *Onzekere Veiligheid* (2008), for example, the Scientific Council for Government Policy refers to the vulnerability of people, society, and the natural environment. UNESCO's 2005 working definition of the precautionary principle concerns morally unacceptable damage to people and the environment.
- 16 The Paris Convention for the Protection of the Marine Environment (1992) refers to “the possibility of causing danger to the health of people or living flora and fauna, or damage to marine ecosystems, that can reduce the recreational value of an area or prevent other legal use of the sea (in this case the north-eastern portion of the Atlantic Ocean)”.
- 17 See the VNO-NCW's *rondje Europa* 1 July 2005–1 January 2006, the recommendations by the Health Council of the Netherlands regarding *Juridische afbakening van het voorzorgbeginsel* (2003), and *Voorzorg met rede* (2008), and the 1992 Agreement on Climate Change.
- 18 House of Representatives, Session Year 2005–2006, 28 089, Government vision paper *Nuchter omgaan met risico's*, no. 15.
- 19 See the European Commission's Communication on the Precautionary Principle. The VNO-NCW refers to “an investigation of the potential advantages and costs”, while the Health Council states in its advisory report *Betekenis van nanotechnologie voor de Gezondheid* that the application of nanoparticles is only permissible if it is clear that the advantages outweigh the risks; in its advisory report *Voorzorg met rede*, the Health Council follows the formulation used by the European Environmental Bureau when it states that “the probable advantages and disadvantages of action and refraining from action should be considered”.

the authorities, businesses, and citizens,²⁰ and at the earliest possible stage *involvement of all stakeholders* in the process during which application of the precautionary principle is being considered.²¹ In applying the precautionary principle, the organisation and processes must be arranged in such a way as to identify uncertainties at an early stage and open them up to discussion; allowance is explicitly made for measures needing to be taken even though substantial uncertainties remain.²²

Active stance

It also appears that application of the precautionary principle requires a continuously active stance and attitude. Various options for action – each with their advantages and disadvantages – must be assessed on their merits and weighed against one another in a careful and transparent manner; in this regard, negative (or possibly negative) consequences must not by definition outweigh positive (or possibly positive) ones. Application of the precautionary principle is not exactly the same as preventing or prohibiting activities, even though that may be the most appropriate approach in some cases.²³

The vulnerability of people, society, and the natural environment demand a proactive approach to uncertainties. This can involve such things as:

- actively initiating research;
- setting up early early-warning systems, with specific attention being paid to health monitoring;
- explicitly taking account of a range of disciplinary and social perspectives in the considerations;
- developing policy aimed at reducing vulnerability and devoting attention to resilience.

The precautionary principle is therefore a principle that calls for action to be taken and that at the same time involves extending responsibilities, given that attention is devoted to the vulnerability of the environment, resulting in a change of focus.²⁴ It is clear that precautionary measures are, by definition, of a provisional nature and either have a finite period of validity or involve an obligation to review or evaluate the measures before a given date.²⁵

20 See the Government vision paper *Nuchter omgaan met risico's*. In its advisory report *Voorzorg met rede*, the Health Council summarises the precautionary principle as a strategy to deal with uncertainties in an alert, careful, reasonable, and transparent manner that is appropriate to the situation.

21 VNO-NCW *rondje Europa* 1 July 2005 – 1 January 2006.

22 Scientific Council for Government Policy (2008) *Onzekere veiligheid: Verantwoordelijkheden rond fysieke veiligheid*, report 82, The Hague, Scientific Council for Government Policy.

23 See the recommendations by the Health Council of the Netherlands in *Voorzorg met rede* (2008) and by the Scientific Council for Government Policy in its report *Onzekere veiligheid*, The Hague, report 82, (2008).

24 Scientific Council for Government Policy (2008) *Onzekere veiligheid: Verantwoordelijkheden rond fysieke veiligheid*, rapport 82, The Hague, Scientific Council for Government Policy.

25 Confederation of Netherlands Industry and Employers *rondje Europa* 1 July 2005 – 1 January 2006.