

# The legal application of the precautionary and ALARA principles

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## *I. Gap between law and technology and the precautionary principle*

1. Technology is an essential element of our society. Without technology, it would be impossible to keep up our personal standard of living. However, the pace of scientific progress causes an increased number of risks. A close link has therefore to be established between law and technology.<sup>1</sup> Nevertheless, the legislator is confronted with a lot of difficulties to guarantee safety and quality of provided products and services. The gap between law and technology has been widened by a spectacular development or even explosion of technology and as a consequence by an accelerated tendency towards specialization.<sup>2</sup> International congresses organized in the past have already shown that this problem deserves more attention.<sup>3</sup>

2. In every innovative field, such as the industrial, the nuclear and the medical fields, European and national legislators have the difficult task to find a balance between two extremes. Detailed regulations, on the one hand, will gradually be maladjusted to the state of scientific and technological knowledge (state of the art). A total lack of regulation, on the other hand, implies that no safety or quality requirements are legally imposed.

3. Even if we agree that the legislator has to make the decision for the optimal degree of safety, a part of its rule making power will necessarily be delegated to other bodies, such as the judge or even the technicians. The legislator cannot regulate everything in detail because the needed expertise is lacking and technology is evolving rapidly. Because the legislator needs to use vague or general terms, in reality the courts will decide, after getting technical advice from an expert.<sup>4</sup> In this context, the directive on product liability can be mentioned. Article one of this directive declares that a producer is liable for damage caused by a defect in his product. According to article 4 a product is defective "when it does not provide the safety which a person is entitled to expect, taking all circumstances into account". Since the legislator has not provided any definition of the notion "safety", the judge has to determine the content of this concept.<sup>5</sup> The application of the precautionary principle also depends on the specific circumstances.

4. Because of the increased complexity of technology, producers are forced to improve their quality and safety system. Preventive action becomes very important since in many cases scientific certainty about harmful effects of a certain product or service only exists after the damage has been suffered. The precautionary principle is based on this existence of scientific uncertainty. A part of this uncertainty is inherent to reality and caused by the coincidences determining future. Another part is linked to the scientific method. When can the results of isolated experiments or researches be generalised? When do new scientific developments change the state of the art? Because it is not possible to examine all possible hypotheses, a certain degree of uncertainty always exists about scientific results.<sup>6</sup> Furthermore, similar isolated researches can give conflicting results causing discord in the scientific community. Law has to convert this scientific uncertainty into social certainty. At this level, the precautionary idea is of great help.<sup>7</sup> The precautionary idea or precautionary philosophy means that protective

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<sup>1</sup> H. H. EBERSTEIN, Technical safety - its legal basis as seen nationally, regionally and internationally, in: *Safety and Law, Proceedings of International Summer-Symposium '83*, Gesellschaft für Sicherheitswissenschaft, GH Wuppertal, 1984, p. 131: "technology must be embodied in our system of law".

<sup>2</sup> H. COUSY, "Safety law, a search for basic principles and characteristics", *Proceedings of International Summer-Symposium '83 Safety and Law*, GH Wuppertal, 1984, p. 21.

<sup>3</sup> In this context, I refer for example to the interesting International Summer-Symposium on Safety Science, that has been organized in Belgium in 1983.

<sup>4</sup> H. COUSY, "Safety law, a search for basic principles and characteristics", in: *Safety and Law, Proceedings of International Summer-Symposium '83*, Gesellschaft für Sicherheitswissenschaft, GH Wuppertal, 1984, p. 28.

<sup>5</sup> H. COUSY, "Safety law, a search for basic principles and characteristics", *o.c.*, p. 29.

<sup>6</sup> O. GODARD, "L'ambivalence de la précaution", in: *Le principe de précaution dans la conduite des affaires humaines*, Fondation Maison des sciences de l'homme, Institut National de la Recherche Agronomique, Paris, 1997, p. 57.

<sup>7</sup> The precautionary idea or philosophy is the main idea on which the legally prescribed precautionary principle is based.

action can be necessary despite scientific uncertainty about the harmful effects of a certain application or product in case of potential risks.

## II. The precautionary principle: an emerging principle

### A. The precautionary principle as a *general* policy principle

5. The precautionary idea was originally accepted as a policy principle in environmental protection law. The precautionary principle became especially popular in this field because of the many scientific uncertainties, such as the difficulties to determine a causal relation between pollution and harmful effects and the fact that long-term consequences cannot be subject to experimental research.<sup>8</sup> The origins of the precautionary principle are situated in Germany, where the principle has formed one of the basic principles of environmental policy since the 1970s.<sup>9</sup> The principle has been adopted in several international declarations<sup>10</sup> and treaties<sup>11</sup> on environmental protection since the eighties. The importance of the principle increased because of the evolution towards sustainable development in the field of environmental protection. This evolution has been influenced by the awareness that harmful effects to the environment can be irreversible.<sup>12</sup>

6. The precautionary principle is in particular used in the field of environmental protection. But the scope of application is wider. In Germany, "Vorsorge" has also been used in health care and international relations. "Friedensvorsorge" means for example pre-emptive action to avoid conflicts becoming violent.<sup>13</sup> For health protection against dioxins, BSE, magnetic fields and ionizing radiation, the same uncertainties exist as for environmental protection and a similar approach seems necessary.

7. In a recent communication, the European Commission explicitly considers precaution to be a policy principle for the European institutions, not only in environmental protection law but also for health and consumer protection.<sup>14</sup> At the European level, the only explicit reference to the principle is made in the context of environmental protection (article 174 EU-Treaty). An implicit reference to the precautionary principle can, however, be found in other dispositions. Indeed, the EU-Treaty provides that "a high level of human health protection shall be ensured in the definition and implementation of all community policies and activities" (article 152 (1)) and that "environmental protection requirements must be integrated into the definition and implementation of the Community policies and activities" (article 6). Furthermore, article 95 (3) of the EU-Treaty determines that "the commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection will take as a base a high level of protection, taking account in particular of any new development based on scientific facts" and that "within their respective powers, the European parliament and the Council will also seek to achieve this objective".

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<sup>8</sup> H. BELVEZE, "Les réflexions sur l'utilisation du principe de précaution au niveau de l'Union Européenne", 1999-09-27.

<sup>9</sup> The other principles are: Verursachersprinzip (polluter pays), Kooperation (consensus), Wirtschaftliche Vertretbarkeit (principle of proportionality) en Gemeinlast Prinzip (common burden principle).

<sup>10</sup> See for example: Second (1987), third (1990) and fourth (1995) Declaration of the North-sea, Declaration on safety and co-operation in Europe (1992), Declaration of Rio on environment and development (1992).

<sup>11</sup> See for example: La Convention de Paris pour la protection du milieu marin pour l'Atlantique du nord-est (1992), Treaty of Helsinki on Transboundary Watercourses and International Lakes (1992), U.N. Framework Convention on Climate Change (1992), Treaty of Sofia on co-operation on the protection and sustainable use of the Donau, Treaty of Rotterdam for the protection of the Rhine, Protocol on biosafety concerning the safe transfer, handling and use of living modified organisms resulting from modern biotechnology (2000).

<sup>12</sup> W. TH. DOUMA, *The Precautionary Principle*, [www.eel.nl/virtue/precprin.htm](http://www.eel.nl/virtue/precprin.htm), T.M.C. Asser Institute, Den Haag, 2000, p. 3; M. PÂQUES, "Les valeurs portées par la convention-cadre des Nations Unies sur les changements climatique et le protocole de Kyoto", *Actualités du droit*, 1999, nr. 2, p. 210; V; TILMAN, "Le concept de développement durable", *Actualité du droit*, 1998, p. 267; T. O'RIORDAN, J. CAMERON, "The History and Contemporary Significance of the Precautionary Principle", in: *Interpreting the Precautionary Principle*, Earthscan Publications Ltd, London, 1994, p. 19-22.

<sup>13</sup> S. BOEHMER-CRISTIANSEN, *l.c.*, p. 39.

<sup>14</sup> COM (2000) 1, Communication from the commission on the precautionary principle, 2000/02/02, p. 10; This communication is part of the Commission's response to the Council resolution of April 1999 urging the European Commission "to be in the future even more determined to be guided by the precautionary principle in preparing

8. The Court of Justice and the Court of First Instance of the European Union consider these articles to be sufficient grounds for the application of the precautionary principle. In its judgement on the validity of the Commission's decision banning the exportation of beef from the United Kingdom to reduce the risk of BSE transmission, the court held that "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" (grounds 63).<sup>15</sup> The Court of First Instance cites this consideration in another judgement concerning protection of consumer health.<sup>16</sup>

#### B. A few national cases

9. The number of national regulations in which the precautionary principle is explicitly mentioned, is limited. Nevertheless, courts have implemented uncertainty in their decisions. On August 21, 1996, the German Supreme Administrative Court decided that the administration is under the obligation to check whether or not the radiation from the nuclear power station Krümmel stays within the limits of the precaution required for by the Atomic Energy Act. The court stressed that the administration has to set higher precautionary standards if the latest scientific findings indicate that the norms set at an earlier date are no longer sufficient. According to the court, this evaluation is a task of the administration and cannot be replaced by an assessment of the court.<sup>17</sup>

10. In an Australian case, a licence to "take or kill" endangered species (the yellow-bellied glider and the giant burrowing frog) was refused through the application of the precautionary principle. The Court established that the precautionary principle was of legal importance in a situation of a scarcity of scientific knowledge of species population, habitat and impacts. The judge used the principle to check whether the decision should have been granted.<sup>18</sup>

11. In Belgium, the president of the court of first instance of Antwerp ordered the closure of a combustion furnace for household waste because of the precautionary principle.<sup>19</sup> According to the court, scientific certainty was lacking that no further damage would be caused to the nearby residents. In appeal, this decision was overruled.<sup>20</sup> The court stated that the administration applied the precautionary principle correctly by prescribing emission limits in the licence. Indeed, this principle has to be applied by the administration and not by the licence owner, except if national legislation explicitly mentions otherwise.

12. In another Belgian case, a licence for a high-voltage line was refused because of the possible harmful effects of exposure to magnetic fields. Although the existing limits were respected, the risk threatened the Constitutional right on health protection (article 23, 3, 2<sup>o</sup>) and on a healthy environment (article 23, 3, 4<sup>o</sup>) and was therefore considered by the "Conseil d'Etat" to be serious and difficult to repair.<sup>21</sup>

#### III. Guidelines for the application of the precautionary principle

13. The different legal texts on the precautionary principle in the field of environmental protection show that one definition can hardly be given.<sup>22</sup> Because of the important differences between the texts, room for interpretation is rather broad for those parties who have to translate the principle in specific actions: experts, administration,

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proposals for legislation and in its other consumer-related activities and develop as priority clear and effective guidelines for the application of this principle".

<sup>15</sup> I.C.J. May 5th, 1998 (cases C-157/96 en C-180/96), *Court of Justice and Court of First Instance*, 1998-5, I, 2211-2263.

<sup>16</sup> Court of First Instance July 16th, 1998 (case T-199/96), *Court of Justice and Court of First Instance* 1998, 7/8, p. 2805-2829; this judgement deals with the Commission's decision limiting the use of bergapteen in cosmetic products.

<sup>17</sup> W. TH. DOUMA, *l.c.*, p. 8; Bundesverwaltungsgericht (11 C 9.95) August 21, 1996.

<sup>18</sup> W. TH. DOUMA, *l.c.*, p. 8-9; Leatch v. National Parks and Wildlife Service and Shoalhaven City Council (81 LGERA 270), 1993.

<sup>19</sup> President Court of First Instance Antwerp February, 2<sup>nd</sup>, 1999, A.J.T. 1998-1999, p. 807, with comment of I. LARMUSEAU.

<sup>20</sup> Antwerp October 11<sup>th</sup>, 1999, *T.M.R.* 2000, p. 52.

<sup>21</sup> Conseil d'Etat (VENTER) August 20, 1999, nr. 82.130.

<sup>22</sup> J. CAMERON, "The Status of the Precautionary Principle in International Law", in: *Interpreting the Precautionary Principle*", Earthscan Publications Ltd, Londen, p. 262-289; O. GODARD, *l.c.*, p. 41-46.

politicians or judges. Of course, the same is true in the European context, since the Treaty of Maastricht has not given a definition at all.<sup>23</sup>

14. The regulators have to find the correct balance between the freedom and rights of individuals, industry and organizations on the one hand and environment, human, animal and plant health on the other hand. If this balance is found, proportionate, non-discriminatory, transparent and coherent actions can be taken.<sup>24</sup> The European Commission is therefore aware of the necessity of a structured decision-making process. The recent communication is a first step to establish guidelines for applying the precautionary principle.<sup>25</sup>

15. According to the European Commission, a structured decision-making process is provided by the three elements of risk analysis: risk assessment, risk management and risk communication.

16. Before adequate measures can be taken, a scientific evaluation has to be performed as good as possible. This risk assessment requires reliable scientific data and logical reasoning, leading to a conclusion which expresses the possibility of occurrence and the severity of a hazard's impact on environment or human, animal and plant health. It will cast light on the objective evidence, the gaps in knowledge and the scientific uncertainties. The Commission stresses that due account should be taken of the views of minority fractions of the scientific community, provided the credibility and reputation of these fractions.<sup>26</sup> For important changes to an operation licence, "Environmental Impact Assessment" is obligatory in the European Union and this gives a good basis for the different scenarios.<sup>27</sup>

17. A precautionary approach can be justified if the scientific evaluation shows that the desired level of protection for environment or health could be jeopardized. The limits of reasonableness would be stepped over if one tries to eliminate every risk that can be presumed. Such an approach would discourage innovation and would open the door for protectionism. The precautionary principle is only applied in this second phase, as a part of risk management. Indeed, the principle may not be confused with the prudential approach of scientists to evaluate scientific uncertainty, for example when formulating hypotheses used to compensate for the lack of scientific or statistical data.<sup>28</sup>

18. An approach inspired by the precautionary principle does not justify a deviation from the other general principles of risk management that are generally used when a complete risk assessment is at hand: proportionality, non-discrimination, consistency, examination of scientific developments.<sup>29</sup>

19. The procedure to evaluate the policy options has to be as transparent as possible. W. DAB stresses that formalization of the decision-making process and public involvement become more important with increasing uncertainty. The most unacceptable, according to W. DAB, is not that the decision-maker is mistaken in this context of uncertainty, but that his approach is not transparent, coherent and explicit. In that case, he can lose faith if he is accused to have sacrificed health for economical reasons.<sup>30</sup> We can witness an increased interest in public involvement in the regulation on Environmental Impact Assessment.<sup>31</sup>

#### *IV. Legal significance of the precautionary principle*

20. The various legal texts in which the precautionary principle is implemented, show that one general definition of the precautionary principle can hardly be given. The principle has to be filled in on a case-by-case basis. Can the precautionary principle be considered a legal rule despite its vague content?

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<sup>23</sup> O. GODARD, *l.c.*, p. 46.

<sup>24</sup> COM (2000) 1, p. 3.

<sup>25</sup> In Common Law countries, some guidelines have already been developed in case-law.

<sup>26</sup> COM (2000) 1, *Communication from the commission on the precautionary principle*, 2000/02/02, p. 14 and 17.

<sup>27</sup> In an international context, see: Dir. 97/11/EC of 3 March 1997 on the evaluation of incidents of certain public and private projects on the environment, *O.J. L 73/5*, 14/03/1997, amending Dir. 85/337/EC; Convention of Aarhus on "l'accès à l'information, la participation, du public au processus décisionnel et l'accès à la justice en matière d'environnement"; Dir. 90/313/EEG of 7 June 1990, *O.J. L158*, 23/06/1990.

<sup>28</sup> COM (2000) 1, *Communication from the commission on the precautionary principle*, 2000/02/02, p. 13.

<sup>29</sup> COM (2000) 1, *Communication from the commission on the precautionary principle*, 2000/02/02, p. 18-21.

<sup>30</sup> W. DAB, "Précaution et santé publique. Le cas des champs électriques et magnétiques de basse fréquence", in: *Le principe de précaution dans la conduite des affaires humaines*, Fondation Maison des sciences de l'homme, Institut national de la Recherche Agronomique, Parijs, 1997, p. 210.

21. A legal rule is compulsory: it forces persons to adopt or not to adopt a certain conduct. Two conditions need to be fulfilled: the rule has to be presented in a text with a normative scope (formal condition) and has to be formulated in a sufficient prescriptive manner (condition as regards content).<sup>32</sup>

22. In the field of environmental protection, the formal condition is fulfilled since it has been adopted in several international treaties, in community law and in national law. In the field of health and consumer protection, however, no text with a normative scope mentions the precautionary principle. In some articles of the European Union Treaty, an implicit reference to the precautionary principle can be found. The European Court of Justice judged these dispositions to be sufficient basis to control the application of the precautionary principle in these fields (see n° 12).

23. The formal condition seems to be fulfilled. Can the same be said about the condition as regards content? The vagueness of the principle weakens but does not eliminate the obliging character. Such rule with a general content is flexible because a margin for interpretation exists for the application of the principle.<sup>33</sup> The principle can only be applied in so many different situations because of this flexibility. Such type of rule in which an indefinite concept is used, such as "public order", "due care" or "precaution", is called a legal standard.<sup>34</sup> In contrast with legal rules prescribing specific obligations, legal standards do not impose certain measures.

24. The obliging character of a legal rule implies the sanctioning of conduct that is not conform to this rule. In contradiction to specific rules, review by the court of measures based on the precautionary principle has to be limited to examining whether the administration committed a manifest error or misuse of power. Otherwise, the court exceeds the limits of its powers of appraisal.<sup>35</sup> The court will only examine whether a policy option is based on sufficient information and non-arbitrary hypotheses about the possible risks of a product or application. In this paper, the precautionary principle is only mentioned as a policy principle. The question whether the precautionary principle can also be considered a general rule of good conduct for individuals with an influence on the existing liability system, is controversial.<sup>36</sup>

25. Via the codification into law systems, the precautionary principle has developed from a policy guideline into a legal rule. The principle can, however, not yet be considered a part of international customary law for the administrations. When the European Union banned the import of beef raised using growth hormones, the case was brought before a WTO panel. The European Union reasoned that its import ban was justified in view of the precautionary principle, which they presented as a binding rule of international customary law.<sup>37</sup> The U.S.A. and Canada denied that the principle already had this status. Canada did admit that it was an emerging principle. The panel and the appeal body concluded that the import ban was not conform to WTO law.<sup>38</sup>

#### V. Important impact of the precautionary principle on safety legislation

26. To guarantee the safety of persons within the European Union, measures are taken which are based on the precautionary principle. A whole range of actions is available to decision-makers, such as funding research programmes or informing the public of risks. This paper only deals with actions that are designed to produce legal

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<sup>31</sup> See footnote 27.

<sup>32</sup> N. DE SADELEER, "Het voorzorgsbeginsel: een stille revolutie" (Precautionary: a silent evolution), *T.M.R.* 1999, p. 94, nr. 36.

<sup>33</sup> N. DE SADELEER, *l.c.*, p. 94, nr. 39.

<sup>34</sup> Ministère de la Justice, *Du standard technique à la norme juridique*, C.N.R.S. et Université de Paris, Parijs, 1995, p. 7; P. LASCOUMES, "La précaution comme anticipation des risques résiduels et hybridation de la responsabilité", *L'Année sociologique*, 1996, vol. 46 (2), p. 362; P. LASCOUMES defines a legal standard as "une référence de jugement qui laisse largement ouverts les pouvoirs d'interprétation et de mobilisation des acteurs sociaux individuels et collectifs" and "il s'agit d'un modèle hypothétique dont il est nécessaire de construire le contenu à chaque utilisation. L'espace d'indétermination placé volontairement dans la règle ou l'acte juridique appelle un acte d'évaluation basé sur des données et des critères extérieurs au droit lui-même".

<sup>35</sup> COM (2000) 1, *Communication from the commission on the precautionary principle*, 2000/02/02, p. 16.

<sup>36</sup> Several papers have been written on this topic, e.g.: G. J. MARTIN, "Précaution et évolution du droit", in: *Le principe de précaution dans la conduite des affaires humaines*, Fondation Maison des sciences de l'homme, Institut National de la Recherche Agronomique, Paris, 1997, p. 331-351 and in: *Recueil Dalloz Sirey* 1995, p. 299-306; J. P. DESIDERI, "La précaution en droit privé", *D.* 2000, p. 238-242; P. SARGOS, "Approche judiciaire du principe de précaution en matière de relation médecin/patient", *J.C.P.* 2000, p. 843-849.

<sup>37</sup> W. TH. DOUMA, *l.c.*, p. 7.

<sup>38</sup> W. TH. DOUMA, *l.c.*, p. 7.

effects open to judicial review. One way of applying the precautionary principle is to enshrine the principle of prior approval before certain products are placed on the market, such as medicinal products, medical devices or food additives. The decision-maker assumes, by way of precaution, that the product is dangerous until it has been proven otherwise. Another application is the ALARA-principle, which means that doses has to be kept "as low as reasonably achievable, economic and social factors being taken into account".

#### A. Prior approval before certain products are placed on the market

27. In the past, users, private individuals, consumer associations, citizens or public authority had to demonstrate the nature of a danger and the level of risk presented by a product or a process. The rules of many countries enshrine today the principle of prior approval before the placing on the market of certain products. The principle of a prior approval applies in particular to substances deemed "a priori" hazardous or which are potentially hazardous at a certain level of absorption.<sup>39</sup> In this case, the legislator has clearly shifted, by way of precaution, responsibility for producing scientific evidence to the business community. The producer has to prove that his products are conform to essential safety requirements. Until then, the public authorities are not legally entitled to authorize use of the substances.

28. However, a complete reversal of the burden of proof is not necessarily conform to the precautionary principle. The precautionary principle is always applied in a context where no persuasive evidence exists about a product's safety.<sup>40</sup> In such cases, the decision about who has the burden of proof determines the substantive outcome.<sup>41</sup> Burden shifting may then produce greater long-term harm than an unshifted burden of proof if it prevents the introduction of new activities and products which, while not free of risks, are better than what they would replace.<sup>42</sup>

29. The reversal of the burden of proof cannot be systematically maintained as a general principle. Of course, action taken in view of the precautionary principle can in certain cases include a clause placing the burden of proof on the producer, manufacturer or importer. This possibility has to be examined on a case-by-case basis. But burden shifting does not need to be an all or nothing solution. Other approaches are possible.

30. In the United States, the EPA has to prove that an existing pesticide is not safe in procedures to suspend or cancel existing pesticides. This burden of proof is, however, not high. The positive evidence of a risk is not necessary. The EPA only needs to show that the safety is not properly assured. The burden then shifts to the manufacturer to establish that his pesticides do not cause an unreasonable risk to the environment.<sup>43</sup>

31. Another approach can be found in the European "new approach" directives to harmonize the regulations of the member states. Following these directives, producers have to follow successfully certain quality procedures before their products can be put into circulation. Producers do not have to prove absolute safety, but they have to investigate their products according to normalized methods and if possible they have to apply the most recent European harmonized safety rules during design and production process. If these harmonized rules are respected, the product is presumed to correspond with essential safety requirements. The new approach directives do not impose strict and detailed obligations but try to implement a new corporate culture.<sup>44</sup>

#### B. Adoption of the ALARA principle

32. The environment or human, animal or plant health will be protected sufficiently by strict legal restrictions like emission limits in environmental law or dose limits for radiological protection purposes, if a threshold can be distinguished in the dose-response relationship. In this case, the scientific world dictates law.<sup>45</sup> But limits are an

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<sup>39</sup> COM (2000) 1, *Communication from the commission on the precautionary principle*, 2000/02/02, p. 21.

<sup>40</sup> O. GODARD, *l.c.*, p. 59.

<sup>41</sup> W. RODGERS, "Benefits, costs and risks: oversight of health and environmental decision-making", *Harvard Environmental Law Review* 1980, n° 4, p. 225.

<sup>42</sup> D. BODANSKY, "The Precautionary Principle in US Environmental law", in: *Interpreting the Precautionary Principle*", Earthscan Publications Ltd, Londen, p. 213.

<sup>43</sup> D. BODANSKY, *l.c.*, p. 211-212.

<sup>44</sup> Because of the increased importance of the precautionary principle, it can be doubted whether the state-of-the-art defence in the directive on product liability can continue to exist. Following this defence, the producer can defend himself against a product liability claim by proving that it was impossible to detect the defect before putting the product on the market because of the state of scientific and technical knowledge.

<sup>45</sup> M. C. BOEHLER, "Le principe de précaution et la radioprotection", *Proceedings Nuclear Inter Jura*, Helsinki, 1997, p. 149.

application of the precautionary principle if the authorities apply an "ample margin of safety" in setting these rules.<sup>46</sup>

33. If no scientific evidence exists about such a threshold, like for chemical products, ionizing radiation and magnetic fields, a linear no-threshold dose-effect relationship is often assumed. This hypothesis implies that even exposure to low doses includes a health risk. The issue is then to know which risks are socially acceptable.

34. For ionizing radiation, regulatory dose limits are still important to protect individuals against deterministic effects. A threshold can be distinguished for these effects. No scientific certainty exists, however, about the existence of a threshold for stochastic effects, like cancer and genetic effects. By way of precaution, the ALARA-principle has been adopted in the Euratom directives on radiological protection and, as a consequence, in national legislation. This principle describes that the doses have to be kept as low as reasonably achievable, economic and social factors being taken into account. Because safety does not mean risk free, it would not be reasonable to aim for a "zero-risk" situation. The optimization or ALARA-principle avoids taking protective measures if the benefits are smaller than the economical or social burden. M.-C. BOEHLER mentioned that because of the precautionary principle, law in the field of radioprotection does no longer serve science but promotes ethical responsible conduct in our insecure world. The linear model is no translation of scientific knowledge but an intellectual construction serving as a basis to take measures.<sup>47</sup>

35. The ALARA-principle has to be applied by individuals and companies on a case-by-case basis. The policy options that, in accordance to the precautionary principle, were taken by government have been transferred by the ALARA-principle to companies and individuals. The principle does not impose specific and detailed obligations but can be considered a demand for self-regulation. Standardization seems necessary to guarantee a correct application of the precautionary principle. Since the recent Euratom directives have stimulated the promulgation of diagnostic reference levels in case of medical exposure and dose constraints, this demand is explicitly put forward.

36. Diagnostic reference levels are dose levels for medical standard procedures. These levels are normally respected when good and normal practice regarding diagnostic and technical performance is applied. If these levels are exceeded, an appropriate local inspection is needed. If necessary, the member states have to take correcting measures. These levels are applicable for diagnostic examinations in nuclear medicine and in radiology. The levels are only applicable for typical examinations and not for complex situations in which additional examinations are necessary (in radiology). Neither can the diagnostic reference levels be applied for therapy. For therapy it is often impossible, taking into account the explicit goal of reaching a certain target dose, to avoid giving high doses to non-target volumes and tissues. It is a physician's responsibility to choose the best compromise between the chances for the patient's recovery and the risk for complications on the basis of his experience.

37. Furthermore, the Member States are forced to establish dose constraints for persons for whom no direct medical benefit is expected, like individuals knowingly and willingly helping in the support and comfort of patients undergoing medical diagnosis or treatment.<sup>48</sup> This concept is defined as a restriction on the prospective doses to individuals that may result from a defined source. The restriction is intended for use at the planning stage in radiation protection whenever optimization is involved. The Directives do not mention by whom these dose constraints and diagnostic reference levels have to be compiled: the government, hospitals, physicians, insurance companies?

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<sup>46</sup> D. BODANSKY, *l.c.*, p. 219.

<sup>47</sup> M. C. BOEHLER, *l.c.*, p. 149.

<sup>48</sup> Article 4 (4) of Directive 97/43.