The precautionary principle in times of intermingled uncertainty and risk: some regulatory complexities

M.B.A. van Asselt* and E. Vos**

*Faculty of Arts and Culture, Maastricht University, The Netherlands (E-mail: marjolein.vanasselt@tss.unimaas.nl)

**Faculty of Law, Maastricht University, The Netherlands (E-mail: e.vos@ir.unimaas.nl)

Abstract This article explores the use of the precautionary principle in situations of intermingled uncertainty and risk. It analyses how the so-called uncertainty paradox works out by examining the Pfizer case. It reveals regulatory complexities that result from contradictions in precautionary thinking. In conclusion, a plea is made for embedment of uncertainty information, while stressing the need to rethink regulatory reform in the broader sense.

Keywords Antibiotics; Pfizer case; precautionary principle; regulation; risk; uncertainty

Introduction

Over the years, the precautionary principle has become a central principle that guides decision-making involving the protection of the environment, human health, and safety. Within the European Union, the application of the precautionary principle to a wide variety of risk issues is discussed as a response to both the BSE and other food crises and to WTO requirements (Vos, 1999; European Commission, 2000; Christoforou, 2001; Wiener and Rogers, 2001; Fischer, 2002; Scott and Vos, 2002; Faure and Vos, 2003). Although precautionary principle is not universally defined, it is generally agreed that scientific uncertainty is the element that triggers the precautionary principle. The precautionary principle looks foremost to situations in which uncertainty and risk intermingle.

Uncertain risks

We argue that the precautionary principle pertains to ‘uncertain risks,’ i.e., situations in which the probability of occurrence or the effect in terms of damage cannot be estimated, and even the potential danger and the relevant causalities may be unknown, although there are suspicions of danger. In such cases, the meaning of ‘risk’ has actually been overshadowed by ‘uncertainty’ (Nowotny et al., 2001). Uncertainty is often, implicitly or explicitly, perceived as something which can be eradicated or at least reduced by research, monitoring, or the passing of time. Yet, many of the uncertainties that are relevant in the context of the precautionary principle cannot be eliminated (Funtowicz and Ravetz, 1993; van der Sluijs, 1997; van Asselt, 2000; Walket et al., 2003). The controversies on the risk of water pollution for the health and death of cows as recorded by Mourik (2004) provide illustrative examples of uncertainties pertaining to causality that could not be solved through science. However, uncertainty is not simply the absence of knowledge (Shackle, 1955; van Asselt, 2000, 2004a). New information can decrease, but also increase, uncertainty as it may reveal the presence of uncertainties that were previously unknown or were underestimated. Experts and scientists quite often have informed ideas on which uncertainties may be important and why, what are underlying sources of uncertainty, whether and how uncertainties may be reduced or at least better understood, which interpretations of uncertainty seem valid and which contradict...
the established state-of-the-art. This whole of answers and insights can be referred to as ‘uncertainty information’ (van Asselt and Petersen, 2003; van Asselt, 2004b).

The ‘uncertainty paradox’
Acknowledgement of the limits of science in providing conclusive evidence, i.e., the impossibility of full certainty, has led to the development of the precautionary principle. At the same time, all legal formulations of the precautionary principle include what is called a ‘knowledge condition’ (Manson, 2002), i.e., the level of proof needed to trigger application (Petersen and van de Zwaan, 2003). Although this knowledge condition is often kept vague or ambiguously formulated, the point is that such a knowledge condition implies that lawyers and policy-makers appeal to scientists and experts for some kind of plausibility ‘proof,’ which request has the tendency to run down to demanding conclusive evidence on whether something is a risk. Such requested certainty about uncertain risks seems highly incompatible if not contradictory to uncertainty as the core of the precautionary principle, which implies that neither definite proof nor evidence is available. This leads to a paradoxical situation. On the one hand, it is increasingly recognised that science cannot provide decisive evidence on uncertain risks, while, on the other hand, policy-makers and authorities increasingly resort to science for more certainty and providing conclusive evidence (compare Weingart, 1999). This uncertainty paradox raises questions about the role of science, knowledge, scientists and knowledge producers in precaution-based regulation of uncertain risks. It seems that this paradox is the consequence of the difficulty in dealing with uncertainty and recognising its meaning. In literature on the precautionary principle, it is often not recognised that uncertainty erodes the traditional positivistic model of knowledge, in which science speaks truth to power. This is illustrated by the Pfizer case, situated at the EU level.

Uncertain risks in regulatory practice: the Pfizer case
The Pfizer case (European Court, 2002) is an excellent example of how regulators and judges deal with uncertain risks and use the precautionary principle during the full regulatory process, as summarised in Figure 1. This case exemplifies how the uncertainty paradox works in practice. Before analysing the case, the main facts of the case are set forth.

EU regulation of food additives and the use of antibiotics in feedstuffs
The incorporation of additives in feedstuffs has been regulated at the Community level since 1970 (European Council, 1970). In 1996 a Community authorisation system was introduced according to which only additives that had obtained prior Community authorisation could be used (European Council, 1996). This regulatory regime includes the possibility for a Member State to temporarily suspend or restrict the use of an authorised additive. In such a case, a Member State has to immediately inform the other Member States and the Commission, and share its grounds on which it considers the additive dangerous. The Commission (or the Council) must thereupon confirm the national decision or decide that the Member States must lift the measures. Under this procedure,
Denmark informed the Commission in January 1998 that it had banned the use of the antibiotic virginiamycin as growth promoter. It relied on a report from its National Veterinary Laboratory that suggested transmission of virginiamycin from animals to humans. The Commission subsequently submitted this report to the Scientific Committee on Animal Nutrition (SCAN) for advice. The SCAN (1998) concluded that the use of virginiamycin did not constitute an immediate risk to public health in Denmark. This advice notwithstanding, the Commission proposed a ban under reference of the precautionary principle and submitted its draft-decision to the Standing Committee on Feeding-stuffs (StCFe) for approval. The draft-decision was heavily debated among the national representatives on this committee, and the committee was unable to reach an opinion. In accordance with the relevant provisions, the Commission subsequently sent its draft decision to the Council (the so-called regulatory committee contre-filet procedure). The Council confirmed the Commission’s position and adopted a regulation banning the use of four antibiotics as additives in animal feeding-stuffs including virginiamycin (European Council, 1998). Pfizer, producer of virginiamycin, immediately challenged this decision before the Court of First Instance (CFI) (European Court, 2002).

Deciding about uncertain risks
In order to unravel the manner in which the Community regulators decided upon the uncertain risk, it is essential to examine the various elements of the decision-making procedure.

The commission's terms of reference
In its terms of reference the Commission asked SCAN to give an opinion on whether the conclusions in the Danish report ‘are scientifically justified’ and on the question ‘whether or not’ the use of the virginiamycin as a growth promoter constitutes a public health risk at present or could constitute such a risk in the future (see terms of reference in SCAN, 1998). These terms of reference can be interpreted as a request for certainty: the Commission asked SCAN for a decisive answer as to whether the risk is a hazard. Hence, instead of asking for uncertainty information, the Commission asked for a plausibility proof.

SCAN's opinion
The terms of reference explain that SCAN had to come up with a short answer to the Commission’s yes-or-no question. SCAN here concluded that the use of virginiamycin as a growth promoter did not constitute an immediate risk to public health in Denmark (see Conclusion I in SCAN, 1998). Yet, throughout its opinion, SCAN also provided uncertainty information albeit not in a systematic manner. In summarising the state-of-the-art evidence, it indicated uncertainty at various points of its opinion, indicating that it did qualify the use of virginiamycin as growth promoter an uncertain risk. SCAN concluded that it did not, however, constitute an immediate hazard. It took the view that monitoring by the Danish government and the EU would enable detection of any significant increases in the resistance, should that occur.

Council regulation 2821/98
Notwithstanding SCAN’s opinion, the Commission proposed to issue a ban. This view was taken over by the Council in Council Regulation 2821/98. The Council arrived at its decision as follows. First it referred to SCAN’s conclusion that on the basis of the Danish claims there is no immediate risk to public health in Denmark. Subsequently, it looked for uncertainty information in SCAN’s opinion (see terms of reference in SCAN, 1998). Notably, both the Commission and the Council evaluated and valued the same
uncertainty information in a different manner than SCAN. For example, while SCAN emphasised that the Dutch farmer is just one case, the Commission argued that “even if general conclusions (…) should not be drawn from a single case,” this case may be “an indication that this might be confirmed by other cases in the future” (Para. 19 of the preamble, European Council 1998). The Commission and the Council experienced, and thereby constructed, more uncertainty about the risk than SCAN did, whilst still referring to SCAN’s opinion. This uncertainty information, as interpreted by the Commission and the Council, was then used to demonstrate that there ‘is’ uncertainty about the transfer of antimicrobial resistance. This uncertainty was used to justify application of the precautionary principle, and to prohibit the use of virginamycin.

The decision-making process in an uncertain risk perspective
Analysing the regulatory process in uncertainty terms, we observe that experts were asked to provide a plausibility proof. SCAN tried to comply with this request but because of the impossibility to provide certainty about uncertain risks, uncertainty information unsystematically crept into its advice. Instead of following the experts’ ‘plausibility proof,’ the institutions seized upon the uncertainty information to develop their own line of reasoning about the salience of the uncertain risk. We do not argue that this is wrong but we want to underline this state of affairs to illustrate the regulatory complexity associated with resort to the precautionary principle in view of the uncertainty paradox. If the Commission had asked SCAN to systematically delineate the uncertainty information, this would have provided a coherent basis for the Commission to evaluate whether or not and why it considers the uncertainties as ‘too risky.’ Yet in the current reasoning it remains implicit on which normative and political grounds the Commission and the Council were hesitant to accept SCAN’s general conclusion and advice.

Ruling about uncertain risks
The Court’s ruling
Pfizer invoked several grounds of which the most important relate to manifest errors of risk assessment and management and a misapplication of the precautionary principle. These pleas forced the Court to have a close look at the scientific arguments involved. The Court examined first whether, as Pfizer submitted, the Council based its conclusion on an improper risk assessment. It then assessed whether the Council made errors in its risk management (Para. 110, European Court, 2002). The Court saw no manifest errors and eventually upheld the Council’s decision.

A closer look at the Court’s reasoning reveals that it relentlessly repeats that it is only in the position to carry out a limited review of the measures (Para. 393, European Court, 2002). Yet, having asserted that, the Court then continues discussing scientific validity and the merits of the scientific arguments raised by both parties. How deeply the involvement of the Court extended into the scientific validity of the argument, is illustrated by the fact that the Court itself examined contents of expert reports (Para. 395–400, European Court, 2002). This deep involvement of the Court in scientific debate can be explained by the complexity arisen due to the interplay of the evaluation of manifest errors of assessment, as submitted by Pfizer, and the breach of the precautionary principle. As a consequence, the Court is forced to judge the scientific validity and the conclusiveness of the scientific arguments. It requires conclusive evidence of Pfizer (Vos, 2004). Interestingly, Pfizer is also asked for conclusive evidence, i.e., certainty about the uncertain risks, which they evidently cannot provide. This is subsequently used against them.
The Court emphasised great uncertainty, while at the same time, it found that sufficiently reliable and cogent scientific evidence and a proper scientific basis were available. Throughout the judgment, it becomes clear that the Court got stuck in a deadlock of being forced to do what it may not, and is unable, to do. Yet, the Court needs to rule.

The Court’s ruling in an uncertain risk perspective

Our analysis of the Pfizer case discloses that the Court attempted to overcome the deadlock by determining that there was a situation of scientific uncertainty, which it then used to argue in favour of the application of the precautionary principle, whereby it upheld the Council’s ban. Like the Council, the Court used uncertainty to legitimise its ruling, although it constructed uncertainty in a different way then the Council and the Commission did (Para. 142, European Court, 2002). It concluded that “the parties’ arguments, supported in each case by the opinions of eminent scientists, show that there was great uncertainty” (Para. 393, European Court, 2002). All the science involved, whether brought in by SCAN or Pfizer, is merely used to demonstrate uncertainty which is in its turn used as sufficient ground to apply the precautionary principle. Apparently the Court interpreted uncertainty as contrasting scientific opinions. Where the Commission used the knowledge contents of SCAN, the Court used the scientific arguments brought forward merely to conclude that there are contrasting scientific opinions, which it takes as enough evidence of uncertainty. As the Court cannot balance the scientific arguments, it is arguably inclined to assume equal standing of opinions and counter-opinions.

It should, however, be questioned whether this interpretation of uncertainty does not narrow down the core element of the precautionary principle, scientific uncertainty, to signifying divergence of expert opinions brought in by the parties. Before the Court the knowledge condition and the plausibility proof evaporated and boiled down to contrasting scientific opinions. Since in nearly all uncertain risk cases a qualified dissident can be found, this interpretation of uncertainty would in precautionary practice drastically make matters worse.

Conclusions: regulatory complexities of uncertainty

Our analysis of the Pfizer case illustrates the regulatory complexities of intermingled uncertainty and risk and how the uncertainty paradox may become manifest in regulatory practice when applying the precautionary principle. The Commission asked SCAN for certainty on whether or not the use of the antibiotic constituted a risk to human health. The SCAN experts tried to provide a satisfactory plausibility proof, but also provided for uncertainty information. Instead of following the requested ‘plausibility proof,’ and apparently unhappy with the outcome, the Community institutions reinterpreted pieces of uncertainty information in order to construct uncertainty, which was considered to be sufficient for application of the precautionary principle. In so doing, the institutions implicitly admitted that reasoning about the ‘plausibility’ of uncertain risk involves normative and subjective judgments, on which basis they implicitly considered it legitimate to ‘re-do’ the work originally delegated to the experts. Hence, from the beginning, the role of the experts was framed in terms of providing certainty about uncertain risks. The whole regulatory endeavour further stabilised this illusion, eventually forcing the Court to evaluate the merits and validity of scientific claims. The Court managed to address the uncertainty paradox by constructing uncertainty as meaning contrasting opinions, something which it was itself able to determine. Such jurisprudence can however easily be used to excavate the meaning of the precautionary principle and could be detrimental to the whole precautionary endeavour.
Building upon our analysis, we conclude that the embedment and integration of uncertainty information in the whole regulatory process is an important challenge. In order to move forward, it is necessary to fundamentally rethink the legal interpretation of the precautionary principle and address the uncertainty paradox. Instead of discussing the conditions for application of the precautionary principle in terms of ‘knowledge and full risk assessment,’ ‘conclusive evidence,’ ‘the level of damage,’ and ‘the burden of proof,’ it is necessary to rethink the value and the role of science, scientific experts and scientific opinions in the regulatory process together with the role of public authorities and courts. Such an exercise necessitates interdisciplinary collaboration between, among others, legal experts, sociologists of science, political scientists, risk analysts, psychologists, and environmental scientists.

References


